Technical Reference Guide

English

459801063624_F

powered by iPatient

Brilliance CT 64-channel

Version 4.1.10

PHILIPS

Table of contents

459801063624_F/728 * MAR 2020

Philips

459801063624_F/728 * MAR 2020

Philips

459801063624_F/728 * MAR 2020

Philips

459801063624_F/728 * MAR 2020

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1 Introduction

The Philips CT systems are advanced continuous-rotation computed tomography systems suitable for a wide range of computed tomographic (CT) applications.

About this Reference Guide

This guide is intended to assist physicists and other personnel in the quality assurance testing of the CT scanner. It includes physics information critical to understanding dose, sensitivity, and other scan information subjects.

This document also includes classifications, ratings, and the hazard labels and symbols included on your system. You must pay special attention to all the information given, and procedures described in the SAFETY and SECURITY sections.

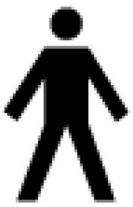
Before attempting to operate the equipment, you must read, note, and strictly observe all **DANGER** notices and safety markings on the CT System.

Before attempting to operate the equipment, you must read the "Instructions for Use" thoroughly, paying particular attention to all **Warnings**, **Cautions** and **Notes** incorporated in it.

NOTICE

Review this information carefully; be aware of system-specific information where applicable.

IEC-60601 Classification



Type of protection against electric shock	Class I equipment
Degree of protection against electric shock	Type B equipment
Degree of protection against harmful ingress of water	Ordinary equipment (IPX0) Round foot switch (IPX1 or better) Continuous CT foot switch (IPX1 or better)
Possible interference with other equipment	IEC 60601-1-2 Group 1 Class A Device for Radiated Emission
Mode of operation	Continuous operation (per IEC 60601-1 edition 3.1) Long time operation with momentary loading (per UL/ANSI/AAMI 60601-1 and NFPA 70)

459801063624_F/728 * MAR 2020

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IEC Statement of Compliance

This equipment is compliant to the following standards:

IEC 60601-1:1988+A1:91+A2:95

IEC 60601-1:2005

IEC 60601-1-1:2000

IEC 60601-1-2:2000+A1:04

IEC 60601-1-2:2007

IEC 60601-1-2:2014

IEC 60601-1-3:1994

IEC 60601-1-3:2008

IEC 60601-1-4:1996+A1:99

IEC 60601-1-6:2006

IEC 60601-1-6:2010

IEC 60601-2-32:1994

IEC 60601-2-44:2001+A1:2002

IEC 60601-2-44:2009

IEC 61223-3-5:2004

IEC 62985: 2017

NOTICE

Compliance to 60601-1-2:2014 (4th Ed.) applies after manufacturing date January 1st 2019. Refer to system label.

Electromagnetic Emissions

The scanner is intended for use in the electromagnetic environment specified below.

The customer or the user of the system should assure that it is used in a professional healthcare facility. The scanner gantry and patient table must only be used within an X-ray shielded location as specified in the accompanying product literature.

459801063624_F/728 * MAR 2020

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Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions, CISPR 11	Group1 Class A for the scanner in combination with the shielded gantry and patient table location.	CT uses RF energy only for internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
Harmonic Emissions EC 61000-3-2	Not Applicable	The CT system, when the gantry and patient table are installed in such a shielded location, is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

WARNING

It is essential that the actual RF shielding effectiveness of the shielded location is verified to establish that it meets the specified minimum values. This is ensured if a lead-shielded patient area is used per the accompanying literature recommendations.

The CT scanner should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the CT scanner should be observed to verify normal operation in the configuration in which it will be used.

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Philips as replacement parts for internal components, may result in increased emissions or decreased immunity of the CT scanner.

Electromagnetic Immunity

The CT scanner is equipped for use in the electromagnetic environment specified below. Your facility should ensure that the system is placed in an environment that meets these conditions.

459801063624_F/728 * MAR 2020

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Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms on a.c. and d.c. power and signal ports 150 kHz to 80 MHz 6 Vrms on a.c and d.c. power and signal ports in ISM bands 150 kHz to 80 MHz See Note 4 for list of ISM bands	Only those cables supplied with the CT system should be used.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	**See Note 2 below** Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity fields from RF wireless communications equipment RF IEC 61000-4-3	380 MHz - 5800 MHz	380 MHz - 5800 MHz 9-28 V/m	IEC 60601-1-2, Edition 4.0, Table - 9 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment
Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Note 2: CT has not been tested for radiated RF immunity over the entire frequency range of 80 MHz to 5.8 GHz. It was step tested at the selected frequencies 88 to 108, 144 to 148, 151, 185, 380 to 390, 425, 430 to 470, 468, 704 to 787, 800 to 960, 902 to 928, 939, 1700 to 1990, 2400 to 2570, and 5100 to 5800 MHz respectively, at minimum of 3 V/m field strength. Test signal was either 80% modulated AM, at 2Hz, 1000 Hz modulation frequencies or Pulse modulation at 18 Hz or 217 Hz.			
Note 3: Only the equipment specified in the CT Installation Manual may be used inside the gantry and patient table room.			
Note 4: The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6765 MHz to 6795 MHz; 13553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.			
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power mains input ±1 kV for signal ports with 100kHz repetition frequency	Main's power quality must comply with the CT planning reference data (PRD).

459801063624_F/728 * MAR 2020

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Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Surge IEC 61000-4-5	±1 kV lines to lines ±2 kV to earth	±1 kV lines to lines ±2 kV to earth	Main's power quality must comply with the CT planning reference data (PRD).
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable	Not Applicable	Main's power quality must comply with the CT planning reference data (PRD). If the user of the CT requires continued operation during power mains interruptions, it is recommended that the CT be powered from an uninterruptible power supply (UPS).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60 Hz	30 A/m, 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

WARNING

Your Clinical suite may include one (or several) third-party UPS devices.

When UPS batteries are not properly maintained, or if they are held in service beyond their usable service life, failure can result in the leaking of electrolyte (sulfuric acid), overheating, and/or the emission of fumes.

To ensure continued safe and reliable performance from these devices, periodic maintenance is required, including possible battery replacement. Based on industry standards, the typical useable service life of a UPS battery is less than five years.

You may consult your local Philips Service representative for help in identifying the specific model of your UPS device(s) and available service provider options in your geography.

Electrical Ratings

Voltage (VAC)	Phase	Frequency (Hz)	Power consumption (kVA)	
			Continuous (IEC) long time (UL/NFPA 70)	Short time (IEC) momentary (UL/NFPA 70)
200	3	50/60	15	110
208	3	50/60	15	110
240	3	50/60	15	110

459801063624_F/728 * MAR 2020

Voltage (VAC)	Phase	Frequency (Hz)	Power consumption (kVA)	
			Continuous (IEC) long time (UL/NFPA 70)	Short time (IEC) momentary (UL/NFPA 70)
380	3	50/60	15	110
400	3	50/60	15	110
415	3	50/60	15	110
440	3	50/60	15	110
480	3	50/60	15	110
500	3	50/60	15	110

CT Scanner - IEC 60601-2-44:2001: The apparent resistance of the supply mains shall not exceed the values provided in the System planning reference data (PRD).

WARNING

To avoid risk of electric shock, this equipment must be connected to a supply mains with protective earth. See the power requirements document for details.

Electric Output Data, per IEC 60601-2-44

Stated values refer to the complete device for the CT scanner in which part of the high voltage generator is integrated with the X-ray tube assembly.

1) NOMINAL X-RAY TUBE VOLTAGE and highest X-RAY TUBE CURRENT obtainable from the HIGH-VOLTAGE GENERATOR when operated at that X-RAY TUBE VOLTAGE	70kV at 0.4A; 60kV at 0.5A
2) Highest X-RAY TUBE CURRENT and the highest X-RAY TUBE VOLTAGE obtainable from the HIGH-VOLTAGE GENERATOR when operated at that X-RAY TUBE CURRENT	0.5A, 60kV
3) Combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which results in the highest electric output power	75kV at 0.4A; 60kW
4) NOMINAL ELECTRIC POWER given as the highest constant electric output power (kW) which the HIGH-VOLTAGE GENERATOR can deliver for a LOADING TIME of 4 seconds at an X-RAY TUBE VOLTAGE of 120 kV, or nearest to 120 kV and the value of LOADING TIME nearest to but not less than 4 seconds	60kW
5) NOMINAL ELECTRIC POWER given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME, which are used in the CT scanner	60kW, 60kV, 0.5A, 4.1 sec

459801063624_F/728 * MAR 2020

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2 Labels and Symbols

System Labels

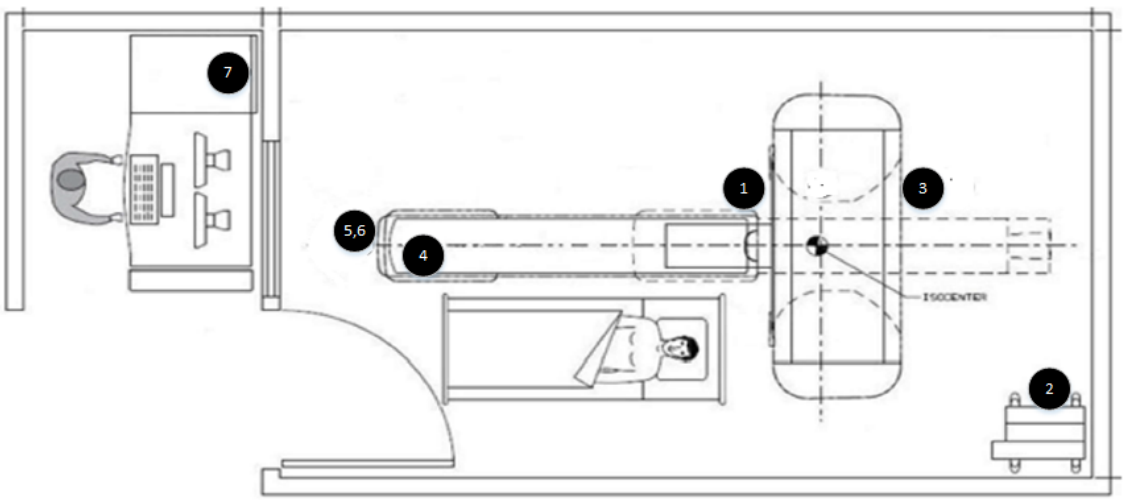
Philips Healthcare products are all designed to meet stringent safety standards. However, all medical electrical equipment requires proper operation and maintenance, particularly with regard to human safety.

It is vital that you read, note, and where applicable, strictly observe all DANGER notices and safety markings on the CT system.

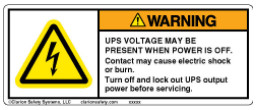
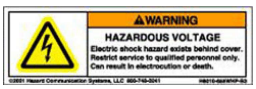
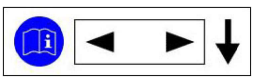
NOTICE

Depending on the system configuration and layout at your site, not all of the labels are applicable.

The following diagram displays the labels and signs visible in the Scanner Suite.

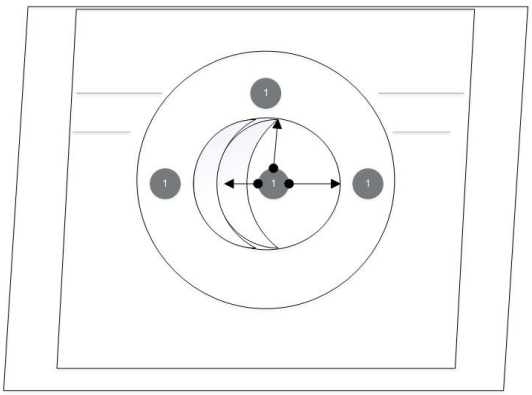


459801063624_F/728 * MAR 2020

Number	Label/Sign	System	Location	Description
1		BR16, BR64, BR Big Bore, Ingenuity, BR iCT	Console UPS	WARNING: UPS voltage may be present when power is off. Contact may cause electric shock or burn. Turn off and lock out UPS output power before servicing.
2		BR iCT	Front of Gantry and in the cone per Diagram	CAUTION: Class 2 patient positioning lasers. 1.0 mW maximum output - wavelength 650 nm. EN/IEC 60825-1:2014. The beam divergence is 90 Deg.
3		BR16, BR64, Ingenuity	Front and Rear of Gantry	CAUTION: Pinch point. Keep hands clear during operation.
3		BR Big Bore	Front and Rear of Gantry	CAUTION: Pinch point. Keep hands clear during operation.
3		BR16, BR64, BR Big Bore, Ingenuity	Rear of Gantry	WARNING: HAZARDOUS VOLTAGE. Electric shock hazard exists behind cover. Restrict service to qualified personnel only. Can result in electrocution or death.
3		iCT, Ingenuity	Rear of gantry	Unique Device Identification (UDI) label. See below for full description.
4		BR16, BR64, BR Big Bore, Ingenuity, BR iCT	Sides of Patient Table	Pressing a tape switch unlocks the table from its driving mechanism and allows for manual movement.
5		BR16, BR64, Ingenuity, BR iCT	End of Patient Table	WARNING: Maximum patient table load is 204 kg, 450 lb

459801063624_F/728 * MAR 2020

Number	Label/Sign	System	Location	Description
6		BR64, Ingenuity, BR iCT	End of Bariatric Patient Table	WARNING: Maximum bariatric patient table load is 295 kg, 650 lb
7		BR64, Ingenuity, BR iCT	Console Rack	WARNING: For connection of Philips Healthcare specified equipment only. Read the installation manual before making any connections.



Unique Device Identification Label

Number	Description
1	Manufacturing site of the finished device.
2	Site of legal manufacturer, the entity responsible for placing the device on the market.
3	Model name of the system.
4	Reference or catalog number.
5	Serial number.
6	Global Trade Identification Number (GTIN) as Device Identifier (DI) and Production Identifier (PI).

459801063624_F/728 * MAR 2020

Number	Description
7	Unique Device Identification GS1 2D DataMatrix barcode (contains information from 7).
8	Electrical rating specific to system.
9	Month and year of device manufacture as per 21 CFR.

Symbols

Use the following information to interpret the symbols used on the system and accessories.

For each symbol, the table below describes the standard in which the symbol is defined — ISO 15223-1:2012 and ISO 15223-1:2016 "Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements".

