GE Healthcare

Revolution™ EVO

Technical Reference Manual

GE Healthcare Japan Corporation does business as GE Healthcare

This manual supports the following configurations:

- Revolution™ EVO EL
- Revolution™ EVO EX
- Revolution™ EVO ES
- Revolution™ EVO
- Revolution™ EVO 48kW

Not all configurations are available in all regions.

This product is certified as a Revolution™ EVO CT System.

CE 0459

Revolution™ EVO
Technical Reference Manual, English
5805441-1EN
Revision: 2

Revision History

REV	DATE	REASON FOR CHANGE
1	June 2019	Initial Release
2	September 2020	Translation correction

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5805441-1EN Rev. 2 (Sep. 2020)

5805441-1EN Rev. 2 (Sep. 2020)

Chapter 9:Reset the System

Chapter 10:Stop/Start the Operating System

Chapter 11:General Information

Chapter 12:Quality Assurance

5805441-1EN Rev. 2 (Sep. 2020)

Chapter 13:Requirements for providing image for Radiotherapy Treatment Planning (RTP)

Chapter 14:CT Acceptance Testing

Chapter 15:Performix™ 40 Plus X-Ray Tube Specifications

5805441-1EN Rev. 2 (Sep. 2020)

Chapter 16:Regulatory Information

Chapter 17:Electromagnetic Compatibility

Chapter 18:System Specifications

5805441-1EN Rev. 2 (Sep. 2020)

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 1
Before You Start

Anyone who operates this system should have received prior training before they attempt to scan or diagnose patients. This training should include medical and X-Ray education, in addition to GE applications training. This guide does not provide medical explanations, but it does suggest potential applications for some of the software features. It describes potential Safety problems, and how to avoid them.

Everyone who uses this equipment must read and understand all instructions, precautions and warnings. This manual should be kept near the equipment. Procedures and safety precautions should be viewed periodically.

This manual is originally written in English.

This Guide addresses three safety classifications:

DANGER: **The most severe label describes conditions or actions which result in a specific hazard. You will cause severe or fatal personal injury, or substantial property damage, if you ignore these instructions.**

WARNING: **This label identifies conditions or actions for which result in a specific hazard. You will cause severe personal injury, or substantial property damage, if you ignore these instructions.**

CAUTION: **This label applies to conditions or actions that have potential hazard. You may cause minor injury or property damage if you ignore these instructions.**

Various parts of your system will have the  icon. This icon on the equipment indicates that the user manual contains additional information and should be consulted

This Manual uses pictures, or icons, to reinforce the printed message. It uses the corresponding international symbol or icon next to the danger, warning or caution message. For example, the upright hand with the lightning bolt across it warns of electrical hazards.

Federal law restricts this device to sale by or on the order of a physician.

Do not use the equipment if a known safety problem exists. Call your local service provider and have the system repaired.

User Information Description

All operator information can be reviewed on a PC with Adobe Reader® version 6 or higher.

We have divided the current User Information into three parts:

- **User Manual :** The User Manual contains all the user information required to operate the scanner in a safe and proper manner. It has detailed information as well as step-by-step procedures. The User Manual is displayed on the Display monitor by clicking on the Learning Solutions icon in the desktop control area.
- **Technical Reference Manual:** This manual details safety information and specifications of the system and includes power off and on procedures.
- **Applications Tips and Workarounds:** This manual details Workaround information for software and system information.

Applications Help

Although we try to make this guide complete and accurate, undocumented changes or unexpected results do occur.

If you can't find the answer to your application question, you may call the Customer Center. Use this phone number for non emergency purposes only, because you may not receive an immediate response.

1. Dial **1-800-682-5327**.
2. Select **1** for Applications Answer line.
3. Select **3** for CT Application assistance.

If your system fails, or you have an emergency, call ***GE Cares*** at **1-800-437-1171**.

5805441-1EN Rev. 2 (Sep. 2020)

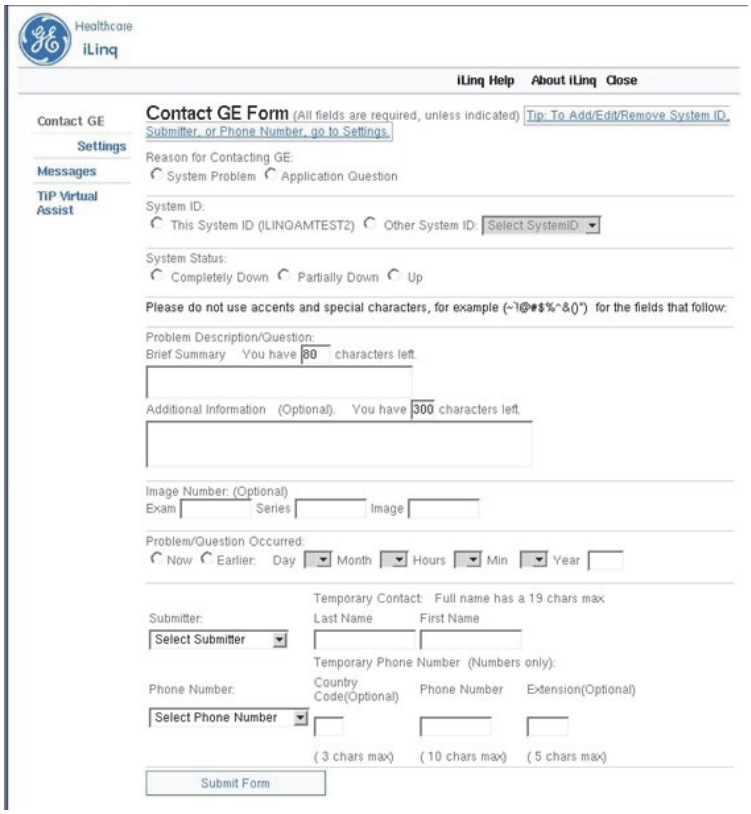
iLinq

If your system has broadband connectivity to GE and a contract, you can click **[iLinq]** to receive help.

iLinq™ delivers tools to the console that help address the challenge of keeping you up to date and improving productivity.

- The **Contact GE** feature puts technologists in touch with GE's technical experts at the Online Center for a fast response to maintenance and application questions. These calls receive top priority.
  - Request GE service without picking up the phone.
  - Auto-sends key status info to speed up the resolution process.
  - Fastest response time available from GE.

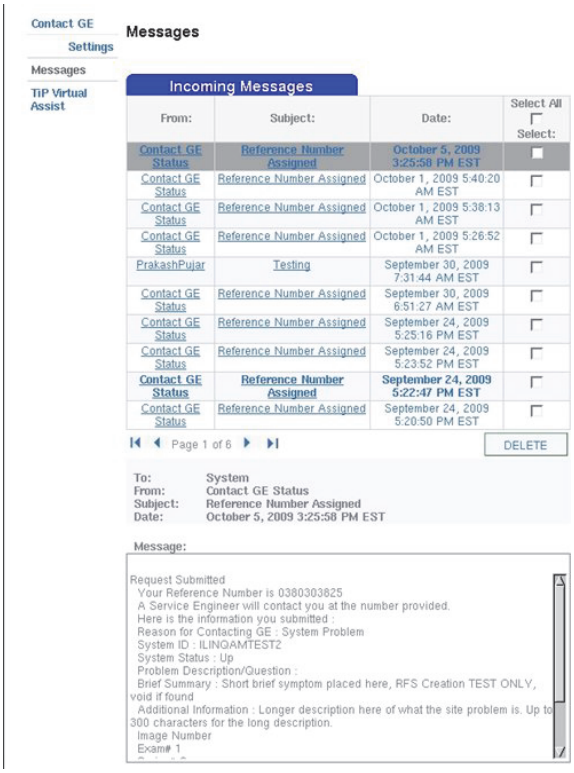
Figure 1-1 Contact GE Window



- The **Messages** feature provides a record of previous Contact GE requests and resolution searches, and other valuable information that GE has sent.
  - Keep track of your Contact GE service history.
  - Reference past questions for quicker answers.

5805441-1EN Rev. 2 (Sep. 2020)

Figure 1-2 Message Window



Please keep User Information readily available. (Reference: IEC60601-1:2005 Clause7.9.2.6)

Send your comments to:

GE Healthcare
CT Application (W1120)
3000 N. Grandview Blvd.
Waukesha, WI 53188
U.S.A.

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 2

X-ray Protection

(Reference: IEC60601-1:2005 7.9.3.1)

CAUTION: **Improperly used X-Ray equipment may cause injury. Read and understand the instructions in this book before you attempt to operate this equipment. The General Electric Company, Medical Systems Group, will gladly assist and cooperate in placing this equipment into use.**

Although this equipment incorporates a high degree of protection against X-Ray outside the useful beam, no practical design can provide complete protection. Nor can any practical design compel a user to take adequate precautions to prevent the possibility of any person carelessly, unwisely, or unknowingly exposing themselves or others to radiation.

Everyone having anything to do with X-Ray must receive proper training and become fully acquainted with the recommendations of the National Council on Radiation Protection and Measurements, and the International Commission on Radiation Protection.

NCRP reports are available from:

NCRP Publications
7910 Woodmont Avenue
Room 1016
Bethesda, Maryland 20814

CAUTION: **Everyone having anything to do with X-Ray must take adequate steps to insure protection against injury.**

All persons authorized to use the equipment must understand the dangers posed by excessive X-Ray exposure. We sell the equipment with the understanding that the General Electric Company, Medical Systems Group, its agents, and representatives have no responsibility for injury or damage which may result from exposure to X-Ray.

GE urges you to use protective materials and devices.

5805441-1EN Rev. 2 (Sep. 2020)

Chapter 3
Safety

Introduction

(Reference: IEC60601-1:2005 7.9.2.1, 7.9.2.2, 7.9.3.1)

The Safety chapter provides information about safety precautions and procedures. It is important for you to read and understand the contents of this chapter so the correct precautions and procedures are followed.

This manual should be kept near the console for easy access.

CAUTION: **This system was designed for use by individuals trained in CT system operation by GE. Study the Safety Chapter of this Manual before you scan the first patient. Use the Index to find the section and page number of an item of interest. Periodically review the User Manual, Applications Tips and Workarounds, and the Technical Reference Manual.**

If necessary, additional training is available from a GE Applications Specialist. Contact your institution's GE sales representative for additional information about further safety and operational training.

WARNING: **Modification of any existing patient data on the system must follow the guidelines specified in the User Manual.**

Watch for electromagnetic compatibility from other hardware. Detailed information concerning Electromagnetic Compatibility can be found in the Technical Reference Manual.

United States Federal Regulation 21CFR 801.109

CAUTION: **Federal law restricts this device to sale by or on the order of a physician.**

CAUTION: **Improper system usage could void your warranty. More importantly, you could endanger your patients and yourself if you do not follow the correct procedures.**

5805441-1EN Rev. 2 (Sep. 2020)

What Do I Need to Know About...

The User Manual and Technical Reference Manual include information required for the safe use of the equipment. This chapter summarizes the most important safety issues. Some of the concepts you need to understand:

- Warning Labels and Symbols
- General Safety Guidelines
- Radiation Safety (Reference: 21CFR 1020.30 (h) (1) (i))
- Electrical Safety
- Laser Safety
- Reconstructed Image Orientation
- Data Safety (Reference: IEC60601-1:2005 7.9.2.13)
- Application Software Safety
- Application Specific Safety Topics
- Accuracy of Measurements
- Operator Console Ergonomics
- Accessories
- Emergency Devices and Emergency Egress
- Maintenance and Cleaning (Reference: IEC60601-1:2005 7.9.2.12, 7.9.2.13, 16.2)
- Cleaning Equipment (Bio Hazard)
- Environmental Concerns (Reference: IEC60601-1:2005 Clause7.9.2.15)

Warning Labels and Symbols

This chapter addresses three safety classifications:

DANGER: **The most severe label describes conditions or actions which result in a specific hazard. You will cause severe or fatal personal injury, or substantial property damage if you ignore these instructions.**

WARNING: **This label identifies conditions or actions which result in a specific hazard. You will cause severe personal injury, or substantial property damage if you ignore these instructions.**

CAUTION: **This label applies to conditions or actions that have potential hazard. You may cause minor injury or property damage if you ignore these instructions.**

Equipment Symbols

This chapter uses the international symbol or icon along with the danger, warning or caution message.

Table 3-1 Symbols used in Labeling

Symbol	Description
	Alternating current
	Protective earthing point
	ON / Power
	OFF / Power OFF

5805441-1EN Rev. 2 (Sep. 2020)

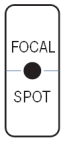
Symbol	Description (Continued)
	Input Power
	Output Power
	Type B applied part
	Functional Earth Ground
	Warning, Caution - consult accompanying documents
	General Warning Symbol
	Electrical Shock Hazard

Table 3-2 Symbols used in Labeling

Symbol	Description
Made for	Indicates the manufacturer (responsible design owner)
By (Made by)	Indicates the Manufacturing Location
	Refer to instruction manual/booklet

Symbol	Description (Continued)
	Pushing Prohibited
	Legal Manufacturer for EU
	Model Number
	Serial Number
	Date of Manufacture
	Prescription Use Only
	Permanent Filtration
	Radiation of Laser Apparatus
	Large Focal Spot
	Small Focal Spot

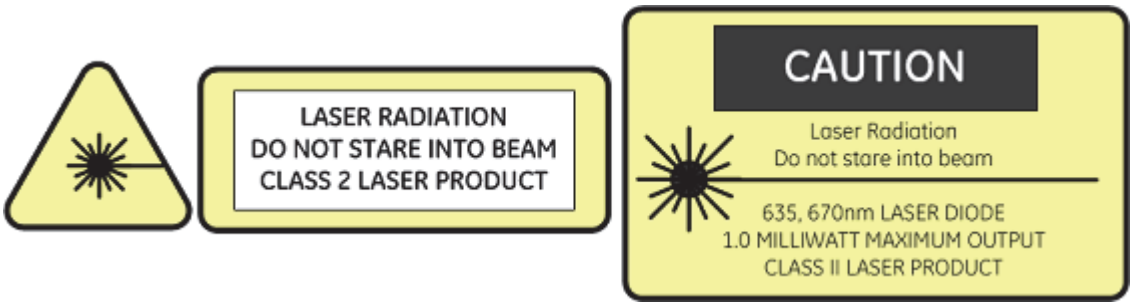
5805441-1EN Rev. 2 (Sep. 2020)

Symbol	Description (Continued)
	Focal spot location indicator
	Hot surface warning
	EC representative of X-ray tube assembly

Equipment warning labels

The following warning labels are used on the equipment:

Figure 3-1 Warning labels located at the bottom of the gantry cover (Reference 21 CFR 1040.10 (h))

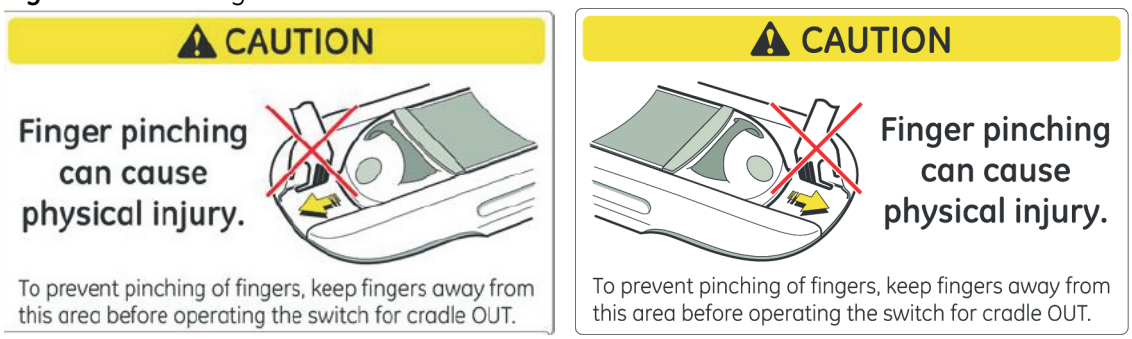


CAUTION: **LASER RADIATION**
DO NOT STARE INTO BEAM
CLASS 2 LASER PRODUCT

Figure 3-2 Labels located on the front of the gantry (Reference 21 CFR 1040.10 (h))

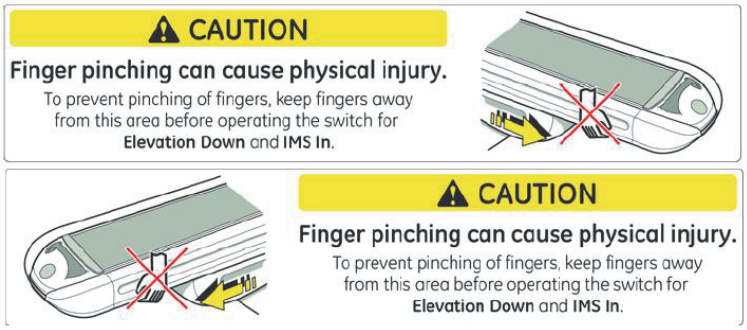
CAUTION: **LASER APERTURE**
Do not stare into beam

Figure 3-3 Warning labels located on the table



CAUTION: **Finger Pinching Can Cause physical injury.**
To prevent pinching of fingers, keep fingers away from this area before operating the switch for cradle OUT.

Figure 3-4 Warning labels located on the IMS table

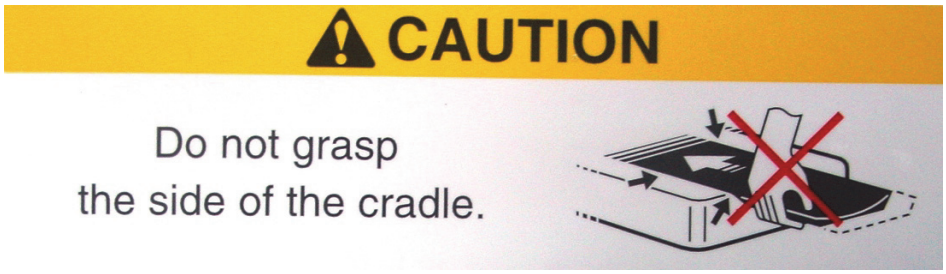


CAUTION: **Finger Pinching Can Cause physical injury.**
To prevent pinching of fingers, keep fingers away from this area before operating the switch for Elevation Down and IMS In.

NOTE: The table type depends on system configuration.

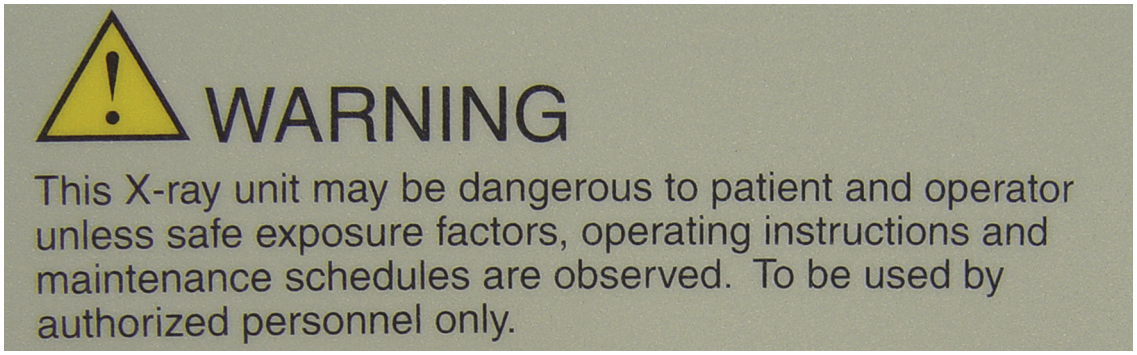
5805441-1EN Rev. 2 (Sep. 2020)

Figure 3-5 Label on the side of the table



CAUTION: **Do not grasp the side of the cradle.**

Figure 3-6 Label located on the operators console for systems manufactured after June 10, 2006 (Reference 21CFR 1020.30 (j))



WARNING: **This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed. To be used by authorized personnel only.**

The following warning labels are on the equipment if the equipment is in compliance with IEC60601-1:2005. (Reference: IEC60601-1:2005 Clause7.9.2.13)

Figure 3-7 Warning label on lower-left side and lower-right of front and rear covers of gantry

CAUTION: **PINCH POINT. Keep hands clear when tilting.**

WARNING: **Do not place your hands inside the gantry opening when tilting the gantry. The gantry can pinch or crush your hands.**

Figure 3-8 Warning label on gantry front cover, table, operator console, and PDU

CAUTION: **AVOID INJURY. Read and understand information in manuals before operating product.**

Figure 3-9 Warning label located on PDU

CAUTION: **PDU CAN MOVE AND DAMAGE CABLES. Do not lean on or move when connected to power.**

Figure 3-10 Warning label on the table

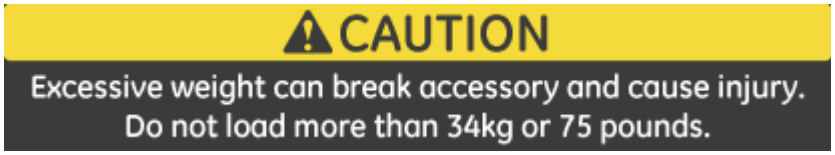
CAUTION: **AVOID INJURY. Do not exceed table maximum capacity of 306 kg (675 lb).**

Figure 3-11 Warning label on the table

CAUTION: **AVOID INJURY. Do not exceed table maximum capacity of 227 kg (500 lb).**

5805441-1EN Rev. 2 (Sep. 2020)

Figure 3-12 Load limit caution



CAUTION: Excessive weight can break accessory and cause injury. Do not load more than 34 kg (75 lb).

Figure 3-13 Accessory caution

CAUTION: Do not hit the accessory against the gantry. Patient injury or equipment damage could result.

Figure 3-14 IV pole load limit caution

CAUTION: Do not load more than 4.5 kg (10 lb). Verify that extension collar is recurely tightened before use.

Figure 3-15 Tray load limit caution

CAUTION: Do not load more than 9 kg (20 lb).

Figure 3-16 Accessory load limit caution

CAUTION: Accessory may fall and cause injury if not latched to cradle. Make sure that accessory is latched to underside of cradle.

5805441-1EN Rev. 2 (Sep. 2020)

General Safety Guidelines

- This product was designed and manufactured to ensure maximum safety of operation. It should be operated and maintained in strict compliance with the safety precautions, warnings and operating instructions contained herein, and in any other documentation specific to the product.
- The system has been designed to meet all the safety requirements applicable to medical equipment. However, anyone attempting to operate the system must be fully aware of potential safety hazards.
- The manufacturer or vendor of the equipment makes no representation, however, that the act of reading this manual renders the reader qualified to operate, test or calibrate the system.
- The owner should make certain that only properly trained, fully qualified personnel are authorized to operate the equipment. A list of authorized operators should be maintained.
- This manual should be kept at hand, studied carefully and reviewed periodically by the authorized operators.
- Unauthorized personnel should not be allowed access to the system.
- Do not leave the patient unobserved at any time.
- Always assist the patient on and off the table to avoid potential injury.
- Become familiar with the functional hardware so that you can recognize serious problems. Do not use the system if it appears damaged or fails. Wait for qualified personnel to correct the problem.
- Abbreviations used in the operator manuals can be found in this manual.
- If the product does not operate properly or if it fails to respond to the controls as described in this manual, the operator should:
  - First ensure the safety of the patient.
  - Next ensure the protection of the equipment.
  - Evacuate the area as quickly as possible in any potentially unsafe situation.
  - Follow the safety precautions and procedures as specified in this manual.
  - Immediately contact the local service office, report the incident and await further instructions.
- The images and calculations provided by this system are intended as tools for the competent user. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis. Users are encouraged to study the literature and reach their own professional conclusions regarding the clinical utility of the system.
- Understand the product specifications, system accuracy, and stability limitations. These limitations must be considered before making any decision based on quantitative values. In case of doubt, please consult your sales representative.

- Do not block the ventilation ports of the electronic equipment. Always maintain at least 6 inches (15 cm) clearance around the ventilation ports to prevent overheating and damage to the electronic hardware.

CAUTION: Prior to powering on the system, the room environmental operating conditions found in the System Specification chapter must be maintained for at least 24 hours. These conditions must be constantly maintained when the system is energized or in use.

CAUTION: Do not load any non-GE approved software onto the computer.

- Watch for the electromagnetic compatibility from other hardware. For more information, refer to the Electromagnetic Compatibility section in the Technical Reference Manual, under the General Safety Guidelines.

DANGER: Make sure all covers are in place before you use the equipment. The covers protect you and your patient from moving parts or electrical shock. The covers also protect the equipment.

NOTE: Only qualified Service personnel should service the system with the covers off.

DANGER: Information on internal gantry components is provided for user education. The gantry contains dangerous voltages and moving parts. TO PREVENT ELECTRICAL SHOCK OR CRUSHING INJURIES, DO NOT REMOVE COVERS OR ENTER THE GANTRY. ONLY TRAINED, QUALIFIED SERVICE PERSONNEL MAY REMOVE GANTRY OR OTHER EQUIPMENT COVERS.

WARNING: This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the system or shielding the location.

WARNING: Imaging functions may be lost without warning. Emergency procedures should be developed to prepare for such an occurrence.

5805441-1EN Rev. 2 (Sep. 2020)

Implantable Device Safety

WARNING: CT Scans may cause interference with implanted or externally worn electronic medical devices such as pacemakers, defibrillators, neurostimulators and drug infusion pumps. The interference could cause operational changes or malfunction of the electronic medical device.

Recommendations prior to scanning:

- If practical, try to move external devices out of the scan range.
- Ask patients with neurostimulators to shut off the device temporarily while the scan is performed.
- Minimize the X-ray exposure to the electronic medical device.
- Use the lowest possible X-ray tube current consistent with obtaining the required image quality.
- Do not scan directly over the electronic device for more than a few seconds.

NOTE: For procedures such as CT Perfusion or CT Interventional scans that require scanning over the electronic medical device for more than a few seconds, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.

Recommendations after scanning

- Have the patient turn the device back on if it had been turned off prior to scanning.
- Have the patient check the device for proper functioning, regardless of whether it was turned on or off.
- Advise patients to contact their healthcare provider as soon as possible if they suspect their device is not functioning properly after a CT scan.

NOTE: Recommendations from FDA Preliminary Public Health Notification: Possible Malfunction of Electronic Medical Devices Caused by Computed Tomography (CT) Scanning date July 14, 2008.

WARNING: The CT System is not classified as defibrillation-proof nor as defibrillation-protected electronic medical equipment. Emergency defibrillation should be performed by appropriately trained, skilled personnel familiar with the limitations and operation of defibrillation equipment and familiar with how to handle equipment that is not defibrillation-protected in the patient environment.

Radiation Safety
(Reference: 21CFR 1020.30 (h) (1) (i))

WARNING: Improperly used X-Ray equipment may cause injury. Read and understand the instructions in this book before you attempt to operate this equipment. If you fail to follow safe X-Ray practices or ignore the advice presented in the manual, you and your patient risk exposure to hazardous radiation.

Authorized Users

This equipment incorporates a high degree of protection against X-Ray radiation outside the useful beam. But this equipment cannot substitute the essential requirement that every user must take adequate precautions to prevent the possibility of any person carelessly, unwisely, or unknowingly exposing themselves or others to radiation.

Everyone having anything to do with X-Ray equipment must receive proper training and become fully acquainted with the recommendations of the National Council on Radiation Protection and Measurements and the International Commission on Radiation Protection.

NCRP reports are available from:

NCRP Publications
7910 Woodmont Avenue
Room 1016
Bethesda, Maryland 20814

WARNING: Everyone having anything to do with X-Ray equipment must take adequate steps to insure protection against injury.

All persons authorized to use the equipment must understand the dangers posed by X-Ray exposure so that they can prevent any injury or damage that may result from such exposure. GE Medical Systems urges you to use protective materials and devices to prevent any injury or damage from X-Ray exposure.

5805441-1EN Rev. 2 (Sep. 2020)

General Radiation Safety

WARNING: Never scan a patient with unauthorized personnel in the scan room. Warn visitors and patients about potential for harm if they fail to follow instructions.

WARNING: Never calibrate, test the system, or warm the tube with patients or personnel present in the scan room without adequate radiation safety precautions being utilized.

- Stay behind a lead screen or lead glass shield during each X-Ray exposure.
- Use technique factors prescribed by the radiologist or diagnostician. Use a dose that produces the best diagnostic results with the least X-Ray exposure.
- Amber indicator lights on the gantry control panel, and rear of the gantry, illuminate during X-Ray exposure.

CAUTION: Use of controls or adjustments, or performance of procedures other than those specified herein, may result in hazardous radiation exposure.

Scans Acquired at the Same Tomographic Plane

IEC standard 60601-2-44: 2001 clause 29.1.105 and 60601-2-44: 2009 clause 203.107 states that you must be warned when scans are acquired at the same tomographic plane, i.e. the same scan location. The need for the warning is to make users aware of the potential dose that can be given to the patient when acquiring scans at the same table location.

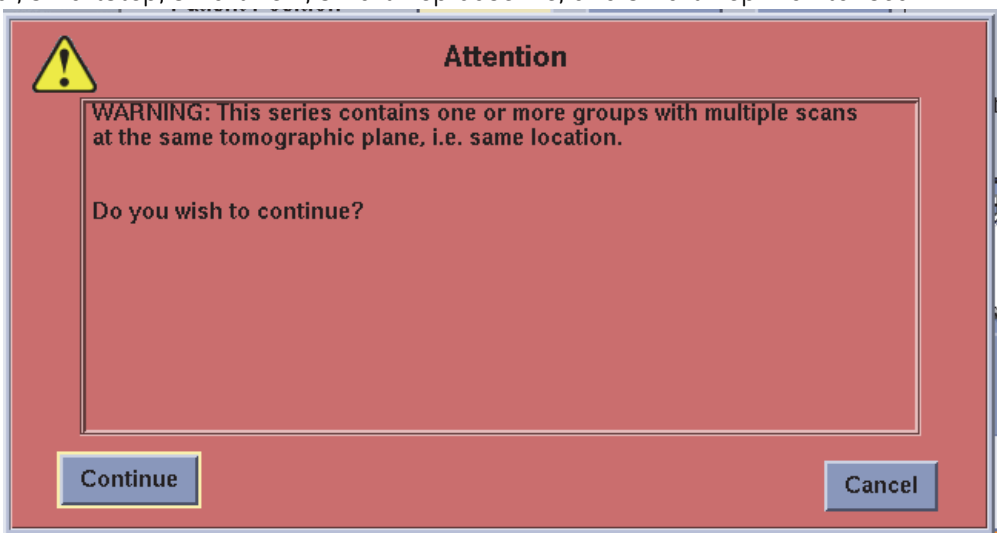
When acquiring scans in this mode:

- Utilize the dose information displayed on the ViewEdit screen. The dose information displayed is covered in the next section, CTDIvol.
- An optional DICOM SR (Structured Report) Dose Report is saved in Series 997.
- Use proper techniques for the application and anatomy you are scanning.

A warning message (Figure 3-17) is posted when **[Confirm]** is selected for the following scan types:

- SmartStep or SmartView
- SmartPrep Baseline and Monitor scans
- Cine scans
- Axial scans with zero table increment (interval)
- VolumeShuttle (Axial)
- Volume Helical Shuttle

Figure 3-17 Warning Message when scanning on the same tomographic plane: Axial, Cine, Helical, SmartStep, SmartView, SmartPrep baseline, and SmartPrep monitor scan



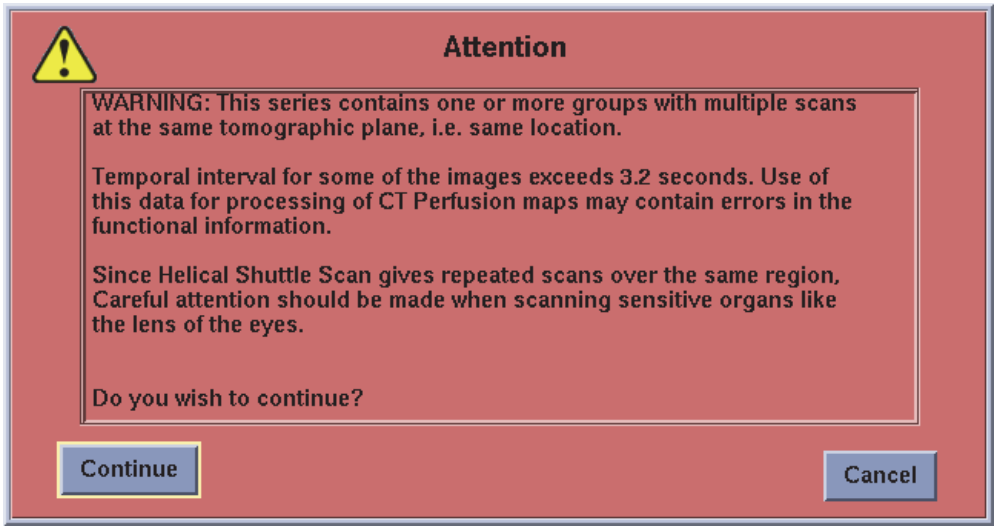
WARNING: This series contains one or more groups with multiple scans at the same tomographic plane, i.e. same location.

Do you wish to continue?

CAUTION: Prolonged exposure to x-ray in one spot may cause reddening or radiation burns. Users must be aware of the techniques used and exposure time to ensure safe operation.

5805441-1EN Rev. 2 (Sep. 2020)

Figure 3-18 Warning Message when scanning on the same tomographic plane for Volume Helical Shuttle



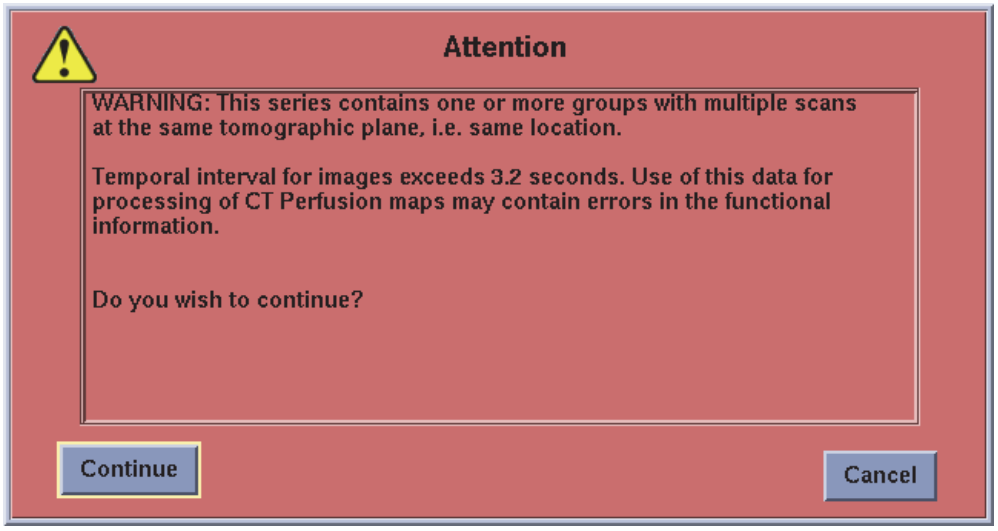
WARNING: This series contains one or more groups with multiple scans at the same tomographic plane, i.e. same location.

Temporal interval for some of the images exceeds 3.2 seconds. Use of this data for processing of CT Perfusion maps may contain errors in the functional information.

Since Volume Helical Shuttle Scan gives repeated scans over the same region, careful attention should be made when scanning sensitive organs like the lens of the eyes.

Do you wish to continue?

Figure 3-19 Warning Message when scanning on the same tomographic plane: VolumeShuttle (Axial)



WARNING: This series contains one or more groups with multiple scans at the same tomographic plane, i.e. same location.

Temporal interval for some of the images exceeds 3.2 seconds. Use of this data for processing of CT Perfusion maps may contain errors in the functional information.

Do you wish to continue?

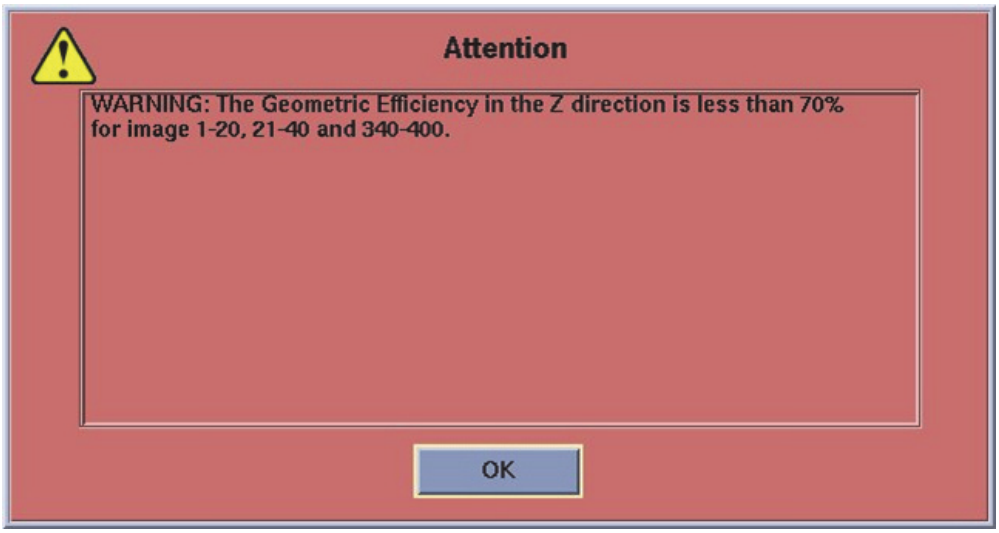
After reading the message, if you wish to continue with the scan, click **[Continue]**.

Geometric Efficiency

A warning message is posted when the Geometric Efficiency in the Z-direction is less than 70%. Geometric Efficiency is a measure of how much of the X-ray beam in the Z-direction is used by the system.

5805441-1EN Rev. 2 (Sep. 2020)

Figure 3-20 Warning message when dose efficiency is less than 70% (Reference: IEC60601-2-44:2009 Clause203.113)



WARNING: The Geometric Efficiency in the Z direction is less than 70% for Image 1-20, 21-40 and 340-400.

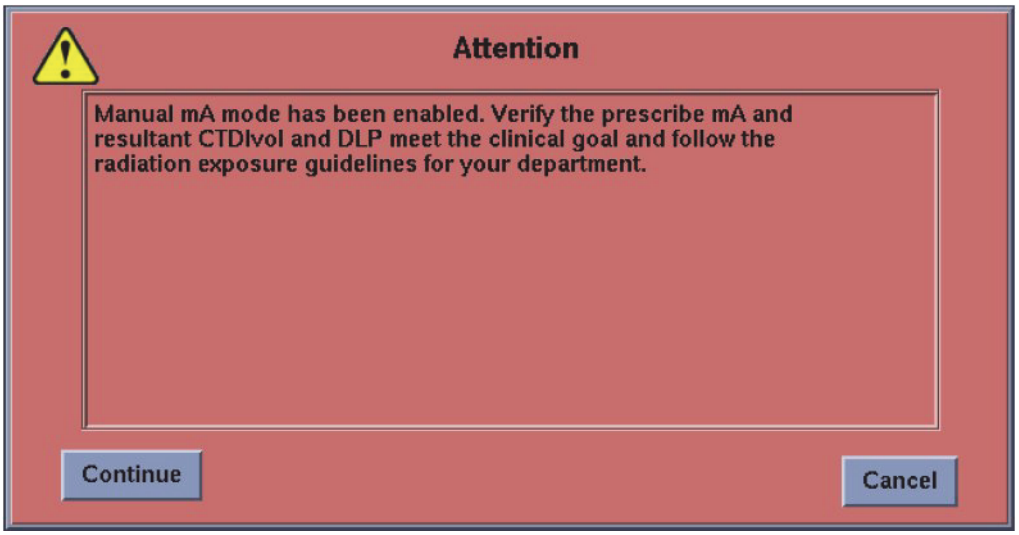
NOTE: Images 1-20, 21-40 and 340-400 is an example of a location where the Geometric Efficiency in Z is less than 70%.

mA mode change

Figure 3-21 Attention Messages when mA mode is changed: Manual mA to AutomA

Attention: **An automatic exposure control mode has been enabled. Verify the Noise Index, Min mA/Max mA values and resultant CTDIvol and DLP meet the clinical goal for the acquisition and follow the radiation exposure guidelines for your department.**

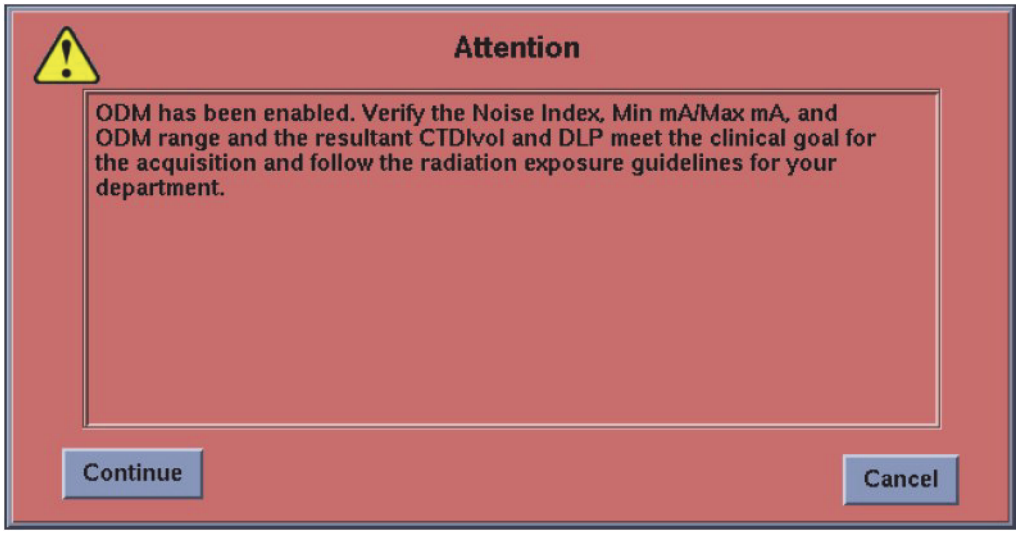
Figure 3-22 Attention Messages when mA mode is changed: AutomA to Manual mA



Attention: **Manual mA mode has been enabled. Verify the prescribe mA and resultant CTDIvol and DLP meet the clinical goal and follow the radiation exposure guidelines for your department.**

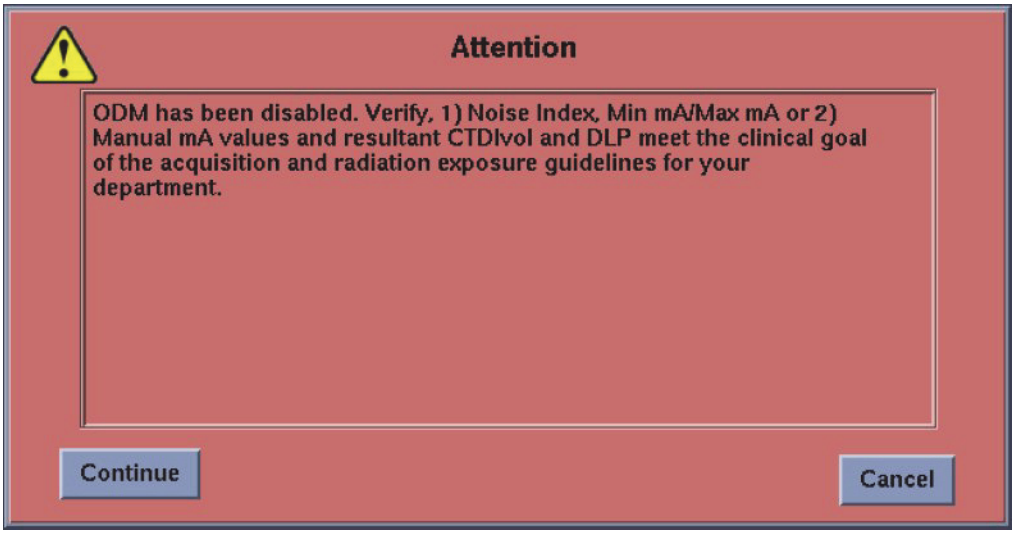
5805441-1EN Rev. 2 (Sep. 2020)

Figure 3-23 Attention Messages when mA mode is changed: Manual mA or AutomA to Organ Dose Modulation



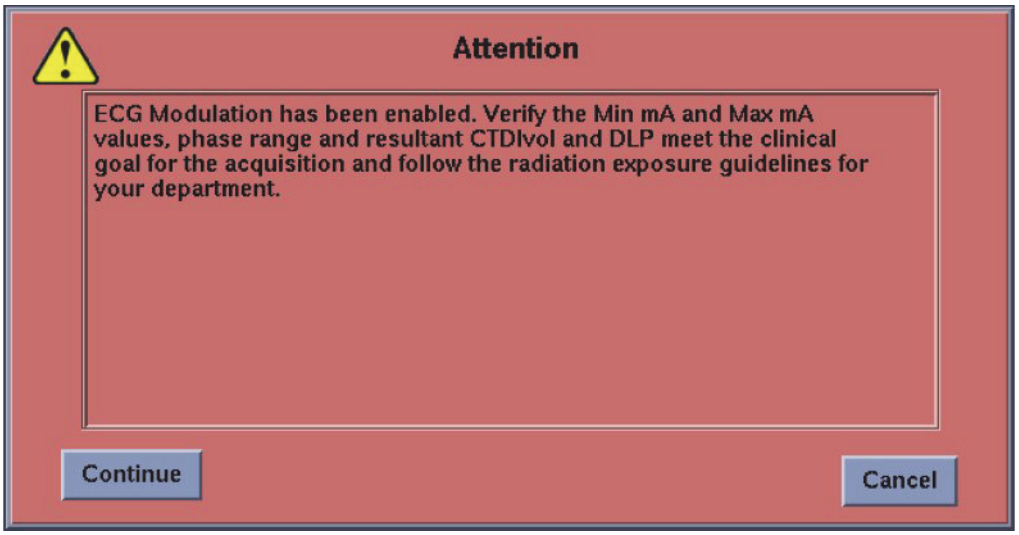
Attention: **ODM has been enabled. Verify the Noise Index, Min mA/Max mA, and ODM range and the resultant CTDIvol and DLP meet the clinical goal for the acquition and follow the radiation exposure guidelines for your department.**

Figure 3-24 Attention Messages when mA mode is changed: Organ Dose Modulation to Manual mA or AutomA



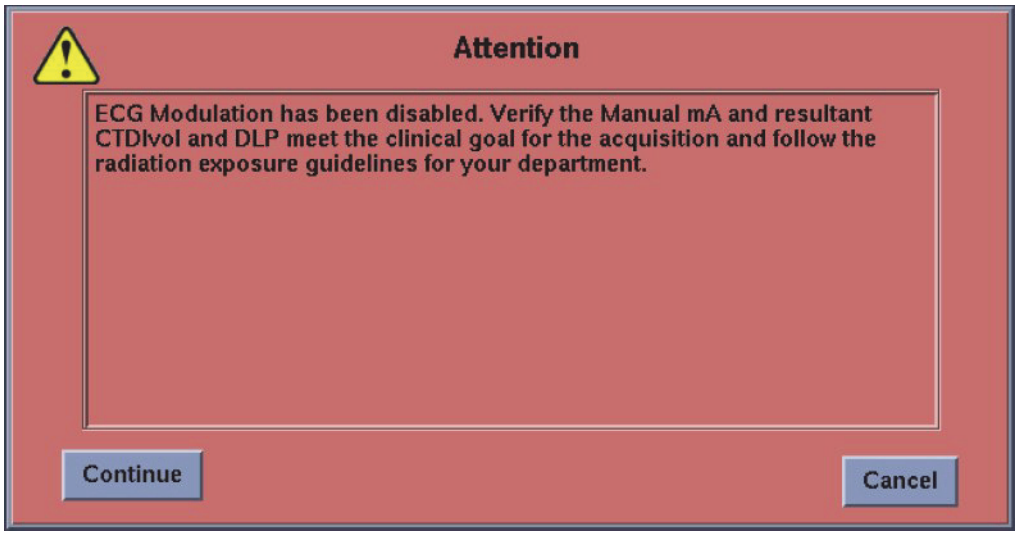
Attention: **ODM has been desabled. Verify, 1) Noise Index, Min mA/Max mA or 2) Manual mA values and resultant CTDIvol and DLP meet the clinical goal of the acquition and the radiation exposure guidelines for your department.**

Figure 3-25 Attention Messages when mA mode is changed: Manual mA to ECG Modulation



Attention: **ECG Modulation has been enabled. Verify the Min mA and Max mA values, phase range and resultant CTDIvol and DLP meet the clinical goal for the acquisition and follow the radiation exposure guidelines for your department.**

Figure 3-26 Attention Messages when mA mode is changed: ECG Modulation to Manual mA



5805441-1EN Rev. 2 (Sep. 2020)

Attention: **ECG Modulation has been disabled. Verify the Manual mA and resultant CTDIvol and DLP meet the clinical goal for the acquisition and follow the radiation exposure guidelines for your department.**

CTDIvol

As you setup the scan parameters from the ViewEdit screen, the Dose Information area at the upper right of the scan monitor contains updated dose information. This dose information is based on a measurement of the CTDI (CT Dose Index), which is the current standard for CT dosimetry and performance. By using a measurement called CTDIvol, a single value is provided to estimate the relative dose for an exam.

The CTDIvol is a weighted average measurement in a reference phantom. This dose is expressed in milliGrays. For additional information on specific CTDIvol doses and their calculations, refer to your Technical Reference manual.

The DLP is the product of the CTDIvol and the scan length for a group of scans. This number can be summed over the entire exam to give an estimate of the total dose. The value is expressed in milliGray centimeters.

The Projected Series DLP shows the DLP that would result from scanning the current group or groups.

The Accumulated Exam DLP displays the total exam DLP up to the current point in time. Scout dose is not included in the DLP totals since standards for reporting scout dose are not yet defined. Scout dose is generally a very small part of the exam.

The dose information updates when technique values such as kV, mA, scan time, slice thickness, and scan field of view are changed.

Dose information is saved a screen save image in Series 999 upon selecting End Exam, Series 997 contains the DICOM Dose Structured Report.

Pediatric and Small Patient Imaging

Adult techniques and protocols should not be used on pediatric patients (under two years of age). The National Cancer Institute and The Society for Pediatric Radiology developed a brochure, (available at http://www.cancer.gov/) and the FDA issued a Public Health Notification, (available at: http://www.fda.gov/, that discuss the value of CT and the importance of minimizing radiation dose, especially in children. More information can also be obtained at http://www.fda.gov/).

X-Ray Tubes

The system uses cooling and reconstruction algorithms specifically designed for GE X-Ray tubes.

You risk three dangers when you do not use GE X-Ray tubes.

- A non-GE tube could cause destructive component failure if the cooling delays do not meet its design requirements.
- The images could exhibit reduced performance or artifacts if your x-ray tube fails to conform with GE tube performance specifications.
- Radiation leakage may exceed GE specifications when a non-GE X-Ray tube is installed in the system.

CAUTION: We cannot guarantee performance or safety if you use a non-GE X-Ray tube because the cooling and reconstruction algorithms depend upon the tube design. Radiation leakage may exceed GE specifications when a non-GE X-Ray tube is installed in the system.

5805441-1EN Rev. 2 (Sep. 2020)

Electrical Safety

DANGER: ELECTRICAL SHOCK HAZARD. Avoid all contact with any electrical conductor. Do not remove or open system covers or plugs. Internal circuits use high voltage capable of causing serious injury.

To guarantee safe, reliable equipment performance, prepare the site according to GE Medical Systems requirements. This includes making sure the equipment is connected to a power supply main with a protective earth. If you have any questions about these requirements, contact GE Medical Systems.

An electrical hazard may exist if any light, monitor or visual indicator stays on after the system is shut down. To prevent possible injury, turn off the main power supply wall switch, and contact your service office immediately.

DANGER: NO USER SERVICEABLE PARTS. Refer service to qualified service personnel. Only allow people who know the proper procedures, and use of the proper tools, to install, adjust, repair, or modify the equipment.

To guarantee safe, reliable equipment performance, prepare the site according to GE Medical Systems requirements. If you have any questions about these requirements, contact GE Medical Systems.

Fuses blown within 36 hours of being replaced may indicate malfunctioning electrical circuits within the system. Have the system checked by qualified service personnel, and do not attempt to replace any fuse.

DANGER: ELECTRICAL FIRE. Conductive fluids that seep into the active circuit components of the system may cause short circuits that can result in electrical fires. Therefore, do not place any liquid or food on any part of the system.

To avoid electrical shocks or burns caused by the use of wrong type of fire extinguisher, make sure that only fire extinguishers approved for use on electrical fires are used.

CAUTION: **Surplus lengths of power cords or other cables from mobile accessory units that may be used during some patient scanning should be stored in safe and isolated areas. For example, excess cable may be wound in a figure eight and stored at the base of the stationary equipment. This minimizes signal interference and protects cables from damage due to traffic.**

CAUTION: **The outlets are not for General Use. Operator Console outlet has a rating for 2.5A at 120VAC and 10A at 120VAC. Gantry outlets have a rating for 3.0A at 120VAC. Accessories should not exceed above rating.**

DANGER: **Do not open the fuse cover on the gantry rear plug-in panel.**
If you cannot scan with ECG gating with the ECG monitor connected, please contact your service representative to investigate the failure.

CAUTION: **Included power cord is only to be used when connecting GE-approved accessories to the gantry or operator console.**

A CT System combined with GE approved accessories complies with the IEC60601-1 standards related to safety and performance of medical electrical systems. Refer to the standard for more information.

- Do not connect electric devices to the CT System that are not approved by GE. It may create increased electrical leakage current and there is possibility of electric shock.
- The GE console monitors, modem, video amp and media tower are intended to be powered by the CT System using cables provided. Do not connect these devices to power sources other than the CT system (for example, wall outlets, or other electrical equipment). It may create increased electrical leakage current and there is possibility of electric shock.
- Note that some powered equipment may only be connected by a signal cable to GE equipment (for example, a network hub). A separation device is required for equipment that is powered by a different power source.

5805441-1EN Rev. 2 (Sep. 2020)

Mechanical Safety (Reference: IEC60601-2-44:2009 201.7.9.2.2)

General Mechanical Safety

- Check for any obstruction around the equipment before attempting to move the table and gantry. When performing table or gantry motions, always monitor the progress of the motion.
- Be especially careful when tilting the gantry or when moving the table with the cradle extender or head holder is in place, to avoid driving these accessories into the gantry covers.

• The **Cradle Unlatch Indicator** is illuminated when the cradle is unlocked. An unlocked cradle could potentially move unexpectedly.

•The **Interference light** illuminates when the cradle has reached a travel limit or encountered interference.

- If the table reaches one of the limits while you are actively pressing the controls, the limit light will turn off when the controls are released.
- Clear an interference by changing the gantry tilt, moving the cradle, or adjusting the table height.

WARNING: **Do not use the table base as a foot rest. You could entrap and injure your foot while lowering the table. Do not place your hands between the table base and the table side panels.**

WARNING: **Be sure that the Gantry will not touch the patient during Remote Tilt operation. Pinching or crushing may happen if the Gantry touches the patient.**

- Avoid any patient contact with the gantry during tilt or cradle movement (manually or software driven).

Figure 3-27 System label on all four corners of gantry

CAUTION: **Pinch Point. Keeps hands clear when tilting.**

WARNING: Do not place your hands inside the gantry cover when tilting the gantry. The gantry can pinch or crush your hands!

The warning message is displayed after pressing Restart, Shutdown or Energy Saving Mode setting is completed. Click Confirm in the pop-up to continue shutdown process.

Figure 3-28 The warning message for gantry rotation

WARNING: System is preparing for shutdown. The gantry will rotate immediately after Confirm is pressed.

Short Footprint Mode

- If the system is set to Short Footprint mode, scannable range is limited accordingly. This should be approved by the customer during pre-installation.
- Only qualified Service personnel should change the setting of the Small Footprint Mode.

Patient Positioning

CAUTION: Improper centering of patient when using AutomA/SmartmA can lead to higher or lower dose than expected.

CAUTION: AutomA and SnapShot Assist all use attenuation information from the scout to set scan parameters. Poor patient centering will impact the results in these scanning modes.

5805441-1EN Rev. 2 (Sep. 2020)

CAUTION: Keep the patient in view at all times.

- Never leave the patient unattended.

CAUTION: If the head is poorly positioned in the head holder and a gantry tilt is used, images with different CT numbers and intensities may be seen at the edges of two rotational interfaces. Make sure the patient is properly positioned in the head holder, and not positioned so that the head is at the junction of the head holder attachment to the cradle. If a repeat scan is needed, make sure the locations with different intensities are in the middle of the beam collimation. Do not repeat using exactly the same prescription.

Figure 3-29 Warning label located on table

CAUTION: AVOID INJURY. Do not exceed table maximum capacity of 306 kg (675 lb).

WARNING: Do not exceed table maximum capacity of 306 kg (675 lb). This could cause the table to fail and the patient could fall.

Figure 3-30 Warning label located on table

CAUTION: AVOID INJURY. Do not exceed table maximum capacity of 227 kg (500 lb).

WARNING: Do not exceed table maximum capacity of 227 kg (500 lb). This could cause the table to fail and the patient could fall.

- The concentrated weight of short, heavy patients can cause the cradle to make contact with the gantry.
  - Make sure you do not drive the cradle into the gantry cover.
  - Make sure you do not pinch the patient's skin or extremities between the cradle and the gantry.
- When considering table load capacity, factor in not only the weight of the patient but also all of the accessories on the table.

5805441-1EN Rev. 2 (Sep. 2020)

CAUTION: **When using the external laser alignment light for patient positioning purposes, be aware that the patient's elevation may be slightly lower with the cradle extended than with the cradle fully retracted. This is because the cradle may bend slightly under a patient's weight. This difference should be taken into consideration for applications where patient position information is critical, such as Treatment Planning. To minimize these effects, after using the external laser alignment system to position the patient, advance the patient to the CT scan plane. Turn on the CT alignment lights to determine if they line up with the markers on the patient. If necessary, compensate for the bend in the cradle by elevating the table. When the CT alignment lights line up with the markers, set the landmark for the scan using the Internal laser alignment light.**

Please see Table X-Y Accuracy for the Flat Tabletop workflow For Flat Tabletop in the User manual to assess the X-Y accuracy of your system.

CAUTION: **When using patient positioning accessories, make sure there are no areas, which might cause a pinch point or interfere with patient tubing or IV.**

CAUTION: **Check to make sure the power injector has enough IV tubing to allow free movement of the cradle. Make sure the unit itself does not interfere with table travel.**

Ensure excess tubing length is secured to the table top. DO NOT loop additional IV tubing in the patient's fingers.

- Check the length of all patient health lines (IV tubing, oxygen line, etc.) and make sure they accommodate cradle travel. Position these lines so they cannot catch on anything within the patient vicinity or between the table and gantry during cradle travel or gantry tilt.

CAUTION: **The patient positioning straps provided with the system do not support the full weight of the patient. Patient positioning straps should be used to aid in patient positioning and are not meant to fully restrain the patient.**

CAUTION: **Care should be taken to ensure the patient positioning straps, patient clothing, or other material will not be caught during table motion.**

- The scannable range is not indicated by the black marks on the table. The scannable range is indicated by the tilt and travel limits button on the gantry controls.

Figure 3-31 Table

CAUTION: If the table is lowered with anything in the red X area as indicated, the table could be damaged along with the equipment or object under the table.

CAUTION: Physically assist all patients on and off the table and into position on the cradle.

CAUTION: The foot pedals at the base of the table for loading and unloading patients are always active. Care should be taken not to activate the foot pedals once the patient has been positioned on the cradle and an exam started.

- Return the gantry tilt to the 0-degree upright position, latch the cradle, and adjust the table to a comfortable height for patient loading and unloading.
- Latch the cradle before you load or unload the patient (the Cradle Unlatch indicator illuminates when the cradle is unlatched).

WARNING: To prevent pinching or crushing of the patient's extremities, keep the patient's hands and feet away from the edge of the moving table top/cradle and its surrounding equipment, or between table base and side panels of the table. Take special care when positioning physically large patients.

5805441-1EN Rev. 2 (Sep. 2020)

WARNING: To prevent pinching or crushing of the patient, watch the patient and equipment carefully at all times during gantry tilt or table movement. If unwanted motion occurs or motion does not stop, press the emergency stop switches on the console or gantry.

Figure 3-32 Load limit Caution

CAUTION: Accessory may fall and cause injury if not latched to cradle. make sure that accessory is latched to underside of cradle.

CAUTION: Excessive weight can break accessory and cause injury. Do not load more than 34kg (75 lb).

WARNING: The head holder may crack, possibly injuring the patient's head or neck, if the patient tries to brace himself or herself on the head holder during positioning. The head holder and cradle extender are only designed to support 34kg (75 lb). Ask the patient to move up into the head holder or manually help the patient into position.

CAUTION: The patient head holder or table extender should be adequately secured to ensure stability. If they are not secured properly, degradation of image quality may result due to introduced motion of the head holder or table extender.

CAUTION: Use of any cradle extension accessories such as the table extension, head holder, coronal head holder, and phantom holder are not accounted for in the table gantry interference matrix. Therefore, additional care needs to be taken to closely monitor any table up/down, in/out or gantry tilt movement to avoid contact of the extended accessory with the gantry.

Figure 3-33 Accessory caution

CAUTION: **Do not hit the accessory against the gantry. Patient injury or equipment damage could result.**

NOTE: Collision sensors are placed under the table surfaces to stop downward motion and minimize the effects of a collision in most cases. Upward motion is still allowed if a collision sensor has been activated.

CAUTION: **Do not attach accessories to the cradle that are damaged or broken such as the table extender, head holder, and patient positioning straps.**

- Check the accessory attachment plate fixed to the end of the cradle. Repair or replace if loose or damaged.
- Use the cradle extender to support the patient's head or feet during a scan.

For VT1700V and VT2000 Tables, to move the patient out of the gantry in an emergency, the cradle can be manually withdrawn by applying a minimum of 60 lb (267 N) of force.

For VT2000x table, to move the patient out of the gantry in an emergency, the cradle can be manually withdrawn by applying a minimum of 80 lb (357 N) of force.

5805441-1EN Rev. 2 (Sep. 2020)

Emergency Patient

This section contains Emergency Patient warnings.

Figure 3-34 Warning message : Emergency Patient

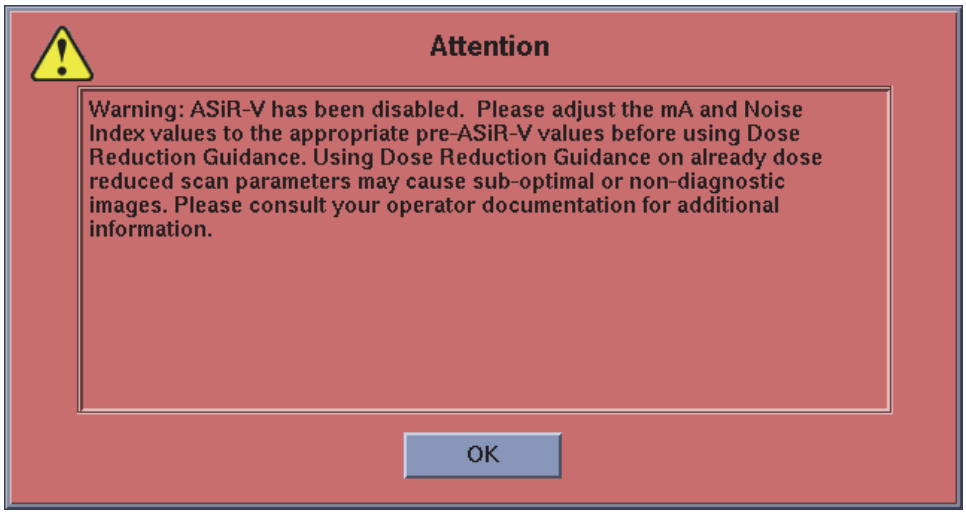
CAUTION: **No Emergency Patient protocol default has been set. Please use Emergency Patient Protocol in Protocol Management to set Emergency Patient protocol defaults.**
Verify the Emergency protocol link.

- **Check that the Protocol content and protocol icon are referenced correctly.**
- **Check the parameters for each link.**
  - **Patient Orientation**
  - **Patient position**
  - **Anatomical reference**
  - **Anatomical coverage**

ASiR-V/ASiR

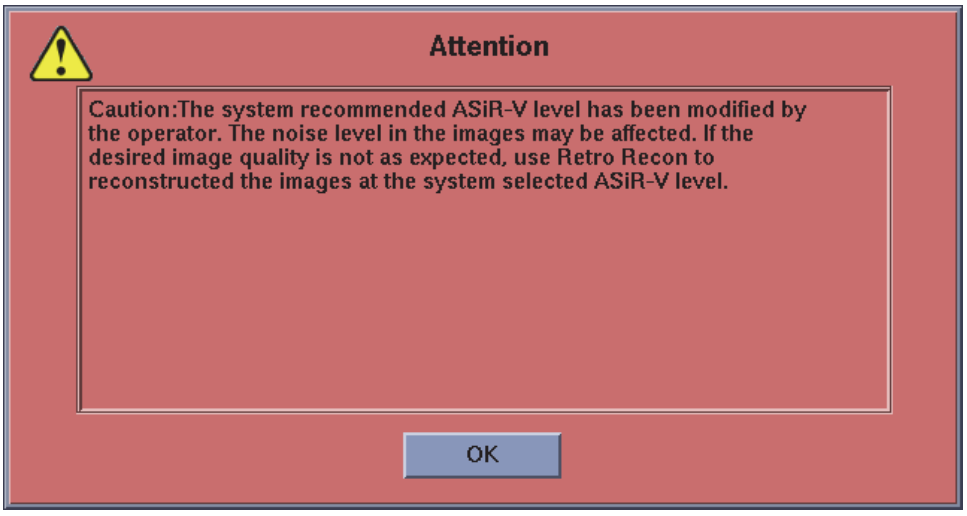
This section contains ASiR-V/ASiR warnings.

Figure 3-35 Warning message when turning Off ASiR-V in a protocol.



WARNING: ASiR-V has been disabled. Please adjust the mA and Noise Index values to the appropriate pre-ASiR-V values before using Dose Reduction Guidance. Using Dose Reduction Guidance on already dose reduced scan parameters may cause sub-optimal or non-diagnostic images. Please consult your operator documentation for additional information.

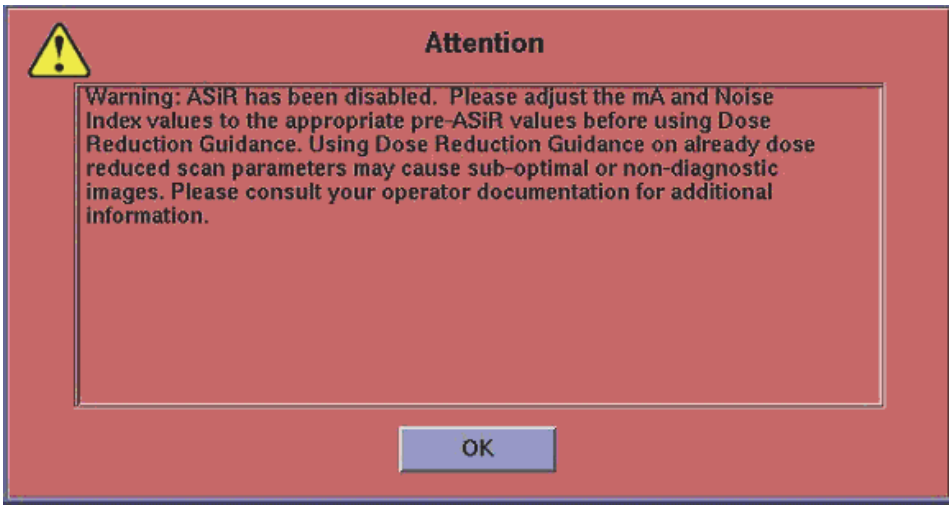
Figure 3-36 ASiR-V Modification Caution



5805441-1EN Rev. 2 (Sep. 2020)

CAUTION: **The system recommended ASiR-V level has been modified by the operator. The noise level in the image may be affected. If the desired image quality is not as expected, use Retro Recon to reconstruct the images at the system selected ASiR-V level.**

Figure 3-37 Warning message when turning Off ASiR in a protocol.



WARNING: **ASiR has been disabled. Please adjust the mA and Noise Index values to the appropriate pre-ASiR values before using Dose Reduction Guidance. Using Dose Reduction Guidance on already dose reduced scan parameters may cause sub-optimal or non-diagnostic images. Please consult your operator documentation for additional information.**

Figure 3-38 ASiR Modification Caution

CAUTION: **The system recommended ASiR level has been modified by the operator. The noise level in the image may be affected. If the desired image quality is not as expected, use Retro Recon to reconstruct the images at the system selected ASiR level.**

5805441-1EN Rev. 2 (Sep. 2020)

VolumeShuttle™ (Axial) and Volume Helical Shuttle

This section contains VolumeShuttle (Axial) and Volume Helical Shuttle warnings.

NOTE: For Volume Helical Shuttle a message will be posted in the Real Time Information Area and an Attention pop-up will be posted with the following messages:

"Table travel did not meet expected time for pass(es) during acquisition."

"Additional information on the errors seen can be found in the GE System Log."

CAUTION: Temporal sampling may be degraded due to changes in timing for the table to move from location to location if proper positioning methods are not followed. Make sure that the patient is securely positioned on the table and that their arms are not allowed to drag on the table, or allow clothing, sheets or blankets to get caught causing a table move problem.

WARNING: Temporal interval for images exceeds 3.2 seconds. Use of this data for processing of CT Perfusion maps may contain errors in the functional information.

Temporal sampling for data acquired for use in CT Perfusion should not exceed 3.2 seconds between data points for optimal results. As the temporal resolution increases, an error in the statistical accuracy of the information may be introduced.

This section contains VoumeShuttle (Axial) warnings.

CAUTION: VolumeShuttle (Axial) is intended for the neuro application of CT Perfusion.

CAUTION: VolumeShuttle (Axial) acquisition for head imaging should be performed with the patient positioned head first into the gantry in the head holder, or with the top of the head positioned 200 mm from the end of the cradle. Degraded image quality may result if alternate positions are used due to excessive body mass on an extended table.

CAUTION: **VolumeShuttle (Axial) for the acquisition of perfusion data should not be used for patients whose weight is greater than 400 lbs (181 kgs). The possibility exists of a scan abort due to the system being unable to move the table within the specified time. Use a Cine or Axial protocol for a single 40 mm location and repeat for a second location if additional coverage is needed.**

This section contains Volume Helical Shuttle warnings.

WARNING: **Prospective reconstruction only allows a preview series to be reconstructed at 5 mm image thickness with 5 mm, 10 mm, 20 mm or 30 mm interval. All additional reconstructions need to be done in Retro Recon.**

Figure 3-39 At End Exam for exams containing Volume Helical Shuttle

WARNING: **For Helical Shuttle acquisitions, use Retro Recon to generate images, or reserve scan files immediately for reconstruction later.**

5805441-1EN Rev. 2 (Sep. 2020)

Cardiac safety

CAUTION: **If, during the scan, the heart rate drops significantly lower than the prescribed heart rate, there is a potential for gaps in the gated image location. To avoid image location gaps, a non-gated image is reconstructed for the period where the patient heart rate dropped below the expected or confirmed heart rate at the start of the exam. A non-gated image may have more motion and may not be reconstructed at the prescribed phase.**

CAUTION: **ECG signal clarity and integrity must be confirmed prior to performing ECG-gated acquisitions. Items which may require adjustments of equipment settings or positioning, or patient set-up include:**

- External Interference
- A typical Patient ECG (e.g. elevated T-Waves, low ECG amplitude or signal strength)
- Suboptimal Patient Connection

ECG lead placement should follow recommended guidelines to optimize results.
If the ECG lead becomes disconnected during the scan, or the heart rate drops below 30 BPM, the images will be reconstructed as non-gated segment images. This is done to avoid inaccuracy of the *z*-location of images where necessary.

CAUTION: **Ensure the ECG patches are not past expiration date and that the gel on the pads is still moist for proper conduction of the ECG signal for successful gating.**

- It is important to explain to the patient the events that will occur during the acquisition of the contrast enhanced cardiac data. Make sure to explain the warm feeling that may occur during the injection of the contrast material.
- Use consistent breathing technique for all the series in a cardiac exam. Practice the consistent breathing instructions with the patient prior to scanning.
- During the practice breath hold, make sure to watch the ECG trigger monitor to determine the average heart rate, minimum heart rate, and ECG pattern during the breath hold.

- Position the patient's arms over the patient's head so they are comfortable and will not move during the acquisition of data.

CAUTION: **A patient with any of the conditions listed below may require additional attention. If patients are scanned with these conditions, the software may not be able to detect the R-peaks and the images therefore may be produced as ungated segment images.**

- **Patients with multiple pre-contractions or extra systole (e.g. PVC, PAC).**
- **Patients with persistent or extreme arrhythmia.**
- **Patients with bi-ventricular lead (dual chamber) pacemakers.**

CAUTION: **Patient motion, respiration, beat-to-beat variability of heart rate, heart motion, or significant change in heart rate over the scan duration could cause an ECG gated acquisition to have degraded image quality. It is important to explain to the patient the pattern of breathing instructions to expect, the warm feeling that can be felt from the contrast injection, and to position the patient comfortably such that the arms will not move with respect to the body during the scan.**

CAUTION: **There is a possibility that the ECG signal may not be detected by the system due to improper lead placements, or a lead falling off during the scan. It is important to place new leads on the patient before the scan. Make sure the leads are attached properly, and use only GE recommended ECG leads. It is important to confirm ECG trace clarity before the scan.**

CAUTION: **Avoid scanning patients with known arrhythmias. If arrhythmias (including pre-ventricular contractions, or extra systole), are seen when reviewing the ECG trace prior to scanning, attempt to regulate the heart rhythm (e.g. practice breathing instructions, calm the patient, or follow procedure established by your institution). It is not advised to scan a patient with arrhythmias as image quality may be degraded.**

CAUTION: **If you do not see the RED line on the R-peak, but somewhere else, it is advised to make the appropriate adjustments to the electrode placement, monitor settings, and equipment to ensure proper gating on the R-peak.**

5805441-1EN Rev. 2 (Sep. 2020)

CAUTION: The heart rate displayed on CT console is a 3-cycle average. You must review the actual waveform pattern to determine ECG trace clarity, trigger location, and if any cycle-to-cycle variability or masked arrhythmias may be present in order to adapt set up and conditions prior to proceeding with the scan acquisition.

CAUTION: Cardiac helical scan modes of SnapShot Segment, Burst, and Burst Plus are optimized for specific heart rate ranges. Select the appropriate scan mode for each patient's heart rate pattern. If the incorrect mode is selected, temporal resolution may be insufficient and degraded image quality could result.

CAUTION: SnapShot Segment Plus is an alternate reconstruction mode which applies a different weighting to data in the area of cardiac cycle transitions compared to SnapShot Segment reconstruction mode. Image quality in these transition areas should be reviewed carefully.

CAUTION: SnapShot Pulse should not be used for studies where function or full multiphase analysis is needed. Settings may limit the cardiac phases available to one or a few neighboring phases impacting the ability to analyze heart motion or review cardiac phase locations outside the prescribed phase.

WARNING: When using SnapShot Pulse scan mode for coronary artery imaging, SnapShot Pulse should only be used for patients with stable heart rates of 65 beats per minute (BPM) or less. Heart rates that are unstable or above 65 BPM inherently exhibit higher heart motion and increase the interscan delay, which could lead to suboptimal image quality. Alternate imaging modes such as cardiac helical should be considered if the optimal conditions for SnapShot Pulse are not met.

CAUTION: Auto mA and ECG Modulation are not valid with SnapShot Pulse acquisitions due to prospective control of X-ray over the scan volume. Only Manual mA values can be prescribed.

CAUTION: Manual edits of the ECG gating R-Peak triggers may be performed retrospectively in some ECG-gated exams as long as scan data exists on the console. Images can be reconstructed with user modified gating triggers and the original gating information can be retrieved after edits have been made.

CAUTION: Heart rate information and phase location will be updated to indicate any movement of trigger locations since heart rate and phase values are calculated based on time between consecutive triggers and are not diagnostic values.

CAUTION: The ECG waveform on the console, the gantry display and the ECG Monitor provided for cardiac imaging should not be used for monitoring patient status. The monitor and waveform are intended for clinical imaging and may not show the accurate status of the patient due to system interference and operation that may occur during imaging.

5805441-1EN Rev. 2 (Sep. 2020)

Laser Safety

(Reference 21 CFR 1040.10(h))

A laser alignment light system is available in order to accurately define the patient scan region except for Radiotherapy Treatment Planning.

WARNING: THE LASER BEAM CAN CAUSE EYE INJURY.

- Tell all patients to close their eyes before you switch ON the alignment lights.

- Instruct your patients to keep their eyes closed until you turn OFF the alignment lights.

NOTE: Closely monitor infants and inforrm patients, and prevent them from accidentally staring into the beam.

CAUTION: For patient safety, it is important to always have patients close their eyes anytime the laser alignment light is on.

CAUTION: The detector and DAS rotate to position the alignment lights over the laser ports.

- Keep your hands away from the gantry opening.

- Make sure the gantry side covers are in place.

CAUTION: Use of controls or adjustments, or performance of procedures other than those specified herein, may result in hazardous radiation exposure.

- The indicator on the gantry display panel lights when you turn ON the alignment lights.
- Warning labels regarding laser safety are provided on the gantry, as described in the Warning Labels and Symbols section.

Reconstructed Image Orientation

CAUTION: **GE CT image reconstruction is in an orientation viewing from the patient's feet. The reconstructed orientation is the orientation in which the image is installed in the image data base, and is the orientation with which images are networked to a remote viewing station.**

Figure 3-40 Patient Orientation

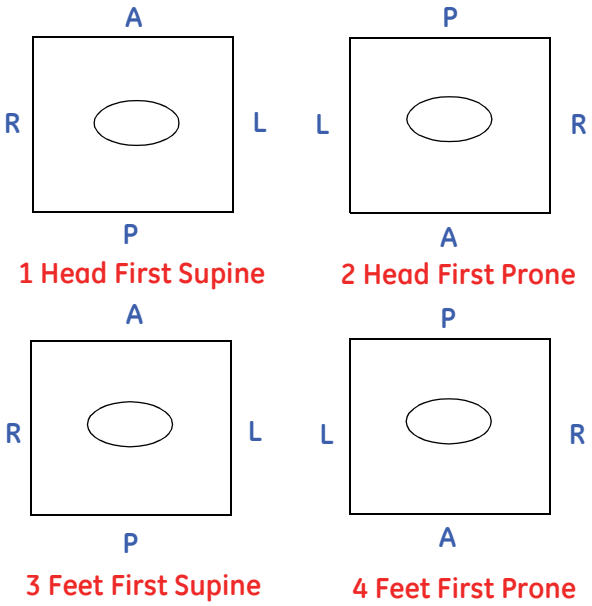


Table 3-3 Patient Orientation

Number	Description
1	Head First Supine
2	Head First Prone
3	Feet First Supine
4	Feet First Prone

The patient position information stored in the image header correctly reflects the orientation (RAS) information for the patient. Viewing applications will correctly reflect Right (R), Left (L), Anterior (A) and Posterior (P) of the patient.

The reconstructed image orientation may differ from preferred anatomical viewing presentation in which the patient's Right is on the viewers Left and patient's Left is on the viewers Right. For example, when the patient is scanned Head First and Prone the patients's Left is on the viewer's Left and the patient's Right is on the viewer's Right. The image presentation will need to be modified to display preferred anatomical viewing. Some

5805441-1EN Rev. 2 (Sep. 2020)

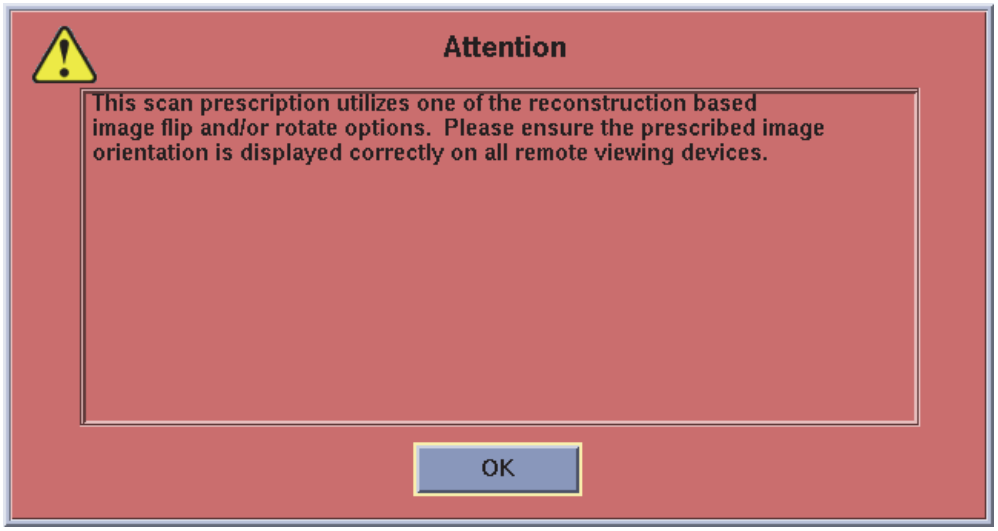
viewing stations may not have the capability to flip the image presentation, but if the capability exists, you must use display tools such as Flip to change the presentation of the image.

Some remote viewing stations may have the capability to set default viewing protocols. This is another tool that can be used to set an anatomical viewing presentation.

Post processing applications such as Direct MPR, Reformat and Volume Viewer automatically orient images in anatomical viewing orientation. These applications create axial images in anatomical viewing presentation. Please see Display Applications for more information. The system also provides the capability to create Gray Scale Presentation State Objects (GSPS) to flip the image orientation.

Flip/Rotate in recon can be used to generate images where right/left or anterior/posterior are flipped or where both R/L and A/P have been flipped to meet desired image display preference. An Attention pop-up is displayed at Confirm for series where Flip/Rotate in recon is selected. Attention: This scan prescription utilizes one of the reconstruction-based image flip or rotate options. Please ensure that this prescribed image orientation is displayed appropriately on all remote viewing devices.

Figure 3-41 Flip Warning Message



CAUTION: **The scan prescription utilizes one of the reconstruction based image flip and/or rotate options. Please ensure the prescribed image orientation is displayed correctly on all remote viewing devices.**

Data Safety
(Reference: IEC60601-1:2005 7.9.2.13)

To ensure data safety:

- Verify and record the patient's identification before starting a scan.
- Observe and record the patient's orientation, position, and anatomical landmarks before starting a scan. Ensure that the patient is positioned within the scan parameters.
- Maintain system image quality by performing Daily QA and other maintenance.

Connectivity - Always verify that the data transferred to another system has been correctly received.

CAUTION: **Do not remove images while scanning. Always remove images when the system is idle. Removing images while the system is acquiring and reconstructing data could cause the system to lock up and require a reboot and/or force the system to go into data base recovery.**

CAUTION: **Saving images in Interchange (CD/DVD/USB) while scanning may cause long interscan delays (ISD) to be missed or may cause Auto Voice to fail to play. Do not copy or restore images using CD-R, DVD-R or USB device while scanning.**

CAUTION: **When comparing GE CT images with other images, consult the DICOM Conformance Statement for the details on the DICOM Image Position, Frame of Reference UID, and Slice Location values stored.**

CAUTION: **Some annotation values are stored in private DICOM elements. When viewing images on a remote station, these annotation values may not be visible on the image. Consult the DICOM Conformance Statement for information on private DICOM data fields.**

5805441-1EN Rev. 2 (Sep. 2020)

CAUTION: If you plan to reconstruct images, you must use files that reside in the disk. Either reserve the scan files you plan to retrospectively reconstruct, or reconstruct unsaved scan files before the system overwrites the files with new scan data. The system refuse to overwrite reserved scan files. Remember to release the reserved scan files when you finish retrospective reconstruction.

CAUTION: CT Numbers are NOT absolute; misdiagnosis is possible. System and patient variables may affect CT Number accuracy. If you rely solely upon CT Numbers without taking variables into consideration, you could misdiagnose an image.

CAUTION: Incorrect data entries or procedures could result in misinterpretation or misdiagnosis.

CAUTION: When entering Patient ID information, the system may contain multiple instances of the same Patient ID. Multiple schedule records can be due to multiple procedures being ordered under separate accession numbers or New and Completed records in the Patient schedule for the same Patient ID.

When entering the Patient ID, verify that the correct Accession number and Exam Description selected is what is desired. Scanning with an incorrect Accession number may cause problems reconciling exams on a PACS system. See the Schedule Patients chapter for more information.

CAUTION: The system posts a warning message when expected disk space required to store scan data from the prescribed exam is insufficient.

CAUTION: The system posts a warning message when expected image space required to store images from prescribed reconstruction is insufficient.

CAUTION: The system posts a warning message when data was interpolated to generate images.

CAUTION: The system posts a warning message if there is a failure during the archive of patient data.

CAUTION: The system posts a warning message if there is a failure during the network of patient image data.

CAUTION: The system posts a warning message when a scan is aborted due to a failure in the acquisition chain.

CAUTION: The system posts a warning message when the system has low disk space. This is due to a partition on the system disk getting too full. Removing images will not help. Contact service to help with recovery. If you reboot the system and see the message asking if you want to run storelog, select the option to remove the logs.

CAUTION: The system posts a warning message if patient orientation has been changed or does not match after start of exam.

CAUTION: The system posts warning message prior to modifying any existing data set by a software utility.

5805441-1EN Rev. 2 (Sep. 2020)

Application Software Safety

CAUTION: **Do not initiate a QuickSnap if the system is actively collecting data with X-ray on.**

CAUTION: **Do not initiate an IQ Snap while the system is actively scanning or reconstructing data.**

Application Specific Safety Topics

Helical scanning

WARNING: **Helical scanning has the inherent ability to produce artifacts when scanning highly sloped anatomy (e.g. pediatric or adult heads). Factors which worsen this effect are: faster table speeds, thicker image thickness, and gantry tilt. In some cases these artifacts could be mistaken for a hemorrhage near the cranium, or a thickening of the skull.**

To reduce the occurrence of these artifacts, you may prescribe slower table speeds or thinner slices (such as 2.5mm) during helical scans near the vertex of a pediatric or adult head.

WARNING: **It has been documented in radiology literature that an artifact may occur in the chest that bears the double margin of the great vessels, which emulates a dissection of the vessel during 0.35 - 1.0 second scans. This can occur in axial or helical scans. If you have scanned axially with a 0.35 - 1.0 second rotation time and observe this phenomenon, re-scan the area with a 2 second axial scan to verify if it is artifact or patient pathology. Segment recon mode for helical and cine acquisitions may be used in Retro Recon to also assess if the area is artifact or pathology.**

Lung Algorithm

- The Lung algorithm setting provides edge enhancement between structures with large density differences, such as calcium and air, resulting in a sharper lung field when compared to Standard algorithm.
- For best image quality, prescribe a 5 mm scan thickness when you plan to use the Lung algorithm. If you plan to prescribe a High Resolution Lung study with 3.75, 2.5, or 1.25 mm, use the Bone algorithm.
- The Lung setting enhances the contrast of small objects. For best viewing and film quality, select a window width of 1,000 to 1,500 and a window level of -500 to -600.
- The Lung algorithm setting increases the CT number values at the edge of high contrast objects. If you plan to take CT number measurements of vessels or nodules in the lung, please check and compare your results with Standard algorithm images. ROI and Histogram functions use CT numbers.
- **Remember:** The edge enhancement provided by the Lung setting may not be appropriate in some clinical cases. Please take individual viewing preferences into account when you choose the Lung setting.

5805441-1EN Rev. 2 (Sep. 2020)

Auto scan

- Press and release **Move to Scan** on the console to advance the cradle.
- If Autoscan is disabled, **Move to Scan** must be pressed for every scan before **Start Scan** will become ready.
- If you select Auto Scan during one group Rx, it remains ON for every group in that series.

SmartStep and SmartView Safety

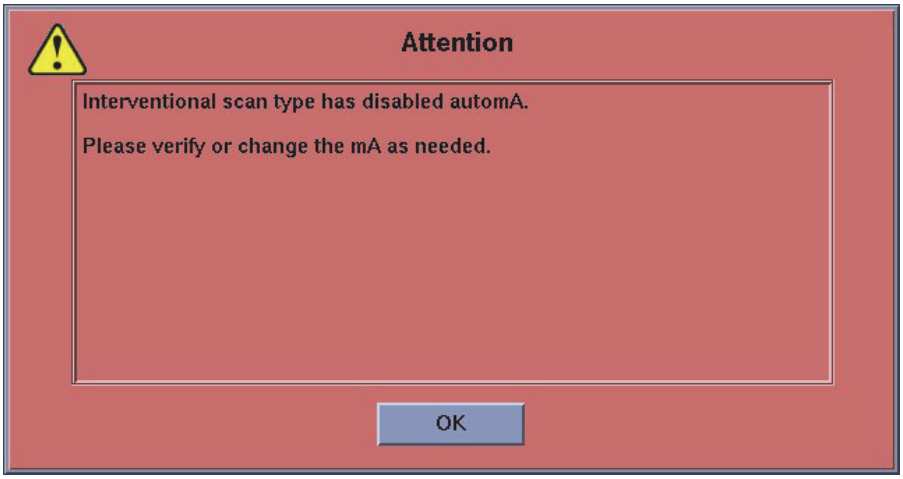
The SmartStep and SmartView option adds several components to the scan room. These are the In-Room Monitor, Hand Held Control for table movement as well as image review, and the X-Ray Control Foot pedal.

Each of the SmartStep/SmartView components is connected to the system by a cable. When using the system, ensure that the cables cannot catch on anything when the gantry or table is moved.

CAUTION: **The cabling provided for the Interventional Hand-held Controller and Foot Pedal provided with the SmartStep and SmartView options may present a trip hazard. Ensure that the cabling cannot catch on anything when the gantry or table is moved and that the cables are out of the way while loading and unloading the patient.**

CAUTION: **Ensure that all cables attached to gantry or hung in gantry strap do not present a trip hazard or loop which could be caught when moving past the cables.**

Figure 3-42 AutomA is active when starting a SmartStep/SmartView series



CAUTION: **Interventional scan type has disabled AutomA.**

Please verify or change the mA as needed.

Table Float

During the scan, the clinician has the option to float the table between scans. When the Table Float mode is selected, the table is unlatched and can be moved freely by anyone at the bedside.

WARNING: **Unintended table motion may cause a serious injury. Table may be bumped or jarred during an interventional procedure. Care must be taken when performing interventional procedures in the float mode. It is the clinician's responsibility to ensure that they have control of the table when in this mode of operation. Table must not be left unattended when in the float mode. Ensure that the table is latched before leaving the table side.**

SmartStep and SmartView Scanning

SmartStep and SmartView scanning allows multiple scans at one location for interventional procedures. The system allows up to 90 seconds of scanning in one place. After 90 seconds, the operator must prescribe a new scan to continue. The accumulated scan time from a procedure is displayed on the In-Room Monitor.

CAUTION: **Exposure time to the patient can be up to 90 seconds per Confirm compared to 60 seconds for all other scan modes except Helical scanning with 20mm beam collimation and Cine mode.**

CAUTION: **Prolonged exposure to X-ray in one spot may cause reddening or radiation burns. User must be aware of the techniques used and exposure time to ensure safe operation.**

CAUTION: **The foot pedal is active if the system is in the "Prepped" state. Care should be taken not to step on the foot pedal and make an unwanted exposure.**

5805441-1EN Rev. 2 (Sep. 2020)

WARNING: **The Foot Pedal should not be detached or attached to the gantry when the system in the Ready to scan state. Always make sure the system is not the prepped/ready state when manipulating the Foot Pedal connection to the gantry.**

In SmartView, if the image latency exceeds the expected timing for the selected rotation speed, the following warning message will be displayed in the SmartView display area. Once the image latency returns to the expected rate, the warning message will be removed.

WARNING: **Average Latency**
xxxxx - xxxxx ms
(where xxxxx represents the image latency time in ms.)

Clinicians working in the scan room should wear appropriate protective clothing. Lead aprons, groin and thyroid protection, as well as protective eye wear are available through the GE Accessories Catalog.

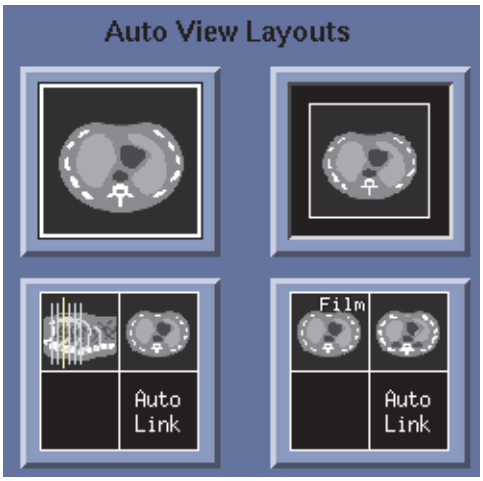
Interventional/biopsy Scanning

CAUTION: **The continuous AutoView layout format should not be used for display of images during an interventional study because it does not allow for quick review of images in a free viewport.**

WARNING: **When scanning for interventional (biopsy) studies, the scan mode, image thickness, number of images per rotation, and the display layout used affect the display of the images. It is recommended to use the Biopsy Mode provided on the system. If manually prescribing biopsy scans, Axial 1i scan mode or Helical scan mode with a slice thickness greater than 2.5 mm must be used. Do not use Cine scan mode for interventional (Biopsy) imaging. Do not use an AutoView layout with more than one AutoView image viewport.**

Refer to the Set Image Display procedure in the Viewing images chapter of the User Manual for more information on how to set up the desired viewing options. Choose one of the following for the best AutoView layouts.

Figure 3-43 AutoView Layouts

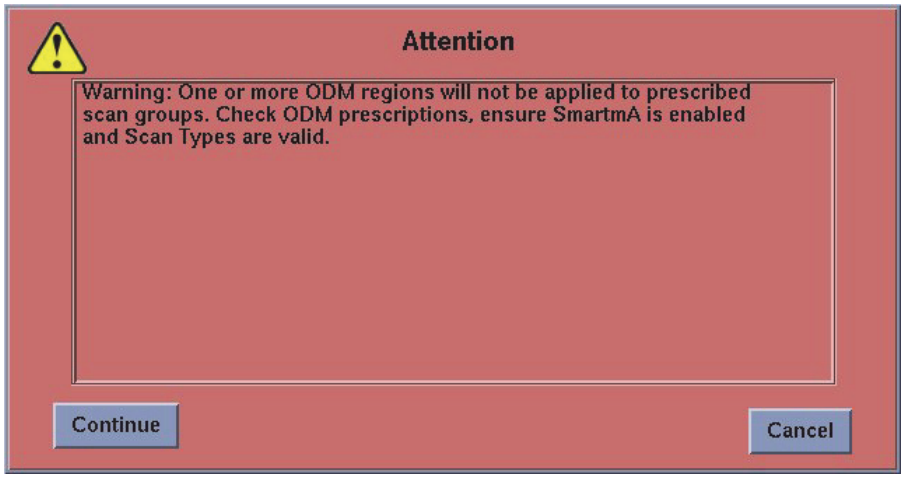


Treatment Planning

Potential inaccuracy can occur in the positional display of the system when the manual cradle release is used inappropriately during Radiotherapy simulation procedures.

Organ Dose Modulation

Figure 3-44 Warning message when ODM prescription is valid but SmartmA is off.

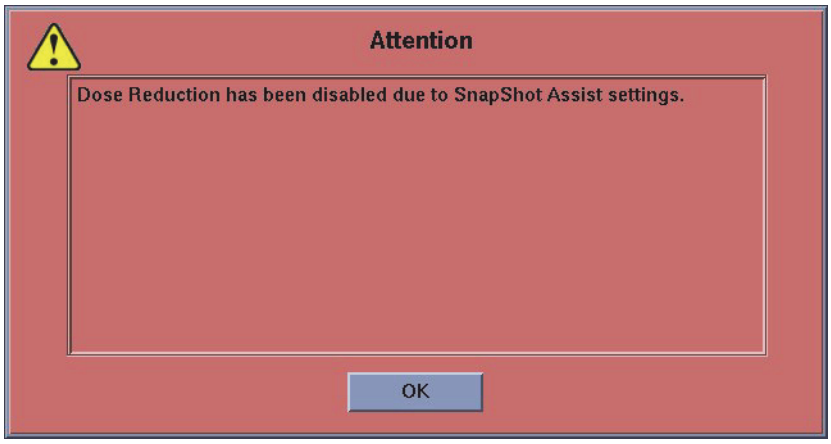


WARNING: One or more ODM regions will not be applied to prescribed scan groups. Check ODM prescriptions, ensure SmartmA is enabled and Scan Types are valid.

5805441-1EN Rev. 2 (Sep. 2020)

Disable Dose Reduction

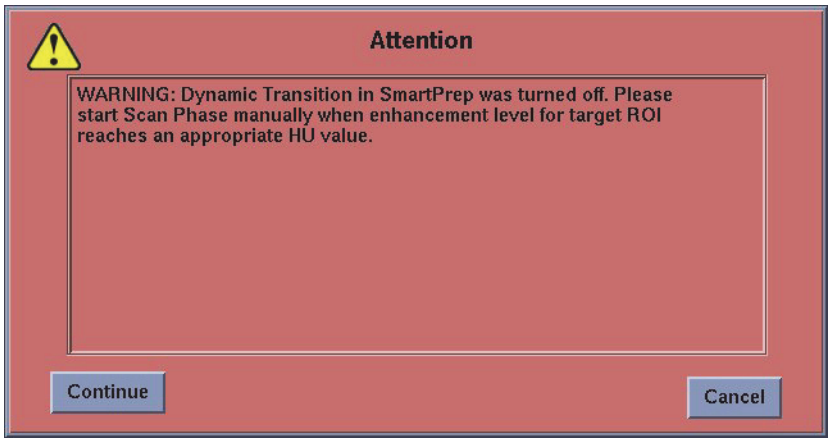
Figure 3-45 Attention Messages when SnapShot Assist setting is applied



Attention: **Dose Reduction has been disabled due to SnapShot Assist settings.**

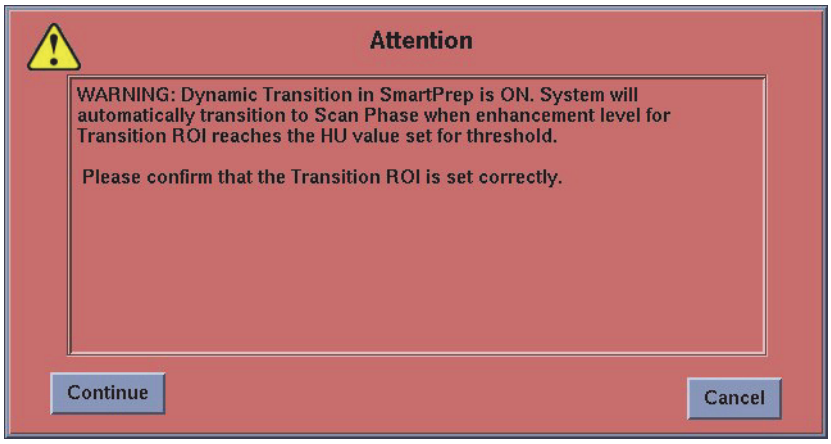
Dynamic Transition

Figure 3-46 Warning Messages when Dynamic Transition is turned off in Scan Progress screen



WARNING: **Dynamic Transition in SmartPrep was turned off. Please start Scan Phase manually when enhancement level for target ROI reaches an appropriate HU value.**

Figure 3-47 Warning Messages when Dynamic Transition is turned on in Scan Progress screen



WARNING: Dynamic Transition in SmartPrep is ON. System will automatically transition to Scan Phase when enhancement level for Transition ROI reaches the HU value set for threshold.
Please confirm that the Transition ROI is set correctly.

Image Check

CAUTION: Images are not for diagnostic use.

Smart Metal Artifact Reduction (MAR)

- When using Smart MAR, always reconstruct the data with and without Smart MAR for a comparative image review.
- Smart MAR images are annotated with an M.

Advanced Applications Safety

CAUTION: 3D or slab reconstructions provide additional supplemental information, complementing diagnosis that should be based on classical techniques.

5805441-1EN Rev. 2 (Sep. 2020)

WARNING: Non-GE acquired images can be loaded in Volume Viewer but GE does not guarantee the quality or reliability of any reconstruction, segmentation, or measurements performed on these images. Non-GE images can easily be identified by the corresponding image annotation.

Follow the DICOM acquisition parameter guidelines listed in each application user guide. Consult GE-published DICOM conformance statement of Volume Viewer which is available on the GE Healthcare website at http://www3.gehealthcare.com/en/Products/Interoperability/DICOM/Computed_Tomography_DICOM_Conformance_Statements

Measurements

WARNING: Do not use 3D or slab views only to perform any measurements (distance, angle, Region of Interest, Report Cursor, Area, Volume...). Always check measurement points' position and refer to 2D baseline views (acquisition images or reformatted images of minimal thickness) to confirm measurements.

CAUTION: The software calculates and displays measurements with a resolution of one decimal (such as 0.1 mm, 0.1 degree, etc.). You should be aware that the real measurement accuracy is generally less for a number of different reasons (image resolution, acquisition conditions...).

Distance, angle and area measurements are valid only if all trace segments are longer than the inte-slice distance.

WARNING: Depending on WW/WL settings, objects may display differently. Check WW/WL before depositing measurement points.

CAUTION: When filming or saving images for diagnostic purposes, always make sure the patient name and geometry information is displayed on all views, and that they match information on the reference view.

CAUTION: When saving images with a new series description, make sure this description matches the saved images.

WARNING: Check with original datasets, the reliablility of segmentations and measurements performed in Saved objects after post processing and reloading.

Segment Tools

WARNING: Before using any segmentation tool (threshold, scalpel, remove & keep object, Auto Select, "floater" filters...) always make sure that it will not remove pathologies or other essential anatomical structures.

WARNING: When using any Segmentation tools (Auto Select, threshold, Paint on slice, Quick Paint...), check contours to check the reliability of the segmentation. Make sure the contours match the correct segmentation and volumes. Check that segmented volumes match contours.

Filming and Saving Images

CAUTION: When filming or saving images for diagnostic purposes, always make sure the patient name and geometry information is displayed on all views, and that they match information on the reference view.

CAUTION: When saving images with a new series description, make sure this description matches the saved images.

CAUTION: Check with original datasets, the reliablility of segmentations and measurements performed in Saved objects after post processing and reloading.

5805441-1EN Rev. 2 (Sep. 2020)

Image reliability

CAUTION: 3D or slab reconstructions provide additional supplemental information, complementing diagnosis that should be based on classical techniques.

WARNING: Always correlate any information (cursor position, image orientation, measurements, image quality...) in any 3D reconstruction (reformatted plane, oblique, MPVR, MIP, Volume Rendering, Navigator endoluminal views, Curved, segmentations, measurements, tracking, saved images...) with the original data (acquisition or baseline images).

WARNING: A 3D view is a two-dimensional projection on the screen of the 3D Volume. There is no indication on a 3D view of how "deep "inside the 3D volume a 3D cursor is. Always check the accuracy and consistency of 3D coordinates by checking cursor position on original data (acquisition images).

Window Width and Level (W/L)

WARNING: The window width and level (W/L) determine how clearly pathologies and other anatomical structures can be discerned. Incorrect W/L settings may result in pathologies and other essential anatomical structures not being displayed correctly. As a single W/L cannot display all features present in an exam, use several different settings, when necessary to explore all exam data.

Volume Rendering

WARNING: When using Volume Rendering, incorrect setting of opacity curve, opacity threshold, transparency setting when merging VR objects, can result in pathology or essential anatomies not being visible. Always correlate Volume Rendering images with original images.

Image quality

WARNING: **At all times, it remains the responsibility of the physician to determine whether the inte-slice distance used for a particular exam is acceptable.**

WARNING: **Loading non-square pixels will result in bad image quality.**

WARNING: **Default Plaque Color Map preset is provided for information. You must check and adjust Values and segment names.**

5805441-1EN Rev. 2 (Sep. 2020)

Accuracy of Measurements

Measure Distance for Axial, Helical, and Cine Images

This section includes information on accuracy of measurements used when reviewing images.

CAUTION: **Measure error using the straight line distance graphic is less than two times the image pixel size.**

CAUTION: **Note that the measurements are accurate only if the trace segments are longer than the slice interval.**

Measure Distance for Scout Images

Accuracy of measurements for scout images in the “X” direction varies with object thickness and distance from ISO center in the “Y” direction. Note the orientations of the “X” and “Y” aea in Figure 3-48 below assume a scout scan plane of 0 degree. If the scout plane is rotated, then the “X” and “Y” orientation changes accordingly.

Figure 3-48 Scout Scan Plane

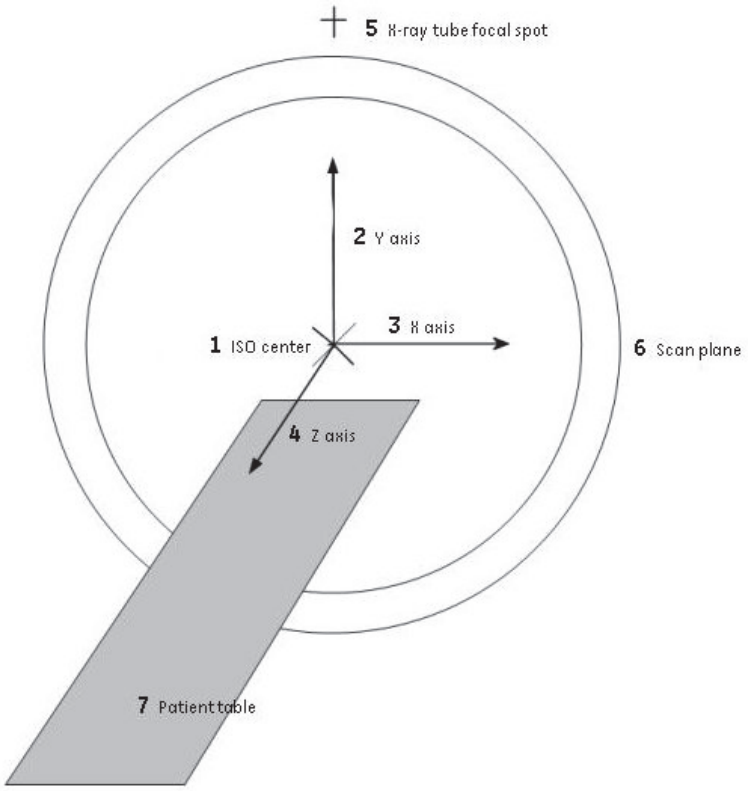


Table 3-4 Scaut Scan Plane

Number	Description
1	ISO center
2	Y axis
3	X axis
4	Z axis
5	X-ray tube focal spot
6	Scan plane
7	Patient table

- For measurements of anatomy in the “X” direction that are at ISO center (“Y”):
  - The measure error using the straight line distance graphic is less than 5 % of the measured distance plus 2 mm.

5805441-1EN Rev. 2 (Sep. 2020)

- For measurements of anatomy in the “X” direction that are NOT at ISO (“Y”):
  - The measure error using the straight line distance graphic is less than 5 % of the measured distance plus 2 mm plus 3 % of measured distance per centimeter from ISO.
- For measurements of anatomy in the “Z” direction:
  - Measure error using the straight line distance graphic is less than two times the image pixel size.

Measure Angle

CAUTION: **Measurement accuracy using the angle graphic is equal to the displayed angle value +/- 10 degrees for an angle measured between segments that are five times larger than the image pixel size. Accuracy improves as the length of the segments increases.**

ROI

CAUTION: **Area measurement accuracy using a region of interest graphic (rectangle, smooth curve, ellipse or free draw) is equal to the displayed area +/- the circumference of the region multiplied by (image pixel size) ^{2}/2. Mean and standard deviation values for the intensity of the pixels in the region are also affected by this accuracy. If the ROI is rotated, the area measurement can vary up to 5%. Region of interest statistics are based on the pixels INSIDE the graphic defining the region.**

Reformat Plane Thickness

Reformat plane thickness equals 1 pixel.

- If each axial pixel represents 0.5mm of anatomy, then the reformat plane thickness equals 0.5mm.
- If pixel size equals 0.9766mm **(500mm/512)**, then the reformat plane represents a slice of anatomy about one millimeter thick.

CAUTION: **CT Numbers are NOT absolute; misdiagnosis is possible. System and patient variables may affect CT Number accuracy. If you rely solely upon CT numbers without taking the following variables into consideration, you could misdiagnose an image.**
For more information, refer to CT Number in the User Manual.

CAUTION: **The limiting measurement resolution of the cursor is 1mm, i.e., the distance less than 1mm but greater than 0.5mm is rounded to 1mm, therefore, the accuracy of this testing is limited by the cursor measurement capability. This is especially important for a thin slice measurement where the FWHM is close to 0.625mm. The results for these thin slice images will not be as accurate as the thick slice ones. This is the limitation of this testing method.**

5805441-1EN Rev. 2 (Sep. 2020)

Operator Console Ergonomics

To optimally use the system and reduce the chance of physical strain and fatigue, the following steps are recommended regarding how you use your operator console.

Posture

Correct posture is very important. To ensure correct posture while sitting at your operator console, follow these basic steps:

1. Face the monitors and keyboard without twisting your body.
2. Sit comfortably erect with the small of your back well supported.
3. Position your forearms parallel to the floor, with your wrists straight.
4. Position the screen so that your eyes are nearly level with the top of the screen.
5. Keep both feet flat on the footrest, with your thighs parallel to the floor.

If you cannot comfortably maintain this position while working at your operator console, you should make the necessary adjustments to your operator console environment.

Equipment Adjustments

Chair

Adjusting the fit and height of your chair is very important for comfort. Follow these basic guidelines:

1. Fit the backrest snugly against your back. People with shorter legs might need a back cushion.
2. Set your chair height to position your forearms parallel with the floor when your hands are placed on the keyboard. If your feet dangle, you need a footrest.

Keyboard

Keyboard height is also important. When typing:

- Your wrists should be as straight as possible.
- Your forearms should be parallel to the floor.
- Your hands and fingers should float over the keys or mouse.

Screen

- The recommended viewing distance from the screen is 18 - 28 inches (45 - 70 centimeters).
- With your head straight, your eyes should be looking directly at the top of the screen.
- You should look at the screen straight-on, not at an angle from the side, top, or bottom.

- Glare from the screen can disrupt your viewing and cause eyestrain. Do not face a window, and position the screen at right angles to bright light sources.

Comfort

Comfort at your operator console indicates you have set up your work area correctly. However, even a well-designed area needs frequent adjustment, especially for different users. Take the time when positioning yourself at your operator console to ensure your comfort.

It is also recommended that if you use the operator console for extended periods (several hours at a time), that you take short breaks to get away from your operator console and perform simple stretching exercises to reduce the chance of fatigue.

Other considerations:

- Stay alert to your patient's condition.
- Use the speakers and microphones on the table, gantry, and console to stay in constant communication with the patient, even while you sit at the console.
- Follow the exam procedures explained in the User Manual. Carefully enter patient information and position before proceeding.

5805441-1EN Rev. 2 (Sep. 2020)

Accessories

WARNING: Pinching from installation of accessories, for example, head holder, phantom holder, foot extender or using a cracked head/phantom holder etc. can cause physical injury.

WARNING: The use of accessories, transducers, and cables other than those specified may result in degraded ELECTROMAGNETIC COMPATIBILITY of the EQUIPMENT and/or SYSTEM.

WARNING: Do not connect accessories that are not approved as part of the system. Do not use accessories from other modalities.

WARNING: None of the accessories support the full weight of a patient. If you sit, stand, or otherwise apply excessive pressure to these devices, they break or come off the cradle and may cause injury. If an accessory breaks, use caution when picking it up and do not continue to use.

CAUTION: When using patient positioning accessories and straps, make sure there are no areas that might cause a pinch point or interfere with patient tubing or IV.

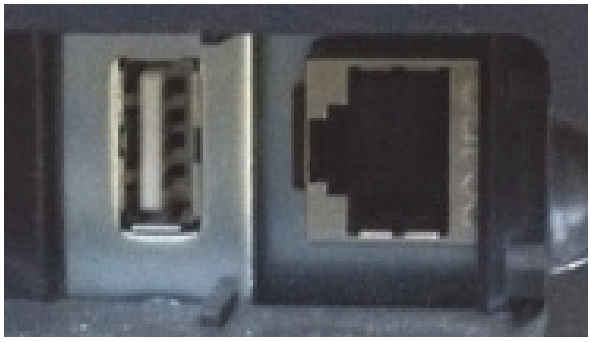
CAUTION: Ensure that all patient accessories attached to table do not present a trip hazard when working around the table or standing near the table when it is moving.

WARNING: Accessories like arm boards and catheter bag holders are not secured to the gantry and may interfere with the gantry if not positioned properly.

WARNING: **All non-medical equipment connected to the USB port of the media tower on the CT operator console must comply with IEC/EN/UL60950-1 and should be approved by GEHC.**

CAUTION: **Do not use the USB or Ethernet port on the front cover of the CT operator console, it is intended for service use only (Figure 3-49).**

Figure 3-49 Service USB/Ethernet Port



GE Approved Accessories (Reference: IEC60601-1:2005 Clause7.9.2.14, IEC60601-2-44:2009 Clause201.7.9.3.1)

With each use, check all accessories for damage and remove them from service if damaged or cracked. Use only GE approved equipment together with this system.

CAUTION: **Using accessories which are not GE approved accessories might affect dose and image quality.**

Table 3-5 GE Approved Accessories Types and Models

Type	Manufacturer/Model
Cardiac Monitor	IVY 3100 - B with ethernet IVY 3150 - B IVY 3150 - C IVY 7800
Respiratory Monitor	Varian RPM (v1.7) Varian RGSC (1.1)

5805441-1EN Rev. 2 (Sep. 2020)

Type (Continued)	Manufacturer/Model (Continued)
External Hard Drive	Seagate FreeAgent 1TB USB 2.0 Seagate FreeAgent 2TB USB 2.0/3.0
Flat Table Top	DIACOR Flat Table Top (E6315JE, E63151JE)
Patient contrast injector: For Xtream Injector option	Nemoto Dual Shot Alpha (CiA425 Class I) / GE 5328194 Nemoto Dual Shot Alpha (CiA425 Class IV) / GE 5328195 Nemoto Dual Shot Alpha 7 (CiA425 Class IV)* Nemoto Dual Shot GX (CiA425 Class IV)* Nemoto Dual Shot GX 7(CiA425 Class IV)* Nemoto A-800 (CiA425 Class IV) / GE 5421942* Nemoto W1000 (CiA425 Class IV)* Medrad ISI900 (for Stellant D) (CiA 425 Class IV)/GE 5335919 ulrich CT motion (XD8000) (CiA425 Class I)
Patient contrast injector: For Enhanced Xtream Injector option	Nemoto Dual Shot Alpha (CiA425 Class IV) / GE 5328195 Nemoto Dual Shot Alpha 7 (CiA425 Class IV)* Nemoto Dual Shot GX (CiA425 Class IV)* Nemoto Dual Shot GX 7(CiA425 Class IV)* Nemoto A-800 (CiA425 Class IV) / GE 5421942* Nemoto W1000 (CiA425 Class IV)* Medrad ISI900 (for Stellant D) (CiA 425 Class IV)/GE 5335919 ulrich CT motion (XD8000) (CiA425 Class IV) Medtron Accutron CT-D (CiA425 Class IV)
Child Positioner	Child Positioner Option

NOTE: *: Out of scope of EC Declaration compatibility with this CT system as of today. The update of compatibility can be confirmed by EC Declaration of Conformity letter of this product.

NOTE: All patient accessories may not be available in all regions.

The standalone software medical devices listed on 5796848-xxx: Authorized Product Matrix Manual.

Additional accessories and supplies are available at http://www3.gehealthcare.com/.

The placement of the cardiac monitor should be on the monitor stand. The monitor should not be placed on the table. It should be positioned so that it is not touching the table or gantry when it is in use.

IV Pole Safety

Care should be taken in the amount of weight placed on pole. Ensure that the pole is tightened prior to use.

CAUTION: The IV pole may bend when excessive weight is placed on the pole. Ensure no more than 4.5 kg (10 lb). is placed on the IV pole.

CAUTION: Ensure that the IV pole extension collar is tightened prior to use to prevent the pole height from collapsing.

Figure 3-50 IV Pole Load Limits

CAUTION: Do not load more than 4.5 kg (10 lb). Verify that extension collar is securely tightened before use.

Table Tray Safety

Care should be taken in the total weight of objects that are placed on the tray.

Figure 3-51 Tray Load Limits

5805441-1EN Rev. 2 (Sep. 2020)

CAUTION: **Do not load more than 9 kg (20 lb).**

CAUTION: **Objects that may be susceptible to tipping should be strapped down with the Velcro™ strap provided.**

Gantry Strap safety

Figure 3-52 Gantry strap

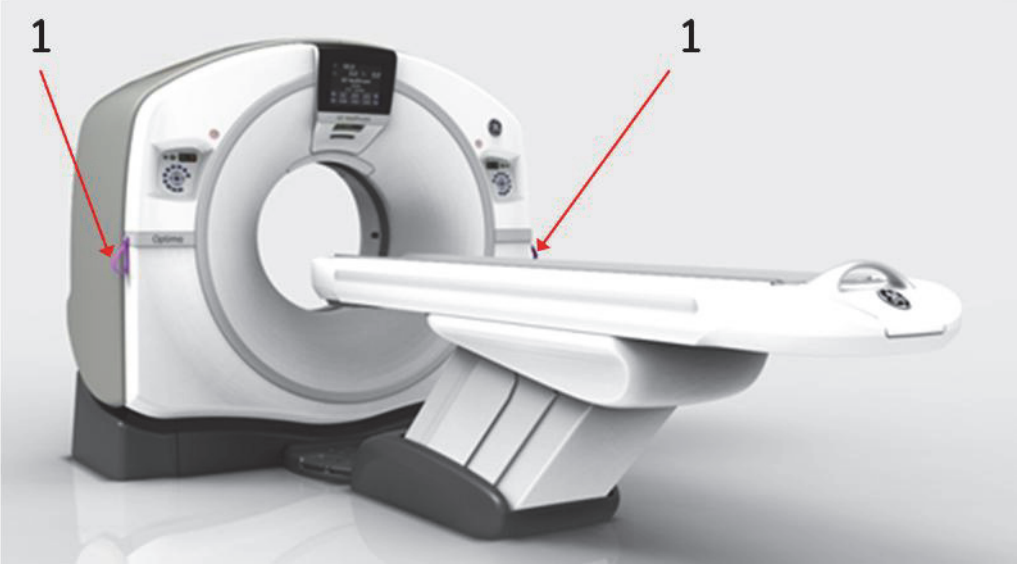


Table 3-6 Gantry strap

Number	Description
1	Gantry strap

CAUTION: **Gantry strap should only be used for Cardiac Monitor, SmartView/SmartStep cables. Placing injector lines through the gantry strap could cause interference issue and patient harm.**

CAUTION: **Gantry straps are designed to hold cables for accessories. Do not use for lifting or support.**

CAUTION: **Ensure that all cables attached to gantry or hung in gantry strap do not present a trip hazard or loop which could be caught when moving past the cables.**

Systems With Metal-Free Cradles and Accessories

CAUTION: **Prevent damage to metal-free accessories! Carefully examine the metal-free clasp assembly on the accessory and the catch on the cradle before attempting to attach the accessory for the first time.**

Figure 3-53 Accessory Load Limit

CAUTION: **Accessory may fall and cause injury if not latched to the cradle. Make sure that accessory is latched to the underside of the cradle.**

- To latch an accessory:
  - Align the accessory tongue with the pocket at the end of the cradle.
  - Keep fingers clear of the cradle.
  - Push the tongue all the way into the pocket until it latches into place.
  - Rubber shims may have been installed on the head holder or foot extender to give it a tighter fit. Please take care when latching the accessory to make sure that it is completely latched. Push the latch forward until you hear a click. Verify that the latch is fully latched.
- To unlatch an accessory:
  - Pinch the two L-shaped parts together and pull the accessory out of the cradle.
  - An alternate method is to apply a light force to the catch towards the cradle, pinch the L-shaped catch together, and pull the accessory out of the cradle.
- Proper operation:
  - Keep the accessory “tongue” and cradle pocket clean and free of fluids and debris.
  - Keep the latch and cradle pocket area clear of sheets, drapes, pads or any item that could interfere with proper latching and cause damage.

5805441-1EN Rev. 2 (Sep. 2020)

- Positioning:
  - Positioning patient anatomy over the area where the head holder or cradle extension attaches to the cradle may produce images where the contrast between two adjacent rotations is different. Make sure the area of interest, especially the head, is properly positioned in the head holder or on the cradle extension.

Xtream/Enhanced Xtream Injector Safety

CAUTION: **The injector and the system are operated independently after the Start Scan button is pressed. When you want to stop both the system and the injector, use the Stop Scan button on the system SCIM and the stop injector function on the injector.**

CAUTION: **When you use Xtream Injector with SmartPrep, injection doesn't start at the beginning of Baseline Phase. It starts at Monitor Phase. Going to Scan Phase without Monitor Phase, injection will not start.**

Limited Access Room Configuration

CAUTION: **Due to access limitations on the left side of the gantry, some procedures may be affected when ancillary equipment is used. Assess the placement of the equipment needed for the procedure before the placement of the patient on the table. Access around the left side of the gantry may also be affected.**

Emergency Devices and Emergency Egress

(Reference: 21CFR 1020.33 (f)(2)(ii))

Emergency Devices

The system has two types of Emergency buttons:

1. **Emergency Stop**- when pressed, all table and gantry motions are halted, generation of X-rays is stopped, laser alignment lights are turned off. The system aborts any data acquisition in progress, and attempts to save all data acquired prior to the abort. Use the Emergency Stop button for patient related emergencies.
2. **System Emergency Off button**- when pressed, the power to all system components is removed, stopping all table and gantry motion and generation of X-rays. The system aborts any acquisitions in progress, and data obtained prior to the abort can become corrupt or lost. Use the System Emergency OFF button for catastrophic emergencies, such as fire or earthquake.

CAUTION: **If you press the Emergency Stop or Emergency OFF buttons during a scan, the system will abort the data acquisition.**

Emergency Stop

NOTE: Emergency Stop should not be used routinely as a method to stop the system for non-emergency situations. Repeated use of the E-Stop to stop the system could cause tube damage.

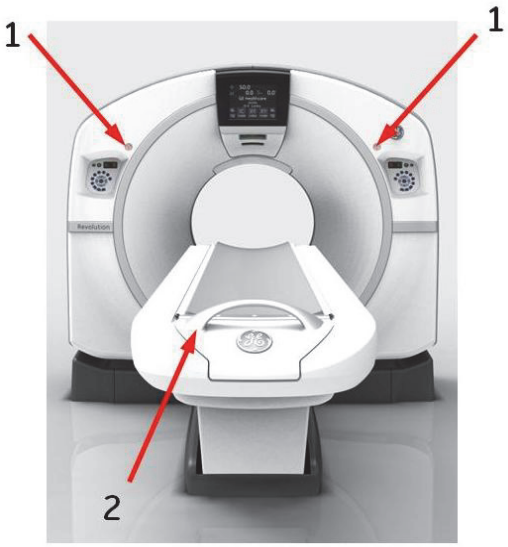
NOTE: Every operator should take a few minutes to locate the Emergency Stops on their system before scanning the first patient.

The system has five **Emergency Stop** buttons:

- One on each control panel on the front of the gantry (Figure 3-54).

5805441-1EN Rev. 2 (Sep. 2020)

Figure 3-54 Front of gantry Emergency Stop Buttons



1 Emergency Stop Buttons
2 Cradle Handle

- Two on the rear cover of the Gantry (Option)
- One on the Scan Interface Control Module (SCIM) (Figure 3-55).

Figure 3-55 Emergency Stop button on the SCIM

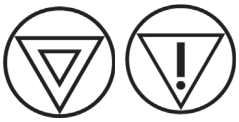
Press an **Emergency Stop** button in the event of a patient-related emergency or if the cradle, table or gantry starts to move unexpectedly.

- Once an **Emergency Stop** button is pressed, the **Reset** gantry key, on the gantry control panel, flashes about once every 2 seconds.
- Press the **Reset** gantry key to restore power to the gantry and table.

When **Emergency Stop** is applied, the moving cradle and tilting gantry may overrun by less than 10 mm and less than 0.5 degrees respectively.
When unintentional interruption of the power supply occurs, the moving cradle and tilting gantry may overrun by less than 25 mm and less than 0.5 degrees respectively.

Emergency Stop button symbols

Emergency Stop buttons may be accompanied by one of the symbols below.



5805441-1EN Rev. 2 (Sep. 2020)

System Emergency OFF Buttons using Main Disconnect Control (For the system with MDC Only)

In the event of a fire, flood, earthquake, or any other catastrophic emergency, all power to the system should be turned off. Pressing the **System Emergency OFF** button immediately removes all power to the system by removing power to the Main Disconnect Control (MDC). Because the system has no time to save data, or shutdown in an orderly fashion, pressing the **System Emergency OFF** button can corrupt system files or result in loss of patient data.

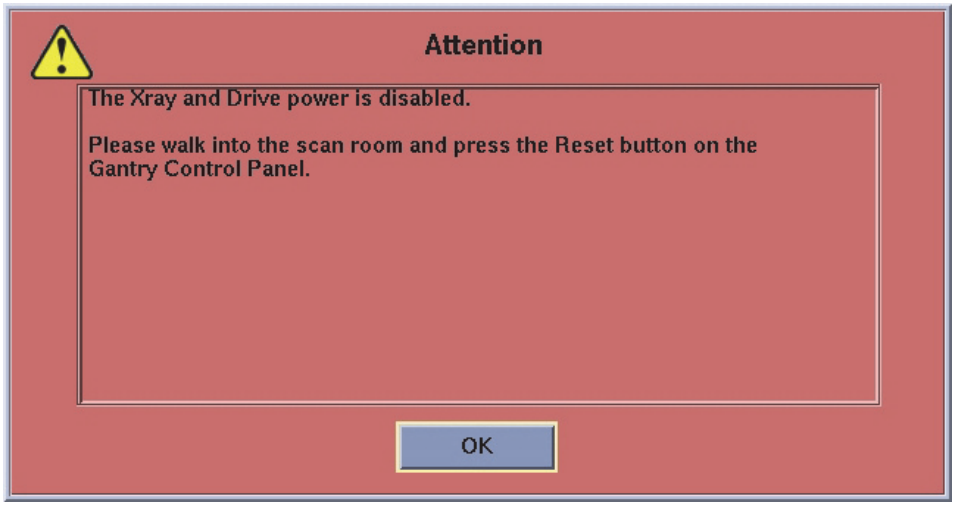
The facility designer determines the quantity and locations of the Emergency OFF buttons. GE recommends placing an Emergency OFF button near the doorway of every room in the system scan suite. Ask your supervisor to show you the location of all the Emergency OFF buttons in the system suite. Follow facility guidelines to report an emergency.

Press the **System Emergency OFF** button (red, circular button located on the wall) in the event of a catastrophic emergency, such as fire or earthquake.

Reset the Emergency OFF Button

1. Press the Start button on the Main Disconnect Control.
   - Power to the Power Distribution Unit (PDU), operator console, and system electronics will be restored.
2. Press the Reset gantry key on the gantry panel.
   - Power to the gantry drives, X-ray system, and table drive will be restored.

Figure 3-56 Attention message - Reset



Attention: **The X-ray and Drive power is disabled.**

Please walk into the scan room and press the Reset button on the Gantry Control Panel.

Emergency Patient Care During X-Ray ON:

- Press **STOP SCAN** to abort X-ray and stop gantry/table movement.
- Press **PAUSE SCAN** to pause scanning after the current scan completes.
- During an exam, the system pauses between scans if you Press any button on the control panel other than the alignment lights. It stops X-Ray if you press the same buttons during a scan.
- Select **Resume** on the screen to continue the exam.

Emergency Egress

System operation may be stopped due to power failure or a safety event (something coming into contact with the collision sensors), or the system may be halted by the operator in response to emergency conditions.

The Cradle unlatch button should only be used in two situations:

1. In emergency egress situations.
2. When using the SmartStep/SmartView scan type.

To safely remove the patient:

1. Press the Cradle Release gantry key or the Emergency Stop button (Figure 3-54) to disengage the clutch.
2. Pull the cradle to its out position, using the Cradle Lip or Cradle Handle (Figure 3-54).
3. Assist the patient off the table.

5805441-1EN Rev. 2 (Sep. 2020)

Maintenance and Cleaning (Reference: IEC60601-1:2005 7.9.2.12, 7.9.2.13, 16.2)

- To guarantee safe, reliable equipment performance, the site must be prepared according to GE Medical Systems requirements, as specified in the Pre-Installation Manual.
- There are no user serviceable parts in this system. The product should be installed, maintained, and serviced by qualified service personnel according to procedures laid down in the product service manuals.
- The system in whole or in part should not be modified in any way without prior written approval by GE Medical Systems.
- Keep the equipment clean. Remove body fluids and/or IV spills to prevent a health risk and damage to internal parts. Clean the equipment with any of the following approved cleaning agents. Follow the cleaning agent's manufacturer instructions. Apply with a cloth or the supplied cleaning agent wipes.
  - Warm water and soap mixture or a mild antiseptic
  - Common household bleach, diluted 10:1
  - Sani-cloth HB
  - Perasafe
  - Incidin Plus
  - Distel
- Also, use dry cleaning for electronic components.
- Do not clean the connectors on the cables for ECG, respiratory equipment etc. If you need to clean them, contact GE Service.
- Planned maintenance must be carried out regularly to ensure safe operation of the equipment.
- For user maintenance of the system and performance tests, refer to the maintenance and calibration information in the Technical Reference Manual.

Cleaning Equipment (Bio Hazard)

CAUTION: Blood Bourne Pathogens Procedure - Before any equipment is serviced or returned to GE Medical Systems, the following criteria must be met:

- Equipment used in a clinical setting must be cleaned and free of any blood and other infectious substances.
- Customers are responsible for the sanitary condition of the equipment. The suggested equipment clean-up procedure for cleaning any fluids or matter discovered in accessible areas or inside under direction of service are as follows:
  - Wear personal protective equipment.
  - Wear proper Nitrile gloves.
  - Before cleanup, take note of sharp corners or objects that could cut the gloves. If gloves tear, remove, wash hands thoroughly, and re-glove.
  - Use cloth or paper towels along with cleaner, taking care not to splash.
  - Sanitize the area using common bleach diluted 10:1 or an approved cleaning agent listed in the Maintenance and Cleaning section. Clean any tools that come in contact with body fluid.
  - Since viruses require moisture to remain active, dry the entire area.
  - When confident the area is clean and dry, place cleaning materials in a red biohazard bag.
  - Remove gloves, turning them inside out, and put gloves in the biohazard plastic bag. Seal and give the bag to appropriate personnel for disposal.

Environmental Concerns (Reference: IEC60601-1:2005 Clause7.9.2.15)

This symbol indicates that the waste of electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

5805441-1EN Rev. 2 (Sep. 2020)

Hazardous Substances

This product consists of devices that may contain mercury, which must be recycled or disposed of in accordance with local, state, or country laws. (Within this system, the backlight lamps in the monitor display contain mercury.)

The X-Ray collimator contains the following potentially hazardous materials:

- Lead: Lead salts are toxic and their ingestion may cause serious problems. The manipulation/ handling of lead is subject to regulations.

The X-Ray tube assembly contains potentially dangerous materials but does not present any danger as long as it is neither opened nor disassembled.

WARNING: Do not discard the X-Ray Tube Assembly among industrial waste or domestic garbage.

WARNING: A damaged X-ray Tube Assembly should not be dispatched through the national postal service.

The X-Ray tube assembly contains the following potentially hazardous materials:

- Lead: Lead salts are toxic and their ingestion may cause serious problems. The manipulation/handling of lead is subject to regulations.
- Oil: Univolt 54 and Crosstrans 206 mineral oil are not toxic, but the prevailing environmental regulations should be observed for their disposal or recuperation. For example, it is forbidden to dispose of these oils in the wastewater or sewage system or in the natural environment.

Your local GEMS field service will advise you on the suitable means of disposal of equipment.

- The X-Ray tube assembly to be discarded should be forwarded to the GEMS Service network, and it will be disposed of in a GEMS recycling center.

Precautions

Take all the necessary precautions for the personnel handling the recovery or destruction of X-Ray tube assemblies, and in particular against the risks due to lead.

These personnel must be informed of the danger involved and of the necessity to observe the safety measures.

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 4
Operator Documentation

The system user information is designed to provide you with safety and operation information for you to safely and effectively use the system.

To start the user information:

- Insert the disk you wish to view in the CD/DVD or DVD-RAM drive of your console.
- Click the **[Learning Solutions]** icon.
- Select the language you wish to review in.

To exit the user information:

- Click **File>Quit** to exit the user information.
- Click on another desktop such as **Exam Rx**.

NOTE: Do not click on the iconify icon.

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 5
Daily Fast Cal Procedure

To maintain image quality, complete the Fast Cal procedure once a day.

NOTE: Tube Warm Up is not required prior to running Fast Cal. The Fast Cal process itself will run Tube Warm Up scans if needed. See Tube Warmup for information on when to perform a Tube Warm up.

1. Display the Scan Monitor screen.
   - Clear the gantry opening.
   - Raise the table above the patient loading level.
   - Set gantry tilt to zero.
2. Select **[Daily Prep]** and **[Fast Cal].**
   - Before the start of every scan day
3. The system automatically selects the Auto Scan function.
   a) The system automatically selects the following sequence of scans:
   - Mylar Window Check
   - Warmup
   - Inter connectivity Map Scan Test
   - Fast Calibration Scan list

Figure 5-1

WARNING: FastCal may not have been performed within the last 24 hours.

b) Follow system instructions to initiate the first scan, and the system acquires the rest of the scan set.

c) Remain near the console during auto scan acquisition, so you can stop X-Ray if someone enters the scanner room.

An unrecognized tube is installed on the system, the following message is displayed:

Figure 5-2

An unrecognized tube has been installed on the system. Fast Calibration techniques are designed specifically for GE tubes and GE can not guarantee that the performance of the system will meet specifications with an unrecognized tube.

5805441-1EN Rev. 2 (Sep. 2020)

Chapter 6
Tube Warmup

The system operates most efficiently within certain parameters. These parameters are established by warming up the tube using a preset group of exposures. When the operator performs a tube warm up at any system prompt, the tube warm-up reduces the possibility of artifacts and may aid in prolonging the life of the tube.

The tube state will be indicated by 3 zones on the scan monitor above the New Patient icon.

- **Green:** Tube is at optimal operating state.

Figure 6-1

- **Yellow:** Tube warm up should be performed to move the tube to the operating state. There are no restrictions during scanning while in this zone.

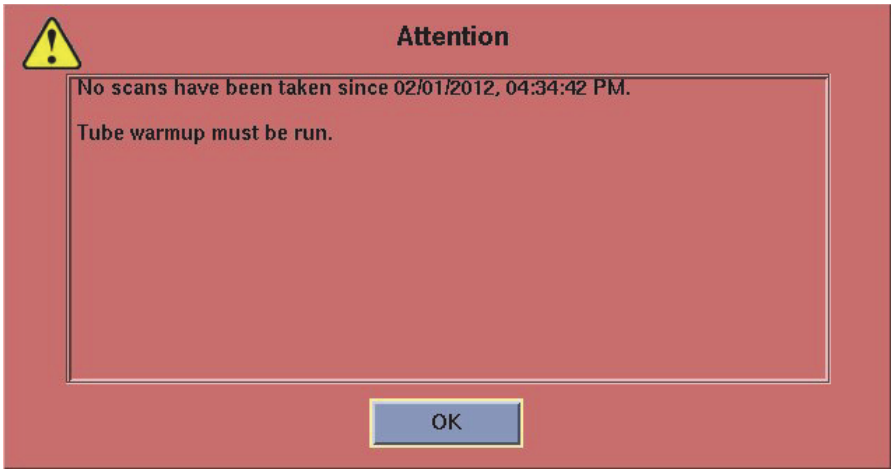
Figure 6-2

- **Blue:** Tube warm up must be performed. Depending on system type mA may be limited until warm up is performed.

Figure 6-3

For best care of your tube, never skip tube warm-up. Perform the warm-up when your tube reaches yellow for faster warm-up and maximum tube life. The interface is provided so you are in control. Only Green means go.

Figure 6-4



Attention: **No scans have been taken since xx/xx/xxxx. xx:xx:xx XX. Tube warmup must be run.**

NOTE: If the detectors are cold due to the A1 power being off, turn the system on and wait 2 hours (h) before performing a tube warm up. This allows the detectors to return to their operating temperature to keep image quality.

NOTE: Failure to run Tube Warmup when requested by the software can lead to serious damage to the x-ray tube and decrease tube life.

Attention: **Please remove any obstruction in the path of the beam.**

NOTE: Failure to perform requested tube warm-up will result in reduction of the maximum mA possible for the exam after a tube warm-up has been cancelled or skipped.

NOTE: A non-GE tube could cause destructive component failure if the cooling delays do not meet its design requirement.

5805441-1EN Rev. 2 (Sep. 2020)

Figure 6-5

Attention: **Tube Warm-up has been cancelled or skipped.**
Large focus maximum mA of 120V and 140V will be limited as follows for this exam.
120kV: 440mA
140kV: 380 mA
Select End Exam and run Tube Warm-up from Daily Prep to enable the full mA range capability.

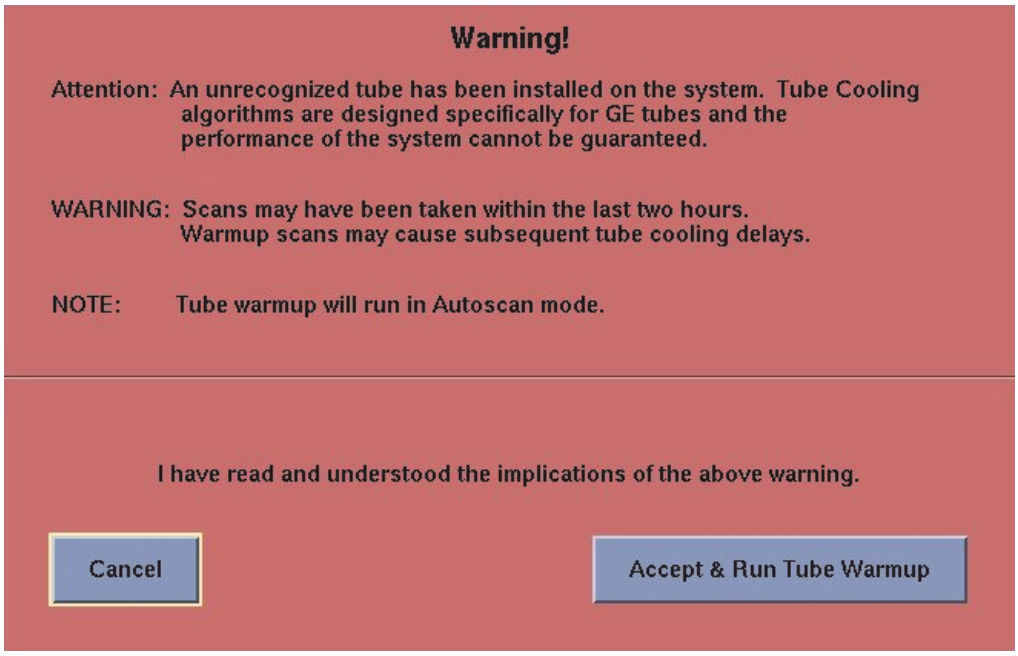
Desired mAs can be achieved by changing rotation time (mAs = mA x rotation time).

To perform a tube warmup:

1. Select **[Daily Prep]** on the Scan Monitor screen.
2. Select **[Tube Warmup]** on the Daily Preparation screen or from the blue or yellow tube state icon.
   - See Figure 6-2 or Figure 6-3.
   - Read the compatibility Warning.

     The following message will display if an unrecognized tube has been installed.

Figure 6-6



- Position the gantry to 0° tilt.

3. Click **[Accept]** when you understand the implications.
   - Tube warmup runs a set of tube heating scans.
   - When finished, the system display returns to the daily prep screen.

A message that tube warm-up has been completed will also be in the system message log.

5805441-1EN Rev. 2 (Sep. 2020)

Chapter 7
Prepare the System

(Reference: IEC60601-1:2005 7.9.2.12, 16.2)

- Clean the Accessories and check for damage.
- Check and remove dried contrast agent from:
  - Mylar ring (around the gantry opening)
  - Detector window
  - Table extension and cradle surfaces — especially the Patient Restraint plastic channels on the table
  - Accessories (Head holders, pads and cushions, etc.)
- Check supplies.

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 8
Check Disk Space

Maintain Image file space on the disk, because the system refuses to scan when it runs out of file space.

Check Image Space

- Check the daily schedule, and multiply the list of patients by the estimated number of images each study requires.
- Compare your estimate to the *remaining* 512^2 images listed in the Feature Status **Date** and **Time** area.
- If your estimate exceeds the available Image Space:
  - Film any previously unfilmed studies. (Optional)
  - Transfer designated images to another suite or console.
  - Archive and remove the oldest images from the system disk.

Always follow the filming and archive routines established for your facility.

NOTE: Do not remove images while actively scanning patients.

Do not reboot the system immediately after removing images, this can cause mismatch of information in the patient list.

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 9
Reset the System

System Shutdown/Reset Procedures

To prevent system software problems, restart your system once every 24 hours (h). (Recommended: Shutdown and restart at the end of the last shift.) If the system has a persistent problem, record the time, circumstances, and error messages, then call service.

Performing an SPRSnap, a QuickSnap and/or an IQ Snap provides additional information to aid the service engineer in resolution of issues.

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 10

Stop/Start the Operating System

Shutdown System

To turn off main disconnect control (MDC) or A1, Shutdown the system.

1. On Display Monitor, select the **[Shutdown]** icon.
   - Dialog is posted

Figure 10-1 Shutdown

2. Select **Shutdown** and click **OK**.

   The warning message is displayed after pressing Restart, Shutdown or Energy Saving Mode setting is completed. Click **Confirm** in the pop-up to continue shutdown process.

Figure 10-2 The warning message for gantry rotation

WARNING: **System is preparing for shutdown. The gantry will rotate immediately after Confirm is pressed.**

If there are open/active patient scan/tube warmup/fastcal or service tool menus, the warning message will be seen before the warning message for gantry rotation (Figure 10-2). Click **Confirm** in the pop-up. End patient exam/tube warmup/fastcal or dismiss the service tool. Then select the **Shutdown** icon again.

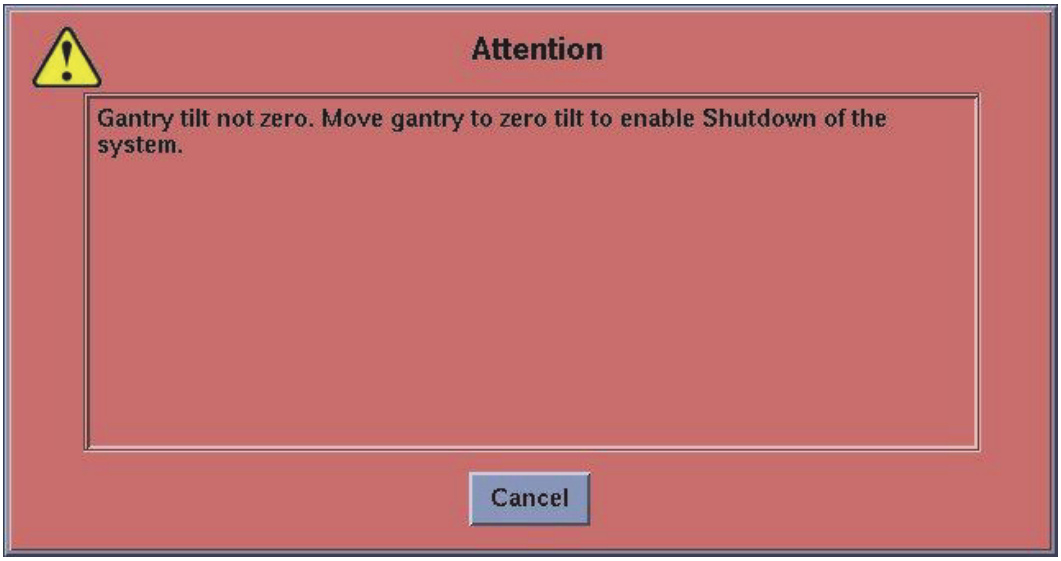
5805441-1EN Rev. 2 (Sep. 2020)

Figure 10-3 The warning message for exit applications

Attention: **System shutdown/Restart cannot be accomplished when scan acquisition hardware is in use. End Exam, exit Daily Prep menu or close any open Service Tool before attempting Shutdown/Restart.**

If the gantry tilt is not zero before shutdown, the warning message will be displayed. Remote Tilt button starts blinking and pressing it to return the gantry to zero tilt. Or click **Cancel** to cancel shutdown.

Figure 10-4 The warning message for gantry tilt

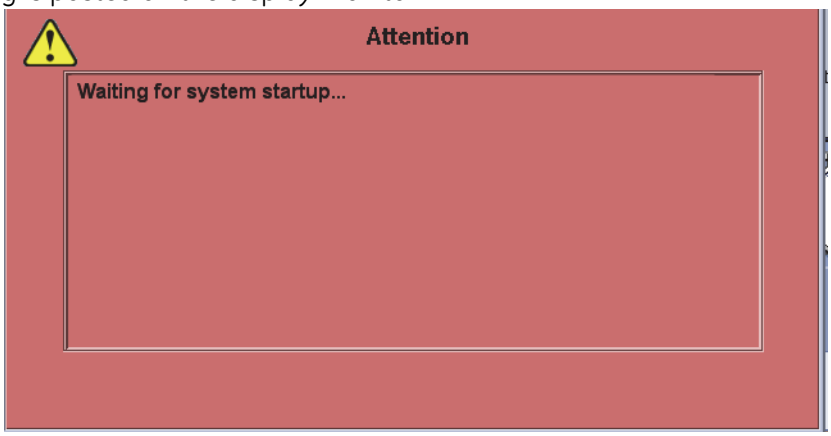


Attention: **Gantry tilt is not zero. Move gantry to zero tilt to enable Shutdown of the system.**

3. For system shutdown, when the "System Halted" message displays on the monitor the system can be powered off. Press the **power switch** on the front of the operator's console to the off position.
4. Press the **STOP** button on the MDC or A1 connector panel.
5. To start operating system from System Halted prompt, power cycle the operator console.

NOTE: If your system has been turnoff overnight, it will take several hours (h) to stabilize before the system is ready for use.

- Dialog is posted on the display monitor



Attention: **Waiting for system startup...**

- A dialog box will be posted

5805441-1EN Rev. 2 (Sep. 2020)

Attention: **OC initializing. Please wait...**

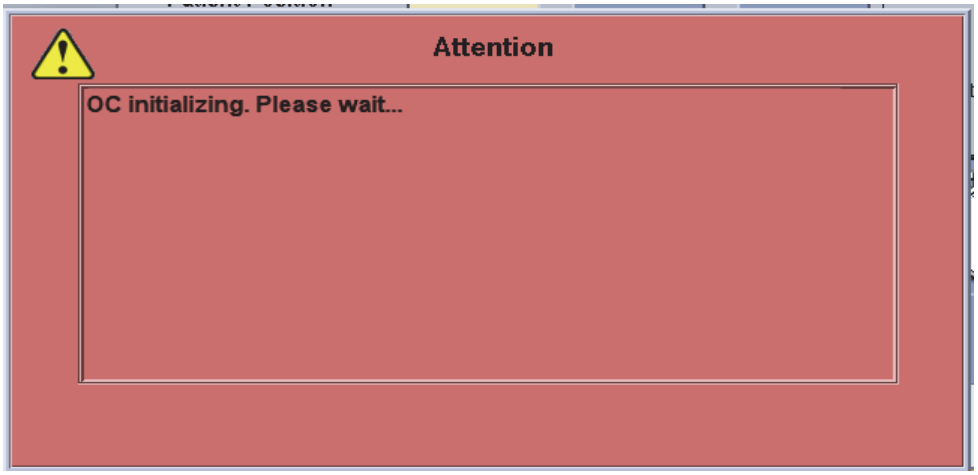
- When this dialog disappears and "System Reset Successful" message is seen in the feature status area, the system is ready to use.

NOTE: If your system has the HIPAA login enabled, you are required to login to the system.

If You Turn OFF the MDC at the End of the Scan Day:

To start the system if main disconnect has been powered off:

1. Press the **START** button on the main disconnect control (A1) to restore power to the PDU, console(s) and subsystem electronics.
2. Press the **RESET** button to turn on the Gantry Control panel to restore power to the Gantry drives, X-Ray system, and Table drive.
   - When this dialog disappears and "System Reset Successful" message is seen in the feature status area, the system is ready to use.



Attention: **OC initializing. Please wait...**

For Systems with UPS (Uninterrupted Power Supply) (Reference: IEC60601-1:2005 Clause7.9.2.4, Clause7.9.2.14)

The CT system may be installed with a GE approved "partial" UPS. A partial UPS is an accessory that can provide temporary power to the system during hospital power failures. It is not intended to support the x-ray power or gantry axial rotation for scanning. It is intended to provide 120V/208V power to critical subsystems as explained below. Follow the UPS manufacturer's manual for recommended operating and servicing requirements (includes preventative maintenance, specification summaries, and troubleshooting guidance).

The partial UPS provides the following features:

- For sites with a history of power quality problems, the UPS provides voltage conditioning and regulation for the system electronics.

5805441-1EN Rev. 2 (Sep. 2020)

- During planned or unplanned power outages (storms, testing of backup systems, transfers of power), the host computer and related electronics will continue to function, allowing the user to save images and complete a controlled shutdown, if necessary.
- During planned or unplanned power outages (storms, testing of backup systems, transfers of power), the patient table and gantry control subsystems will continue to function, allowing the user to safely remove a patient from the scanner, if necessary.
- If the user hits the Emergency OFF button for system power, the GE approved partial UPS will not try to provide backup power. “Emergency OFF” intends to remove all system power to prevent a safety hazard.

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 11
General Information

(Reference: IEC60601-1:2005 7.9.3.1)

This section provides a simple introduction to CT, or Computed Tomography, for people with no detailed physics or medical diagnostic education.

System components:

- The system components are explained in the User Manual.

Emergency Stop:

- Emergency Stop procedures are described in the Safety chapter.

Indications for Use of the CT Scanner System

The Computed Tomography X-ray system is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, Spectral, and Gated acquisitions for all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

CT Description

Computed tomography (CT) is a medical imaging method employing tomography created by computer processing. Digital geometry processing is used to generate a three-dimensional image of the inside of an object from a large series of two-dimensional X-ray images taken around a single axial of rotation. The word "tomography" is derived from the Greek tomos (slice) and graphein (to write). Computed tomography is known as computed axial tomography (CAT or CT scan).

CT produces a volume of data, which can be manipulated, through a process known as windowing, in order to demonstrate various bodily structures based on their ability to block the X-ray/Röntgen beam. Although historically the images generated were in the axial or transverse plane, orthogonal to the long axis of the body, modern scanners allow this volume of data to be reformatted in various planes or even as volumetric (3D) representations of structures.

Traditional CT systems collect 1 row of data at a time. The Revolution™ EVO scanner system may improve customer productivity and open the door for new applications and unparalleled scan speeds via a Revolutionary 64-row data acquisition system.

Revolution™ EVO uses 64ch A/D converter ASIC with an 8-to-1 miniaturization of conventional multi-slice technology, and enables 64 slice mode and 32 slice mode.

CT Operation Theory

The CT Scanner consists of the following subcomponents:

- X-ray source
- CT Detector
- Rotating Gantry
- Power Distribution Unit
- Patient Table
- Operator's console

X-ray Source

The source and detector components are housed on a gantry with a cylindrical patient bore. An X-ray tube that is part of the source subcomponent is housed on the rotating gantry, diametrically opposite to the detector. The high voltage generator is the second part of the X-ray source. It provides high voltage to the X-ray tube across the anode and the cathode, along with current to the filament, which is part of the cathode. The filament produces an electron beam that is accelerated towards the tube's anode or target. The electron beam impinges on the anode and X-rays are produced. The generator also supplies the X-ray tube with “bias voltages” that control the width, length and position of the focal spot on the target.

5805441-1EN Rev. 2 (Sep. 2020)

The X-ray tube's heat capacity and dissipation determine the frequency and length of CT exposures. A Helical and Cine exposure can last up to 60* seconds (s) and axial exposures last from 0.35 to 2.0 seconds (s).

NOTE: *: In case of 20mm beam collimation, Helical/Cine scan can last up 120 seconds (s).

CT Detector and DAS

The CT Detector is a wide coverage cone beam detector with multiple detector rows along the longitudinal plane. The Detector channels are arranged as an arc diametrically opposite to the X-ray tube on the rotating CT gantry. The detector consists of a scintillator that converts X-rays into light, diodes for light conversion into current and analog to digital converter that converts the current into digital signal. The data acquisition system (DAS) samples each detector cell up to about 2500 times per gantry rotation, amplifies and quantifies the current from the cells and transmits the resultant data to the Operator's console.

Power Distribution Unit

The PDU (Power Distribution Unit) distributes power to the rotating gantry, patient table and the operator's console.

Operator's Console

The Operator's Console (OC) contains the reconstruction engine that converts the data transmitted from the DAS into a single matrix of pixel values, called an image. The display processor takes a copy of the digital matrix data, and converts it into television shades of gray, and sends the image to the LCD for display. The OC also contains and controls the computer, X-ray, and cradle drives.

DICOM Print

The Revolution™ EVO can send a camera request to a camera that has DICOM print capabilities.

X-Ray

The X-Ray tube contains filaments, a cathode and an anode. The filament provides the electrons that create X-Rays. The X-Ray system generates a current that heats the filament until electrons start to “boil off” and break away from the filament. We refer to the filament current as “mA.” Increasing the mA increases the number of electrons that become available to make X-Ray. Higher concentrations of electrons improve image resolution.

The X-Ray system creates a high voltage, or kV, potential between the cathode and anode. The negative charge on the cathode repels the electrons that boil off the filament. The positive charge on the anode attracts the negatively charged electrons. The electrons strike the rotating anode target and displace electrons in the target material. This interaction creates heat and X-Ray photons. The target rotates to help spread the heat over a larger area. Increasing the kV increases the electron strike speed, which in turn increases the intensity or "hardness" of the X-Ray photon beam.

Figure 11-1

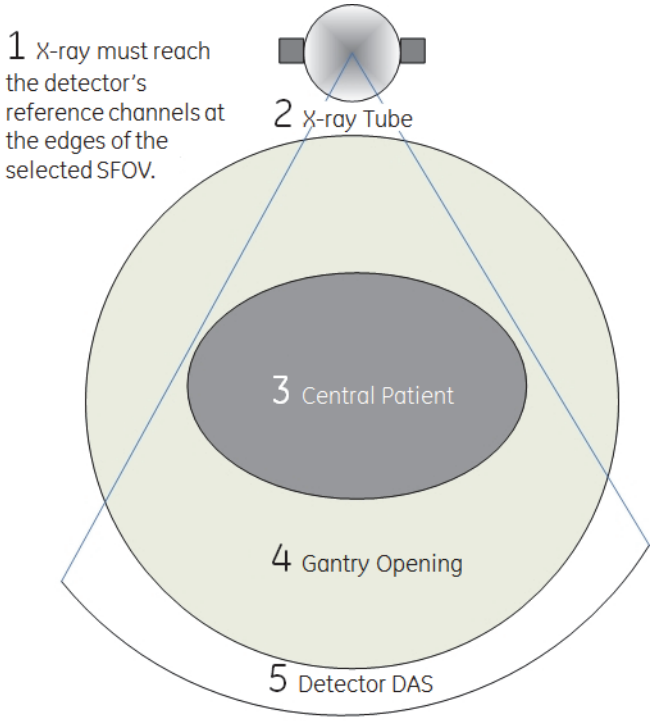


Table 11-1

Number	Description
1	X-ray must reach the detectors reference channels at the edges of the selected SFOV.
2	X-ray Tube
3	Centered Patient
4	Gantry Opening
5	Detector DAS

5805441-1EN Rev. 2 (Sep. 2020)

Tube Warmup

Warmup provides an automated group of low technique exposures designed to safely bring the X-Ray tube to operating temperature before you start to scan for the day. Warmups increase tube life and help produce more consistent, quality images.

Revolution™ EVO Theory of Operation

System Overview

The Revolution™ EVO CT scanner is a premium-tier, 3rd generation CT scanner. It will support all clinical applications currently supported by the Revolution™ EVO product line.

The distinguishing feature of Revolution™ EVO is the ability to simultaneously collect 64 rows of scan data. This data collection is accomplished via a 64-row detector and a 64-row DAS (Data Acquisition System).

System Characteristics

- 64 or 32 slice system.
- Revolution™ EVO variable rotation scan speeds (0.35*, 0.4*, 0.5*, 0.6*, 0.7, 0.8, 0.9, 1.0 and 2.0 seconds (s) per rotation).

NOTE: Rotation scan speed with * are available with the corresponding rotation time option.

NOTE: 0.375, 0.425, 0.450, and 0.475 second(s) rotation speeds are available for Cardiac scan with CardIQ SnapShot option and the corresponding rotation time option.

NOTE: **For the 0.35 second and 0.35 second for cardiac option licensed:** 0.35 second/0.35 second for cardiac is licensed for use with a GE x-ray tube. Use of third party x-ray tube will require the purchase of an additional license for this feature.

- Helical acquisitions at significantly faster table speeds.
- Potential for new applications due to faster coverage and no tube cooling delays.
- The ability to generate 64 axial images per gantry Revolution.
- Every system EMC compliant with improved reliability and uptime.
- World-class User Interface.

Tube - Performix™ 40 Plus

- 72kW peak power (large spot, 5 second (s) exposure) with 72kW Power option
- 48kW peak power with 48kW Power option
- 24kW peak power (small spot, 5 second (s) exposure)
- 3.5kW steady state capability
- 0.35 second (s) peak gantry speed capability with 0.35 second (s) option

NOTE: 72kW power option is licensed for use with a GE x-ray tube. Use of third party x-ray tube will require the purchase of an additional license for this feature.

Detector

- 64 rows in Z axis = 64 physically separated cells in Z.
- Detector cell segregation in Z provides post-patient collimation.
- 1.09 mm (0.625 effective cell) actual detector cell size in Z.
- 0.625mm effective cell size in Z at ISO center — All 64 rows.
- 64 data rows output (64 slice system)

Scaleable Data Acquisition Sub-System (DAS)

- 64 rows input from detector.
- 64 rows output to SRU (Scan Reconstruction Unit).
- Supports 2460 Hz sampling.
- Forward error correction applied to output data.
- Control functions:
  - Error detection and reporting.
  - Heater Control

Patient Scanning

Revolution™ EVO uses a “shorter” geometry than HiSpeed CT/i and LightSpeed™ RT. Since X-Ray intensity varies as the square of the distance, the benefit of the Lite geometry, measured at ISO center, is: $(630/541)^2 = 1.36 = 36\%$ better X-Ray flux utilization. It also reduces the centrifugal force on the tube which allows for faster rotational speeds.

Table 11-2 Geometry information

Parameter	Revolution™ EVO	HiSpeed CT/i
ISO Height	1015 mm	1092.9 mm
Focal spot to ISO	541 mm	630 mm
Focal spot to det	949 mm	1100 mm
SFOV	500 mm	480 mm
Bore	700 mm	700 mm

NOTE: Helical scan range varies based on the helical pitch and gantry rotation speed selected.

- Table maximum capacity is 227 kg (500 Pounds) for VT1700V Table and VT2000 Table or 306 kg (675 Pounds) for VT2000x Table.

5805441-1EN Rev. 2 (Sep. 2020)

EMI/EMC

All systems built to global regulatory emissions (EMC) and immunity (EMI) compliance standards to improve reliability, uptime and performance in its intended environment.

Network (Reference: IEC60601-1:2005 14.13a), b))

Purpose of Revolution™ EVO Scanner Connection to Network

The Revolution™ EVO Scanner is intended to be connected to a network in order to support the following functionality:

- DICOM services to retrieve images from other DICOM-compliant machines
- DICOM services to push images to other DICOM-compliant machines
- DICOM services to query for images on other DICOM-compliant machines
- DICOM services to print images on DICOM complaint printers
- DICOM services to confirm that images have been permanently stored on a DICOM-compliant machine
- DICOM services to get DICOM modality worklist information from a remote hospital or radiology department information system computer
- DICOM services to allow a Modality Performed Procedure Step to be communicated to the Hospital/Radiology information system
- DICOM services to verify the remote DICOM system is connected properly to the Revolution™ EVO scanner device
- Services to provide authentication and authorization against Enterprise directory servers

All of the above features are optional on the Revolution™ EVO Scanner.

Network Interface Technical Specifications

Connection Name:	Hospital network port
Physical network connection type:	IEEE 802.3-1998 1000/100/10 BaseT Ethernet
Speeds and duplex modes supported:	10Mbps, 100Mbps, and 1Gbps half and full duplex Auto-negotiate
Default IP Address (from factory):	IP Address – 192.9.101.1 Subnet Mask – 255.255.255.0 Gateway – empty
IP addressing:	IPv4 static
QoS Support:	n/a

Network Information Flows Specifications

Flow Name	DICOM image retrieve
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Get a DICOM image or set of image from a network device
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	CT Image Storage MR Image Storage Enhanced SR X-Ray Radiation Dose SR – CT Radiation Dose RT Structure Set Storage Positron Emission Tomography Image Storage
Ports (default)	4006
Traffic characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency max	n/a

Flow Name	DICOM image push
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Send a DICOM image or a set of images to a network device
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	CT Image Storage MR Image Storage Grayscale Softcopy Presentation Sate Storage Enhanced SR X-Ray Radiation Dose SR – CT Radiation Dose RT Structure Set Storage Positron Emission Tomography Image Storage
Ports (default)	4006
Traffic characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency max	n/a

Flow Name	DICOM image query
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Find a list of DICOM images from a network device
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below

5805441-1EN Rev. 2 (Sep. 2020)

Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Study Root Query/Retrieve Information Model - FIND Study Root Query/Retrieve Information Model - MOVE
Ports (default)	4006
Traffic characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency max	n/a

Flow Name	DICOM Storage Commit
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Used to confirm that local DICOM images have been permanently stored on a remote DICOM device
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Storage Commitment Push Model SOP Class
Ports (default)	4006
Traffic characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency max	n/a

Flow Name	DICOM modality worklist information
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Transfer patient information for HIS/RIS system to CT scanner
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Basic Modality Worklist Information Model – FIND SOP Class
Ports (default)	4006
Traffic characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency max	n/a

Flow Name	Modality Performed Procedure Step
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Send a report about a performed patient exam to the HIS/RIS system
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Modality Performed Procedure Step SOP Class
Ports (default)	4006
Traffic characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency max	n/a

Flow Name	DICOM Print

Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Send a DICOM image to a DICOM printer
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Basic Grayscale Print Management Meta SOP Class Basic Color Print Management Meta SOP Class Print Job SOP Class Pinter SOP Class
Ports (default)	4006
Traffic characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency max	n/a

Flow Name	Enterprise Authentication / Authorization
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Authenticate local user against Enterprise Server
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Microsoft Active Directory / Novell eDirectroy
Ports	3002, 3003, 3004, 6386
Traffic characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency max	n/a

Required characteristics and configuration for network support of Revolution™ EVO Scanner specifications

The network must meet the specific requirements above for all traffic flows associated with the subset of features, use cases and workflow required by the responsible organization's users.

In addition, the network must be "flat" (limited to a single IP broadcast domain).

Remote Host Parameters

The Revolution™ EVO Network function has new enhancements to support DICOM networking. When adding or updating a remote list, there are some new parameters needed. All of the following information, except for Comments, needs to be provided in order to set up a remote host:

- The Host name to be entered is the name of the device. If the device is DICOM, the name must match exactly to the name given to the device.
- The Network address of the device is provided by the institution's network administrator.