Symbol	Description
	CAUTION: Dangerous voltage
	Emergency stop (IEC 60601-1, 3rd Edition)
	Caution
	Follow **Instructions for Use**
	Refer to the **Instructions for Use**

459801063624_F/728 * MAR 2020

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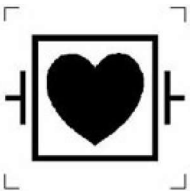
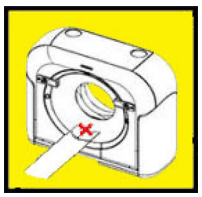
Symbol	Description
	Type B Applied Part
	Defibrillation-proof type CF applied part
 	CAUTION: Hand pinch point or crush hazard
	CAUTION: Hand pinch point or crush hazard
	Normal sized patient
	CAUTION: Radiation of laser apparatus

459801063624_F/728 * MAR 2020

Symbol	Description
	Non-ionizing electromagnetic radiation
	Emitting X-ray source
	Date of manufacture
	Factory of manufacture
	Body weight
	Product complies with the requirements of the applicable European Union directives
	Complies with standards of CSA certification in United States and Canada
	CAUTION: Be aware of possible pinch points between the foot extension and the gantry

459801063624_F/728 * MAR 2020

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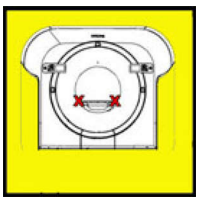
Symbol	Description
	CAUTION: Be aware of possible pinch points between the therapy top and the gantry
	Radiation

459801063624_F/728 * MAR 2020

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459801063624_F/728 * MAR 2020

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3 Safety

Important Safety Directions

Philips Healthcare products are all designed to meet stringent safety standards. However, all medical electrical equipment requires proper operation and maintenance, particularly with regard to human safety.

It is vital that you read, note, and where applicable, strictly observe all **DANGER** notices and safety markings on the CT system.

It is vital that you follow strictly all safety directions under the heading **Safety** and all **Warnings** and **Cautions** throughout this **Instructions for Use** to help ensure the safety of both patients and operators.

In particular, you must read, understand and know the **Emergency Procedures** described in this **Safety** section before attempting to use the equipment for any patient examination. You should also note the following information given in the **Introduction** section of this **Instructions for Use**:

- intended use of the Philips CT system
- contraindications
- training for operators of the Philips CT system

WARNING

The X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed.

WARNING

Do not use the CT system for any application until you are sure that the Image Performance Quality Assurance has been satisfactorily completed, and that the Preventative Maintenance Program is up to date. If any part of the equipment or system is known (or suspected) to be operating improperly or wrongly-adjusted, DO NOT USE the system until a repair has been made.

WARNING

Operation of the equipment or system with improperly-operating or wrongly-adjusted components could expose the operator or the patient safety hazards. This could lead to fatal or other serious personal injury.

459801063624_F/728 * MAR 2020

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You can find information about the Image Performance Quality Assurance and the Preventative Maintenance Program in the **Image Performance Quality Assurance** and **User Information** sections of this document.

WARNING

Do not use the CT system for any application until you have received adequate and proper training in its safe and effective operation. If you are unsure of your ability to operate this equipment safely and effectively DO NOT USE IT. Operation of this equipment without proper and adequate training could lead to fatal or other serious personal injury. It could also lead to clinical misdiagnosis.

For information about training, please refer to **Training** in the **Introduction** section of this document.

WARNING

Never attempt to remove, modify, over-ride or forcibly move any safety device on the equipment. Interfering with safety devices could lead to fatal or other serious personal injury.

WARNING

Do not use the CT system for any purpose other than those for which it is intended. Operation of the CT system for unintended purposes, or with incompatible equipment, could lead to fatal or other serious injury. It could also lead to clinical misdiagnosis.

Intended use of the CT system is described under the heading **Intended Use** in the **Introduction** section of this document. Compatibility is discussed under the heading **Compatibility** in the **Introduction** section of this document.

Scanner Suite

Familiarize yourself with the scanner suite at your site:

- The wall-mounted emergency stop removes the power supply for the entire CT system. Gantry movement and X-ray generation stops immediately.
- Route all system cables and patient tubing so that it does not become damaged or impede the free movement of personnel.
- If installed, the door-switch interlock helps avoid unnecessary radiation.

459801063624_F/728 * MAR 2020

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WARNING

Do not use the CT system for any application until you read, understand, and know all the safety information, safety procedures and emergency procedures contained in this SAFETY section. Operation of the CT system without a proper awareness of how to use it safely could lead to fatal or other serious personal injury.

Emergency Procedures

Emergency Stop

To bring scanner and Patient table movements and X-ray production to an immediate halt, press one of the red **Stop** buttons. One button is located on the Scan control box, and one on each gantry control panel.

Reset from Emergency Stop

Use this procedure to reset from emergency stop:

1. Locate the button that was pressed to initiate the stop.
2. Turn the button until it disengages from the stop position and returns to its original position.
3. Turn the key clockwise on the scan control box.

WARNING

After the Stop button is pressed, the table is locked in place for two seconds. Then it will be free floating with no up/down capabilities. Make sure that you maintain control of the table so that it does not move.

WARNING

During all movements of the gantry (automatic and manual) and the patient table, keep the patient under continuous observation to avoid pressing the patient against the gantry or between table parts, as well as to avoid disconnecting any infusion or resuscitation apparatus.

WARNING

Make sure that the motion of the table is in the direction that will ensure that the patient can be easily released and will not get pressed against the gantry covers.

459801063624_F/728 * MAR 2020

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Emergency Patient Release

If the patient's head is lying on one side of the gantry opening and the trunk and legs are lying on the other side of the opening, the patient should be released in the direction of the patient table support.

If the head is likely to touch the roof of the gantry opening, lower the head by removing the head support or the pillow, and turn the head to the side before moving the patient table.

To release the patient **in the event of a power failure or in an emergency stop situation**, either **pull the patient out** or **push the patient in** according to the procedure outlined in the applicable sections.

NOTICE

In the event of a power failure or an emergency stop, you cannot move the patient table down. Be prepared to help the patient from the table.

Pulling the Patient Out

1. Grasp the handle at the end of the patient table.
2. If the patient can safely be pulled out, pull the patient table out.
3. Help the patient dismount.

Pushing the Patient In

1. Grasp the handle at the end of the patient table.
2. If the patient can be safely pushed in, push the patient table towards the back of the gantry.
3. Help the patient dismount.

Rapid or Emergency release of the patient table can also be achieved by grabbing the tape switches along either side of the table, or by pressing one of the foot switches. This unlocks the table from its driving mechanism and allows it to be manually extended or retracted.

NOTICE

For Safety purposes, the Tape and Foot Switches act as an Emergency Clutch of the main patient table unit, preventing dangerous outward movement.

Electrical Safety & Grounding

Covers or cables should only be removed by qualified and authorized service personnel.

459801063624_F/728 * MAR 2020

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WARNING

Do not remove covers or cables from this equipment. High electrical voltages are present within this equipment. Removing covers or cables could lead to serious or fatal personal injury.

Only use this equipment in rooms or areas that comply with all applicable laws (or regulations which have the force of law) concerning electrical safety for this type of equipment.

This equipment is permanently installed, grounded equipment (IEC Class I). It employs redundant protective earth connections to maintain safe operation. The mains power supply and grounding connections must conform to the power requirements, site planning and installation documents for this product.

Do not connect this equipment or any of its components to a wall receptacle. Approved accessories (such as injectors) should be connected to grounded wall receptacles per the accessory equipment's instructions for use.

Mechanical Safety

Covers should only be removed by qualified and authorized service personnel.

WARNING

Do not remove covers from this equipment. Removing covers could lead to serious or fatal personal injury.

Explosion Safety

This equipment must not be used in the presence of explosive gases or vapors, such as certain anaesthetic gases. Use of electrical equipment in an environment for which it was not designed can lead to fire or explosion.

WARNING

Flammable or potentially explosive disinfecting sprays must not be used, since the resultant vapor could ignite, causing fatal or other serious personal injury and/or damage to equipment.

459801063624_F/728 * MAR 2020

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Implosion Hazard

WARNING

Do not subject the system to serious mechanical shock, as the cathode ray tube (CRT) can fracture if struck or jarred. This may result in flying pieces of glass and phosphor coating that can cause serious injury.

Fire Safety

Use of electrical equipment in an environment for which it was not designed can lead to fire or explosion.

Conductive fluids that seep into the active circuit components of the operator's console may cause short circuits that can result in electrical fires. Therefore, do not place any liquid or food on any part of the consoles or other modules of the system.

Fire regulations for the type of medical area being used should be fully applied, observed and enforced. Fire extinguishers should be provided for both electrical and non-electrical fires.

All operators of this medical electrical equipment should be fully aware of and trained in the use of fire extinguishers and other fire-fighting equipment, and in local fire procedures.

WARNING

Only use extinguishers on electrical or chemical fires which are specifically labelled for those purposes. Using water or other liquids on an electrical fire can lead to fatal or other serious personal injury.

If it is safe to do so, attempt to isolate the equipment from electrical and other supplies before attempting to fight a fire. This will reduce the risk of electric shocks.

Electromagnetic Compatibility

The Philips CT system complies with the requirements of applicable EMC standards.

Mobile Telephones and Similar Products

Portable and mobile radio frequency (RF) communications equipment can affect the CT system.

459801063624_F/728 * MAR 2020

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WARNING

You should not allow portable radio transmitting devices (such as mobile telephones) into the examination room - whether switched on or off. Such devices could exceed EMC radiation standards could interfere with the proper functioning of the CT system. This could, in extreme cases, lead to fatal or other serious personal injury or to clinical mis-diagnosis. 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 CT system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electronic and Implanted Stimulators

Emissions from the CT system may affect other electronic equipment that does not meet the EMC immunity limits.

The FDA Preliminary Public Health Notification: Possible Malfunction of Electronic Medial Devices Caused by Computed Tomography (CT) Scanning, July 14, 2008, advises that with any CT scanner, there is a possibility that the X-rays used during CT examinations may cause some implanted and external electronic medical devices (pacemakers, defibrillators, neurostimulators, and drug infusion pumps) to malfunction.

Philips recommends that users check the device manufacturer's recommendations/precautions regarding use in a CT Scanner. Further, the following FDA recommendations should be considered.

Recommendations prior to scan:

1. Ask the patient if he/she has any implanted or external electronic medical devices.
2. Use CT Surview scans to determine if implanted or externally worn electronic medical devices are present and if so, their location relative to the programmed scan range.
3. For CT procedures in which the medical device is in, or immediately adjacent to, the planned scan range, make these adjustments:

- Determine the device type.
- If practical, try to move external devices out of the scan range.
- Minimize X-ray exposure to the implanted or externally worn electronic medical device by using the lowest possible X-ray tube current consistent with obtaining the required image quality, and making sure that the X-ray beam scans over the device for less than a few seconds.

WARNING

For CT procedures that require scanning over the medical device for more than a few continuous seconds (as with CT perfusion or interventional exams) users should prepare to treat possible adverse reactions.

459801063624_F/728 * MAR 2020

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Recommendations after scan:

1. Have the patient turn the device back on if it had been turned off prior to scanning.
2. Have the patient check the device for proper functioning.
3. Advise the patient to contact his/her health care provider as soon as possible if he/she suspects the device is not functioning properly after a CT scan.

Radiation Safety

X-ray and gamma rays are dangerous to both operator and others in the vicinity unless established safe exposure procedures are strictly observed.

WARNING

To avoid overexposure to radiation, ensure the scan room is clear of personnel during servicing and related service scanning. Follow the procedures established for your site.

The useful and scattered beams can produce serious or fatal bodily injuries to patients and persons in the surrounding area if used by an unskilled operator. Adequate precautions must always be taken to avoid exposure to the useful beam, as well as to indirect radiation including scattered radiation from within the scanner as well as anything in the path of the beam.

Those authorized to operate, participate in or supervise the operation of the equipment must be thoroughly familiar and comply completely with the current established safe exposure factors and procedures described in publications, such as the “Diagnostic X-ray systems and their major components,” section of subchapter J of Title 21 of the Code of Federal Regulations, and the National Council on Radiation Protection (NCRP) No. 102, “Medical X-ray and gamma ray protection for energies up to 10 MEV equipment design and use,” as revised or replaced in the future.

Operators are strongly urged to comply with the current recommendations of the International Commission on Radiological Protection, or in Japan, the Medical Law and its enhanced regulations, or in the United States, with those of the US National Council for Radiological Protection.

- ICRP, Pergamon Press, Oxford, New York, Beijing, Frankfurt, Sao Paulo, Sydney, Tokyo, Toronto
- NCRP, Suite 800, 7910 Woodmont Avenue, Bethesda, Maryland 20814, USA

Individuals responsible for the planning of X-ray and gamma ray equipment installations must be thoroughly familiar and comply completely with NCRP No. 49, “Structural shielding design and evaluation for Medical of X-rays and gamma rays of energies up to 10 MEV,” as revised and replaced in the future.

459801063624_F/728 * MAR 2020

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In Japan, users should refer to Medical Law and its enhanced regulations, Laws Concerning the Prevention from Radiation Hazards due to Radioisotopes and Others and its enhancement regulations, Industrial safety and Health Law, Laws Concerning the Prevention from Electrical Dissociation Radiation Hazards, Ordinance by Local Government on Fire Prevention and Dangerous Article.

Failure to observe these warnings may cause serious or fatal bodily injuries to the operator or those in the area.

Radiation Warning Lamps

The radiation warning lamps on the gantry panels, on the scan control panel, as well as site radiation warning lamps, must light up if scanning has been triggered.

If a radiation warning lamp does not light up:

- Shut down the system immediately and contact Customer Service.
- Press the **Emergency Stop** button if there is danger to you or the patient.

Installation and Environment

Except for installations requiring certification by the manufacturer per United States Federal Performance Standard, see that a radiation protection survey is made by a qualified expert in accordance with NCRP 012, Section 7, as revised or replaced in the future.

Perform a survey after every change in equipment, workload or operating conditions which might significantly increase the probability of persons receiving more than the maximum permissible dose equivalent. In Japan, report the installation to the Competent Authority.

WARNING

To avoid potential injury, do not attempt to unpack any part of the CT system. Unpacking and installation of the system must be completed by a qualified expert. Contact Philips Service for further information.

Coolant Leaks

Parts of your CT system are liquid-cooled. This is a closed-circuit, sealed system.

CAUTION

If coolant leaks are detected, shut down the scanner and immediately contact the nearest Philips field service office.

459801063624_F/728 * MAR 2020

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Laser Safety

WARNING

Follow these Laser Safety warning instructions:

- **Do not stare into the laser beam and instruct the patient not to stare into the beam.**
- **The use of optical instruments, such as eyeglasses with large diopter or mirrors, with this product will increase eye hazard.**
- **Ensure that the Patient wears protective glasses specific to the laser radiation generated by the system in any situation where direct exposure of the patient's eyes from the laser beam is possible.**

CAUTION

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

Protection Measures

Take the following protection measures to protect both yourself and the patient.

Only the patient should be in the scan room for scanning. Anyone who has to be near the patient during scanning must wear protective clothing (lead apron), wear a PEN dosimeter and/or film badge, and stay in the zone shielded by the system (to the side of the gantry or behind a mobile protective wall).

The physician is responsible for protecting the patient from unnecessary radiation.

- Use protective shielding whenever appropriate to minimize dose to sensitive organs.
- Use the applicable exams for children.