5805441-1EN Rev. 2 (Sep. 2020)

- The Network protocol is DICOM. If the Revolution™ EVO will be sending to this device, the device must be DICOM and the DICOM network protocol must be selected.
- The Port number is unique to the device. If the device is an Advantage Windows workstation or HiSpeed CT/i, X/i, or NX/i system, the number will be 4006.
- The AE Title is unique to the device. If the device is an Advantage Windows workstation or another GE Medical Systems system, the AE Title will be the same as the Host name.
- The Comment field allows you to input a comment.
- The Archive Node refers to the archiving responsibility of the device:
  - If Auto is selected, the CT system will automatically check to see if the device is a Storage Commitment Provider.
  - If Yes is selected, the device will be responsible for archiving images. When the device has received and saved the images, a notification message will be displayed on the scanner console and the Archive status for the exam will be "A" for archived.
  - If No is selected, the device will not be responsible for archiving.

NOTE: The device must be a Storage Commitment Provider in order for remote archive node to function.

NOTE: Connection of the Programmable Electrical Medical System (PEMS) to a NETWORK/DATA COUPLING/IT-NETWORK that indludes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties.

NOTE: The Site's IT or Site's RESPONSIBLE ORGANIZATION should identify, analyze, evaluate and control these RISKS.

NOTE: In case of subsequent changes to the NETWORK/DATA COUPLING/IT-NETWORK, it could introduce new RISKS and require additional analysis.

NOTE: Changes to the NETWORK/DATA COUPLING/IT-NETWORK include:

- Changes in the it-network configuration
- Connection of additional items to the NETWORK/DATA/IT-NETWORK COUPLING
- Disconnecting items from the NETWORK/DATA COUPLING/IT-NETWORK
- Update of equipment connected to the NETWORK/DATA COUPLING/IT-NETWORK
- Update of equipment connected to the NETWORK/DATA COUPLING/IT-NETWORK

- Access to the local host refers to the device's ability to access the Revolution™ EVO. Select Yes if you want the device to be able to send to and/or query the Revolution™ EVO.
- The Custom search feature enables the Custom search dialog box to be automatically displayed when you select receive from the remote browser. If Yes is selected, the feature is enabled. If No is selected, the Custom search dialog box will not automatically be displayed. You can, however, get to the search feature once the remote browser is displayed, by simply selecting Search, on the remote browser.

Image Transfer Capability

The specifications are based upon a 1000baseT network.

Image transfer time using DICOM protocols is 10fps on a 1000baseT network.

Network Compatibility

The BrightSpeed Series, LightSpeed™ QX/i, Plus, Ultra, RT, RT^{16}, Xtra, Pro^{16}, Pro^{32}/VCT, Discovery™ Series, Revolution™ Series, Optima™ Series and Brivo Series image formats are DICOM. This image format may only be transferred between systems using a DICOM network protocol. The receiving station must support DICOM receive for the CT scanner's images to be transferred (send or receive) to it.

Use the following table for network compatibility. The table lists the network protocol to use and the features available for that system. The far left column lists the system the user is at (from).

Table 11-3 Network Compatibility

From	**To**				
	BrightSpeed Series, LightSpeed™ Series. Discovery™ Series, Optima™ Series, Revolution™ Series, Brivo Series***	**HiSpeed Advantage**	**CT IC**	**HiSpeed NX/i, X/i, or QX/i**	**3rd Party DICOM Station**
BrightSpeed Series, LightSpeed™ Series. Discovery™ Series, Optima™ Series, Revolution™ Series, Brivo Series***	DICOM Query Send Receive	Advantage*** Query Receive	Advantage*** Query Receive	DICOM**** Query Send Receive	DICOM* Query** Send Receive**

5805441-1EN Rev. 2 (Sep. 2020)

From	To				
	BrightSpeed Series, LightSpeed™ Series. Discovery™ Series, Optima™ Series, Revolution™ Series, Brivo Series***	**HiSpeed Advantage**	**CT IC**	**HiSpeed NX/i, X/i, or QX/i**	**3rd Party DICOM Station**
HiSpeed Advantage	DICOM Send	Advantage Query Send Receive	Advantage Query Send Receive	Advantage Send	DICOM Send
CT IC	DICOM Send	Advantage Query Send Receive	Advantage Query Send Receive	Advantage Send	DICOM Send
HiSpeed FX/i, DX/I, LX/i	DICOM Query Send Receive	Advantage Query Receive	Advantage Query Receive	DICOM Query Send Receive	DICOM* Query** Send Receive**
3rd Party DICOM Station	DICOM Query Send Receive	DICOM Query Receive	DICOM Query Receive	DICOM Query Send Receive	DICOM* Query** Send Receive**

* Some 3rd party stations use the ODINA network protocol. In this case use DICOM protocol and port number 104.

** Query capability is only available only if station is a query retrieve provider.

*** Advantage Net is not available on PC Base Systems.

**** Except for IRIX OC.

***** BrightSpeed Series, LightSpeed™ QX/i, Plus, Ultra, RT, RT^{16}, Xtra, Pro^{16}, Pro^{32}/VCT. Discovery™ Series, Optima™ Series, Revolution™ Series and Brivo Series

NOTE: LightSpeed™ VCT/Pro^{32}, BrightSpeed, Optima™ CT660 and Revolution™ CT/EVO based systems do not support Advantage Network Protocol.

Table 11-4 Advantage Windows Network Compatibility

From					
	AW 1.X	**AW 2.X**	**AW 3.X**	**AW4.X**	**BrightSpeed Series, LightSpeed™ Series. Discovery™ Series, Optima™ Series, Revolution™ Series, Brivo Series*****
BrightSpeed Series, LightSpeed™ Series, Discovery™ Series, Optima™ Series, Revolution™ Series, Brivo Series***	DICOM Send	DICOM Send	DICOM Send	DICOM Query Send Receive	DICOM Query Send Receive
AW 1.X	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	DICOM Query Send Receive
AW 2.X	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	DICOM Query Send Receive
AW 3.X	SdC Net V1 Query Send Receive	SdC Net V2 Query Send Receive	SdC Net V3 Query Send Receive	SdC Net Query Send Receive	DICOM Query Send Receive
AW 4.X	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	DICOM Query Send Receive

NOTE: Advantage Windows systems do not support Query Retrieve provider. Send images from the Advantage Windows to the BrightSpeed Series, LightSpeed™ QX/i, Plus, Ultra, RT, RT^{16}, Xtra, Pro^{16}, Pro^{32}/VCT. Discovery™ Series, Optima™ Series, Revolution™ Series and Brivo Series.

NOTE: BrightSpeed Series, LightSpeed™ QX/i, Plus, Ultra, RT, RT^{16}, Xtra, Pro^{16}, Pro^{32}/VCT. Discovery™ Series, Optima™ Series, Revolution™ Series, Brivo Series or HiSpeed QX/i PC Based Systems do not support Advantage Network Protocol.

***** BrightSpeed Series, LightSpeed™ QX/i, Plus, Ultra, RT, RT^{16}, Xtra, Pro^{16}, Pro^{32}/VCT. Discovery™ Series, Optima™ Series, Revolution™ Series and Brivo Series

System Data and Control Flow

Figure 11-2 CT System Data and Control Flow Illustration

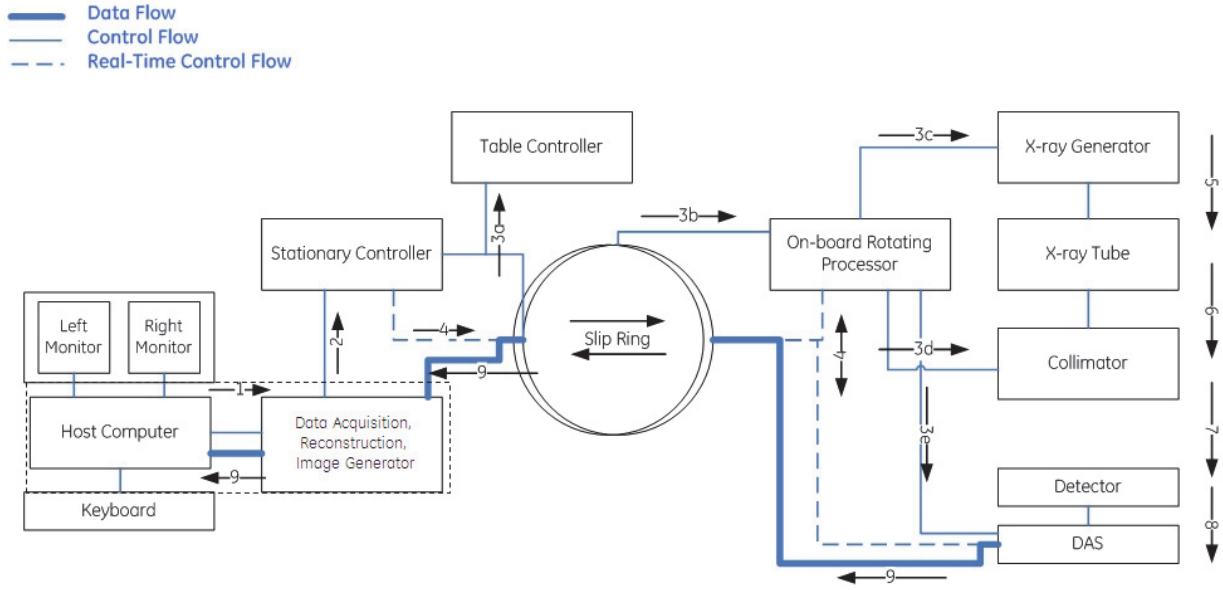


Table 11-5 System Components and Functions

Component	Functions	Data and Control Flows	
Host Computer	User interface, image display	1	Scan and recon prescription from operator
DIP	Scan and recon control and Image generation	2	Scan prescription to “master” controller
Stationary Controller **On-Board Controller** **Table Controller** **Slip-ring**	Stationary base real-time control and “master” controller Rotating base real-time control Patient table real-time control Signal and power transfer between stationary and rotating components	3	Scan parameters distributed • table position • rotating parameters • kV and mA selections • X-ray beam collimation and filter selections • detector slice thickness and SDAS gain selections
		4	Real-time control signals during scanning
X-ray Generator	High voltage generation	5	High Voltage
X-ray Tube	X-ray generation	6	Un-collimated X-ray beam
Collimator	Formation of the X-ray beam	7	Collimated X-ray beam
Detector	Conversion of X-ray to analog signal data	8	Analog scan data

DAS	Conversion of analog signal data to digital data	9	Digital scan data

X-ray Generation and Detection Details

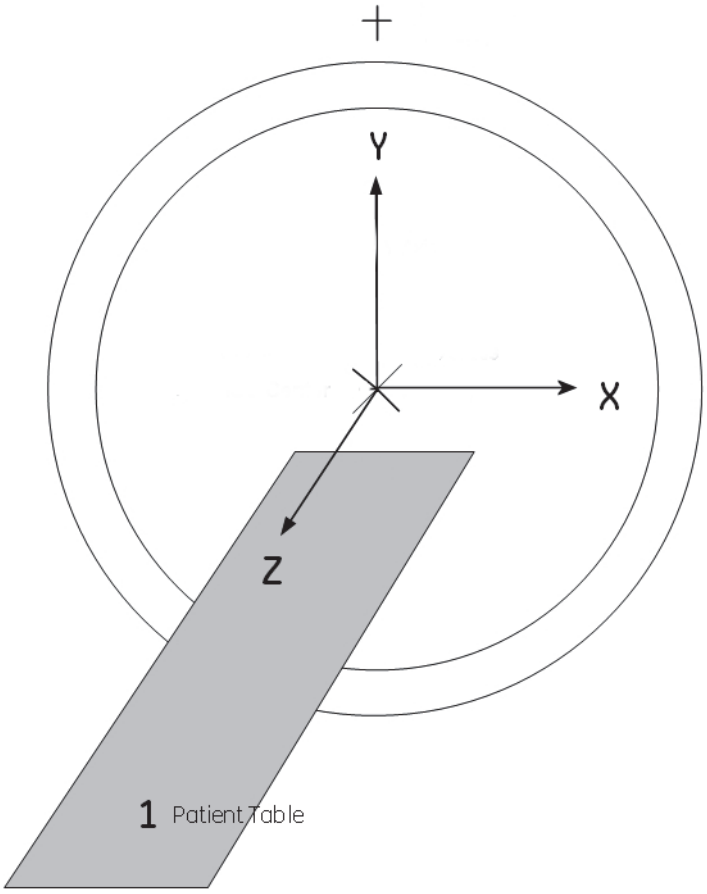
Overview

The distinguishing feature of Revolution™ EVO is the capability to simultaneously collect multiple rows of scan data.

Gantry Coordinate System

X, Y, Z: Scanner gantry coordinate system:

- X = Tangent to circle of rotation.
- Y = Radial (from ISO toward tube focal spot).
- Z = Longitudinal (in/out of the scan plane).



5805441-1EN Rev. 2 (Sep. 2020)

Table 11-6 Gantry Coordinate System

Number	Description
1	Patient Table

Components

Figure 11-3 X-ray generation and detection components viewed from side of gantry

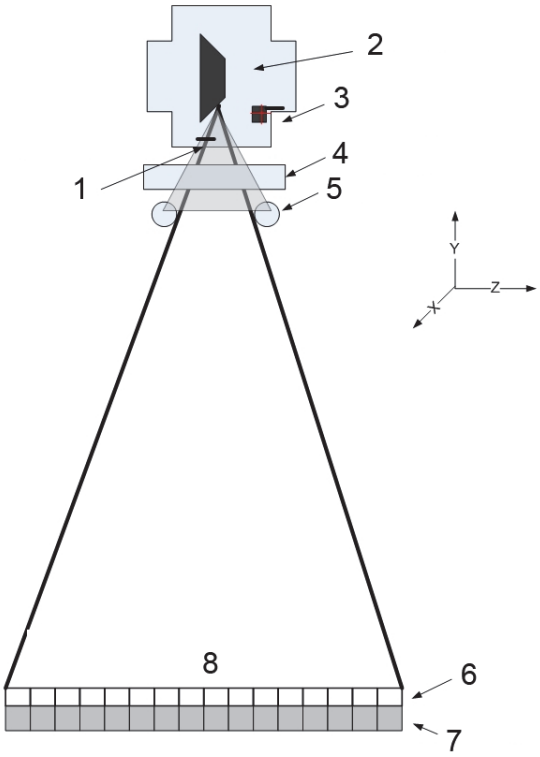


Table 11-7 X-ray Tube Assembly

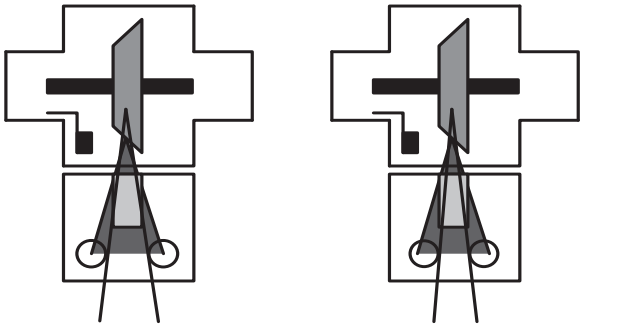
Number	Description
1	Uncollimated X-Ray Beam
2	Anode/Target
3	Cathode with Bias Voltages
4	Bowtie Filter
5	Tungsten Cams
6	Detector Collimator
7	Detector Pixels

Number	Description
8	Detector Collimator + 53 Detector Modules (64 rows each)

CAM Collimator

The pre-patient collimation of the X-Ray beam is accomplished via 2 independently controlled tungsten cams (see Table 11-4 on page 18).

Figure 11-4 CAM collimator examples



1 Wide beam centered, e.g., 40 mm or 64 x 0.625 mm

2 Narrow beam centered, e.g., 20 mm or 32 x 0.625 mm

Table 11-8 CAM collimator examples

Number	Description
1	Wide beam centered, e.g., 40 mm or 64 x 0.625 mm
2	Narrow beam centered, e.g., 20 mm or 32 x 0.625 mm

Z-Axis Cell Summation

The Revolution™ EVO detector is segmented into cells in the Z dimension, providing post-patient collimation of the X-Ray beam. This post-patient collimation is provided by the segmentation of the detector cells, and not by a separate post-patient collimator as some CT systems use.

The post-patient collimation determines the Z-axis slice thickness of the scan data.

The Z dimension extent of each cell are 0.625mm.

64 Slice Configuration

The 64 macro rows are labeled 32A, 31A, 30A, 29A, 28A, 27A, 26A, 25A, 24A, 23A, 22A, 21A, 20A, 19A, 18A, 17A, 16A, 15A, 14A, 13A, 12A, 11A, 10A, 9A, 8A, 7A, 6A, 5A, 4A, 3A, 2A, 1A, 1B, 2B, 3B, 4B, 5B, 6B, 7B, 8B, 9B, 10B, 11B, 12B, 13B, 14B, 15B, 16B, 17B, 18B, 19B, 20B, 21B, 22B, 23B, 24B, 25B, 26B, 27B, 28B, 29B, 30B, 31B, and 32B. 32A is closest to the patient table.

5805441-1EN Rev. 2 (Sep. 2020)

Figure 11-5 Channel summation in Z — Examples
This illustration shows 64 slice system in the 64 X 0.625 mm mode. Only one half of the detector is shown...

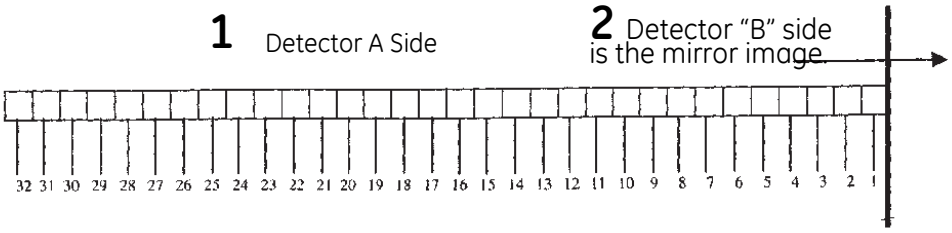


Table 11-9 Channel summation in Z -Examples

Number	Description
1	Detector "A" Side
2	Detector "B" side is the mirror image.

Collimator Theory

Dynamic Z-axis tracking provides automatic and continuous correction of the x-ray beam position to block unused x-ray at the beginning and end of a helical scan to reduce unnecessary radiation.

The X-ray tube collimator contains two cams that are used to control the width of the X-ray beam in the Z-Axis.

The cams are used by the Z-Axis Tracking control system to maintain a narrow X-ray beam aperture to ensure the optimal trade-off between dose and Image Quality is achieved. In helical scan modes, the cams are used by the Dynamic Z-Axis Tracking control system to limit the x-ray beam coverage to the area of the detector used in image reconstruction, reducing dose to the patient while maintaining Image Quality.

Z-Axis Tracking

The purpose of tracking is to follow the focal spot so that we can keep the most uniform part of the X-ray beam and the narrowest possible beam on the detector to reduce dose and still avoid artifacts.

The focal spot moves in the Z-axis due to thermal changes in the tube and mechanical forces during gantry rotation and tilt angle.

In order to maintain the narrowest possible beam, the system employs a closed loop control system called as "Z-Axis Tracking". The closed loop control system uses measured beam position data from the detector to position the collimator cams in real time. Each cam can be independently adjusted for optimal beam performance.

The schematic diagram in Figure 11-5 demonstrates the factors involved in collimation control in the tracking architecture.

Figure 11-6 Z-Aixs Tracking Architecture

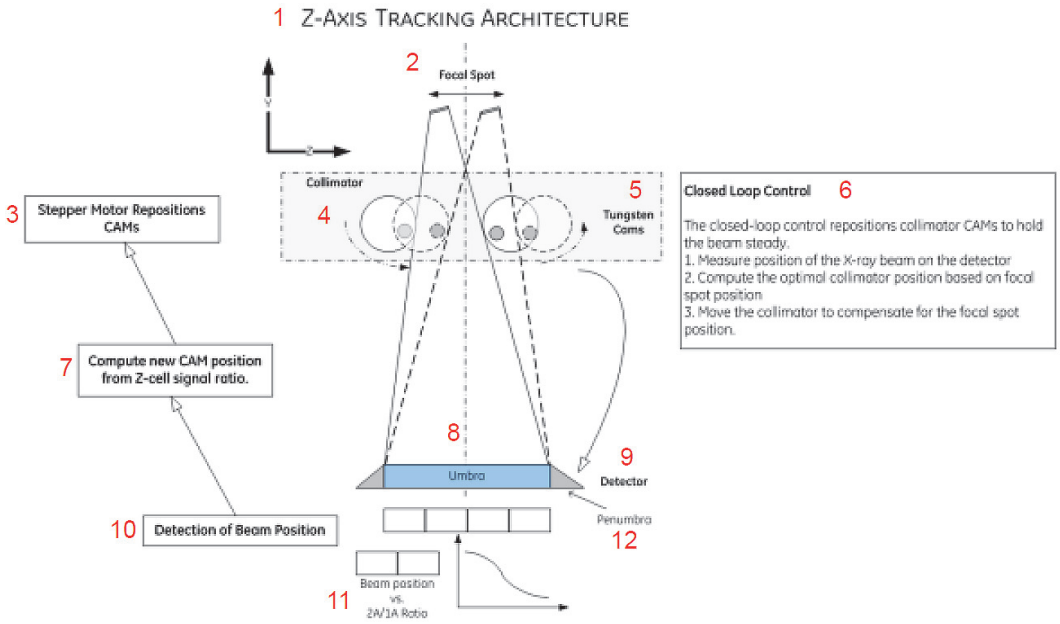


Table 11-10 Z-Axis Tracking Architecture

Number	Description
1	Z-Axis Tracking Architecture
2	Focal Spot
3	Stepper Motor Repositions CAMs
4	Collimator
5	Tungsten CAMs
6	Closed Loop ControlThe closed-loop control repositions collimator CAMs to hold the beam steady. 1. Measure position of the X-ray beam on the detector 2. Compute the optimal collimator position based on focal spot position 3. Move the collimator to compensate for the focal spot position.
7	Compute new CAM position from Z-cell signal ratio.
8	Umbra
9	Detector
10	Detection of Beam Position
11	Beam position verses 2A/1A Ratio

5805441-1EN Rev. 2 (Sep. 2020)

Number	Description
12	Penumbra

Dynamic Z-Axis Tracking

Beam tracking at the beginning and the end of helical scan acquisitions allows the system to control the X-ray beam to target only the portion of the detector used by image reconstruction, thereby limiting patient dose and maintaining image quality.

At the beginning of a helical scan, the lead cam will be closed to block the portion of the X-ray beam that is not needed by image reconstruction. As the scan progresses, the lead cam will open until the prescribed aperture width is achieved and normal Z-axis tracking begins. Near the end of the scan, the trailing cam will begin to close to block the unused portion of the X-ray beam. See Figure 11-7.

The amount of dose reduction achieved by this technique is a function of the aperture, pitch and scan length prescribed by the user.

Figure 11-7 Dynamic Z-Axis Tracking Architecture

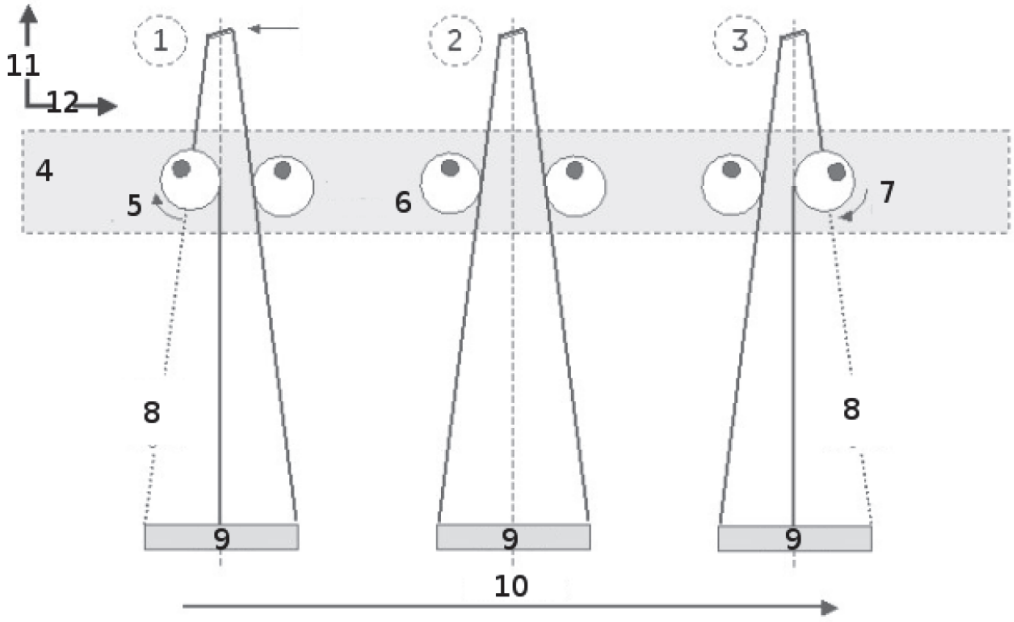


Table 11-11 Dynamic Z-Axis Tracking Architecture Descriptions

Number	Description
1	Start of helical scan, lead cam closed and begin to open
2	Middle of scan, cams open and normal Z-axis tracking
3	End of helical scan, trailing cam closes
4	Collimator

Number	Description
5	Leading Cam Opens
6	Tungsten Cams
7	Trailing Cam Closes
8	Blocked X-ray Region
9	Detector
10	Table Travel
11	Y Axis
12	Z Axis

The tracking adjustment factor is to account for the dose reduction provided by Dynamic Z-Axis Tracking (see Collimator Theory section of the General Information Chapter for more details). The tracking adjustment factor should be used for all helical scans except Cardiac and Volume Helical Shuttle scans. These scan techniques do not employ Dynamic Z-Axis Tracking. A tracking adjustment factor of 1 should be used for Cardiac Helical scans.

NOTE: Due to the scan length dependent nature of Dynamic Z-axis tracking the system Noise and Low Contrast Detectability specifications are reported without the scan length dependent dose reduction impact of Dynamic Z-axis Tracking. This ensures that the system can achieve or exceed the provided system specifications regardless of the chosen scan length. For short scan lengths, such as those typically used for phantom scans, the dose reduction impact of Dynamic Z-axis Tracking may result in dose values lower than the provided system specifications, which is to be expected and may be accounted for by adjusting the specified dose by the tracking adjustment factor provided in the Quality Assurance chapter.

Automatic Exposure Control (Reference NEMA XR 28-2013 Section 2.3)

Patients come in all shapes and sizes. For the purpose of achieving a desirable image quality with a scan technique that reflects the patient's size and shape, there are several approaches to employing automatic and manual mA setting modes of CT operation. These approaches are designed to adjust the X-ray output of the system according to the X-ray attenuation presented by a patient's anatomy. For example, the patient's weight or BMI1 may be used as a guide to set a fixed mAs for the acquisition. Alternatively, some measure of patient thickness or girth, such as anterior-posterior (AP) thickness, lateral width, or patient circumference can be used as a basis to choose an appropriate fixed mAs value, i.e., a value that yields an image adequate for diagnosis with a patient dose as low as reasonably achievable. However, these methods have at least two inherent limitations. First, as they produce a fixed mAs value, they do not adjust for differences in body-region thickness and associated variation in X-ray attenuation along the patient length and/or around the patient circumference. Second, the use of weight, thickness or circumference is

5805441-1EN Rev. 2 (Sep. 2020)

an incomplete surrogate for X-ray attenuation, which is one of the most relevant physical parameters affecting image quality and which depends on the elemental composition and density of human tissue as well as on its shape and thickness.

Automatic Exposure Control (AEC), on the other hand, is designed to adjust the scanner radiation output to meet a desired, pre-set level of image quality/noise criterion by empirically assessing the patient's attenuation and automatically modulating the mA accordingly. AEC can provide a desired level of image quality/noise at a lower patient dose than would be possible with a fixed scanner radiation output. In general, CT systems may accomplish AEC in two ways:

1. Modulating the mA dynamically during scanning in the X-Y and/or Z dimensions to adapt to variations in the patient's attenuation.
2. Adjusting the mAs to a fixed value based on measurement and calculation of the patient's overall attenuation: the mAs is constant during scanning, but its value has been quantitatively determined so as to yield an average pre-set level of image noise.

Most AEC systems operate as described in number 1, above. Discussion of AEC hereafter applies to these types of systems unless otherwise indicated.

How AEC works

On the basis of a patient's attenuation, AEC sets mA values as the X-ray tube rotates around the patient. The technology uses knowledge about the scanner's imaging chain and the measured attenuation of the patient to appropriately adjust mA values in order to achieve the desired, constant image noise/quality criterion.

Larger patients typically require scanning at a higher mAs than the mAs used for smaller patients. Similarly, thicker projections (e.g., laterally through the shoulders vs. AP through the shoulders) typically require more mAs to achieve the same resultant image noise/quality criterion. Finally, anatomy with greater attenuation (e.g., abdomen or pelvis compared to the lungs) requires more mAs to achieve the same image noise/quality criterion.

Adaptation to anatomy

As patient attenuation changes throughout the course of the scan, either rotationally around the patient or along the length of the patient, AEC is designed to adjust dynamically the mA for each body part and projection. If the attenuation does not change, AEC sets the mA at a constant value that is appropriate for the overall patient thickness and that achieves the desired image noise/quality criterion.

When to use AEC

AEC technology has the greatest impact when the portion of the patient being scanned has non-uniform size, shape, or density. In these cases, AEC adjusts scanner radiation output to the changing anatomy and modulates the mA in the Z-direction (along the patient) and/or in the XY-direction (around the patient). Even though AEC is used, before scanning the operator

must still select scan parameters, including AEC parameters, which provide a desired image noise/quality criterion. Scan parameters including AEC parameters must be chosen to carefully balance patient radiation dose and image performance.

Even when the patient's anatomy has consistent size, shape, and density throughout the planned scan range, AEC technology chooses the appropriate exposure settings to achieve the image noise/quality criterion requested by the user.

When bismuth or other shields are considered for use in the planned scanned range, consult the system user manual for specific information.

When not to use AEC

AEC might not be available for all scanning modes or on all scanners. When AEC is available, if users do not understand the relationship between AEC parameters, image noise, and dose, AEC should not be used. Also, if the patient cannot be centered in the scanner, AEC is not recommended because the attenuation calculations used for AEC are designed with the assumption that the patient is centered in the gantry. Finally, if there is any question, radiologic technologists should always consult their medical physicist and radiologist to ensure that proper exposure techniques are used.

AEC does not guarantee reduction of radiation doses in all patients

The use of AEC does not always result in dose reduction, especially when compared to a fixed mA/mAs protocol. For example, when providing the desired image noise/quality criterion setting for a large patient, AEC might appropriately increase the scanner radiation output as compared to that for an average-sized patient. For most examinations of average-sized or small patients, and for the same image noise/quality criterion settings, AEC use will result in the same or lower $CTDI_{vol}$ as that of a fixed mA/mAs protocol. (However, a larger patient would appropriately require more fixed mA than for a smaller patient.)

NOTE: Radiologic technologists must be fully aware that proper patient centering is critical for accurate AEC function. Improper patient centering can result in an exposure that is either too high or too low to achieve the desired image noise/quality criterion. Note that proper patient centering can be more challenging for smaller pediatric patients, and so special care should be taken.

Effect of AEC control setting

For a given patient, changing the image noise/quality criterion setting in AEC will affect the patient dose: asking for lower image noise/higher image quality criterion will result in more dose to the patient as the noise index value is decreased (made smaller). In contrast, asking for higher image noise/lower image quality criterion by increasing (make larger) the noise index value will result in less dose to the patient.

5805441-1EN Rev. 2 (Sep. 2020)

AEC considerations of patient size, shape, composition, and age

For a given AEC image noise/quality criterion setting, larger patients and more attenuating body regions may result in a higher scanner radiation output. Smaller patients and less attenuating body regions may result in a lower scanner radiation output.

While AEC can be an effective dose-reduction tool for pediatric patients, special care should be taken with this patient group. The GE Healthcare online education module available on the Image Gently website describes issues to consider when using our AEC features with pediatric patients.

Dynamic AEC scanning

When a scanning protocol contains multiple X-ray tube rotations at the same table location, the effect on patient dose of incorrect selection of protocol settings will be multiplied by the number of rotations. For such protocols, operators must take extra care when setting manual mAs or AEC parameters to achieve the desired level of image noise/quality criterion. For example, in perfusion scanning, the image noise can often be much higher (yielding a lower dose) than for routine diagnostic scanning of the same region because the primary application of perfusion-scan data is for quantitative analysis and characterization of perfusion parameters rather than for diagnostic visualization. The manufacturer's reference protocol provides an indication as to whether use of AEC is or is not recommended with these scan modes.

How to tell if the dose has changed

For every patient, and any time AEC settings are changed, in order to confirm a correct level of scanner radiation output for that patient's size and exam protocol, users should examine the predicted $CTDI_{vol}$ and DLP displayed prior to performing the scan, as a step in operator confirmation of system settings. When a large patient is scanned at a particular setting of image noise/quality criterion, the $CTDI_{vol}$ and DLP will be higher than for a smaller patient at the same AEC settings. Predicted $CTDI_{vol}$ and DLP values are displayed on the scanner's dose display on the user interface prior to confirmation of settings for scanning. After scanning, the values are updated to reflect the average of the actual mAs values used in the scan and are displayed on the user interface as well as recorded in the DICOM secondary screen capture and DICOM radiation dose structured reports.

Summary

AEC is a versatile and powerful tool designed to tailor the scanner's radiation output to each patient based on the patient's size, age, shape and attenuation and the user's requested level of image noise/quality criterion. AEC technology uses measured patient attenuation values to adjust the mA dynamically in order to achieve the requested level of image noise/quality criterion. However, AEC settings must be chosen with the same care used to choose all other parameters that affect radiation dose to the patient. Before the scan parameters are confirmed, careful attention must be paid to $CTDI_{vol}$ and DLP displayed on

the user interface; scanner radiation output associated with the prescribed protocol must be checked and confirmed prior to scanning. Used properly, AEC is a key technology to help ensure that the appropriate radiation dose is used for every patient.

AutomA (Reference: IEC60601-1-3:2008 Clause5.2.4.5b), IEC60601-2-44:2009 Clause203.106)

A significant factor in the quality of a CT image is the amount of x-ray quantum noise contained in the scan data used to reconstruct the image. Most technologists know how the choices of x-ray scan technique factors affect image noise. That is, noise decreases with the inverse square root of the mAs and slice thickness. Noise also decreases approximately inversely with kVp. For example, increasing the mA from 100 to 400 (a factor of 4) will decrease quantum noise by a factor of 2 (the square root of 4). Quantum noise also increases with increasing helical pitch; however, the exact relationship is dependent on the details of the helical reconstruction process.

The most significant factor that influences the quantum noise in the scan data is the x-ray attenuation of the patient section being scanned. The x-ray attenuation is related to the size and tissue composition of the patient section. Figure 11-8 shows a distribution of patient attenuation area values (PAA) for adult abdominal images that ranges from 19 to about 41 with a mean of 27.6 (for this patient sample set). The patient attenuation area (also called the Patient Attenuation Indicator, PAI)[1] is computed for the patient section as the square root of the product of the sum of raw pixel attenuation values times the pixel area.

1.T Toth, Z.Ge, and M. Daley, "The influence of bowtie filter selection, patient size and patient centering on CT dose and image quality", Poster SU-FF-I42, 2006AAPM Conference (MedPhy, Vol 33, No.6, June 2006)

5805441-1EN Rev. 2 (Sep. 2020)

Figure 11-8 Adult abdominal patient distribution in terms of average patient attenuation

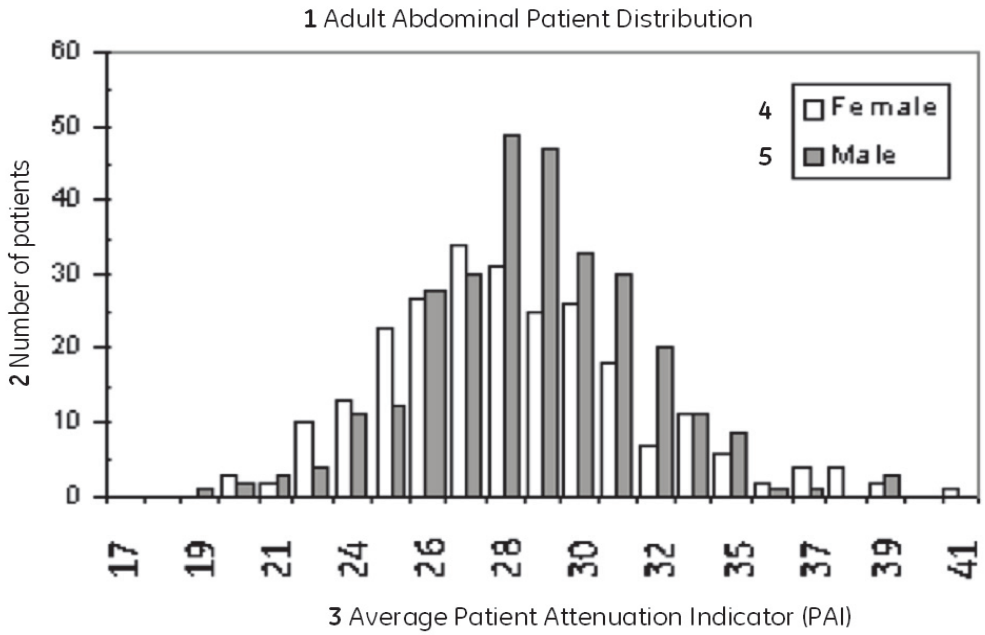
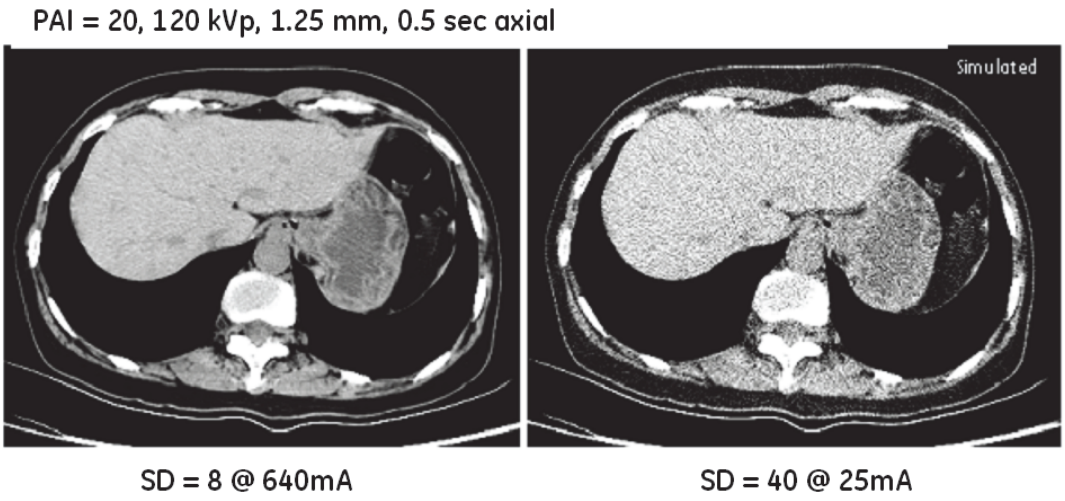


Figure 11-9 Example small patient (PAI = 20) with factor of 5 noise increase (simulated)



For a given fixed scan technique, the quantum noise varies by about a factor of 5 from the smallest to the largest patients attenuation (PAI range of 17 to 41). Figure above shows an example of a five times noise increase simulated for a small patient (20 PAI). With a fixed mA scan protocol, the technologist must select the mA using a qualitative estimate of the patient attenuation. This is may be accomplished using patients weight, diameter measurements, body mass index, or just as a qualitative visual classification. Because these methods provide very rough x-ray attenuation estimates and do not account for

attenuation changes within the patient region being scanned, the technologist must use a high enough technique margin to avoid the possibility of compromising the diagnostic quality of the images with too much noise. Since dose is inversely related to the square of the noise, many patients are likely to be receiving more dose than necessary for the required diagnostic quality using such manual methods.

Automatic tube current modulation: AutomA is an automatic tube current modulation feature that can make necessary mA adjustments much more accurately than those estimated for the patient by the user and thereby can obtain a more consistent desired image noise in spite of the wide range of patients. Since image noise variability is substantially reduced, a significant overall patient dose reduction is possible with proper scan parameter selection.

AutomA (Z-axis modulation) adjusts the tube current to maintain a user selected quantum noise level in the image data. It regulates the noise in the final image to a level desired by the user. AutomA is the CT equivalent of the auto exposure control systems employed for many years in conventional X-ray systems. The goal of AutomA is to make all images contain similar x-ray quantum noise independent of patient size and anatomy.

The AutomA tube current modulation is determined from the attenuation and shape of scout scan projections of the patient just prior to CT exam sequence.

SmartmA (angular or xy modulation) has a different objective than Z-modulation. It adjusts the tube current to minimize X-rays over angles that have less importance in reducing the overall image noise content. In anatomy that is highly asymmetric, such as the shoulders, x-rays are significantly less attenuated in antero-posterior (AP) direction than in the lateral direction. Thus, the overwhelming abundance of AP x-rays can be substantially reduced without a significant effect on overall image noise.

Angular modulation was first introduced on GE single slice scanners in 1994[1,2].

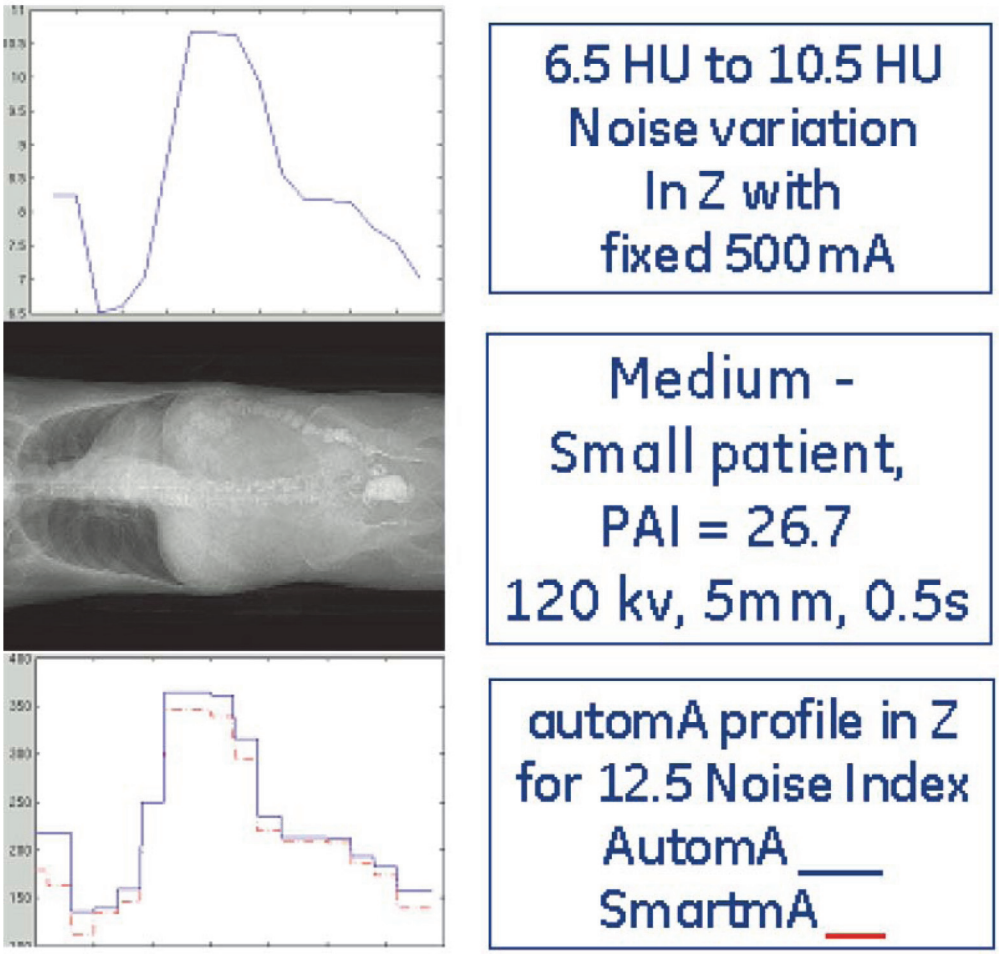
AutomA Theory

AutomA is an automatic exposure control system that employs Z axis tube current modulation and is available on Revolution™ EVO scanner. A noise index parameter allows the user to select the amount of X-ray noise that will be present in the reconstructed images. Using a single patient scout exposure, the CT system computes the required mA to be used based on the selected noise index setting. The noise index value will approximately equal the standard deviation in the central region of the image when a uniform phantom (with the patient's attenuation characteristics) is scanned and reconstructed using the standard reconstruction algorithm.

1.L. Kopka and M. Funke, "Automatically adapted CT tube current: Dose reduction and image quality in phantom and patient studies," Radiology 197 (P), 292 (1995).
2.D.R. Jacobson, W. D. Foley, S. Metz, and A. L. Peterswen, "Variable milliampere CT: Effect on noise and low contrast detectability, "Radiology 210(P), 326 (1996)

5805441-1EN Rev. 2 (Sep. 2020)

Figure 11-10 Example noise variation with fixed mA and mA variation with AutomA with a Noise Index setting



The system determines the tube current using the patient's scout projection data and a set of empirically determined noise prediction coefficients for a reference technique. The reference technique is the selected kVp, and an arbitrary 2.5 mm slice at 100 mAs for an axial reconstruction using the standard reconstruction algorithm. The scout projections contain density, size and shape information about the patient. The total projection attenuation (projection area) contains the patient density and size information and the amplitude and width of the projection contains the patient shape information. These patient characteristics determine how much x-ray will reach the detector for a specified technique and hence predict the image standard deviation due to x-ray noise for the standard reconstruction algorithm.

To predict the image noise at a given z position for the reference technique, the projection area and oval ratio are obtained from the patient's scout. The oval ratio is an estimate of the patient asymmetry that is determined from the amplitude and width of the projection data. The expected x-ray noise for the reference technique (reference noise) is then calculated as

a function of the projection area and oval ratio from the scout using polynomial coefficients that were determined by a least squares fit of the noise measurements from a set of phantoms representing a clinical range of patient sizes and shapes.

Knowing the reference noise and the difference between the reference technique and the selected prescribed technique, the mA required to obtain the prescribed noise index is calculated using well known x-ray physics equations. That is, the noise is inversely related to the square root of the number of photons and the number of photons is proportional to the slice thickness, slice acquisition time, and mA. In the GE AutomA design, an adjustment factor for helical pitches is also incorporated in the calculation to account for noise differences that scale between helical selections and the axial reference technique.

AutomA FAQs

1. What suggestions do you have for a new AutomA user?

- If you are not familiar with the concept of noise index (image noise) you can use the GE reference protocols that have AutomA enabled as a starting point, use the standard deviation from an acceptable image for approximation of a noise index, or consult the literature until you find the highest noise index value that provides acceptable diagnostic quality. Experiment by scanning some phantoms with different noise index values to gain some confidence. A 30 cm diameter water phantom or a 35 cm diameter low density polyethylene phantom have an attenuation similar to the average adult abdominal patient (27.6 PA).
- It is important to review the image quality that is obtained with the noise index selected to optimize your mA range and noise index values accordingly.
- You should also check the mA table on the scan set up screen to see what mA is actually being used. If you see that it is frequently at the maximum mA range, consider increasing the noise index if more noise can be tolerated in your reconstructed images without compromising the diagnostic value, or increase the maximum mA limit if it is not at the maximum limit of the x-ray generator and you have determined that you require lower noise in your images than you are currently obtaining. Each dose step decrease will increases the Noise Index by 5% and reduces the mA in the mA table about 10%.
- If you normally reconstruct images with thin sections for 3D reformatting and thicker slices for axial viewing it is important to understand that the first prospective reconstructed slice thickness is used for calculating AutomA. Generally you would want to set the noise index for the thicker slice images. For example, you might want a noise index of 10.0 for 5 mm thick images for viewing but you may also want 0.625 mm slices for 3D reformatting. If you prescribe the 0.625 mm slice recon first followed by the 5 mm recon, AutomA will calculate the mA needed to obtain an image noise of 10 for the 0.625 mm slices since it is prescribed first. In this case, to avoid excessively high mA and high dose, you need to readjust the noise index using

5805441-1EN Rev. 2 (Sep. 2020)

the following approximation:

$$RxNoiseIndex_{thin} = RxNoiseIndex_{thick} \times \sqrt{\frac{ViewingSliceThickness}{FirstRxSliceThickness}}$$

Example:

$$28.3 = 10 \times \sqrt{\frac{5mm}{0.625}}$$

2. Why is the standard deviation I measure in the image some times different than the noise index I selected for the scan?

- There are many factors that can account for this. But, first consider that the noise index setting you make only causes the tube current to be adjusted so that the system projects a similar X-ray intensity through the patient to the detector. Hence it regulates the X-ray noise or quantum noise in the scan data. The noise in the image depends on other factors as well. The selection of reconstruction algorithms, reconstructed slice thickness selection (if different than your prospective selection), and the use of image space filters will also change the noise in the image. In addition, it is very difficult to make standard deviation measurements on patient data since the standard deviation is affected by small CT number variations of the anatomy and by patient motion or beam hardening artifacts. Even with uniform phantoms, standard deviation measurements will produce some variability in measured results because of the inherent nature of quantum statistics.
- Another situation that can cause significant differences between the selected noise index and the image standard deviation is when very large patients provide insufficient detector signal. In these cases, electronic noise sources can become the dominant image noise source instead of X-ray noise. In these cases at various threshold levels, special projection data dependent filters begin to be applied to help preserve image quality. The highest kVp is recommended when excessively large patients are to be scanned.
- Another factor is how well the patient is centered in the SFOV. Image noise can increase significantly if the patient is mis-centered. This occurs because the bowtie filter projects maximum x-rays intensity at isocenter since this is the region of maximum attenuation if the patient is centered. If the patient is mis-centered, there are fewer x-rays projected to the thickest part of the patient, and hence image noise will increase. The optimum strategy is to find the highest noise index sufficient for the clinical task and let AutomA select the mA without using significant constraints.

3. Will I get a dose reduction when I use AutomA?

- AutomA will use a dose that depends on the noise index you select and the size of the patient you are scanning. If, you do not obtain a dose reduction over a population of patients, you may have selected a lower noise index than you really need and this results in higher mA values on average than your fixed mA protocols. One strategy to avoid using more dose is to set the max mA parameter to the same level as your

fixed mA protocols. This will cap the maximum dose to the same level as your fixed mA protocol. Hence, AutomA will never be allowed to use more dose then you previously used. However, image noise will increase in regions where the mA is limited by the max mA selection and the IQ will degrade with increasing patient size. The optimum strategy is to find the highest noise index sufficient for the clinical task and let AutomA select the mA without using significant mA limits.

4. Why do my images seem noisier when I use AutomA?

- AutomA will produce an x-ray intensity to maintain the noise index you select. Thus, you may need to use a lower noise index. This may be the case if you find that the average mA for your population of patients is generally lower than your previous fixed mA protocols. This situation indicates you are using lower dose and hence higher noise levels would be expected.
- Certain patient images may also be noisier than your experience suggests. For example, your experience tells you to expect significantly lower noise in thin patients than obese patients. Since AutomA makes the image noise approximately the same for all patients, you may have to re-learn what to expect. What is most important, is to find the highest noise index that allows you to make a confident diagnosis for the clinical problem since this results in the lowest patient dose.
- If you desire somewhat lower noise in small patients, you may want to create Small, Nominal, and Large patient protocols. You can use the slightly a slightly lower noise index for the small patients and a slightly higher noise index for large patients.
- A conditional noise limiting strategy you can employ, is to increase the low mA range parameter. If you find that images are generally not acceptable to you below some minimum mA value, then you may set this value as the low mA range limit. This will prevent AutomA from using lower mA values than you desire. Note, however, that this defeats the purpose of AutomA and causes the image noise to decrease below the selected noise index and thereby increases the dose.
- Yet another possibility for higher noise than you might expect is if you are looking at multiple reconstructed images that have thinner slices than the prospective scan Rx slice thickness. AutomA uses prospective slice thickness as a factor when the mA table is generated. You need to be sure the noise index is set for the first prospective image based on image thickness you will use for axial image viewing (see FAQ 1). This caveat applies equally for fixed mA as well as AutomA scanning.
- Higher noise images can also occur when patients are not well centered in the scan field of view. The bowtie filter attenuation increases with distance away from isocenter. Hence the thickest part of the patient should be approximately centered in the scan field of view. Otherwise image noise will increase since the patient thickness adds to the bowtie filter thickness. This is especially important for highly asymmetric anatomy such as through the shoulders. Again, this effect is no different with AutomA than with fixed mA.
- Recognize also that there are also some obese patients that exceed the capabilities of the tube and generator to satisfy the selected noise index. This is also no different

5805441-1EN Rev. 2 (Sep. 2020)

than fixed mA scanning. For such obese patients, one strategy is to select a higher kVp setting when possible.

5. **Why is the mA that is annotated on the image sometimes slightly different than the mA I see in the mA table?**

   - The mA displayed on the image is determined by measuring the generator mA during the scan and averaging the measured result over the total number of views used to reconstruct the image. The number of views used to produce the image may be more than one gantry rotation for a helical scan. Hence the annotated value is a combination of the mA table values that depends on how many views from each rotation were used for the image. In addition, the generator is automatically adjusting the filament current to account for changing conditions during the scan to keep the mA within the desired tolerance of the commanded mA table. For example, this is why you may see an mA value of 41 in the image where the mA table indicated 40.

6. **I understand that noise in the image noise changes with reconstruction parameter selections, but why is the noise sometimes different when I retro reconstruct the same scan data at a different display field of view?**

   - When you select a reconstruction algorithm, the system may sometimes re-adjust the actual filter kernel. This readjustment will change the image standard deviation. This will happen if the display field of view selection exceeds a certain size and is especially apparent with higher resolution algorithms such as bone and edge. The change in kernel is required when the DFOV selection makes the pixel size too large to support the intended spatial resolution. This characteristic is independent of AutomA.

ECG-Modulated mA Theory

Electrocardiograph Tube Current Modulation

Modulating tube current based on an electrocardiograph (ECG) signal is a technical innovation that significantly reduces radiation dose to cardiac patients. The concept is based on the fundamental principles of cardiac CT imaging.

ECG-modulated mA Theory

The motion of the heart has always been challenging for diagnostic imaging of the heart and surrounding areas. Motion can cause blurring and mis-registration artifacts in images. Cardiac CT acquires images when the heart motion is minimal. The motion is generally least near the end of the diastolic phase of the cardiac cycle. The motion is generally greatest during the systolic phase of the cardiac cycle, in which the heart is contracting. The ECG-modulation feature takes advantage of this fact, and only provides full tube current to the patient during the diastolic period of the cardiac cycle, which is most likely to produce the best image quality. The tube current is modulated to a lower mA setting during systole to decrease the dose to the patient.

ECG-modulated mA applies to cardiac helical scans only. Cardiac helical acquisitions utilize retrospectively gated reconstructions. Without ECG-modulation, radiation is on for the entire length of the scan and images can be created at any phase of the cardiac cycle. ECG electrodes are connected to the patient prior to the scan and an ECG monitor stores the ECG data during the scan. The scanner measures one full heart period as the time from one QRS complex to the next. The QRS complex is the portion of the ECG waveform corresponding to ventricular depolarization signaling contractions. A particular time period in the cardiac cycle is prescribed in terms of a percent phase of the heart period. With the ECG gating information and acquisition data from the entire scan, the image reconstruction software can retrospectively create images centered on any phase in the cardiac cycle. For most patients, 75% is considered to be the best phase for imaging of the coronary arteries.

The ECG-modulated mA feature requires the user to input the maximum and minimum tube current values and the start and end cardiac phase for the tube to be at maximum current for each cycle. Minimum tube current can be no less than 20% of the maximum. Twenty-percent of the peak mA may yield adequate image quality at systole to assess cardiac function from images generated outside of the maximum mA phases. Start and end phases can be prescribed from 0 to 99% of the cardiac cycle. The scan will start off at the maximum tube current. The algorithm uses a moving average of the heart periods to predict when the next QRS complex will occur. Once the initial average is set, the system will start modulating the tube current. To guarantee the tube current is at the minimum and maximum values when it should be, the system must take into account the time required for the generator to ramp the tube up to maximum current and down to minimum current.

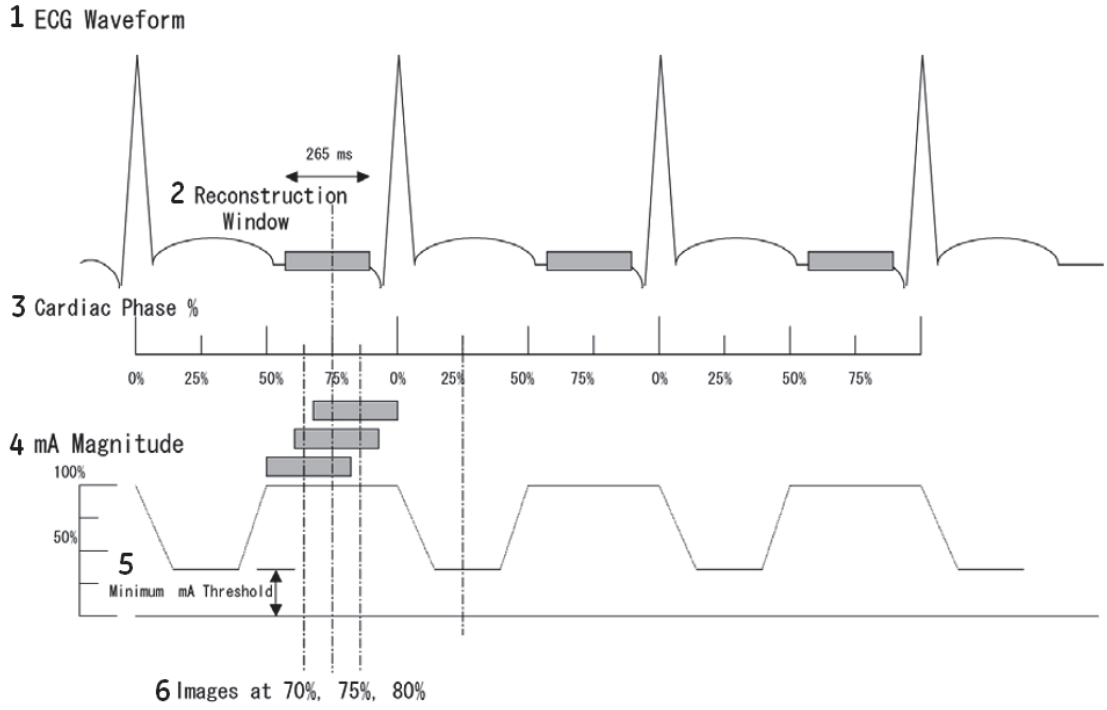
In the event that the patient should experience a pre-ventricular contraction (PVC) or a missed beat, there is the possibility that the images at full mA could become shifted from the prescribed phases. The system has special checks in place for these abnormal heart

5805441-1EN Rev. 2 (Sep. 2020)

beat situations and will immediately ramp the tube up to full current in order to minimize the number of noisy images that can occur during these abnormal cycles. Once the heart has settled into a normal rhythm again, the system will resume modulation.

Figure 11-11 ECG Waveform

In this example, Start Phase = 70%, End Phase = 80 %



Organ Dose Modulation

The tube current is reduced where tube position is between -90 degree (°) and +90 degree (°). See Figure 11-12 and Figure 11-13.

The tube current reduction is up to 40% while increasing of pixel noise standard deviation within less than 10%.

Figure 11-12 mA modulation of Organ Dose Modulation

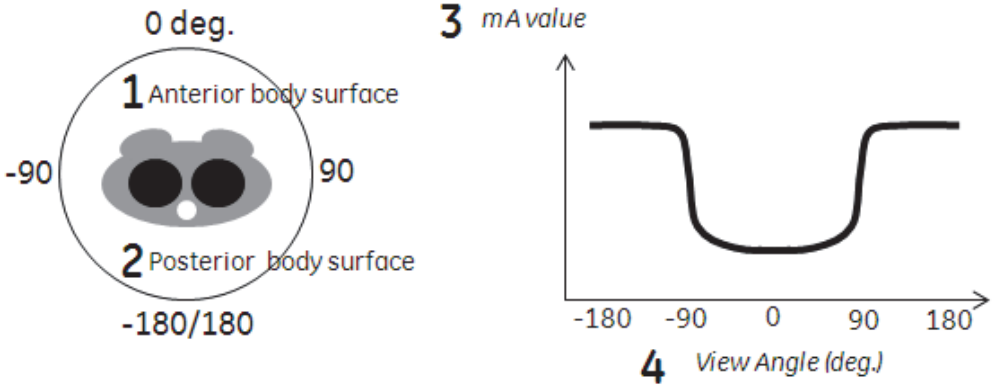


Table 11-12 Descriptions

Number	Description
1	Anterior body surface
2	Posterior body surface
3	mA value
4	View Angle (deg. (°))

5805441-1EN Rev. 2 (Sep. 2020)

Figure 11-13 mA modulation angle of Organ Dose Modulation

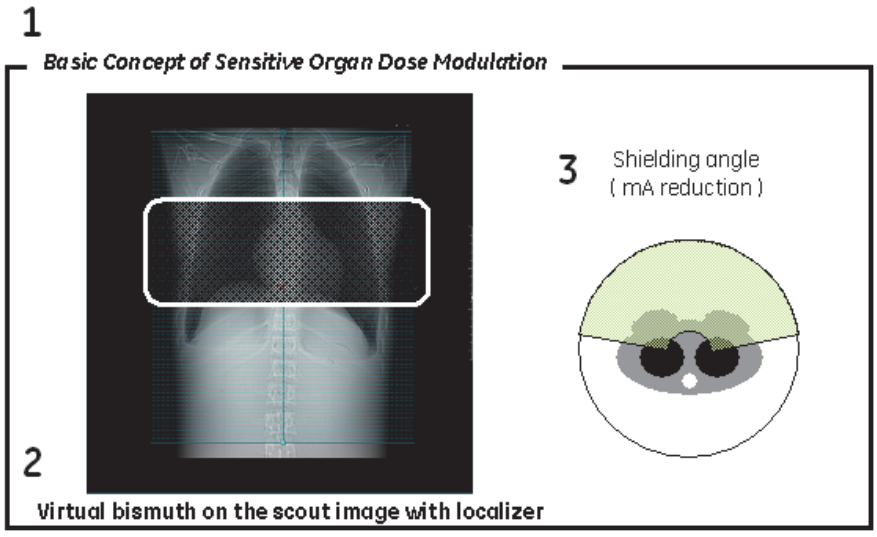


Table 11-13 Descriptions

Number	Description
1	Basic concept of sensitive organ dose modulation
2	Virtual bismuth on the scout image with localizer
3	Shielding angle (mA reduction)

System Operational Modes

Overview

The Revolution™ EVO scanner provides unique data collection functionality unmatched by any competitor's system. Even with this powerful data collection capability, the basic modes of operation presented to the user will remain unchanged from HiSpeed CT/i:

Helical scan mode is a continuous 360 degrees (°) scanning with table increment and no inter scan delay.

Axial scan is a contiguous axial slices acquired simultaneously with each 360 degrees (°) rotation, with the time between scans set by the user-selected inter scan delay (ISD) or intergroup delay (IGD).

Cine scan mode is a contiguous axial slices acquired simultaneously with each 360 degrees (°) rotation. Half-scan imaging and segmented reconstruction is supported with acquisitions times of 0.65 times that of the scan speed.

- Scout
- Axial
  - Axial Scanning
  - VolumeShuttle (Axial)
- Helical
  - Helical Scanning
  - Volume Helical Shuttle
- Cardiac
  - SnapShot Segment
  - SnapShot Segment Plus
  - SnapShot Burst
  - SnapShot Burst Plus
  - SnapShot Pulse
- Cine
  - Cine Scanning

Scout (Reference YY0310)

Scout imaging is used for anatomical location in conjunction with scan and recon prescription, to provide an anatomical cross-reference for axial images, and to provide quick feedback to the user as to the anatomy scanned. Scout supports the following features:

- All kV and mA stations available, dependant on generator and tube limitations.
- 0.625mm resolution in Z.

5805441-1EN Rev. 2 (Sep. 2020)

- The table speed is either 100 mm/sec for Scout or 175 mm/sec for Fast Scout.
- Data collected in 8 X 0.625mm mode. Reconstruction algorithms “combine” data to maintain 0.625mm resolution in Z.

Scout Orientation

- Presets: Anterior Posterior, Right Lateral, Posterior Anterior, Left Lateral
- Manual: 0-359 degrees (°) in increments of one degree (°).

Scout images are autominified to fit the display.

Table 11-14 Scout length example

Scout Length (mm)	Pixel Size
500	500 mm/512 pixel
1,000	1,000 mm/512 pixel
1,500	1,500 mm/512 pixel
2,000	2,000 mm/512 pixel

Pediatric Imaging

Adult techniques and protocols should not be used on pediatric patients. Refer to the User Manual on Imaging Pediatric and Small Patients.

Axial and Cine Scans

Axial scanning is expected to be used less on Revolution™ EVO than on HiSpeed CT/i. The goal for Revolution™ EVO is to support virtually all applications using helical scanning. There may be applications, such as high-resolution Inner Auditory Canal (IAC) or lungs, where axial scanning is required for image quality reasons.

Axial and Cine imaging features include:

- All kV and mA stations available, dependent on generator and tube limitations.
- Rotation speeds: 0.35, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 2.0 seconds (s) for Axial.
- Rotation speeds: 0.35, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0 seconds (s) for Cine.
- Variable image thickness: 0.625, 1.25, 2.5, 5 and 10 mm.
- Sample rates: 984 Hz to 2468 Hz (depending on rotation speed)
- Segmented reconstruction option is available for cine scans.
- Half-scan imaging and segmented reconstruction is supported with 237 degree (°) rotation (0.65 rotation) data.

NOTE: 0.35 second option enables 0.35, 0.4, 0.5 and 0.6 second(s) scan.
0.35 second for cardiac or 0.4 second option enables 0.4, 0.5 and 0.6 second(s) scan.
0.5 second option enables 0.5 and 0.6 second(s) scan.

Table 11-15 Axial/Cine Tube Scanning Performance

Scan Time (s)	ISD (s)	mA	Number of Scans (xxx)	Number of Scans (yyy)
1	1	560	4	16
1	1	520	8	26
1	1	480	14	37
1	1	440	18	45
1	1	400	24	55
1	1	360	32	68
1	1	320	43	86
1	1	280	58	110
1	1	240	74	135
1	1	200	94	168

xxx: 120 kV scans under thermal equilibrium condition (infinitely repeatable scans with about 10 minutes ISD).
yyy: 120 kV scans under cool condition (two hours past from last scan).

Revolution™ EVO can acquire 64 axial slices (64 slice configuration) in a single rotation. These slices can be reconstructed independently or may be combined to produce composite images.

Table 11-16 Axial Slice Thickness Selections

Scan Mode	1i	2i	4i	8i	16i	32i	64i	128i
2 X 0.625	1.25	N/A	N/A	N/A	N/A	N/A	N/A	N/A
4 X 0.625	2.5	1.25	N/A	N/A	N/A	N/A	N/A	N/A
8 X 0.625	5.0	2.5	1.25	N/A	N/A	N/A	N/A	N/A
16 X 0.625	10.0	5.0	2.5	1.25	0.625	N/A	N/A	N/A
32 X 0.625	N/A	10.0	5.0	2.5	1.25	0.625	N/A	N/A
64 X 0.625	N/A	N/A	10.0	5.0	2.5	*1 1.25	*1 *2 0.625	*1 *2 0.625

*1 Prescribed in Retro Recon only.
*2 64 slice system only.

5805441-1EN Rev. 2 (Sep. 2020)

NOTE: The 1i, 1.25 mm mode is intended for high resolution lung screening with an allowable increment of no less than 5 mm. This is a special higher resolution mode and normal imaging specification like noise, CT number accuracy, and uniformity do not apply.

The 2i, 1.25 mm mode is intended for biopsy applications. Normal imaging specifications like noise, CT number accuracy and uniformity do not apply.

128i images from 64x0.625 have ¼ detector offset.

64i images from 32x0.625 have ¼ detector offset.

VolumeShuttle (Axial)

VolumeShuttle (Axial) Mode is a repetitive axial scan mode, where the table shuttles (moves back and forth) between two adjacent axial locations with minimal interscan delay. No gaps are allowed with VolumeShuttle (Axial) Mode. Only 40 mm detector coverage is allowed.

A mean ISD of 1.1s and a maximum ISD of 1.5s between x-ray OFF and x-ray ON for the 40 mm table movements shuttling in the Z-direction.

Revolution™ EVO provides the single-injection 80 mm (2* wider coverage, 128 slice-width (64 slice mode) or 64 slice-width (32 slice mode)) Volume Shuttle acquisition scan.

Helical Scans

The 64-row detector and 64-row DAS provide the greatest benefits when used in the helical mode. In the helical mode, data from 64 detector rows is selectively combined and weighted during reconstruction in order to achieve the optimal balance between image z-axis resolution, noise, and helical artifacts.

Helical imaging features include:

- All kV and mA stations available, dependent on generator and tube limitations.
- 60* second (s) maximum helical scan time.
  * : In case of 20mm beam collimation, Helical scan can last up 120 seconds (s).
- Pitches: 0.984:1, 0.969:1, 0.531:1, 0.516:1, 1.375:1* and 1.531:1*
- Rotation Speeds: 0.35, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0 seconds (s).
- Variable image thickness (recon parameter): 0.625, 1.25, 2.5, 3.75, 5, 7.5 and 10mm.
- Sample Rates: 984 Hz to 2460 Hz (depends on rotation speed).
- Segmented reconstruction option.
- Half-scan imaging and segmented reconstruction is supported with 237 degree (°) rotation (0.65 rotation) data.
- The minimum image interval is 1/10th of the prescribed image thickness.
- 0.1mm minimum incremental retrospective recon image spacing.

- Multiple Acquisition Maximum Scan Time: Multiple scans may be acquired in one series to produce up to 3,000 contiguous helical images. Up to 3,000 rotations helical coverage is possible in multiple series.
- IGD between scans is from 1sec to 600sec.

NOTE: 0.35 second option enables 0.35, 0.4, 0.5 and 0.6 second(s) scan.
0.35 second for cardiac or 0.4 second option enables 0.4, 0.5 and 0.6 second(s) scan.
0.5 second option enables 0.5 and 0.6 second(s) scan.

* 1.375:1 or 1.531:1 is not available for Ped Head and Head SFOV.

Table 11-17 Single Helical Scan Tube Scanning Performance

Scan Time (s)	Maximum mA
3	560
5	560
10	560
20	445
30	385
40	350
50	325
60	310

Table 11-18 20mm Beam Collimation Helical Scan Tube Scanning Performance --- In case of 20mm beam collimation, Helical scan can last up 120 seconds(s).

Scan Time (s)	Maximum mA
3	560
5	560
10	560
20	445
30	385
40	350
50	325
60	310
70	295
80	285
90	275

5805441-1EN Rev. 2 (Sep. 2020)

Scan Time (s)	Maximum mA
100	265
110	250
120	235

Table 11-19 Multiple Helical Scan Tube Scanning Performance

No. of Scans	Max mA				
	3s Scan Time	5s Scan Time	10s Scan Time	20s Scan Time	30s Scan Time
2	560	560	460	360	315
3	560	550	425	335	285
4	560	530	405	315	240
5	560	505	390	--	--
6	545	490	365	--	--

Once the Revolution™ EVO helical data is collected, it can be reconstructed at image thickness greater than or equal to 1x the detector macro-row size. Premium image quality (near axial image quality) is achieved at 2x the detector macro-row size. The thinnest image thickness possible, which has image quality slightly degraded from 1.5:1 pitch on HiSpeed CT/i, is 1x the detector macro-row size.

Premium Image Quality Helical Example

Premium image quality (near axial image quality) is achieved as follows:

- Detector macro-row size = 50% of the desired image slice thickness.
- Pitch (table travel over beam collimation) = at lowest pitch.

Revolution™ EVO “Premium” IQ example for 64 slice mode:

- 2.5mm images
- 64 x 0.625 mm detector mode
- table speed of 20.625 mm/rotation (0.516)

Image Interval

The Revolution™ EVO has the ability to generate images at very small spacing and thereby exceed the number of native acquisition channels. When the scanner operates in a helical mode of data acquisition with its 64x0.625 mm (64 slice mode) or 32x1.25 mm (32 slice mode) detector configuration and a 1.375:1 helical pitch, images can be reconstructed spacings as small as 0.1 mm (64 slice mode) or 0.125 mm (32 slice mode). The table below shows the average number of slices (images) that can be generated per 360 deg of gantry

rotation. The average number of slices (images) per gantry rotation is calculated by dividing the total number of reconstructed slices (images) by the number of rotations during the data acquisition.

Table 11-20

Number of rotations	Z Coverage (mm)	Generated slices (images)/rotation	
		64 slice mode	32 slice mode
1.71	30	176	140
2.00	46	230	184
3.00	101	337	269
4.00	156	390	312
5.00	211	422	337
6.00	266	443	354

Volume Helical Shuttle

NOTE: Volume Helical Shuttle is licensed for use with a GE x-ray tube. Use of third party x-ray tube will require the purchase of an additional license for this feature.

Volume Helical Shuttle is a repetitive helical scan mode allowing the table to move continuously back and forth across a prescribed area, where each pass has temporal time sampling information. Adaptive scan-control architecture and dynamic pitch reconstruction improves temporal sampling and extends Z coverage enabling dynamic studies. A repetitive helical scan mode allows the table to move continuously back and forth across a prescribed area where each pass has temporal time sampling information. The resulting acquisition can be used to create time resolved studies such as CT Angiography (CTA) of head, neck, and body and perfusion studies. Z-coverage is extended for dynamic (4D) CTA and perfusion studies up to 312.5mm (500 slices) and 140mm, respectively.

The Volume Helical Shuttle feature utilizes dynamic helical pitch reconstruction for good helical image quality during the acceleration and deceleration of the table as shown in Figure 11-14. The Volume Helical Shuttle feature enhances the Volume (Axial) Shuttle feature to provide a further increase in the achievable dynamic system coverage.

Table 11-21

Application	Coverage	Scan Mode
Angiography	Time per pass times number of passes in 60 seconds (s) or less	0.984:1 pitch 0.4 sec. (s) Rotation time
Body Perfusion	140 mm	1.375:1 pitch 0.4 sec. (s) Rotation time

Figure 11-14 Volume Helical Shuttle Illustration

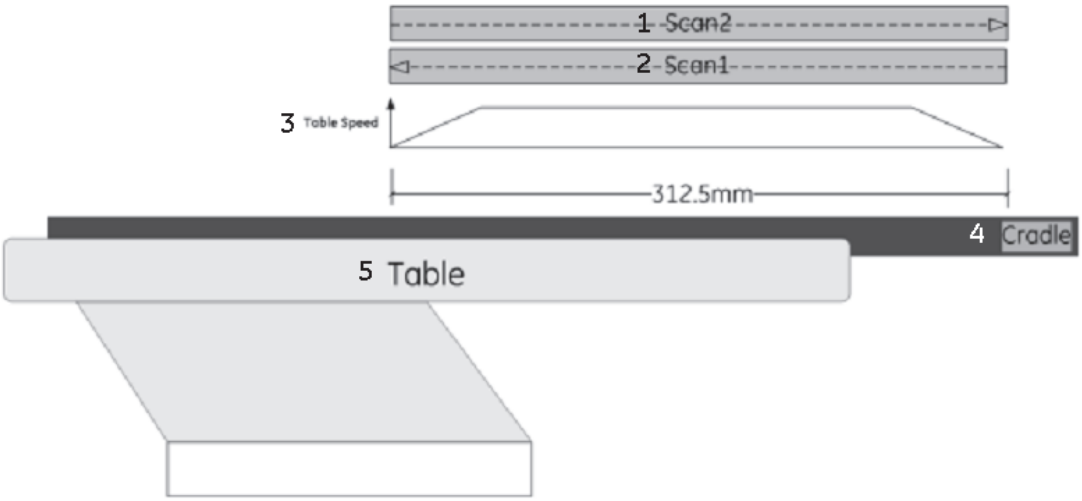


Table 11-22 Volume Helical Shuttle

Number	Description
1	Scan2
2	Scan1
3	Table Speed
4	Cradle
5	Table

Cardiac Overview

Cardiac helical is a lower pitch helical scan is available for cardiac applications in conjunction with the CardIQ SnapShot option. In this scanning mode, heart rate monitoring is performed during the helical acquisition and the associated EKG gating information is stored with the scan data such that a cardiac gated SnapShot reconstruction algorithm can be applied for prospective and retrospective images. SnapShot reconstruction is used to minimize the motion of the heart in the resultant images. The pitch factor for the cardiac helical scan is determined by the system and is a function of the patient heart rate.

Cardiac Helical imaging features include:

- All kV and mA stations available, dependent on generator and tube limitations.
- 60 second (s) maximum cardiac helical scan time.

- Rotation Speeds: 0.35, 0.375, 0.4, 0.425, 0.45, 0.475 and 0.5 seconds (s).
  - 0.35 second or 0.35 second for cardiac option enables 0.35, 0.375, 0.4, 0.425, 0.45, 0.475 and 0.5 seconds (s).
  - 0.4 second option enables 0.4, 0.425, 0.45, 0.475 and 0.5 seconds (s).
  - 0.5 second option enables 0.5 seconds (s).

NOTE: For the 0.35 second and 0.35 second for cardiac option licensed: 0.35 second/0.35 second for cardiac is licensed for use with a GE x-ray tube. Use of third party x-ray tube will require the purchase of an additional license for this feature.

- Pitches: determined by system, ranging from .16 - .325, based on patient heart rate. A higher heart rate will use a higher pitch factor.
- Variable image thickness of:
  - 0.625, 1.25 and 2.50 mm for 40 mm detector coverage for 64 slice configuration.
  - 1.25 and 2.5 mm for 40mm detector coverage, 0.625, 1.25 and 2.50 mm for 20 mm detector coverage for 32 slice configration.
- SnapShot Segment, Segment Plus, Burst, Burst Plus, and Segmented (non-gated) reconstruction options.
- Cardiac phase location parameter of 0 to 99% of R-to-R cycle.

Once the cardiac helical data has been collected, it can be reconstructed at one or more arbitrary heart cycle phase locations. Segmented reconstruction is also available retrospectively if non-gated images are desired.

Cardiac Cine acquisition for cardiac imaging is available in conjunction with SnapShot Pulse and prospective cardiac gating. In this step and shot cine scanning mode, the heart rate is monitored during the scan and the R-peak triggers the acquisition of data for that location. The table moves to the next location and waits for the next R-peak to trigger acquisition of data for the phase specified. SnapShot Pulse is a lower dose mode compared to cardiac helical modes. A padding value allows for flexibility of neighboring phase locations to accommodate small fluctuations in heart rate (a few BPM or less). However, a stable heart rate of 65BPM or less is recommended for SnapShot Pulse.

Cardiac Cine imaging features include:

- All kV and mA stations available, dependent on generator and tube limitations.
- Rotation speeds 0.35* seconds (s).
  - * available if the 0.35 second or 0.35 second for cardiac option is installed.
- Image thickness of 0.625 mm.
- Retrospective gated cardiac volumes are limited to common phases across all cine locations in the acquisition.

NOTE: Cardiac Cine imaging and 0.35sec scan are licensed for use with a GE x-ray tube. Use of third party x-ray tube will require the purchase of an additional license for this feature.

System Image Quality Features

Calibration Scans

- Tube Warmup
  - Tube Warmup is used to ready the X-ray tube for patient scanning or calibration.
- Air calibration
  - Air calibration is one of the most important calibrations in CT. A periodic air calibration for the CT scanner is required and it has to be done daily. This calibration is called Fast Calibration. Fast Calibration can be accessed from the Daily Prep menu.
- Detailed and Spectral calibration
  - Detailed and spectral calibration is performed during periodic maintenance of the system. It is not required to be run by the user as the scanner components are stable and the calibration will not need frequent updates.
- Water Cal
  - Water calibration or CT Number Adjustment is used to adjust the HU of water to 0. This calibration is also not required to be performed periodically by the user.

Scan and Recon Prescription User Interface (UIF)

All scan and recon options are clearly explained to the user.

Axial scan prescription describes various detector configuration, scan speeds, etc. Axial recon prescription describe various recon slice thickness combinations and how these are restricted by scan parameters.

Revolution™ EVO helical scan and recon prescriptions are more challenging than axial. Revolution™ EVO helical scanning will be: 64 = 64 detector macro rows x 4 pitches. Once the scan data is collected, the Revolution™ EVO recon algorithms support image reconstruction at image thickness of the detector macro-cell size. Therefore, image slice thickness is now a recon parameter and not a scan parameter. Desired image thickness must be taken into account during scan parameter selection.

X-Ray Tube Capacity Affects Prescriptions and Interscan Delays

The system provides prescription alternatives when:

- Current prescription requires excessive prep, interscan, or intergroup delay.
- Technique requirements exceed the prescribed delays.

Although the rotating anode increases the tube's heat tolerance, it still has a physical limit. The anode transfers its heat to the oil filled tube housing. The housing, in turn, dissipates heat into the surrounding air.

The system keeps a running total of estimated tube heat. When you request scans during Scan Prescription, the system estimates the number of heat units these scans will produce, and compares this value with the running total.

If the prescription estimate exceeds the current capacity, the system displays a series of prescription Optimize screens that recommend increased delays, alternative Scan Technic settings, or offer to split the current scan group into smaller groups.

Focal Spot

The X-Ray tube contains a small filament and a large filament. The small filament concentrates the focal spot size, which improves spatial resolution but cannot tolerate high technique. The large filament tolerates high technique but loses some of the small filament's spatial resolution.

The system automatically selects the focal spot size based on:

- power (kw)

Example: Reduce mA setting from 10mA to 200mA (120kV) to enable Small Filament.

Focal Spot Selection

On CT systems, the focal spot selection effects the slice thickness for thin slices scanning, with a larger filament producing a slightly larger effective slice thickness.

Focal Spot Selection Table

In order to provide the best image quality, and maximize patient throughput, the Revolution™ EVO system bases the automatic filament selection upon the following table:

Table 11-23 Focal Spot Selection

	Performix 40 Plus Tube	
	Small Filament All Algorithms	**Large Filament All Algorithms**
80 kV	10 to 300 mA	> 300 mA
100 kV	10 to 240 mA	> 240 mA
120 kV	10 to 200 mA	> 200 mA
140 kV	10 to 170 mA	> 170 mA

Scan Control

Confirm Rx to X-Rays on: < 40 seconds (s) for any state of tube

Data Collection

The detector and DAS assembly mounts opposite the X-Ray tube on the rotating base. The X-Ray beam leaves the X-Ray tube, passes through the gantry opening, and enters the detector. Any material (patient or phantom) positioned within the gantry opening absorbs or deflects the weaker X-Ray photons. The numbers of photons that enter the detector depends upon the intensity of the X-Ray beam and the density of the material in the gantry opening. An increase in density causes a decrease in the number of photons that enter the detector.

The Revolutionary new Revolution™ EVO detector allows 64 rows of data to be collected at a time for both axial and helical imaging. This allows 64 axial images to be generated in a single gantry rotation in the axial mode. This allows helical images to be taken at faster speeds, and with lower power, than single slice scanners.

The DAS measures the detected X-Ray at regular time intervals, called views, and transmits the information to the image reconstructor for reconstruction into a display image. The total degrees of gantry rotation and the scan time determine the number of raw views per image.

For scans greater than 1 second (s), the raw views are summed together before image reconstruction. This allows the system to maintain constant image reconstruction times and spatial resolution/aliasing for all scan speeds. (Note that image reconstruction of more raw views reduces aliasing at the expense of reconstruction time.)

Example: A 1-second (s) and a 2-second (s) scan both gather data over 360 degrees (°), so both scans reconstruct the same number of views per image. A segmented reconstruction uses data acquired over 235 degrees (°), so it reconstructs fewer views per image.

Table 11-24 Scan Parameters

Scan Choice	Determines:
kV	X-Ray energy intensity and calibration data used
mA	X-Ray dose
Scan Time and Interscan Delay	Length of scan rotation in seconds (s); length of delay in seconds (s) between exposures
Scan Rotation (normal scan, partial scan)	Degrees of scan rotation during data collection (X-Ray on)
Gantry Tilt	Angle X-Ray travels through patient
Spacing	Z-Axis distance between scan centers
Thickness	Width of image
Azimuth	X-Ray tube location during scout scan
SFOV — Scan Field of View	Centimeters of data available, and any special processing applied or available, for image reconstruction.

Reconstruction

This reconstruction description includes only “Filtered Back Projection” algorithm. Other “overlapped recon”, “ASiR-V”, etc. are described in the following sections.

The scanner compares the collected data with the calibration data then converts the detector channel views into a two dimensional matrix. The system converts each matrix element (pixel) into a CT number. Axial image will be displayed after reconstruction is completed.

64slice config:

Conjugate Cone-Beam Back Projection utilized two sets of counter-opposed projections to provide 128 distinct projection measurements per rotation for axial and a helical acquisition mode to significantly improve z-resolution and provide up to 128 reconstructed slices for one rotation.
The overlapped reconstruction feature enables 128 slices per rotation in Axial scanning modes and delivers improved Z-axis visualization performance relative to non-overlapped reconstruction.

32slice config:

Conjugate Cone-Beam Back Projection utilized two sets of counter-opposed projections to provide 64 distinct projection measurements per rotation for axial and a helical acquisition mode to significantly improve z-resolution and provide up to 64 reconstructed slices for one rotation.
The overlapped reconstruction feature enables 64 slices per rotation in Axial scanning modes and delivers improved Z-axis visualization performance relative to non-overlapped reconstruction.

Your choices control the image outcome. Choose parameters to enhance or tailor the acquisition and processing to the anatomy of interest. Select scan technique and image parameters that provide optimum resolution.

Reconstruction Algorithms: Standard, Standard#, Soft, Soft#, Detail, Chest, Bone, Bone Plus, Lung, Ultra, Edge and Edge Plus.

Reconstruction Matrix: 512 x 512

Display FOV: Variable center/off-center, prospective/retrospective target selection.

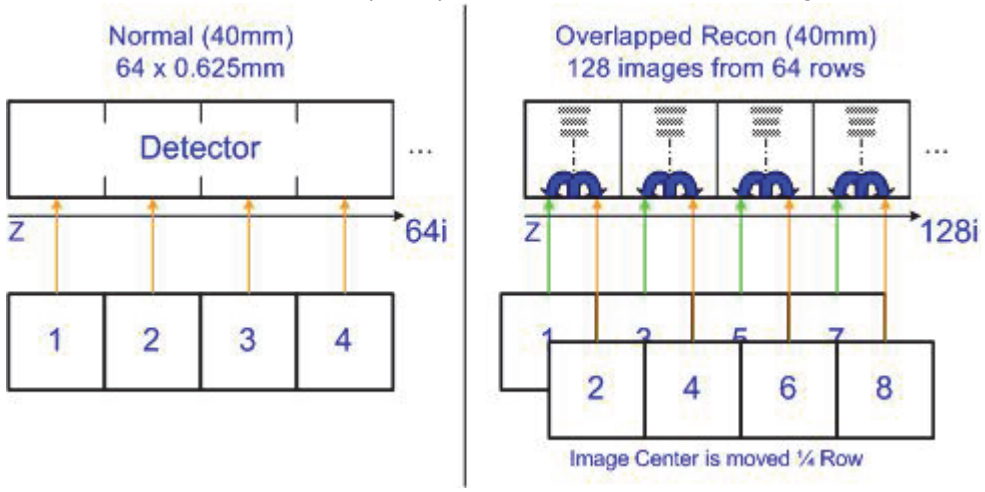
Minumum DFOV: 5.0 cm

5805441-1EN Rev. 2 (Sep. 2020)

Overlapped Recon (Axial)

Overlapped Recon (Axial) generates 128 images per rotation from a 40mm acquisition and 64 images per rotation from a 20mm acquisition. This reconstruction mode is only available for 40mm or 20mm Axial scan type. Image thickness remains the same but the image interval is 50 % of the image thickness and the image location moves ¼ row outward. This reconstruction mode is only available in Retro Recon.

Figure 11-15 Overlapped Recon (Axial) for 40mm Detector Coverage



SmartView

- Rotation speed: 0.5, 0.8 and 1.0 sec.
- Slice shickness: Single: 2.5mm, 5mm, 10mm, Triple: 1.25mm, 2.5mm, 5.0mm
- Nominal image lag: 0.2sec
- Recon: 12 flame per sec for single images, 24 flame per second (s) of three-image display

Image Check

Image check function provides 340x340 matrix images for confirming Axial images with real time and tracking to up to maximum scanable length with real time. Reconstruction time is as follows.

- FPS = Up to 55 fps --- Helical
- TTFI (Time To First Image) = Up to 2 sec after X-ray on
- TTLI (Time To Last Image) - Scan_duration = Up to 1sec at maximum helical scan range
- Reconstruction matrix = 340 x 340

NOTE: Specifications of FPS, TTFI, and TTLI are not compatible and limited to the specific conditions of operation such as rotation speed and helical pitch.

Preferred Viewing Orientation: Images may be reconstructed flipped right/left, top/bottom, or right/left/top/bottom for anatomical viewing.

The system has disk space for 3,520 scan rotations at 32 or 64 slice mode. The system stores the most recent scan data in the oldest scan file with an unreserved status. The system continually overwrites the scan files with data.

CAUTION: **If you plan to reconstruct images, you must use files that reside in the disk. Either reserve the scan files you plan to retrospectively reconstruct, or reconstruct unsaved scan files before the system overwrites the files with new scan data. The system refuses to overwrite reserved scan files. Remember to release the reserved scan files when you finish retrospective reconstruction.**

Adaptive Statistical Iterative Reconstruction-V (ASiR-V)

NOTE: ASiR™-V is licensed for use with a GE x-ray tube. Use of third party x-ray tube will require the purchase of an additional license for this feature.

ASiR™-V is a reconstruction technique that enables reduction in image noise (standard deviation), streak artifact at low signal condition and improvement in LCD (Low Contrast Detectability), while preserving the structure details in the image. ASiR™-V may be used to reduce the image noise (standard deviation) and streak artifact in diagnostic images and thereby reduce the dose required for routine imaging.

The scanner allows the user to select levels of ASiR™-V setting in 10 % increments. These "levels" provide a varying degree of noise removal from the images.

Adaptive Statistical Iterative Reconstruction (ASiR)

NOTE: ASiR is licensed for use with a GE x-ray tube. Use of third party x-ray tube will require the purchase of an additional license for this feature.

Adaptive Statistical Iterative Reconstruction (ASiR) is a new reconstruction technique that enables reduction in image noise and improvement in image quality. ASiR can be used to reduce the image noise in diagnostic images and thereby reduce the dose required for routine imaging.

The scanner allows the user to select levels of ASiR settings in 10% increments. These “levels” provide a varying degree of noise removal from the images.

Helical Scan Data Usage

In general, every data channel will contribute to at least one image during helical image reconstruction. Some data channels are not used at the very beginning and end of the helical scan due to to the physics of multi-slice scanning and helical view weighting algorithms.

During helical image reconstruction, some data channels in the middle of the helical scan are not used if the image interval prescribed is GREATER THAN the image reconstruction slice thickness.

For example, all data channels will be used for 0.6mm images, 0.5 pitch, if the image interval is less than or equal to 0.3 mm.

Calibration Scans

Calibrations scans of air, and uniform objects called phantoms, provide the baseline information the system needs to produce patient images. The system needs calibration data for every possible combination of kV, detector row thickness, focal spot size, and scan field of view.

The Revolution™ EVO “Fast Calibration” is calculated to reduce calibration time by 33 %, compared to prior GE technology.

Warm-up Required

If Tube Warm-up is skipped or cancelled, the mA will be limited to 440 mA for 120 kV and 380 mA for 140 kV for the first exam.

A Warm-up of the tube is required:

- Immediately before Calibration.
- When the tube has cooled to the point that a warm-up is required to ensure optimal image quality.

Data Storage

2,100 GB Disk (system, image, scan disks) stores up to 460,000 512^2 images and 3,520 scan rotations at 32 or 64 slice mode or up to 1,500 scan data files, or up to 300 exams.

Despite storage space, the system eventually runs out of disk space. If your facility plans to preserve image data, you must periodically transfer images and scan information to the designated archive media.

DVD (9.4 GB) stores up to 7,168 images.

Image Display

Requested images pass through the IP (image processor) on their way to the LCD screen. The Image Processor uses a bulk memory to store images selected for Auto View, MID, paging, magnification, rotation, reformat or 3D (3D optional).

The images appear on the image monitor or LCD. The LCD screen contains a display matrix of 1024 x 1024 picture elements, or 1,048,576 pixels. The 1024 display can be further divided into viewports. The number of viewports displayed determine the number of pixels within a viewport. Each pixel displays one of the 256 available shades of gray.

The Revolution™ EVO system reconstructs axial and continuous images of 512^2 pixels. Images from other scanners may display 128, 320, or 1024 pixel image matrices.

The amount of anatomy represented by each pixel equals the Display Field of View diameter in mm divided by the matrix width/height.

The system assigns a unique CT number value, originally called a Hounsfield Unit, to each pixel. The two dimensional pixel represents a three dimensional portion of patient tissue. The pixel value represents the proportional amount of X-Ray beam that passed through anatomy and entered the detector.

Gray Scale

The monitor translates the computed pixel value into a shade of gray. Your window Width and Level choices control which range of CT values receive emphasis. The window Width assigns the quantity of pixel values to the gray scale. The window Level determines the center pixel value in the gray scale.

Figure 11-16 Gray Scale

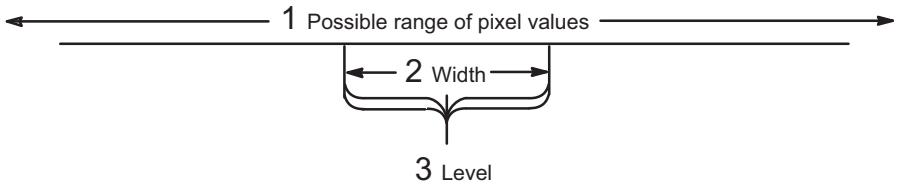


Table 11-25 Gray Scale

Number	Description
1	Possible range of pixel values
2	Width
3	Level

- Window Width = selected range of pixel values
- Window Level = middle value

5805441-1EN Rev. 2 (Sep. 2020)

The system displays every pixel value that falls outside the gray scale as either black or white. It assigns a gray value to every pixel that falls within the selected window. IF enabled, the filmed image displays a gray scale icon along the left border of the image.

The system displays the currently selected window Width and window Level along the bottom of the screen: W = xxxxx and L = xxxxx. To determine the pixel values currently represented by the gray scale: Divide the window Width by 2; add and subtract this number to/from the window Level.

Example: W=320; L= -1500; 320 / 2 = 160
-1500 + 160 = -1340; -1500 - 160 = -1660
The gray scale represents values from -1340 to -1660

To find the best gray scale for an image, decrease the window width to 2. Increase or decrease levels until the tissue of interest turns gray. Now increase the window width until it includes the rest of the image.

CT Number

Image reconstruction supports two ranges of pixel CT numbers, the Normal Range and an Extended Range.

- Normal Range is -1024 to 3071.
- Extended Range is -31743 to 31743.

NOTE: The display application supports pixels with the range of -32767 to 32767.

The system references CT number zero to water and CT number -1000 to Air. Lung and fat have negative pixel values and normally appear black. A CT number over 200 represents dense material like contrast agent, calcium, bone, and normally appears white.

Inverse Video reverses video white to black, but pixel values remain the same.

CAUTION: **CT Numbers are NOT absolute; misdiagnosis is possible. System and patient variables may effect CT Number accuracy. If you rely solely upon CT numbers without taking the following variables into consideration you could misdiagnosis an image.**

The following variables effect CT Number accuracy:

- Partial volume effects of anatomy
- Scans acquired with IV or oral contrast agents
- X-Ray tube deterioration
- Improperly calibrated system (poorly centered phantom, used wrong phantom, replaced current calibration files with extremely old Cal files)
- Beam hardening due to patient anatomy, especially bone.

- Metal Artifacts: In case of images including metal artifacts, check the CT number degradation at metal artifacts and its peripheral area of continuos images to avoid misdiagnosis.

To reduce CT Number variations:

- Warm-up the X-Ray tube whenever the system recommends it; make sure the tube design matches the software configuration parameters
- Center the patient anatomy of interest in the gantry opening. Select an SFOV that encompasses the patient.
- Acquire comparable images with similar scan and reconstruction choices.
- Maintain consistent table height throughout the exam.
- Test image quality on a regular basis to provide the numerical data to track system performance over time.

To decrease the potential for misdiagnosis:

- Use ROI to compare pathology to surrounding tissue
- Scan structures with slice thicknesses about one-half the thickness of the lesion or less.

Example: Prescribe scan thickness of 5mm or less to scan a Lesion with a 10mm thickness. (Display an axial image and use the Measure Distance and ROI functions to determine the size of the pathology.

Center ROI measurements over the midpoint of the pathology to minimize partial volume effects.

Variables You Cannot Control

The mixture of tissue types, such as fat with tissue within the same voxel (a pixel with depth), varying patient sizes, differences between CT machines and X-Ray tubes, all lead to CT number variance. In a well calibrated scanner, water has a CT number that ranges from -3 to +3. The CT number remains uniform across all kV settings. However, as the X-Ray tube ages, kV decreases and pixel values become less dependable.

Pixels

The anatomic image consists of rows and columns of small, square, picture elements called pixels. The monitor screen displays 1,048,576 pixels in a matrix of 1024 horizontal rows of 1024 pixels. Add number of viewports selected for viewing to determine the number of pixels used for display in each viewport. The monitor screen pixel size remains the same, but the amount of anatomy the pixels represent varies with the scan and display field of view (SFOV & DFOV). A pixel also represents a specific anatomic area. The system identifies each two dimensional pixel by its location, area and value.

5805441-1EN Rev. 2 (Sep. 2020)

Pixel Coordinates

Describe pixel location two ways.

- Matrix Coordinates: Upper left pixel = (0,0);
  lower right pixel = (511,511);
  pixel in center of matrix = (255,255);
  pixel ten columns to the right = (10,0)

Figure 11-17 Pixel Coordinates

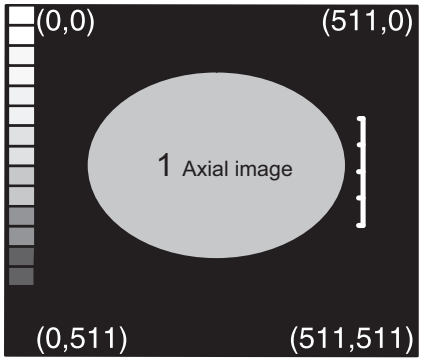


Table 11-26 Pixel Coordinates

Number	Description
1	Axial image

NOTE:

- The illustration above represents a 512 x 512 matrix viewport.
- RAS: Anatomic distance from the center of the landmark slice

Target the image; decrease the DFOV diameter. Center the reconstruction on coordinates other than the SFOV center.

Magnifying and targeting can displace the central SFOV pixel from the central monitor pixel. Look at the DFOV coordinates and magnification annotation to find the SFOV center, or display the grid. The grid always appears over the pixel in the center of the DFOV Matrix (coordinate 255,255).

RAS Coordinates

These three distances in millimeters appear on the upper left of the viewport on which the mouse cursor is on, when Continuous Report Cursor is selected.

- The pixel with the R/L and A/P coordinates closest to zero, represents the SFOV center. The S/I coordinate always equals the table location at isocenter.

- Coordinates transition from R to L, A to P, and S to I, to show relationships between current location, landmark location, and isocenter.

Figure 11-18 RAS Coordinates

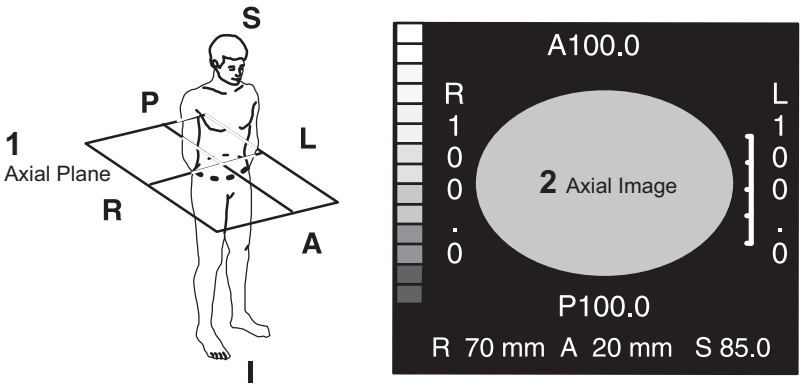


Table 11-27 RAS Coordinates

Number	Description
1	Axial plane
2	Axial image

Right:	Coordinate location falls to the patient's right of the mid-sagittal plane (right of isocenter)
Left:	Coordinate location falls to the patient's left of the mid-sagittal plane (left of isocenter)
Anterior	Coordinate location falls above the mid-coronal plane (above isocenter)
Posterior:	Coordinate location falls below the mid-coronal plane (below isocenter)
Inferior:	Scan location falls between the selected landmark and patient's feet
Superior:	Scan location falls between the selected landmark and patient's head

The DFOV and matrix determine pixel size.

5805441-1EN Rev. 2 (Sep. 2020)

A reconstructed pixel represents an area determined by dividing the Display FOV (in mm) by the reconstruction matrix, squared. You may magnify pixels up to eight times the reconstructed size, or minify them to one half size. The anatomic area represented by each monitor pixel decreases as the magnification factor increases; anatomic area/monitor pixel increases as the magnification factor decreases.

Pixel Size in millimeters	
DFOV in cm	**512 x 512**
5	0.10
10	0.20
15	0.29
20	0.39
22	0.43
25	0.49
30	0.59
35	0.68
40	0.78
45	0.88
50	0.98

The DFOV determines the anatomic area imaged by a single reconstruction.

- Area equals πr^2 (Area =3.14 x radius x radius)
- The 50cm FOV has a 25cm radius, so its area equals 1963cm^2.
- The ROI or magnification factor determines the anatomic area covered by a magnified image.

Example: A monitor pixel represents 0.5 by 0.5mm. Magnify pixel size by 2. Each monitor pixel now represents 0.25 by 0.25mm of anatomy.

Figure 11-19 Pixel size equals DFOV P matrix size

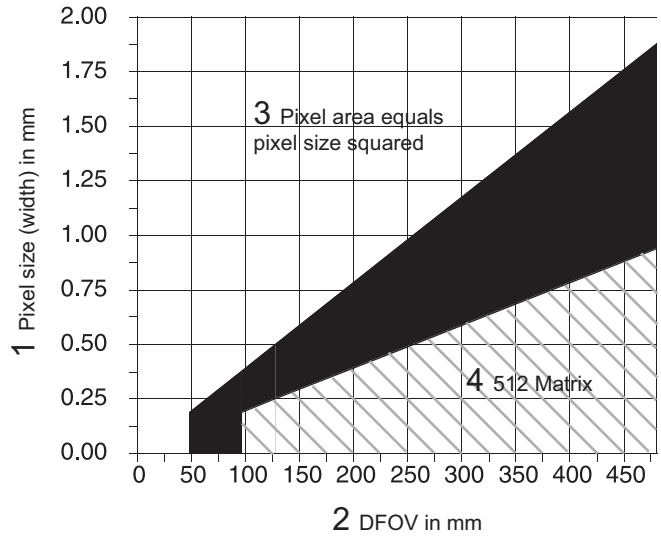


Table 11-28 Pixel size equals DFOV P matrix size

Number	Description
1	Pixel size (width) in mm
2	DFOV in mm
3	Pixel area equals pixel size squared
4	512 Matrix

Pixels and CT Numbers

Besides anatomic location and area, each CT pixel also represents a CT number, which in turn indicates tissue density.

- An ROI averages the values of the enclosed pixels, and displays the resulting **Mean** value.
- **Standard Deviation** describes the difference between the minimum and maximum ROI value.
- A large ROI provides a larger, more accurate statistical sample than a small ROI.

An image pixel represents a three dimensional volume, or voxel. It represents anatomy with a location, an area, and a pixel (density) value. The system flattens the 0.625, 1.25, 2.5, 3.75, 5, 7.5, 10 mm scan thickness into a two dimensional screen image. If a pixel represents a variety of tissues, the system averages the contents to produce an averaged, rather than accurate, pixel value. Uniform tissues (within the voxel) produce fairly accurate pixel values.

CT pixel shading shows relative density. Denser materials weaken X-Ray and produce whiter pixels. (Assumes Inverse Video OFF)

MR pixel shading reflects relative physiology. Whiter pixels represent molecules that relaxed earlier after magnetic alignment than the darker areas.

Reformat displays non axial planes created from contiguous pixels extracted from multiple images. 3D locates similar pixel values within contiguous images, and generates a mathematical model to produce images that appear three dimensional. BMD samples pixel values to estimate bone or tissue density.

Reconstruction assigns one value to every image pixel. CT uses pixel values of -32,767 to +32,767. If Extended HU is turned off, then pix values are limited between 3,071 HU and -1,024 HU. MR uses pixel values of +16,000. The screen pixel translates the assigned value into one of the 256 shades of gray. Vary the gray scale window width and level to select anatomy for display. Window Width determines the quantity of gray pixel values. Window Level selects the center Window Width pixel value.

Example: Two windows may contain identical widths of 100 values, but display completely different anatomy, because one has a level of -100 and the other has a level of 150

Window Width

The system uses 256 gray shades to display 63,486 CT pixel values. The Window Width selection determines the number of CT values represented by each shade of gray. A narrow window assigns fewer pixels to each gray level than a wide window.

Example: WW = 256 System assigns one pixel value to each gray shade WW = 2560 System assigns ten pixel values to each gray shade.

Window Level

The Level equals the CT number value of pixel in the center of the Window Width range. The Level value receives the middle shade of gray. The system displays pixel values that fall between the center and upper window level as gray to off white. It displays pixel values that fall between the center and lower window values as gray to charcoal. When you change the level, the window width moves up and down the CT number line. The CT values change with Window Level, but the Window Width and number of pixels per gray level don't change.

Inverse Video reverses display conventions. Dense or high numbers are portrayed as black rather than white.

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 12
Quality Assurance

Introduction (Reference: IEC60601-1-3:2008 Clause6.4)

In order to assure consistent image quality over the system's lifetime, establish and maintain a regular Quality Assurance (QA) program.

Constancy testing of the system should be performed in accordance with IEC 61223-2-6 or per your facility's specific QA program.

Scan a known material (usually a phantom) under a prescribed set of conditions.

- Compare the results to previous or optimum values.
- Repeat these tests on a regular basis to detect changes in image quality values before the problem becomes visible.
  - If you notice a degradation in image quality, or a change in QA values, you can schedule a site visit and let the service person or imaging physicist run more detailed tests.
  - Early intervention could prevent a major breakdown.

Quality Assurance begins with baseline performance data acquired during system installation, or after the repair or replacement of an X-Ray tube, collimator, detector, DAS, or PDU circuitry.

- Compare subsequent QA results against the baseline.
- You can save baseline images for a visual comparison with your daily QA checks, but the measurement values provide a more objective way to monitor quality.

NOTE: Copy the QA Data Form found at the end of this section. Use the form to record baseline data and subsequent QA data.

QA Phantom (Reference 21CFR 1020.33 (d)(1))

21CFR 1020.33 (d)(1) requires a phantom for Quality Assurance that is capable of providing an indication of contrast scale, noise, nominal tomographic section thickness, the spatial resolution capability of the system for low and high contrast objects, and measuring the mean CT number of water or a reference material.

Use the Quality Assurance Phantom to assess system performance and establish an ongoing Quality Assurance program.

The phantom design provides maximum performance information with minimum effort.

Before beginning the QA process, please record the serial number of the QA phantom on the QA data form provided.

This phantom measures six aspects of image quality.

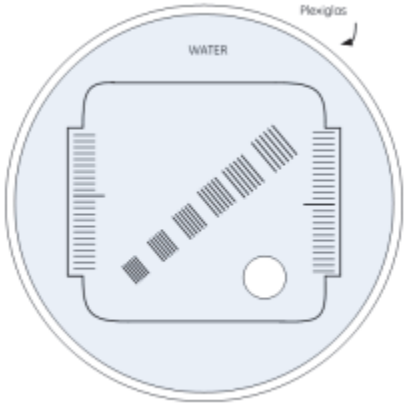
- Contrast Scale
- High Contrast Spatial Resolution
- Low Contrast Detectability
- Noise and Uniformity
- Slice Thickness
- Laser Light Accuracy

The QA phantom contains two sections, each corresponding to a single scan plane.

- **Section 1:** Resolution block S0 mm scan location.
- **Section 2:** Water section is between S40 - S80 mm scan locations.

The following illustration contains a list of the sections and corresponding tests.

Figure 12-1 QA Phantom

	**Section 1** • High Contrast Resolution • Contrast Scale • Slice Thickness • Laser Accuracy Location: S0 mm

5805441-1EN Rev. 2 (Sep. 2020)

	**Section 2** • Noise and Uniformity • Low Contrast Detectability Location: S80 mm (Any location between S40 to S80 mm)

QA Schedule (Reference 21CFR 1020.33 (d)(2))

Each facility determines QA and phantom calibration schedule.

GE recommends that you acquire scans of both Sections 1 and 2 of the QA Phantom each day.

Create a Scan Protocol file for these QA scans.

Figure 12-2 QA Phantom Alignment

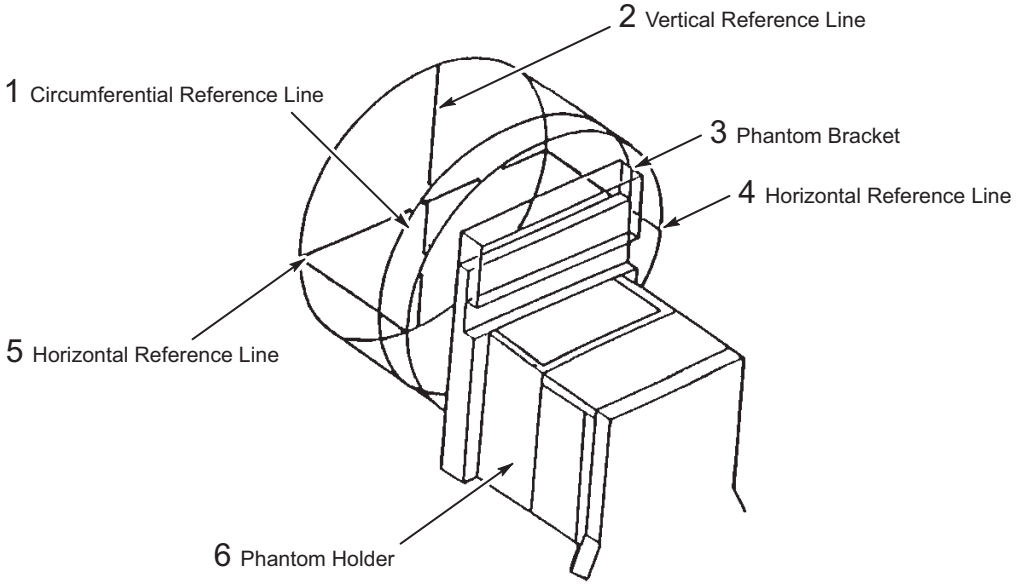


Table 12-1 QA Phantom Alignment

Number	Description
1	Circumferential Reference Line

Number	Description
2	Vertical Reference Line
3	Phantom Bracket
4	Horizontal Re ference Line
5	Horizontal Re ference Line
6	Phantom Holder
NOTE: Reference Lines are etched into the plastic and are unpainted.	

QA Water Phantom Positioning and Handling

It is important to highlight a few design aspects of the QA water phantom, and to offer advice on positioning and handling the QA phantom during QA activities.

1. Visually inspect the QA Water Phantom, and the Phantom Holder for damage before each use. If damaged do not use the broken piece. Have it replaced immediately.
2. The bracket on the phantom, used to support it on the phantom holder, is not a handle. The phantom should not be carried or held by the bracket. While transporting the QA phantom from point to point, the user should carry it securely with both hands to avoid dropping it. A dropped phantom can potentially cause injury.
3. The fit of the bracket onto the phantom holder is meant to be snug. This minimizes motion during scanning which could lead to false failures in the QA images. This snug fit requires the user to take care when positioning or removing the phantom from the QA Phantom holder.
4. When positioning or removing the phantom from the holder, the patient cradle should be moved fully out of the gantry to Home position and lowered far enough so the user can lift the QA phantom straight up off the holder. If the table is not moved to this position, and the user reaches into the bore to adjust the phantom, this can put stress on the bracket causing it to break.
5. If the QA phantom is broken, cracked or is leaking, it should immediately be discarded and replaced with a new QA phantom. Care should be taken to avoid any sharp edges which may develop on the broken pieces, and potentially cause injury. If the phantom is leaking water onto the floor there is a potential slip and fall hazard. If the phantom is leaking while on or near the scanner there is a potential for water to get under table or gantry covers and cause damage.

5805441-1EN Rev. 2 (Sep. 2020)

System Performance (Reference 21CFR 1020.33 (d)(2))

This section outlines the instructions for use of the Quality Assurance Phantom, including a schedule of testing appropriate for the system, allowable variations for the indicated parameters, and a method to store as records, quality assurance data, in compliance with 21 CFR 1020.33 (d)(2).

Maintain Image Quality

Many factors affect Image Quality:

- Proper alignment of X-Ray tube, DAS, detector, and table
- KV and mA adjustments within specifications
- Current Calibration files
- Tube Warmup every time the system recommends it
- Daily Fastcals
- Appropriate pixel size, slice thickness, reconstruction algorithm, and special processing selections during Scan Rx
- Patient remains motionless during scan acquisition

At least three people must cooperate to produce optimum images:

- Service representative aligns the system and adjusts kV and mA
- Operator follows facility guidelines to maintain daily image quality, prescribe the exams, and update the calibration files
- Patient follows operator (and autovoice) instructions during exam

A QA program helps locate the source of image quality problems:

- Replaces patient with phantom
- Provides standard Scan Rx parameters
- Provides System Performance tests and comparisons

Position the QA Phantom

Place the QA phantom on the phantom holder, and level it.

Turn the knob facing the cradle clockwise to tilt the top of the phantom away from the gantry.

Use the laser alignment lights to position the phantom:

1. Align the axial light to the circumferential line marking Section 1.
2. Align the coronal light to the horizontal lines on either side of the phantom.
3. Align the sagittal light (where it strikes the top of the phantom) to the vertical line on the top of the phantom.
4. Position the phantom and select  .

Prescribe the QA Series for the Resolution, Low Contrastability, and Noise and Uniformity Tests (Reference 21CFR 1020.33(j)(2))

1. Click **[New Patient]** to display the Patient/Exam Parameters screen.
   - Use the same ID for all related QA tests so you can store the exams together.
2. Enter any additional information in the corresponding data field(s). (Optional)
3. Exam Description: Enter up to 22 characters to describe the test. (Recommended)
4. If available, select a QA protocol from the anatomical selector.

If your facility hasn't created a QA protocol, use the following parameters to finish the QA series prescription:

On the Helical ViewEdit screen select the following parameters:

Table 12-2 Parameters for QA

Interface	Input	
Entry	**Head First**	
Position	**Supine**	
Anatomical Reference	**QA**	
Scan Range	**I0 - S80**	
Thickness	**5mm**	
Detector Coverage	**40 mm** Aperture	
Recon Interval	**5mm**	
Tilt	**0** degrees (°)	
Scan FOV	**Small Body**	
kV	**120**	
mA	**135**	
Scan Type	**Helical**	
Rotation Speed	**1.0** second (s)	
Pitch	**0.516:1**	
Prescribe 3 scan recons		
	Algorithm, DFOV	**Test**
Recon 1 Scan Range: S0-S40	Standard, 25 cm DFOV	a) Contrast Scale b) High Contrast Resolution
Recon 2 Scan Range: S0-S40	Bone, 15.0 cm DFOV	b) High Contrast Resolution

5805441-1EN Rev. 2 (Sep. 2020)

Interface	Input	
Recon 3 Scan Range: S40-S80	Standard, 22.7 cm DFOV	c) Low Contrast Detectability d) Noise and Uniformity
Matrix	**512**	
Contrast	**None**	
Special Processing	**None**	

Analyze the QA Images

1. Display the first QA image, which is section #1 at scan location S0.
2. Copy the QA Data Form at the end of this section.
3. Record the data from the tests that follow in the corresponding area of the form.
4. Compare the current values to previously recorded values.
   - If you notice a significant change in values, check the Small SFOV calibration status.
5. Calibrate the Small SFOV if the most recent calibration date falls outside the guidelines established by your facility.
6. Report significant changes, or values that fall outside suggested windows, to your supervisor or imaging physicist.
7. Follow facility procedures to notify service personnel.
8. Perform the following:
   a) **Contrast Scale** test at scan location S0 of the helical scan.
   b) **High Contrast Spatial Resolution** test at scan location S0 of the helical scan.
   c) **Low Contrast Detectability** test at scan location S40 - S80 of the helical scan.
   d) **Noise and Uniformity** test at scan location S40 - S80 of the helical scan.
   e) **Slice Thickness** test at scan location S0 of the axial slice thickness scans.
   f) **Alignment Light Accuracy** test at scan location S0 of the Alignment Light test scan.

Contrast Scale

Section 1 of the Phantom Tests the Contrast Scale

CT assigns CT numbers, also called (HU) Hounsfield Units, to the attenuation values of X-Ray passing through a variety of material densities.

Software makes the attenuation visible by assigning shades of gray to groups of numbers selected with the Window Width/ Level functions during image Display.

For test purposes, the CT values of water and plexiglass in the phantom represent the standard against which you track the system contrast scale over time.

The test for contrast scale follows: (Reference 21CFR 1020.33(j)(2))

Figure 12-3 Contrast Scale Phantom Section

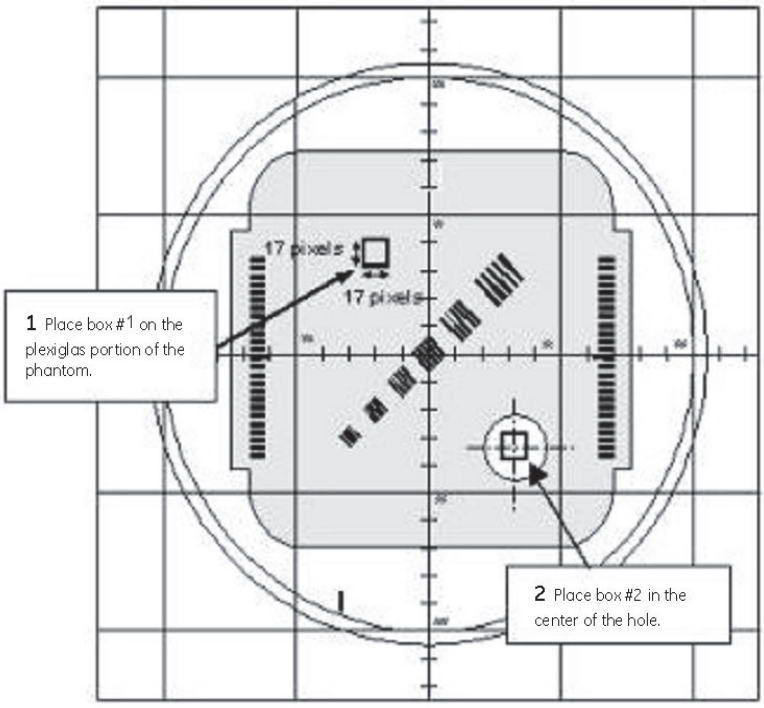


Table 12-3 Contrast Scale Phantom Section

Number	Description
1	Place box #1 on the plexiglas portion of the phantom
2	Place box #2 in the center of the hole

1. Select a **Box ROI** with an area around 70 mm^2 on the image, as shown in Figure 12-3.
2. For consistency, use the same size cursor and location each time you perform this test.
3. Select **Grid** to provide a reference.
4. Select **Box ROI** to position a cursor over the Plexiglass resolution block (refer to Box #1 in Figure 12-3).
5. Record the mean CT number on the QA Data Form.
6. **Optional:** Record the Standard deviation
7. Select **Box ROI** to position a cursor over water (see Box #2 in Figure 12-3).
8. Record the mean CT number for water on the QA Data form.
9. Optional: Record the Standard deviation

5805441-1EN Rev. 2 (Sep. 2020)

10. Subtract the CT number of water from the CT number of Plexiglass
    - Record the difference on the QA Data form.
    - The difference should equal 120 ± 12.

High Contrast Spatial Resolution

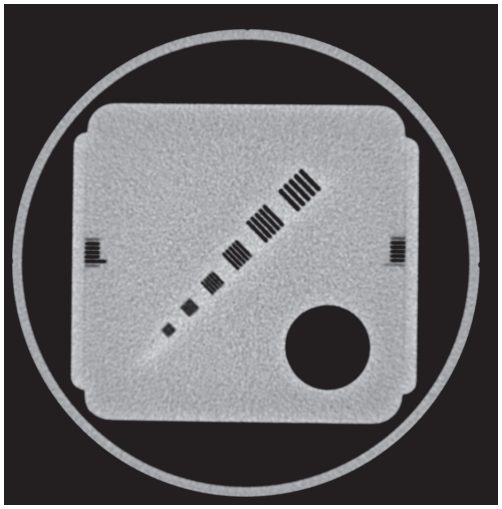
Figure 12-4 of the phantom contains six sets of bar patterns in a Plexiglass block used to test high contrast spatial resolution.

Each pattern consists of sets of equally sized bars and spaces.

Water fills the spaces and provides about 12% (120 HU) contrast.

The resolution block contains the following bar sizes: 1.6 mm, 1.3 mm, 1.0 mm, 0.8 mm, 0.6 mm and 0.5 mm.

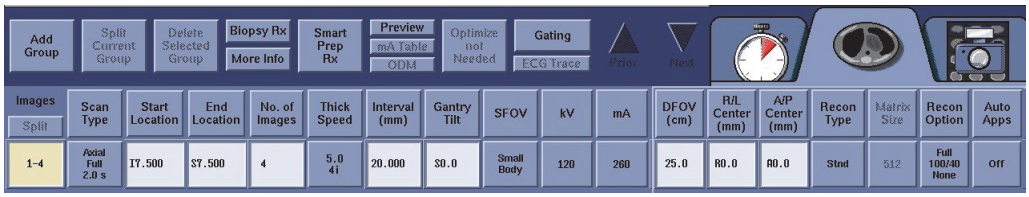
Figure 12-4



Phantom Scan procedure.

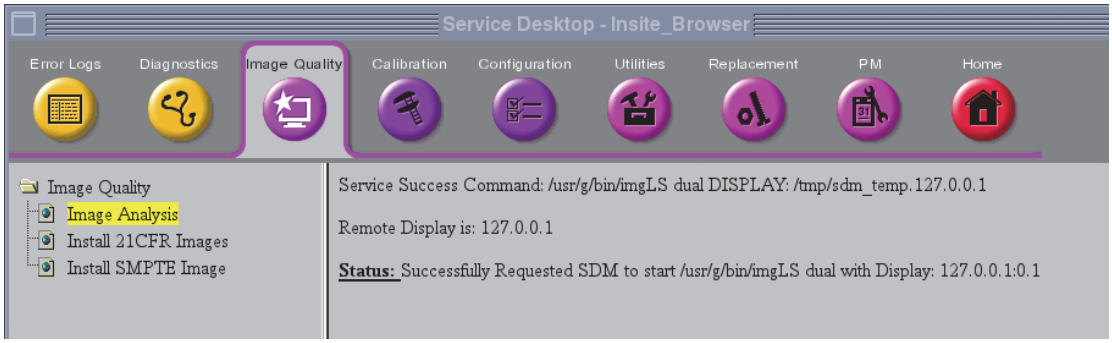
1. Align the axial light to the circumferential line.
2. Align the coronal light to the horizontal lines on either side of the phantom.
3. Align the sagittal light (where it strikes the top of the phantom) to the vertical line on the top of phantom.
4. Click [New Patient] to display the patient/Exam parameters screen.

5. Select the QA Scan Protocol. “Service” in Anatomical Selector, “MANUFACTURING”, Protocol# 45.7 – “ImgSer 20cmQA”
   If you need set each scan parameters, please follow the scan protocol below.

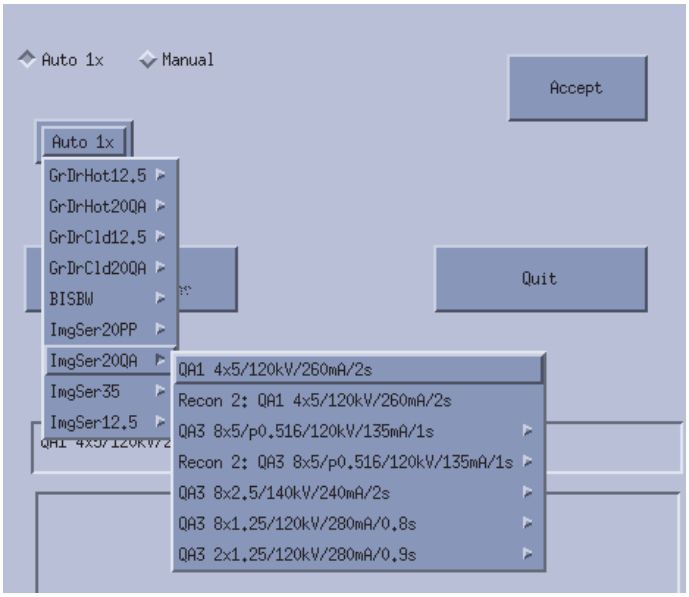


Measurement procedure.

1. Use “Image Analysis Tool” in Image Quality Tab, Service menu.

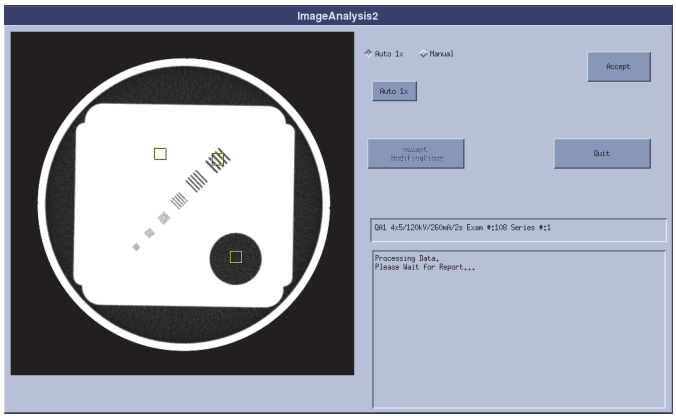


2. Select a phantom scanned image showing Six patterns.
3. Select “Auto 1x”, ImgSer20QA”, “QA1 4x5/120kV/260mA/2s”, and click “Accept”.

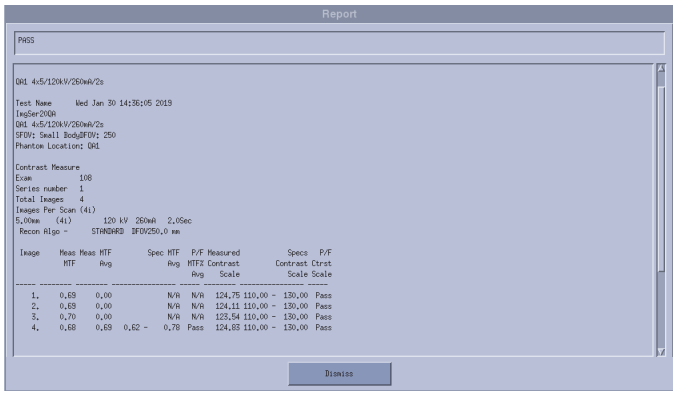


5805441-1EN Rev. 2 (Sep. 2020)

4. Measure High Contrast Spatial Resolution automatically.



5. Confirm measurement value. “Meas MTF Avg” will be within 0.62 to 0.78.



MTF (optional)

The **Modulation Transfer Function** (MTF) mathematically quantifies high contrast resolution.

MTF measures the contrast preserved for a sine wave pattern as a function of frequency.

An MTF curve begins at 1 for zero frequency, and decreases as frequency increases.

Example: An MTF of 1 equals total preservation of contrast

Example: An MTF of 0.5 equals 50% loss of contrast

The limiting resolution equals the frequency at which MTF falls to 0.

An MTF curve is shown in Figure 12-31.

Measure Frequency in line pairs per centimeter.

One line pair per centimeter equals one 5mm Plexiglass bar next to one water filled 5mm space.

Optional: Consult the publication listed as Reference 1 in section for MTF measurement instructions (Droege RT, Morin RL. "A Practical Method to Measure the MTF of CT Scanners," Medical Physics, Volume 9, No. 5, pp 758-760, 1982).

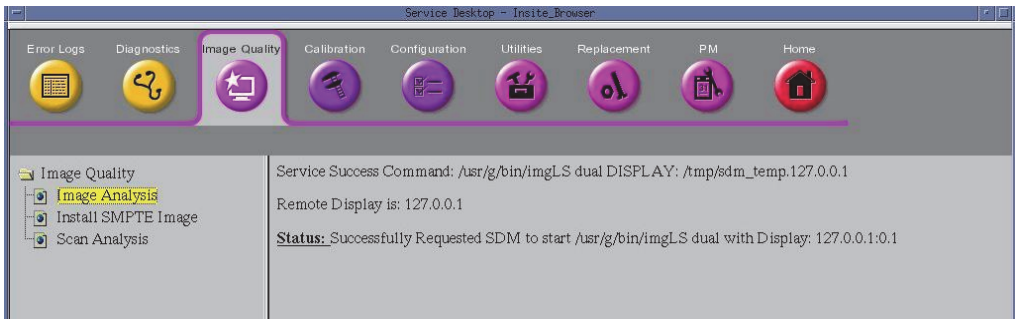
Low Contrast Detectability

Low Contrast Detectability (LCD) refers to the visibility of small objects at low contrast levels. In practical terms, it can be defined as the contrast required to resolve an object of a given diameter at a given dose. Traditionally, one would image a tissue-equivalent phantom containing small, low-contrast objects, and visually inspect the images. GE recommends a statistical method of quantifying LCD based upon the noise properties of a standard image. Since this method yields a quantitative measurement, as opposed to a visual verification, it is suitable for daily tracking of system image quality.

Procedure:

Scan the Quality Assurance Phantom using the Daily Image Quality protocol. Analyze the images from Recon 3, the water section (Locations S40 to S80), using the Image Analysis tool, which can be found on the Image Quality tab of the Service Desktop. See Figure 12-5.

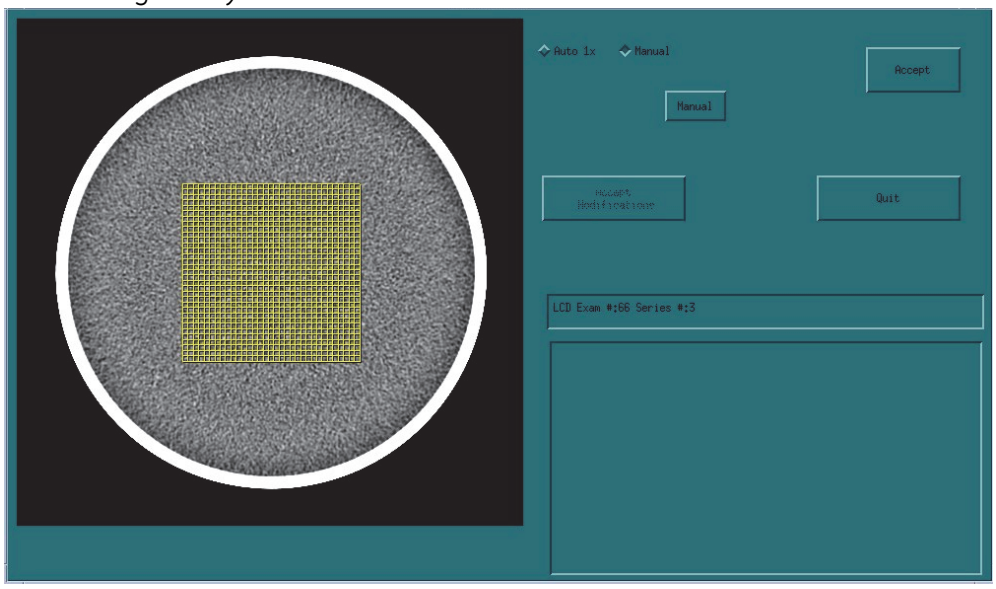
Figure 12-5 Image Quality Tab on the Service Desktop



Using the image list-select browser, highlight all the images to be analyzed. Select the Image Analysis tool, click the Manual radio button (not Auto 1x), and select LCD under the Manual tools menu. Click **[Accept]** to begin the analysis.

5805441-1EN Rev. 2 (Sep. 2020)

Figure 12-6 Image Analysis Tool

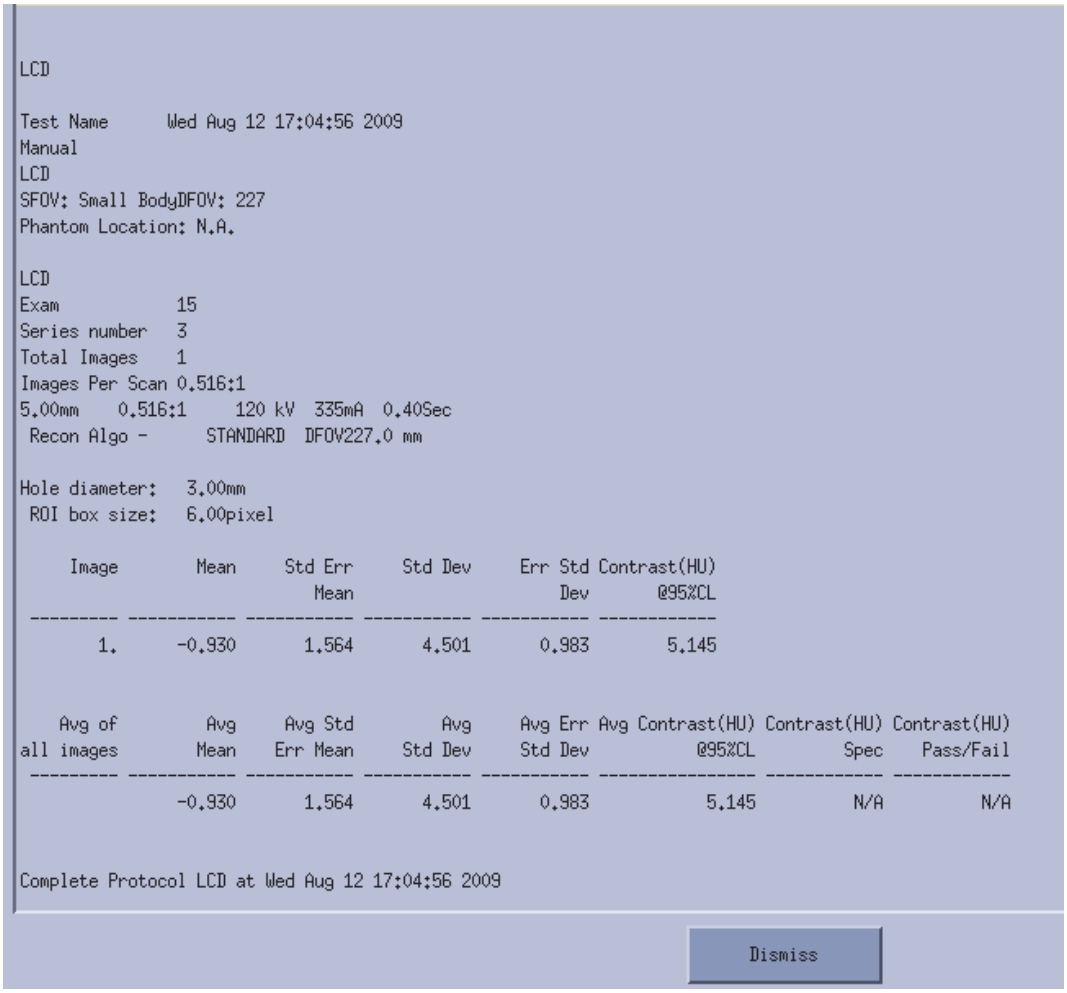


A dialog box will now open, allowing the selection of object size, in millimeters, for the analysis.

Figure 12-7 Dialog Box

Enter the value ***3.0*** and click **[OK]**. After a few seconds (s) of calculation, a report window will open, displaying the results:

Figure 12-8 Report



LCD

Test Name Wed Aug 12 17:04:56 2009
Manual
LCD
SFOV: Small BodyDFOV: 227
Phantom Location: N.A.

LCD
Exam 15
Series number 3
Total Images 1
Images Per Scan 0.516:1
5.00mm 0.516:1 120 kV 335mA 0.40Sec
Recon Algo - STANDARD DFOV227.0 mm

Hole diameter: 3.00mm
ROI box size: 6.00pixel

Image	Mean	Std Err Mean	Std Dev	Err Std Dev	Contrast(HU) @95%CL
1.	-0.930	1.564	4.501	0.983	5.145

Avg of all images	Avg Mean	Avg Std Err Mean	Avg Std Dev	Avg Err Std Dev	Avg Contrast(HU) @95%CL	Contrast(HU) Spec	Contrast(HU) Pass/Fail
	-0.930	1.564	4.501	0.983	5.145	N/A	N/A

Complete Protocol LCD at Wed Aug 12 17:04:56 2009

Dismiss

A 1 % contrast means that the mean CT number of the object differs from its background by 10 HU. Therefore, divide contrast in HU by 10 to convert to % contrast.

Record the “Contrast @ 95% CL" value from Figure 12-8 on the QA Data Form.

Noise and Uniformity (Reference 21CFR 1020.33 (j)(2))

Section 2 (Figure 12-9) of the phantom tests noise and uniformity. Use any scan location from S40 - S80 (Recon 3).

Noise limits low contrast resolution, and masks anatomy with similar structure to surrounding tissue.

QA phantom Section 2 (Recon 3) provides a uniform image by which to assess image CT number noise and uniformity.

Use the **Standard** algorithm to reconstruct the image.

5805441-1EN Rev. 2 (Sep. 2020)

Figure 12-9 Noise and Uniformity Section

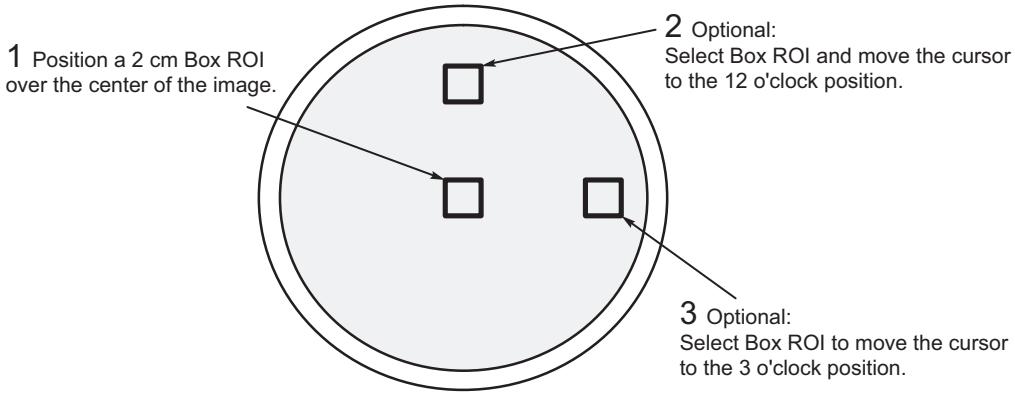


Table 12-4 Noise and Uniformity Section

Number	Description
1	Position a 2 cm Box ROI over the center of the image.
2	**Optional**: Select **Box ROI** and move the cursor to the 12 o'clock position.
3	**Optional**: Select **Box ROI** to move the cursor to the 3 o'clock position.

Image noise equals the standard deviation of CT numbers within a region of interest (ROI).

Noise results from electronic, mechanical, and mathematical differences in detected X-Ray energy, electronic outputs, and reconstruction algorithms.

Tube Warmups, up to date calibration files, and daily Fastcals minimize noise and help provide uniform images.

See Figure 12-9. (Reference 21CFR 1020.33(j)(2))

1. Select **Erase** to remove previous ROI data.
2. Select **Box ROI** to position a 2 cm Box ROI over the center of the image.
3. Record the mean CT number and standard deviation on the QA Data Form.
   - QA data form (Table) is at end of this section.
4. **Optional:** Select **Box ROI** and move the cursor to the 12 o'clock position.
5. Record the mean CT number and standard deviation on the QA Data Form.
6. **Optional:** Select **Box ROI** to move the cursor to the 3 o'clock position.

7. Record the mean CT number and standard deviation on the QA Data Form.
   - If the Image is reconstructed with Standard algorithm and Small SFOV, the Mean of Center ROI should equal 0 ± 3.
   - Standard deviation of the center ROI should equal 4.3 ± 0.6.
   - The uniformity difference between the center ROI and the average of the edge ROIs should be 0 ± 3.

Slice Thickness

Section 1 of the phantom also tests slice thickness.

Both sides of the resolution block contain a pattern of air filled holes designed to demonstrate slice thickness (see Figure 12-10).

Figure 12-10 Slice Thickness Section

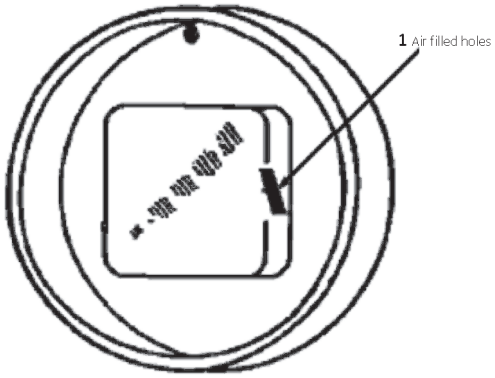


Table 12-5 Noise and Uniformity Section

Number	Description
1	Air filled holes

The resolution block contains holes drilled 1mm apart and positioned to form a line at 45 degrees (°) to the scan plane.

Each visible hole in the image represents 1mm of beam thickness.

The software assigns less negative CT numbers to partial hole images or holes located on the edge of the slice profile.

5805441-1EN Rev. 2 (Sep. 2020)

Prescribe the QA Series for the Slice Thickness Test - Phantom Section #1

1. Select a protocol from the anatomical section to select a QA protocol (if available).
2. If your facility hasn't created a QA protocol, use the following parameters to finish the QA series prescription:
3. On the Axial ViewEdit screen select the following parameters:
4. Analyze the slice thickness in all three images.

Table 12-6 QA Protocol for Slice Thickness

Interface	Input		
Entry	**Head First**		
Position	**Supine**		
Anatomical Reference	**QA**		
Landmark Location	**0** on resolution phantom at circumferential line/cross hatch.		
Scan Type	**Axial**		
Scan Range	Prescribe 1 scan group with 3 recons		
Group 1	**Thickness**	**Scan Range**	**Interval**
Recon 1	5mm/8i	I17.5 - S17.5	0
Recon 2	2.5mm/16i	I18.75 - S18.75	0
Group 2	**Thickness**	**Scan Range**	**Interval**
Recon 1	1.25mm/16i	I9.37 - S9.37	0
Recon 2	10mm/2i	I5.0 - S5.0	0
Tilt	**0** degrees (°)		
Scan FOV	**Small Body**		
kV	**120**		
mA	**200**		
Rotation Speed	**1** second (s)		
DFOV	**25**cm (phantom diameter: approximately 21.5cm)		
Algorithm	**Standard**		
Matrix	**512**		
Contrast	**None**		
Special Processing	**None**		

5. To determine slice thickness, display the image at the recommended window level and width, and count the visible holes.
   - Black lines in the image represent a full millimeter of slice thickness.
   - Gray lines count as fractions of a millimeter; two equally gray holes count as a single 1mm slice thickness.
   - See Figure 12-11.

Recommended window width: 250

Recommended window level:

- -100 for 1.25mm
- -25 for 2.5mm
- + 50 for 5.0mm
- + 120 for 10 mm

Figure 12-11 Slice Thickness Lines

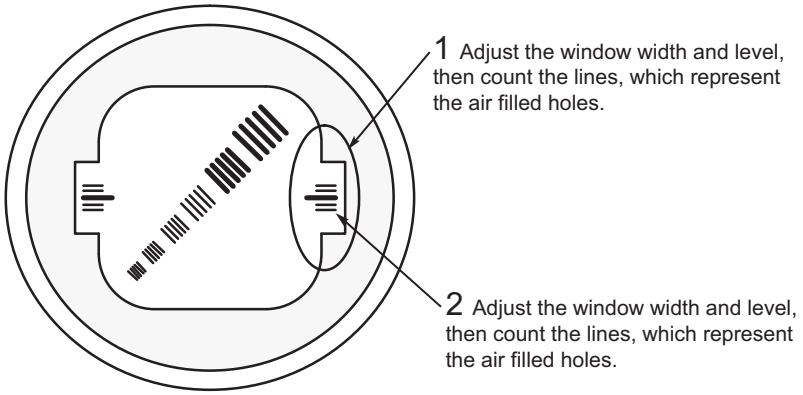


Table 12-7 Slice Thickness Lines

Number	Description
1	Adjust the window width and level, then count the lines, which represent the air filled holes.
2	Each black line represents one millimeter of slice thickness. Gray lines represent fractions of a millimeter.
NOTE: The slice thickness bars are less distinctive in helical scans.	

You should see one line for each millimeter of scan thickness.

Figure 12-11 represents a 5mm image.

5805441-1EN Rev. 2 (Sep. 2020)

Alignment Light Accuracy (Crucial During Biopsies) (Reference 21CFR 1020.33(g)(2))

This section provides the means to visually determine the location of the scanner's reference plane.

The manufacturers drilled deeper center holes on the reference to help identify them in the image.

The center hole position corresponds precisely to the etched marker placed on the circumference of the phantom.

When you use an accurate light, and align the phantom's circumferential etched marker to the axial light, the resulting image should contain a symmetrical hole pattern around the center (longer) hole in the slice thickness pattern.

See Figure 12-12.

Prescribe the QA Series for Alignment Light Accuracy - Phantom Section 1

Select a protocol from the anatomical selector to select a QA protocol. (If available) If your facility hasn't created a QA protocol, use the following parameters to finish the QA series prescription:

On the Axial ViewEdit screen select the following parameters:

Table 12-8 Parameters for Alignment Lights Check

Interface	Input
Entry	**Head First**
Position	**Supine**
Anatomical Reference	Type **EX** for the external alignment light test Type **IN** for the internal alignment light test.
Landmark Location	**0** on resolution phantom at circumferential line/cross hatch.
Scan Type	**Axial**
Scan Range	**I8.75 - S8.75**
Thickness	**2.5 mm/8i**
Tilt	**0** degrees (°)
Scan FOV	**Small Body**
kV	**120**
mA	**260**
Rotation Speed	**1** second (s)
DFOV	**25**cm (phantom diameter: approximately 21.5cm)

Interface	Input
Algorithm	**Standard**
Matrix	**512**
Contrast	**None**
Special Processing	**None**

Figure 12-12 Alignment Light Section

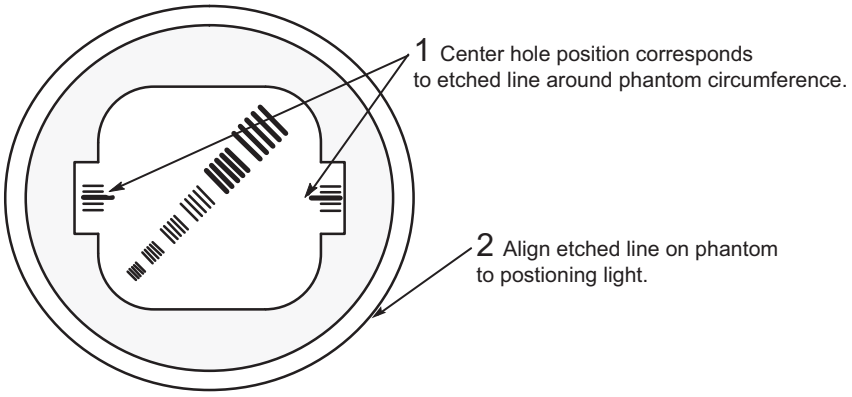


Table 12-9 Alignment Light Section

Number	Description
1	Center hole position corresponds to etched line around phantom circumference.
2	Align etched line on phantom to postioning light.

1. Align the phantom to the Internal light and scan it.
   - The actual scan plane should equal 0 ± 2.0mm.
2. Align the phantom to the External light and scan it.
   - The actual scan plane should equal 0 ± 2.0mm.
3. Align the vertical, horizontal and circumferential lines on the phantom to the corresponding laser lines.
   - Azimuth 0 laser: Center phantom left and right within the FOV
   - Azimuth 90 and 270 lasers: Center phantom up and down within the FOV.
4. Scan the phantom.
5. Display the resulting phantom image.
   - See Figure 12-12.

5805441-1EN Rev. 2 (Sep. 2020)

6. Select **Grid** to check sagittal and coronal light accuracy.
   - See Figure 12-13.
7. Center the phantom to isocenter, ± 4.0mm, along the sagittal and coronal planes.
   - See Figure 12-12.

Figure 12-13 Grid Check

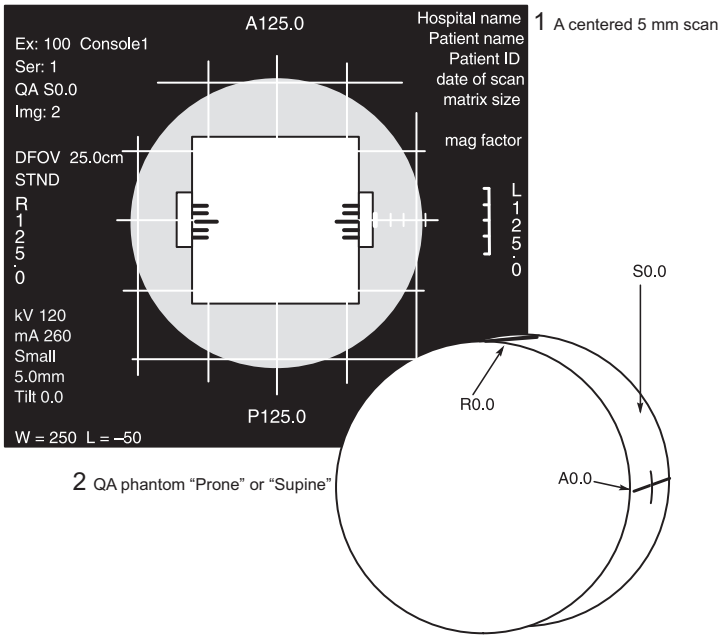


Table 12-10 Grid Check

Number	Description
1	A centered 5 mm scan
2	QA phantom “Prone” or “Supine”

Typical Results and Allowable Variations

Because the human eye determines clinical image quality, it remains subjective and difficult to define.

GE expects the standards of allowable variation in image quality parameters to vary with the installation and image evaluator(s).

GE encourages you to establish and follow a Quality Assurance (QA) program so you can discover any degradation of image quality before it effects clinical images.

Over time, institutions use the QA procedure to establish a correlation between acceptable clinical image quality and acceptable variations in the image performance indices included in the program.

Compare your images to the set of performance images that accompanied your system.

This section contains typical variations; **don't** mistake them for absolutes.

Compare any parameter variation to the maximum deviation specified in the next section called, Dose and Performance.

Make sure you used the prescribed technique, then follow your facility guidelines to inform service when the variations reach the specified maximum deviation.

Contrast Scale

The difference in CT numbers between the Plexiglass resolution block and water should equal 120, with a suggested allowable variation of 10%.

High Contrast Spatial Resolution

The MTF average for an ROI in the 1.6mm bar pattern should be within 0.62 to 0.78 for the standard algorithm.

Axial Scan Slice Thickness

Slice thickness should not vary as Table from the expected value, when evaluated according to instructions.

This method is only intended to identify gross changes in slice thickness, possibly due to hardware failure. More precise slice thickness measurements can be obtained by following the methodology described along with Table 12-35.

5805441-1EN Rev. 2 (Sep. 2020)

Noise & CT Number of Water

When you correctly image and analyze the water section of the phantom, you should see:

- CT number for water of 0 ± 3 HU for the center ROI.
- The uniformity difference between the Center ROI and the average of the edge ROIs should be 0 ± 3HU for the Small Body Scan FOV (0 ± 10HU maximum deviation if Large Body Scan FOV is used).
- Expect the noise in the center of the image to approximately equal 4.3 ± 0.6HU, when using the Small Body Scan FOV.

The tolerance applies to the average of all the acquired images and not to each of the individual images.

References

Droege RT, Morin RL. "A Practical Method to Measure the MTF of CT Scanners," Medical Physics, Volume 9, No. 5, pp 758-760, 1982.
Jacobson DR. "Quality Assurance for Computed Tomography — Correlation with System Performance," Application of Optical Instrumentation in Medicine XI, D. Fullerton, Editor, Proc. SPIE 419, pp 157-165, 1983.
AAPM, "Phantoms for Performance Evaluation and Quality Assurance of CT Scanners," Report No. 1, American Association of Physicists in Medicine, 1977

Low Contrast Detectability

The expected contrast value for a 3 mm object, when measured as described in Table 12-11, is less than 5.3 HU. Typical variation is ± 0.5 HU.

The tolerance applies to the average of all the acquired images and not to each of the individual images.

QA Master Data Form

Table 12-11 QA Master Data Form

QA Data Form				QA Phantom Serial #: _____		
CONTRAST SCALE				**HIGH CONTRAST RESOLUTION**		
Mean CT # Water	Mean CT # Plastic	Mean CT # Plastic Minus Mean CT # Water	Measured Std. Dev.	Bar Size	Specification	Meas MTF Avg
		Specification 120 ± 12		1.6	0.62 to 0.78	
				1.3	--	
				1.0	--	
				0.8	--	
SLICE THICKNESS				**ALIGNMENT LIGHT ACCURACY**		
Slice Width	Specification		# of Visible Lines	Light / Reference		Centered Y / N
5.00	5 ± 0.5			INT Axial		
2.50	2.5 ± 0.5			EXT Axial		
1.25	1.25 ± 0.5			90 / 270 Laser		
				0 Laser		
LOW CONTRAST DETECTABILITY				**NOISE AND UNIFORMITY**		
Object Size (mm)	Specification		Measured Contrast		Specification	Measurement
3.0	< 5.3 HU			Center Mean CT #	0 ± 3 HU	
				Center Std. Dev. CT #	4.3 ± 0.5 HU	
				CT # Uniformity	0 ± 3 HU	
				(Center Means - Outer Means)		

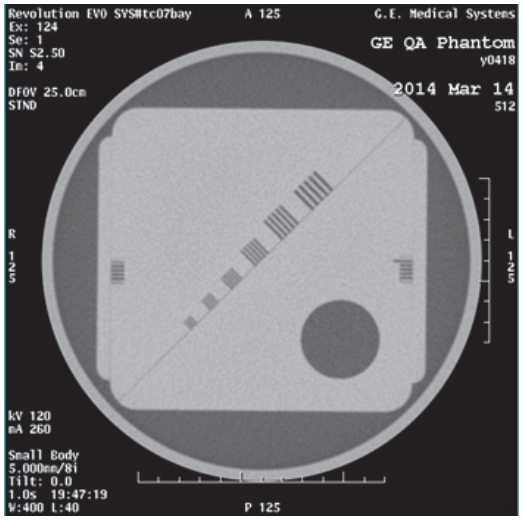
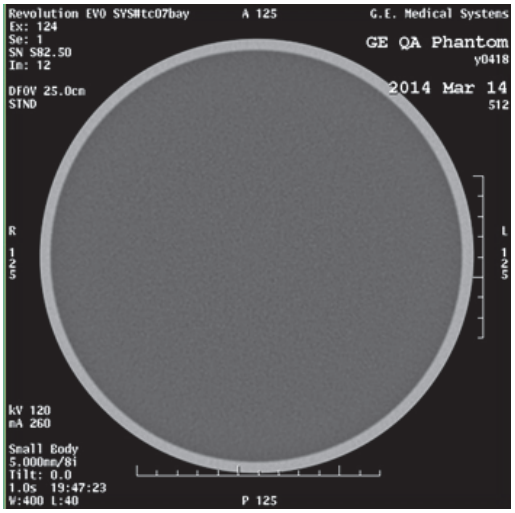
5805441-1EN Rev. 2 (Sep. 2020)

QA Phantom - Representative Images (Reference 21CFR 1020.33 (d)(3)(i))

This section contains representative images obtained with the phantom(s) using the same processing mode and CT conditions of operation as described in previous section for a properly functioning system.

The representative QA Phantom images are also shipped with each phantom on CD for restoring on the system and comparison to any daily QA testing.

Figure 12-14 Representative Images

High Contrast Spatial Resolution Section	Noise/CT Number/LCD Section
	

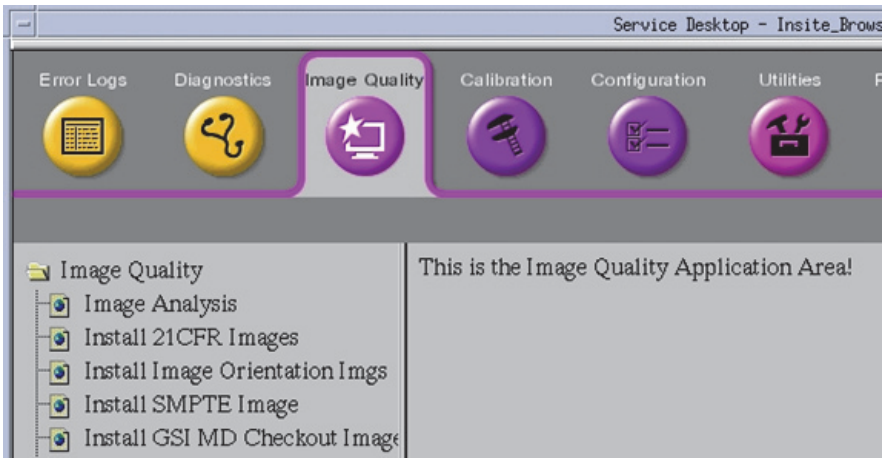
Digital Representative Images (Reference 1020.33 (d)(3)(ii))

Digital Images of Table 12-11, Figure 12-17, and Figure 12-18 are provided by CD-ROM and installed with the system.

To access digital form of the representative images stored on the system, use the following steps to install the images in the system browser so they can be reviewed:

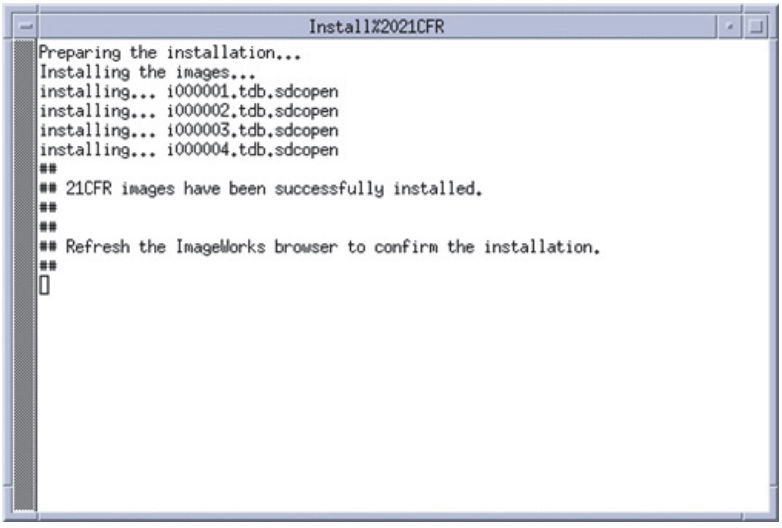
1. Click the [Service] icon in the display area. The Service desktop will display the Common Service Desktop user interface.
2. Click on Image Quality. In the Image Quality menu, click on Install 21 CFR Images.

Figure 12-15



A pop-up window will display showing that the images are being installed in the database.

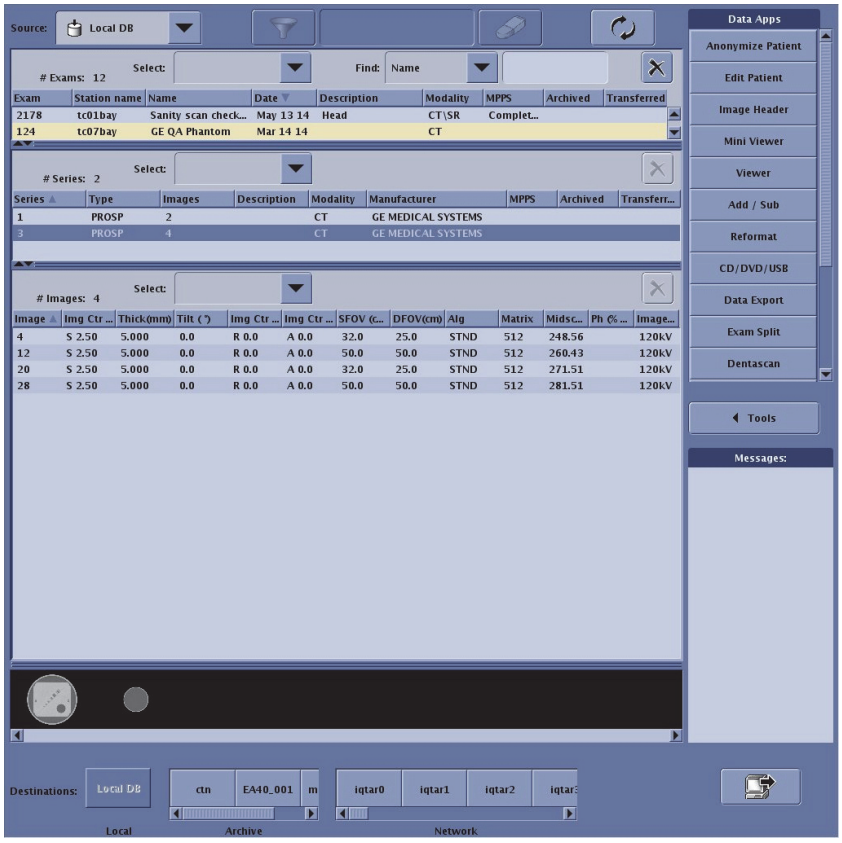
Figure 12-16



5805441-1EN Rev. 2 (Sep. 2020)

3. Go to Image Works desktop. Select Exam 124 GE QA Phantom (21 CFR1020.33 images), then click [Viewer].

Figure 12-17

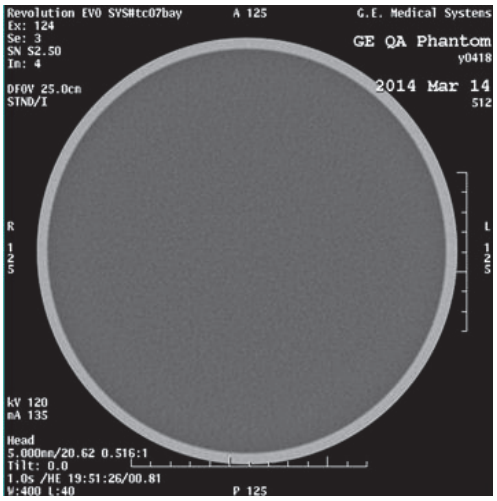


- Series 1 – Helical Head
- Series 2 – Helical Body
- Series 3 – Axial Head
- Series 4 – Axial Body

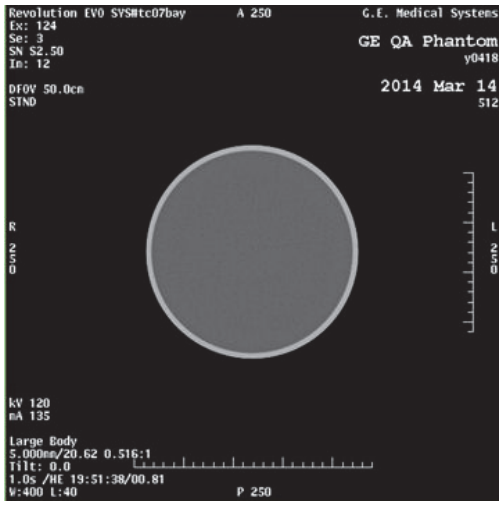
Digital Images are provided with the system in exam 124.