Phantom Handling

The liquid-filled phantoms require no special precautions during normal daily use. However, they do contain a specialized aqueous solution (phantom liquid), which is mostly water, developed specifically for Philips scanners which requires personal protection.

459801063624_F/728 * MAR 2020

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WARNING

Follow these Safety warning instructions when refilling or when coming into contact with the phantom liquid:

- **Handle an opened or damaged phantom with care.**
- **The phantom solution is a strong eye irritant and may be harmful to skin.**
- **Exercise care in handling: wear protective gloves and safety glasses.**
- **The solution contains surfactant and biocide.**
- **If the solution splashes on eye or skin, immediately wash with clear water for at least 10 minutes.**

Residual Risks to be Considered

Residual Thermal Hazards

Though the system is designed to zeroize thermal hazards, the following residual risks must be considered:

- When covers are removed, service personnel may be exposed to thermal hazards. The system complies with the IEC60601-1 clauses for internal markings and service manuals have warning instructions for these hazards which should be followed by service personnel to ensure their safety.
- During servicing, avoid touching components that can be hot, e.g., X-ray tube, High Voltage Generator (Power Block Booster [PBB] and Power Block Unit [PBU]), DMS Assembly, Heat Exchanger, and Linear Induction Motors (LIMs). The compressor motor surface can get hot during operation. Make sure the compressor has cooled before removing air inflect filters. Be sure to allow the components listed above to cool to a safe temperature before performing any maintenance procedure on them.
- Wear safety glasses with side shields while working on the gantry with covers open and power on, in the unlikely event that an anode crack failure in the tube causes a failure of the seals, and coolant (Tyfocor®) maybe released from the tube.
- If burning smell, smoke or any sign of fire or flame or electrical sparks are detected, remove personnel from the immediate vicinity, turn off power to the system and contact Philips service.
- This equipment must not be used in the presence of explosive gases or vapors, such as certain anesthetic gases. Use of electrical equipment in an environment for which it was not designed can lead to fire or explosion.

Residual Risks Related to Moving Parts

Though the system is designed to zeroize risks because of moving parts, the following residual risks must be considered:

459801063624_F/728 * MAR 2020

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- For patients connected to life support systems, extra care should be taken by the operator to ensure that the all connections are positioned in a manner to avoid pulling or disconnecting during the scan. During all movements of the gantry (automatic and manual) and the patient table, keep the patient under continuous observation to avoid pressing the patient against the gantry or between table parts.
- Make sure that the motion of the table is in the direction that will ensure that the patient can be easily released and will not get pressed against the gantry covers.
- For all patient table types, take care when using attachments (such as the head and foot holders) to avoid collision with the gantry. Non-original patient supports may cause danger for the patient through collisions with the gantry. Positioning aids must be used exclusively for their intended purpose: head holder only for positioning the head, table top extension only for positioning the feet.
- Be aware of possible pinch points between the foot extension and the gantry
- Ensure that the infant cradle does not collide with the gantry during table top movement
- Make sure that the patient is strapped securely to avoid dangling of the hands.
- When using the radiation Therapy Table Top, users should be aware of possible pinch points
- During studies, the patient table and gantry movements (if applicable) are automatic. Ensure enough clearance between the patient and the gantry. Before initiating the scan, perform manual movements to check the clearance. Auto scan means that automatic motions are expected without using the enable button.
- While moving the table or Gantry, avoid placing your feet under the table side covers or between the Gantry and Patient table. Avoid inserting your fingers between the table top and the table carriage. Avoid placement of ancillary equipment (such as wheelchairs, IV pumps or beds) under the table. The table could collide with these items during movement.
- Use caution when opening or closing the front cover. When lifting the front cover make sure to stand aside and let the cover lift to the fully open position. The locking pins MUST be engaged whenever the front cover is fully opened for servicing. Failure to comply may result in serious injury to service personnel.
- There are multiple pinch points underneath the gantry covers. Pay attention to all safety labels and follow service instructions to minimize risk of injury.
- Verify that the rotor is not spinning, by viewing through the gantry cone before opening the covers. Use caution when opening or servicing the scanners. Never service the rotating frame when or if rotational movement is enabled. In case of a power failure or fault condition the rotor can spin (approximately 25 minutes or longer) after the power is removed from the system. Wait until the rotor stops before opening covers Failure to comply may result in equipment damage, serious injury or death to service personnel.
- Check for rotational interference between rotor and cones (by hand rotation). Be aware and careful of pinch points during service operations.
- The Rotor contains heavy parts, such as the X-ray Tube, DMS, etc., and is perfectly balanced. When this balance is disturbed by removing a part from it, it will start an uncontrolled mechanical rotational motion to reach a new equilibrium point. This motion cannot be stopped and may injure the service engineer.

459801063624_F/728 * MAR 2020

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- Wear proper clothing to reduce the risk of injury due to hair, clothing or jewelry getting caught in parts of the system during servicing.
- Install the vertical safety support brace whenever personnel are working under the table. It is especially CRITICAL when performing repair or replacement on the vertical drive system. If the motor/brake assembly is removed without it, the patient support will free fall to the ground. The patient support scissors support a weight of ~600 pounds (272 kg); a fall may result in personnel injury or death

Residual Laser Radiation Risks

Though the system is designed to zeroize laser radiation risks, the following residual risks must be considered:

- The system has class 2 lasers that may be exposed to users and patients of the system during clinical use and care should be taken to avoid staring into the laser beam. Approved patient eye protection should be used for all head exams to minimize risk; the use of optical instruments (such as eyeglasses with large diopter or mirrors) with this product will increase the risk of eye injuries
- Service personnel can access class 3 lasers. Care needs to be taken to avoid looking directly into the laser beam or at its reflection on smooth, mirror-like surfaces like waveguides or plated metal. Service personnel are advised to remove power from the transmitter electronics box when working in areas of the gantry where there is a risk of eye exposure to laser energy

Residual Mechanical Gravity Related Hazards

Though the system is designed to zeroize mechanical gravity related hazards, the following residual hazards must be considered:

- If coolant leaks are detected, shut down the scanner and immediately contact the nearest Philips field service office. The floor may be slippery and present a risk of slipping or tripping.
- During maintenance procedures, check the entire X-segment cooling circuit for any obvious leakage
- All cables should be routed between the injector, the patient, the table and the CT scanner so they do not impede the free movement of personnel. Route all cables between the PIM, the patient, the patient table, and the CT scanner so that they do not impede the free movement of personnel. Route cables in existing troughs, ducts, or adjacent to system components to prevent obstructions that can cause personnel to trip and fall
- If the monitor is located on a cart, make sure that the cables connected to the device are not in the way of the patient or the personnel in the scan room. The additional monitor cart inside the scanner room should not be used to hold anything but the original monitor. The 21-inch monitor-base should always be on top of the stand and secured properly. When not in use, the cart and its cables should be moved to a corner of the room so they do not interfere with routine activities in the scanner room. Care must be taken not to collide with the monitor stand or trip on the monitor cables.

459801063624_F/728 * MAR 2020

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- Make sure that the patient is strapped securely to avoid dangling of the hands. Ensure that the patient is placed securely on the patient table and is not in danger of falling. During all movements of the gantry and the patient table (automatic and manual), keep the patient under continuous observation to ensure safety of the patient.
- If a head holder or support is not engaged securely, it can come loose causing injury to the patient. Positioning aids must be used exclusively for their intended purpose: head holder only for positioning the head, table top extension only for positioning the feet.
- Follow all service instructions when installing or servicing the system. Pay attention to clearance requirements to prevent excessive strain on wheel castors to minimize the risk of roll-over and toppling. Minimize the clearance between the Gantry/Patient Table/CIRS Rack base and the floor when transporting these components.. Use assistance wherever specified (e.g. CIRS rack removal from pallet). Wheel castors should be secured to minimize tipping hazard. Ensure components are attached to floor as specified during service and replacement procedures. Failure to comply may result in serious injury or death to service personnel.
- Handling equipment without proper tools, training, and adherence to all warning labels, etc., can cause damage to equipment or harm to personal.
- Make sure the gantry and other system components are on level ground. The system may move/roll on uneven ground. Block/brace the wheels on gantry as instructed to avoid undesired movement

Residual Lifting and Ergonomics Related Risks

Though the system is designed to zeroize lifting and ergonomics related risks, the following residual risks must be considered:

- System components such as gantry caster, jun-air compressor, CIRS racks, patient support and battery are very heavy. Caution should be used when moving these items and two people should be involved whenever instructed. Failure to comply with instructions can result in injury.
- While parts of the system are designed to take handling into account, care should be taken by users when handling heavy phantoms or accessories to avoid loss of control or unstable footing that could result in dropping the part which may cause injury

Residual Loss of Communication and Noise Related Risks

Though the system is designed to zeroize loss of communication and noise related risks, the following residual risks must be considered:

- The operator should watch the patient at all times during system operation to monitor patient status and avoid patient distress in case of failure of communication.

Residual Risks Related to Mechanical Expelled Parts

Though the system is designed to zeroize risks related to mechanical expelled parts, the following residual risks must be considered:

459801063624_F/728 * MAR 2020

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- Compliance with standards for design combined with periodic maintenance and inspection of the system according to detailed service instructions are designed to detect any problems in the system such as structural breakdown or human error that might lead to the possibility of a part coming loose and, if system enclosures are breached, becoming a projectile that could injure a person.
- Service personnel should wear protective glasses whenever instructed. The S-clips on the shipping crates are under tension and can fly off during removal. Failure to comply can result in injury to personnel.

Residual Risk of Accidental Radiation

Though the system is designed to zeroize risks accidental radiation, the following residual risks must be considered:

- All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection.
- The radiation warning lamps on the gantry panels, on the scan control panel, as well as site radiation warning lamps, must light up if scanning has been triggered. If the radiation warning lamps do not light up shut down the system immediately and contact Customer Service. Press the Emergency Stop button if there is danger to you or the patient.
- If there is any indication that X-rays are not turned off after releasing the foot pedal switch, press one of the STOP buttons on the gantry control panels or the Pause button on the scan control box. This stops the generation of X-rays, scanner rotation, and patient table motion.
- Only the patient should be in the scan room for scanning. When occupancy of the scanner room is unavoidable, attention should be paid to the zones of occupancy as documented in the Technical Reference Guide. Anyone who has to be near the patient during scanning must wear protective clothing (lead apron), wear a PEN dosimeter and/or film badge, and stay in the zone shielded by the system (to the side of the gantry or behind a mobile protective wall). The physician is responsible for protecting the patient from unnecessary radiation. Use protective shielding whenever appropriate to minimize dose to sensitive organs.
- Use the applicable exams for children. Use pediatric exams based on the age, weight, and indications to avoid over exposure. Philips recommends the use of the infant mode for newborns up to 18 months of age
- When performing Advanced Interventional procedures, prepare the appropriate radiation shielding equipment and materials to avoid accidental radiation exposure.
- For CT procedures that require scanning over the medical device for more than a few continuous seconds (as with CT perfusion or interventional exams) users should prepare to treat possible adverse reactions.
- Properly center all patients in the gantry. Patients not properly centered may be under or over exposed to radiation if the table height is set too high or too low
- To avoid overexposure to radiation, ensure the scan room is clear of personnel during servicing and related service scanning. Follow the procedures established for your site.

459801063624_F/728 * MAR 2020

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- The useful and scattered beams can produce injuries to patients and persons in the surrounding area if used by an unskilled operator. Adequate precautions must always be taken to avoid exposure to the useful beam, as well as to indirect radiation including scattered radiation from within the scanner as well as anything in the path of the beam.
- Follow Safety warning instructions when refilling or transporting phantoms

Residual Risk of Potential Electrical Hazards

Though the system is designed to zeroize risks potential electrical hazards, the following residual risks must be considered:

- Compliance with standards for design combined with planned maintenance and inspection of the system according to service instructions are designed to detect any problems with the system that might lead to potential electrical hazards, such as damaged couch or gantry covers exposing electrical components or improper system grounding. However, hazardous voltages are still present within the system that can cause serious injury. The operator should not remove covers or override safety locks present on the system. If covers are damaged or removed, the operator should not operate the system until repaired by a qualified service personnel.
- Before installing and prior to any service or maintenance activity, make sure to switch off the system at the main power supply and the UPS (ensure no power is applied to the Ghost) as a precaution against electrical hazards.
- Never remove or connect the Gantry cone cables with power ON to the rotor and/or stator as a precaution against electrical hazards.
- Front end electronics is energized through the slip rings even when you Power OFF the system. Therefore, before you remove the rear cover, to avoid any electrical danger, switch off all circuit breakers on the gantry left column, and on the main power supply to the scanner, and wait at least ten minutes for energy to be discharged as a precaution against electrical hazards.
- Batteries can present a risk of electrical shock or burn from high short circuit current. Observe proper precautions. Servicing should be performed by qualified service personnel knowledgeable of batteries and required precautions. Keep unauthorized personnel away from batteries. When servicing the battery, wear rubber gloves, electrically insulated footwear, and insulated tools
- The Philips CT system complies with the requirements of applicable EMC standards. Emissions from the CT system may affect other electronic equipment that does not meet the EMC immunity limits. There is a possibility that the X-rays or other electromagnetic radiation from the CT may cause some implanted and external electronic medical devices (pacemakers, defibrillators, neurostimulators, and drug infusion pumps) to malfunction. Philips recommends that users check the device manufacturer's recommendations/precautions regarding use in a CT scanner prior to exposing a patient to a scan.
- Touch current can reach the patient in the patient area by any chance contact through various paths (i.e. operator touching the patient and accidentally coming into contact with exposed electrical components of the system). The patient area is defined as any area less

459801063624_F/728 * MAR 2020

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than 15ft away from the table. The operator should not make contact with potential voltage sources and the patient at the same time in the patient area to avoid potential electromagnetic harms to a patient from leakage current.

Residual Risk of Misrepresentation

Though the system is designed to zeroize misrepresentation, the following residual risks must be considered:

- The system is intended for use is by trained users that understand the technological limitations and the types of artifacts that can be caused inherently by the CT scanner technology and by impacts from techniques used to generate images.
- User are expected to perform image analysis to verify that measurement results when making critical measurements are correct
- The system requires routine calibration and maintenance. Users are expected to perform daily image quality checks and periodic calibrations and maintenance as specified in the user manuals. Failure to do so can result in image artifacts or inaccurate measurements.
- Errors in RTP may occur when there are problems with geometrical accuracy of the system for RTP (e.g., table sag over distance while table is loaded, image perpendicularity). The overall treatment planning accuracy is dependant on a quality assurance plan by the clinician that takes into account the accuracy of the CT Scan data.
- Spatial positioning errors in RTP and final treatment may occur if the user does not use the oncology radiation therapy flat table top (“Therapy Table Top”) and its compatible accessories. To reduce these errors in final treatment, offsets between the lasers and CT center should be measured by scanning a phantom designed for this specific purpose, and then the measured values should be entered into the RTP system. The overall treatment planning accuracy is dependant on the quantification of any geometric inputs used by the system.
- Errors in RTP may occur if positional accuracy is compromised. In order to maintain positional accuracy, users should evaluate Therapy Table Top alignment immediately following any possible events which could cause misalignment (e.g. forceful table contact, system service). Any malfunction or damage should be evaluated by qualified Philips service personnel, and quality assurance procedures should be repeated after any subsequent repairs or adjustments.
- Patient positioning lasers should not be used for absolute marking in RTP as they are not designed for this purpose and may compromise accuracy. Instead, high accuracy external lasers (supplied by a third party) designed for marking patients for therapy should be used for this purpose.
- RTP accurancy may be compromised if the system is used for RTP prior to completion of both Image Performance QA procedures and any preventive maintenance to be conducted in accordance with the maintenance schedule provided for the system. The system is intended for use by trained personnel. Errors in geometric accuracy can impact the treatment location targeted by the RTP system, which could then potentially harm surrounding healthy tissue. Additionally, errors in determining the CT tissue density can impact the calculations used for therapy beam strength, which can thereby reduce the effectiveness of the treatment.

459801063624_F/728 * MAR 2020

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- Systems used for radiation therapy planning are expected to be maintained and calibrated consistent with AAPM Report No. 083 - Quality assurance for computed-tomography simulators and the computed-tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66.
- List of Commonly Recognized CT Artifacts and their Causes:
  - Patient-based artifacts: motion artifact, transient interruption of contrast, clothing artifact, and jewelry artifact.
  - Physics-based artifacts: beam hardening, cupping artifact, streak and dark bands, metal artifact/high-density foreign material artifact, partial volume averaging, quantum mottle (noise), photon starvation, and aliasing in CT.
  - Hardware-based artifacts: ring artifact, tube arcing, out of field artifact, and air bubble artifact.
  - Helical and multichannel artifacts: windmill artifact, cone beam effect, multiplanar reconstruction (MPR) artifact, zebra artifact, and stair step artifact.

Residual Risks Related to Biocompatibility

Though the system is designed to zeroize risks related to biocompatibility, the following residual risks must be considered:

- The clinical suite may include one (or several) third-party UPS devices. When UPS batteries are not properly maintained, or if they are held in service beyond their usable service life, failure can result in the leaking of electrolyte (sulfuric acid), overheating, and/or the emission of fumes. To ensure continued safe and reliable performance from these devices, periodic maintenance is required, including possible battery replacement. Based on industry standards, the typical useable service life of a UPS battery is less than five years. You may consult your local Philips Service representative for help in identifying the specific model of your UPS device(s) and available service provider options in your geography.
- Blood and bodily fluids from patients may leak onto surfaces of the system which present potential health risks. Take appropriate health and safety precautions when cleaning and disinfecting the system to minimize the risk of cross contamination. To prevent transmission of biological infection hazard and to prevent damage to the system, cleaning should be performed using materials and methods as described in the system instructions for use. Cleaning should be done using a commercial biocide approved by your governing authority to clean the surface of the system and should ensure that no remnants of cleaning materials remain on the system surface including the console, gantry, table, and accessories.
- Applied parts, which patients and users, may come into contact with during normal operation are designed for biocompatibility according to ISO 10993, however an individual may still have a reaction to such contact. Service personnel may be exposed to additional internal parts and surfaces during their normal duties and should follow all instructions and precautions to minimize their exposure to possible irritants.
- Coolant or other substances that leak from the system may cause harm. Field service should be contacted immediately upon detection
- Service personnel may be exposed to chemical substances during service operations and should take proper precautions to avoid risk.

459801063624_F/728 * MAR 2020

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- The system contains hazardous materials. Incorrect disposal of any of these materials may lead to serious environmental pollution. This system may contain devices that contain mercury, which must be recycled or disposed of in accordance to local, state, or federal laws. Within this system, the backlights in the monitor display contain mercury.

Residual Risk of Sharp Edges

Though the system is designed to zeroize risks related to sharp edges, the following residual risks must be considered:

- Sharp and rough edges are present inside the gantry and on other non-accessible surfaces and service tools. All service instructions should be followed to minimize risk of injury.
- The system and its accessories are designed to withstand day to day usage. However, if carts or other equipment collide with the system or its accessories, they may be damaged and sharp edges can become exposed
- The system and its accessories are designed to withstand cleaning and disinfection as required for clinical usage. Care should be taken to follow the instructions regarding recommended cleaning materials, frequency and process to avoid damaging the equipment and to ensure effectiveness.

459801063624_F/728 * MAR 2020

Undesirable Side Effects

Undesirable side effect is a form of harm that may affect any person near or in the device, due to a natural reaction arising from exposure to a device, during normal conditions of use, caused by a factor other than a failure of control.

Undesirable side effects identified are as follows:

- Radiation Effects.

  *Radiation exposure used for image creation. This type of ionizing radiation is essential for acquisition of an x-ray image suitable for clinically relevant diagnostic interpretation. The effects of this type of harm may manifest over an extended period of time (long-term effect of radiation exposure).
- Emotional Trauma/Anxiety.

Compatibility with Other Devices

CT/AMI Philips is performing compatibility testing for combinations of CT/AMI systems and accessories. The compatibility test results are verified to support device intended use in combination with other devices. Ask your Philips Representative or go to *www.philips.com/IFU* for the available compatibility statements."

Safe De-Installation of the CT System

Detailed instructions for dismantling the CT system is included in the CT System De-Installation document intended for Philips/trained technicians who dismantle the system.

For any information regarding the system dismantling procedure, please refer to the customer service contact information.

Customer Service Contact Information

local Philips Healthcare representative. Alternatively, contact:

Philips Healthcare

PO Box 10 000

5680 DA BEST

The Netherlands

Facsimile: +31 40 276 2205

459801063624_F/728 * MAR 2020

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4 System and Data Security

Philips Healthcare is dedicated to helping you maintain the confidentiality, integrity, and availability of electronic protected health information and the hardware and software products that create and manage these data.

Maintaining security of Philips Healthcare's products should be an important part of your facility's security-in-depth strategy. You should implement a comprehensive, multi-layered strategy (including policies, processes, and technologies) to protect information and systems from external and internal threats. Your security strategy should follow industry-standard practices, addressing physical security, personnel security, procedural security, risk management, security policies, and contingency planning.

The practical implementation of technical security elements varies by site and may employ a number of technologies, including firewalls, virus scanning software, authentication technologies, etc. As with any computerbased system, protection must be provided such that firewalls and/or other security devices are in place between the medical system and any externally accessible systems. These perimeter and network defenses are essential to good security practice.

This information provides guidelines to help the operator and owner understand some of the possible ways security can be compromised, and then insure that safeguards are in place to prevent this from happening. For specific information about security within their institutions, operators and owners can consult with the following officers at your location:

- Information Systems Security Officer
- Chief Information Officer
- HIPAA Officer (in the U.S.A.)
- Safety Officer

459801063624_F/728 * MAR 2020

Regulatory Controls

Protect Patient's Health Information

One of the most important assets to protect with security measures is the patient's health related information. Many governments require maintaining the confidentiality of this information. Therefore, strict security measures must be taken to guard this protected information.

NOTICE

De-identify patient studies when exporting via network or removable media, in compliance with your local privacy policies. See "Anonymize All Patients" in the Instructions for Use for more information.

(Users in the U.S.A. may find guidelines at http://www.hhs.gov/ocr/privacy/.)

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Prevent Unauthorized Device Modification

Philips Healthcare sells highly complex medical devices and systems. We are required to follow government-regulated quality assurance procedures to verify and validate modifications to the operation of our medical devices.

Operators and owners of this medical equipment must permit only Philips-authorized changes to be made to these systems, either by Philips' personnel or under Philips' explicit published direction.

CAUTION

Although the Philips CT operates on a personal computer (PC) platform, the installation of PC software not specified in the Philips system documentation may adversely affect the operation and security of the system, as well as the networks to which the system is connected. These adverse effects may not be immediately apparent to the user. Users should therefore not install unauthorized software onto their system.

Security Issues and Guidelines

In addition to the patient information and device integrity needs discussed in the preceding section on regulatory requirements, the following topics, issues, and guidelines should be understood and addressed by operators and owners.

Network Security

The CT system must be placed on a secure local computer network that has protections against viruses and other harmful computer system intruders. Make sure the equipment is connected to a local network that uses appropriate protection, such as a firewall, network access controls, and network virus scanner. Clinical data transferred across the network is not encrypted.

- The Host system can connect to IPv6 enabled remote nodes such as ISP systems and PACS systems.
- The Host system time can be configured to synchronize with an NTP server.

CAUTION

Connection of the System to a network that includes other equipment could result in unidentified risks to privacy of patient, user, operator, and other data. You should identify, evaluate, and control these data-privacy risks on-site. Changes to a network (including configuration, additional connections, disconnections, updates, and upgrades) may introduce new data-privacy risks and require further analysis.

459801063624_F/728 * MAR 2020

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Hard Drive Encryption

Encryption can be enabled on the Host system hard drive using an additional license. To enable encryption, contact Philips Service.

NOTICE

If encryption is enabled on the hard drive, the system performance might be impacted.

It is recommended to start using the system once disk encryption is completed.

NOTICE

When you transfer data to an USB drive, you can either select the compression mode as compressed or non-compressed.

Remote Service

Philips Healthcare has a global, remote service network for connecting many of your Philips systems to our advanced service resources. This secure tunnel approach provides your equipment with a single point of network access to on-site Philips equipment using Virtual Private Network (VPN) and iSSLink point-to-point connection technologies. The remote service function is a secure connection through explicit authorization and authentication control which includes the encryption of data.

Data Disaster and Recovery Planning

If not already in place, it is recommended that your facility develop a data disaster and recovery plan for the system. The plan should specify:

- system and patient-data backup plan
- safeguards in place to store protected health information and backup data
- procedures for restoring system and patient data in the event of a local disaster
- If the removable media is to be stored for safekeeping, protect the data from “fading” loss by storing it in a suitable environment and performing media renewal as recommended by the media manufacturer.
- If removable media is used to store patient data, protect the information from media obsolescence by planning and performing data migrations to newer storage technologies.

459801063624_F/728 * MAR 2020

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Access Control

Room Access Control

Local procedures should be put in place to limit physical access to medical equipment, to prevent accidental, casual, or deliberate contact by unauthorized individuals.

Access to the room containing the CT should be controlled by policy and procedures that identify who is authorized to occupy specific areas. Check with your Safety and Security Office for more information on what measures are in place or how to implement room access controls.

Local Administrator

The Local Administrator user account has access to system management options.

The Local Administrator can change his/her own password if the previous password is known.

If the password for the Local Administrator user account requires a reset, please contact your Philips Service Representative.

Individual Access Control/User Accounts

Individual clinical user accounts are created and managed by the Local Administrator account. All authorized clinical users have the same read/write permissions to perform scans, reviews, analysis, and other standard tasks.

NOTICE

All login credentials (such as user names and passwords) should be kept confidential. It is recommended to regularly change user passwords.

Once an account is created by the Local Administrator, enter the credentials at login. Only one user can login to the system at any time: concurrent clinical users are not supported.

User Account Roles

The following user account roles are supported by the system:

- Clinical
- Philips Service
- Local Administrator
- Third-party Service

The ability to enable or disable access to external input and output devices such as USB drives or DVD drives is available only to Philips Service and Third-party Service user accounts.

459801063624_F/728 * MAR 2020

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Manage Clinical User Accounts

Use the Local Administrator account to create and manage clinical users. The Local Administrator does not have permissions to perform scans, reviews, analysis, and other clinical tasks.

To access the Local Administrator account, enter the user name and password (provided by your Philips representative) on the login screen. The default Local Administrator login name and password will require change upon first login, and the new login information should be stored in a secure location.

Create User

When creating user accounts, it is recommended that:

- the default clinical user account be disabled (see chapter “Manage Users” on page 45); and
- a unique user account is created for each person using the system.

To create a user:

1. Enter the Local Administrator user name and password on the login screen.
2. Select **Create User**.
3. Enter the clinical user name, select **Clinical** from the drop-down list, then enter and re-enter password.
4. If required for the user, select **Access to Exam Card Manager**.
5. If required for the user, select **Access to Dose Management**.
6. Click **OK** and then **Logoff**.

NOTICE

It is recommended to take regular backup of user accounts. Record all clinical user logon information and store it in a safe place.

Manage Users

Once logged on as the Local Administrator, you can create users, remove users, reset a user password, enable or disable user accounts. You can also provide access to the following options:

- Exam Card Manager
- Dose Management options in the Preferences window
- View Audit Trail Logs (applicable only for Local Administrator role)

Remove a user

Only non-factory users can be removed. Select a user from the Users list. Click **Remove User** and confirm the permanent deletion of the account.

Reset a user password

459801063624_F/728 * MAR 2020

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Select a user from the Users list. Click **Reset Password**. Give and confirm the new password. The password will require change upon first login after reset.

It is recommended to regularly change user passwords. See chapter “Password Complexity Rules” on page 46.

Enable or Disable a user account

Select the user and check or uncheck the box to disable or enable the selected user account. One active user should be available in the selected role to disable the user account.

Grant or remove access to Audit Trail Logs

Select a user account with the Local Administrator role and check or uncheck the box to grant or remove access to the Audit Trail Logs.

Grant or remove access to the Exam Card Manager

Select a Clinical or Philips Service user account and check or uncheck the box to grant or remove access to the Exam Card Manager.

Grant or remove access to the Dose Management

Select a Clinical or Philips Service user account and check or uncheck the box to grant or remove access to Dose Management options in the Preferences window.

NOTICE

It is recommended to take regular backup of user accounts. Record all clinical user logon information and store it in a safe place.

Password Complexity Rules

- Password cannot contain the user's user ID.
- New password should not be same as old password.
- By default, the password must contain at least 8 characters and must satisfy at least 3 rules from below:
  - 1 uppercase letter
  - 1 lowercase letter
  - 1 number;
  - 1 special character: **!@#$%&*().**
- Password is case sensitive
- By default, passwords must be reset every 180 days.
- By default, after 5 consecutive failed login attempts, the account is locked.

Password character length, reset period, and number of failed login attempts allowed can be configured by the Local Administrator.

459801063624_F/728 * MAR 2020

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Change the Password Policy

Once logged on as the Local Administrator, you can change the default password policy for all users.

NOTICE

Only Philips Service user can reset the Local Administrator user password.

To change the default password policy:

1. Login as local administrator user.
2. Click the **Password Policy** button on the left.
3. Enter the login attempts allowed. The value can be between 3 and 10. The default value is 5 attempts.
4. Enter the number of days after which the password should expire. The value can be between 30 and 180 days. The default value is 180 days.
5. Enter the number of days before which the password expiry message should be displayed. The value can be between 1 and 30 days. The default value is 5 days.
6. Enter the length of the password. The value can be between 4 and 14 characters. The default length is 8 characters.
7. Select the check box to enable password complexity. When this check box is selected, all the password complexity rules are applied. Refer to Password complexity rules.
8. Click **Save**.