Figure 12-18 Representative Images (Reference 21CFR 1020.33(d)(3)(ii))

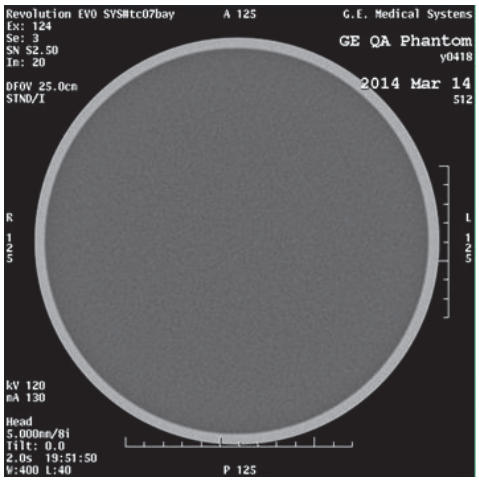
1



2



3



4

Table 12-12

Number	Phantom	Technique
1	Helical Head (Typical Noise 0.43 %)	120 kV, 135 mA, 1 sec., 5 mm, 0.516:1 Pitch
2	Helical Body (Typical Noise 0.32 %)	120 kV, 135 mA, 1 sec., 5 mm, 0.516:1 Pitch
3	Axial Head (Typical Noise 0.42 %)	120 kV, 130 mA, 2 sec., 5 mm
4	Axial Body (Typical Noise 0.32 %)	120 kV, 130 mA, 2 sec., 5 mm

DOSIMETRY (Reference: IEC60601-2-44:2009+A1:2012 Clause203.5.2.4.1, IEC60601-2-44:2009+A1:2012 Clause203.109.1)

Dosimetry information is provided in terms of the CTDI and $CTDI_W$ dose indices. Optionally $CTDI_{vol}$ and its associated DLP (dose length product) is automatically computed and displayed on the patient Rx menu to assist in managing patient dose. This section provides a brief description to help you better understand these dose reporting standards.

General Information

Dose is the amount of energy imparted by the X-ray beam at a given point in an exposed material (patient tissue, phantom, air, etc.) and is measured in units of mGy (milliGray). The old unit was the RAD, which equals 10 mGy. Dose is dependent on the energy absorption factors of the material and on the X-ray exposure. The X-ray exposure is measured in C/kg (coulombs per kilogram) and is dependent on the technique factors used for the scan. An absorbed dose of 1 mGy means that 1 Joule per gram of energy has been imparted. The dose is generally proportional to the exposure, which increases with increasing mA, kV and scan time and decreases with increasing patient size. The X-ray exposure to a point occurs from both direct X-ray from the tube and from scattered X-ray due to adjacent material exposure.

Patient biological risk is related to dose but is also highly dependent on the specific organs exposed and the age and gender of the patient. The effective dose is a way to characterize the stochastic risk to the patient population. The effective dose is the sum of the doses weighted in accordance with the specific radio-sensitivity of the particular organs or tissues exposed. Weighting values are published in ICRP 60 (International Committee on Radiation Protection, Publication 60). The effective dose is a whole body dose equivalent value that has been scaled to represent the dose of the exposed organs. Although we can accurately describe the X-ray exposure potential to a patient for a CT scan, we cannot easily determine the patient dose or risk in terms of effective dose. This is because each patient is anatomically unique and the specific details of his or her anatomy along with the source exposure must be processed using time-consuming monte-carlo computer programs (or other more approximate methods) to predict how radiation will be scattered and accumulated within various patient organs.

Since it is not possible to characterize the specific dose given to individual patients, the CT dose indices are provided to help make relative comparisons. These dose index values can be used to compare CT systems and to help select appropriate operating conditions for scanning. However, it is important to recognize that the dose reported by these indices is inversely proportional to phantoms size (see Figure 12-19). This means that for the same scan technique (protocol), smaller phantoms (patients) will produce a higher absorbed dose than larger phantoms (patients) - see “Influence of phantom diameter, kVp and scan mode upon computed tomography dose index”, Edward L. Nickoloff, Ajoy K. Dutta, and Zheng F. Lu, Medical Physics 30, 395 (2003). **Therefore, it is critical to remember that the body scan**

FOV's uses the 32cm CTDI phantom and all pediatric and head filter uses the 16cm CTDI phantom for dose reporting purposes ($CTDI_{vol}$ display on Scan Rx Menu). Table 12-14 indicates the phantom size used for each SFOV.

At this manual, dosimetry information was measured with the following instrument (Calibration Tolerance: ±5%):

1. Radiation Meter RadCal 9015
2. Radiation meter Converter RadCal 9060
3. CT Probe RadCal 10x5 - 3CT (for CTDI)
4. Ion-chamber RadCal 10x5 - 1800 (for stray (scatter) radiation)

Figure 12-19 Relationship between dose and phantom size for head and body filters at 120kV. Similar curves are obtained for the 80, 100, and 140 kVs.

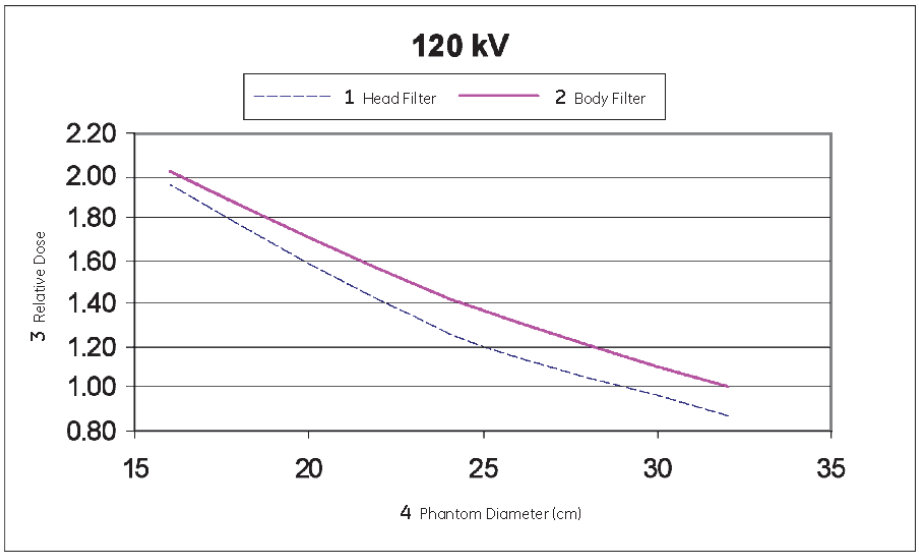


Table 12-13

Number	Description
1	Head Filter
2	Body Filter
3	Relative Dose
4	Phantom Diameter (cm)

5805441-1EN Rev. 2 (Sep. 2020)

Table 12-14 SFOV selection vs. CTDI phantom used for dose reporting (IEC60601-2-44:2009+A1:2012 Clause203.112)

SFOV type	CTDI phantom	Protocol Type
Ped Head	16 cm Phantom	Head
Head		
Ped Body	32 cm Phantom	Body
Small Body		
Large Body		
Cardiac Small		
Cardiac Large		

$CTDI_W$

(Reference IEC 60601-2-44 and 21 CFR 1020.33 (c))

$CTDI_W$ or weighted $CTDI_{100}$ is a dose index which consists of 2/3 of the $CTDI_{100}$ peripheral dose plus 1/3 of the $CTDI_{100}$ central dose. The $CTDI_{100}$ dose is defined as the integral of the dose profile, Da(z), produced in a single axial scan along a line perpendicular to the imaging plane from -50 mm to +50 mm, divided by the product of the number of slices, n, and the nominal tomographic section thickness (row detection width), T.

Mathematical Definition of $CTDI_{100}$ and $CTDI_W$

$$CTDI_{100} = \frac{1}{nT}\int_{-50mm}^{+50mm} Da(z)dz$$

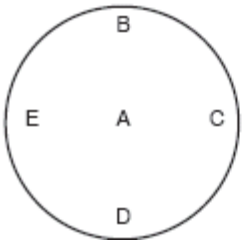
n = number detector macro rows per scan
T = Nominal Tomographic Section Thickness (row detector width)
Da(z) = dose profile in Z axis (asborbed in air)

$$CTDI_W = (2/3)xCTDI_{100\ peripheral} + (1/3)xCTDI_{100cent}$$

$CTDI_W$ is measured using either a 16 cm (for head scanning) or a 32 cm (for body scanning) PMMA phantom of at least 14 cm in length. The measurements are taken at the center and peripheral (see Figure 12-20 points A and B). The doses measured at these locations within the PMMA phantom, are quoted as the dose absorbed in air rather than PMMA (absorption in air is about 11% higher than absorption in PMMA).

The CTDI phantom should be on the patient table.

Figure 12-20 CTDI Dose Reference Phantom Description (Reference 21CFR 1020.33 (c)(1))



1	Head Phantom	16 cm dia.
2	Body Phantom	32 cm dia.
3	Material	PMMA (polymethyl methacrylate)
4	Thickness	>14 cm thick
5	A thru E	Pencil chamber openings
6	A	Center
7	B thru E	Peripheral 1 cm from surface 0, 90, 180, or 270 degrees (°) direction

Table 12-15

Number	Phantom	Description
1	Head Phantom	16 cm diameter
2	Body Phantom	32 cm diameter
3	Material	PMMA (polymethyl methacrylate)
4	Thickness	> 14 cm thick
5	A through E	Pencil chamber openings
6	A	Center
7	B through E	Periphial 1 cm from surface 0, 90, 180, or 270 degrees (°) direction

$CTDI_{100}$ dose tables and index factors are provided in the following section. To determine the $CTDI_{100}$ dose, select the appropriate standard technique dose (small or large filters at Table 12-17) and multiply by the factors for describing the technique used (see Table 12-16 to Table 12-21).

The $CTDI_{100}$ values at the four peripheral locations are very similar due to the geometry of the system and phantom. The "B" position is the maximum. The four locations "B, C, D, and E" are averaged to give one value representative of all peripheral positions. All measurements made on the 16cm, and 32cm CTDI phantoms are with the phantom placed on the patient cradle without additional attenuating materials present.

Table 12-16 Helical Travel and Scan Mode Adjustment Factors

Acquisition Mode Parameters for $CTDI_{100}$ and $CTDI_w$											
	Helical mm/Rotation per Pitch and Acquisition Mode (mm)				**Axial and Cine Slice Thickness (mm)**						
Aperture (mm)	**~0.5:1**	**~0.9:1**	**1.375:1**	**1.531:1**	**64i**	**32i**	**16i**	**8i**	**4i**	**2i**	**1i**
40.00	20.62	39.37	55.00	61.25	*1 0.625	*1 1.25	2.50	5.00	10.0	N/A	N/A
20.00	10.62	19.37	27.50	30.63	N/A	0.625	1.25	2.50	5.00	10.0	N/A
10.00	N/A	N/A	N/A	N/A	N/A	N/A	0.625	1.25	2.50	5.00	10.0
5.00	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1.25	2.50	5.00

5805441-1EN Rev. 2 (Sep. 2020)

Acquisition Mode Parameters for $CTDI_{100}$ and $CTDI_w$											
	Helical mm/Rotation per Pitch and Acquisition Mode (mm)				Axial and Cine Slice Thickness (mm)						
2.50	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1.25	2.50
1.25	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1.25

*[1] Available in retro recon only.

Table 12-17 Typical Techniques (Reference 21CFR 1020.33 (c) (1))

Typical Techniques for $CTDI_{100}$ and $CTDI_w$	
Small-axial-cine	Large-axial-cine
25 cm SFOV	50 cm SFOV
120kV	120kV
260 mAs	260 mAs
40 mm Aperture, 8i 5 mm	40 mm Aperture, 8i 5 mm

Table 12-18 $CTDI_{100}$ Dose Values (Reference 21CFR 1020.33 (c)(2)(i) and (c)(2)(ii))

$CTDI_{100}$ DOSE VALUES (mGy) AT TYPICAL TECHNIQUE				
SFOV	**Filter**	**Phantom Size**	**Position Center**	**Position Peripheral**
Ped Head Head	Small	16 cm	43.78	43.37
Ped Body Small Body Cardiac Small	Small	32 cm	13.03	23.19
Large Body Cardiac Large	Large	32 cm	13.60	27.17

Table 12-19 kV and mAs Adjustment Factors (Reference 21CFR 1020.33(c)(2)(iii))

KV Adjustment Factor						
kV	Ped Head Head		Ped Body Small Body Cardiac Small		Large Body Cardiac Large	
	Center	Peripheral	Center	Peripheral	Center	Peripheral
80	0.34	0.36	0.28	0.35	0.26	0.33
100	0.64	0.65	0.59	0.65	0.58	0.63
120	1.00	1.00	1.00	1.00	1.00	1.00
140	1.42	1.41	1.44	1.42	1.51	1.44
mAs ADJUSTMENT FACTOR = Rx mA * Rx single rotation time in seconds (s) / 260						

Table 12-20 Aperture Adjustment Factors for Large Spot

CTDI Aperture Adjustment Factors for Large Spot						
SFOV Acquisition Mode	Ped Head Head		Ped Body Small Body Cardiac Small		Large Body Cardiac Large	
	Center	Peripheral	Center	Peripheral	Center	Peripheral
64 X 0.625	1.00	1.00	1.00	1.00	1.00	1.00
32 X 0.625	1.07	1.08	1.07	1.08	1.07	1.08
16 X 0.625	1.26	1.27	1.26	1.27	1.26	1.27
8 X 0.625	1.56	1.59	1.56	1.59	1.56	1.59
4 X 0.625	1.70	1.77	1.70	1.77	1.70	1.77
2 X 0.625	2.36	2.50	2.36	2.50	2.36	2.50

Table 12-21 Aperture Adjustment Factors for Small Spot

CTDI Aperture Adjustment Factors for Small Spot						
SFOV Acquisition Mode	Ped Head Head		Ped Body Small Body Cardiac Small		Large Body Cardiac Large	
	Center	Peripheral	Center	Peripheral	Center	Peripheral
64 X 0.625	1.00	1.00	1.00	1.00	1.00	1.00
32 X 0.625	1.07	1.07	1.07	1.07	1.07	1.07
16 X 0.625	1.21	1.22	1.21	1.22	1.21	1.22
8 X 0.625	1.40	1.42	1.40	1.42	1.40	1.42
4 X 0.625	1.66	1.72	1.66	1.72	1.66	1.72
2 X 0.625	2.35	2.48	2.35	2.48	2.35	2.48

5805441-1EN Rev. 2 (Sep. 2020)

Example 1 - The $CTDI_{100}$ large body peripheral dose for a 55 mm/sec helical scan (64X0.625) in 1.375:1 mode, scan at 250 mA, 1.0 Sec per rotation and 120 kV is determined as follows:

27.17 mGy	Body peripheral dose at typical technique from CTDI Table 12-18
x 1.00	120 kv factor from CTDI kv Table 12-19
x 1.00	Aperture adjustment factor from $CTDI_{100}$ aperture factor for 64 X 0.625 and large spot Table 12-21 (i.e. at 120 kV, 250 mA > 200 mA)
x 0.962	mA adjustment factor (250mA x 1 sec/rot/260 mA) Table 12-19
=26.1 mGy	$CTDI_{100}$ Body Peripheral dose

Example 2 - The CTDI100 large body center dose for example 1 is determined as follows:

13.60 mGy	Body center dose at typical technique from CTDI Table 12-18
x 1.00	120 kv factor from CTDI kv Table 12-19
x 1.00	Aperture adjustment factor from $CTDI_{100}$ aperture factor for 64 X 0.625 or 32 x 1.25 and large spot Table 12-21 (i.e. at 120 kV, 250 mA > 200 mA)
x 250/260	mA adjustment factor (250mA x 1 sec/rot/260) Table 12-19
=13.1 mGy	$CTDI_{100}$ Body center dose

Example 3 - The $\mathbf{CTDI_w}$ large dose for example 1 and 2 is computed as:

$26.1 \times 2/3 + 13.1 \times 1/3 = 21.8$ mGy

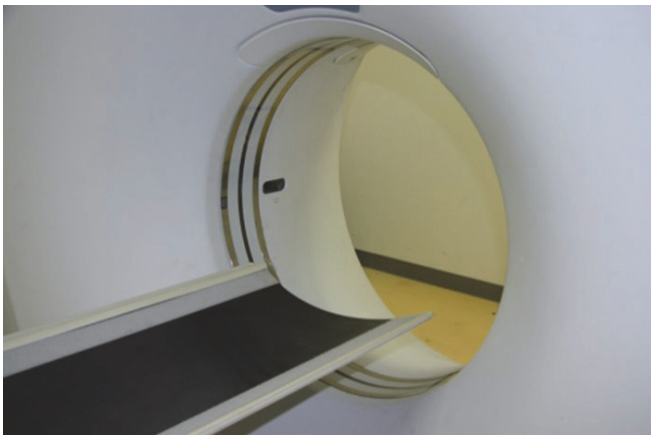
Table 12-22 Dose Calculations for 306 kg/675 lb patient table / VT2000x - Dose Scaling

CTDI Table Adjustment Factors						
Table Type	**Ped Head Head**		**Ped Body Small Body Cardiac Small**		**Large Body Cardiac Large**	
	Center	**Peripheral**	**Center**	**Peripheral**	**Center**	**Peripheral**
VT1700V (500lbs (227kg)) Table/ VT2000 (500lbs (227kg) Long) Table	1.000	1.000	1.000	1.000	1.000	1.000
VT2000x (675lbs (306kg) Long) Table	0.978	0.976	0.986	0.985	0.983	0.983

Measuring Method for $CTDI_{100}/CTDI_w$

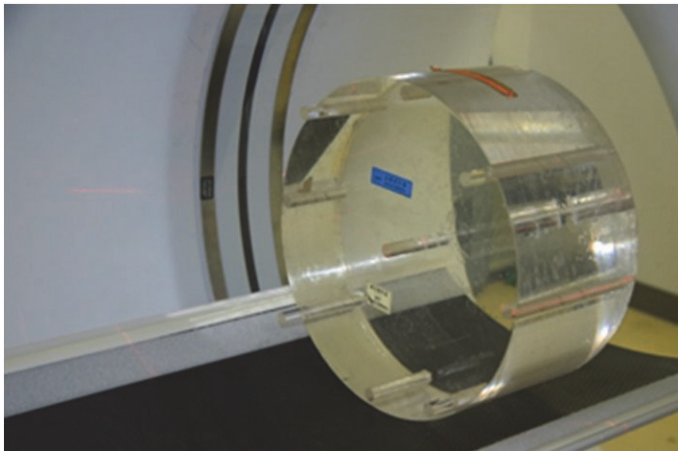
1. Remove the soft pad from the patient cradle as shown in Figure 12-21.

Figure 12-21 The patient cradle with soft pad removed.



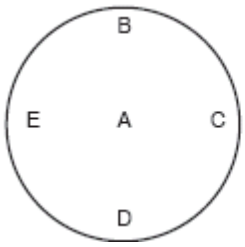
2. Place the CTDI phantom on the cradle as shown in Figure 12-22. To help with consistency of the results, ensure that the phantom is at least 20cm from the end of the patient cradle. The location and labeling of the dosimeter probe holes are illustrated in the figure. Dosimeter holes are located in the center, on top, to the right, on the bottom and to the left, A, B, C, D and E, respectively.

Figure 12-22 32cm CTDI phantom on the patient cradle



5805441-1EN Rev. 2 (Sep. 2020)

Figure 12-23 CTDI Dose Reference Phantom



1	Head Phantom	16 cm dia.
2	Body Phantom	32 cm dia.
3	Material	PMMA (polymethyl methacrylate)
4	Thickness	>14 cm thick
5	A thru E	Pencil chamber openings
6	A	Center
7	B thru E	Peripheral 1 cm from surface 0, 90, 180, or 270 degrees (°) direction

Table 12-23 CTDI Dose Reference Phantom Description (Reference 21CFR 1020.33 (c)(1))

Number	Phantom	Description
1	Head Phantom	16 cm diameter
2	Body Phantom	32 cm diameter
3	Material	PMMA (polymethyl methacrylate)
4	Thickness	> 14 cm thick
5	A through E	Pencil chamber openings
6	A	Center
7	B through E	Periphial 1 cm from surface 0, 90, 180, or 270 degrees (°) direction

3. To correctly align the phantom in the x and y directions, acquire an axial scan of the CTDI phantom using acquisition parameters suggested in Table 1; subsequently overlay a grid on the reconstructed axial image of the phantom using the grid tool located in the ImageWorks desktop. When correctly aligned, within ±10mm, the x and y axes will overlay all holes A, B, C, D and E. If the grid axes do not overlay the hole locations, use the cradle positioning Up/Down buttons on the CT gantry to modify the y position of the cradle and manually maneuver the phantom to center the phantom in the x direction. Repeat the process and acquire as many images of the CTDI phantom as are needed to ensure that the phantom is properly aligned in the x and y directions. In addition, this alignment should be per-formed for all images of axial scan considering lean in Z direction. An example of (left) a misaligned, and (right) a correctly aligned phantom are shown in Figure 12-24.

Figure 12-24 Example of a (left) misaligned and (right) a correctly aligned phantom. Note the overlaid grid lines passing through all five hole locations in the correctly aligned phantom

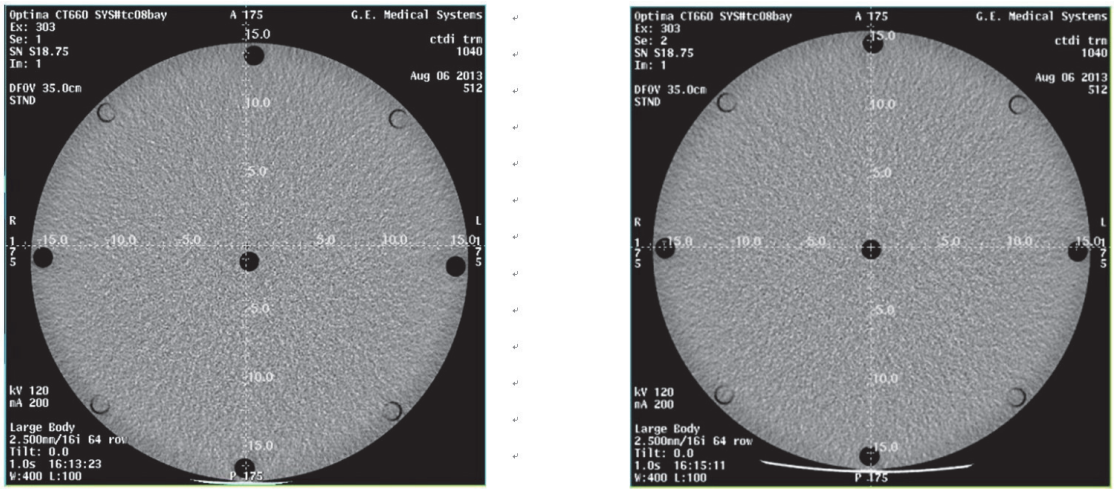


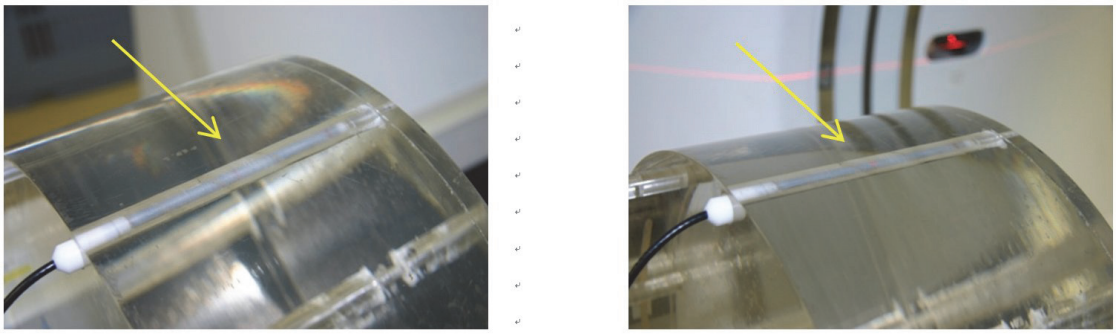
Table 12-24 Suggested technique to acquire the images for alignment (Figure 12-24)

Parameters	Values
Scan Mode	Axial
Rotation Time	1.0 s/rot
kV	120 kV
mA	200 mA
Slice Collimation	64 x 0.625
SFOV	Head (for 16cm phantom) Large Body (for 32cm phantom)
Image Thickness	2.5 mm
Recon Filter	Stnd
DFOV	20cm (for 16cm phantom) 35cm (for 32cm phantom)
ww / wl	400 / 100

5805441-1EN Rev. 2 (Sep. 2020)

4. Place the dosimeter in the top probe position hole (B) as shown in Figure 12-25 and ensure that all remaining empty holes are filled using solid acrylic rods.

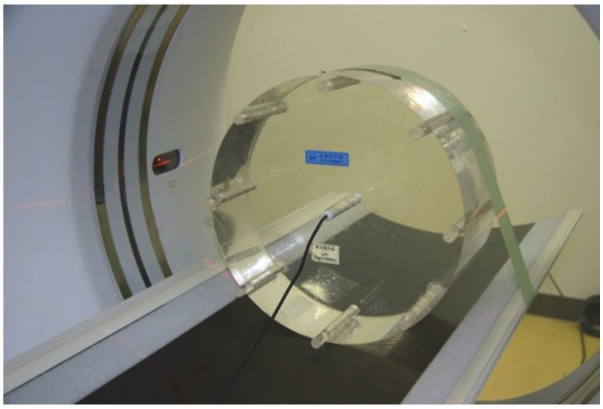
Figure 12-25 Photograph of the dosimeter probe in the top probe position (B) with (left) the center alignment mark indicated, and (right) the laser light as it appears when properly aligned



To ensure that the dosimeter probe is aligned in the z direction, enable the laser alignment lights and use the cradle positioning In/Out buttons until the laser light lies along the center alignment mark on the dosimeter surface.

5. When satisfied that the CTDI phantom is properly aligned in the x, y, and z axes, securely position the CTDI phantom on the cradle by covering the phantom with adhesive tape, fastening the tape on both sides to the cradle. This is illustrated in Figure 12-26 with the probe shown in the center position.

Figure 12-26 The CTDI phantom, secured to the table with adhesive tape, with the probe in the center location



6. Remove the dosimeter probe from the top probe position (B) and replace it in the center probe position (A), filling all empty probe holes with acrylic rods, as appropriate. This process is illustrated in Figure 12-26. Acquire an axial scan and record the dose measured by the dosimeter from the scan using the following technique:

Table 12-25 Sample technique of 120kV, Large Body SFOV, 260mA and 64x0.625mm

Parameters	Values
Phantom	32cm phantom
Scan Mode	Axial
Rotation Time	1.0 s/rot
kV	120 kV
mA	260 mA
Slice Collimation	64 x 0.625 / 40mm
SFOV	Large Body SFOV

NOTE: Additional Information: If a set of "Radiation Meter RadCal 9015" and "CT Probe RadCal 10x5 - 3CT" is used, the displayed dose of RadCal 9015 is:

A) To be multiplied with calibration factor.

B) Already adjusted value of 1cm though the probe length is 10cm.

As a result of A) and B), measured CTDI100 is calculated by the following equation.

[Measured dose (mGy)] = [Displayed Dose (mGy)] x [Calibration Factor] x 10.0 / [Aperture in mm]

7. Repeat the same axial scan technique and measurement process ten times and record the average measured dose of the ten scans to get the dose measurement of position B and is the $CTDI_{peripheral}$ at position B.

8. Repeat the scan and measurement process steps (1 to 7 above) for all other probe positions (A, C, D, and E) making sure to fill the empty probe holes with acrylic rods each time. These will give $CTDI_{peripheral}$ values for positions C,D, and E, as well as the $CTDI_{center}$ value (position A).

9. The $CTDI_w$ value is obtained from the $CTDI_{center}$ and $CTDI_{peripheral}$ values above by the equation:

   $CTDI_w = 1/3CTDI_{center} + 2/3CTDI_{peripheral}$

   Where the $CTDI_{peripheral}$ is the average of the 4 values obtained in step 8.

5805441-1EN Rev. 2 (Sep. 2020)

$CTDI_{vol}$ (Reference IEC 60601-2-44)

The volume $CTDI_W$ ($CTDI_{vol}$) describes the average dose over the total volume scanned for the selected CT conditions of operation. The system computes $CTDI_{vol}$ automatically.

NOTE: System computations may vary slightly from manual calculations due to differences in round-off or truncation operations.

The **$CTDI_{vol}$** is defined as follows:

a) For axial scanning

$$CTDI_{vol} = \frac{N \times T}{\Delta d} CTDI_w$$

b) For scanning without pre-programmed movement of the table (cine, test borus, Axial Shuttle, and fluoro modes)

$$CTDI_{vol} = n \times CTDI_w$$

where n is equal to the maximum number of pre-programmed rotations and can be calculated as the total x-ray on time divided by the gantry rotation speed.

where N is the number of slices produced in a single axial scan, T is the slice thickness (or row detection width), and Δd is the table travel in *z*-direction between consecutive scans.

c) For helical scanning

$$CTDI_{vol} = \frac{CTDIw}{CT\ pitch\ factor}$$

The following Scan Mode adjustment factor should be used:

Table 12-26 CT Pitch Factor

CT Pitch Factor								
	40 mm Aperture				20 mm Aperture			
Pitch Factor	0.516	0.984	1.375	1.531	0.531	0.969	1.375	1.531

Cardiac Pitch Factor									
Pitch Factor	0.160	0.180	0.200	0.220	0.240	0.260	0.280	0.300	0.325

d) Scanning Mode Specific Dosimetry Information

Volume Helical Shuttle (Reference IEC60601-2-44:2009+A1:2012 Clause201.3.212 d))

For Shuttle mode Scanning

$$CTDI_{vol} = n \quad \frac{N \times T}{(N \times T) + R} \quad CTDI_W$$

N	is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source.
T	is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.
n	is equal to the total number of rotations for the entire scan series.
R	is the distance between the two positions.

$CTDI_w$ is the WEIGHTED $CTDI_{100}$.

NOTE: $CTDI_w$ is evaluated as the WEIGHTED $CTDI_{100}$ with time-weighted average CT CONDITIONS OF OPERATION.

Volume Helical Shuttle, as described in the previous chapter uses dynamic helical reconstruction to extend the coverage and usability of the radiated data by design.

Since the feature is designed for use with applications that may require multiple passes over the same anatomical area and the fact that the table speed is lower

5805441-1EN Rev. 2 (Sep. 2020)

than the steady state prescribed table speed during ramp-up and ramp-down, the helical pitch with time weighted average is applied for Volume Helical Shuttle.

In other words of the definition in IEC60601-2-44:2009+A1:2012, CTDIvol for multiple helical scans over the same exposed area can be described as follows:

$$CTDI_{vol} = \frac{CTDI_w}{Helical\_Pitch\_Factor} \times Number\_of\_Passes$$

The helical pitch factor can be further described as coverage in one rotation (Dd) in millimeters divided by the total detection width (**N**umber of Rows x Slice **T**hickness)

$$Helical\_Pitch\_Factor = \frac{\Delta d}{NxT}$$

For Volume Helical Shuttle the Dd is defined as the ratio of the mean coverage per pass and total number of rotations.

$$\Delta d = \frac{Total\_Coverage\_Per\_Pass(mm)}{Total\_Number\_of\_Rotations\_Per\_Pass}$$

The number of rotations is defined as:

$$Total\_Number\_of\_Rotations\_Per\_Pass = \frac{Total\_Xray\_ON\_time\_Per\_Pass(s)}{Rotation\_Speed(s)}$$

(Total_Number_of_Rotations_Per_Pass) x (Number_of_Passes) = n

Total_Coverage_Per_Pass = (N x T) + R

Example 4 - The **$CTDI_{vol}$** head dose for a 10 mm 8i × 1.25 mm (16 X 0.625 acquisition mode) axial scan, at 150 mA, 1.0 sec per rotation, 120 kV and a 30 mm table increment is determined as follows:

43.78/43.37 mGy	Center and peripheral dose from $CTDI_{100}$ Table 12-18
x 1.00	120 kv factor from CTDI kV Table 12-19
x 1.21/1.22	8 X 0.625 aperture adjustment factor from $CTDI_{100}$ aperture factor small spot Table 12-21 (i.e. 120 kV, 150 mA < 200 mA)
x 0.577	mA Adjustment factor (150 mA x 1 sec/rot/260 mA) Table 12-19
= 30.6/30.5 mGy	$CTDI_{100}$ (center, peripheral dose)
30.5 mGy	$CTDI_w$ = (30.6 X 1/3 + 30.5 X 2/3)
10.2 mGy	$CTDI_{vol}$ = 30.5 X $\frac{8x1.25}{30}$

Example 5 - The $CTDI_{vol}$ dose for a cardiac helical scan using the large SFOV, 32 × 0.625 mm slice thickness with helical pitch of 0.325, scan at 250 mA, 0.5 seconds (s) per rotation, and 140 kV is determined as follows:

13.60/27.17 mGy	Body center and peripheral dose from $CTDI_{100}$ Table 12-18
x 1.51/1.44	140 kv factor from CTDI kV Table 12-19
x 1.07/1.08	32 X 0.625 aperture adjustment factor from $CTDI_{100}$ aperture factor large spot Table 12-20 (i.e. 140 kV, 250 mA > 170 mA)
x 0.481	mA Adjustment factor (250 mA x 0.5 sec/rot/260 mA) Table 12-19
= 10.6/20.3 mGy	$CTDI_{100}$ (center, peripheral dose)
= 17.1	$CTDI_w$ = (10.5 x 1/3 + 20.0 x 2/3) mGy
= 52.5	$CTDI_{vol}$ = 17.1/0.325

Example 6 - The $CTDI_{vol}$ dose for a cardiac helical scan using the large SFOV, 32 × 0.625 mm slice thickness with helical pitch of 0.325, scan at 250 mA, 0.5 seconds (s) per rotation, and 140 kVp is determined as follows:

13.60/27.17 mGy	Body center and peripheral dose from $CTDI_{100}$ Table 12-18
x 1.51/1.44	140 kv factor from CTDI kVp Table 12-19
x 1.07/1.07	32 X 0.625 aperture adjustment factor from $CTDI_{100}$ aperture factor small spot Table 12-21 (i.e. 140 kVp, 250 mA < 335 mA)
x 0.48	mA Adjustment factor (250 mA x 0.5 sec/rot/260 mA) Table 12-17
= 10.54/20.09 mGy	$CTDI_{100}$ (center, peripheral dose)
= 16.91 mGy	$CTDI_w$ = (10.54 x 1/3 + 20.09 x 2/3)
= 52.03 mGy	$CTDI_{vol}$ = 16.91/0.325

5805441-1EN Rev. 2 (Sep. 2020)

Conversion Factors from 32cm to 16cm (Reference IEC60601-2-44:2009+A1:2012 Clause 203.112)

$CTDI_{vol}$ of 16cm phantom is converted by multiplying the $CTDI_{vol}$ of 32cm phantom and the following factors.

Table 12-27 Conversion Factors from the CTDIvol based on the 32 cm phantom to the CTDIvol based on the 16 cm phantom (Reference IEC60601-2-44:2009+A1:2012 Clause 203.112

Aperture (mm)	Ped Body Small Body Cardiac Small				Large Body Cardiac Large			
	80kV	100kV	120kV	140kV	80kV	100kV	120kV	140kV
40	2.32	2.23	2.20	2.18	2.09	2.03	1.99	1.96
20	2.32	2.23	2.20	2.18	2.09	2.03	1.99	1.96
10	2.32	2.23	2.19	2.18	2.09	2.03	1.99	1.96
5	2.31	2.23	2.19	2.18	2.09	2.03	1.99	1.96
2.5	2.31	2.22	2.19	2.17	2.08	2.02	1.99	1.95
1.25	2.30	2.22	2.18	2.17	2.08	2.02	1.98	1.95

$CTDI_{vol}$ (16cm phantom) = $CTDI_{vol}$ (32cm phantom) x (conversion factor)

CTDI (Reference 21CFR 1020.33 (C) (2)) Dose Calculations

CT Dose Index (**CTDI**) was established by the FDA and has been in use for many years. It is the basis for the $\mathbf{CTDI_{100}}$ methodology because it defined a way to determine the dose at specific points (center and peripheral) in a head or body size reference phantom (see Figure 12-19). The **CTDI** dose is defined as the dose absorbed in the phantom material (PMMA) at a point when a volume of 7 contiguous slices is scanned adjacent to each side of the point.

Mathematical Definition of CTDI

$$CTDI = \frac{1}{nT} \int_{-7T}^{7T} D(z)dz$$

n = number detector macro rows per scan
T = row detection width
D(z) = Z axis dose profile (absorbed in PMMA)

The contiguous adjacent slices contribute to much of the total dose for large aperture cases, but it greatly underestimates the dose for narrow slices because the index is defined for 14 slices and typical modern procedures will include scattered dose from more than 7 adjacent slices.

5805441-1EN Rev. 2 (Sep. 2020)

Peak Skin Dose (Estimated Phantom Peripheral Dose) (Reference NEMA XR 28-2013 Section 2.5)

This section provides information on the relationship between peak CT Skin Dose and CTDI as standardized in IEC 60601-2-44, the most commonly used dose metric used to estimate dose to the patient. The peak skin dose is actually a point dose and is of particular interest to assess possible deterministic skin effects, especially in applications such as CT Perfusion and interventional procedures where the same anatomical area is irradiated for relatively long durations of time.

As $CTDI_{100}$ is measured using a 10cm long pencil ionization chamber, at fixed locations within a perfectly symmetrical and centered cylindrical phantom, the metric is not a direct measure of patient dose given the non-uniform patient composition and natural differences in patient sizes relative to the fixed sizes of the CTDI phantoms. In general terms, the dose to the skin can be calculated only by estimating the amount of dose absorbed at surface of the object. The peripheral $CTDI_{100}$ measurement is measured at the surface (1cm inside the surface of the phantom). However, for scans performed without table movement (such as CT Perfusion and Fluoroscopy), the integrated-$CTDI_{100(Peripheral)}$ can be a significant overestimation of the peak skin dose as much as a factor of two[1].

As an informative description, a basic CT Skin Dose Index (CTSD, EPPD) is provided below. While this is not the peak skin dose (a point dose) for a patient, it is a metric that can be readily calculated based on either the $CTDI100_{peripheral}$ value and associated kV, mA, and aperature adjustment factors found in this chapter of the Technical Reference Manual or the peak of the dose profile given in the Table 12-28 below and the following adjustment equation. This metric helps to address the overestimation of peak skin dose by use of $CTDI_{vol}$ values especially for scanning without table movement such as found in CT perfusion and interventional procedures.

Actual peak skin dose will vary due to a variety of factors that include actual patient size and centering in the bore.

Table 12-28 Peak of dose profile in mGy for available apertures and kV and bowtie filter combinations for a single one-second (s) rotation at 260 mA. The head values are from the peripheral locations of the 16cm CTDI phantom and the body values are from the peripheral locations of the 32cm CTDI phantom.

kV	Filter	Aperture (mm)					
		1.25	2.5	5	10	20	40
80	head	11.31	11.81	12.07	13.45	14.29	15.62
80	body	6.69	6.89	7.58	8.27	8.73	10.15
100	head	20.33	21.30	21.59	24.28	25.70	27.98

1.The following article provides an explanation of the relationship between CTDIvol and peak skin dose for helical and cine-mode exams: J. A. Bauhs, T. J. Vrieze, A. N. Primak, M. R. Bruesewitz, and C. H. McCollough, 2008, "CT dosimetry: comparison of measurement techniques and devices," Radiographies Vol. 28, pp. 245-253. Available at: http://radiographics.rsna.org/content/28/ I/245.full.pdf+html.

kV	Filter	Aperture (mm)					
		1.25	2.5	5	10	20	40
100	body	12.93	13.25	14.50	15.91	17.19	19.42
120	head	30.87	32.32	33.04	37.08	39.11	42.58
120	body	20.16	20.72	21.67	24.67	27.09	30.44
140	head	43.11	45.41	46.21	51.76	55.16	59.97
140	body	29.73	30.40	32.89	36.91	40.23	44.29
Note: The values within this table have an expected vaariance of ± 40%. (In the case of Segment Scanning, an expected variance would be more than ± 40 %.)							

Maximum peak of dose profile (max $\{D_{peripheral}(z)\}$) =Peak dose from Table 12-28 * (actual scan mA/260mA) * gantry rotation speed in seconds (s).

COMPUTED TOMOGRAPHY SKIN DOSE INDEX (CTSD, EPPD) is an indicator of the peak ABSORBED DOSE in skin tissue located within the area of coverage of the RADIATION FIELD.

a) For Axial scanning

$$CTSD\ (EPPD) = \frac{N \times T}{\Delta d}\ CTDI_{100(peripheral)}$$

N	is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source.
T	is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.
Δ d	is the PATIENT SUPPORT travel in z-direction between consecutive scans.
$CTDI_{100(peripheral)}$	is the average of the four values of $CTDI_{100}$ measured around the dosimetry PHANTOM periphery.

NOTE: For axial scanning with a total table travel of less than N × T, this definition may overestimate the dose.

NOTE: For the selected CT CONDTIONS OF OPERATION, but irrespective of any scanning length that may be used clinically, the axial-scanning CTSD, EPPD is an index of dose based on a convention of 100 mm range of integration along the *z*-axis. For axial scanning, CTSD corresponds to the dose averaged over the PHANTOM central section peripheral holes.

b) For Helical scanning

$$\text{CTSD (EPPD)} = \frac{\text{CTDI100 (peripheral)}}{\text{CT pitch Factor}}$$

NOTE: CT PITCH FACTOR will be a function of time when Δ d or N × T are variable during the exposure.

NOTE: For helical scanning with a small number of rotations and a table travel per rotation of less than N × T, this definition may overestimate the dose.

NOTE: For the selected CT CONDTIONS OF OPERATION, but irrespective of any scanning length that may be used clinically, the helical-scanning CTSD, EPPD is an index of dose based on a convention of 100 mm range of integration along the *z*-axis. For helical scanning, CTSD, EPPD corresponds to the dose averaged over the PHANTOM central section peripheral holes.

c) For scanning without movement of the PATIENT SUPPORT

$$\textit{CTSD (EPPD)} = n \times \max\{D_{peripheral}(z)\}$$

n	is equal to the number of rotations.
$\max\{D_{peripheral}(z)\}$	is the maximum value of the four dose profiles measured in the PHANTOM periphery produced in a single axial rotation along lines z perpendicular to the tomographic plane, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethyl methacrylate (PMMA) dosimetry PHANTOM.

NOTE: c) includes situations where the PATIENT SUPPORT may be moved manually, for example, during an interventional procedure.

d) For Axial and Helical scanning involving table travel in two derections ("shuttle" mode)

$$\text{CTSD (EPPD)} = n \frac{N \times T}{(N \times T) + R} \max\{D_{peripheral}(z)\}$$

n	is the total number of rotations for the entire scan series.
N	is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.
R	is the range of table travel during the entire LOADING.
max $[D_{peripheral}(z)\}$	is the maximum value of the four dose profiles measured in the PHANTOM periphery produced in a single axial rotation, with time weighted average CT CONDITIONS OF OPERATION, along lines *z* perpendicular to the tomographic plane, where dose is reported as absorbed dose in air and is evaluated within a polymethyl methacrylate (PMMA) dosimetry PHANTOM.

5805441-1EN Rev. 2 (Sep. 2020)

Other Dosimetry Information

Dose Length Product (DLP)

The dose length product (**DLP**) is a simple calculation and is given in milliGray-Centimeters (mGy-cm). The **DLP** is computed and displayed on Scan Rx Menu for each group prior to the scan as well as an accumulated **DLP** for all scans taken up to the current time during the exam. Note that system computations may vary slightly from manual calculations due to differences in round-off or truncation. The final exam accumulated **DLP** provides a convenient measure for maintaining patient or procedure dose management statistics. The **DLP** is computed given the $CTDI_{vol}$ described above as follows:

DLP = $\mathbf{CTDI_{vol}} \times L$

L: Table travel during the entire LOADING adjusted for dynamic collimation made if applicable

The total scan coverage can be determined from the Scan Rx Menu as the product of the table speed in cm/sec and the total exposure time in seconds (s). For helical scanning, the total scan coverage (length) will be longer than the image length due to the having to obtain additional scan views at both the beginning and end of a scan in order to have sufficient data for reconstruction of the end images. - this is known as helical over beaming. Differences between the displayed and manually calculated DLP value may occur if the total coverage as a function of x-ray on-off time is not used.

Adjustment method of L by Dynamic Z axis tracking (dynamic collimation modes) follows the equations below.

L (cm) = [Table travel during the entire LOADING] - [Adjustment factor for dynamic collimation made]

Table travel during the entire LOADING: Table speed (cm/sec) x Total Exposure Time (sec)

Adjustment factor for dynamic collimation made: The value in the following table (cm)

Table 12-29 Adjustment Factor for L (cm) when small focul spot is used

Rotation Time (s)	20mm Aperture				40mm Aperture			
	p0.531	p0.969	p1.375	p1.531	0.516	0.984	p1.375	p1.531
1	0.399	0.407	0.708	0.826	0.679	1.060	1.668	1.737
0.9	0.401	0.409	0.711	0.829	0.682	1.065	1.675	1.745
0.8	0.401	0.409	0.711	0.830	0.682	1.065	1.675	1.746
0.7	0.403	0.412	0.715	0.835	0.685	1.071	1.685	1.756
0.6	0.402	0.412	0.715	0.834	0.684	1.071	1.683	1.754
0.5	0.404	0.415	0.719	0.838	0.687	1.076	1.691	1.763
0.4	0.406	0.419	0.725	0.845	0.692	1.085	1.703	1.777
0.35	0.408	0.422	0.728	0.849	0.695	1.091	1.619	1.685

Table 12-30 Adjustment Factor for L (cm) when large focul spot is used

Rotation Time (s)	20mm Aperture				40mm Aperture			
	p0.531	p0.969	p1.375	p1.531	0.516	0.984	p1.375	p1.531
1	0.382	0.389	0.677	0.789	0.679	1.061	1.669	1.739
0.9	0.383	0.391	0.680	0.793	0.682	1.066	1.677	1.747
0.8	0.383	0.391	0.680	0.793	0.682	1.066	1.677	1.747
0.7	0.385	0.394	0.684	0.798	0.686	1.072	1.686	1.757
0.6	0.385	0.394	0.684	0.797	0.685	1.072	1.685	1.756
0.5	0.386	0.397	0.687	0.801	0.688	1.077	1.692	1.764
0.4	0.388	0.401	0.693	0.808	0.693	1.086	1.705	1.779
0.35	0.390	00404	0.697	0.812	0.696	1.093	1.620	1.687

For the **Volume Helical Shuttle** feature however, the opposite holds true. The system produces images beyond the actual start and end locations of the scan. Hence, to obtain the total coverage for this feature, multiply the mean detector coverage in one rotation times the total number of rotations.

DLP = $CTDI_{vol}$ x ((N x T) + R)

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source.

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

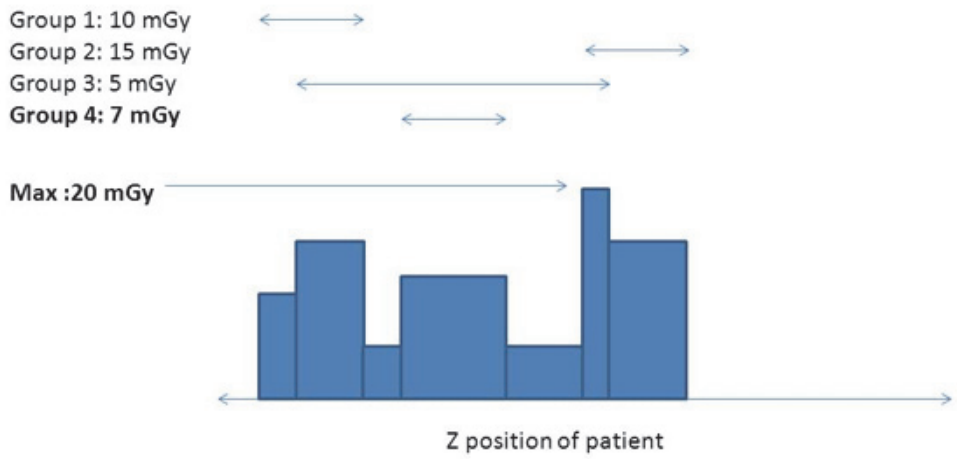
R is the distance between the two positions.

Max Z Location $CTDI_{vol}$

Max Z location $CTDI_{vol}$ represents the peak of the $CTDI_{vol}$ summation profile by table location. The $CTDI_{vol}$ values for each scan group are summed into the total profile for the range of *z* locations covered. Max Z location $CTDI_{vol}$ describes the maximum total exposure of any point along *z* of the patient. For example, the first group has a $CTDI_{vol}$ of 10mGy and 10mGy will be the max since it is the only exposure. A second group will contribute a $CTDI_{vol}$ of 15mGy to a different region. 15mGy will become the new max. A fourth group contributes 7 mGy, but only overlaps with one previous region. The max remains 20mGy. Max Z loc $CTDI_{vol}$ is displayed when Alert Value (AV) checking is enabled in Dose Check.

5805441-1EN Rev. 2 (Sep. 2020)

Figure 12-27 Max Z location CTDIvol and scan groups



Dose Efficiency (Reference IEC 60601-2-44: 2009 clause 201.3.213)

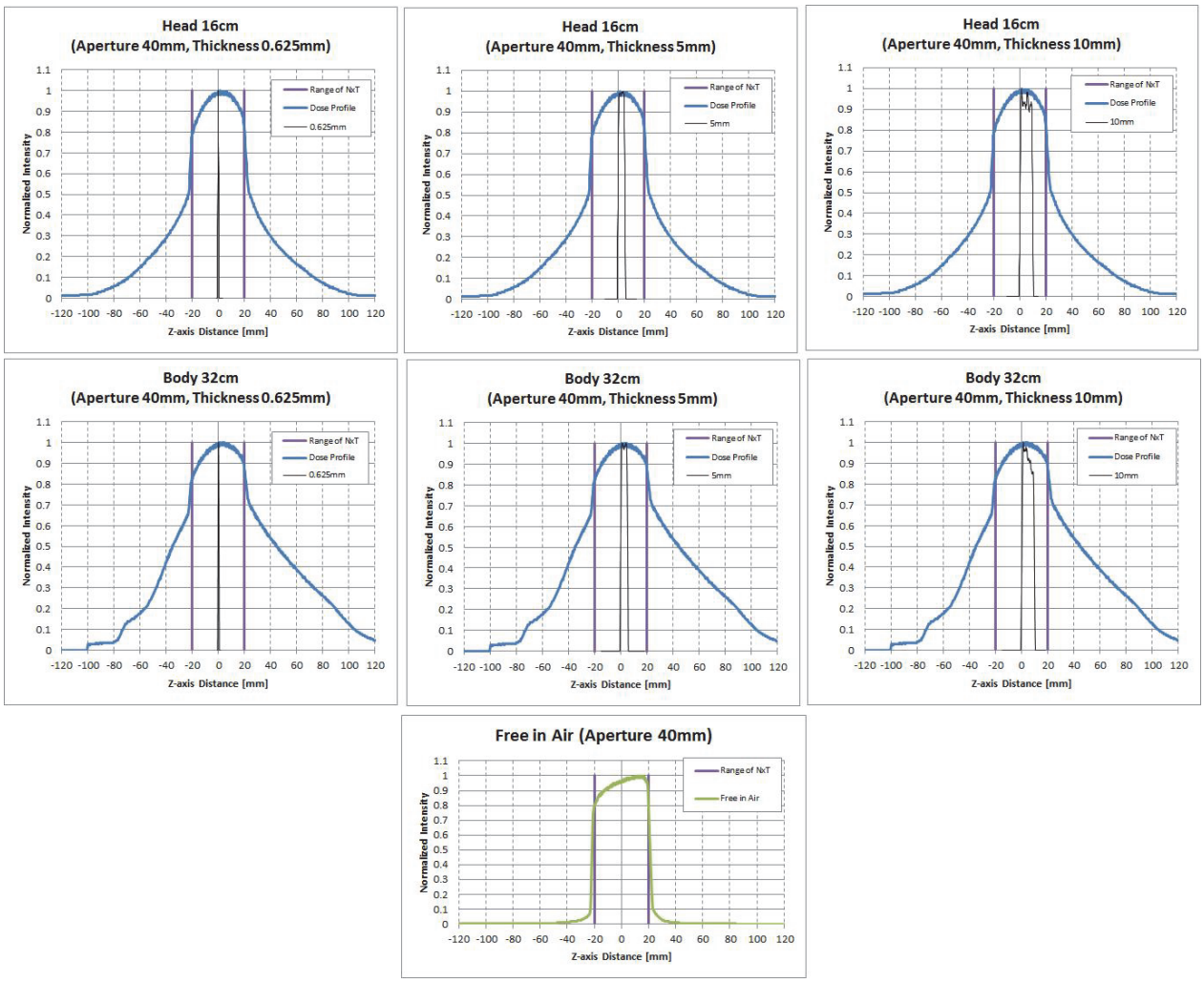
The dose efficiency, which is a function of focal spot size and beam collimation, is also automatically computed and displayed on the Scan Rx Menu. The dose efficiency is a measure of how much of the Z-axis X-ray beam is used by the system.

Dose Profile (Reference IEC 60601-2-44, IEC 60601-2-44: 2002 clause29.1.103.1/2, IEC60601-2-44:2009 clause 203.110/111, IEC60601-2-44:2009+A1:2012 clause 203.110/111 and 21CFR 1020.33(c)(2)(iv) and (c)(3)(iv))

The dose profile is the dose measured as a function of a line in the Z-Axis of the system. The dose profile, like the dose efficiency calculation is a function of focal spot size and beam collimation. The Full Width at Half Maximum (FWHM) measurements of the dose profiles in air represent the beam width at iso-center. The dose profile plots, along with the Detection Sensitivity Profiles (defined as the active detector length measured at iso-center) are represented in Figure 12-28 through Figure 12-29.

GE recommends use of Thermo luminescent dosimeters or solid-state dosimeters for the measurements of dose profiles. The measurements provided were taken with a solid state probe. The profiles have been intentionally made symmetric to remove any variations due to the measurement system.

Figure 12-28 40mm Aperture: CTDI free air, Dose Phantom and Sensitivity Profile



5805441-1EN Rev. 2 (Sep. 2020)

Figure 12-29 20mm Aperture: CTDI free air, Dose Phantom and Sensitivity Profile

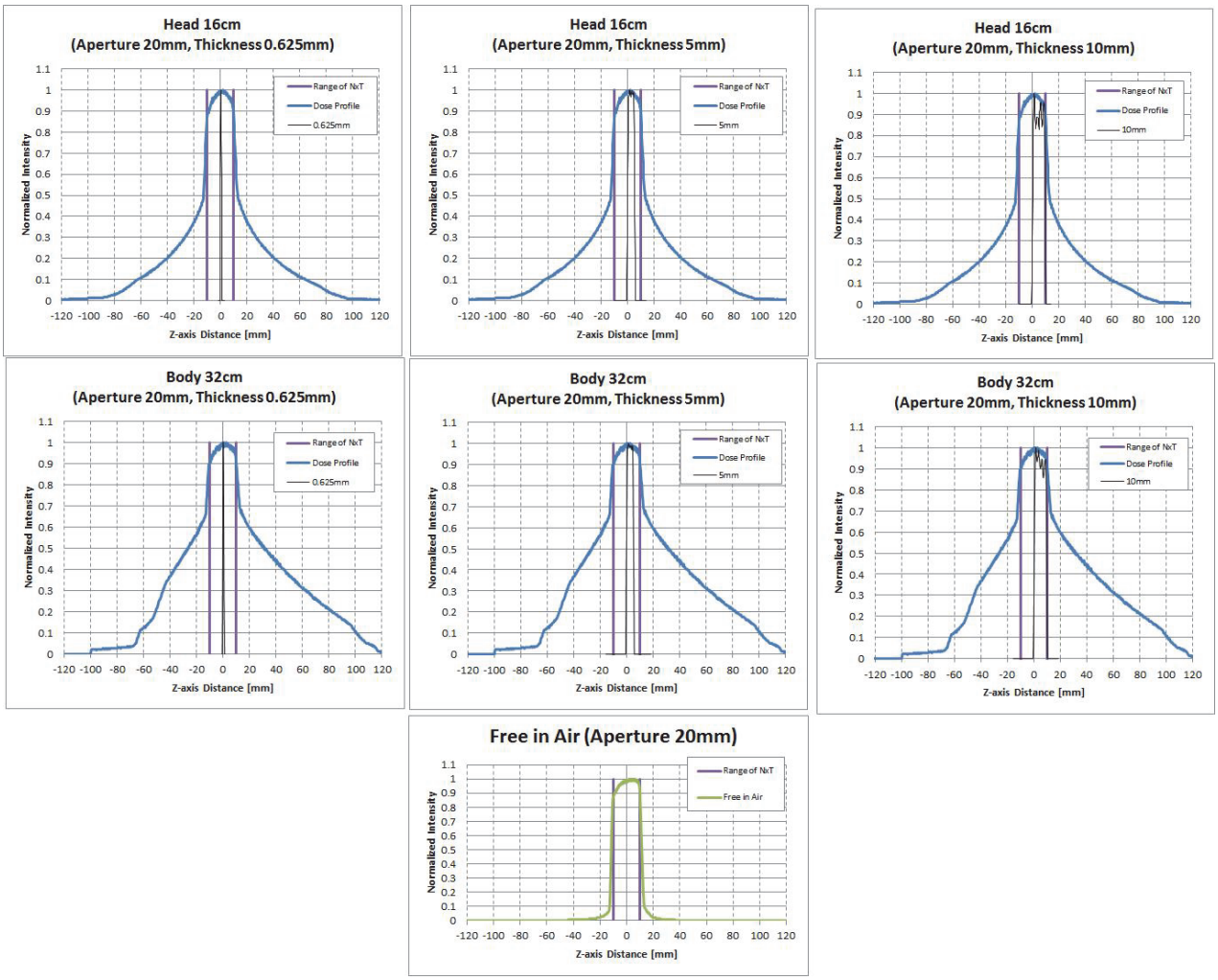
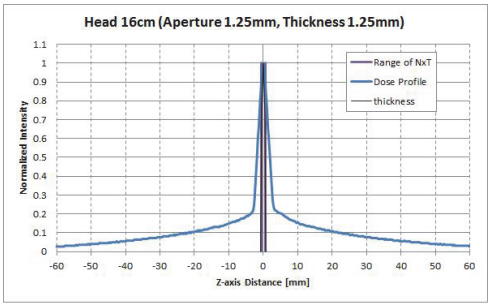
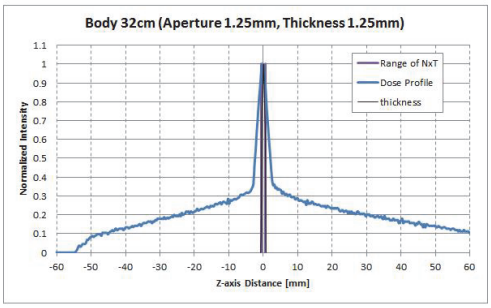
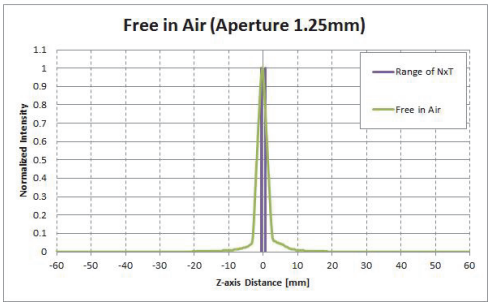


Figure 12-30 1.25mm Aperture: CTDI free air, Dose Phantom and Sensitivity Profile







5805441-1EN Rev. 2 (Sep. 2020)

Table 12-31 Dose Profile in Air Full Width at Half Maximum (FWHM)

Dose Profile Full Width at Half Maximum (FWHM in mm)		
Aperture (mm)	Small Focal Spot	Large Focal Spot
1.25	3.1	3.3
2.50	4.4	4.5
5.00	7.9	8.3
10.00	13.1	13.4
20.00	22.7	23.1
40.00	42.7	43.4

Table 12-32 Geometric Efficiency Table (Reference: IEC60601-2-44:2009 Clause203.113))

Geometric Efficiency (%)		
Aperature	**Focal Spot Size**	
	Small	**Large**
1.25	45.93	43.82
2.5	61.49	59.57
5	70.93	60.76
10	82.43	76.25
20	92.70	89.31
40	95.61	94.94

Dose Deterministic Effects (IEC 60601-2-44:2009 Clause 203.5.2.4.5)

There is the possibility that in normal use, the patient could be exposed to radiation dose levels of 1Gy $CTDI_{100}$ (peripheral) or above, at which deterministic effects may occur. Management of the high radiation dose is critical to maintain radiation safety. The available settings concerning the radiation dose level include: mA, kV, scan time, Aperture, SFOV, etc.

The table below provides the scan duration (seconds (s)) required to meet 1Gy $CTDI_{100}$ (peripheral) at 200 mA exposure at same scan location.

Table 12-33 Dose Deterministic Effects (IEC 60601-2-44:2009 Clause 203.5.2.4.5)

Cine scan duration at 200 mA required to meet 1Gy $CTDI_{100}$ Peripheral											
SFOV		Pediatric Head		Head		Pediatric Body		Small Body		Large Body	
CTDI Phantom		16cm		16cm		32cm		32cm		32cm	
kV	Aperture (mm)	Small Focal Spot	Large Focal Spot	Small Focal Spot	Large Focal Spot	Small Focal Spot	Large Focal Spot	Small Focal Spot	Large Focal Spot	Small Focal Spot	Large Focal Spot
80	40	84	84	84	84	196	196	196	196	181	181
	20	79	79	79	79	183	183	183	183	170	169
	10	69	69	69	69	161	161	161	161	149	149
	5	59	59	59	59	138	138	138	138	128	128
	2.5	49	49	49	49	114	114	114	114	106	106
	1.25	34	34	34	34	80	79	80	79	73	73
100	40	46	46	46	46	103	103	103	103	92	92
	20	43	42	43	42	96	95	96	95	86	85
	10	38	36	38	36	84	81	84	81	76	73
	5	32	29	32	29	72	65	72	65	65	58
	2.5	27	26	27	26	60	58	60	58	54	52
	1.25	18	18	18	18	42	41	42	41	37	37
120	40	29	29	29	29	65	65	65	65	57	57
	20	27	27	27	27	61	60	61	60	53	53
	10	24	23	24	23	53	51	53	51	47	45
	5	21	18	21	18	46	41	46	41	40	36
	2.5	17	17	17	17	38	37	38	37	33	32
	1.25	12	12	12	12	26	26	26	26	23	23
140	40	21	21	21	21	46	46	46	46	39	39
	20	19	19	19	19	43	42	43	42	36	36
	10	17	16	17	16	37	36	37	36	32	31
	5	14	13	14	13	32	29	32	29	27	24
	2.5	12	12	12	12	27	26	27	26	23	22
	1.25	8	8	8	8	18	18	18	18	16	15

Scout Dose

Generally, because of short scan times and low mA, the scout dose will be a small part of the total patient exam dose, additionally a standardized scout dose calculation method has yet to be developed for CT, therefore scout dose is not currently reported by the system.

5805441-1EN Rev. 2 (Sep. 2020)

Noise

Reference 21CFR 1020.33 (c)(3)(i))

Noise is the statistical measure of the CT numbers represented by an array of pixels contained in a 2x2cm central region of interest (ROI). Noise equals the standard deviation expressed in Hounsfield units, divided by 1000 to represent the contrast scale between air and water, and then multiplied by 100 to give a value in percent.

Phantom Used

(Reference 21 CFR 1020.33 (c)(3)(v))

For head scanning, an outsider diameter of 20cm cylindrical water phantom, such as GE Quality Assurance (QA) phantom should be used. For body scanning, an outsider diameter of 30cm to 35cm cylindrical water phantom should be used. It is recommended to use 35cm Polyethylene phantom in body scanning technique. A 35cm diameter Polyethylene phantom may be obtained through GE.

Procedure

(Reference 21CFR 1020.33 (c)(3)(v))

The image Standard Deviation in the center is acquired with Typical Technique and Standard 512 Reconstruction at 5mm, 8i acquisition mode.

Typical Noise

Table 12-34 Image Noise

Scan FOV	Phantom	kV	mA	Standard Deviation (%)
Head: Head SFOV, 25cm DFOV	QA Phantom	120	260	0.43
Body: Large Body SFOV, 35cm DFOV	35cm poly phantom	120	260	1.4

Nominal Slice Thickness and Sensitivity Profile

(Reference 21CFR 1020.33 (c)(3)(iii) and (c)(3)(iv)

Phantom Used

(Reference 21 CFR 1020.33 (c)(3)(v))

The sensitivity profile is a graph of the axial thickness of an image. To create the original measurements for Axial or Cine scans, scan a Slope Wire Phantom centered at ISO, which consists of two rows of 0.05mm tungsten wires in air that make 14.04 degree (°) angles with

the scan plane (slope 4:1). FWHM values reported are averaged ones of all the wires across all the images in the acquisition. For Helical scans, the slice sensitivity profile is measured by taking scans of a Gold Foil Phantom made by QRM, model # QRM-SSP-07, with the smallest image reconstruction intervals available. The gold foil (1 mm diameter x 0.025 mm thickness) embedded in tissue equivalent plastic is used to provide simulated point spread function in the axial direction.

Procedure

(Reference 21CFR 1020.33 (c)(3)(v))

Same conditions as Noise (see Table 12-35) except slice thickness.

The Slice Thickness and Sensitivity Profile are acquired with Typical Technique and Standard 512 reconstruction at each slice thickness and acquisition mode.

Typical Nominal Slice Thickness

Table 12-35 Nominal Slice Thickness - Axial Scan Modes (FWHM in mm) (Reference YY0310)

Slice Sensitivity Profile (SSP) Full Width at Half Maximum (FWHM in mm) Axial Scans					
Aperture (mm)	Selected Slice Thickness				
	0.625	1.25	2.50	5.00	10.0
40.00	*1 0.742	0.980	2.350	5.373	9.560
20.00	0.609	1.028	2.323	5.226	9.450
10.00	0.513	1.113	2.404	4.836	9.730
5.00	N/A	1.102	2.387	4.805	N/A
2.50	N/A	1.092	2.388	N/A	N/A
1.25	N/A	1.085	N/A	N/A	N/A

*1 64 slice system only.

5805441-1EN Rev. 2 (Sep. 2020)

Table 12-36 Nominal Slice Thickness - Helical Scan Modes (FWHM in mm) (Reference YY0310)

Slice Sensitivity Profile (SSP) Full Width at Half Maximum (FWHM in mm) - HELICAL SCANS							
Aperture & Helical Pitch	**Selected Slice Thickness & Reconstruction Mode**						
	Full Mode						
	0.625	**1.25**	**2.50**	**3.75**	**5.00**	**7.5**	**10.0**
40.00, 0.516:1	0.66	1.09	2.22	3.53	4.84	7.23	9.68
20.00, 0.531:1	0.68	1.12	2.23	3.57	5.03	7.28	9.71
	Plus Mode						
	0.625	**1.25**	**2.50**	**3.75**	**5.00**	**7.5**	**10.0**
40.00, 0.516:1	1.00	1.37	2.74	4.09	5.70	7.51	10.00
20.00, 0.531:1	1.02	1.40	2.76	4.23	6.00	7.52	10.00
	Full Mode						
	0.625	**1.25**	**2.50**	**3.75**	**5.00**	**7.5**	**10.0**
40.00, 0.984:1	N/A	1.10	2.34	3.93	5.08	7.37	9.82
20.00, 0.969:1	N/A	1.12	2.34	3.80	5.00	7.34	9.82
	Plus Mode						
	0.625	**1.25**	**2.50**	**3.75**	**5.00**	**7.5**	**10.0**
40.00, 0.984:1	0.96	1.38	2.98	4.62	5.89	7.51	9.99
20.00, 0.969:1	0.98	1.39	2.95	4.51	6.01	7.54	10.03
	Full Mode						
	0.625	**1.25**	**2.50**	**3.75**	**5.00**	**7.5**	**10.0**
40.00, 1.375:1	N/A	1.16	2.32	3.81	5.26	7.33	9.80
20.00, 1.375:1	N/A	1.14	2.35	3.85	5.08	7.37	9.79
	Plus Mode						
	0.625	**1.25**	**2.50**	**3.75**	**5.00**	**7.5**	**10.0**
40.00, 1.375:1	1.00	1.44	2.76	4.53	6.11	7.50	10.00
20.00, 1.375:1	0.99	1.44	2.80	4.53	5.92	7.51	9.99
	Full Mode						
	0.625	**1.25**	**2.50**	**3.75**	**5.00**	**7.5**	**10.0**
40.00, 1.531:1	N/A	1.27	2.50	3.81	5.08	7.42	9.52
20.00, 1.531:1	N/A	1.24	2.50	3.68	4.99	7.35	9.59
	Plus Mode						
	0.625	**1.25**	**2.50**	**3.75**	**5.00**	**7.5**	**10.0**
40.00, 1.531:1	1.01	1.50	3.03	4.55	5.71	7.51	9.82
20.00, 1.531:1	0.96	1.49	3.05	4.50	5.84	7.45	9.98

Table 12-37 Nominal Slice Thickness 64 Slice- Cardiac Scan Modes (FWHM in mm)

Slice Sensitivity Profile (SSP) Full Width at Half Maximum (FWHM in mm) - CARDIAC HELICAL SCANS				
Aperture (mm)	Selected Slice Thickness & Reconstruction Mode 64 Slice System			
	Segment (60 BPM, 0.22:1 pitch)			
40.00	**0.625**	**1.25**	**2.50**	**3.75 to 10.0**
	0.84	1.08	2.28	N/A
Burst (90 BMP, 0.22:1 pitch)				
40.00	**0.625**	**1.25**	**2.50**	**3.75 to 10.0**
	0.84	1.05	2.26	N/A
Burst Plus (135 BPM, 0.20:1 pitch)				
40.00	**0.625**	**1.25**	**2.50**	**3.75 to 10.0**
	0.84	1.08	2.31	N/A

Modulation Transfer Function (MTF)

(Reference 21CFR 1020.33 (c) (3) (ii))

An MTF of 100% or 1.0 indicates no signal loss. An MTF of 0.0 indicates total signal loss. In practice, small, high contrast objects become impossible to resolve when MTF reaches the 0.05 – 0.02 range.

Phantom Used

(Reference 21 CFR 1020.33 (c)(3)(v))

GE Performance phantom has a 0.05mm diameter tungsten wire perpendicular to the imaging plane. This phantom can be used to evaluate the system Modulation Transfer Function (MTF) combined with an automated software tool implemented in the GE system.

Procedure

(Reference 21CFR 1020.33 (c)(3)(v))

Same conditions as Noise (see Table 12-35) except DFOV.

The MTF data is acquired with Typical Technique, 25cm DFOV and Standard 512 Reconstruction at 5mm, 8i acquisition mode using Standard reconstruction algorithm.

5805441-1EN Rev. 2 (Sep. 2020)

Typical Modulation Transfer Function (MTF)

Figure 12-31 Typical MTF Curve (Reference: IEC60601-2-44:2009 Clause203.6.7.2b), Clause203.110, 21CFR 1020.33 (c)(3)(iii))

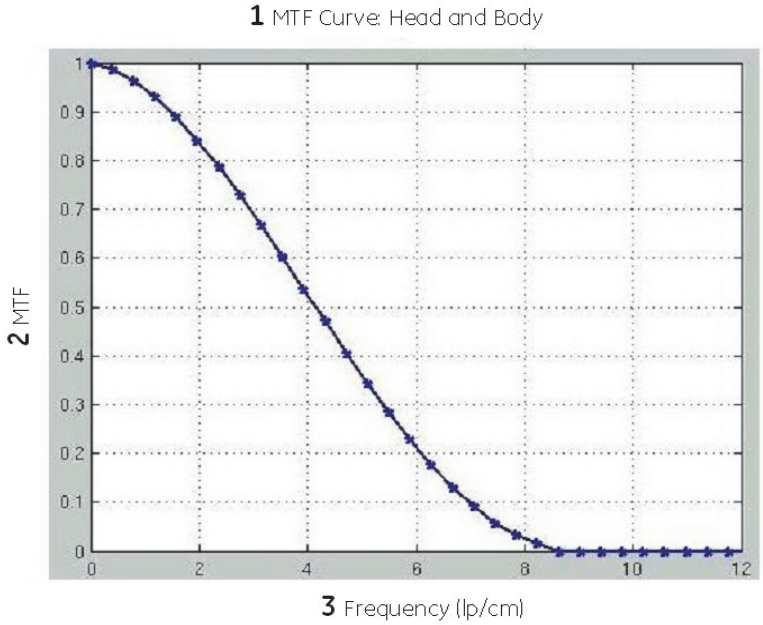


Table 12-38 MTF Curve

Number	Description
1	MTF Curve: Head and Body
2	MTF
3	Frequency (lp/cm)

Maximum Deviation

(Reference IEC 60601-2-44 and 21CFR 1020.33 (c))

In order to come up with “the maximum deviation,” manufacturers must imagine every possible situation, however unlikely, that might occur within the entire user community.

Our statements of deviation include a maximum deviation to assure compliance with the regulation, as well as a statement of expected deviations (2s) in the large majority of our systems.

GE bases the expected deviations on the results of extensive multiple system testing.

Typical Dose (Reference 21CFR 1020.33 (c)(2)(v))

Deviations may be greater than the expected deviation range for low mA or narrow aperture scans where variation may be greater (up to a factor of two) due to the inherent deviation in small values.

Expected deviation equals ±15% with a maximum deviation anticipated for tube output equals ± 40%.

Dose Profile (Reference 21CFR 1020.33 (c)(2)(v))

The maximum deviation relating to dose profiles (FWHM or Full Width at Half Maximum) should equal ± 30% or 1.5mm, whichever is larger.

This value includes variability inherent in the measurement of dose profile with solid state dosimeters. The expected deviation equals ± 10% or 0.5mm, whichever is larger.

Performance (Reference 21CFR 1020.33 (c)(3)(v))

Noise

The noise squared (σ^2) in a CT image is inversely proportional to the X-Ray dose.

The maximum deviation equals ± 15%.

MTF

With the protocol used to generate the data reported here, expected deviations for values on the MTF curve: ± 10%.

Maximum deviations may reach ± 20%.

Slice Thickness and Sensitivity Profile

With the protocol used to generate the data reported here, the slice sensitivity profiles (FWHM) may vary ± 10% or 0.5mm whichever is larger.

In the case of cardiac exams, a larger variation could be observed due to the inherent nature of the cardiac reconstruction (half - scan).

With other methods, the maximum deviation may reach 1.5mm for all thicknesses; thin slices are most affected by these measurement errors.

Frequency of constancy tests (Refer to Section 4.7 of IEC 61223-2-6)

The constancy tests shall be repeated as indicated for the individual test methods.

5805441-1EN Rev. 2 (Sep. 2020)

However, the frequency of each constancy test may be reduced if the system under test proves to be within tolerance for a period of 6 months. In this case the dose measurement may be repeated annually; all other tests may be done quarterly.

In addition, the constancy tests should be repeated:

- Whenever malfunction is suspected; or
- Immediately after the CT scanner undergone maintenance that could affect the performance parameter under test;
- Whenever the constancy test leads to results outside the established criteria, to confirm the test result.

Radiation Protection

A qualified radiological health physicist should review scan room shielding requirements.

Consider equipment placement, weekly projected workloads, and materials used for construction of walls, floors, ceiling, doors and windows.

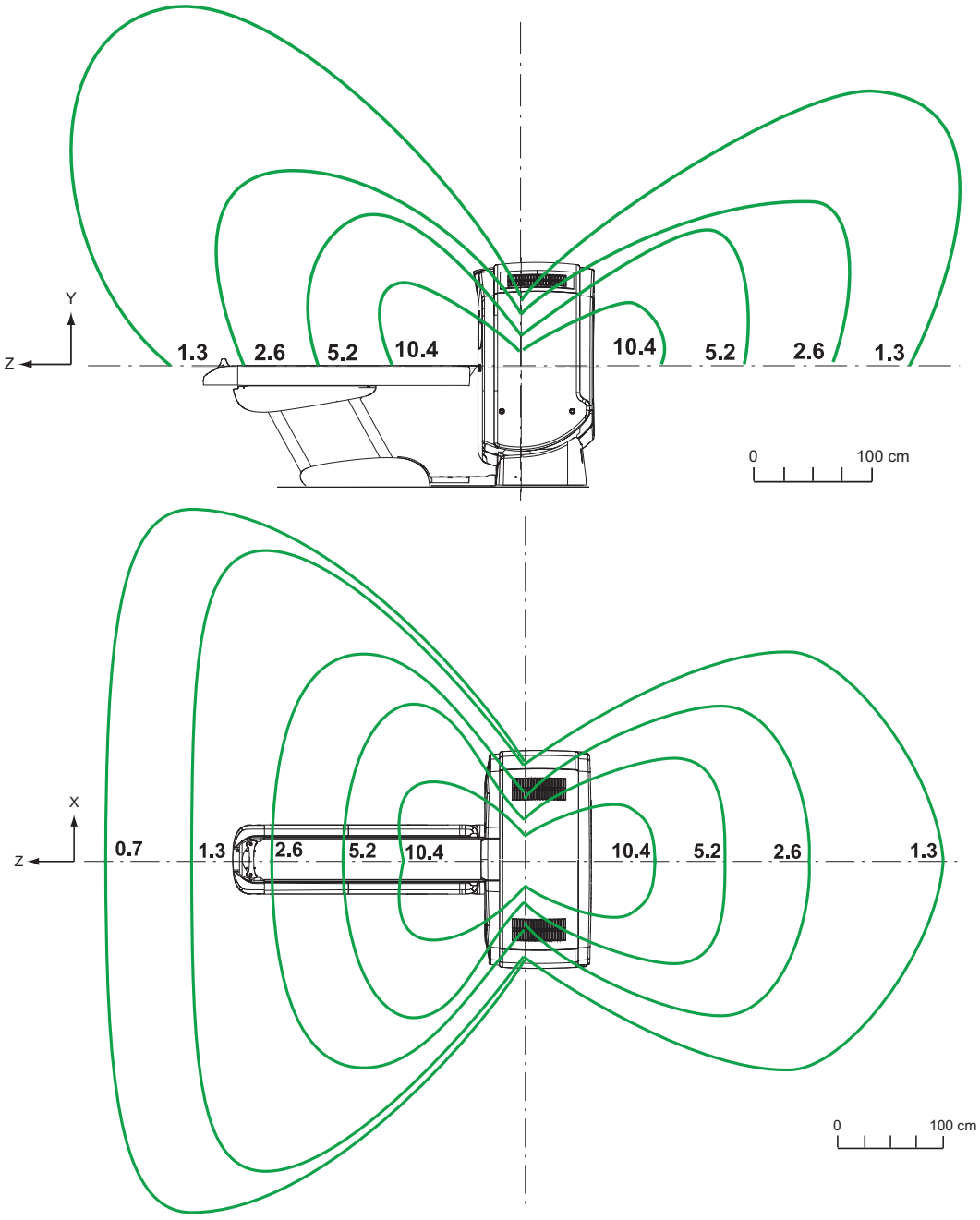
The following scatter radiation illustrations depict measurable radiation levels within the scan room while scanning a 32cm CTDI body phantom (body).

Stray Radiation (Scatter Radiation) (Reference: IEC60601-2-44:2009 Clause203.11, Clause203.13.2)

Typical Scatter Survey (Large Filter (Body) - Phantom 32cm CTDI)

NOTE: The 32 cm CTDI Phantom should be placed on the patient table.