NOTICE

Click **Restore Factory Settings** to revert to the default factory remote set password policy.

User Account Backup and Restore

User account information (excludes the password) can be backed up and restored to any of the Philips CT systems running software version 4.8 by the Local Administrator or Philips Service Representative.

Local Area Network Access

Non-clinical users can access the Local Area Network (LAN) administrative tool for DICOM configuration. For more information, contact your Philips representative.

459801063624_F/728 * MAR 2020

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Positioning of Display Monitors

Unauthorized visual access to protected information can be minimized by positioning the system's display monitor to prevent viewing from doorways, hallways and other traffic areas. To help in limiting unauthorized visual access, an unattended CT display automatically goes blank after a set period of time.

Emergency Login

An emergency access option available at the login screen. By default, the Emergency user login is not enabled. The Local Administrator needs to enable the user and can also set a password if required.

To log in to the system, when there is no password set for your emergency user name:

1. Enter the user name as **Emergency**.
2. Enter your user name in the **Emergency User** field. The user name may consist of letters, numbers, and underscores and special characters.

   The name can be between 2-53 characters long consisting of alphabets, numbers and special characters "_" ' and ".".
3. Click **Emergency Login**.
4. Follow the on screen prompts.

To log in to the system, when there is a password set for your user name:

1. Enter the user name as **Emergency**.
2. Enter the password that the Local Administrator provided you. The Emergency login password can be changed only by using the Reset Password option.
3. Enter your user name in the **Emergency User** field. The user name may consist of letters, numbers, and underscores only.

   The name can be between 2-53 characters long consisting of alphabets, numbers and special characters "_" and ".".
4. Click **Emergency Login**.
5. Follow the on screen prompts.

After using the emergency login, the console will display **Emergency User** and **Emergency_<Emergency user name>** in the upper right corner of the console screen while the system is in use. After 5 exams under the emergency login, the user is required to login again using the same user name that was used earlier.

Note: An appropriate number of authorized clinical users should be maintained in order to avoid the use of the emergency clinical user login.

459801063624_F/728 * MAR 2020

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System Logoff

The system does not support automatic log off in order to avoid unexpected system log off during extended clinical exams. The system must be manually logged off and shutdown by the user if desired. However, to protect sensitive data, the screen will go blank if no user activity is detected after a set period of time.

Automatic Screen Blanking

The system is capable of automatically blanking the console displays after a set period of time in which no mouse or keyboard input occurs. By default, this period is 60 minutes. The Local Administrator can enable or disable this feature, or change the time period.

System Hard Drive

Clinical images that reside in the system hard drive are encrypted if the Philips-Service enables encryption on the hard drive based on Hospital request. Even then, it is recommended to restrict access and establish local access controls to only authorized users.

System Backup Media

The clinical data that is backed up on removable media is not encrypted and should be stored in a secure location to avoid unauthorized access.

Removable and Portable Media

When using removable media (CD-ROMs, DVDs, and USB drives) be aware of these security issues:

- Inserting removable media (such as a USB drive or CD-ROM) can introduce a virus to the medical device. Be certain to scan the portable media for malware before inserting the media into the scanner.
- Patient data that is transferred to removable media is not encrypted, handle and store media according to your privacy protection policies.
- If the media is to be discarded it must be destroyed or disabled so that the data can no longer be accessed.
- If removable media is used to store patient data, protect the information from media and technical obsolescence by planning and performing data migrations to newer storage technologies.
- If the removable media is to be stored for safekeeping, protect the data from “fading” loss by storing it in a suitable environment and performing media renewal as recommended by the media manufacturer.

459801063624_F/728 * MAR 2020

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CAUTION

Removable media that contains images and/or other medical information should be stored in a secure area that is not accessible by unauthorized individuals.

User Logging and Audit Trails

When any of the following events occur, the system logs the event in an ePHI audit log:

- Application activity
- Audit log used
- Transferring DICOM instances begins
- DICOM instances are accessed or a study is deleted
- DICOM instances transferred
- Patient-record event
- PHI-export
- PHI-import
- Query information
- Security alert
- User authentication

ePHI audit logs are accessible only to the Local administrator through the use of a special viewer.

The Local administrator can, however, provide this privilege to another Local Administrator that he or she has created on a case by case basis. ePHI audit logs are available up to 8 months from the initial date of the log. Logs older than 8 months are deleted from the archive. ePHI audit logs can be backed up and restored.

The system also supports a number of system-level event logs to assist with system troubleshooting and repair, including successful and unsuccessful user log in.

Data Integrity Checks

- The system supports basic system level data and database integrity checks.
- If you suspect improperly altered or destroyed clinical data, notify your local IT security office or notify Philips service.

System Application Control

The system utilizes McAfee Application Control, a whitelist file verification method. This is an alternate approach to preventing virus and malware infection. The whitelist allows only trusted software provided by Philips to run, and blocks untrusted software.

459801063624_F/728 * MAR 2020

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CAUTION

Whenever media is inserted into the CT system, be sure that the media has not been previously exposed to potential viruses, worms and trojans that infect desktop PCs.

In the event that an unauthorized application is opened, or an infected file is found, the white-list will prevent it from execution. The system will display an error detailing the disallowed file activity and log this information. If you see this error or notice unfamiliar system behavior or performance changes, especially after the system has been restarted, contact a Philips Field Service Engineer to have the system checked.

Performing Data Sanitization on Hard Drive

You can clear the hard drive contents by using the Secure Erase BIOS feature or a third-party application that, ideally, is U.S. Department of Defense (DOD) 5220.22-M approved.

To run Secure Erase, enter the F10 Bios Setup menu by powering on the system and pressing F10 as soon as the HP logo appears.

NOTICE

It is recommended to backup all data before performing data sanitization.

1. Select the **Security** menu and scroll down to the **Hard Drive Utilities** menu.
2. Select **Secure Erase**.
3. Select the desired drive.
4. Select **Continue**. The estimated time to complete Secure Erase will be displayed along with a final warning not to remove power.
5. Select **Continue**. The elapsed time will be displayed until “Secure Erase Complete” is displayed.
6. Press **Esc** twice to return to the drive selection menu. Repeat step 3 to Secure Erase additional drives or exit BIOS Setup, if done.

NOTICE

The Secure Erase process will take a long time. The amount of time varies based on the hard drive capacity and write speed.

Data Sanitization can be performed by qualified and authorized IT personnel or Philips service representative. No clinical persons are allowed to perform Data Sanitization.

459801063624_F/728 * MAR 2020

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Third Party Software used with the System

The following third party software are supplied with the Philips CT system:

- Adobe Acrobat Reader DC 19.012.20034
- McAfee Solidifier 8.2.1.143
- Microsoft Windows 10 Enterprise 2016 LTSB (64-bit) Version: 10.0.14393
- Techsmith Snagit 19.1.2
- Tevfik Karagulle CopSSH 6.4.0
- Wind River Systems VxWorks 5.4.2

Open Source Software used with the System

The following opens source software are used with the CT system:

- 7-Zip 4.57
- 7-Zip 64-bit 9.2
- ACLogic CeasarFTP 0.99E
- Boost C++ library and templates 1.65.1
- CLIPS 6.3
- Free Software Foundation GNU zip 1.2.4
- ICSharpCode.SharpZipLib.dll (#ZipLibrary) 0.85.5
- Joe Richards CPAU.exe-CPAU 01.10.00cpp
- Json.net 8.0.3
- Log4net 1.2.10.0
- NPlot Charting Library for .NET 9.9.2
- OpenCV 2.0 2
- Philippe Jounin TFTPD32 3.03
- Prism 6.2.0
- RedHat Cygwin (Support Telnet Commands over SSH) 2.87
- SharpZipLib (ICSharpCode.SharpZipLib) 0.85.5
- Simon Tatham Putty 0.67.0.0
- TightVNC 2.8.11
- WeifenLuo.WinFormsUI.Docking 2.7.0.0

ePHI De-Identified Items

The following items are **blanked** as part of ePHI de-identification:

459801063624_F/728 * MAR 2020

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- INSTANCE CREATOR UID
- ACCESSION NUMBER
- INSTITUTION NAME
- INSTITUTION ADDRESS
- REFERRING PHYSICIANS NAME
- REFERRING PHYSICIANS ADDRESS
- REFERRING PHYSICIANS TELEPHONE NUMBERS
- STATION NAME
- STUDY DESCRIPTION
- INSTITUTIONAL DEPARTMENT NAME
- PHYSICIANS OF RECORD
- PERFORMING PHYSICIANS NAME
- NAME OF PHYSICIANS READING STUDY
- OPERATORS NAME
- ADMITTING DIAGNOSES DESCRIPTION
- DERIVATION DESCRIPTION
- OTHER PATIENT IDS
- OTHER PATIENT NAMES
- MEDICAL RECORD LOCATOR
- MEDICAL ALERTS
- ETHNIC GROUP
- OCCUPATION
- ADDITIONAL PATIENTS HISTORY
- PREGNANCY STATUS
- PATIENT COMMENTS
- DEVICE SERIAL NUMBER
- PROTOCOL NAME
- IMAGE COMMENTS
- REQUESTING PHYSICIAN
- REQUESTING SERVICE
- REQUESTED PROCEDURE DESCRIPTION
- ADMISSION ID
- SPECIAL NEEDS
- CURRENT PATIENT LOCATION
- PATIENT STATE
- SCHEDULED PROCEDURE STEP DESCRIPTION

459801063624_F/728 * MAR 2020

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- REQUESTED PROCEDURE ID
- NAMES OF INTENDED RECIPIENTS OF RESULTS
- REQUESTED PROCEDURE COMMENTS
- IMAGING SERVICE REQUEST COMMENTS
- STORAGE MEDIA FILE SET UID
- ELSCINT1_PATIENT_LANGUAGE
- REFERENCED FRAME OF REFERENCE UID
- RELATED FRAME OF REFERENCE UID
- Main Header (Imagio) structure
- Sub-header (Imagio) structure
- Worklist Blob File

The following items are **removed** as part of ePHI de-identification:

- REFERENCED STUDY SEQUENCE
- REFERENCED PATIENT SEQUENCE
- REQUESTED PROCEDURE CODE SEQUENCE
- SCHEDULED PROCEDURE STEP SEQUENCE
- REQUEST ATTRIBUTES SEQUENCE
- CONCEPT_SEQUENCE

The following items are **modified to 1** as part of ePHI de-identification:

- STUDY DATE
- SERIES DATE
- ACQUISITION DATE
- CONTENT DATE
- PATIENTS BIRTH DATE

The following item is **rounded** as part of ePHI de-identification:

- PATIENTS AGE

The following item is **rounded the nearest 10** minutes as part of ePHI de-identification:

- PATIENTS BIRTH TIME

The following items are **changed to one** entered by operator as part of ePHI de-identification:

- PATIENTS NAME
- PATIENT ID

459801063624_F/728 * MAR 2020

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The following item is **rounded as per logic described below** as part of ePHI de-identification:

- PATIENTS SIZE

  The rounding is according to the following guidance:

Actual Height	Round to the Nearest
H < 50 cm	1 cm
50 cm < H < 100 cm	2 cm
H > 100 cm	5 cm

Tab. 1: Metric:

Actual Height	Round to the Nearest
H < 2 ft	0.5 inch
2 ft < H < 4 ft	1 inch
H > 4 ft	2 inch

Tab. 2: English:

The following items are **retained with no change** as part of ePHI de-identification:

- SERIES DESCRIPTION
- REFERENCED SOP INSTANCE UID
- PATIENTS WEIGHT
- STUDY ID
- FRAME OF REFERENCE UID
- SYNCHRONIZATION FRAME OF REFERENCE UID
- SPECIFIC CHARACTER
- STUDY TIME
- SERIES TIME
- ACQUISITION TIME
- CONTENT TIMESET

The following item is **retained only if it is “M” or “F” for “Other” it will be set to blank** as part of ePHI de-identification:

- PATIENTS SEX

The following items are **newly generated** as part of ePHI de-identification:

- STUDY INSTANCE UID

459801063624_F/728 * MAR 2020

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- SERIES INSTANCE UID
- ELSCINT1_PATIENT_DATA_MODIFIED

The following item is **set to “Yes**" as part of ePHI de-identification:

- PATIENT_IDENTITY_REMOVED

The following item is **set to "Basic Application Confidentiality Profile"** as part of ePHI de-identification:

- DE_IDENTIFICATION_METHOD

Software Distribution

Software Distribution option allows you to download and install software patches released by Philips. The software patches are automatically downloaded on the scanner, when the system is connected to Philips Remote Service (PRS). The download happens only when the scanner is not in use. The software patches can be downloaded manually too from PRS by Philips Service, Third Party Service users. For the hospitals not connected to PRS, the software patches can be downloaded from Philips site and copied on the scanner using removable media by Philips Service, Third Party Service users.

Notes:

- The automatic download of software patches may affect the system performance. Philips Service Personnel, Third Party Service or Local Administrator can disable the automatic download of the software patches using the Software Distribution option.
- The software patches require more than 11GB free space for the download.
- Once the download is complete, the clinical users will receive a patch availability notification during login. Philips Service Personnel, Third Party Service or Local Administrator can install the downloaded software patches.
- The software patch which requires post-installation intervention would only be available for installation by Philips Service user.
- Any failed software patch installation prevents clinical user login with a notification on the screen.

459801063624_F/728 * MAR 2020

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5 Quality Assurance

Read this section carefully and follow all instructions regarding scheduling and performance of **Quality Assurance** (QA) checks. These instructions represent the manufacturer's required QA and constancy performance checks. If additional testing is required by your national or local authorities, please contact your Philips Service Engineer.

- **Short Tube Conditioning** brings the tube to normal operating temperature. This process is required daily before any scans are performed on patients, or after 8 to 10 hours of scanner inactivity.
- **Air Calibration** is part of normal system maintenance. The test should be performed once a week.
- **Head IQ Check** must be run at least once a week (follow local regulations).
- **Body IQ Check** must be run at least once a month (follow local regulations).
- **Constancy Test** must be run at least once a month and is used for both Head and Body Quality Assurance.
- The infant phantom is used to check the performance in the infant scanning mode.
- **Monitor Calibration** must be run daily if the DIN 6868-157 standard is followed.

NOTICE

Prior to testing image quality, the system should be fully calibrated. This should be done by ensuring that all Calibrations have been run at the recommended frequency.

NOTICE

If table looseness is detected when performing Quality Assurance (QA) checks or when positioning a patient on the table, report the findings to your local Service Representative.

System Performance Phantom

The phantom consists of two portions which cover the aspects of head and body scans. This section covers the specifications of both the head and body portions of the phantom. Familiarize yourself with this information before you scan either portion. The illustration below shows the entire phantom.