Figure 12-32 ISO- Contour 1.3, 2.6, 5.2, and 10.4 μGray/scan Technique 140 kV, 100 mA, 1 second (s), 40 mm)



5805441-1EN Rev. 2 (Sep. 2020)

Table 12-39 Typical Scatter Survey (Large Filter (Body) - Phantom 32cm CTDI)

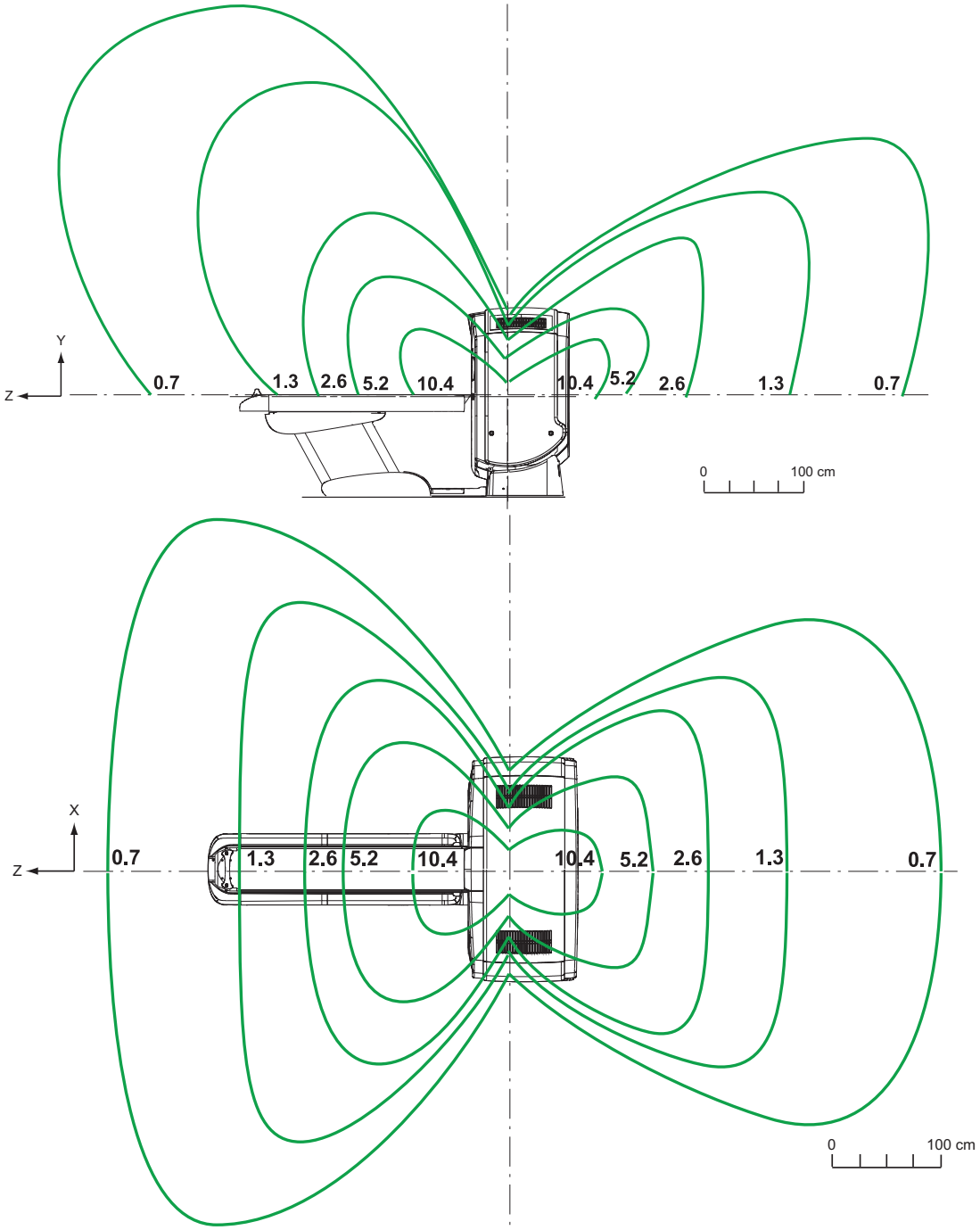
μGray/scan (Vertical) Z-Axis (m)														
Y-Axis (m)	**F3.0**	**F2.5**	**F2.0**	**F1.5**	**F1.0**	**F0.5**	**0**	**R0.5**	**R1.0**	**R1.5**	**R2.0**	**R2.5**	**R3.0**	
	1.6	2.1	2.8	3.8	2.6	1.1	-	0.2	0.3	2.5	3.5	2.5	1.9	**U1.5**
	1.7	2.3	3.5	5.1	8.3	3.5	-	0.3	2.8	6.4	4.2	2.9	2.0	**U1.0**
	1.7	2.8	3.9	7.3	15.1	27.9	-	-	16.0	7.8	4.7	3.0	2.1	**U0.5**
	1.5	2.1	4.3	7.3	16.9	65.4	ISO	67.3	19.2	8.5	4.6	2.9	2.0	**0**
	0.1	0.1	-	-	6.4	30.7	-	27.4	14.7	7.3	4.2	2.8	2.0	**L0.5**

μGray/scan (Horizontal) X-Axis (m)														
Z-Axis (m)	**-3.0**	**-2.5**	**-2.0**	**-1.5**	**-1.0**	**-0.5**	**0**	**0.5**	**1.0**	**1.5**	**2.0**	**2.5**	**3.0**	
	1.0	1.2	1.3	1.6	1.5	1.5	1.5	1.5	1.5	1.6	1.3	1.2	1.0	**F3.0**
	1.3	1.4	1.8	1.9	2.4	2.2	2.1	2.2	2.4	1.9	1.8	1.4	1.3	**F2.5**
	0.9	1.9	2.2	3.0	3.2	3.5	4.3	3.5	3.2	3.0	2.2	1.9	0.9	**F2.0**
	0.7	1.2	2.8	4.0	5.8	6.4	7.3	6.4	5.8	4.0	2.8	1.2	0.7	**F1.5**
	0.3	0.5	1.5	4.7	9.1	14.0	16.9	14.0	9.1	4.7	1.5	0.5	0.3	**F1.0**
	0.2	0.2	0.5	0.7	6.2	39.2	65.4	39.2	6.2	0.7	0.5	0.2	0.2	**F0.5**
	0.1	0.1	0.2	0.2	-	-	ISO	-	-	0.2	0.2	0.1	0.1	**0**
	0.1	0.1	0.1	0.2	-	-	67.3	-	-	0.2	0.1	0.1	0.1	**R0.5**
	0.1	0.1	0.2	0.3	3.4	16.7	19.1	16.7	3.4	0.3	0.2	0.1	0.1	**R1.0**
	0.1	0.2	0.3	1.6	6.3	7.6	8.5	7.6	6.3	1.6	0.3	0.2	0.1	**R1.5**
	0.2	0.3	0.9	2.7	3.8	4.5	4.6	4.5	3.8	2.7	0.9	0.3	0.2	**R2.0**
	0.3	0.6	1.4	2.3	2.7	2.9	2.9	2.9	2.7	2.3	1.4	0.6	0.3	**R2.5**
	0.5	0.9	1.5	1.7	1.9	2.0	2.0	2.0	1.9	1.7	1.5	0.9	0.5	**R3.0**

Typical Scatter Survey (Small Filter (Head) - Phantom 16cm CTDI)

NOTE: The 16 cm CTDI Phantom should be placed on the patient table.

Figure 12-33 ISO- Contour 0.7, 1.3, 2.6, and 5.2 μGray/scan Technique 140 kV, 100 mA, 1 second (s), 40 mm



5805441-1EN Rev. 2 (Sep. 2020)

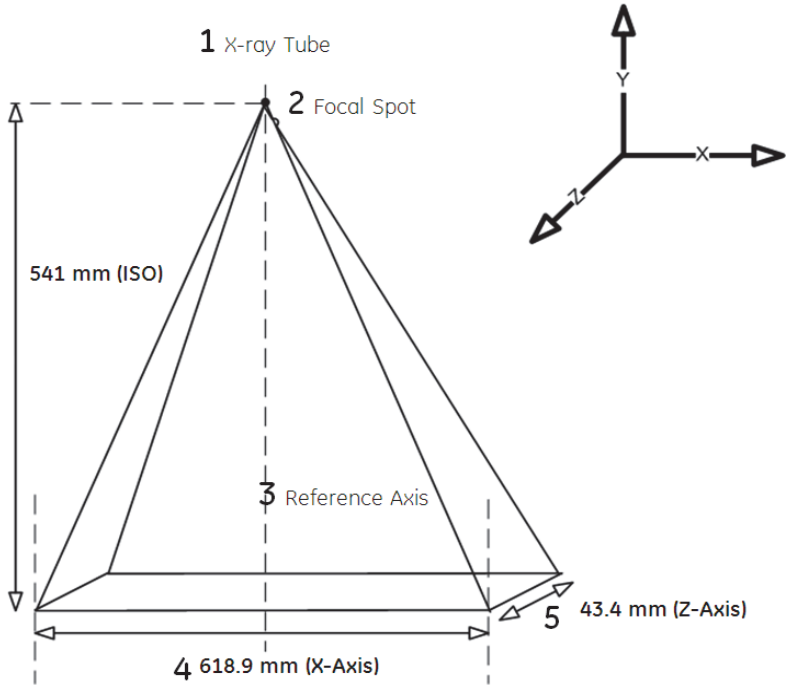
Table 12-40 Typical Scatter Survey (Small Filter (Head) - 16cm CTDI)

μGray/scan (Vertical) Z-Axis (m)														
Y-Axis (m)	**F3.0**	**F2.5**	**F2.0**	**F1.5**	**F1.0**	**F0.5**	**0**	**R0.5**	**R1.0**	**R1.5**	**R2.0**	**R2.5**	**R3.0**	
	1.3	1.6	2.3	3.4	2.9	1.5	-	0.2	0.2	1.1	2.2	1.6	1.1	**U1.5**
	1.3	1.8	2.6	4.2	7.1	3.1	-	0.2	1.9	4.2	2.6	1.7	1.3	**U1.0**
	1.3	1.7	2.8	5.0	11.5	30.8	-	-	10.9	5.0	2.6	1.6	1.1	**U0.5**
	1.1	0.7	2.3	4.0	9.9	51.0	ISO	42.3	10.0	4.4	2.4	1.5	1.0	**0**
	0.1	0.1	-	-	7.7	29.2	-	20.3	9.2	4.2	2.4	1.6	1.1	**L0.5**

μGray/scan X-Axis (m)														
Z-Axis (m)	**-3.0**	**-2.5**	**-2.0**	**-1.5**	**-1.0**	**-0.5**	**0**	**0.5**	**1.0**	**1.5**	**2.0**	**2.5**	**3.0**	
	0.7	0.8	0.9	0.9	0.9	0.9	1.1	0.9	0.9	0.9	0.9	0.8	0.7	**F3.0**
	0.8	1.0	1.2	1.3	1.3	1.3	0.7	1.3	1.3	1.3	1.2	1.0	0.8	**F2.5**
	0.9	1.3	1.6	1.9	2.1	2.2	2.3	2.2	2.1	1.9	1.6	1.3	0.9	**F2.0**
	0.6	1.1	2.1	2.9	3.6	3.9	4.0	3.9	3.6	2.9	2.1	1.1	0.6	**F1.5**
	0.2	0.4	1.3	4.0	6.8	8.9	9.9	8.9	6.8	4.0	1.3	0.4	0.2	**F1.0**
	0.2	0.2	0.5	0.6	5.2	31.6	51.0	31.6	5.2	0.6	0.5	0.2	0.2	**F0.5**
	0.1	0.1	0.1	0.2	-	-	ISO	-	-	0.2	0.1	0.1	0.1	**0**
	0.1	0.1	0.1	0.1	-	-	42.3	-	-	0.1	0.1	0.1	0.1	**R0.5**
	0.1	0.1	0.1	0.3	2.2	9.8	10.0	9.8	2.2	0.3	0.1	0.1	0.1	**R1.0**
	0.1	0.1	0.3	1.1	3.6	4.4	4.4	4.4	3.6	1.1	0.3	0.1	0.1	**R1.5**
	0.1	0.2	0.6	1.8	2.3	2.5	2.4	2.5	2.3	1.8	0.6	0.2	0.1	**R2.0**
	0.2	0.4	1.0	1.3	1.5	1.5	1.5	1.5	1.5	1.3	1.0	0.4	0.2	**R2.5**
	0.3	0.6	0.8	1.0	1.0	1.0	10.0	1.0	1.0	1.0	0.8	0.6	0.3	**R3.0**

Radiation Field

Figure 12-34 Maximum Symmetrical Radiation Field



- Focal Spot Position and Tolerance -- “X” axis ± 0.25 mm
- Focal Spot Position and Tolerance -- “Z” axis ± 0.81 mm

Table 12-41 Maximum Symmetrical Radiation Field

Number	Description
1	X-Ray Tube
2	Focal Spot
3	Reference Axis
4	618.9 mm (X-Axis)
5	43.4 mm (Z-Axis)

5805441-1EN Rev. 2 (Sep. 2020)

Other Dosimetry Information (Organization of Dose information in User Manual) (Reference NEMA XR 28-2013 Section 2.6)

Simulating the Surface of Humanoid Phantom

Because the CTDI is an averaged dose to a homogeneous cylindrical phantom, the measurements are only an approximation of patient dose. Another limitation is that CTDI overestimates dose for scans where the patient table is not incremented, such as in interventional and perfusion CT. For these CT applications, the CTDI can overestimate peak dose by a factor of two.

Technical Reference Manual Dose Related Information

Table 12-42 TRM Dose Related Information

Chapter (TRM)	Title
3	$CTDI_{vol}$
11	Pediatric Imaging, AutomA, AutomA Theory, AutomA FAQs
12	DOSIMETRY Dose Profile Rradiation Protection Radiation Field
13	Dose
17	Dose Performance

User Manual Dose Related Information

Table 12-43 User Manual Dose Related Information

Chapter (User Manual)	Title
4	Pediatrics and small patients
10	Scan Scan parameters (AutomA) Optimize patient dose View the Dose Report
11	Scan applications ASiR-V/ASiR

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 13

Requirements for providing image for Radiotherapy Treatment Planning (RTP)

Introduction

Read and study this addendum to Installation and Setup Manual which is shipped with the DIACOR Flat Table Top before using this system to create images for Radiotherapy Treatment Planning.

Alignment of the top of the PATIENT SUPPORT (IEC60601-2-44: 2012 Clause 201.101.2)

Alignment of the PATIENT SUPPORT in the vertical plane (tilt)

After installing Flat Table Top, measure the longitudinal horizontal (level) of the top surface of Flat Table Top on the retracted top of the PATIENT SUPPORT, without load using a level gauge.

The flat table top must be level within ±0.5º.

If horizontal (level) is more than ±0.5º, please refer to the manual which comes with DIACOR Flat Table Top for the details and contact your service representative to perform the adjustment.

Alignment of the PATIENT SUPPORT in the horizontal plane

The axis of the horizontal movement of the top of the PATIENT SUPPORT to be perpendicular to the x-axis of the TOMOGRAPHIC PLANE.

a) After installing Flat Table Top, install "Locking Bar". Execute scout scan for "locking Bar" and observe the image on Exam Desktop.

b) Measure the coordinates of the point at the intersection of "Locking Bar" edge and Flat Table Top edge (Point A) on the one side per Figure 13-1.

c) Measure the coordinates of the point at the intersection of "Locking Bar" edge and Flat Table Top edge (Point B) on another side per Figure 13-2.
Calculate the angle (X) per the followings:

$$X_{(degrees)} = \tan^{-1}\left(\frac{Y_b - Y_a}{X_b - X_a}\right) \times \frac{180}{\pi}$$

X_a and Y_a are the coordinates of Point A, X_b and Y_b are the coordinates of Point B.

(Example for Figure 13-1 and Figure 13-2)

$$X_{(degrees)} = \tan^{-1}\left(\frac{875.90 - 875.60}{252.30 - (-249.7)}\right) \times \frac{180}{\pi}$$

$$= 0.03$$

5805441-1EN Rev. 2 (Sep. 2020)

Figure 13-1 Point A measurement

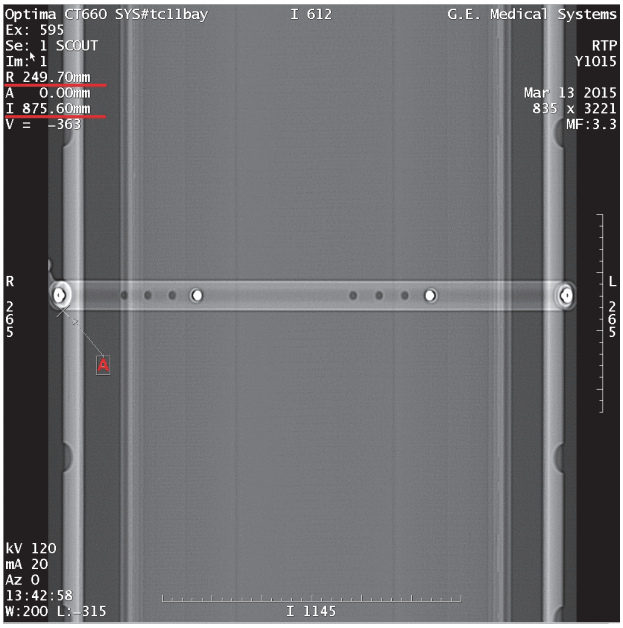
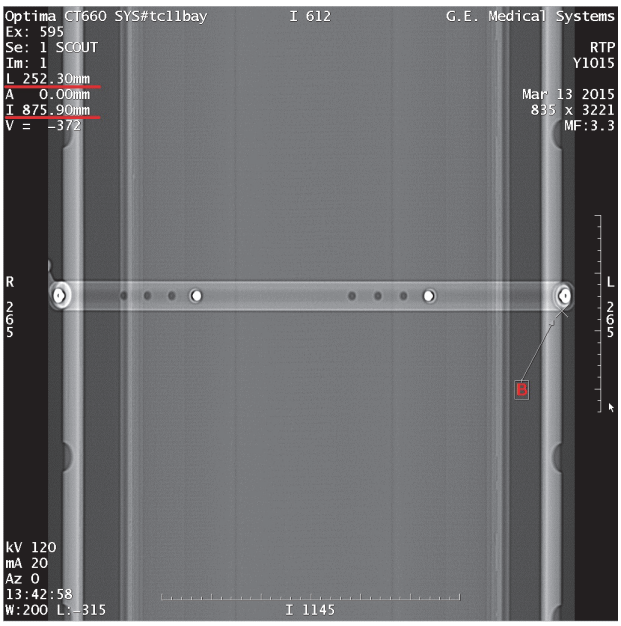


Figure 13-2 Point B measurement



d) If the angle (X) is more than ±1°, please refer to the manual which comes with DIACOR Flat Table Top for the details and contact your service representative to perform the adjustment.

The difference between the center of the top of the PATIENT SUPPORT and the sagittal light marker.

Test Equipment and Accessory Tools

- QA Device tool / CIVCO MT-TG66
- Ruler

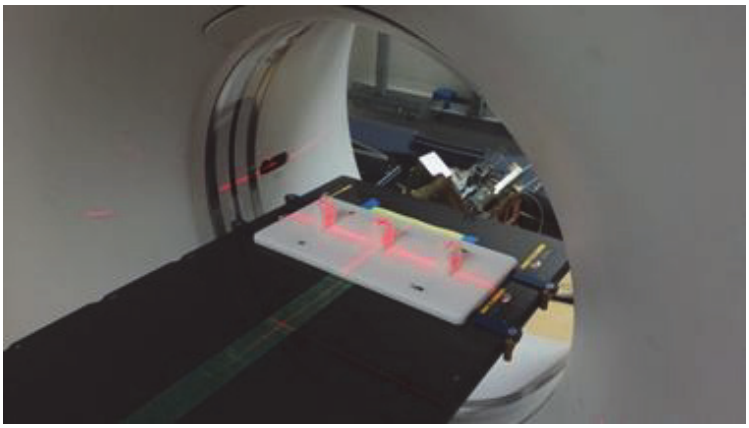
a) After installing the Flat Table Top, align two "Locking Bar" on the Flat Table Top. One is at H4 position and another is at H3 position.

b) Install the QA device on the locking bars, according to the QA device installation manual.

c) Make sure that the QA device clings to the surface of the Flat Table Top.

d) Move cradle into the gantry bore to align the internal axial laser with the cross target that is on the top of middle leg. See Figure 13-3.

Figure 13-3 QA device at H3 and H4 positions



e) Set this position of cradle to be 0mm along longitudinal direction by press the  button on the gantry panel.

f) Measure the difference (d1 =X.Xmm) between an external sagital laser (not Gantry laser) and the sagittal line on the top of middle leg with using a ruler.

g) Remove the QA device and two "Locking Bar" and re-align two "Locking Bar" on the Flat Table Top. One is at F4 position and another is at F5 position.

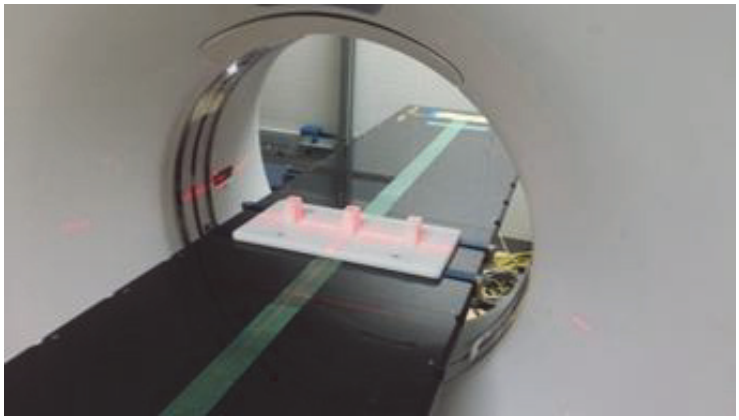
h) Install the QA device on the locking bars, according to the QA device installation manual.

i) Make sure that the QA device clings to the surface of Flat Table Top.

j) Move the cradle into the gantry bore to align the internal axial laser with the cross target that is on the top of middle leg. See Figure 13-4.

5805441-1EN Rev. 2 (Sep. 2020)

Figure 13-4 QA device at F4 and F5 positions



k) Read and record this longitudinal position from Gantry Extreme display.

l) Verify that longitudinal position exceeds 1,000mm.

m) Measure the difference (d2 =X.Xmm) between an external sagital laser (not Gantry laser) and the sagittal line on the top of middle leg with using a ruler.

– If the sagittal light marker does not extend to the internal axial laser (the scan plane), the measurement for d1 and d2 shall be taken at the external.

– If d1 or d2 exceed 2mm, please refer to the manual which comes with DIACOR Flat Table Top for the details and contact your service representative to perform the adjustment.

Top of the PATIENT SUPPORT (IEC60601-2-44: 2012 Clause 201.101.3)

DIACOR Flat Table Top is available as a GE Authorized accessory. Refer to the GE Approved Accessories list in the Safety chapter.

Table sag (stiffness of the PATIENT SUPPORT) (IEC60601-2-44: 2012 Clause 201.101.4)

Product Configuration		Differences in height (the sag) [mm]		
Table Type	**Flat Table Top**	**|Position2-Position1|**	**|Position3-Position2|**	**|Position4-Position3|**
VT1700V (500 Pounds (227 kg)) Table VT2000 (500 Pounds (227 kg) Long) Table VT2000x (675Pounds (306 kg) Long) Table	DIACOR FTT	3.0	3.0	4.0

Integral light markers for PATIENT marking (IEC60601-2-44: 2012 Clause 201.101.5)

A laser alignment light system is available in order to accurately define the patient scan region but not intended for purpose of patient marking for Radiotherapy Treatment Planning.

Radiotherapy Treatment Planning requires use of an External laser light system.

Typical scan mode to provide images for RTP (IEC60601-2-44: 2012 Clause 201.101.6)

CT images can be used for RTP typical operating conditions.

Head: Axial, 120kVp, 260mA, 1.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Head scan FOV, 25 cm display FOV and standard algorithm.

Body: Axial, 120kVp, 260mA, 1.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Large body scan FOV, 35 cm display FOV and standard algorithm.

GE Reference Protocols

The Advantage 4D in reference protocols is appropriate for Radiotherapy Treatment Planning. Other protocols are not appropriate for Radiotherapy Treatment Planning.

Noise, Mean CT Number and Uniformity with RTP characteristics are as follows:

Head: Axial, 120kVp, 260mA, 1.0 second(s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Head scan FOV, 25 cm display FOV and standard algorithm.

Body: Axial, 120kVp, 260mA, 1.0 second(s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Large body scan FOV, 35 cm display FOV and standard algorithm.

Table 13-1 Expected results for head and body scanning conditions

	Noise	Mean CT number	Uniformity
Head, QA phantom	<= 0.49% or <= 4.9 HU	0 +/- 3HU	0 +/- 3HU
Body, 35cm poly phantom	<= 1.4% or <= 14 HU	-92 +/- 6HU	0 +/- 8HU

5805441-1EN Rev. 2 (Sep. 2020)

HU-value conversion (IEC60601-2-44: 2012 Clause 201.101.7)

Relative values of the lower front section with HU CT operating conditions of the conversion table of water measured electron density and mass values.

Gammex Model 467, Gammex, Inc. Website : www.gammex.com

Scan protocols for Head and Body scanning conditions for Radiotherapy Treatment Planning:

Head: Axial, 120kVp, 260mA, 1.0 second(s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Head scan FOV, 25 cm display FOV and standard algorithm.

Body: Axial, 120kVp, 260mA, 1.0 second(s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Large body scan FOV, 35 cm display FOV and standard algorithm.

NOTE: Center 4 images is available due to phantom (Gammex model 467) thickness.

Material	Electron Density Relative to Water	Physical Density g/cm^3	Average HU	HU Accuracy (FOV: Head 25cm /Large body 35cm)
Air	0.001	0.001	-965	±20
Water (CT Solid Water 451)	0.99	1.02	0	±50
soft-tissue-equivalent material (LV1 Liver 482)	1.06	1.1	75	±55
bone-equivalent materials (B200 Bone Mineral 487)	1.1	1.15	232	±65
bone-equivalent materials (SB3 Cortical Bone 450)	1.69	1.82	1,262	±115

Geometric accuracy of image data

Gantry tilt

It shall be possible to set the gantry tilt to zero-position with an accuracy of within ±1° with reference to the plane through the x-axis and perpendicular of table top.

The test method is according to IEC 61223-3-5, Annex D.

If Gantry tilt zero-position accuracy exceeds ±1°, please contact your service representative to perform the adjustment.

Angular alignment of CT images

Position a PHANTOM with markers aligned to the horizontal or vertical plane in the scan field. Scan the PHANTOM and check orientation of the markers in the image. The deviation of the marker from the vertical or horizontal reference shall be less than 3 mm over a distance of 20 cm.

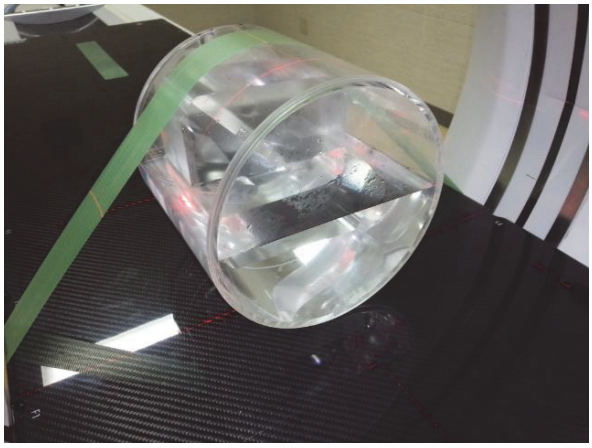
Test Equipment and Accessory Tools

– GE QA Phantom

a) Fill QA phantom about half-full of water.

b) Set QA phantom on Flat Table Top to align the water surface to the horizontal alignment laser at the center of water section of QA Phantom. See Figure 13-5.

Figure 13-5 QA Phantom (half-full of water) Setting



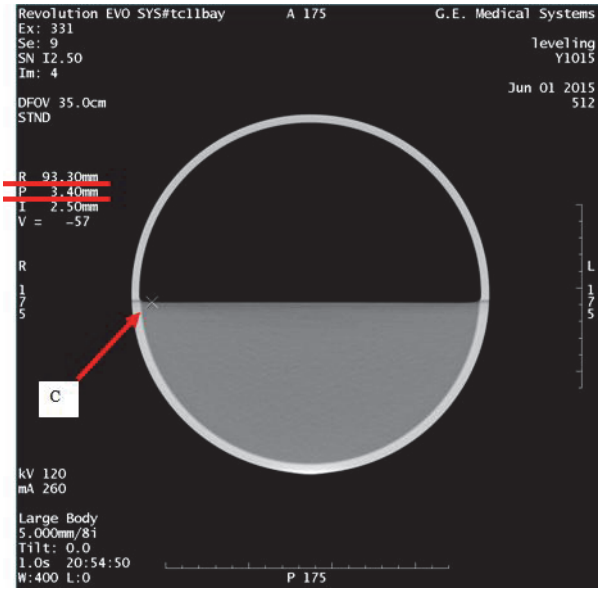
c) Set the landmark(0), execute the following scan:

Axial, 120kVp, 260mA, 1.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Large body scan FOV, 35 cm display FOV and standard algorithm.

d) Observe the image on Exam Desktop. Measure the coordinates of the point at the edge of water on the one side (Point C) per Figure 13-6.

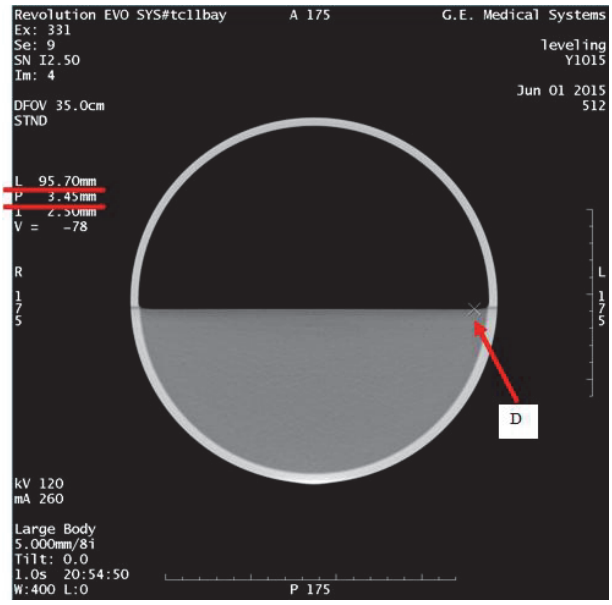
5805441-1EN Rev. 2 (Sep. 2020)

Figure 13-6 Point C measurement



e) Measure the coordinates of the point at the edge of water another side (Point D) per Figure 13-7.

Figure 13-7 Point D measurement



f) Calculate the angle (H) per the followings:

$$H_{(degrees)} = \tan^{-1}\left(\frac{Y_d - Y_c}{X_d - X_c}\right) \times \frac{180}{\pi}$$

X_c and Y_c are the coordinates of Point C,X_d and Y_d are the coordinates of Point D. (Example for Figure 13-6 and Figure 13-7)

$$H_{(degrees)} = \tan^{-1}\left(\frac{(-3.45) - (-3.40)}{95.70 - (-93.30)}\right) \times \frac{180}{\pi}$$

$$= 0.015 < 0.85 \left(= \tan^{-1}\left(\frac{3mm}{20cm}\right) \times \frac{180}{\pi}\right)$$

If Angular (H) is more than 0.85°, please contact your service representative to perform the adjustment.

Accuracy of image z-position for helical scans

A PHANTOM with markers at z-position 0 cm, 15 cm and 30 cm is used. The markers have to be visible in the CT-image (e.g. metal beads). The PHANTOM is positioned in a way that marker "0 cm" is in the field of the light marker. The table is set to zero for that position. A helical scan with a protocol intended for providing images for RTP is executed over a scan range covering all three markers on the PHANTOM and overlapping images are reconstructed using the thinnest available TOMOGRAPHIC SECTIONS. For each marker the

5805441-1EN Rev. 2 (Sep. 2020)

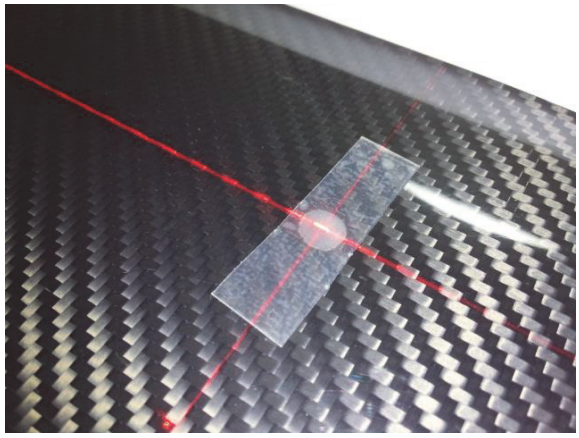
slice position with the maximum contrast for the marker shall be identified and recorded. The deviation of the image positions from their corresponding nominal *z*-values shall be less than 1 mm.

Test Equipment and Accessory Tools

- Metal wire (about 0.6mm in diameter and 5mm long) x 3pcs
- Ruler

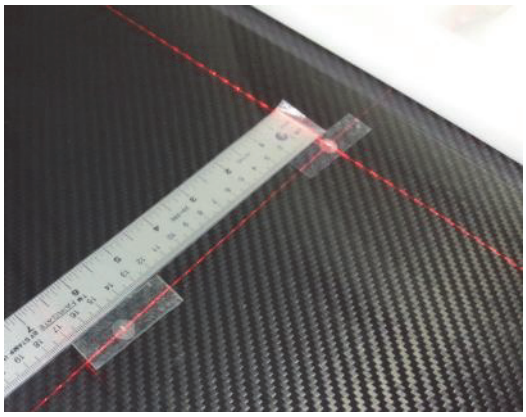
a) Set a landmark (0). Then Set the 1st metal wire on Flat Table Top to align the alignment laser at the Scan center. See Figure 13-8.

Figure 13-8 A metal wire setting at 0 cm (1st)



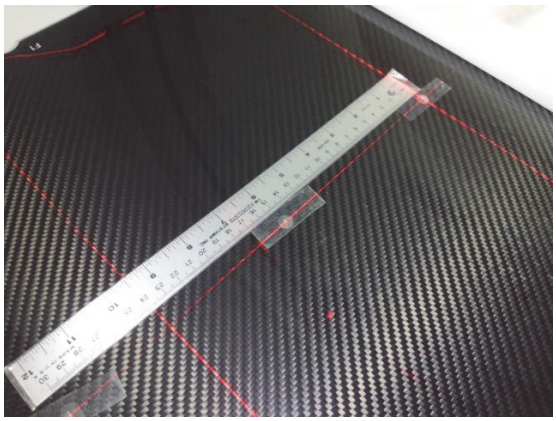
b) Set the 2nd metal wire on Flat Table Top to align an sagittal alignment laser at the point is 15cm from 1st metal wire by using a ruler. See Figure 13-9.

Figure 13-9 A metal wire setting at 15cm (2nd)



c) Set the 3rd metal wire on Flat Table Top to align an sagittal alignment laser at the point is 30cm from 1st metal wire by using a ruler. See Figure 13-10.
This Flat Table Top with 3pcs metal wires is used as a phantom.

Figure 13-10 A metal wire setting at 30cm (3rd)



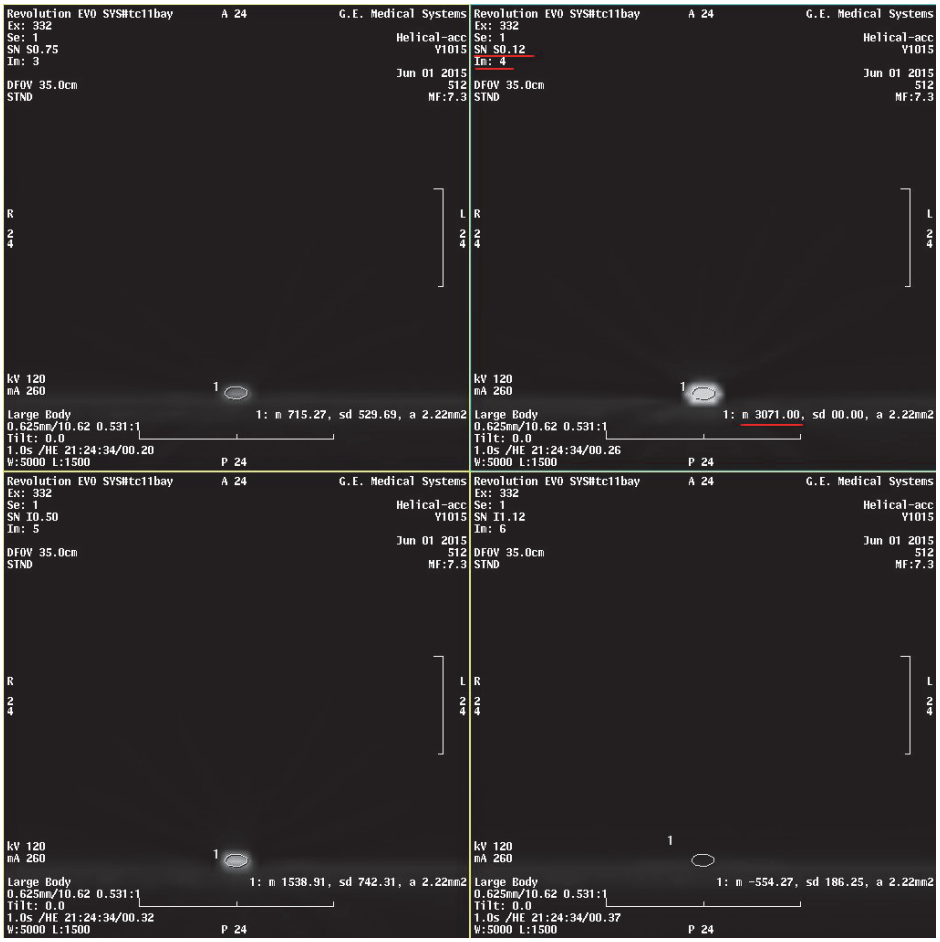
d) Execute the following scan:

   Helical Full, 120kVp, 260mA, 1.0 second (s) gantry rotation, 0.625mm nominal image thickness, pitch 0.531, Interval 0.625mm, start location S(I)2.000 mm, end location S(I)303.000mm, Large body scan FOV, 35 cm display FOV and standard algorithm.

e) Observe the image around 1st metal wire position on Exam Desktop.

   Set ROI at metal wire on each images and distinguish the image and its position with the maximum contrast. the maximum difference between the average of CT number in ROI and the CT number of air is interpreted as the maximum contrast. See Figure 13-11.

Figure 13-11 The maximum contrast image selection at 0cm



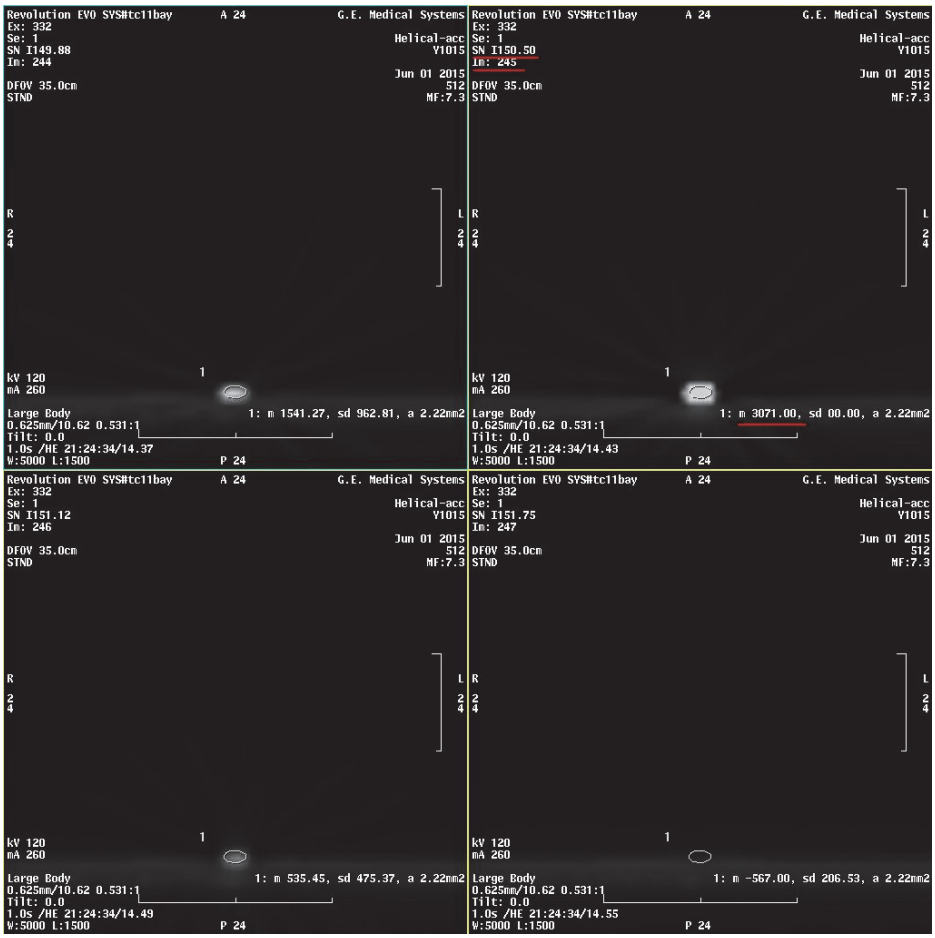
In this case, "Im:4" is the maximum contrast image.

1st metal wire position (D0) = S0.12

f) Observe the image around 2nd metal wire position on Exam Desktop.

Set ROI at metal wire on each images and distinguish the image and its position with the maximum contrast. the maximum difference between the average of CT number in ROI and the CT number of air is interpreted as the maximum contrast. See Figure 13-12.

Figure 13-12 The maximum contrast image selection at 15cm



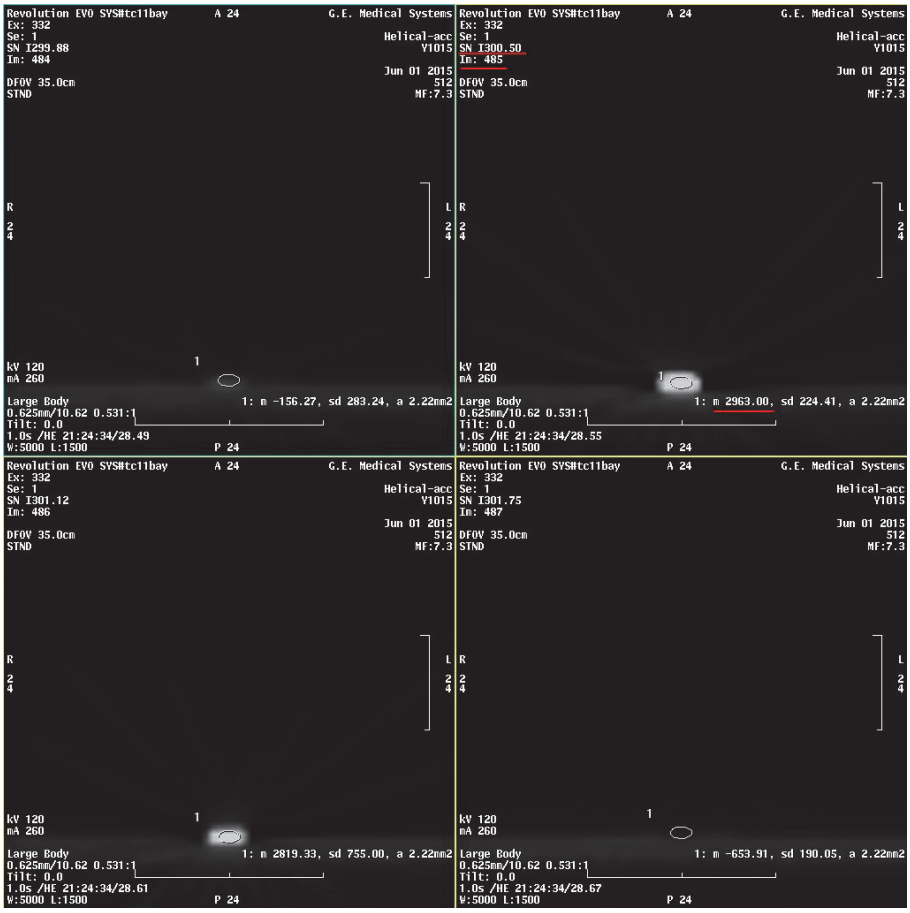
In this case, "Im:245" is the maximum contrast image.

2nd metal wire position (D15) = I150.50

g) Observe the image around 2nd metal wire position on Exam Desktop.

Set ROI at metal wire on each images and distinguish the image and its position with the maximum contrast. the maximum difference between the average of CT number in ROI and the CT number of air is interpreted as the maximum contrast. See Figure 13-13.

Figure 13-13 The maximum contrast image selection at 30cm



In this case, "Im:485" is the maximum contrast image.

3rd metal wire position (D30) = I300.50

If image z-position for helical scans (D0, D15, D30) is more than 1mm different from the actual position, please contact your service representative.

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 14
CT Acceptance Testing

This section describes the procedures for CT acceptance testing, based on IEC 61223-3-5, and additional testing required by MHLW PAL EP6 (Japan) and JJG 1026-2007 (China).

Positioning of The Patient Support

(Reference IEC 61223-3-5 Clause 5.1)

Positional accuracy of the patient support includes both longitudinal positioning and backlash evaluation.

The accuracy of longitudinal patient support positioning is evaluated by moving the patient support a defined distance in one direction and confirming the distance traveled.

The accuracy of moving the patient support in one direction and moving it back to the starting position is referred to as backlash.

The test procedure and data evaluation process are well documented in IEC 61223-3-5.

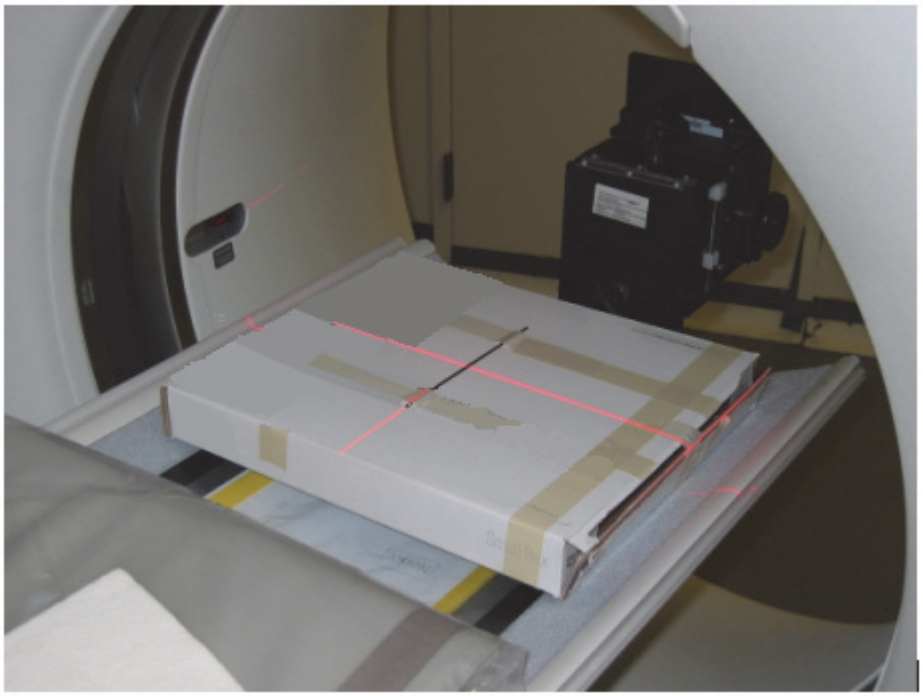
Patient Positioning Accuracy

(Reference IEC 61223-3-5 Clause 5.2)

Test Equipment

A thin wire with a diameter of 1mm or less or equivalent is preferred. In order to be aligned with the laser light, the wire can be taped down on a flat surface and then placed on the cradle (see Figure 14-1).

Figure 14-1 A thin wire is taped on a flat box for patient positioning accuracy testing.



Test Procedure for Internal/external Laser Light Accuracy (Reference 21CFR1020.33 (g) (4))

1. Remove cradle pad.
2. Put the wire with the box on the cradle and use the level to position the box as horizontal as possible in both z and x directions.
3. Align the wire with the **internal** laser light field and make it parallel to the scan plane, and use coronal Laser light to center the wire in the up/down direction.
4. Landmark the wire using **internal** landmark.
5. Scan the wire using the scan protocol as listed in Table 14-1.

6. For the external laser light accuracy, move the cradle out and align the wire with the **external** laser light field, and use coronal laser light to center the wire in the up/down direction.
7. Landmark the wire using **external** landmark.
8. Scan the wire using the protocol as listed in Table 14-1.

Table 14-1 Scan protocols for axial internal/external light accuracy

	Scan mode	kV	mA	Scan speed(s)	SFOV	Aperture/ Slice thickness (mm)	Scan Range and Orientation	Recon kernel	DFOV (cm)
Internal Light	Axial	120	260	1	small body	20/0.625 mm	I9.688 to S9.688 head first	bone	10
External Light	Axial	120	260	1	small body	20/0.625 mm	I9.688 to S9.688 head first	bone	10

Test Procedure for Sagittal and Coronal Light Accuracy

1. Remove the cradle pad.
2. Put the wire with the box flat on the cradle and use the level to position the box as horizontal as possible in both z and x direction.
3. Position the wire along the iso center using both **sagittal** (left/right) and **coronal** (up/down) laser light, and for this test, the wire should be perpendicular to the scan plane.
4. Landmark the wire using **internal** landmark.
5. Scan the wire using the protocol as listed in Table 14-2.

Table 14-2 Scan protocol for sagittal/coronal light accuracy

Scan mode	kV	mA	Scan speed(s)	SFOV	Aperture/ Slice thickness (mm)	Scan Range and Orientation	Recon kernel	DFOV (cm)
Axial	120	260	1	small body	20/0.625 mm	I9.688 to S9.688 head first	bone	10

Data Evaluation

1. Select the image with the maximum wire CT number for evaluation. (See Figure 14-2). For internal laser light, confirm that the wire is in the image with image location between I2 and S2. Record the image location in Table 14-3.

2. For external laser light, follow the similar procedure as in step 1 and record the image location in Table 14-3.
3. For sagittal laser light, select the image in the middle row (image #16, for example), adjust the window width and window level, so that the wire is round and clear in the image (for example, ww =1500, wl =0). Then, place the cursor at the center of the wire. Record the Left/Right coordinate value in Table 14-3. See Figure 14-3 for details.
4. For coronal laser light accuracy, record the A/P coordinate value in Table 14-3.
5. The specifications for both internal and external light accuracy are +/- 2mm (I2 –S2). Sagittal light accuracy is +/- 2mm. (L2 –R2) Coronal light accuracy is +/- 2mm (A2 - P2).

Table 14-3 Patient Positioning Accuracy Results and Specifications (Reference 21CFR1020.33 (g) (4))

	Axial Internal Light	**Axial External Light**	**Sagittal Light**	**Coronal Light**
Measured				
Specifications	± 2mm or I2- S2	± 2mm or I2-S2	± 2mm or L2-R2	± 2mm or A2-P2
Pass/fail				

5805441-1EN Rev. 2 (Sep. 2020)

Figure 14-2 Internal and External Light Accuracy Image. Left image with maximum wire CT number is used for evaluation and the image location with the brightest wire is I0.31.

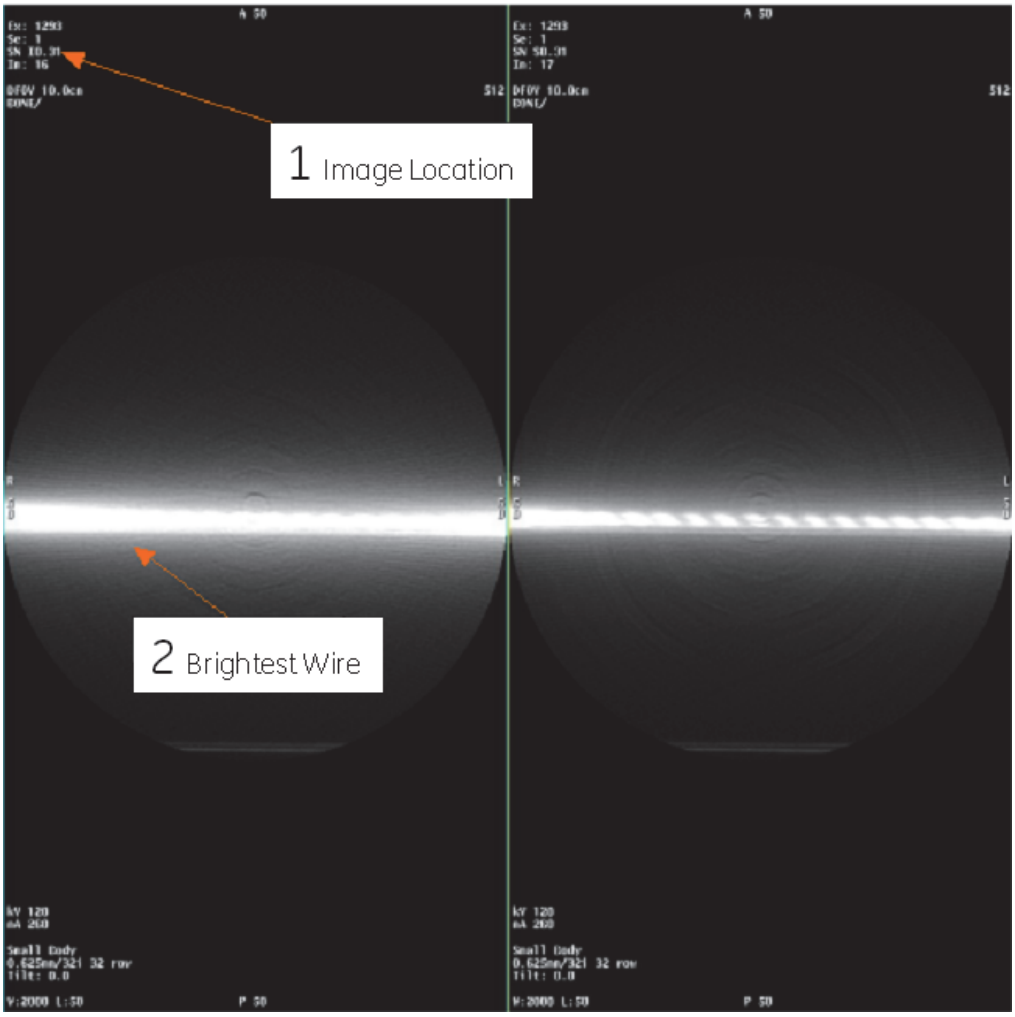


Table 14-4 Image Location and Brightest Wire

Number	Description
1	Image Location
2	Brightest Wire

Figure 14-3 The sagittal and coronal light accuracy. Cursor coordinates are the values next to “R or L” and “A or P”.

Table 14-5 Cursor Coordinates and Cursor

Number	Description
1	Cursor coordinates
2	Cursor

5805441-1EN Rev. 2 (Sep. 2020)

Preview Image Accuracy Test

IEC 61223-3-5 Clause 5.2.1.3.3

Test Equipment

Mount the QA phantom on the phantom holder.

Test Procedure for Preview image accuracy test

1. Center the QA phantom at high contrast spatial resolution section.
2. Scan the scout scan of 90 degree (°), as Figure 14-4.
   If QA phantom is tilted to AP direction, then adjust the tilt and center the QA phantom again.
3. Perform an axial scan according to Table 14-6 with the phantom position as shown in Figure 14-4. Displaying the Scout with "Show Localizer", then positioning the Axial scan center "X" on the edge of high contrast spatial resolution block as Figure 14-4.

Figure 14-4

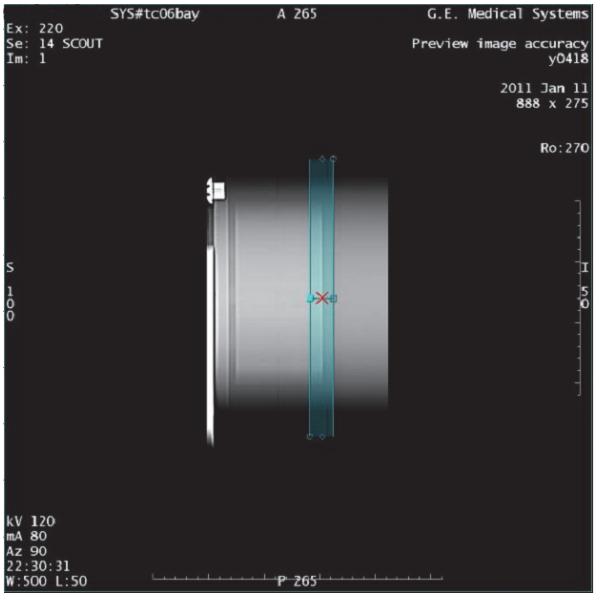


Table 14-6

Scan mode	kV	mA	Scan speed(s)	SFOV	Aperture/ Slice thickness (mm)	Scan Range and Orientation	Recon kernel	DFOV (cm)
Axial	120	260	1	small body	20/0.625 mm	Block edge head first	std	25

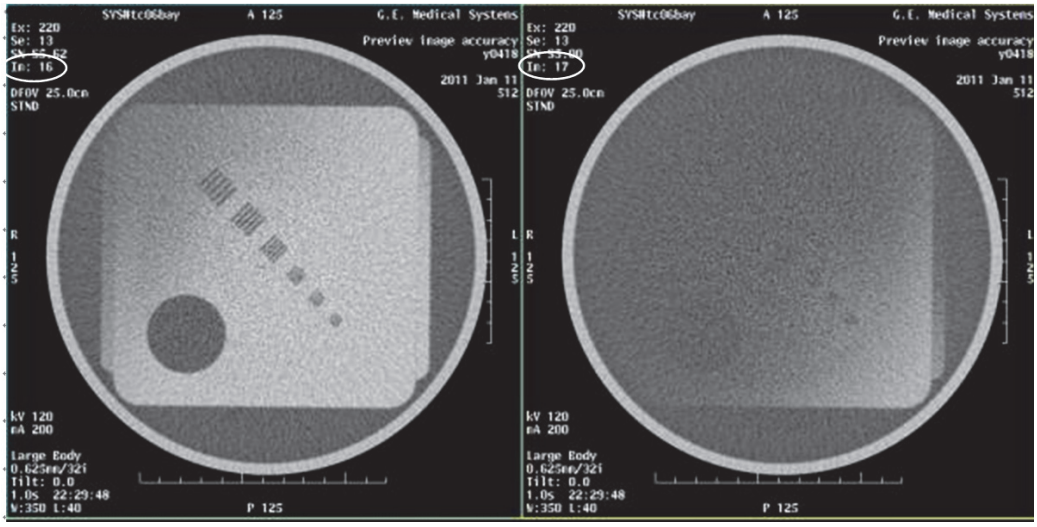
Data Evaluation

1. Review images to determine the image number which includes the edge of high contrast spatial resolution block. Confirm the image number is between 14 and 19. (Specification is within ± 2mm.) See Figure 14-5.

Table 14-7

Items	Edge Image Number
Measured	
Specification	Between 14 and 19
Pass/Fail	

Figure 14-5



5805441-1EN Rev. 2 (Sep. 2020)

Tomographic Section Thickness

(Reference IEC 61223-3-5 Clause 5.3)

Tomograhic Section Thickness for Axial Scan

Test Equipment

Per IEC 61223-3-5, any test device containing one or preferably two ramps with known angles to the scan plane and with a linear attenuation coefficients of not less than that of aluminum and suitable for measuring all available tomographic section thickness should be used.

GE Performance Phantom has a pair of tungsten wires with a slope of 1:2 (27^{o}) vs. the scan plane in both top and bottom of an acrylic block insert, but at opposite direction. (See Figure 14-6 for the top wire.)

Figure 14-6 View from the top of a GE Performance phantom with tungsten wire at 27^{0} vs. the scan plane.

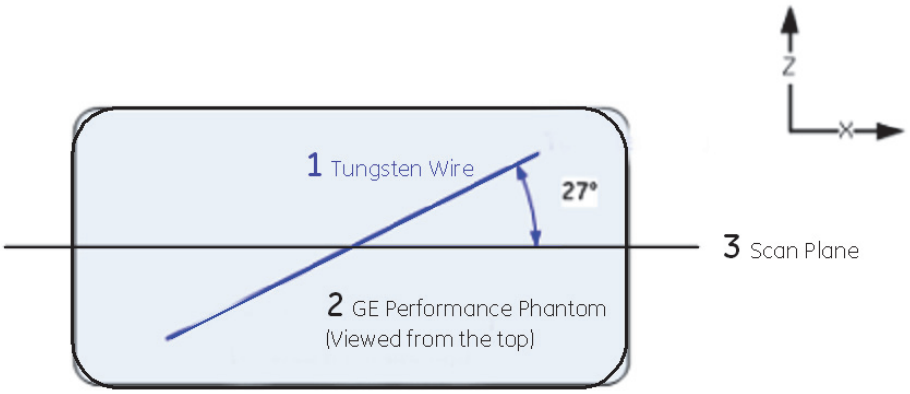


Table 14-8 GE Performance Phantom with tungsten wire

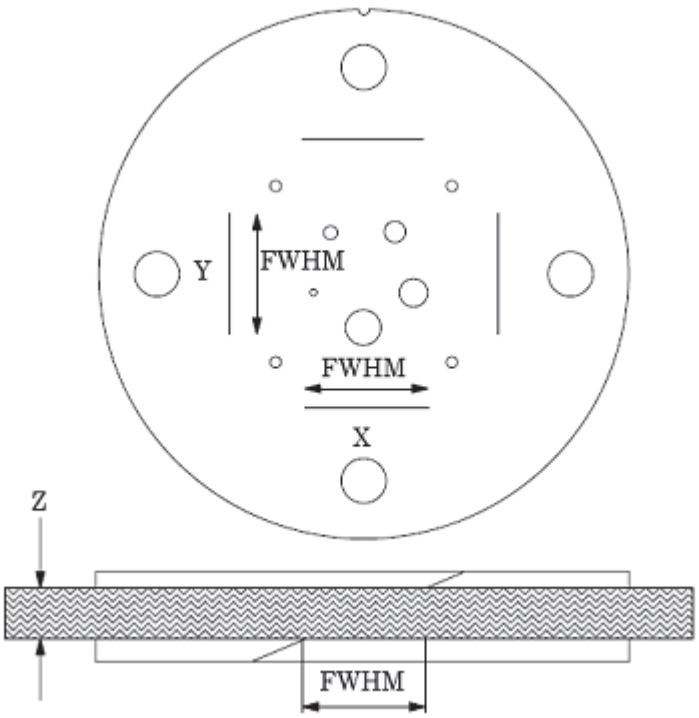
Number	Description
1	Tungsten Wire
2	GE Performance Phantom (Viewed from the top)
3	Scan Plane

The thin tungsten wire has a diameter of 0.05mm, and linear attenuation much higher than that of aluminum. With a slope of 1:2, the magnification at the scan plane is by 2x, therefore, a slice thickness of 0.625mm (FWHM) in z will be projected to a length of 1.25mm (FWHM) in the scan plane.

Catphan®600 is commercially available and has a module CTP404, which has two pairs of wire ramps with angle of 23^0 vs. the scan plane (see Figure 14-7). For Catphan®600, the magnification factor in the imaging plane is $1/\tan(23^0) = 2.35$, slightly greater than the wire in GE performance phantom.

Testing can be done with either the GE Performance Phantom or the Catphan®600.

Figure 14-7 Catphan®600 module CTP404 has two pairs of wire ramps, one pair parallel vs. x-axis, the other parallel vs. y-axis. Ramp angle at 23^0, equal to a slope of 1:2.35.



Test Procedure

1. Center GE Performance phantom at the mark. If Catphan®600 is used, center it at module CTP404.
2. Scan the phantom using the scan protocols as listed in Table 14-9. This table provides the protocols for all the apertures available from the system. To evaluate specific aperture, please select related protocol(s) from Table 14-9. Images with other slice thickness can be retrospectively reconstructed.
3. Table 14-10 lists all the slice thickness combinations for each aperture. “N/A” means this slice thickness is not available for the aperture.
4. Due to limited z-axis width of both phantom inserts, only center few rows are useful for the slice thickness analysis when the phantom is centered in the middle of insert along

5805441-1EN Rev. 2 (Sep. 2020)

z-axis, especially when the aperture is wide (for example, 40mm). To study the slice thickness for outer images, the phantom has to be offset in z-axis by 10mm.

5. To study the slice thickness for the outer images at the tableside (A-side), move the phantom and center it at S10. To study the slice thickness of the outer images at the gantry side (B-side), move the phantom to I10.

Table 14-9 Scan protocols for measuring slice thickness

Scan mode	kV	mA	scan speed (s)	Scan Range, orientation	SFOV	Aperture /slice thickness (mm)	Recon kernel	DFOV (cm)
Axial *1*2	120	200	1	I18.75 to S18.75 head first	small body	40 /2.5	detail	15
Axial	120	200	1	I9.688 to S9.688 head first	small body	20 /0.625	detail	15
Axial	120	200	1	I4.688 to S4.688 head first	small body	10 /0.625	detail	15
Axial	120	200	1	I1.875 to S1.875 head first	small body	5 /1.25	detail	15
Axial	120	200	1	I0.625 to S0.625 head first	small body	2.5 /1.25	detail	15
Axial	120	200	1	S0 to S0 head first	small body	1.25 /1.25	detail	15

NOTE: *1 64 x 0.625 mm and 32 x 1.25 mm only available in retrospective recon mode (64slice system).
*2 64 x 0.625 mm is not applicable. 32 x 1.25 mm only available in retrospective recon mode (32slice system).

Table 14-10 Combination of aperture and slice thickness

Aperture (mm)	Slice thickness (mm)				
	0.625	1.25	2.5	5.0	10.0
40	*1*2	*1*2			
20					
10					
5.0	N/A				N/A
2.5	N/A			N/A	N/A
1.25	N/A		N/A	N/A	N/A

NOTE: *1 64x0.625 mm and 32x1.25 mm only available in retrospective recon mode (64slice system).
*2 64 x 0.625 mm is not applicable. 32 x 1.25 mm only available in retrospective recon mode (32slice system).

Data Evaluation

The tomographic section thickness of an axial scan is evaluated by measuring the width of the wire ramp along x-axis direction and then multiply the measured in-plane width by the tangent of the ramp angle (vs. the scan plane.) For GE Performance phantom, the tangent of the ramp angle is **0.5**; for Catphan®600, it is **0.42**.

1. Use proper size ROI (ROI should be placed within the wire to get accurate CT number) to measure the CT number of both wire and background.
2. Adjust the window width to 1, and the window level to average of the CT number of the wire and the background.
3. In window width and level adjusted, measure the width of both top and bottom wire.
4. Take average of the two widths, and multiply the average by 0.5 for GE Performance phantom, and 0.42 for Catphan®600.
5. For a step-by-step example, see the next section.
6. The deviation of measured slice thickness is specified in Table 14-11.

5805441-1EN Rev. 2 (Sep. 2020)

CAUTION: **The limiting measurement resolution of the cursor is 1mm, i.e., the distance less than 1mm but greater than 0.5mm is rounded to 1mm, therefore, the accuracy of this testing is limited by the cursor measurement capability. This is especially important for thin slice measurement where the FWHM is close to 0.625mm. The results for these thin slice images will be not as accurate as the thick slice ones. This is the limitation by this testing method.**

Table 14-11 Deviation for the slice thickness @ each aperture

Aperture (mm)	Slice thickness (mm)				
	0.625*3	**1.25**	**2.5**	**5.0**	**10.0**
40	0.625±0.5 *1*2	1.25± 0.625 *1*2	2.5±1.0	5.0±1.0	10.0±1.0
20	0.625±0.5	1.25± 0.625	2.5±1.0	5.0±1.0	10.0±1.0
10	0.625±0.5	1.25± 0.625	2.5±1.0	5.0±1.0	10.0±1.0
5.0	N/A	1.25± 0.625	2.5±1.0	5.0±1.0	N/A
2.5	N/A	1.25± 0.625	2.5±1.0	N/A	N/A
1.25	N/A	1.25± 0.625	N/A	N/A	N/A

NOTE: *1 64 x 0.625 mm and 32 x 1.25 mm only available in retrospective recon mode (64slice system).
*2 64 x 0.625 mm is not applicable. 32 x 1.25 mm only available in retrospective recon mode (32slice system).
*3 The limiting resolution of the cursor measurement is 1mm, i.e., the distance less than 1mm but greater than 0.5mm is round to 1mm, therefore, the accuracy of this testing is limited by the cursor. This is especially important for thin slice measurement where the FWHM is close to 0.625mm. The results for these thin slice images will be not as accurate as the thick slice ones.

A Step-by-step Example for Slice Thickness Measurement Using GE Performance Phantom

1. Scan the GE Performance phantom using 2.5mm/0.625mm slice mode protocol as listed in Table 14-9 and reconstruct the images at 2.5mm slice thickness.
2. In Figure 14-8, place a narrow rectangular ROI (make sure it is entirely within the wire) to measure the CT number of the wire. Place a similar ROI in the background. In this example, ROI 1 is placed at the background, and ROI 2 is inside the wire. The CT number for ROI 1 =-0.63HU, ROI 2 = 227.17HU. Take the average ~114HU.
3. Set the window width to 1, and window level to 114HU. See the image in Figure 14-9 with new window width and window level.
4. The width of both wires is measured in Figure 14-10. In this case, the length of top wire is measured at 4mm, and the bottom is measured at 4mm. The average of two widths is 4mm.
5. Multiply the average by 0.5 for the GE Performance phantom, 4mm * 0.5 =2mm
6. Therefore, the measured slice thickness (FWHM) is 2mm. According to Table 14-11, the expected slice thickness for this slice mode is 2.5mm+/-1mm.

5805441-1EN Rev. 2 (Sep. 2020)

Figure 14-8 Place two ROIs to measure the CT number of wire and background.

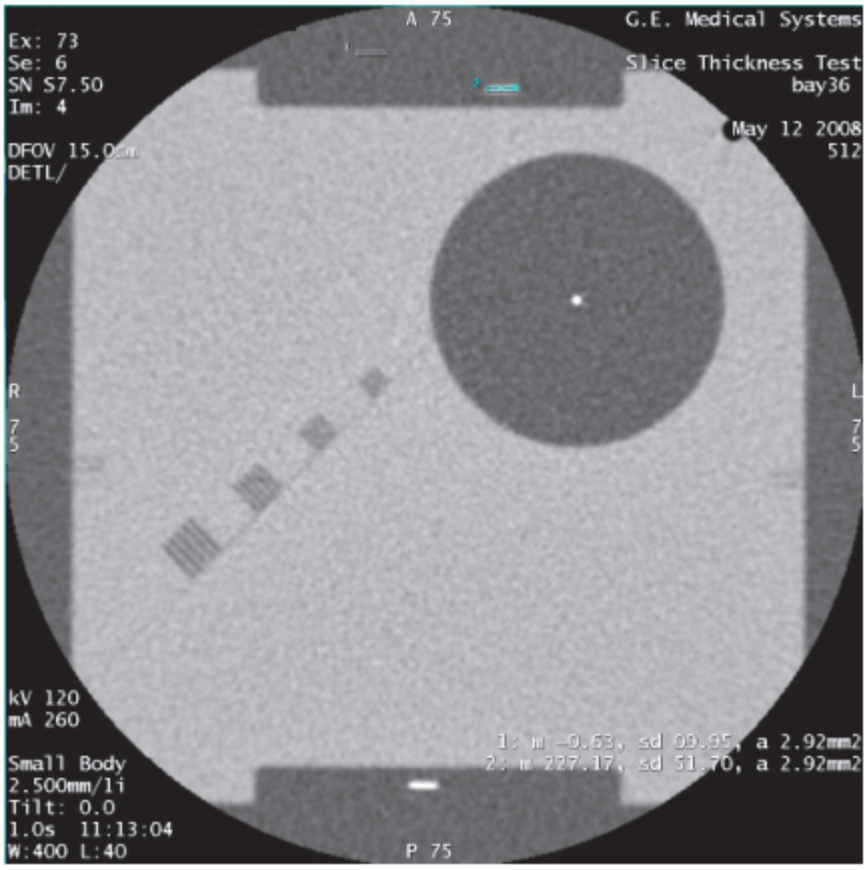
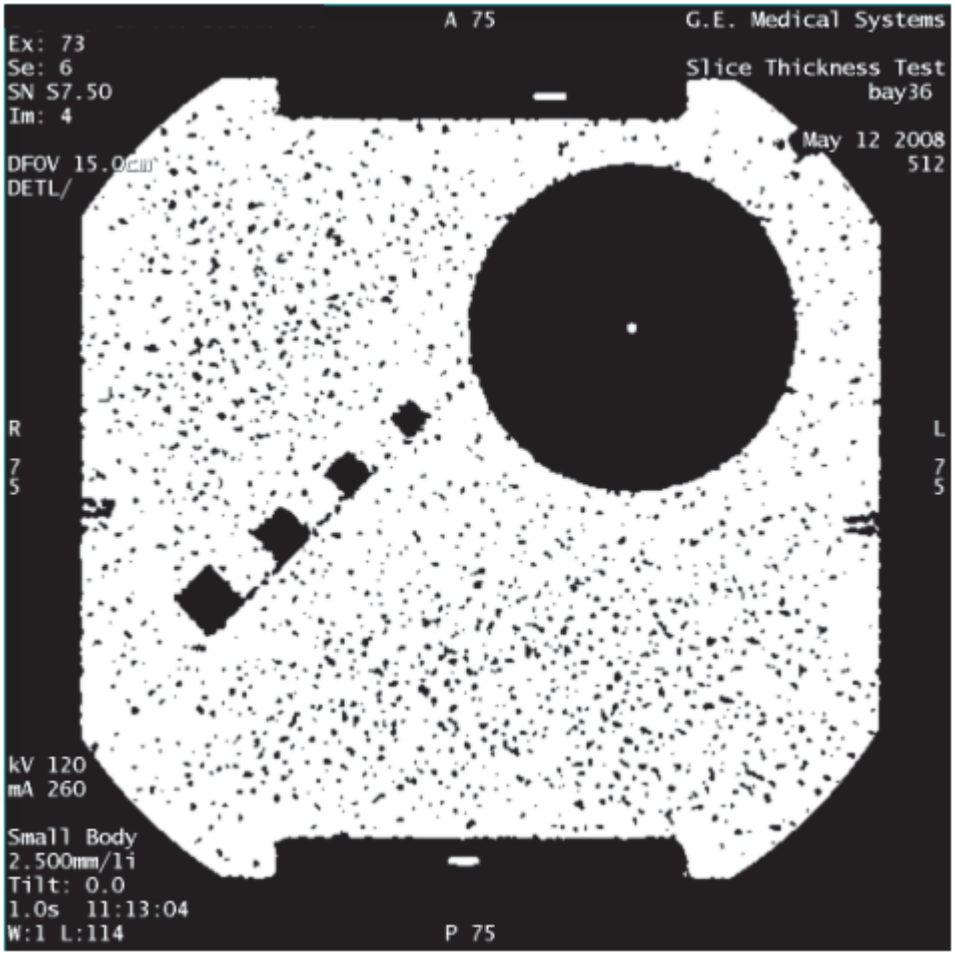
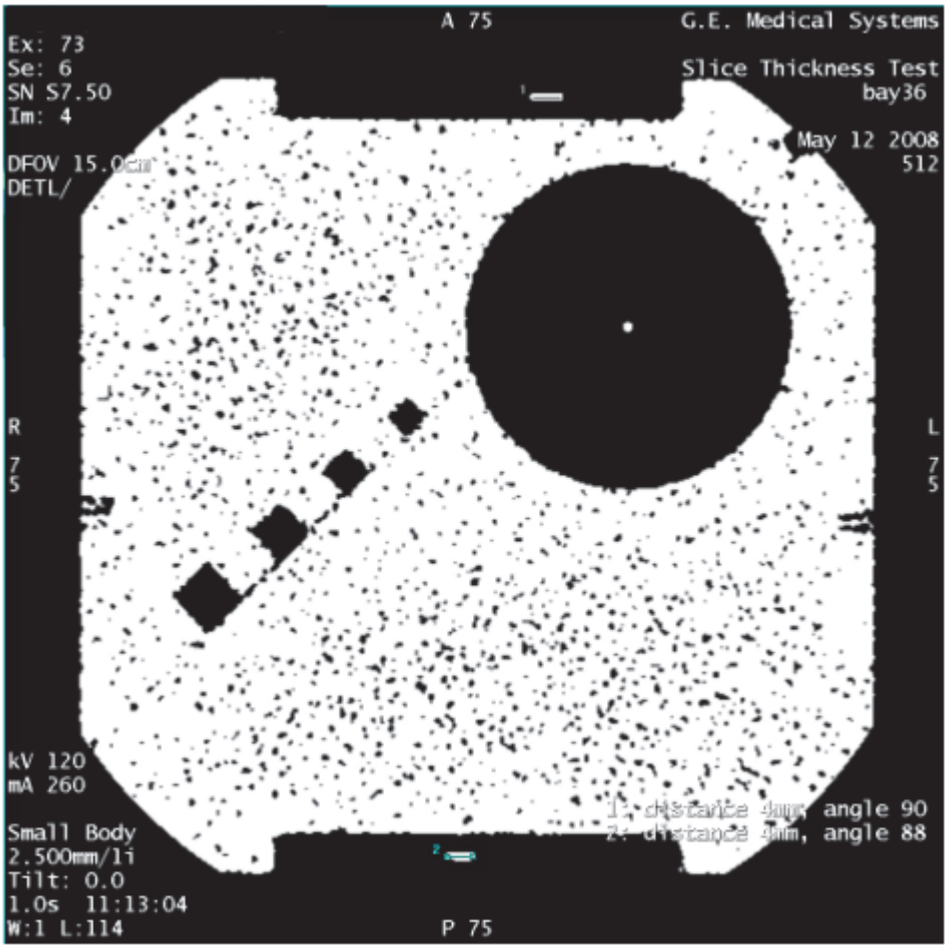


Figure 14-9 To measure FWHM from the image, set WW =1, and WL =114.



5805441-1EN Rev. 2 (Sep. 2020)

Figure 14-10 Measured the width of both top and bottom wires: 4mm, 4mm.



Tomographic Section Thickness for Helical Scan

Per IEC 61223-3-5, the slice thickness for helical scan is optional. However, if the testing is desired, refer to Annex G of IEC 61223-3-5 for detailed testing device and procedures.

Dose

(Reference IEC 61223-3-5 Clause 5.4)

For details in dosimetry, refer to Chapter 12 of the Technical Reference Manual, “Quality Assurance”-> “Dosimetry”.

The dose measurement methodology in the Technical Reference Manual follows those described in IEC 60601-2-44.

In this section, the protocols are proposed for $CTDI_W$, $CTDI_{free\ air}$ per IEC 61223-3-5, Clause 5.4 under head and body scan conditions. The specifications for $CTDI_W$ and $CTDI_{free\ air}$ under these proposed CT operating conditions are listed.

Scan Protocols and Dose Specifications for $CTDI_W$

Table 14-12 describes the scan protocols for $CTDI_W$ under head and body conditions.

Table 14-13 is the expected $CTDI_W$ value and maximum deviation allowed, due to variations in tube output, phantom setup, dosimeter centering and calibration errors.

Table 14-12 $CTDI_W$ scan protocols for Head and body conditions

Scan conditions	CTDI phantom	Scan mode	kV	mA	Scan speed (s)	Scan Range Orientation	SFOV	Aperture /Slice thickness (mm)	Recon kernel	DFOV (cm)
Head	16cm CTDI phantom	Axial	120	260	1	I17.5 to S17.5 head first	Head	40mm/8x5	stnd	25
Body	32cm CTDI phantom	Axial	120	260	1	I17.5 to S17.5 head first	Large Body	40mm/8x5	stnd	50

Table 14-13 Expected Head and Body $CTDI_W$ and Maximum Variation using scan protocols defined in Table 14-12

	Head	Body
$CTDI_W$	43.5mGy+/-40%	22.7mGy+/-40%

NOTE: These dose values are for the normal table (VT1700V or VT2000) only. For the heavy patient table VT2000x, convert them into values for VT2000x using dose scaling factors (Table 12-22).

Scan Protocols and Dose Specifications for $CTDI_{free\ air}$ (Reference: IEC60601-2-44:2009 Clause203.109.2)

Table 14-14 describes the scan protocols for $CTDI_{free\ air}$ under head and body conditions.

Table 14-15 is the expected $CTDI_{free\ air}$ value and maximum deviation allowed due to the variations in tube output, dosimeter centering and calibration errors.

Table 14-14 Scan Protocols for $CTDI_{free\ air}$

Scanning Conditions	Scan mode	kV	mA	Scan speed (s)	Scan Range	SFOV	Aperture (mm)	Recon kernel	DFOV (cm)
Head	Axial	120	260	1	I7.5 to S7.5 head first	Head	40mm/8x5	stnd	25

5805441-1EN Rev. 2 (Sep. 2020)

Scanning Conditions	Scan mode	kV	mA	Scan speed (s)	Scan Range	SFOV	Aperture (mm)	Recon kernel	DFOV (cm)
Body	Axial	80	260	1	I17.5 to S17.5 head first	Large Body	40mm/8x5	stnd	50
Body	Axial	100	260	1	I17.5 to S17.5 head first	Large Body	40mm/8x5	stnd	50
Body	Axial	120	260	1	I17.5 to S17.5 head first	Large Body	40mm/8x5	stnd	50
Body	Axial	140	260	1	I17.5 to S17.5 head first	Large Body	40mm/8x5	stnd	50
Body	Axial	120	260	1	I 7.5 to S7.5 head first	Large Body	20mm/4x5	stnd	50
Body	Axial	120	260	1	I2.5 to S2.5 head first	Large Body	10mm/2x5	stnd	50
Body	Axial	120	260	1	S0 to S0 head first	Large Body	5mm/1x5	stnd	50
Body	Axial	120	260	1	S0 to S0 head first	Large Body	2.5mm/ 1x2.5	stnd	50
Body	Axial	120	260	1	S0 to S0 head first	Large Body	1.25mm /1x1.25	stnd	50

Table 14-15 Expected $CTDI_{free\ air}$ for scan conditions under Table 14-14

Scanning Condition	Scan mode	kV	mA	SFOV	Aperture (mm)	Expected $CTDI_{free\ air}$ and maximum deviations
Head	Axial	120	260	Head	40mm/8x5	75mGy+/- 40%
Body	Axial	80	260	Large Body	40mm/8x5	22mGy+/- 40%
Body	Axial	100	260	Large Body	40mm/8x5	40mGy+/- 40%
Body	Axial	120	260	Large Body	40mm/8x5	62mGy+/- 40%

Scanning Condition	Scan mode	kV	mA	SFOV	Aperture (mm)	Expected $CTDI_{free\ air}$ and maximum deviations
Body	Axial	140	260	Large Body	40mm/8x5	88mGy+/- 40%
Body	Axial	120	260	Large Body	20mm/4x5	66mGy+/- 40%
Body	Axial	120	260	Large Body	10mm/2x5	77mGy+/- 40%
Body	Axial	120	260	Large Body	5mm/1x5	96mGy+/- 40%
Body	Axial	120	260	Large Body	2.5mm/ 1x2.5	101mGy+/- 40%
Body	Axial	120	260	Large Body	1.25mm /1x1.25	137mGy+/- 40%
NOTE: **CTDIfree air Reproducability:** Each CTDIfree air value shall be within ±10 % of the mean of a set of 10 measurements.						

NOTE: These dose values are for the normal table (VT1700V or VT2000) only. For the heavy patient table VT2000x, convert them into values for VT2000x using dose scaling factors (Table 12-22).

Noise, Mean CT Number and Uniformity

(Reference IEC 61223-3-5 Clause 5.5)

Test Equipment

For head scanning, an outsider diameter of 20cm cylindrical water phantom, such as **GE Quality Assurance (QA) phantom** should be used for noise, CT number and uniformity measurement.

For body scanning, an outsider diameter of 30cm to 35cm cylindrical water phantom should be used. **It is recommended to use 35cm Polyethylene phantom in body scanning technique. A 35 cm diameter Polyethylene phantom may be obtained through GE.**

Test Procedure

The detail test procedures and data evaluation for noise, mean CT number and uniformity measurements are well described in IEC 61223-3-5 Sections 5.5.3 and 5.5.4.

Expected Results and Variations for Noise, Mean CT number and

5805441-1EN Rev. 2 (Sep. 2020)

Uniformity

This is for Noise, Mean CT number and Uniformity results and Variations.

Table 14-16 describes the scanning protocols for head condition using 20cm GE Quality Assurance (QA) phantom and body condition using 35cm GE Polyethylene phantom.

Table 14-17 describes the expected results and variations based on scanning conditions in Table 14-16.

Table 14-16 Scan Protocols for Head and Body Scanning Conditions

scanning condition	Scan mode	kV	mA	scan speed (s)	Scan range	SFOV	Aperture/ slice thickness (mm)	recon kernel	DFOV (cm)
Head	Axial	120	260	1	I17.5 to S17.5 head first	Head	40/ 8x5	stnd	25
Body	Axial	120	260	1	I17.5 to S17.5 head first	Large body	40/ 8x5	stnd	35

Table 14-17 Expected results for head and body scanning conditions in Table 14-16

	Noise	Mean CT number	Uniformity
Head, QA phantom	<= 0.49 % or <= 4.9 HU	0+/- 3HU	0+/- 3HU
Body, 35cm poly phantom	<= 1.4 % or <= 14 HU	-92 +/- 6HU	0+/- 8HU

Spatial Resolution

(Reference IEC 61223-3-5 Clause 5.6)

Test Equipment

GE Performance phantom has a 0.05mm diameter tungsten wire perpendicular to the imaging plane. This phantom can be used to evaluate the system Modulation Transfer Function (MTF) combined with an automated software tool implemented in the GE system.

Test Procedure and Data Evaluation

1. Center the GE performance phantom along the mark.
2. Scan the phantom using the scan protocols as listed in Table 14-18
3. Due to limited width of the tungsten wire for GE performance phantom in z-axis, select the center two images (**images #4 and #5**) for MTF analysis.
4. GE provides an automated tool for the MTF analysis. Use automatic MTF evaluation tool (ImageAnalysis2) from the system to find the MTF results.
   - From “Service” desktop -> “Image Quality” tab ->”Image Analysis” button -> ImageAnalysis2->”Manual” button-> “MTF_50_10”
   - Select the **center two images (image 4 and 5)** from the ImageWorks browser
   - Click “Accept” button to calculate the mean MTF50 and MTF10 values. See Figure 14-11.
   - If ImageAnalysis2 doesn’t analyze the proper wire image (GE Performance phantom has several wires), move the outer rectangular ROI to the area where the wire is located, and click “Accept Modification” button. MTF values for the wire will be re-calculated. See Figure 14-11.
   - In case of edge plus 5cm DFOV, a wire image is not displayed. Shift the retro-recon center horizontally and vertically by 2.5cm from the ISO center, and calculate the MTF50 and MTF10 values.
5. The ImageAnalysis2 displays the MTF50 and MTF10 values for each individual image and also the average of these values. See Figure 14-11.

Table 14-18 Scan protocols for spatial resolution evaluation for head and body conditions. “stnd” recon kernel is used for normal resolution, and “edge plus” kernel is high res kernel.

Scan mode	kV	mA	Scan Speed(s)	Scan range /Orientation	SFOV	Slice thickness (mm)	Recon kernel	DFOV (cm)
Axial	120	200	1	I17.5 to S17.5 Head First	Head	8x5	stnd	25
Axial	120	200	1	I17.5 to S17.5 Head First	Head	8x5	edge plus	5
Axial	120	200	1	I17.5 to S17.5 Head First	Large body	8x5	stnd	25
Axial	120	200	1	I17.5 to S17.5 Head First	Large body	8x5	edge plus	5

5805441-1EN Rev. 2 (Sep. 2020)

Figure 14-11 ImageAnalysis2 for MTF analysis using wire images from GE Performance phantom (top) and the MTF results for the images selected from ImageWorks browser.

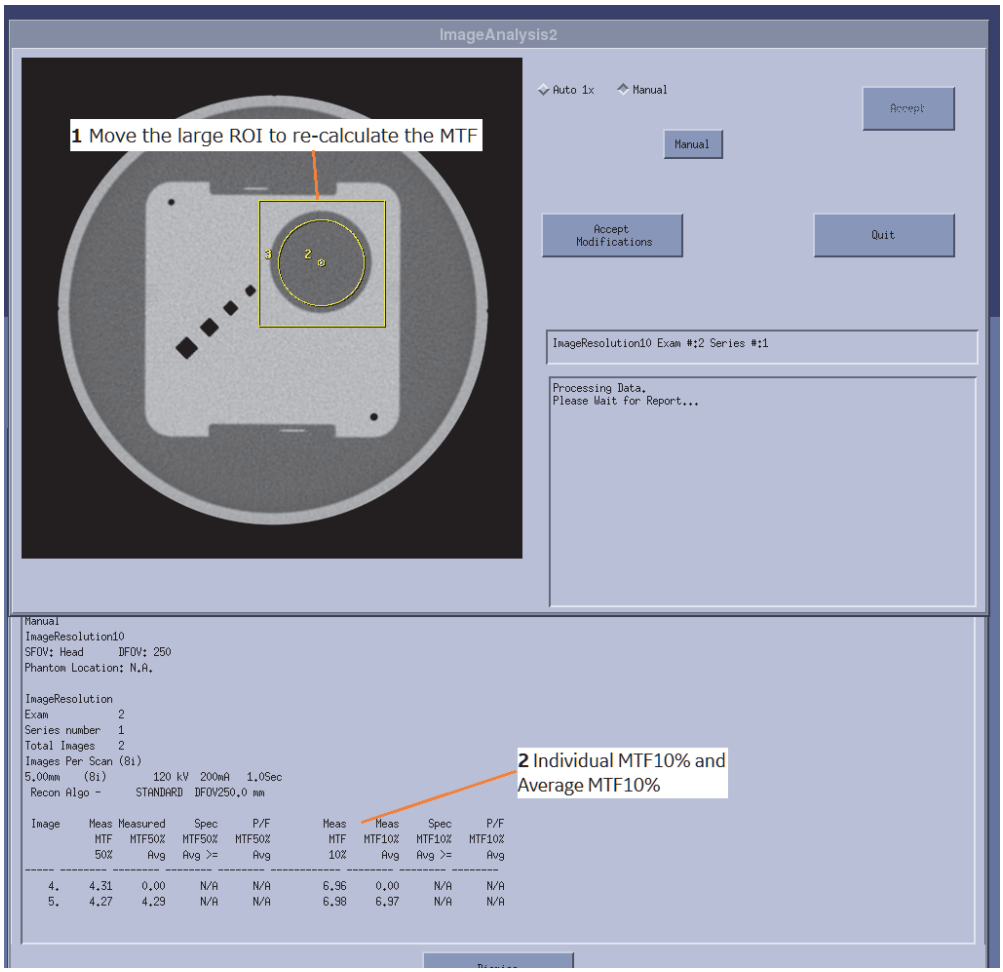


Table 14-19 ImageAnalysis2 for MTF analysis using wire images from GE Performance phantom (top) and MTF results of the images selected from ImageWorks browser

Number	Description
1	Move the large ROI to re-calculate the MTF.
2	Individual MTF and Average MTF

Expected Results and Tolerance

Expected MTF50 and MTF10 values are listed in Table 14-20 for the scan conditions from Table 14-18. The accuracy specification is listed as ">=" (no less) than the expected values.

Table 14-20 Expected MTF50 and MTF10 with Tolerance.

SFOV	Algorithm	50 % MTF	10 % MTF
Head	Standard	>=4.2	>=6.8
	Edge plus	>=12.1	>=16.0
Large Body	Standard	>=4.2	>=6.8
	Edge plus	>=12.1	>=16.0

Low Contrast Resolution (or low contrast detectability (LCD))

(Reference IEC 61223-3-5 Optional)

Low contrast resolution is optional for IEC 61223-3-5, but required by other regulatory bodies, such as MHLW and SFDA, as part of the acceptance test.

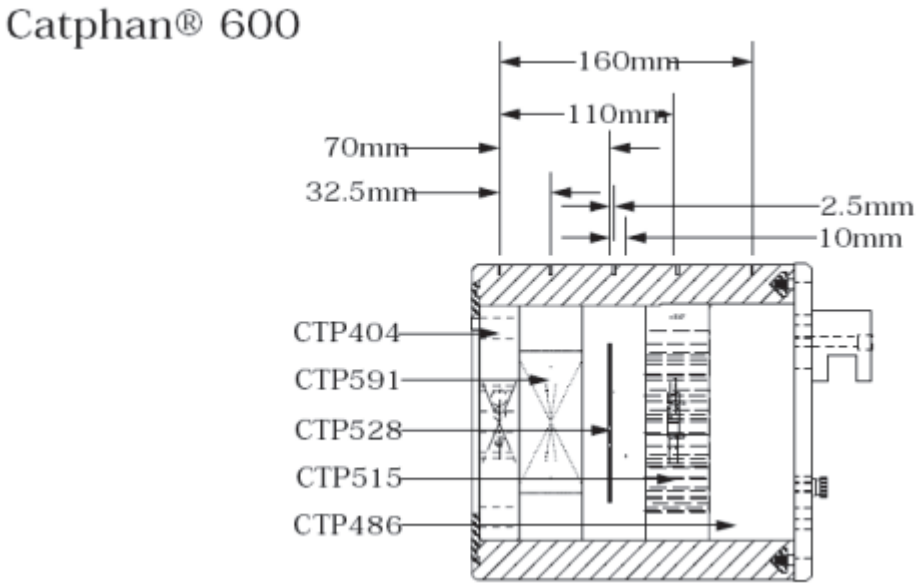
Test Equipment

Catphan®600 is a commercially available CT phantom. Its solid image uniformity module CTP486 can be used to evaluate the low contrast resolution (LCD) in a statistical manner (see Figure 14-12). Module CTP515 can be used to evaluate visual low contrast resolution. However, the visual low contrast resolution is highly subjective and requires observer's study based on a large population to get accurate results, therefore, in this section, a statistical method is used.

The alternative to Catphan®600 for the statistical low contrast resolution measurement is the GE Quality Assurance (QA) phantom. The uniform water section of the phantom can be used to measure the statistical Low Contrast Detectability (or LCD).

5805441-1EN Rev. 2 (Sep. 2020)

Figure 14-12 Module CTP486 is used for Low Contrast Detectability (statistical) evaluation.



Test Procedure and Data Evaluation Using Catphan®600

1. Center Catphan®600 at the module CTP486.
2. Scan the phantom using the protocols as listed in Table 14-21.
3. Due to limited width along z-axis for the module CTP486, use only **center 4 images (#3, 4, 5, 6)** for analysis.
4. GE scanner has an automated tool to calculate statistical LCD values.
   - From **Service** desktop > click **[Image Quality]** tab >click **[Image Analysis]** button > in **[ImageAnalysis2]** >**[Manual]** button >**[LCD]**. (See Figure 14-13).
   - Select the center four image(s) from the Image Works browser
   - Click “Accept” button.
   - In the LCD popup window “Input hole diameter (mm)”. Click the “OK” button to use the default value of 3.00 for the object size (=3mm).
     – A result panel will show the calculated LCD values for each individual image and the average from all four images as shown in Figure 14-13. The individual results are listed under column “ % Contrast @95% CL”. The average LCD result is listed under the column “ Avg % Cnst@ 95% CL” as shown in Figure 14-13.

Table 14-21 Scan Protocols for Catphan®600

5 mmSlice Thickness										
Scan mode	**kV**	**mA**	**Scan speed (s)**	**Scan Range**	**Pitch**	**SFOV**	**Aperture/ slice thickness (mm)**	**recon kernel**	**DFOV (cm)**	**Images for LCD analysis**
Axial	120	280	2	I17.5 to S17.5, head first	N/A	small body	40 8x5	stnd	22.7	center 4 images
Helical	120	300	1	I1.50 to S1.50, head first	0.516	small body	40 8x5 (interval 1.0mm)	stnd	22.7	4 images

10 mmSlice Thickness										
Scan mode	**kV**	**mA**	**Scan speed (s)**	**Scan Range**	**Pitch**	**SFOV**	**Aperture/ slice thickness (mm)**	**recon kernel**	**DFOV (cm)**	**Images for LCD analysis**
Axial	120	280	1	I15.0 to S15.0, head first	N/A	small body	40 4x10	stnd	22.7	center 2 images
Helical	120	170	1	I3.75 to S3.75, head first	0.516	small body	40 4x10 (interval 2.5mm)	stnd	22.7	4 images

Figure 14-13 The tool (upper half) panel and the result panel which displays the LCD results for each individual image and the average of four images.

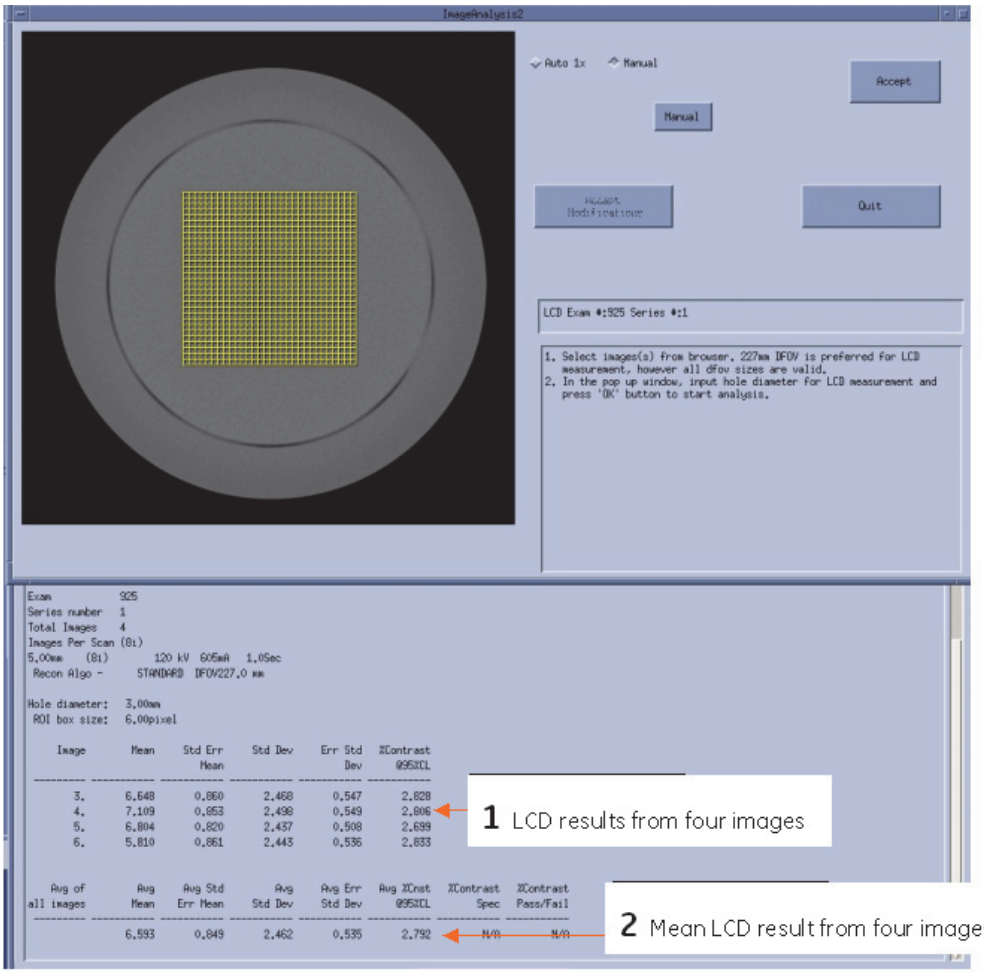


Table 14-22 The tool (upper half) panel and the result panel which displays the LCD results for each individual image and the average of four images

Number	Description
1	LCD results from four images
2	Mean LCD result from four images

Test Procedure and Data Evaluation Using GE QA Phantom

1. Center the GE QA phantom at the middle of the **water section**.
2. Scan the phantom using the protocols as listed in Table 14-23.

3. For axial mode, only 1 scan is required. To avoid beam collimation induced artifacts, use only **center 4 images (#3, 4, 5, 6)** for analysis in the axial mode.
4. For helical mode, repeat the same scan four times to generate 4 images. All **4 images** should be selected for analysis.
5. GE scanner has an automated tool to calculate statistical LCD values.
   - From **Service** desktop > click **[Image Quality]** tab >click **[Image Analysis]** button > in **[ImageAnalysis2]** >**[Manual]** button >**[LCD]**. (See Figure 14-13).
   - For axial mode, select the **center 4 images** from the ImageWorks browser; for helical mode, select **all 4 images** reconstructed.
   - Click "Accept" button.
   - In the LCD popup window "Input hole diameter (mm)". Click the "OK" button to use the default value of 3.00 for the object size (=3mm).
   - A result panel will show the calculated LCD values for each individual image and the average from all four images as shown in Figure 14-13. The individual results are listed under column " % Contrast @95% CL". The average LCD result is listed under the column " Avg % Cnst@ 95% CL" as shown in Figure 14-13.

Table 14-23 Scan protocols for QA phantom

Scan mode	kV	mA	Scan speed (s)	Scan Range	Pitch	No of scans	SFOV	slice mode (mm)	recon kernel	DFOV (cm)	Images for LCD analysis
Axial	120	260	1	I17.5 to S17.5, head first	N/A	1	small body	40/ 8x5	stnd	22.7	center 4 images
Helical	120	135	1	S0 to S0 head first	0.516	4	small body	40/ 5	stnd	22.7	all 4 images

Expected Results and Variations

- For Catphan®600, the expected statistical Low Contrast Resolution value and tolerance are listed in Table 14-24 for scan conditions in Table 14-21.
- Due to added attenuation from the acrylic shell of the QA phantom, and also lower dose (mAs) used in both axial and helical scan modes, as in Table 14-23, the expected statistical Low Contrast Detectability (Resolution) specifications are different from the ones for Catphan®600. See Table 14-24.

5805441-1EN Rev. 2 (Sep. 2020)

Table 14-24 Statistical Low Contrast Detectability (Resolution) Specifications

Phantom	Scan Mode	LCD Specification
Catphan®600	Axial	<= 3.5HU
	Helical	<= 3.5HU
GE QA phantom	Axial	<= 6.0HU
	Helical	<= 6.0HU

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 15

Performix™ 40 Plus X-Ray Tube Specifications

X-Ray Tube Model Numbers

The Performix 40 Plus X-Ray Tube Assembly, designed for the Revolution™ EVO systems, has the base model number 2137130. Throughout this chapter, model numbers may contain "-x" (i.e. 2137130-x). In these instances "x" can be the blank character or any integer. For example, in 2137130-x, "-x" refers to 2137130, 2137130-2, 2137130-3, etc. Note that in addition to the tube model numbers, unique serial numbers are assigned to each tube assembly and insert manufactured. These serial numbers can be found on the labeling on the tube housing.

Table 15-1 Tube Model And Catalog Numbers

Component	Model Number	Catalog No.
Performix™ 40 Plus Tube Assembly	2137130-x 2137130-x	D3887T D3888T
Performix™ 40 Plus Insert (X-ray Tube)	5401074-x	N/A

Environmental Specifications

Non-Operating Environment

(Reference: IEC 60601-2-28:2010 Clause201.7.9.3.101s)

Maintain a temperature range between -40°C and 70°C (from 10% to 100% relative humidity) during storage and shipment of the tube assembly. Use GE Healthcare transport packaging during shipment. Commercial airline shipment is permissible.

Operating Environment

Maintain a CT room ambient temperature range of 18°C - 26°C and 30% to 60% (non-condensing) relative humidity (50% nominal) during operation. This CT room ambient temperature range ensures that the temperature inside the gantry covers does not exceed the tube maximum ambient operating temperature of 45°C. Operating altitude range (relative to sea level): -150m to 2400m.

System errors may result when attempting to operate the anode rotation circuit if the tube assembly has been brought into the operating environment shortly after being stored or transported at temperatures below 18°C. Error-free operation can be ensured by allowing the oil circulation pump and heat exchanger to be operated for 40 min. prior to energizing the anode rotation circuit if the storage or transportation ambient was below 18°C (this 40 min. period covers tube assemblies maintained down to the non-operating environment lower limit of -40°C).

X-ray Characteristics

Leakage Technique Factors

(Reference: IEC 60601-1-3:2008 Clause12.3, IEC 60601-2-28:2010 Clause203 and 21CFR 1020.30(h)(2)(i) and (h)(4)(i))

The X-ray Tube Assembly is rated for a continuous anode input power of 3.5kW. This value is utilized in determining the following leakage radiation measurement loading factors for the Performix™ 40 Plus X-Ray Tube Assembly:

- 140 kV
- 25 mA

5805441-1EN Rev. 2 (Sep. 2020)

Total Filtration

(Reference: IEC 60601-1-3:1994, IEC 60601-2-28:1993 and 21 CFR 1020.30(h)(2))

Permanent Filtration

(Reference: IEC 60601-1-3:2008, IEC 60601-2-28:2010 Clause 201.7.2.102 and 21 CFR 1020.30(h)(2))

The Quality Equivalent Filtration of the Performix™ 40 Plus X-ray Tube Assembly is 4.9 mm Al minimum at a tube potential in the range of 70-75 kV. This filtration is non-removable from the assembly in normal use.

Performix™ 40 Plus X-Ray Tube Assembly

Classification

(Reference: IEC 60601-2-28:2010 Clause201.6)

The Performix™ 40 Plus X-Ray Tube Assembly has the following classification:

- Type of protection against electric shock: CLASS 1.

Reference Axis for Target Angle and Focal Track Spots

(Reference IEC 60601-2-28:2010 Clause201.7.9.3.101n)

The reference axis for the target angle and focal spot dimensions is normal to the longitudinal axis of both the X-ray tube and the x-ray tube assembly, and passes through the focal spot as shown in Figure 15-1 below.

Figure 15-1 Reference Axis for target angle and focal track

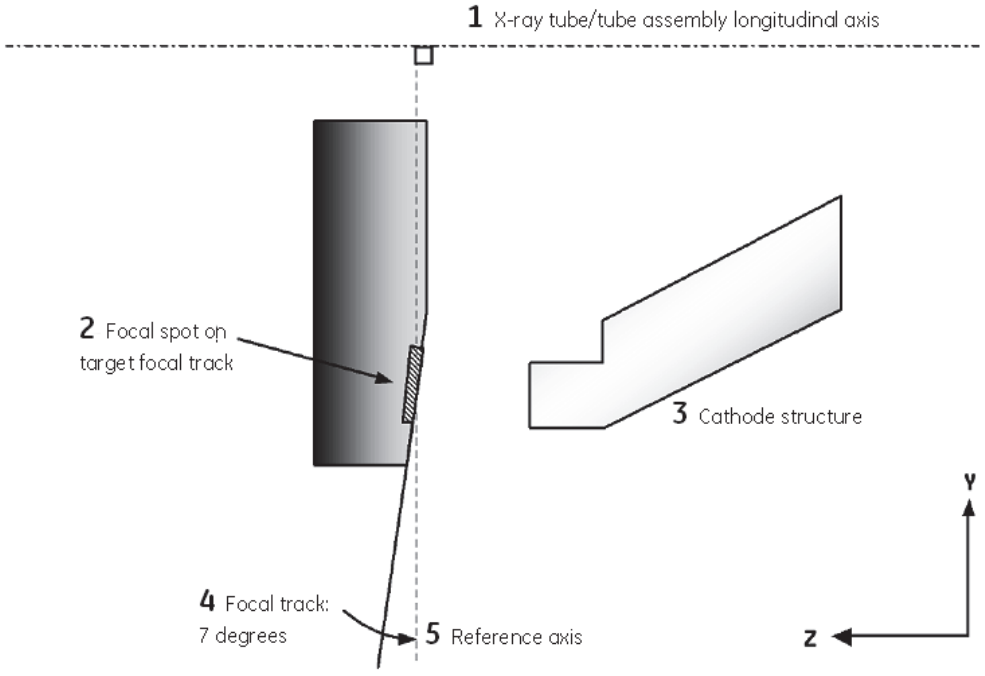


Table 15-2 TReference Axis for target angle and focal trackI

Number	Description
1	X-ray tube/tube assembly longitudinal axis
2	Focal spot on target focal track
3	Cathode structure

5805441-1EN Rev. 2 (Sep. 2020)

Number	Description
4	Focal track: 7 degrees (°)
5	Reference axis

HV Connection

(Reference: IEC 60601-2-28:2010 Clause201.7.9.3.101r); IEC60526)

The Performix™ 40 Plus X-ray Tube is a bipolar x-ray tube assembly. The anode (+) and cathode (-) high voltage cables are connected to the X-Ray tube assembly with 3-conductor connectors complying with US Federal Standard design. This x-ray tube assembly is designed for use with the Revolution™ EVO x-ray generator (part number **2371333-6**).

The accessible metal parts of the X-Ray Tube Assembly body and flexible conductive housing of high-voltage cables must be connected to the conductive enclosure of the high-voltage generator.

Focal Spot Location and Principal Dimensions

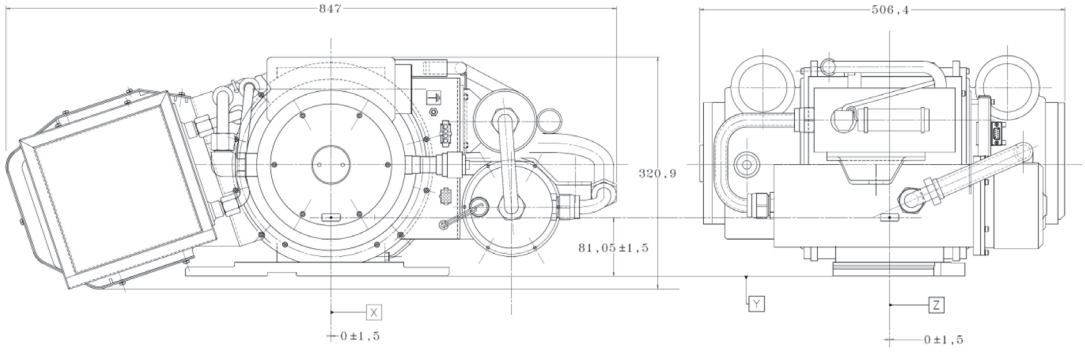
(Reference: IEC 60601-2-28:2010 Clause201.7.9.3.101n)

The position of the focal spots within the X-ray Tube Assembly is shown in Figure 15-2 below.

This position is referenced to three mutually orthogonal reference planes visually indicated in the figure (x, y, z). When the X-ray Tube Assembly is mounted at the 12:00 position in the Revolution™ EVO system, the z-reference plane is parallel to the scan plane, the y-reference plane is parallel to the table top, and the x-reference plane is perpendicular to both the scan plane and the table top.

Principal dimensions (height, width, depth) are also shown in this diagram. All dimensions are in mm.

Figure 15-2 Focal Spot and Principal Dimensions



The focal spot position is visually indicated on the X-ray Tube housing by the use of three labels (solid circle with the words "Focal Spot").

Pressure and Thermal Management

The Performix^{TM} 40 Plus X-Ray Assembly is designed to be used with GE heat exchanger assembly part number 5352112-x. The X-ray Tube Assembly and heat exchanger contain the following pressure and thermal management features: bellows assembly, overpressure switch, pressure relief valve and oil temperature sensors.

Type designations of suitable anode rotor driving and control equipment:
(Reference: IEC 60601-2-28:2010 Clause201.7.9.3.101)

This x-ray tube assembly is designed for use only with the rotor controller integral to the Revolution™ EVO x-ray generator (part number 2371333-6).

Data for auxiliary supplies required.
(Reference: IEC 60601-2-28:2010 Clause201.9)

A pressure switch and a thermal switch are integrated into the x-ray tube assembly to provide feedback to the CT system concerning conditions of over-temperature and over-pressure.

- Tube thermal switch: 76.7±2.8, 24V DC with 2 pin female Molex connector
- Pressure switch: 5±1 PSI, 24V DC with 2 pin male Molex connector

5805441-1EN Rev. 2 (Sep. 2020)

Figure 15-3 Electrical Connection Diagram (Including HV cable)

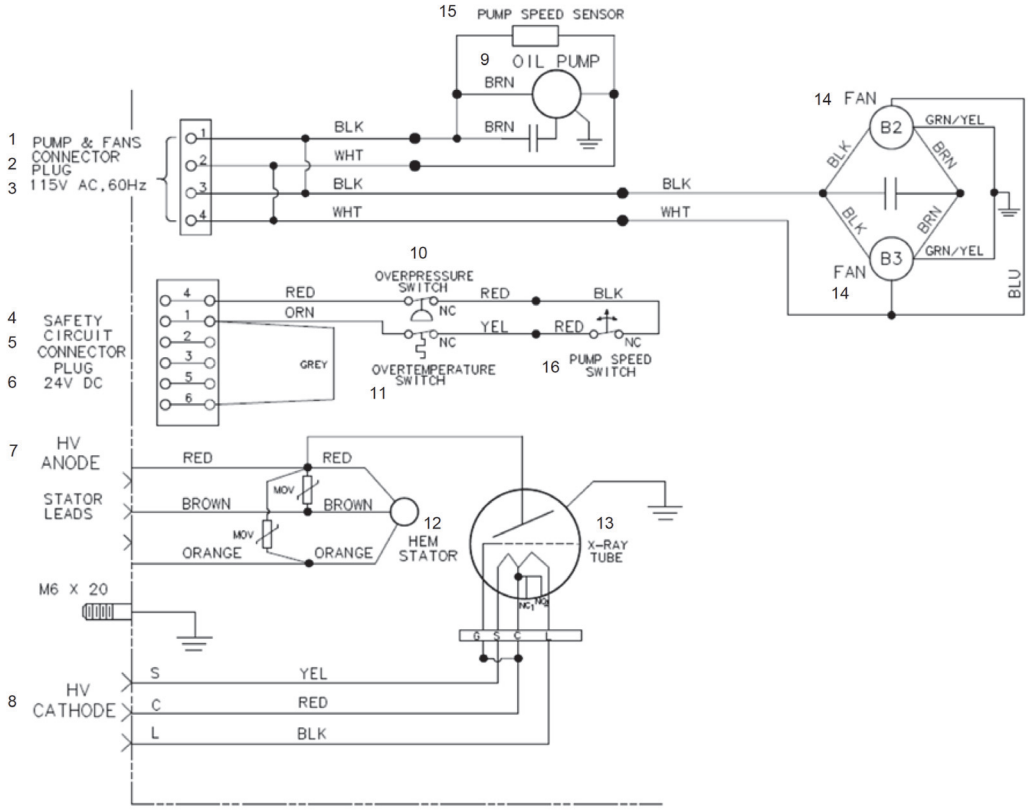


Table 15-3 Electrical Connection Diagram (Including HV cable)

Number	Description
1	Pump and Fans
2	Connector plug
3	115 VAC
4	Safety circuit
5	Connector plug
6	24 VDC
7	HV Anode
8	HV Cathode
9	Oil Pump
10	Overpressure switch
11	Overtemperature switch

Number	Description
12	Hem stator
13	X-ray tube
14	Fan
15	Pump speed sensor
16	Pump speed switch

Nominal Tube Voltage

(Reference: IEC 60613:2010 Clause4.2)

140 kVp

Construction

(Reference: IEC 60601-2-28:2010 Clause201.15)

The X-Ray Tube Housing is made of a lead-lined lightweight alloy. It is filled under vacuum with specially processed insulating oil. A sealed cooling system for the insulating oil is integral to the x-ray tube assembly. An expansion volume compensates for oil dilation at permissible temperatures. The mass of the X-Ray Tube Assembly is approximately 91kg. The mounting mechanism is integral to the tube assembly.

5805441-1EN Rev. 2 (Sep. 2020)

Performix™ 40 Plus X-Ray Tube Assembly Heating and Cooling Curves

(Reference: IEC 60613:2010 Annex A A.3.3 and 21 CFR 1020.30(h)(1)(ii))

Figure 15-4 Performix™ 40 Plus X-Ray Tube Assembly Heating and Cooling Curves (based on anode input power)

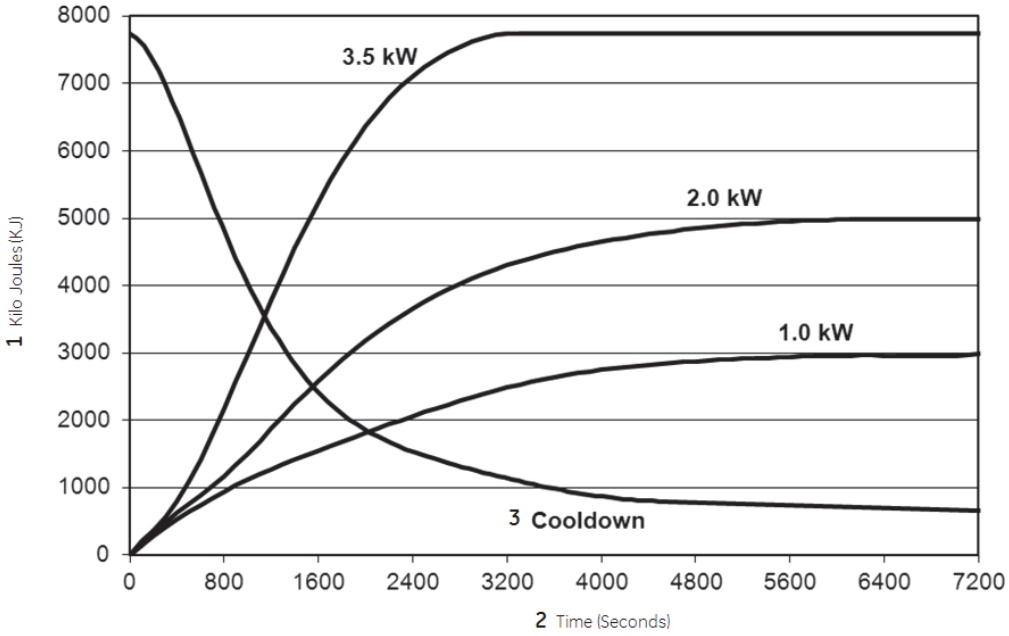


Table 15-4 X-Ray Tube Assembly Heating and Cooling Curves

Number	Description
1	Kilo Joules (KJ)
2	Time (s)
3	Cooldown

Thermal characteristics

(Reference IEC 60613:2010 Annex A A.3.3)

Maximum Continuous Dissipation

(Reference: IEC 60613:1989)

Nominal Continuous Input Power

(Reference: IEC 60613:2010 Clause6.6)

- Maximum continuous heat dissipation of X-Ray Tube Assembly: 4.8kW (3.5 kW from maximum continuous anode power, 830W from pump and fans, 492 W from stator, 17W from filament)

Heat Storage Capacity

(Reference: IEC 60613:1989)

- Maximum X-ray Tube Assembly heat content: 7.7MJ (10.8 MHU)

Beam Limiting Devices

The Performix™ 40 Plus X-Ray Tube Assembly must always be equipped with a beam-limiting device in order to meet requirements for the maximum X-Ray beam extent required for its specified applications.

The beam-limiting devices compatible with Performix™ 40 Plus tube assembly are:

- Collimator Assembly 5345001-X

Any Performix™ 40 Plus X-Ray Tube Assembly having beam limiting devices other than those listed above is obliged to be checked for compliance examination for beam quality and leakage radiation according to the requirements of IEC Standard 60601-1-3 and 21 CFR 1020.30(k)(m).

Throughout this manual, model numbers may contain a "-x" (i.e. 2137130-x). In these instances "x" can be any numeric or alpha numeric character. For example, in 2137130-x, "-x" refers to 2137130, 2137130-2, 2137130-3, etc.

Nominal CT Scan Power Index

(Reference: IEC 60613:2010 Clause 6.9)

The nominal CT scan power index is 55.1 kW when employing the large focal spot.

The nominal CT scan power index is 24 kW when employing the small focal spot.

Envelope Voltage

(Reference: IEC 60613:2010 Clause 4.5.2)

0 kV with respect to earth (ground)

Envelope Current

(Reference: IEC 60613:2010 Clause 4.5.1)

3.5% at an x-ray tube voltage of 120kV

5805441-1EN Rev. 2 (Sep. 2020)

Performix™ 40 Plus X-Ray Tube (Insert)

Target Material

(Reference: IEC 60601-2-28:2010 Clause 201.7.9.3.101a)

The target material is a Tungsten-Rhenium focal track on a molybdenum alloy substrate backed by graphite.

Nominal Anode Input Power

(Reference IEC 60613:2010 Clause6.2)

The nominal anode input power is 72kW for an anode heat content of 383 kJ (corresponds to an equivalent anode input power of 63W).

Maximum Anode Heat Content

(Reference IEC 60613:2010 Annex A A.3.3)

The maximum anode heat capacity is 5.0 MJ (7.0 MHU).

Nominal CT Anode Input Power

(Reference: IEC 60613:2010 Clause 6.4)

The nominal CT anode input power is 67.2 kW for the large focal spot.

Continuous Anode Input Power

(Reference: IEC 60613:2010 Clause 6.7)

The continuous anode input power is 3.5 kW.

Maximum Anode Heat Dissipation

1,070 kHU/min (13.2 kW)

Focal Spots

(Reference: IEC 60601-1-3:2008 Clause6.7.3, IEC 60336)

Small Focal Spot:

0.9mm (W) x 0.7mm (L) IEC 60336: 2005

0.7mm (W) x 0.6mm (L) IEC 60336: 1993

Loading Factors: 120kV, 100mA

Large Focal Spot:

1.2mm (W) x 1.1mm (L) IEC 60336: 2005

0.9mm (W) x 0.9mm (L) IEC 60336: 1993

Loading Factors: 120kV, 300mA

Reference Axis:

The reference axis for focal spot characteristics is defined to be normal to the mounting surface of the X-ray Tube housing and passing through the center of the focal spot.

Target Angle with Respect to Reference Axis

(Reference IEC 60601-2-28:2010 Clause201.7.9.3.101c))

The target angle is 7° with respect to reference axis, which is normal to longitudinal axis of the X-Ray tube.

Anode Rotation

(Reference IEC 60601-2-28:2010 Clause201.7.9.3.101j))

8400 RPM

X-ray Tube Minimum Inherent Filtration

(Reference: IEC 60601-1-3:2008 Clause7.1)

The minimum inherent filtration of the X-ray tube is 0.0 mm Al equivalent at 70 kV.

5805441-1EN Rev. 2 (Sep. 2020)

Anode Heating and Cooling Curve

(Reference: IEC 60613:2010 Annex A A.3.3 and 21 CFR 1020.30(h)(1)(i) and (h)(1)(iii))

Figure 15-5 Performix™ 40 Plus Anode Heating and Cooling Curve

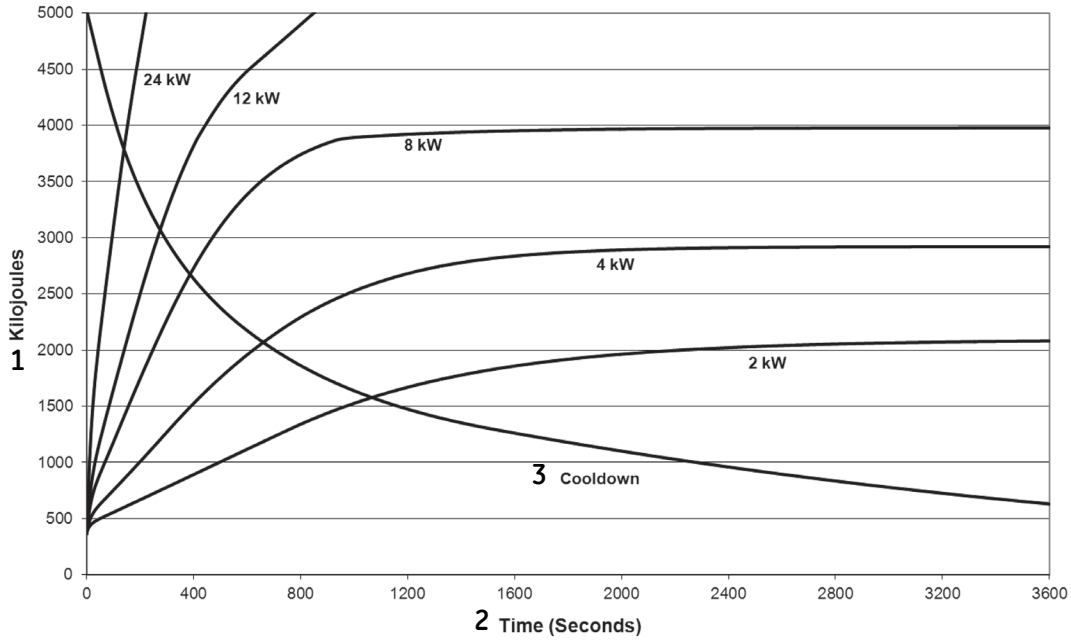


Table 15-5 Anode Heating and Cooling Curves

Number	Description
1	Kilo Joules (KJ)
2	Time (s)
3	Cooldown

Single Load Ratings

(Reference: IEC 60613:2010 Clause 7.2 and 21 CFR 1020.30(h)(2)(iii))

Application of the single load ratings shown in Table 15-6 below are controlled by CT system software and are limited by either anode loading or filament emission.

Table 15-6 Single load ratings for an initial anode heat content of 383kJ

kV	5-second (s) exposure		10-second (s) exposure	
	Large Focal Spot mA	Small Focal Spot mA	Large Focal Spot mA	Small Focal Spot mA
80	400	300	400	300
100	480	240	480	240
120	600	200	570	200
140	515	170	485	170

Serial Load Ratings

(Reference: IEC 60613:2010 Clause 7.3 and 21 CFR 1020.30(h)(2)(iii))

Application of the serial load ratings shown in Table 15-7 below are controlled by CT system software and are applicable for repeat exposures 10 minutes (min) after each exposure.

Table 15-7 Serial load ratings (10 min inter-exposure delay) for an initial anode heat content of 383kJ

kV	5-second (s) exposure		10-second (s) exposure	
	Large Focal Spot mA	Small Focal Spot mA	Large Focal Spot mA	Small Focal Spot mA
80	400	300	400	300
100	480	240	480	240
120	540	200	485	200
140	465	170	415	170

Maximum Filament Current

(Reference: IEC 60601-2-28:2010 Annex AA AA.2)

The maximum filament current is 6.15 A for the large filament. The maximum filament current is 6.54 A for the small filament.

5805441-1EN Rev. 2 (Sep. 2020)

Cathode Emission Characteristics

(Reference: IEC 60613:2010 Clause4.4)

The following figures are the Cathode Emission and V-I curves.

Figure 15-6 Cathode Emission Curves (Large Focal Spot))

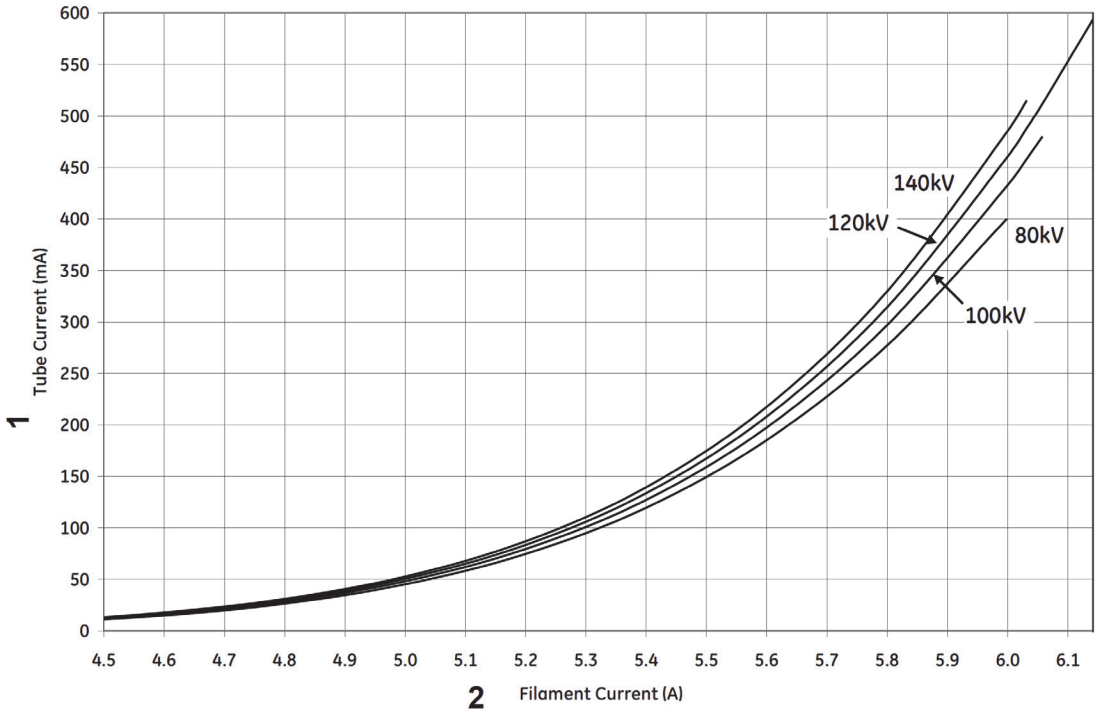


Table 15-8 Cathode Emission Curves (Large Focal Spot)

Number	Description
1	Tube Current (mA)
2	Filament Current (A)

Figure 15-7 Cathode Emission Curves (Small Focal Spot)

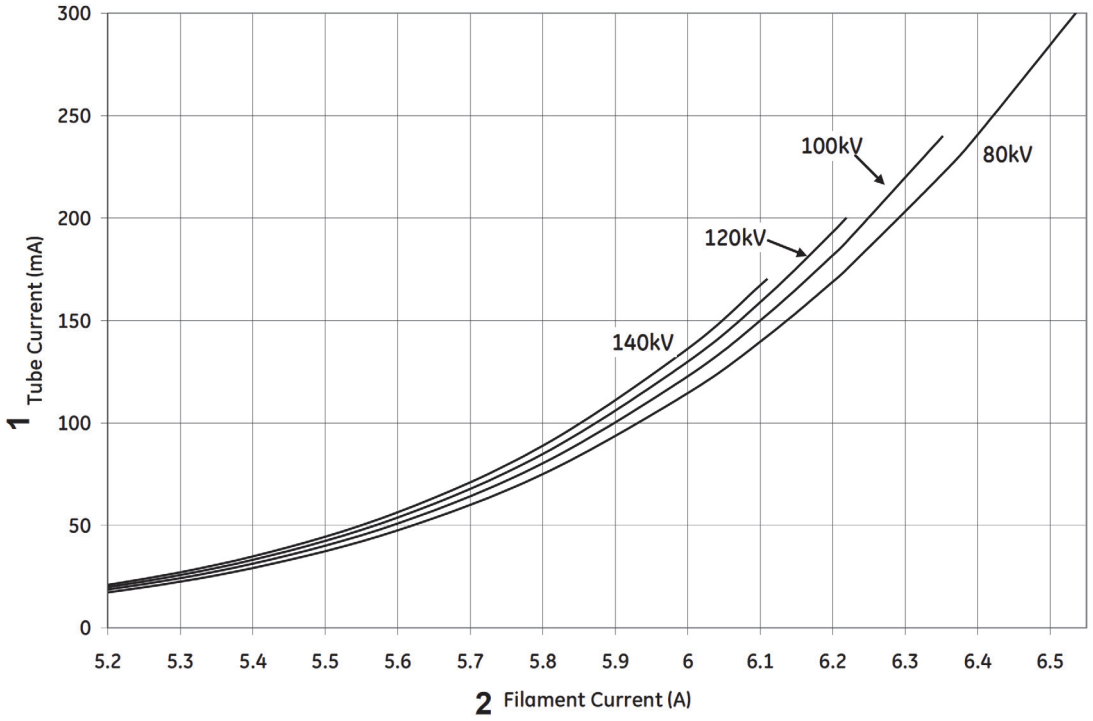
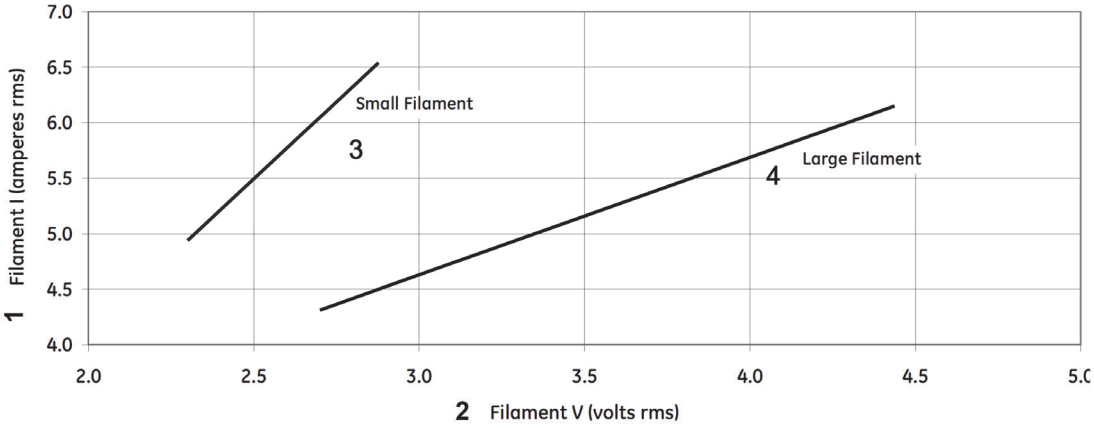


Table 15-9 Cathode Emission Curves (Small Focal Spot)

Number	Description
1	Tube Current (mA)
2	Filament Current (A)

Figure 15-8 Filament V-I Characteristic



5805441-1EN Rev. 2 (Sep. 2020)

Table 15-10 Filament V-I Characteristic

Number	Description
1	Filament I (amperers rms)
2	Filament V (volts rms)
3	Small Filament
4	Large Filament

Environmental Health & Safety (EHS) Information

The X-Ray Tube assembly (Part Number 2137130-x) contains potentially dangerous materials but does not present any danger as long as it is neither opened nor disassembled.

WARNING: **Do not discard the X-Ray Tube Assembly among industrial waste or domestic garbage.**

WARNING: **A damaged X-Ray Tube Assembly should not be dispatched through the national postal service.**

Your local GEHC field service will advise you on the suitable means of disposal. The X-Ray Tube Assembly to be discarded should be forwarded to the GEHC Service network, and it will be disposed of in a GEHC recycling center.

Hazardous Materials

The X-Ray Tube Assembly contains the following potentially dangerous materials:

Lead: Lead salts are toxic and their ingestion may cause serious problems. The working of lead is subject to regulations.

Oil: *Univolt 54 and Crosstrans 206* mineral oil are not toxic, but the prevailing environmental regulations should be observed for their disposal or recuperation. For example, it is forbidden to dispose of these oils in the wastewater or sewage system or in the natural environment.

Precautions

Take all the necessary precautions for the personnel handling the recovery or destruction of X-Ray Tube Assemblies, and in particular against the risks due to lead. These personnel must be informed of the danger involved and of the necessity to observe the safety measures.

WARNING: **Electric Shock Hazard**
To avoid the risk of electric shock, this X-ray Tube Assembly must only be connected to a high voltage generator with protective earth. (See High Voltage Connection above)

Routine Maintenance

Cleaning of the two inlet air filters of the heat exchanger assembly should be performed annually; refer to the compatible CT system Service Manual for details about cleaning of these filters.

5805441-1EN Rev. 2 (Sep. 2020)

Chapter 16
Regulatory Information

Applicable Regulations and Standards:

This product complies with the requirements of the following regulations and standards:

Council Directive 93/42/EEC concerning medical devices when it bears the following CE marking of conformity:

CE 0459

Initial year of CE mark: 2014
Authorized representative for Europe/European registered place of business:

GE Medical Systems SCS
283 rue de la Minière
78530 BUC France
Tel +33 130704040

This product has passed all conformity assessment (approval) procedures that correspond to the requirements of applicable technical regulations of the Customs Union.

EAC

Manufacturer:

GE Healthcare Japan Corporation
7-127, Asahigaoka, 4-chome, Hino-Shi, Tokyo
191-8503 Japan

Manufacturing site: See Product-Manufacturer Matrix.

Code of Federal Regulations, Title 21, Part 820 -Quality System Regulation

Code of Federal Regulations, Title 21, Sub chapter J -Radiological Health

Federal U.S. law restricts this device for sale by or on the order of a physician.

NOTE: "Rx only" is indicated on the gantry as the above statement.

GE Medical Systems is ISO 9001 and ISO 13485 certified.

Representative of applicable standards of Underwriter's Laboratories, Inc. (UL), an independent testing laboratory

Representative of applicable standards of the Canadian Standards Association (CSA)

Representative of applicable standards of the International Electrotechnical Commission (IEC) and European Norm(EN) :

- The Revolution™ EVO system complies with IEC 60601-1: 1988, amended 1991 and 1995, UL 60601-1: 2003, CAN/CSA C22.2 No.601.1, and EN 60601-1: 1990, amended 1991 and 1995.
- The Revolution™ EVO system complies with IEC 60601-1:2005, ANSI/AAMI ES60601-1:2005, CAN/CSA C22.2 No.60601-1: 08, and EN 60601-1: 2006.

The system is classified as a Class I, IPX0 equipment, not suitable for use in the presence of a flammable anaesthetic mixture with oxygen or nitrous oxide. It is rated for continuous operation with intermittent loading. No sterilization is applied. The patient table cradle and patient support accessories are considered a Type B applied part.

- The Revolution™ EVO system complies with IEC 60601-1-1: 2000.
  - All portions of the Revolution™ EVO system are suitable for use in the patient environment.

The system should be used only with GE approved equipment.

- The Revolution™ EVO system complies with IEC 60601-1-2: 2007, IEC 60601-1-2: 2014.
  - Detailed information concerning Electromagnetic Compatibility can be found in the Electromagnetic Compatibility chapter of the Technical Reference Manual.
- The Revolution™ EVO system complies with radiation protection in accordance with IEC 60601-1-3: 1994.
- The Revolution™ EVO system complies with radiation protection in accordance with IEC 60601-1-3: 2008.
- The Revolution™ EVO system complies with applicable portions of IEC 60601-2-28.

X-ray Source Assembly	Performix™ 40 Plus Tube Unit Assembly	IEC 60601-2-28 (1993)
X-ray Source Assembly	Performix™ 40 Plus Tube Unit Assembly	IEC 60601-2-28 (2010)

5805441-1EN Rev. 2 (Sep. 2020)

- The Revolution™ EVO system complies with the applicable portions of IEC 60601-2-32: 1994.

Associated Equipment	Patient Table	IEC 60601-2-32: 1994

- The Revolution™ EVO system complies with IEC 60601-2-44.

CT SCANNER...	Revolution™ EVO System	IEC 60601-2-44: 2001, amended 2002
CT SCANNER...	Revolution™ EVO System	IEC 60601-2-44: 2009
CT SCANNER...	Revolution™ EVO System	IEC60601-2-44: 2009+A1: 2012
CT SCANNER...	Revolution™ EVO System	IEC 60601-2-44: 2009+A1:2012+ A2:2016

Intended use of the system (Reference: IEC60601-1:2005 Clause7.9.2.1)

The system is intended to be used for head, whole body Computed Tomography applications.

Indications for use of the system

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisitions. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

NOTE: Some option manuals may indicate own indications for use.

Intended purpose and medical effectiveness (MHLW)

The intended purpose and medical effectiveness is to produce cross-sectional images of the patient by computer reconstruction of X-ray transmission data taken at different angles for medical examination.

5805441-1EN Rev. 2 (Sep. 2020)

Chapter 17
Electromagnetic Compatibility

This equipment complies with IEC60601-1-2 Edition 2/ 3/ 4 EMC standard for medical electrical equipment. This equipment generates, uses, and can radiate radio frequency energy. The equipment may cause radio frequency interference to other medical and non-medical devices and radio communications.

To provide reasonable protection against such interference, this product complies the radiated and conducted emission levels as per CISPR11 Group1 Class A standard limits.

Detailed requirements and recommendations about the power supply distribution and installation are listed in the Site Preparation Manual.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the user (or qualified service personnel) should attempt to correct the problem by one or more of the following measure(s):

- reorient or relocate the affected device(s)
- increase the separation between the equipment and the affected device
- power the equipment from a source different from that of the affected device
- consult the point of purchase or service representative for further suggestions

The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users' authority to operate the equipment.

All interconnect cables to peripheral devices must be shielded and properly grounded, except when technologically prohibited. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference.

Do not use devices which intentionally transmit RF Signals (Cellular Phones, Transceivers, or Radio-Controlled Products) in the vicinity of this equipment as it may cause performance outside the published specifications.

Recommended separation distances are detailed in the PIM document (Pre-installation Manual).

The medical staff in charge of this equipment is required to instruct technicians, patients, and other people who may be around this equipment to comply fully with the above equipment. In order to achieve the Electromagnetic Compatibility for a typical installation, further detailed data & requirements are described in the Site Preparation Manual.

1.0 GENERAL SCOPE

This equipment complies with IEC60601-1-2 Edition 2/ 3/ 4 EMC standard for medical electrical equipment.

1.1 The statement of the environments

This system is suitable to be used in the electromagnetic environment, as per the limits & recommendations described in the tables hereafter:

- Emission Compliance level & limits (Table 17-1)
- Immunity Compliance level & recommendations to maintain equipment clinical utility (Table 17-2).

NOTE: This system complies with above mentioned EMC standard when used with supplied cables up to maximum lengths referenced in the MIS MAPS or system cable interconnect diagrams.

1.2 Stacked components & equipment

This system should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, this system should be observed in order to verify normal operation in the configuration in which it will be used.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

1.3 Cable shielding & grounding

All interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference.

5805441-1EN Rev. 2 (Sep. 2020)

1.4 External components

The use of accessories, transducers, and cables other than those specified may result in degraded ELECTROMAGNETIC COMPATIBILITY of this system.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

2.0 ELECTROMAGNETIC EMISSION

The Emissions compliance statement is shown below.

Note the table is formatted similar to previous versions of emissions statements because the emissions requirements do not change in IEC EMC Edition 4 relative to previous editions 2 / 3.

Table 17-1 Emission Compliance Statement

This system is intended for use in the electromagnetic environment specified below. The customer or the user of this system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF emissions CISPR11	Group 1	This system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class A	
Harmonic emissions IEC 61000-3-2	Not applicable	This system is suitable for use in all establishments other than those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC61000-3-3	Not applicable	

3.0 ELECTROMAGNETIC IMMUNITY

The Immunity compliance statement is shown below.

Table 17-2 Immunity Compliance Statement Supporting IEC 60601-1-2: 2004, IEC60601-1-2:2007 and IEC 60601-1-2:2014

This system is intended for use in the electromagnetic environment specified below. The customer or the user of this system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**IEC 60601-1-2 Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV contact ±8 kV air ±15 kV air	Edition 2 and 3 Series ±6 kV contact ±8 kV air Edition 4 Series ±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile if floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines 5 kHz and 100 kHz rate ±1 kV for input/output lines 5 kHz and 100 kHz rate	Edition 2 and 3 Series ±2 kV for power supply lines 5 kHz rate ±1 kV for input/output lines 5 kHz rate Edition 4 Series ±2 kV for power supply lines 100 kHz rate ±1 kV for input/output lines 100 kHz rate	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line-line ±2 kV line-earth	Edition 2,3, and 4 Series ±1 kV line-line ±2 kV line-earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short inter-ruptions and voltage variations on power supply input lines IEC61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 5 s	[Edition 2 and 3] <5 % *U*T (>95 % dip in *U*T) for 5 s [Edition 4] 0 % *U*T for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of this system requires continued operation during power mains interruptions, it is recommended that this system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic fields IEC61000-4-8	3 A/m 30 A/m	Edition 2 and 3 Series 3 A/m Edition 4 Series 30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *U*T is the a.c. mains voltage prior to application of the test level.			

Table 17-3 Immunity Compliance Statement Supporting IEC 60601-1-2: 2004, IEC60601-1-2:2007 and IEC 60601-1-2:2014

This system is intended for use in the electromagnetic environment specified below. The customer or the user of this system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**IEC 60601-1-2 Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6 Radiated RF Fields / Proximity Fields from Wireless Transmitters IEC 61000-4-3	3Vrms 150 kHz to 80 MHz 3 V/m 80 MHz – 2.7 GHz 80 % AM 1 kHz	3Vrms 150 kHz to 80 MHz 3 V/m 80 MHz - 2.7 GHz 80 % AM 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of this system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter Recommended Separation Distance (see Table 17-4) $d = \left[\frac{3.5}{3}\right]\sqrt{P}$ 80 MHz to 800 MHz (see Table 17-4) $d = \left[\frac{3.5}{3}\right]\sqrt{P}$ 800 MHz to 2.7 GHz (see Table 17-4) $d = \left[\frac{7}{3}\right]\sqrt{P}$ where P IS the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

This system is intended for use in the electromagnetic environment specified below. The customer or the user of this system should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	IEC 60601-1-2 Compliance Level	Electromagnetic Environment Guidance
Proximity Fields from Wireless Transmitters	9 V/m to 28 V/m spot frequencies 385 MHz: 27 V/m 450 MHz: 28 V/m [c] 710 MHz: 9 V/m 745 MHz: 9 V/m 780 MHz: 9 V/m 810 MHz: 28 V/m 870 MHz: 28 V/m 930 MHz: 28 V/m 1720 MHz: 28 V/m 1845 MHz: 28 V/m 1970 MHz: 28 V/m 2450 MHz: 28 V/m 5240 MHz: 9 V/m 5500 MHz: 9 V/m 5785 MHz: 9 V/m PM 18 Hz or 217 Hz (50% duty cycle)	9 V/m to 28 V/m spot frequencies 385 MHz: 27 V/m 450 MHz: 28 V/m [c] 710 MHz: 9 V/m 745 MHz: 9 V/m 780 MHz: 9 V/m 810 MHz: 28 V/m 870 MHz: 28 V/m 930 MHz: 28 V/m 1720 MHz: 28 V/m 1845 MHz: 28 V/m 1970 MHz: 28 V/m 2450 MHz: 28 V/m 5240 MHz: 9 V/m 5500 MHz: 9 V/m 5785 MHz: 9 V/m PM 18 Hz or 217 Hz (50% duty cycle)	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Revolution EVO including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this system is used exceeds the applicable RF compliance level above, this system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this system.

[b] Over the frequency range 150 kHz to 80 MHz field strengths should be less than 3 V/m.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 17-4 Recommended separation distances between portable and mobile RF communications equipment and this system

Recommended separation distances between portable and mobile RF communications equipment and this system			
This system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this system can help prevent electromagnetic Interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this system as recommended below, according to the maximum output power of the communications equipment			
	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{3}\right]\sqrt{P}$	$d = \left[\frac{3.5}{3}\right]\sqrt{P}$	$d = \left[\frac{7}{3}\right]\sqrt{P}$
Rated Maximum Output Power (P) of Transmitter Watts (W)	Separation Distance meters	Separation Distance meters	Separation Distance meters
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) at frequencies noted below should be used no closer than 30cm (12 inches) to any part of this system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 17-5 Spot Frequencies

Spot Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (Watts)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	27
450	430-470	GMRS 460 FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2.0	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	9
810 870 930	800-960	GSM 800/900 TETRA 800 IDEN 820 CDMA 850 LTE Band 5	Pulse modulation [b] 18 Hz	2	28
1720 1845 1970	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UTMS	Pulse modulation [b] 217 Hz	2	28
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation [b] 217 Hz	2	28
5240 5300 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	9

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and this system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

$$E = \frac{6}{d}\sqrt{P}$$

5805441-1EN Rev. 2 (Sep. 2020)

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m

3.1 LIMITATIONS MANAGEMENT:

Adhering to the distance separation recommended in Table 17-3, between 150KHz & 2.5GHz, will reduce disturbances recorded at the image level but may not eliminate all disturbances. However, when installed and operated as specified herein, the system will maintain its essential performance by continuing to acquire, display, and store diagnostic quality images safely.

**For example. a 1W mobile phone (800MHz to 2.5GHz carrier frequency) shall be put 2.3 meters apart from this system (in order to avoid image interference risks).*

4.0 INSTALLATION REQUIREMENTS & ENVIRONMENT CONTROL:

In order to minimize interference risks, the following requirements shall apply.

4.1 This product complies the radiated emission as per CISPR11 Group1 Class A standard limits.

This system is predominantly intended for use, in non-domestic environments, and not directly connected to the Public Mains Network. This system is predominantly intended for use (e.g. in hospitals) with a dedicated supply system, and with a X-ray shielded room. In case of using in a domestic environment (e.g. doctors' offices), in order to avoid interferences, it is recommended to use a separated AC power distribution panel & line, with an X-ray shielded room.

4.2 Subsystem & accessories Power supply distribution

All components, accessories subsystems, systems which are electrically connected to this system, must have all AC power supplied by the same power distribution panel & line.

4.3 Low frequency magnetic field

In case of a digital system, the Gantry (digital detector) shall be apart 1 meter from the generator cabinet, and 1 meter apart from the analog (CRT) monitors. These distance specifications will minimize the low frequency magnetic field interference risk.

4.4 Static magnetic field limits

In order to avoid interference on this system, static field limits from the surrounding environment are specified.

Static field is specified less than <1 Gauss in Examination room, and in the Control Area.

Static field is specified less than <3 Gauss in the Technical Room.

4.5 Electrostatic discharge environment & recommendations

In order to reduce electrostatic discharge interference, install a charge dissipative floor material to avoid electrostatic charge buildup.

The relative humidity shall be at least 30 percent.

The dissipative material shall be connected to the system ground reference, it applicable.

5805441-1EN Rev. 2 (Sep. 2020)

Chapter 18
System Specifications

(Reference: IEC60601-1:2005 Clause7.9.3.1, IEC60601-1-3:2008 Clause5.1.1)

System Component Labeling

Table 18-1 Model Numbers

Component	Model Number	Rating Plate Locations	Certified Component?
Gantry	**(Scanner ID)** 5454001-x	Lower, left gantry base in rear	Y
CT Operator Computer Console	5946404-x (Type A) 5441626-x (Type B)	Rear of Cabinet	Y
VT1700V (500 lbs (227 kg)) Table or VT2000 (500 lbs (227 kg) Long) Table or VT2000x (675 lbs (306 kg) Long) Table	5122080-1x 5121647-x 5380966-x	Right side, low on front leg	Y
Performix™ 40 Plus Tube unit	2137130-x (Assembly)	On housing center	Y
Collimator	5345001-x	Tube at 12 o'clock on collimator front	Y
Generator	2371333-x	On Power Module housing	Y
Power Distribution Unit	2326492-81	Back horizontal surface of top cover	N

Throughout this manual, model numbers may contain a "-x" (i.e. 2137130-x). In these instances "x" can be any numeric or alpha numeric character. For example, in 2137130-x, "-x" refers to 2137130, 2137130-2, 2137130-3, etc.

All patient tables may not be available in all regions.

All the following figures are examples of the rating plate and name plate.

For IEC 60601-1:2005 (Third Edition) (Reference: IEC60601-1:2005 Clause7.2.7)

Figure 18-1 System Name Plate

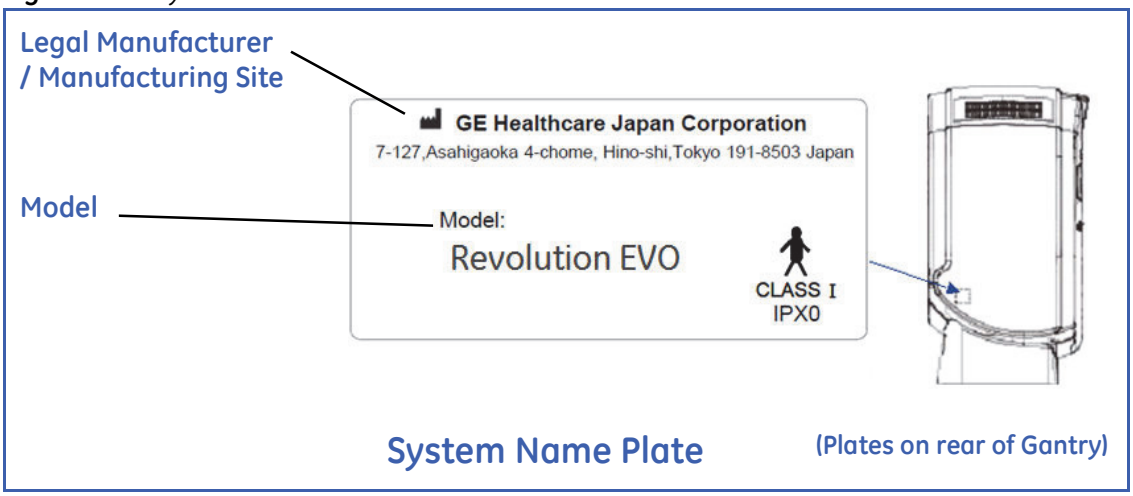
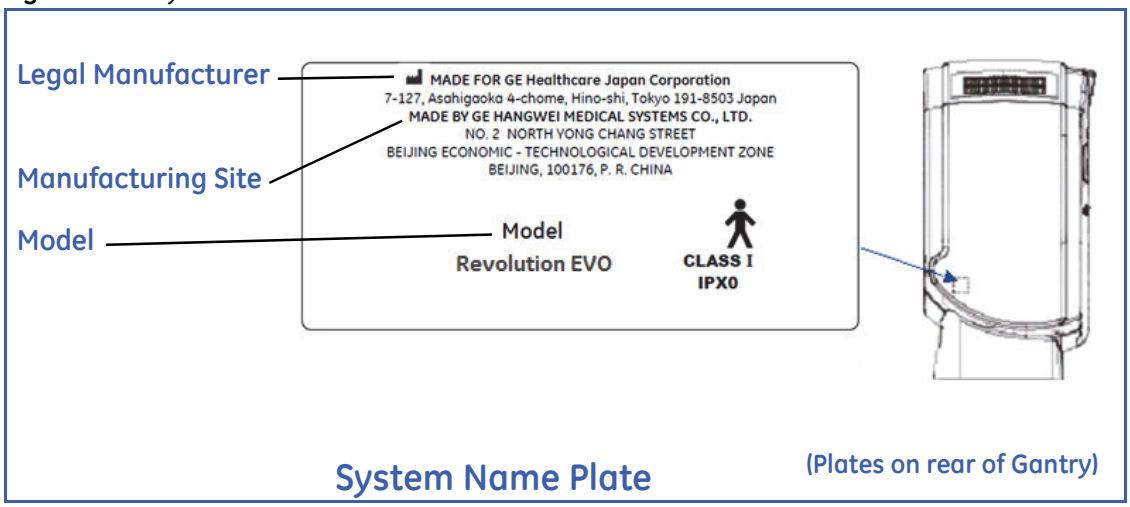


Figure 18-2 System Name Plate



5805441-1EN Rev. 2 (Sep. 2020)

Figure 18-3 System Name Plate

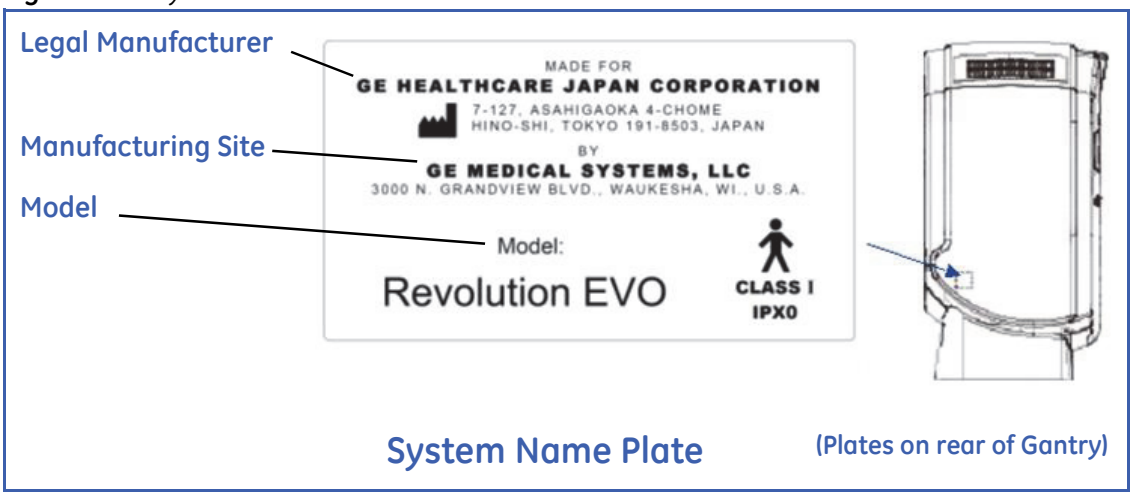


Figure 18-4 Gantry Rating Plates

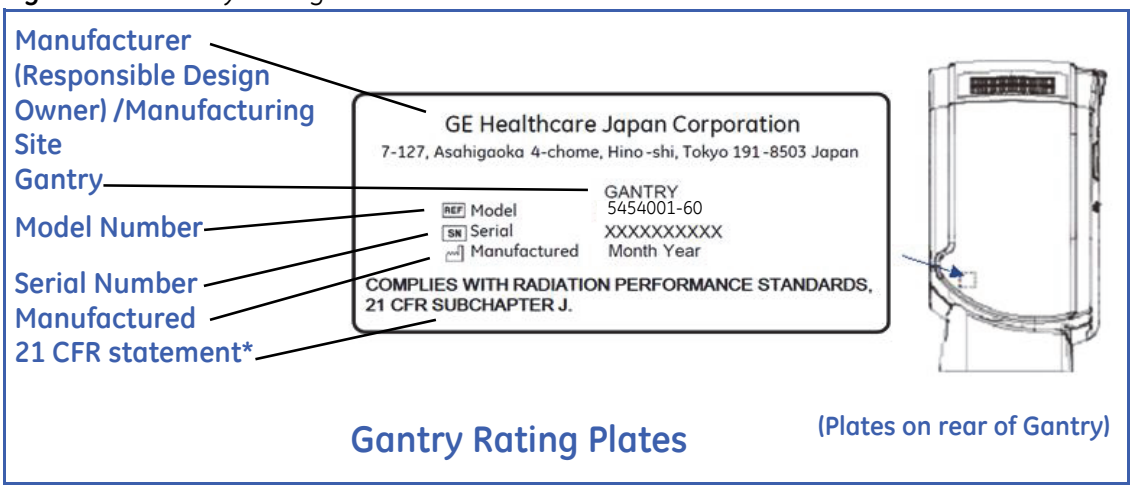


Figure 18-5 Gantry Rating Plates

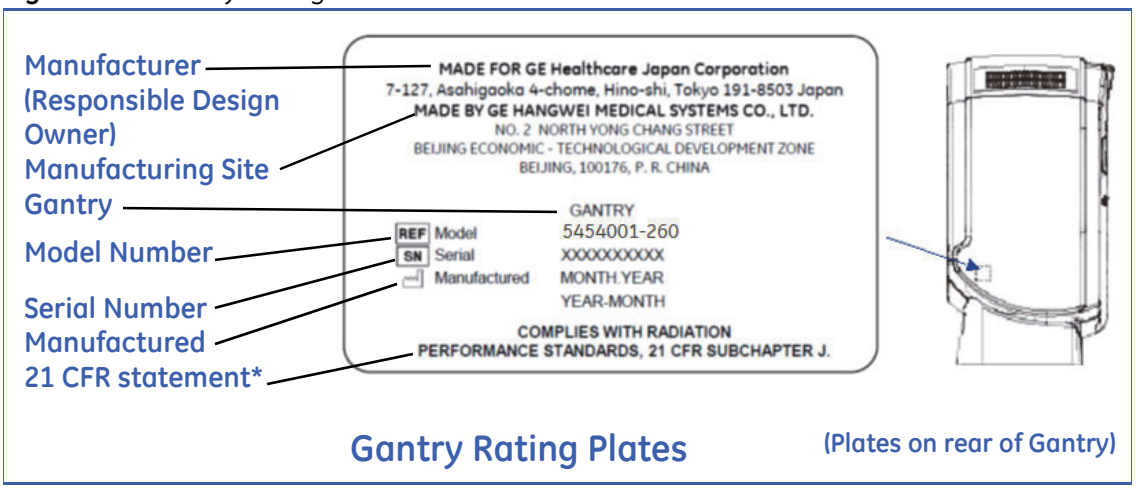


Figure 18-6 Gantry Rating Plates

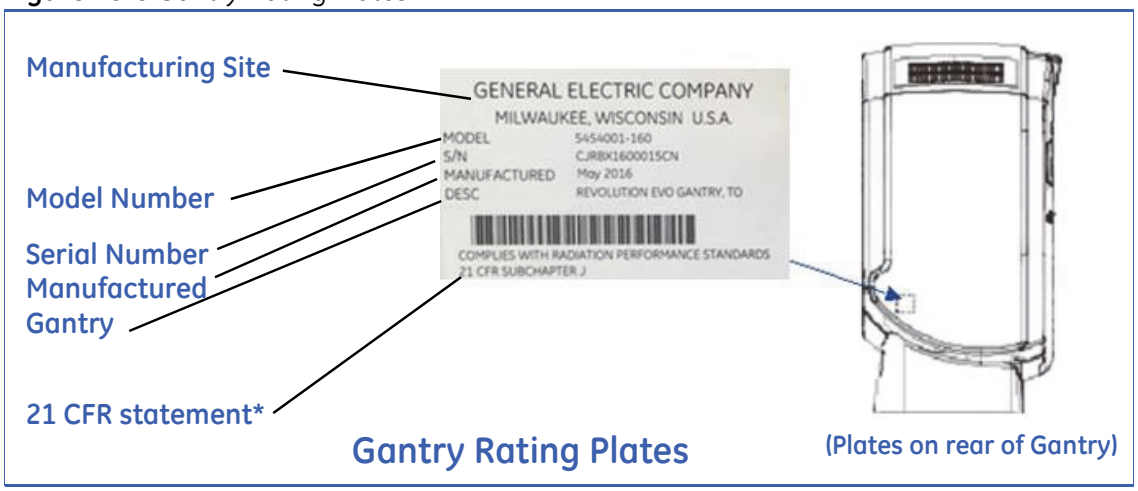


Figure 18-7 Table Rating Plates (For 675 Pounds (306 kg) Long Table)

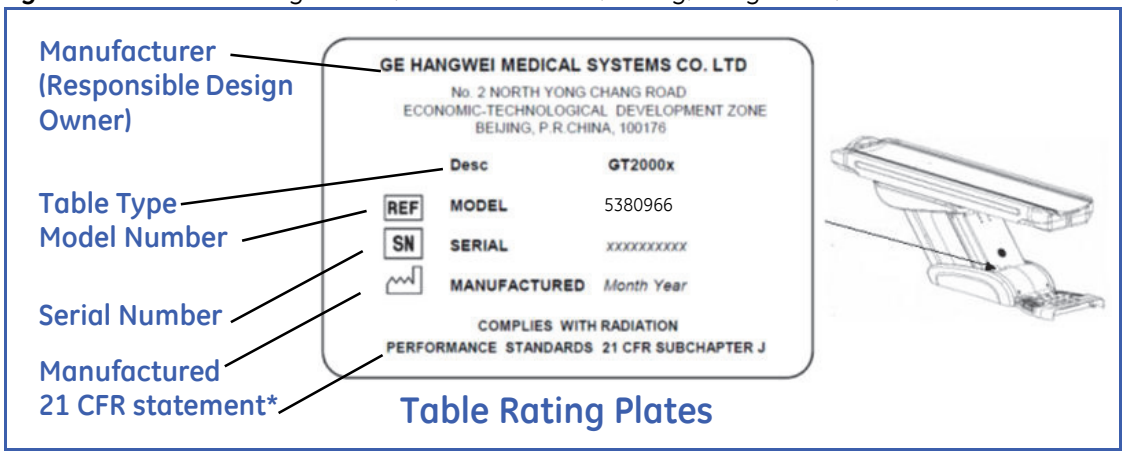
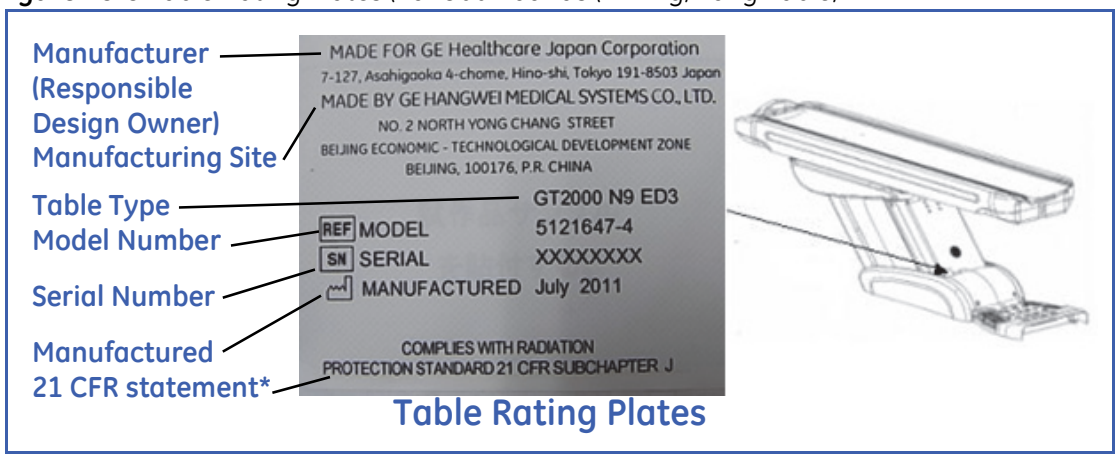


Figure 18-8 Table Rating Plates (For 500 Pounds (227 kg) Long Table)



5805441-1EN Rev. 2 (Sep. 2020)

Figure 18-9 Table Rating Plates (For 500 Pounds (227 kg) Table)

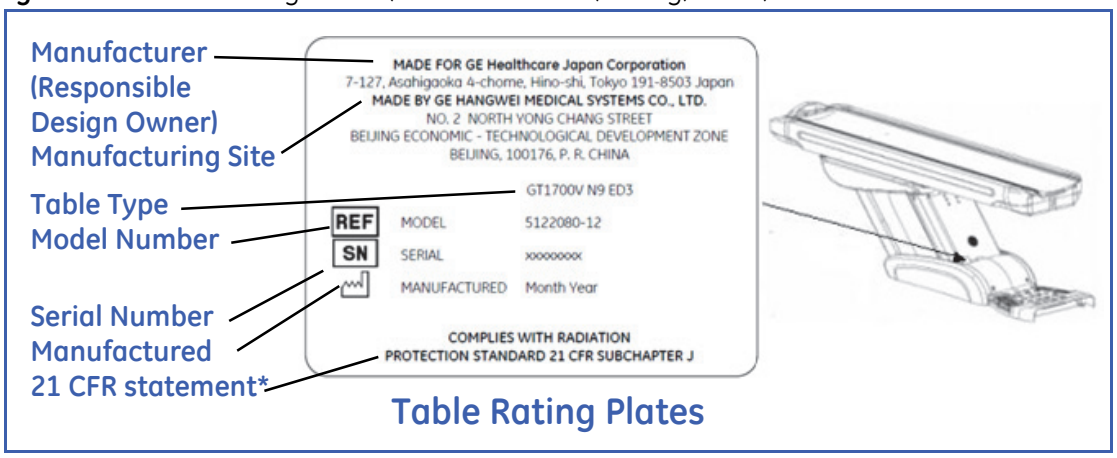
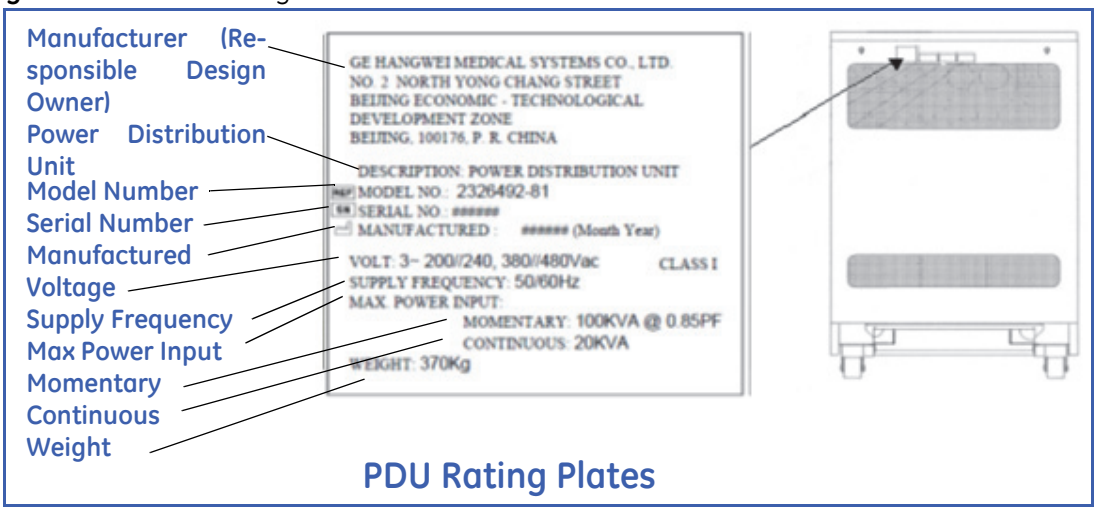
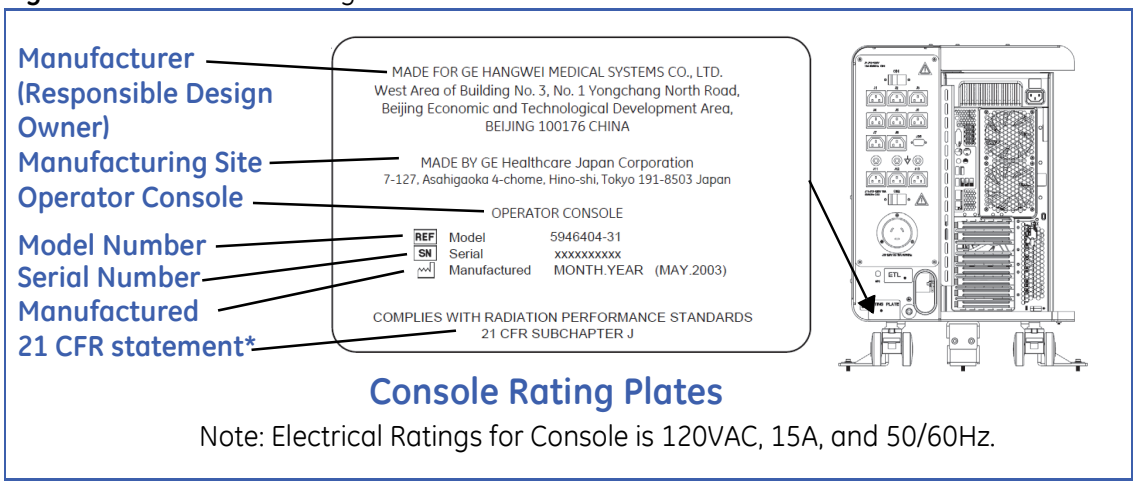


Figure 18-10 PDU Rating Plates



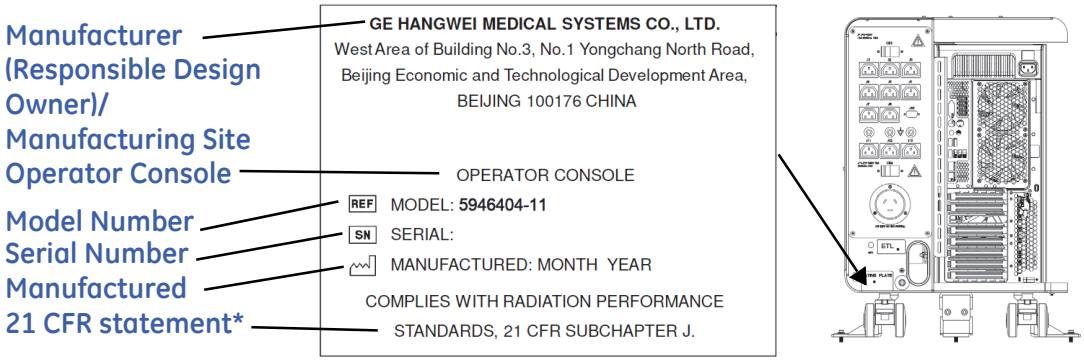
NOTE: Electrical Ratings on the PDU Rating Plate are the ratings for the CT System.