459801063624_F/728 * MAR 2020

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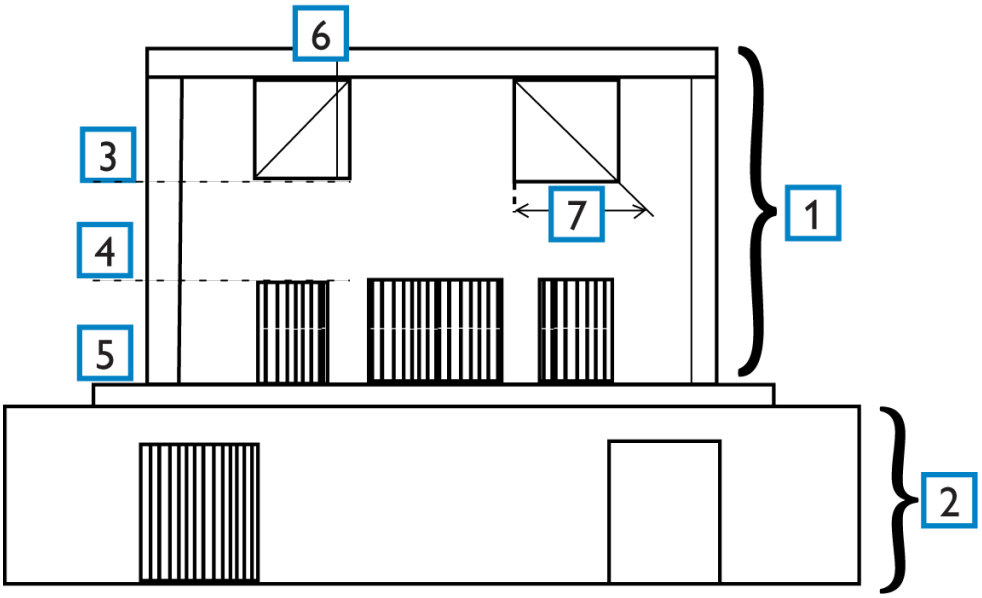


1. Head section
2. Body section
3. Physics layer
4. Water layer (phantom liquid layer)
5. Multi-pin layer
6. Impulse response wire
7. 45 degree angle wedge

Head Section

The head phantom is a Polyvinyl chloride (PVC) shell filled with water (phantom liquid). It is 200 mm outer diameter and consists of three layers:

- Physics layer for resolution test and tomographic section thickness (slice width) measurements
- Water layer (phantom liquid layer) for measuring noise and uniformity
- Multi-pin layer for checking contrast scale

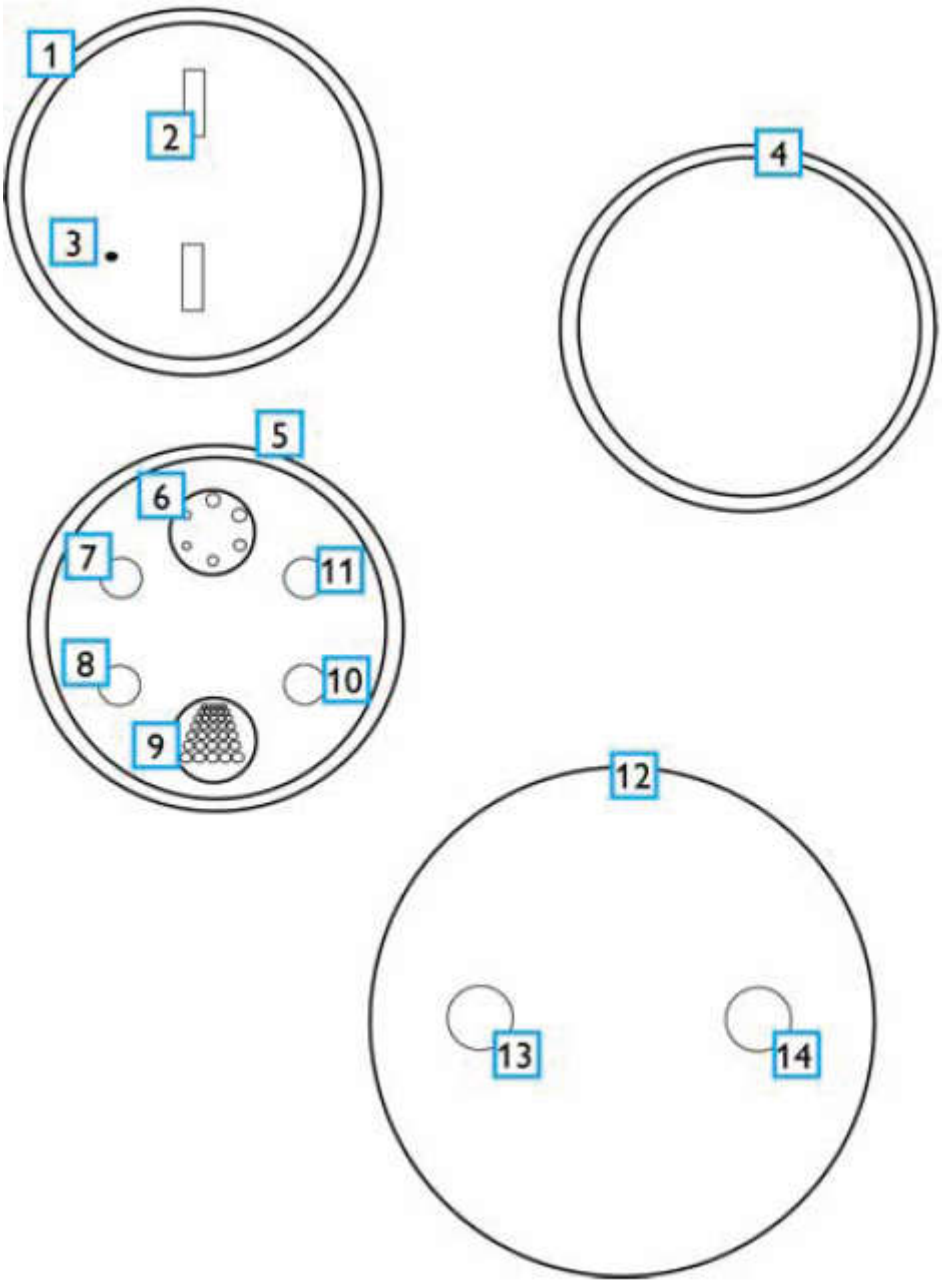
Body Section

The body phantom is a nylon cylinder 300 mm outer diameter. It includes these features:

- Teflon pin
- Water (phantom liquid) pin

459801063624_F/728 * MAR 2020

Phantom Composition



Item	Description
1	Physics Layer
2	Aluminum strips embedded at 45 degrees
3	0.18 mm copper wire for impulse response measurement
4	Water Layer (phantom liquid layer)
5	Multi-pin layer

459801063624_F/728 * MAR 2020

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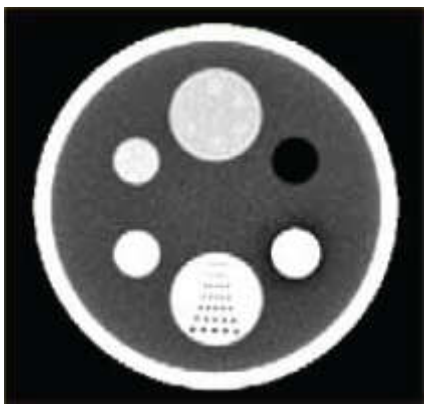
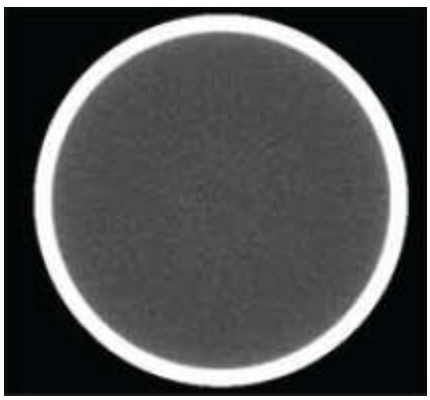
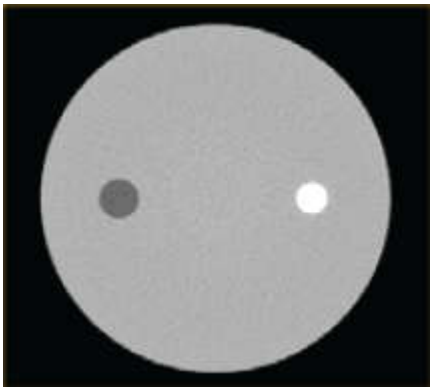
Item	Description
6*	Nylon (Aculon) body with six smaller Lexan pins of 3 mm, 4 mm, 5 mm, 6mm, 7 mm and 8 mm respectively
7	Lexan pin
8	Acrylic pin
9	Acrylic with seven rows of holes of different diameters. Each row has five equi-distant holes of the same diameter: • **Row 1** - 1.00 mm holes, 2.00 mm apart • **Row 2** - 1.25 mm holes, 2.50 mm apart • **Row 3** - 1.50 mm holes, 3.00 mm apart • **Row 4** - 1.75 mm holes, 3.50 mm apart • **Row 5** - 2.00 mm holes, 4.00 mm apart • **Row 6** - 2.50 mm holes, 5.00 mm apart • **Row 7** - 3.00 mm holes, 6.00 mm apart
10	Teflon pin
11	Polyethylene pin
12	Body layer
13	Water (phantom liquid) hole
14	Teflon pin
* Not all phantoms include this item.	

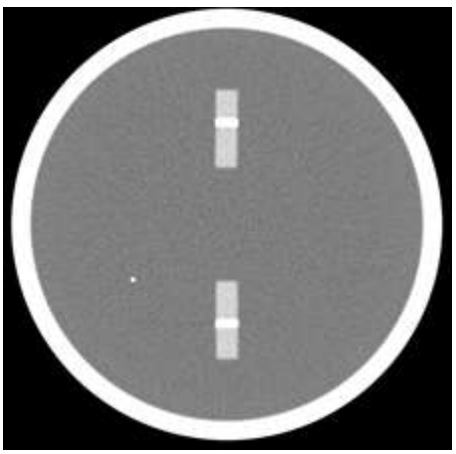
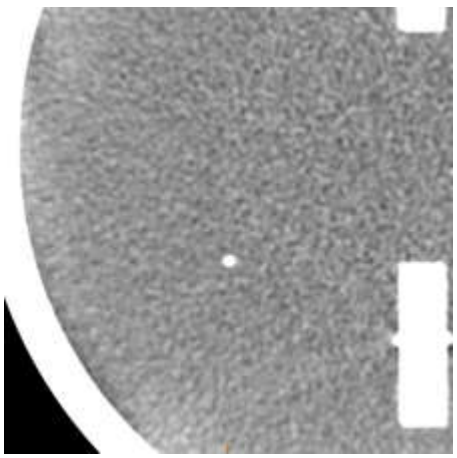
Representative Quality Assurance Images

Quality assurance images acquired during the weekly and monthly checks can be stored on CD or DVD if desired. The digital data of the following images are stored on the Reference QA Images CD.

Multi-pin layer, QA Axial Head 2D	Water (phantom liquid) layer, QA Axial Head 2D
	

459801063624_F/728 * MAR 2020

Body layer, QA Axial Body 2D


Physics layer (slice width image, QA Axial Head 2D)	Impulse response (modified-100 FOV, QA Axial Head 2D)
	

System Performance Harmonized Phantom

Either the Harmonized or System Performance Phantom is supplied as part of every CT system. Familiarize yourself with this information before you scan either portion.

The system phantom is used for CT numbers calibrations and Quality Assurance tests.

The phantom kit consists of the following parts:

- Harmonized phantom - Head section
- Harmonized phantom - Body section
- Harmonized phantom - Physics section
- Harmonized phantom - Infant head section is optional. Head adult section can be used for Infant Body IQ testing.

459801063624_F/728 * MAR 2020

Philips

The system phantom is used for the image quality tests and calibrations which can be accessed from the Quality Assurance menu including the automatic phantom centering.

1. IQ check (available for all users)
2. Constancy test (do not have to install the Body section)
3. Acceptance test (available for service users)
4. HCOR calibration (available for service users)
5. Performance test (available for service users and used in special cases)

The graphic displays the phantom sections that are installed on the phantom holder.

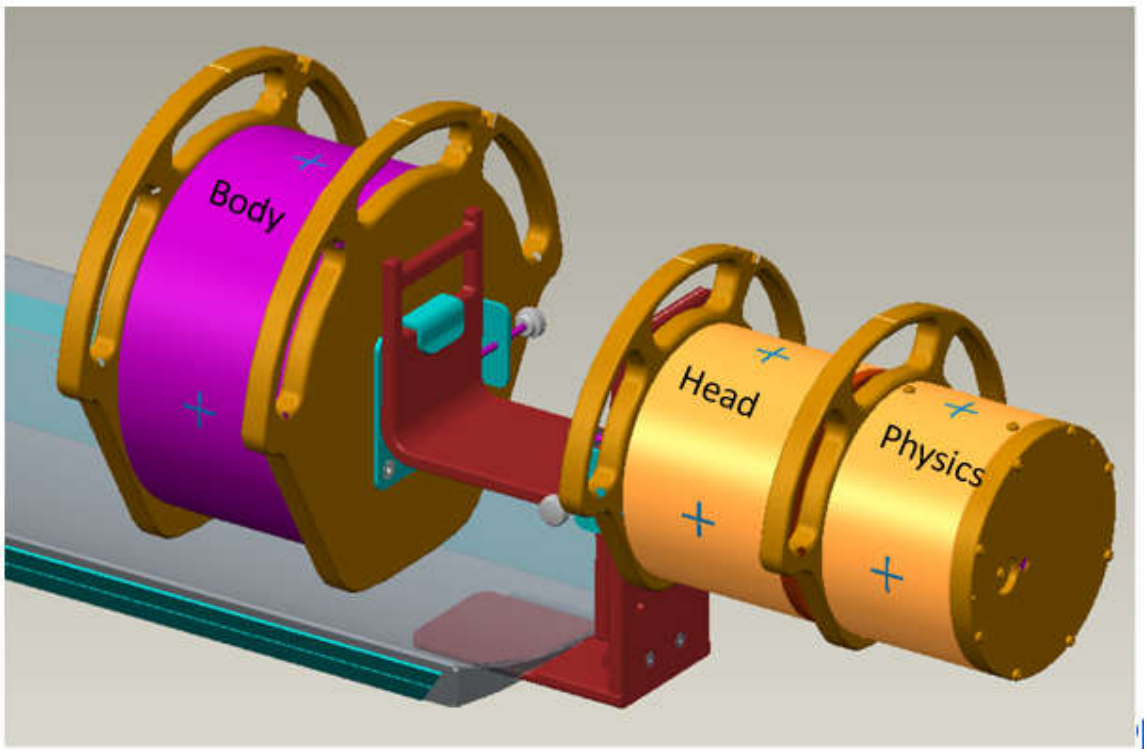


Fig. 1: Harmonized Phantom sections

The graphic displays the possible setups of system phantom.