Figure 18-11 Console Rating Plates



Note: Electrical Ratings for Console is 120VAC, 15A, and 50/60Hz.

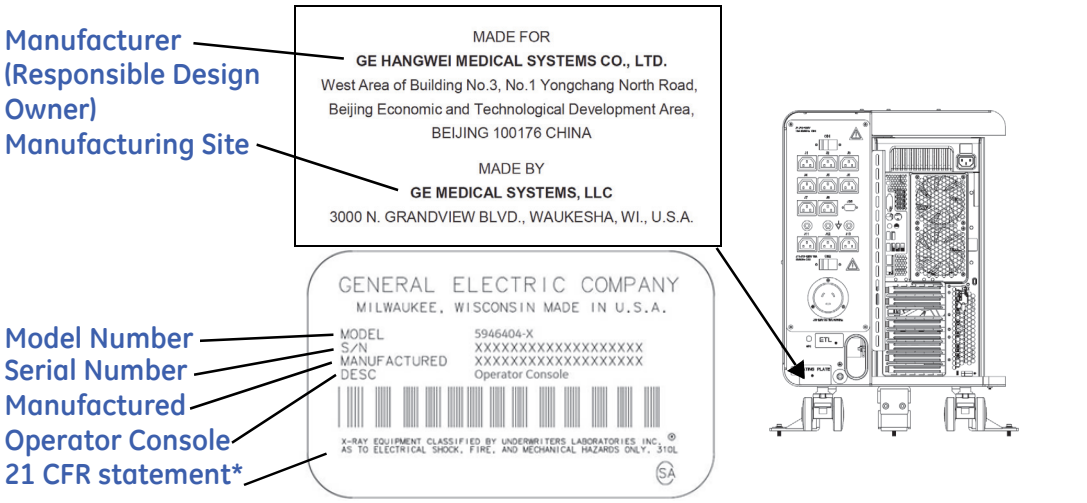
Figure 18-12 Console Rating Plates



Console Rating Plates

Note: Electrical Ratings for Console is 120VAC, 15A, and 50/60Hz.

Figure 18-13 Console Rating Plates

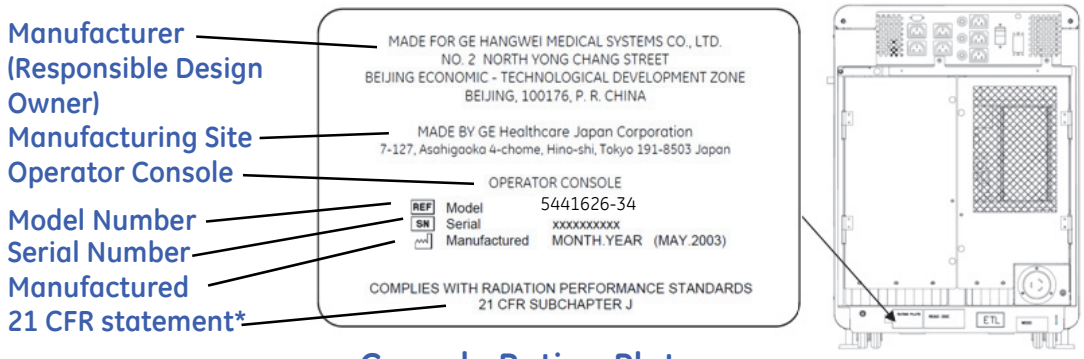


Console Rating Plates

Note: Electrical Ratings for Console is 120VAC, 15A, and 50/60Hz.

5805441-1EN Rev. 2 (Sep. 2020)

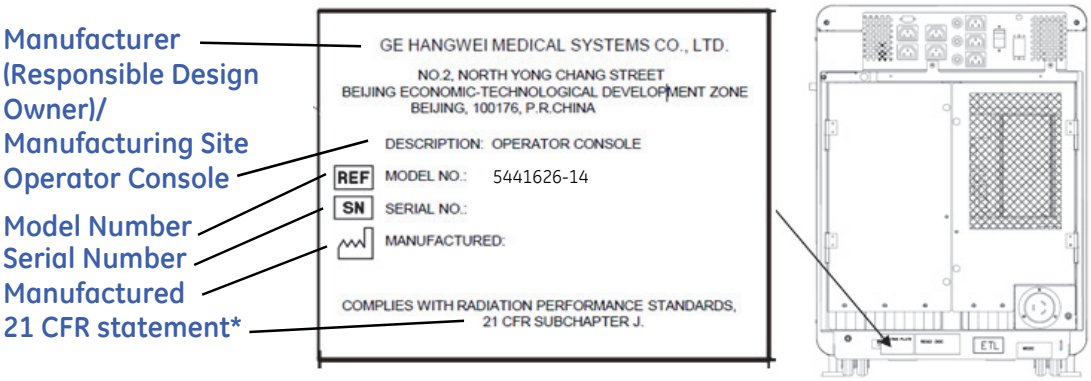
Figure 18-14 Console Rating Plates



Console Rating Plates

Note: Electrical Ratings for Console is 120VAC, 15A, and 50/60Hz.

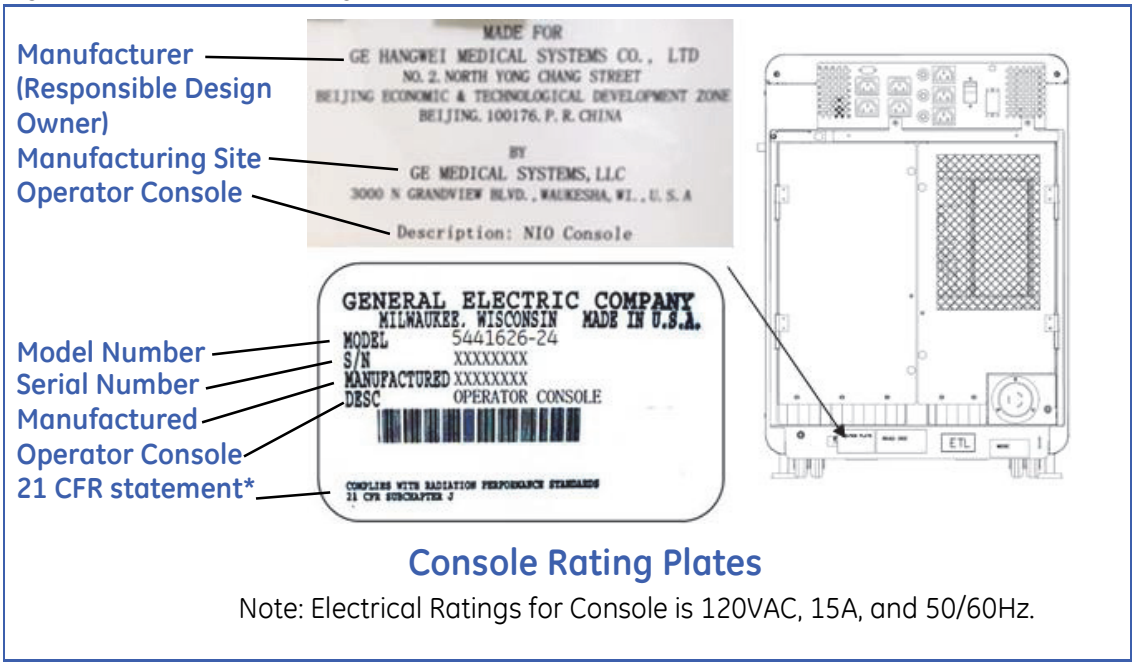
Figure 18-15 Console Rating Plates



Console Rating Plates

Note: Electrical Ratings for Console is 120VAC, 15A, and 50/60Hz.

Figure 18-16 Console Rating Plates



Console Rating Plates

Note: Electrical Ratings for Console is 120VAC, 15A, and 50/60Hz.

NOTE: *21 CFR statement : This is a statement of compliance with US radiation regulation, not safety warning or caution information.

5805441-1EN Rev. 2 (Sep. 2020)

Table 18-2 Translated Text

Month	Translated Text
January	
February	
March	
April	
May	
June	
July	
August	
September	
October	
November	
December	

System Configuration

Table 18-3 Maximum mA

kV	Max mA		
	Small Focal Spot (24 kW peak)	Large Focal Spot	
		75kVA System (48kW peak)	100kVA System (72kW peak)
80	300	400	400
100	240	450	480
120	200	400	560 (600*)
140	170	340	515
* 600mA is only applied to Cardiac Cine (Snap Shot Pulse).			

Table 18-4 System Dimensions

Component		Size (inches) (wide, height, depth, foot print)	Size (cm) (wide, height, depth, foot print)	Weight (lbs)	Weight (kg)
Gantry		80.7(w), 76.3(h), 40.9(d)	205(w), 194(h), 104(d)	4012	1820
Computer Console	NIO (Type A)	15.7(w), 22.7(h), 24.3(d)	40(w), 58(h), 62(d)	143	65
	NIO (Type B)	18.5(w), 25.8(h), 29(d)	47(w), 66(h), 74(d)	176	80
	Console peripherals	51.2(w), 35.2(d)	130(w), 89.5(d)	146	66
VT1700V (500 Pounds (227 kg)) Table		25.6(w), 41.2(h), 92.9 (d), 175.6(f)	65(w), 105(h), 236.0(d), 446(f)	981	445
VT2000 (500 Pounds (227 kg) Long) Table		25.6(w), 41.2(h), 114.6(d), 225.0(f)	65(w), 105(h), 291.0(d), 572(f)	1113	505
VT2000x (675 Pounds (306 kg) Long) Table		25.6(w), 41.2(h), 114.6(d), 225.0(f)	65(w), 105(h), 291.0(d), 572(f)	1122	509
Power Distribution Unit		27.6(w), 41.8(h), 21.7(d)	70(w), 106(h), 55(d)	816	370
Total System Weight	VT1700V (500 Pounds (227 kg)) Table			6131	2781
	VT2000 (500 Pounds (227 kg) Long) Table			6263	2841
	VT2000x (675 Pounds (306 kg) Long) Table			6272	2845

5805441-1EN Rev. 2 (Sep. 2020)

Purchasable Options

The following table lists options that may be available to purchase.

Table 18-5 Purchasable Options (Software)

Operator Instruction Name*1	Software Option Name*2	Data Sheet Name*3
0.35 second	Liquid-0.35-Routine	0.35sec rotation
0.35 second for cardiac	Sub-0.4-second-Scan	0.35sec rotation for cardiac
0.4 second	0_4Speed	0.4sec rotation
0.5 second	SmartSpeed	0.5sec rotation
64slice option	Patient-64-slice	64slice option(64ch)
Overlapped reconstruction	Overlapped recon - Axial	Overlapped reconstruction(64sl or 128sl)
72kW Power	100kVA	72kW Power
48kW Power	75kVA	48kW Power
SmartScore Pro	SmartScore Pro	SmartScore
ECG Viewer ECG Editor	EKG Viewer	ECG Trace
CardIQ SnapShot	CardIQ SnapShot	CardIQ SnapShot
SnapShot Pulse	CardIQ SnapShot-Cine	SnapShot Pulse
Cardiac Filters	NoiseReductionFilter	Cardiac Enhance
Adaptive Statistical Iterative Reconstruction -V (ASiR-V)	ASIR-V	ASIR-V
Adaptive Statistical Iterative Reconstruction (ASiR)	ASIR	ASiR (Adaptive Statistical Iterative Reconstruction)
VolumeShuttle (Axial)	AxialShuttle	Volume Shuttle
Volume Helical Shuttle	HelicalShuttle	Volume Helical Shuttle
SmartStep	SmartStep	SmartStep
Xtream Injector	Xtream Injector	Xtream Injector
Enhanced Xtream Injector	Enhanced Xtream Injector	Enhanced Xtream Injector
Exam Split	Exam Split	Exam Split
AutoBone Xpress	AutoBone_Xpress	AutoBone Xpress
AVA Xpress	AVA_Xpress	AVA Xpress

***1 : Operator Instruction Name is an option name described in User manual.**
***2 : Software Option Name is an option key name listed in Service Desktop.**
***3 : Data Sheet Name is an option name described in Product Data Sheet.**

Operator Instruction Name*1	Software Option Name*2	Data Sheet Name*3
Smart Metal Artifact Reduction (MAR)	MAR	Smart MAR
CardIQ Xpress 2.0 Reveal	CardIQP_Xpress_Reveal	CardIQ Xpress 2.0 Reveal
CardEP	CardEP	CardEP
Advantage CTC Pro3D EC	CT_Colono_Pro3D_EC	Advantage CTC Pro3D EC
CT Perfusion 4D Neuro	CT_Perfusion_4D_Neuro	CT Perfusion 4D Neuro
CT Perfusion 4D Multi-Organ	CT_Perfusion_4D_MultiOrgan	CT Perfusion 4D Multi Organ
Advantage Dentascan	DentaScan	Denta Scan
Image Check	Image Check	Image check
SmartView	Real Time CT Fluoro	SmartView
AW server connection	AWE connection	AWE connection
Emergency Patient on Gantry display	XtDisplay-OneStopScanning	One step scanning mode
ECG Wave on Gantry display	XtDisplay-ECGWave	ECG Wave on Gantry
SnapShot Assist	SnapShot Assist	SnapShot Assist
Temporal Enhance	SnapShot Assist Temporal Enhance	Temporal Enhance
Tube License	Enhanced Rotor Management-DS	Tube License
Anti-Virus	Anti-Virus	Anti-Virus
***1 : Operator Instruction Name is an option name described in User manual.** ***2 : Software Option Name is an option key name listed in Service Desktop.** ***3 : Data Sheet Name is an option name described in Product Data Sheet.**		

NOTE: Some options may be included with the standard feature set for certain counties.

Purchasable Option Descriptions

The following table lists options that may be available to purchase.

Table 18-6 Purchasable Options Desccriptions

Operator Instruction Name*1	Description
0.35 second	Enables from 0.35 s to 0.6 s rotation time.
0.35 second for cardiac	Enables from 0.35 s to 0.5 s rotation time for cardiac scan. Enables from 0.4 s to 0.6 s rotation time for Axial/Cine/Helical scan.
0.4 second	Enables from 0.4 s to 0.6 s rotation time.
0.5 second	Enables 0.5 and 0.6 s rotation time.
64slice option	Enables 64 slice mode.
Overlapped reconstruction	Provides reconstruction of overlapped 128 slices per rotation on 64-slice system (64 slices per rotation on 32-slice system) for Axial scan mode.
72kW Power	Enables mA prescription up to 72 kW.
48kW Power	Enables mA prescription up to 48 kW, provides maximum mA limitation.
SmartScore Pro	Acquires prospective ECG gating measurements, which provide information that is valuable for scan timing. Using the measurements, the system synchronizes the collection of data with the cardiac cycle.
ECG Viewer ECG Editor	Provides users the capability to view and retrospectively modify intervals and adjust location of triggers for cardiac cycles based on ECG waveform displayed on the console. This capability may improve successful cardiovascular acquisition rate in cases with suboptimal triggers or irregular heartbeats such as PVCs, PACs and arrhythmias.
CardIQ SnapShot	Low pitch ECG-gated helical acquisition mode where the pitch value is set based on the patient's heart rate. Three acquisition and reconstruction modes: SnapShot Segment, Burst and Burst Plus and one additional reconstruction mode. SnapShot Segment Plus. Patient's heart rate must be within 30-120 BPM range.
SnapShot Pulse	Axial step and shoot mode used to acquire images during a specified phase of the heart cycle with padding. Padding provides additional phase information to account for heart rate variation in the heart rate by adding time before and after the center phase of the acquisition. When used for coronary artery imaging the patient's heart rate should be within 30-65 BPM.
***1 : Operator Instruction Name is an option name described in User manual.**	

Operator Instruction Name*1	Description
Cardiac Filters	Cardiac noise reduction filters C1, C2, C3 can be selected to reduce noise in the images for SnapShot Segment, SnapShot Burst, SnapShot Burst Plus or SnapShot Pulse acquisitions.
Adaptive Statistical Iterative Reconstruction -V (ASiR-V)	An advanced reconstruction technique that enables reduction in image noise and streak artifact, and improvement in low contrast detectability(LCD) and image quality.
Adaptive Statistical Iterative Reconstruction (ASiR)	An advanced reconstruction technique that enables reduction in image noise and improvement in low contrast detectability (LCD) and image quality.
VolumeShuttle (Axial)	Repetitive axial scan mode where the table shuttles back and forth between two adjacent locations with 40mm detector coverage. Used for perfusion studies of the brain.
Volume Helical Shuttle	Adaptive scan-control architecture and dynamic pitch reconstruction maintains temporal sampling and extends Z coverage enabling dynamic studies. A repetitive helical scan mode allows the table to move continuously back and forth across a prescribed area where each pass has temporal time sampling information. The resulting acquisition can be used to create time resolved studies such as CT Angiography (CTA) of head, neck, and body and perfusion studies. Z-coverage is extended for dynamic (4D) CTA and perfusion studies up to 312.5mm (500 slices) and 140mm, respectively.
SmartStep	A mode of scanning designed to be used by the Radiologist or Physician during interventional procedures. Accomplished by using the integrated Hand Held Controller (HHC) and foot switch.
Xtream Injector	Enables Class1 functionality on a CiA425 complaint injector allowing only ON/OFF control. Xtream Injector is a start synchronization of system and injector.
Enhanced Xtream Injector	Enables Class4 functionality on a CiA425 complaint injector allowing ON/OFF and injector parameters to be set from the system. Enhanced Xtream Injector is a start synchronization of the system and injector and injection parameter communication between the system and injector.
***1 : Operator Instruction Name is an option name described in User manual.**	

5805441-1EN Rev. 2 (Sep. 2020)

Operator Instruction Name*1	Description
Exam Split	Provides you with the capability to “split” a series of patient images into separate groups. These new smaller image groups can be networked to desired reading stations for multiple “reads” and multiple billings on select patient exams.
AutoBone Xpress	Faciliates removal of bone and CT Table from CT Angiography (CTA) studies of the head, neck, abdomen and extremities.
AVA Xpress	Provides enhanced analysis of vascular features, which include stenosis analysis, pre/post stent planning procedures and directional vessel tortuosity visualization.
Smart Metal Artifact Reduction (MAR)	A reconstruction technique that reduces photon starvation artifacts caused by metal implantations.
CardIQ Xpress 2.0 Reveal	Provides the user with multiple tools to post process images from cardiac data sets. This feature may also be called CardIQ Xpress 2.0 Reveal in the manuals.
CardEP	Post processing image analysis software for the application of cardiovascular and electrophysiology imaging.
Advantage CTC Pro3D EC	Provides comprehensive software package for evaluation of quick, accurate, noninvasive colon exams. This feature may also be called Advantage CTC Colon VCAR with Electronic Cleansing in the manuals.
CT Perfusion 4D Neuro	Package includes protocols for neuro stroke and brain tumor perfusion.
CT Perfusion 4D Multi-Organ	Multi-organ package includes protocols for neuro stroke and tumor perfusion imaging and body tumor including liver perfusion imaging.
Advantage Dentascan	Allow specific analysis to aid in the pre-surgical evaluation of dental implants.
Image Check	Near real-time image reconstruction mode in a 340 x 340 matrix to confirm scan range coverage.
SmartView	Enables a real-time fluoro mode of scanning designed for interventional procedures.
AW server connection	Enables connection to AW Server as client, and operates all Advantage Windows Server applications at CT console.
Emergency Patient on Gantry display	Provides users the ability to access "Start new Patient" to "Confirm to scan" from the Gantry display.
***1 : Operator Instruction Name is an option name described in User manual.**	

Operator Instruction Name*1	Description
ECG Wave on Gantry display	Provides users the capability to display ECG waveform on Gantry display to review patient heart rate during cardiac scanning.
SnapShot Assist	Enables a mode that guides the user in selecting the appropriate cardiac imaging mode based on patient profile.
Temporal Enhance	Reconstruction mode to create images to support SnapShot Freeze cardiac image post processing.
Tube License - Enhanced Rotor Management-DS	Enables ASiR-V / ASiR, Volume Helical Shuttle and Cardiac scan when using a Non-GE tube.
Anti-Virus	Enables McAfee® Endpoint Security for Linux (ENSL) to detect threats and potentially unwanted software, then protects CT system from threats.
***1 : Operator Instruction Name is an option name described in User manual.**	

NOTE: Some options may be included with the standard feature set for certain countries.

Table 18-7 Supplementary equipments Types and Models

Type	Monufacturer/Model
Partial UPS	Eaton Powerware 9155-10GE
Bar Code Reader	Honeywell 3800g
	Honeywell 1300g
SmartStep Monitor (includes LCD monitor, video splitter, and mountings)	GE5115174-3
SmartStep Handheld Control	GE2199947-2
SmartStep Foot pedal	GE2199945-2

5805441-1EN Rev. 2 (Sep. 2020)

Helical High-Contrast Spatial Resolution (Reference YY0310)

3D MTF

Measurement basis: In-plane (XY) limiting resolution is determined by the reconstruction filter cutoff. The 50%, 10%, and 4% MTF are demonstrated on the GE Performance Phantom. MTF is calculated from a two-dimensional Fourier transform of the point spread function using pixel data around a 0.05mm tungsten wire. A tolerance of ± 10 % applies to all measurements.

Table 18-8 Scan Parameters (XY Plane)

Scan Parameter	
Scan Type	Helical
kV	120
mA	200
Scan Time	0.5 - 1.0 second (s) gantry rotation
Table Travel/Rotation	10 mm - 55 mm
Scan Thickness	5.0 mm
Pitch	0.516/0.531 to 1.531:1
SFOV	Head, Large Body or Small Body
DFOV	5 cm for Edge Plus, 25cm for Standard
Algorithm	Standard and Edge Plus kernels

Line pair values decrease with large focal spot; limiting resolution is unaffected.

Measurement basis: Z-plane limiting resolution is determined by active Z-axis length of the detector. The 50%, 10%, and 4% MTF are demonstrated by scanning a Gold Foil Phantom (a gold foil, (1mm diameter x 0.025mm thickness), embedded in tissue equivalent plastic) with the smallest image reconstruction interval available during prospective reconstruction. The MTF is calculated from the Fourier transform of the slice sensitivity profile obtained from the reconstructed images. A tolerance of ± 10 % applies to all measurements.

Table 18-9 Scan Parameters (Z-Plane)

Scan Parameter	
Scan Type	Helical
kV	120
mA	200
Scan Time	0.5 - 1.0 second (s) gantry rotation

Scan Parameter	
Scan Mode	20 mm aperture
Image Interval	Smallest available
Image Thickness	0.625 mm
Pitch	0.531:1
SFOV	Head, Large Body, or Small Body
DFOV	10 cm
Algorithm	Detail kernel

Table 18-10 Standard and Edge Plus Algorithm Results (XY Plane)

	X/Y LP/CM Typical (Standard)	X/Y LP/CM Typical (Edge Plus)
50%	4.2	12.1
10%	6.8	16.0
4%	7.5	18.3
0%	---	More than 18.3

Table 18-11 Algorithm Results (Z direction)

	Z LP/CM Typical Detail
50%	7.3
10%	12.2
4%	14.2
0% (Calculated)	19.7

5805441-1EN Rev. 2 (Sep. 2020)

Axial High Contrast Spatial Resolution

(Reference: IEC60601-2-44:2009 Clause203.6.7.2b), IEC60601-2-44:2009 Clause203.110, 21CFR1020.33 (c) (3) (ii) and YY0310)

Measurement basis: In-plane (XY) limiting resolution is determined by the reconstruction filter cutoff. The 50%, 10% and 4% MTF are demonstrated on the GE Performance Phantom. MTF is calculated from a two-dimensional Fourier transform of the point spread function using pixel data around a 0.05mm tungsten wire at the 4 center images of 40 mm aperture. A tolerance of ± 10 % applies to all measurements.

Table 18-12 Scan Parameters

Scan Parameter	
Scan Type	Axial
kV	120
mA	130
Scan Time	2.0 second (s) gantry rotation
Scan Mode	40 mm aperture
Image Thickness	5 mm
SFOV	Head, Large Body, Small Body, Ped Head, or Ped Body
DFOV	5 cm for Edge Plus, 25 cm for Standard
Algorithm	Standard and Edge Plus kernels

Line pair values decrease with large focal spot; limiting resolution is unaffected.

Figure 18-17 Typical In-plane (XY) Resolution

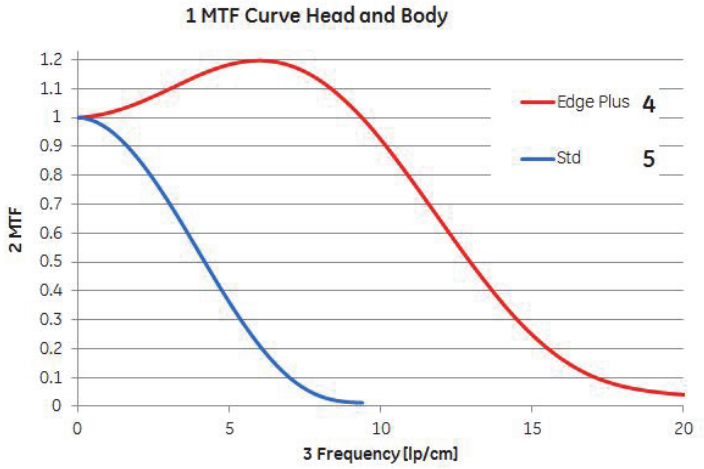


Table 18-13 Typical In-plane (XY) Resolution

Number	Description
1	MTF Curve Head and Body
2	MTF
3	Frequency (lp/cm)
4	Edge Plus
5	Standard

Table 18-14 Algorithm Results

	X/Y LP/CM Typical (Standard)	X/Y LP/CM Typical (Edge Plus)
50%	4.2	12.1
10%	6.8	16.0
4%	7.5	18.3
0%	---	More than 18.3

5805441-1EN Rev. 2 (Sep. 2020)

Helical Low-Contrast Detectability - Statistical

(Reference YY0310)

One 8 inch (20 cm) CATPHAN®600 phantom: the specifications listed in Table 18-15 apply with a ±10% tolerance.

Table 18-15 Standard Algorithm Statistical LCD Results – Helical (5 mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm, 5mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.30 %	12.56 mGy	Helical, 40mm aperture, 0.516:1 pitch, 1mm interval, 5mm slice thickness, 120kV, 85mA, 1 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, 4 image
	3mm	0.30 %	43.58 mGy	Helical, 40mm aperture, 0.516:1 pitch, 1mm interval, 5mm slice thickness, 120kV, 295mA, 1 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, 4 image

Table 18-16 Standard Algorithm with ASiR Statistical LCD Results – Helical (5 mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm with ASiR Reconstruction, 5mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.32 %	9.97 mGy	Helical, 40mm aperture, 0.516:1 pitch, 1mm interval, 5mm slice thickness, 120kV, 75mA, 0.9second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR, 4 image
	3mm	0.32 %	28.07 mGy	Helical, 40mm aperture, 0.516:1 pitch, 1mm interval, 5mm slice thickness, 120kV, 190mA, 1 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR, 4 image
	2mm	0.32 %	53.77 mGy	Helical, 40mm aperture, 0.516:1 pitch, 1mm interval, 5mm slice thickness, 120kV, 455mA, 0.8 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR, 4 image

5805441-1EN Rev. 2 (Sep. 2020)

Table 18-17 Standard Algorithm with ASiR-V Statistical LCD Results – Helical (5 mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm with ASiR-V Reconstruction, 5mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.30 %	8.12 mGy	Helical, 40mm aperture, 0.516:1 pitch, 1mm interval, 5mm slice thickness, 120kV, 55mA, 1 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR-V, 4 image
	3mm	0.30 %	22.90 mGy	Helical, 40mm aperture, 0.516:1 pitch, 1mm interval, 5mm slice thickness, 120kV, 155mA, 1 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR-V, 4 image
	2mm	0.30 %	42.84 mGy	Helical, 40mm aperture, 0.516:1 pitch, 1mm interval, 5mm slice thickness, 120kV, 290mA, 1 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR-V, 4 image

Table 18-18 Standard Algorithm Statistical LCD Results – Helical (10 mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm, 10mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.30 %	8.12 mGy	Helical, 40mm aperture, 0.516:1 pitch, 2.5mm interval, 10mm slice thickness, 120kV, 55mA, 1 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, 4 images
	3mm	0.30 %	28.80 mGy	Helical, 40mm aperture, 0.516:1 pitch, 2.5mm interval, 10mm slice thickness, 120kV, 195mA, 1 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, 4 images

Table 18-19 Standard Algorithm with ASiR Statistical LCD Results – Helical (10 mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm with ASiR Reconstruction, 10mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.32 %	5.69 mGy	Helical, 40mm aperture, 0.516:1 pitch, 2.5mm interval, 10mm slice thickness, 120kV, 55mA, 0.7 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR, 4 images
	3mm	0.32 %	16.03 mGy	Helical, 40mm aperture, 0.516:1 pitch, 2.5mm interval, 10mm slice thickness, 120kV, 155mA, 0.7 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR, 4 images
	2mm	0.32 %	31.02 mGy	Helical, 40mm aperture, 0.516:1 pitch, 2.5mm interval, 10mm slice thickness, 120kV, 300mA, 0.7 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR, 4 images

5805441-1EN Rev. 2 (Sep. 2020)

Table 18-20 Standard Algorithm with ASiR-V Statistical LCD Results – Helical (10 mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm with ASiR-V Reconstruction, 10mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.30 %	4.87 mGy	Helical, 40mm aperture, 0.516:1 pitch, 2.5mm interval, 10mm slice thickness, 120kV, 55mA, 0.6 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR-V, 4 images
	3mm	0.30 %	14.77 mGy	Helical, 40mm aperture, 0.516:1 pitch, 2.5mm interval, 10mm slice thickness, 120kV, 100mA, 1 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR-V, 4 images
	2mm	0.30 %	29.54 mGy	Helical, 40mm aperture, 0.516:1 pitch, 2.5mm interval, 10mm slice thickness, 120kV, 200mA, 1 second (s) gantry rotation speed, small body scan FOV, 22.7 cm display FOV, standard algorithm, Full Mode, ASiR-V, 4 images

Test method is as follows:

1. Measure mean CT # values of an array of pixel groups with an area equal to the size of the detectable object size
2. Calculate the standard deviation for the means of the pixel groups.
3. Statistically calculate the % contrasted change needed to insure with 95% confidence that an object with this contrast could be detected with the above background noise, and 95% confidence that it's not detected when present.

NOTE: These dose values are for the normal table (VT1700V or VT2000) only. For the heavy patient table VT2000x, convert them into values for VT2000x using dose scaling factors (Table 12-22).

NOTE: Due to the scan length dependent nature of Dynamic Z-axis Tracking (IEC60601-2-44 ed3), the system Noise and Low Contrast Detectability specifications are reported without the scan length dependent dose reduction impact of Dynamic Z-axis Tracking. This ensures that the system can achieve or exceed the provided system specifications regardless of the chosen scan length. For short scan length, such as those used for phantom scans, the dose reduction impact of Dynamic Z-axis Tracking may result in dose values lower than provided system specifications, which is to be expected and may be accounted for by adjusting the specified dose by the tracking adjustment factor provided in Chapter 12. Recommended scan length for phantom evaluation is at least the width of the beam aperture.

Axial Low-Contrast Detectability - Statistical

(Reference YY0310)

One 8 inch (20 cm) CATPHAN®600 phantom: the specifications listed in Table 18-21 apply, with a ±10% tolerance.

Table 18-21 Standard Algorithm Statistical LCD Results – Axial (5mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm, 5mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.30 %	12.95 mGy	40mm aperture, 120 kV, 170 mAs, 0.5 to 2.0 second (s) gantry rotation speed, axial acquisition mode with 5 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm
	3mm	0.30 %	44.18 mGy	40mm aperture, 120 kV, 580 mAs, 1.0 to 2.0 second (s) gantry rotation speed, axial acquisition mode with 5 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm

5805441-1EN Rev. 2 (Sep. 2020)

Table 18-22 Standard Algorithm with ASiR Statistical LCD Results – Axial (5mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm with ASiR Reconstruction, 5mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.32 %	12.19 mGy	40mm aperture, 120 kV, 160 mAs, 0.5 to 2.0 second (s) gantry rotation speed, axial acquisition mode with 5 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR
	3mm	0.32 %	31.99 mGy	40mm aperture, 120 kV, 420 mAs, 1.0 or 2.0 second (s) gantry rotation speed, axial acquisition mode with 5 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR
	2mm	0.32 %	63.22 mGy	40mm aperture, 120 kV, 830 mAs, 2.0 second (s) gantry rotation speed, axial acquisition mode with 5 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR

Table 18-23 Standard Algorithm with ASiR-V Statistical LCD Results – Axial (5mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm with ASiR-V Reconstruction, 5mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.30 %	7.62 mGy	40mm aperture, 120 kV, 100 mAs, 0.5 to 2.0 second (s) gantry rotation speed, axial acquisition mode with 5 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR-V
	3mm	0.30 %	22.85 mGy	40mm aperture, 120 kV, 300 mAs, 1.0 or 2.0 second (s) gantry rotation speed, axial acquisition mode with 5 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR-V
	2mm	0.30 %	43.41 mGy	40mm aperture, 120 kV, 570 mAs, 2.0 second (s) gantry rotation speed, axial acquisition mode with 5 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR-V

Table 18-24 Standard Algorithm Statistical LCD Results – Axial (10mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm, 10mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.30 %	7.62 mGy	40mm aperture, 120 kV, 100 mAs, 0.5 to 2.0 second (s) gantry rotation speed, axial acquisition mode with 10 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm
	3mm	0.30 %	24.75 mGy	40mm aperture, 120 kV, 325 mAs, 0.5 to 2.0 second (s) gantry rotation speed, axial acquisition mode with 10 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm

5805441-1EN Rev. 2 (Sep. 2020)

Table 18-25 Standard Algorithm with ASiR Statistical LCD Results – Axial (10mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm with ASiR Reconstruction, 10mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.32 %	6.09 mGy	40mm aperture, 120 kV, 80 mAs, 0.5 to 2.0 second (s) gantry rotation speed, axial acquisition mode with 10 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR
	3mm	0.32 %	15.99 mGy	40mm aperture, 120 kV, 210 mAs, 0.5 or 2.0 second (s) gantry rotation speed, axial acquisition mode with 10 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR
	2mm	0.32 %	31.23 mGy	40mm aperture, 120 kV, 410 mAs, 1.0 or 2.0 second (s) gantry rotation speed, axial acquisition mode with 10 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR

Table 18-26 Standard Algorithm with ASiR-V Statistical LCD Results – Axial (10mm Slice Thickness)

Reconstruction Mode	Object Size	% Contrast	Dose	Suggested Technique
Standard Algorithm with ASiR-V Reconstruction, 10mm Nominal Image Thickness, 22.7 cm Display Field of View	5mm	0.30 %	4.57 mGy	40mm aperture, 120 kV, 60 mAs, 0.5 to 2.0 second (s) gantry rotation speed, axial acquisition mode with 10 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR-V
	3mm	0.30 %	12.95 mGy	40mm aperture, 120 kV, 170 mAs, 0.5 or 2.0 second (s) gantry rotation speed, axial acquisition mode with 10 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR-V
	2mm	0.30 %	24.37 mGy	40mm aperture, 120 kV, 320 mAs, 1.0 or 2.0 second (s) gantry rotation speed, axial acquisition mode with 10 mm nominal image thickness, small body scan FOV, 22.7 cm display FOV, 512 recon, and standard algorithm ASiR-V

Test method is as follows:

1. Measure mean CT # values of an array of pixel groups with an area equal to the size of the detectable object size
2. Calculate the standard deviation for the means of the pixel groups.
3. Statistically calculate the % contrasted change needed to insure with 95% confidence that an object with this contrast could be detected with the above background noise, and 95% confidence that it's not detected when present.

NOTE: These dose values are for the normal table (VT1700V or VT2000) only. For the heavy patient table VT2000x, convert them into values for VT2000x using dose scaling factors (Table 12-22).

Helical Image Noise (Reference: IEC60601-2-44:2009 Clause203.6.7.2a), 21CFR 1020.33 (c) (3) (i) and YY0310)

Measurement Basis: Noise is demonstrated on the following phantom:

- Head, Small Body: 8.5 inch AAPM water phantom or GE Quality Assurance phantom provided with the system using 25mm x 25mm box ROI.
- Large Body: GE 35PP phantom using 14cm x 14cm Box ROI or smaller size of ROI

Standard Algorithm

Head

0.43 % ± 0.06 % at 44.0 mGy $CTDI_{vol}$ (equivalent to 0.30 % at 90 mGy)

Suggested Scan Technique

120kV, 135mAs, 0.5 to 1.0 second (s) gantry rotation, 0.516:1 pitch (adjust mA and rotation speed so that the CTDIvol equals 44.0 mGy ± 1 mGy. This corresponds to approximately 135 mAs) with 5mm nominal image thickness, Head scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

Small Body

0.43 % ± 0.06 % at 19.9 mGy $CTDI_{vol}$ (equivalent to 0.30 % at 41 mGy)

Suggested Scan Technique

120kV, 135mAs, 0.5 to 1.0 second (s) gantry rotation, 0.516:1 pitch (adjust mA and rotation speed so that the CTDIvol equals 19.9 mGy ± 1 mGy. This corresponds to approximately 135 mAs) with 5mm nominal image thickness, Small Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

Large Body

Less than 1.4 % at 22.8 mGy $CTDI_{vol}$

Suggested Scan Technique

120kV, 135mAs, 0.5 to 1.0 second (s) gantry rotation, 0.516:1 pitch (adjust mA and rotation speed so that the CTDIvol equals 22.8 mGy ± 1 mGy. This corresponds to approximately 135 mAs) with 5mm nominal image thickness, Large Body scan FOV, 35 cm display FOV, 512 recon, and standard algorithm.

ASiR-V Reconstruction

Small Body

0.43 % ± 0.06 % at 4.7 mGy $CTDI_{vol}$

Suggested Scan Technique

120kV, 35mAs, 0.5 to 1.0 second (s) gantry rotation, 0.516:1 pitch (adjust mA and rotation speed so that the $CTDI_{vol}$ equals 4.7 mGy ± 1 mGy. This corresponds to approximately 35 mAs) with 5 mm nominal image thickness, Small Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm with ASiR-V reconstruction.

NOTE: Due to the scan length dependent nature of Dynamic Z-axis Tracking (IEC60601-2-44 Ed3), the system Noise and Low Contrast Detectability specifications are reported without the scan length dependent dose reduction impact of Dynamic Z-axis Tracking. This ensures that the system can achieve or exceed the provided system specifications regardless of the chosen scan length. For short scan length, such as those used for phantom scans, the dose reduction impact of Dynamic Z-axis Tracking may result in dose values lower than provided system specifications, which is to be expected and may be accounted for by adjusting the specified dose by the tracking adjustment factor provided in Chapter 12. Recommended scan length for phantom evaluation is at least the width of the beam aperture.

NOTE: These dose values are for the normal table (VT1700V or VT2000) only. For the heavy patient table VT2000x, convert them into values for VT2000x using dose scaling factors (Table 12-22).

ASiR Reconstruction

Small Body

0.43 % ± 0.06 % at 11.1 mGy $CTDI_{vol}$

Suggested Scan Technique

120kV, 75mAs, 0.5 to 1.0 second (s) gantry rotation, 0.516:1 pitch (adjust mA and rotation speed so that the $CTDI_{vol}$ equals 11.1 mGy. This corresponds to approximately 135 mAs) with 5 mm nominal image thickness, Small Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm with ASiR reconstruction.

Large Body

Less than 1.4 % at 12.7 mGy $CTDI_{vol}$

Suggested Scan Technique

120kV, 75mAs, 0.5 to 1.0 second (s) gantry rotation, 0.516:1 pitch (adjust mA and rotation speed so that the $CTDI_{vol}$ equals 12.7 mGy. This corresponds to approximately 135 mAs) with 5 mm nominal image thickness, Large Body scan FOV, 35 cm display FOV, 512 recon, and standard algorithm with ASiR reconstruction.

5805441-1EN Rev. 2 (Sep. 2020)

NOTE: Due to the scan length dependent nature of Dynamic Z-axis Tracking (IEC60601-2-44 Ed3), the system Noise and Low Contrast Detectability specifications are reported without the scan length dependent dose reduction impact of Dynamic Z-axis Tracking. This ensures that the system can achieve or exceed the provided system specifications regardless of the chosen scan length. For short scan length, such as those used for phantom scans, the dose reduction impact of Dynamic Z-axis Tracking may result in dose values lower than provided system specifications, which is to be expected and may be accounted for by adjusting the specified dose by the tracking adjustment factor provided in Chapter 12. Recommended scan length for phantom evaluation is at least the width of the beam aperture.

NOTE: These dose values are for the normal table (VT1700V or VT2000) only. For the heavy patient table VT2000x, convert them into values for VT2000x using dose scaling factors (Table 12-22).

NOTE: Utilizing ASiR, images obtained can have equivalent IQ to an acquisition with up to 1.67 times the mA. (Equivalent IQ is equivalent Image noise SD.)

Axial Image Noise (Reference: IEC60601-2-44:2009 Clause203.6.7.2a), 21CFR 1020.33 (c) (3) (i) and YY0310)

Measurement Basis: Noise is demonstrated on the following phantom:

- Head, Small Body, Large Body (Small Phantom), Ped Head, or Ped Body: 8.5 inch AAPM water phantom or GE Quality Assurance phantom provided with the system using 25mm x 25mm box ROI.
- Large Body (Large Phantom): GE 35PP phantom using 14cm x 14cm Box ROI or smaller size of ROI

Standard Algorithm

Head

0.43 % ± 0.06 % at 43.5 mGy $CTDI_{vol}$

Suggested Scan Technique:

120kVp, 130mA, 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Head scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

Small Body

0.43 % ± 0.06 % at 19.8 mGy $CTDI_{vol}$

Suggested Scan Technique:

120kVp, 130mA, 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Small Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

Large Body

Large Phantom

1.22 % ± 0.18 % at 22.7 mGy $CTDI_{vol}$

Suggested Scan Technique:

120kVp, 130mA, 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Large Body scan FOV, 35 cm display FOV, 512 recon, and standard algorithm.

Small Phantom, 80kVp

0.51 % ± 0.075 % at 22.0 mGy $CTDI_{vol}$

Suggested Scan Technique:

80kVp, 400mA, 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Large Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

Small Phantom, 100kVp

0.47 % ± 0.075 % at 22.7 mGy $CTDI_{vol}$

Suggested Scan Technique:

100kVp, 210mA, 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Large Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

Small Phantom, 120kVp

0.47 % ± 0.075 % at 22.7 mGy $CTDI_{vol}$

Suggested Scan Technique:

120kVp, 130mA, 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Large Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

Small Phantom, 140kVp

0.47 % ± 0.075 % at 22.8 mGy $CTDI_{vol}$

Suggested Scan Technique:

140kVp, 180mA, 1.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Large Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

Ped Head

0.43 % ± 0.075 % at 43.5 mGy $CTDI_{vol}$

Suggested Scan Technique:

120kVp, 130mA, 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Ped Head scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

Ped Body

80kVp

0.47 % ± 0.075 % at 19.1 mGy $CTDI_{vol}$

Suggested Scan Technique:

80kVp, 375mA, 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Ped Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

100kVp

0.43 % ± 0.075 % at 19.9 mGy $CTDI_{vol}$

Suggested Scan Technique:

100kVp, 205mA, 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Ped Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

120kVp

0.43 % ± 0.075 % at 19.8 mGy $CTDI_{vol}$

Suggested Scan Technique:

120kVp, 130mA, 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Ped Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

140kVp

0.43 % ± 0.075 % at 19.5 mGy $CTDI_{vol}$

Suggested Scan Technique:

140kVp, 180mA, 1.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Ped Body scan FOV, 25 cm display FOV, 512 recon, and standard algorithm.

ASiR-V Reconstruction

Small Body

0.43 % ± 0.06 % at 4.95 mGy

Suggested Scan Technique:

120kV, 65mAs, 0.5 to 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Small Body scan FOV, 25cm display FOV, 512 recon, and standard algorithm with ASiR-V reconstruction.

NOTE: These dose values are for the normal table (VT1700V or VT2000) only. For the heavy patient table VT2000x, convert them into values for VT2000x using dose scaling factors (Table 12-22).

ASiR Reconstruction

Small Body

0.43 % ± 0.06 % at 11.0 mGy

Suggested Scan Technique:

120kV, 145mAs, 0.5 to 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Small Body scan FOV, 25cm display FOV, 512 recon, and standard algorithm with ASiR reconstruction.

Large Body

Less than 1.4 % at 12.6 mGy

Suggested Scan Technique:

120kV, 145mAs, 0.5 to 2.0 second (s) gantry rotation, 5mm nominal image thickness, 8i mode reconstruction, Large Body scan FOV, 35cm display FOV, 512 recon, and standard algorithm with ASiR reconstruction.

NOTE: These dose values are for the normal table (VT1700V or VT2000) only. For the heavy patient table VT2000x, convert them into values for VT2000x using dose scaling factors (Table 12-22).

NOTE: Utilizing ASiR, images obtained can have equivalent IQ to an acquisition with up to 1.67 times the mA. (Equivalent IQ is equivalent Image noise SD.)

CT Number Linearity

- CT number of water 0 HU ± 3 HU for 120kVp (Head, Small Body, Ped Head, or Ped Body)
- CT number of water 0 HU ± 6 HU (Large Body for all kVps or Ped Body for 80/100/140kVps)
- CT number of air -1000 HU ± 10 HU
- CT number of Poly -92 HU ± 6 HU for 120kVp (Large Body)

CT Number Uniformity

- CT number of uniformity ± 3 HU for 120kVp (Head, Small Body, Ped Head, or Ped Body)
- CT number of uniformity ± 8 HU (Large Body for all kVps or Ped Body for 80/100/140kVps)

5805441-1EN Rev. 2 (Sep. 2020)

Dose Performance (Reference: IEC60601-2-44:2009 Clause203.109.1)

Table 18-27 Helical Dose and Axial Dose Performance

$CTDI_{100}$ Expressed in mGy			
	Ped Head Head	Ped Body Small Body	Large Body
Center	43.8	13.0	13.6
Peripheral	43.4	23.2	27.2
$CTDI_w$ Expressed in mGy*			
	Ped Head Head	Ped Body Small Body	Large Body
	43.5	19.8	22.7
$CTDI_{100}$ Expressed in mGy/100mAs			
	Ped Head Head	Ped Body Small Body	Large Body
Center	16.8	5.0	5.2
Peripheral	16.7	8.9	10.5
$CTDI_w$ Expressed in mGy/100mAs			
	Ped Head Head	Ped Body Small Body	Large Body
	16.7	7.6	8.7

NOTE: *$CTDI_w$ = $CTDI_{100}$ peripheral x 2/3 + $CTDI_{100}$ center x 1/3

Helical Scan Technique:120kVp, 260 mAs, 0.35 to 1.0 second (s) gantry rotation, 64 x 0.625, pitch 0.98:1 or 0.968:1, 5mm slice thickness.

Axial Scan Technique:120kVp, 260 mAs, 0.35 to 2.0 second (s) gantry rotation, 64 x 0.625, 5mm nominal image thickness.

Measurement Basis: Helical $CTDI_{100}$ and $CTDI_w$ is identical to the measured axial $CTDI_{100}$ and $CTDI_w$ data for the case for 1.0:1helical pitch. Otherwise, the appropriate helical scan mode scan mode correction factor should be applied. Both Axial and Helical measurements are adjusted for 260 mAs technique. Large focal spot tables apply for all gantry speeds from 0.4 to 1.0 second (s) .

Expected deviation equals ± 15%. Deviations may be greater than the expected deviation range for low mA or narrow aperture scan where variation may be greater (up to a factor of two) due to the inherent deviation in small values.

Maximum deviation anticipated for tube output equals ± 40%.

NOTE: These dose values are for the normal table (VT1700V or VT2000) only. For the heavy patient table VT2000x, convert them into values for VT2000x using dose scaling factors (Table 12-22).

Tomographic Section Thickness for Axial Scanning (Reference: IEC60601-2-44:2009 Clause203.6.7.2a)

- Tomographic section thickness 0.625 mm ± 0.5 mm (Slice thickness 0.625 mm)
- Tomographic section thickness 1.25 mm ± 0.625 mm (Slice thickness 1.25 mm)
- Tomographic section thickness 2.5 mm ± 1.0 mm (Slice thickness 2.5 mm)
- Tomographic section thickness 5.0 mm ± 1.0 mm (Slice thickness 5.0 mm)
- Tomographic section thickness 10.0 mm ± 1.0 mm (Slice thickness 10.0 mm)

Subsystem Specifications

Operator Console

For console size and weight, see Table 18-4.

PC Based System

- A Commercial-Off-The-Shelf (COTS) PC HP Z840 PC Workstation with Dual Intel Xeon E5-2620v3 dual 2.4GHz Six core and 32 GB FBD DDR4-2133 ECC DIMM (8x 4GB) or HP Z820 PC Workstation with Dual Intel Xeon E5-2640 dual 2.5GHz Six core and 32 GB FBD DDR3-1333 ECC DIMM (8x 4GB) or compatible
- 2 x 300GB SAS 10k RPM HDD
- 5 x 300GB SAS 10K RPM HDD, RAID 5 system

LCD Monitor

- Active display diagonale 19 inch
- Active Pixel Format 1280 H x 1024 V (SXGA)
- Horizontal and Vertical viewing angle more than 170 degrees (°)
- Horizontal frequency 31.0kHz - 80.0kHz
- Vertical frequency 50Hz - 75Hz

Image Processor

- Dual Monitor Capability
- Nvidia Quadro K620, 2000 or compatible

Image Reconstruction Engine

- Up to 50 frames per second (s) on Z840 PC Workstation or 35 frames per second (s) on Z820 PC Workstation.

5805441-1EN Rev. 2 (Sep. 2020)

- Includes COTS (Commercial Off The Shelf) Graphic Processor add-in card for 2D & 3D back projection
- Adaptive Statistical Iterative Reconstruction (ASiR-V/ASiR) Architecture

Revolution™ EVO Operator Console user interface features

- Two, large 19 inch LCD monitors
  - Scan/recon monitor mainly for scan and recon control with no image display
  - Image monitor mainly for image display, analysis, processing, and management
  - Each monitor provides a 1280 x 1024 high resolution, flicker-free display
- Scan control keyboard assembly with intercom speaker, mic and volume controls
- Three button mouse or Scroll mouse with mouse pad
- BrightBox (trackball assembly) - optional

Data Acquisition

64-Row Detector

- 54,272 individual elements composed by 64 rows of 0.625 mm thickness at isocenter
- 64 x 0.625 mm (64 slice mode) or 32 x 0.625 mm, 32 x 1.25 mm (32 slice mode)
- 98% absorption efficiency (at 120 kV)

64-Row DAS (64 Slice Configuration)

- 64 Slice configuration
- 2 - 0.35 second (s) scan
- 2,460 Hz maximum sample rate
- 861 - 1968 views per rotation

Table

Load Capacity (Reference YY0310)

- 227 kg (500 lbs) with ± 0.25 mm positional accuracy guaranteed (VT1700V, VT2000)
- 306kg (675 lbs) with ± 0.5 mm positional accuracy guaranteed (VT2000x)

Maximum Cradle Travel (Reference YY0310)

- No less than 1700 mm (VT1700V)
- No less than 2000 mm (VT2000, VT2000x)
- Table Height, Gantry Tilt and scanning software determine the scannable range.

Cradle Speeds

- 100 mm/sec for Scout or 175 mm/s for Fast Scout (VT1700V, VT2000, VT2000x)
- 5.0 - 175.0 mm/sec (VT1700V, VT2000, VT2000x)

Cradle Position Accuracy (Reference YY0310 and 21CFR1020.33(i))

Position repeatability :

(Table Loading Weigh ≤ 227 kg / 500 lbs)

– ± 0.25mm (VT1700V, VT2000, VT2000x)

(227 kg / 500 lbs < Table Loading Weigh ≤ 306 kg / 675 lbs)

– ± 0.5mm (VT2000x)

Longitudinal Accumulated Position Error :

(Table Loading Weight ≤ 227 kg / 500 lbs)

– ± 0.25mm±0.06% (VT1700V, VT2000, VT2000x)

(227 kg / 500 lbs < Table Loading Weight ≤ 306 kg / 675 lbs)

– ± 0.5mm±0.06% (VT2000x)

Elevation Travel Time

- FAST < = 22 seconds (VT1700V, VT2000)
- FAST < = 20 seconds (VT2000x)

Full Range

- SLOW < 45 seconds (VT1700V, VT2000)
- SLOW < 38 seconds (VT2000x)

Elevation Accuracy

± 1.5mm

Elevation Range (Reference YY0310)

- 430mm to 991mm (VT1700V, VT2000)
- 525mm to 991mm (VT2000x)

Gantry

Gantry LCD Display

- LCD size : 12.1 inches with Touch Panel

Tilt Limits (Reference YY0310)

+30° (± 0.5°) to -30° (± 0.5°) with 0.5° increments

Tilt Speed

60 degrees (°) /min nominal (-30° to 30° in 60 seconds (s) ± 20%) or 90 degrees (°) /min nominal for Fast mode (-30° to 30° in 40 seconds (s) ± 20%)

5805441-1EN Rev. 2 (Sep. 2020)

Gantry Opening Diameter (Reference YY0310)

700mm ± 5mm

Isocenter to Tube Distance

541mm

Tube Focus to Detector Distance

949mm

X-ray Fan Angle

≥ 56.37 degree (°)

Acoustical Running Noise (Reference YY0310)

≤ 70 dBA at 1.0 second (s) gantry rotation at a distance of 1 meter from gantry surface.

Rotational Speeds (Reference YY0310)

360 degrees (°) in 0.35, 0.375, 0.4, 0.425, 0.45, 0.475, 0.5, 0.6, 0.7, 0.8, 0.9, 1, and 2 seconds (s)

NOTE: 0.375, 0.425, 0.45, 0.475 available with CardIQ SnapShot option and the corresponding rotation speed option.
0.35 second option enables 0.35, 0.4, 0.5 and 0.6 second(s) scan.
0.35 second for cardiac or 0.4 second option enables 0.4, 0.5 and 0.6 second(s) scan.
0.5 second option enables 0.5 and 0.6 second(s) scan.

Scout Orientation (Reference YY0310)

Presets: AP, RLAT, PA, LLAT

Manual: 0 to 359 degrees (°), increments of 1 degree (°)

Rotational Freedom

1 continuous rotate

Half Value Layer
(Reference: IEC 60601-1-3:2008 Clause7.1, IEC 60601-2-44:2009 Clause203.7.1and 21 CFR 1020.30(m)(1))

The “Half Value Layer” of the X-ray Tube Assembly is provided in Table 18-28 below:

Table 18-28 Half Value Layer Measurements

User SFOV Selection Half Value Layer by kVP	21 CFR 1020.30(m), IEC 60601-1-3: 2008, IEC 60601-2-44: 2009 Requirement	IEC 60601-1-3: 1994 Requirement	IEC 60601-2-44: 2002 Requirement	Performix™ 40 Plus	
				Ped Head Ped Body Head Small Body Cardiac Small	Large Body Cardiac Large
80 kV	≥ 2.9 mm Al	≥ 2.3 mm Al	≥ 2.4 mm Al	5.0 mm Al	5.8 mm Al
100 kV	≥ 3.6 mm Al	≥ 2.7 mm Al	≥ 3.0 mm Al	6.1 mm Al	7.2 mm Al
120 kV	≥ 4.3 mm Al	≥ 3.2 mm Al	≥ 3.8 mm Al	7.6 mm Al	8.1 mm Al
140 kV	≥ 5.0 mm Al	≥ 3.8 mm Al	≥ 4.6 mm Al	8.4 mm Al	9.2 mm Al

5805441-1EN Rev. 2 (Sep. 2020)

Quality Equivalent Filtration
(Reference: IEC 60601-1-3:2008 Clause4.2, IEC 60601-2-44:2009 Clause203.7.3 and 21 CFR 1020.30(h)(2)(ii) and (h)(4)(i))

The Quality Equivalent Filtration of the X-ray tube assembly is provided in Table 18-29 below:

Table 18-29 Quality Equivalent Filtration

User SFOV Selection		**Performix™ 40 Plus**	
		PedHead Ped Body Head Small Body Cardiac Small	**Large Body Cardiac Large**
Minimum QEF Values			
Tube QEF		4.9 mm	4.9 mm
Collimator (Filter)	Filter name	Filter 1 - small	Filter 3 - large
	C (graphite)	1.938 mm	1.938 mm
	Al (aluminum)	0.19 mm	0.19 mm
	Cu (copper)	-	0.068 mm
Collimator Filter QEF		0.3 mm	2.7 mm
Total QEF		5.2 mm	7.6 mm
Nominal QEF Values			
Tube QEF		5.5 mm	5.5 mm
Collimator (Filter)	Filter name	Filter 1 - small	Filter 3 - large
	C (graphite)	1.998 mm	1.998 mm
	Al (aluminum)	0.25 mm	0.25mm
	Cu (copper)	-	0.075 mm
Collimator Filter QEF		0.4 mm	3.1 mm
Total QEF		5.9 mm	8.6 mm

X-Ray Tube

Refer to the Performix™ 40 Plus X-Ray Tube Specifications chapter.

Laser Alignment Lights

Maximum Output Power

<1.0 mW/laser beam

Maintenance

- Laser alignment lights do not require user maintenance.
- Qualified service personnel must inspect the lights periodically to assure proper alignment.

Laser Alignment Light Accuracy (Reference: IEC60601-2-44:2009 Clause203.115, YY0310 and 21CFR1020.33 (g) (3))

The sagittal, coronal, and transverse alignment lights are within ± 1 mm of the system imaging coordinates.

Generator Subsystem Specifications (Reference: IEC60601-1:2005 Clause7.2.7, 21CFR1020.30 (h)(3)(i))

Main Power Supply

Line Voltage (Reference 21CFR1020.30 (h) (3) (i))

- Nominal: Taps selections of 200 to 240 V in 20 V Steps or 380 to 480 V in 20 V Steps
- Daily Variation: Nominal ± 10%

3-Phase 50/60 Hz ± 3Hz (Reference 21CFR1020.30 (h) (3) (i))

- Phase-to-phase balance within 2% of lowest phase-to-phase voltage.
- Line regulation 6% or less at 100 kVA, 85% P.F.

Maximum 3-Phase Power Demand at Full Rated Output (Reference 21CFR1020.30 (h)(3)(ii) and (h)(3)(iii))

100 kVA

CONTINUOUS 3-Phase Power Demand

20KVA

Maximum Line Current Demand (Reference: IEC60601-2-44:2009 Clause203.12.3, 21CFR 1020.30 (h)(3)(ii) and (h)(3)(iii))

120A @ 480 V

Maximum line current demand defined at 140 kV and 515 mA.

5805441-1EN Rev. 2 (Sep. 2020)

Generator Rating and Duty Cycle

The gantry contains a high frequency generator and on board computer control

Maximum Output Power (IEC60601-2-44)

72.1 kW power @ 140 kV, 515 mA
(72 kW power @ 120 kV, 600 mA)

Highest Constant Load at 4s (Reference: IEC 60601-2-28 201~203)

The system can acquire 48kW at 120kVp (400 mA maximum) for 4s scan duration.
The system can acquire 67kW at 120kVp (550 mA maximum) for 4s scan duration if the 72kW option is enabled. The single exposures are controlled by system software.

kV Choices

80, 100 120, 140 kV

Maximum mA

600 mA

Regulation

Recovery within 2 kV for 10% line variation in 50msec

Rise Time

< 2msec, to attain 75% of selected value

Fall Time

< 10 msec to fall below 75% of selected value

Generator Duty Cycle (Reference 21CFR1020.33 (h) (3) (v))

The generator duty cycle is determined by the tube protection algorithm based on tube type used.

kV, mA, and Time Accuracy (Reference: IEC60601-2-44:2009 Clause201.7.9.2.9, Clause201.12.1.101)

Kilovolts

kV Selections

80, 100, 120, and 140 kV

Basic kVp Accuracy (Reference 21CFR1020.30 (h) (3) (vi) and YY0310)

KVp Accuracy (Mean) = ± 3% (KVp Accuracy (Peak) = ± (3% + 2KV))
Excludes first 10 msec of exposure

kVp During First 10 ms (Reference 21CFR1020.30 (h) (3) (vi) and YY0310)

Basic accuracy (see above) ± 5 kV

Milliamperes

mA Selections

10 to 600 mA, by 5 mA increments

- Patient scanning subject to Scan limitations or 72 kW maximum

mA Accuracy (Reference 21CFR1020.30 (h) (3) (vi) and YY0310)

Patient scanning selections of 10 to 600 mA

mA Accuracy = ± (5% + 1.0mA)

5805441-1EN Rev. 2 (Sep. 2020)

Linearity of X-ray Output (Reference IEC 60601-2-44)

Linearity of X-ray output for the small focal spot and large focal spot is as shown in Figure 18-18 below. The expected accuracy is ± 10 %.

Figure 18-18 Dose verses mA chart

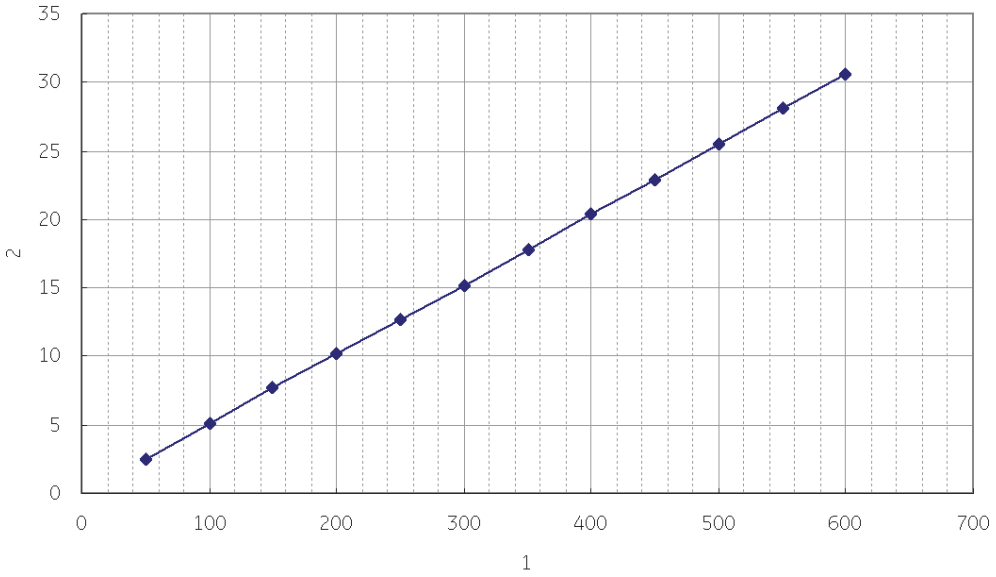


Table 18-30 Dose verses mA chart desctiptions

Number	Description
1	mA
2	Dose (mGy)

Table 18-31 Scan Ptotocol for Linearity X-ray Output

kV	mA	Scan speed (s)	SFOV	Aperture (mm)
120	10-200 mA (Small Focus) 205-600 mA (Large Focus)	1	Large body	40

Exposure Time

X-ray Exposure Time Accuracy (Reference 21CFR1020.30 (h) (3) and YY0310)

1.8 to 120.0 seconds (s) exposures: ± **5% + 10 ms**

Scan Selections

Normal Axial Scan Selections

0.35, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1, or 2 seconds(s)

0.35 second option enables 0.35, 0.4, 0.5 and 0.6 second(s) scan.

0.35 second for cardiac or 0.4 second option enables 0.4, 0.5 and 0.6 second(s) scan.

0.5 second option enables 0.5 and 0.6 second(s) scan..

Volume (Axial) Shuttle

Up to 5 minutes (min) of Elasped time or 99 passes.

Volume Helical Shuttle

Up to 60 seconds (s) of Elapsed Time.

Cine (Continuous scans without cradle movement)

Up to 60* seconds (s) for a single continuous exposure.
*: In case of 20mm beam collimation, Cine scan can last up 120 seconds (s).

Helical (Continuous scans with cradle movement)

Up to 60* seconds (s) for a single continuous exposure.
*: In case of 20mm beam collimation, Helical scan can last up 120 seconds (s).

SmartView

Up to 90 seconds (s) per confirm.

Cardiac

- SnapShot Segment - 60 seconds (s)
- SnapShot Segment Plus - 60 seconds (s)
- SnapShot Burst - 60 seconds (s)
- SnapShot Burst Plus - 60 seconds (s)
- SnapShot Pulse - This is not time dependant.

Scout

For VT1700V

- Scan range 50 to 1600mm at 100mm/sec (± 3%) or 175mm/sec (±3%)

5805441-1EN Rev. 2 (Sep. 2020)

For VT2000, VT2000x

- Scan range 50 to 1900mm at 100mm/sec (± 3%) or 175 mm/sec (± 3%)

Accuracy Subject to Following Conditions

Line Voltages

- Line voltage in specified range for nominal system voltages of 200 to 240V or 380 to 480V.
- Line to line voltages balanced within 2%.

Line Regulation

6% or less.

Transient Voltage Variations Caused by External Loads Must Not:

- Exceed 5%
- Exceed 5 cycles duration
- Occur more than 10 times per hour (h)

To comply with the requirements of **21 CFR 1020.30**, accuracies are stated in terms of maximum theoretical deviation from selectable operating parameters for all technique factor combinations.

For radiation output, the coefficient of variation is less than 0.05 for successive exposures with constant technique factors.

Measurement Basis (Reference 21CFR1020.30 (h) (3) (viii))

Kilovolts

Precision 10,000:1 voltage dividers built into system reduce generated anode and cathode voltages.

Resulting low voltage signals provide continuous closed-loop control of the average kV.

Signals are noise filtered and periodically monitored by the computer system.

Tube voltage is defined as the average kV during X-ray exposure, excluding transient at the beginning and end. Then, the kV signal used by the generator was verified against an independent HV divider and Digital Oscilloscope measurement of the kV waveform. So scan mode is “Stationary”.

Milliamperes

The generator contains a precision resistor (sh3 or sh4 on kV PCB in HV tank) network in series with the low voltage output terminal of the high voltage transformer. The X-ray tube emission current passes through this resistor and the resultant voltage drop is used for measurement and control.

Exposure Time

Traditional Exposure time interval: Duration of time High voltage remains at or above 75% of selected value.

Revolution™ EVO Exposure time interval: Duration of the Expose Command signal within the Stationary Controller, minus the HV rise time, plus its fall time with respect to the Expose Command signal.

Revolution™ EVO HV components reside on the gantry rotating base.

During stationary scans, use an oscilloscope to measure the HV rise and fall times, with respect to the Expose Command signal.

Use the oscilloscope to measure the Expose Command signal during stationary scans, to verify internal time measurements.

Use the internal timer to monitor time during axial/helical scans.

Environmental Specifications

Ratings and duty cycles of all subsystems apply if the site environment complies with the following.

The specified environment must be constantly maintained, weekends, holidays, and throughout the night.

Shutdown the CT system whenever the air conditioning fails.

Optional: Turn air conditioner OFF during CT shutdown for repair.

System Cooling Requirements

The cooling requirements do not include cooling for the room lighting, personnel, or non-CT equipment present. Cooling requirements are listed by subsystem to allow planning for each room of the CT suite.

- The recommended cooling requirements assume patient throughput limited by the tube cooling algorithm.

5805441-1EN Rev. 2 (Sep. 2020)

Table 18-32 System

Subsystem	Minimum Allowance (Watts / BTU/Hr)
Gantry 500 Pounds (227 kg) Table 500 Pounds (227 kg) Long Table 675 Pounds (306 kg) Long Table PDU Operator Console LCD Monitor	5480/18700 300/1030 300/1030 300/1030 1000/3400 840/2870 100/340
Cooling values should not be used for calculating system input power requirements.	

Temperature and Humidity Specifications (Reference: IEC60601-2-44:2009 Clause201.5.7)

Ambient Temperature

Scan Room (Recommended for Patient Comfort)

70° - 79° F (21° - 26° C) for patient comfort

Control Room (including Console/Computer)

64° - 79° F (18° - 26° C).

Table and Gantry In Exam Room (when room is unoccupied)

64° - 79° F (18° - 26° C)

Equipment Room (if separate room to hold PDU)

64° - 84° F (18° - 29° C)

Rate of Change

5°F/Hr Max (3°C)

Room Temperature Uniformity

5°F Max Gradient (3°C)

Relative Humidity (All Areas)

- 30% - 60% (non-condensing) during operation, all areas.
- Rate of Change 5% RH/Hr Max

NOTE: Use a temperature and humidity recorder to monitor the designated system area during pre-installation and installation, to verify true temperature and humidity conditions.

Electromagnetic Interference

Consult GE Medical Systems for recommendations when the peak 60 Hz/50 Hz field within the gantry region exceeds 0.01 gauss peak.

Consider the following when trying to reduce suspected Electromagnetic Interference (EMI):

- The external field strength from a source of magnetic field decreases rapidly with the distance from the source.
- A bank of three single phase transformers generates a smaller magnetic field (less external leakage) than a three-phase transformer with an equivalent power rating.
- Large electric motors generate substantial EMI.
- Steel reinforcing in the building structure can act as an effective conductor of EMI.
- High powered radio signals can affect computers.
- No substitute exists for proper screening of cables and cabinets.

Pollution (Reference: IEC60601-1:2005 Clause7.9.2.12, Clause16.2)

Individual components contain filters to optimize environmental conditions.

- Keep air pollution to a minimum.
- Keep the CT suite clean at all times.
- Do not have dust and fume generating work near the system.
- Keep component filters clean and free from obstructions

Carpeting

- Install anti-static carpeting - or- treat existing carpets with an anti-static solution.
- Static discharges affect operation and may cause system failures.

Do NOT use steel wool to clean tile floors in scan suite. Fine metal fibers can enter enclosures and cause internal shorts.

5805441-1EN Rev. 2 (Sep. 2020)

Lighting

Patient Comfort

Use a variable indirect light source between 20 – 100 foot candles in the scan room

Control Room

Select and position subdued light to reduce monitor reflections, and prevent operator eye strain

Equipment Room

Provide a bright light source for use during maintenance.

Altitude

- Minimum Altitude: 492 feet (150 meters) below sea level (103.13 kPa)
- Maximum Altitude: 7,874 feet (2400 meters) above sea level (75.6 kPa)

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5805441-1EN Rev. 2 (Sep. 2020)

Chapter 19
Planned Maintenance

(Reference: IEC60601-1:2005 Clause7.9.2.12, Clause7.9.2.13, Clause16.2, 21CFR 1020.30(h)(1)(ii))

The following chart gives a description, and frequency of Planned Maintenance (P.M.) procedures. Please refer to the related CT Service Methods (Gen) for the details of each P.M. procedure and P.M. report charts. Revolution™ EVO P.M.s are based on gantry revolutions.

P.M.s will be done every 0.67 million gantry revolutions or four months, whichever comes first. The average Revolution™ EVO scanner does 2,000,000 revolutions per year; therefore the average scanner has approximately three Planned Maintenance activities per year.

Table 19-1 Revolution™ EVO PM Schedule

Sub- System	Description	Schedule
Console	General Console Cleaning and Inspection	A, B, C
Gantry	Grease main bearing	A, B, C
Gantry	Handling & removal of slip ring brush debris	A, B, C
Gantry	Schleifring Maintenance and Brush Inspection	A, B, C
Gantry	DAS/Duct Cleaning	A, B, C
High Voltage	mA and kV Meter verification (HHS)	C
High Voltage	High Voltage Tank Feedback Resistor Verification	C
Table	General Table PM	A
System	Verify emergency stop buttons	A, B, C
System	Update site log	A, B, C
System	Check PM Manual	A, B, C
Revolution™ EVO Total time w/o camera (units in hours (h))		4

Schedule A, B, C - P.M. happens in order every 0.67 million gantry revolutions or four months, whichever comes first.

5805441-1EN Rev. 2 (Sep. 2020)

Appendix A
Reference Noise Index

Table A-1 Configured to deliver lower noise in the images at a higher mA value

	Anatomy	Mode	10.0 mm	7.5 mm	5.0 mm	3.75 mm	2.5 mm	1.25 mm	0.625 mm
1	Head	Normal	2.20	2.40	2.80	3.00	3.80	5.20	7.00
2	Orbit	Normal	2.20	2.40	2.80	3.00	3.80	5.20	7.00
3	Neck	Normal	5.20	5.72	6.63	7.02	9.10	12.22	12.60
4	Upper	Normal	7.80	8.58	9.88	10.66	13.52	18.33	19.00
5	Chest	Normal	7.80	8.58	9.88	10.66	13.52	18.33	19.00
6	Abdomen	Normal	7.80	8.58	9.88	10.66	13.52	18.33	19.00
7	Spine	Normal	7.80	8.58	9.88	10.66	13.52	18.33	19.00
8	Pelvis	Normal	7.80	8.58	9.88	10.66	13.52	18.33	19.00
9	Lower	Normal	7.80	8.58	9.88	10.66	13.52	18.33	19.00
10	Misc	Normal	7.80	8.58	9.88	10.66	13.52	18.33	19.00

Table A-2 Configured to deliver average noise in the images at a average mA value

	Anatomy	Mode	10.0 mm	7.5 mm	5.0 mm	3.75 mm	2.5 mm	1.25 mm	0.625 mm
1	Head	Normal	2.20	2.40	2.80	3.00	3.80	5.20	7.00
2	Orbit	Normal	2.20	2.40	2.80	3.00	3.80	5.20	7.00
3	Neck	Normal	5.20	5.72	6.63	7.02	9.10	12.22	12.60
4	Upper	Normal	9.10	10.01	11.57	12.35	15.86	21.45	22.10
5	Chest	Normal	9.10	10.01	11.57	12.35	15.86	21.45	22.10
6	Abdomen	Normal	9.10	10.01	11.57	12.35	15.86	21.45	22.10
7	Spine	Normal	9.10	10.01	11.57	12.35	15.86	21.45	22.10

	Anatomy	Mode	10.0 mm	7.5 mm	5.0 mm	3.75 mm	2.5 mm	1.25 mm	0.625 mm
8	**Pelvis**	**Normal**	9.10	10.01	11.57	12.35	15.86	21.45	22.10
9	**Lower**	**Normal**	9.10	10.01	11.57	12.35	15.86	21.45	22.10
10	**Misc**	**Normal**	9.10	10.01	11.57	12.35	15.86	21.45	22.10

Table A-3 Configured to deliver higher noise in the images at a lower mA value

	Anatomy	Mode	10.0 mm	7.5 mm	5.0 mm	3.75 mm	2.5 mm	1.25 mm	0.625 mm
1	**Head**	**Normal**	2.20	2.40	2.80	3.00	3.80	5.20	7.00
2	**Orbit**	**Normal**	2.20	2.40	2.80	3.00	3.80	5.20	7.00
3	**Neck**	**Normal**	5.20	5.72	6.63	7.02	9.10	12.22	12.60
4	**Upper**	**Normal**	10.40	11.44	13.13	14.17	18.07	24.57	25.30
5	**Chest**	**Normal**	10.40	11.44	13.13	14.17	18.07	24.57	25.30
6	**Abdomen**	**Normal**	10.40	11.44	13.13	14.17	18.07	24.57	25.30
7	**Spine**	**Normal**	10.40	11.44	13.13	14.17	18.07	24.57	25.30
8	**Pelvis**	**Normal**	10.40	11.44	13.13	14.17	18.07	24.57	25.30
9	**Lower**	**Normal**	10.40	11.44	13.13	14.17	18.07	24.57	25.30
10	**Misc**	**Normal**	10.40	11.44	13.13	14.17	18.07	24.57	25.30

5805441-1EN Rev. 2 (Sep. 2020)

5805441-1EN Rev. 2 (Sep. 2020)

5805441-1EN Rev. 2 (Sep. 2020)

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