459801063624_F/728 * MAR 2020

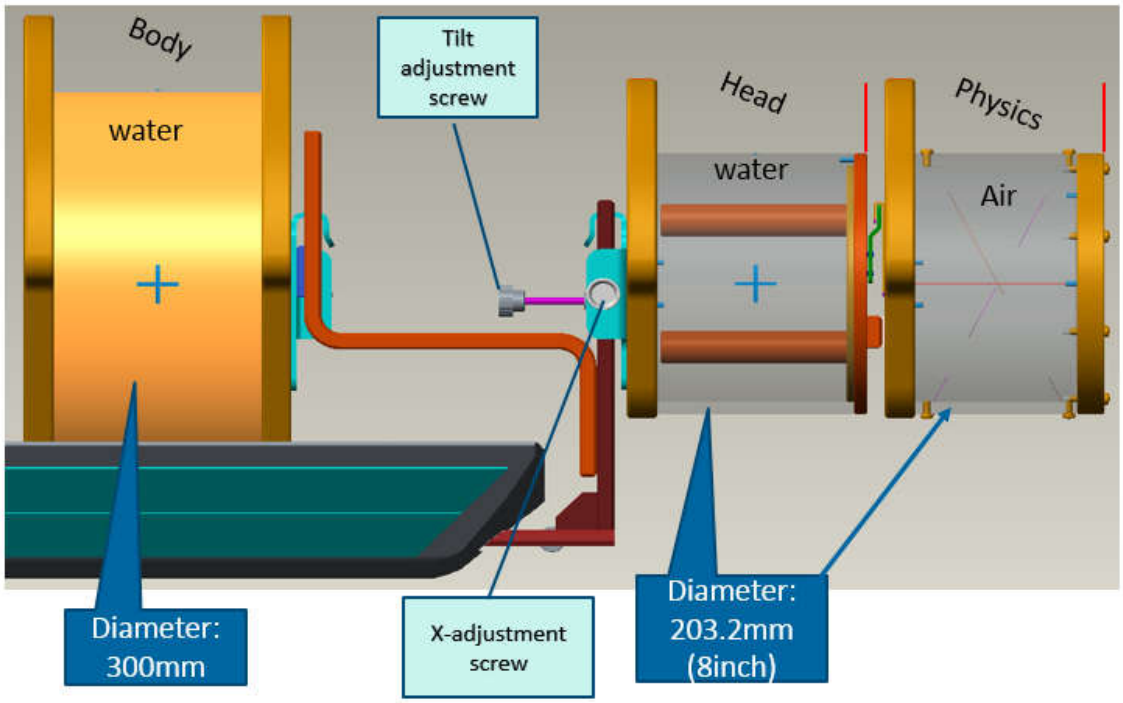


Fig. 2: Harmonized Phantom setup

Using Phantom with the Radiology Flat Top

For systems using the Radiology Flat Top for therapy planning, the following setup is used for Body section. You do not need to remove the Flat Table Top for IQ testing and calibrations.

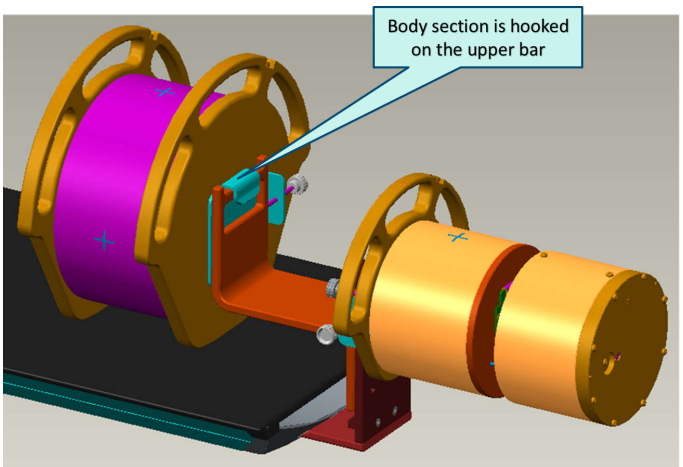
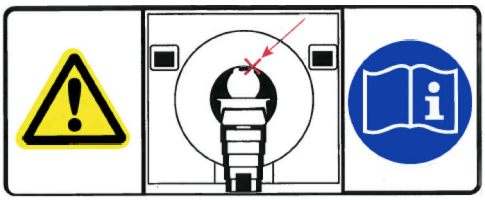


Fig. 3: Harmonized Phantom with Radiology Flat Table Top

CAUTION

Do not raise the system table to its maximum vertical height when the head or body phantom is mounted to it. The phantoms may collide with the gantry covers.

459801063624_F/728 * MAR 2020



Instructions for Phantom Installation

1. Insert the system phantom holder by sliding it into the couch table top bayonet. Lock the bolt at the left hand side of the holder to prevent it from sliding out.
2. Insert the Head section and ensure that the X-adjustment bolt is not interfering by shifting the phantom to your right until it is hooked securely. Gently shift it to the left until the adjusting x-screw touches the holder.
3. Install the Body section in the same way on the rear branch of the holder hooking it on the lower holder bar:

   - in case the Flat Top is installed, the Body section is hooked on the upper bar of the rear holder branch.

   - in both cases above the end opposite to hooking mechanism of the body section lays freely either on the table top or on the flat top.
4. To install the Physics section used for Resolution and Slice thickness measurement, slide it down onto the interconnecting mechanism of the Head section. Verify it is securely connected to head section and cannot fall off. To verify this check if both sections are concentric to each other. Refer to chapter “Using Phantom with the Radiology Flat Top” on page 63.
5. To install the Infant Head section, remove the physics section (if installed) and hook it on the Head section in the same way as described above.

Using Phantom with the Therapy Top

For systems using the Therapy Top for therapy planning, the following setup is used for IQ testing. You do not need to remove the Therapy Top for IQ testing and HCOR calibrations.

459801063624_F/728 * MAR 2020

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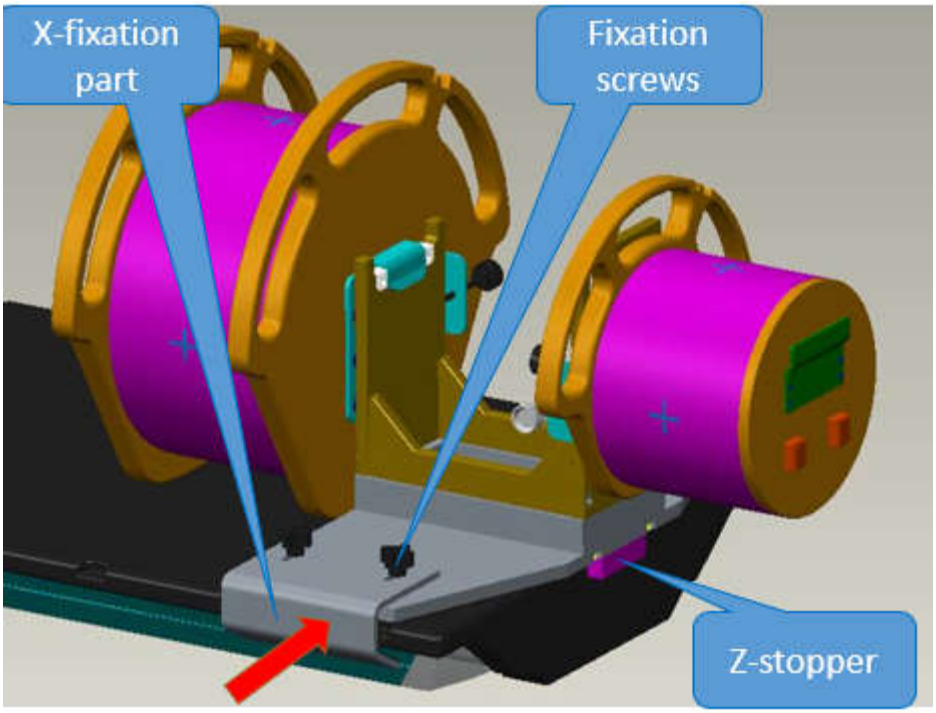
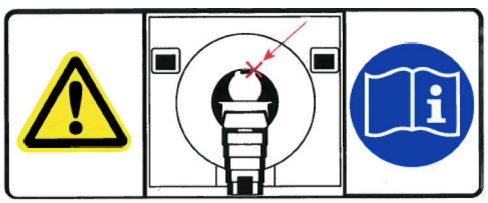


CAUTION

Do not raise the system table to its maximum vertical height when the head or body phantom is mounted to it. The phantoms may collide with the gantry covers.



Instructions for Phantom Installation on Therapy Top option

1. Insert the system phantom holder by sliding it on top of the Therapy Top and push in it until it is stopped by Z-stopper and then push it to the right until it stopes. Slide the X-fixator part to the left (see red arrow in picture above) and lock two Fixation screws to prevent it from sliding out.
2. Insert the Head section and ensure that the X-adjustment bolt is not interfering by shifting the phantom to your right until it is hooked securely. Gently shift it to the left until the adjusting x-screw touches the holder.
3. Install the Body section in the same way on the rear branch of the holder:

459801063624_F/728 * MAR 2020

- the end opposite to hooking mechanism of the body section lays freely either on the therapy top.

4. To install the Physics section used for Resolution and Slice thickness measurement, slide it down onto the interconnecting mechanism of the Head section. Verify it is securely connected to head section and cannot fall off. To verify this, check if both sections are concentric and parallel to each other.
5. To install the Infant Head section, which is optional and can be used for IQ testing, remove the physics section (if installed) and hook it on the Head section in the same way as described above.

Instructions to run HCOR calibrations using Therapy Top option

The HCOR calibration is normally performed by service. It is possible to run HCOR calibration without removing the Therapy top.

Harmonized Phantom - Head Section

Harmonized Head phantom has only one layer.

Head section is enclosed in clear shell of 203 mm outer diameter, filled with phantom liquid.

It is used for Head HCOR calibrations and Image Quality (IQ) tests, measuring uniformity, CT accuracy and noise, and measuring and calculating low contrast resolution during the IQ Check.

It contains two plastic pins made of following materials: Polyethylene and Acrylic used to measure linearity and provides contrast scale together with water and air measured out-side the phantom.

NOTICE

Poly (methyl methacrylate) (PMMA) is also known as acrylic or acrylic glass.

Harmonized Phantom - Body Section

The body phantom is a single 300 mm outer diameter PMMA shell, filled with phantom liquid. The body section is used for Body HCOR calibration and IQ tests measuring noise, uniformity and CT accuracy.

Harmonized Phantom - Physics Section

The physics phantom or section is a single 203 mm outer diameter PMMA shell, filled with air.

It contains:

- A steel wire parallel to z-axis for resolution measurement using Impulse Response algorithm followed by MTF calculation.
- Two steel slant wires with opposite slope of 1:2 for Slice thickness measurement.

459801063624_F/728 * MAR 2020

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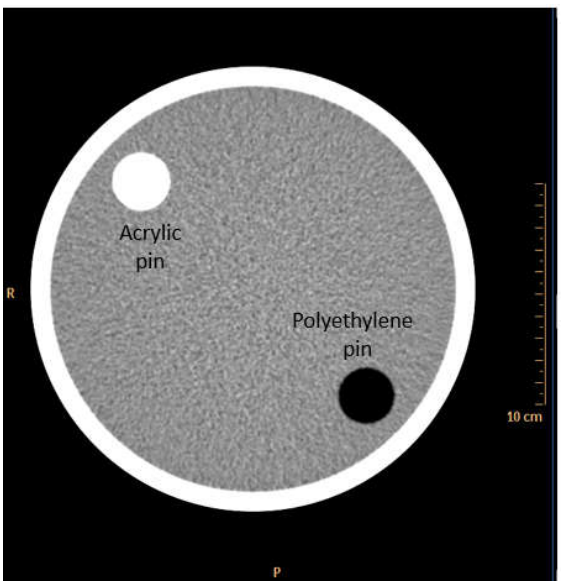
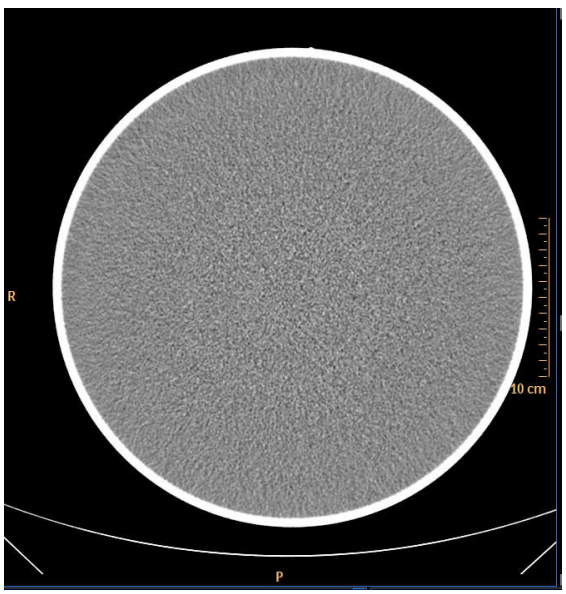
Harmonized Phantom - Infant Section (Optional)

The Infant phantom is a single 110 mm outer diameter PMMA shell, filled with phantom liquid. The Infant section is used for Infant Head HCOR calibration and IQ tests measuring uniformity and CT accuracy.

The Infant Body HCOR calibration is performed on the (adult) Head section phantom.

Representative Quality Assurance Images

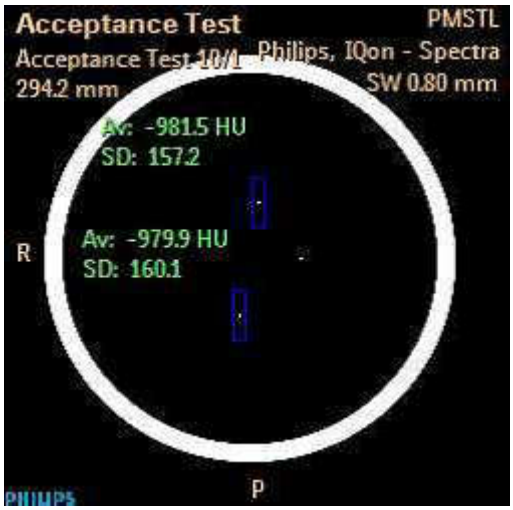
Quality assurance images acquired during the weekly and monthly checks can be stored on CD and DVD if desired. The digital data of the following images are stored on the Reference QA Images CD.

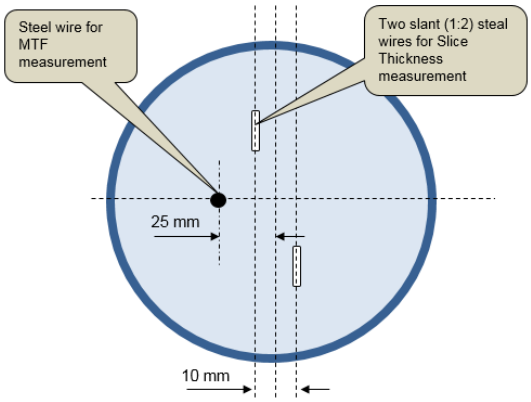
QA Axial Head 2D	QA Axial Body 2D
	

459801063624_F/728 * MAR 2020

Physics layer for Resolution and Slice Thickness measurement

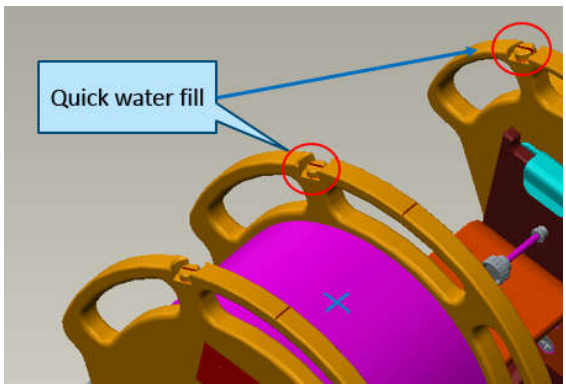
(QA Axial Head 2D)

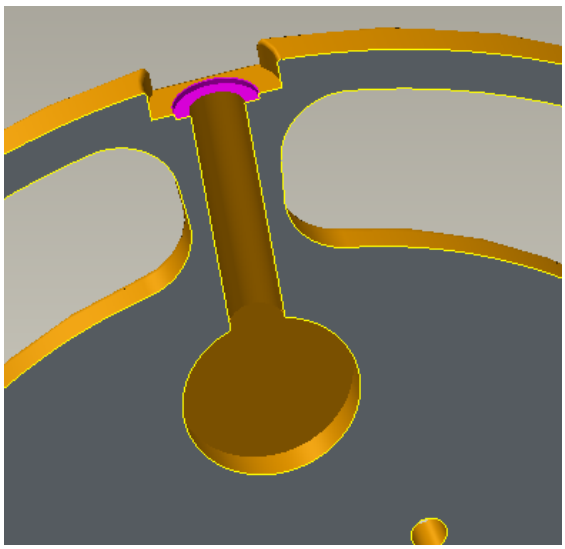




Phantom Maintenance

The system phantom is certified during scanner manufacturing process and does not require routine calibrations. Adding phantom liquid (water) solution will possibly be needed because of air outgassing. Before use, verify the cylindrical volumes of the phantom are filled with phantom liquid. Take care to allow small air bubbles to escape to the bubble trap chamber by tilting slightly the phantom. The scanned areas should be free of bubbles not to interfere with measurements. Adding water is performed using specially designed opening on the phantom handle.





459801063624_F/728 * MAR 2020

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Daily Short Tube Conditioning

Short Tube Conditioning brings the tube to normal operating temperature. This process is required daily before any scans are performed on patients, or after 8 to 10 hours of scanner inactivity.

WARNING

Do not perform Short Tube Conditioning when there is a person in the scanning room.

1. Check the scan room to ensure no people are present, and that the table is positioned up and into the gantry.
2.  Click the **Tool** icon.
3. Click **Quality Assurance**.
4. From the **Quality Assurance** dialog box, click **Short Tube Conditioning**. The **Procedure** column lists the additional tests that may be performed at the same time (for example, Constancy Test, Air Calibration, and so on).
5. Click **Next** and follow the screen prompts.
6. Click **Start** when ready.
7. After procedure is complete, click **Exit** to close the program.

Weekly Tests

Air Calibration and the **Head IQ Check** must be performed at least once a week. If time permits, both tests can be performed at the same time; however, it is not required to run the tests together.

Weekly Air Calibration

Air Calibration is part of normal system maintenance. The procedure helps to reduce ring artifacts.

- To ensure proper operation of the scanner, conduct this procedure at least once per week.
- Because this procedure must be done at stable, operating temperature, perform at midday after a number of patients have been scanned for best results. Allow about 20 minutes for completion.
- Ensure that no objects are in the scan field (in the gantry).

459801063624_F/728 * MAR 2020

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NOTICE

If you discover any objects in the scan field (for example, the head holder) after you begin **Air Calibration**, remove the objects from the scan field and restart the process.

WARNING

Do not perform Air Calibration if there is a person in the scanning room.

1. Check the scan room to ensure no people are present.
2. Ensure the table (and/or phantom) does not extend into the gantry.
3.  Click the **Tool**s icon.
4. Click **Quality Assurance**.
5. From the **Quality Assurance** dialog box, click **Air Calibration**. The **Recommended In** column lists the additional tests that may be performed at the same time (for example, Short Tube Conditioning, Air Calibration, and so on).
6. Click **Next** and follow the screen prompts.
7. After calibration is complete, click **Exit** to close the program.

WARNING

If ring artifacts are observed in the acquired images, perform Air Calibration. If ring artifacts persist, contact your Philips Service Representative.

Weekly Head IQ Check

Head IQ Check should be performed weekly to ensure best possible image quality from your scanner.

WARNING

Do not perform the IQ Check if there is a person in the scanning room.

1. Attach phantom holder to the end of the patient table.
2. Check the scan room to ensure no people are present.
3. Place the system Head and Body phantom(s) or Harmonized Head Phantom on the holder.

459801063624_F/728 * MAR 2020

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4.  Click the **Tools** icon to open the system utilities.
5. From the **Tools** menu, click **Quality Assurance**. The Quality Assurance dialog displays.
6. Select **IQ Check** and any other tests to be run. The **Procedure** column lists the additional tests that may be performed at the same time (for example, Short Tube Conditioning, Air Calibration, and so on).
7. Click **Next**. Select the appropriate IQ Check procedure.
8. Click **Next**. Follow the on-screen instructions for all the tests, including phantom placement. After completing the steps, click **Start** to automatically move the table and begin the check.

NOTICE

Do not skip the Automatic Centering step. This vertically aligns the phantom and correctly positions the table for the scan.

9. When the check is complete, the **Quality Assurance** dialog box displays.

NOTICE

IQ Check and **Constancy Test** report data may be recorded manually but may not be electronically exported to an external device (such as USB). If you need to export an electronic copy of a report, contact your Philips service representative.

If any Test Failed

If a test fails, click on the **Report** icon to view the failure or failures.

Ensure the phantom is properly aligned and level. Repeat the test.

NOTICE

Check the images for any foreign objects such as pins from another section of the phantom or possibly ring artifacts. If ring artifacts are seen, allow the scanner to warm up for 10 to 15 minutes by repeating the **Short Tube Conditioning** procedure multiple times.

If any test fails again, report the findings to your local Service representative before scanning patients in order to ensure safe operation.

459801063624_F/728 * MAR 2020

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Monthly Constancy Test

WARNING

Do not perform the Constancy Test if there is a person in the scanning room.

The following test should be performed once a month:

1. Attach phantom holder to the end of the patient table.
2. Check the scan room to ensure no people are present.
3. Place the system Head and Body phantom(s) or Harmonized Head and Body Phantom(s) with Physics layer on the holder.
4. Click the **Tools** icon and then select **Quality Assurance**.

5. Select **Constancy Test**. The **Procedure** column lists additional tests that may be performed at the same time (for example, Short Tube Conditioning, Air Calibration, and so on).
6. Click **Next**.
7. Click **Next**. Follow the on-screen instructions for all the included tests, including phantom placement. After completing the steps, click **Next** again.

NOTICE

Ensure that you are running all the tests that make up the **Constancy Test**. Do not deselect any of the sub-tests.

8. The **Instructions** page opens, with instructions to correctly set up the phantom. After completing these instructions, click **Start.**

NOTICE

The test should be performed with Automatic Centering step. This vertically aligns the phantom and correctly positions.

In case the phantom is not found during the IQ test, exit the test and perform . Afterwards, return to the test and skip the Automatic Centering step.

459801063624_F/728 * MAR 2020

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9. Type your name in the **User Name** field and the reason for the test (for example, monthly constancy test). Click **OK**.

   Click **Start**. If a temperature stabilization message displays, click **Close** to proceed.

10. When the test is complete, the **Quality Assurance** dialog box displays.

NOTICE

IQ Check and **Constancy Test** report data may be recorded manually but may not be electronically exported to an external device (such as USB). If you need to export an electronic copy of a report, contact your Philips service representative.

If any Test Failed

If a test fails, click on the **Report** icon to view the failure or failures.

Ensure the phantom is properly aligned and level. Repeat the test.

NOTICE

Check the images for any foreign objects such as pins from another section of the phantom or possibly ring artifacts. If ring artifacts are seen, allow the scanner to warm up for 10 to 15 minutes by repeating the **Short Tube Conditioning** procedure multiple times.

When prompted: **Do you want to continue the last attempt and perform only the failed modes?** Click **Yes** to repeat only the failed tests. Click **No** to repeat all the tests.

If Any Test Failed a Second Time

If the test fails a second time, click on the **Report** icon to view the failures and report the findings to your local Service Representative before scanning patients in order to ensure safe operation.

Monthly Body IQ Check

Body IQ Check should be performed monthly to ensure best possible image quality from your scanner.

WARNING

Do not perform the IQ Check if there is a person in the scanning room.

459801063624_F/728 * MAR 2020

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1. Attach phantom holder to the end of the patient table.
2. Place the system Head and Body phantoms or the Harmonized Body Section on the holder.
3. Check the scan room to ensure no people are present.
4.  Click the **Tools** icon to open the system utilities.
5. From the **Tools** menu, click **Quality Assurance**. The Quality Assurance dialog displays.
6. Select **IQ Check** and any other tests to be run. The **Procedure** column lists the additional tests that may be performed at the same time (for example, Short Tube Conditioning, Air Calibration, and so on).
7. Click **Next**. Select the appropriate IQ Check procedure.
8. Click **Next**. Follow the on-screen instructions for all the tests, including phantom placement. After completing the steps, click **Start** to automatically move the table and begin the check.

NOTICE

The test should be performed with Automatic Centering step. This vertically aligns the phantom and correctly positions.

In case the phantom is not found during the IQ test, exit the test and perform . Afterwards, return to the test and skip the Automatic Centering step.

9. When the check is complete, the **Quality Assurance** dialog box displays.

NOTICE

IQ Check and **Constancy Test** report data may be recorded manually but may not be electronically exported to an external device (such as USB). If you need to export an electronic copy of a report, contact your Philips service representative.

If any Test Failed

If a test fails, click on the **Report** icon to view the failure or failures.

Ensure the phantom is properly aligned and level. Repeat the test.

459801063624_F/728 * MAR 2020

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NOTICE

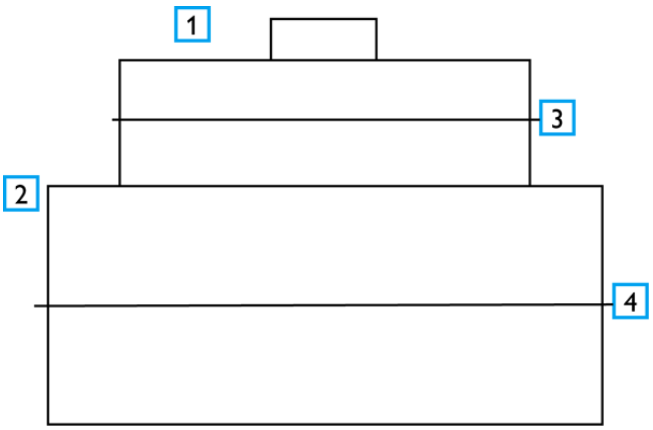
Check the images for any foreign objects such as pins from another section of the phantom or possibly ring artifacts. If ring artifacts are seen, allow the scanner to warm up for 10 to 15 minutes by repeating the **Short Tube Conditioning** procedure multiple times.

If any test fails again, report the findings to your local Service Representative before scanning patients in order to ensure safe operation.

Infant Phantom Testing

The infant scanning mode is recommended for scanning infants under eighteen months of age. This section provides instructions for using your infant phantom to check the performance in the infant scanning mode.

The Infant Phantom is intended to radiographically simulate the infant imaging condition.



1. Head section
2. Body section
3. Head section centerline
4. Body section centerline

This phantom consists of a head section and a body section.

- The Body section consists of an approximately 15 cm diameter cylindrical acrylic shell.
- The Head section is made of an approximately 11.4 cm outer diameter cylindrical PVC shell with an approximately 1.5 mm wall thickness.

Before use, fill the cylindrical volumes of the phantom with the phantom liquid. Take care to allow all air bubbles to escape the chamber through the top fill box.

The Harmonized Phantom set uses

- Adult Head Section for Infant Body testing
- Infant Head Section mounted on the Adult Head Section, for Infant Head testing

Attach & Scan Phantom

Before you can use the infant phantom for quality assurance testing, you must attach it to the patient table. Use this procedure to install the phantom.

459801063624_F/728 * MAR 2020

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1. Attach phantom holder to the end of the table.
2. Move the patient table away from the gantry (OUT).
3. Check the mounting bracket to ensure it is tightly attached.
4. Insert the infant phantom by sliding its hooks onto the Head Phantom.
5. Turn on the laser markers.
6. Move the patient table to position the phantom in isocenter.
7. Move the patient table towards the gantry (IN).
8. Position the table so that the laser markers line up with the centerline on the phantom holder. Zero the table.
9. Click **Patient**. Enter the demographic information. Select **Infant** from the Age Group.
10. Click **Reference Exam Cards**.
    - Click the **Head** exam card group. Select the **Brain 0-18m** exam card.
    - Click the **Abdomen** exam card group. Select the **Abd/Pel 0-10 kg** exam card.
    - Click **OK**.
11. Set the surview to scan the entire Infant Phantom(s).
12. Using the surview, plan the Infant Brain Helical scan to (at minimum) cover the Head part of the Infant phantom (see the parameters in the table). Perform the scan.
13. Using the same surview, plan the Infant Body Helical scan to (at minimum) cover the Body part of the Infant phantom (see the parameters in the table). Perform the scan.
14. Set a circular ROI at the phantom image center and note the mean CT value. It should yield the following result.
    - For head section using ROI with a diameter of 30 mm ± 3 mm the CT number should measure 0±4 CT numbers (or HU)
    - For body section using ROI with a diameter of 40 mm ± 3 mm the CT number should measure 0±6 CT numbers (or HU)

NOTICE

Your Service Engineer can adjust the CT number level if it is out of specification.

1. Perform Air calibration and recheck.
2. If still out of limits call FSE.

Infant Scan Protocols	Head	Body
Resolution	Standard	Standard
Collimation	16 x 0.625	64 x 0.625
Scan Angle	360°	360°

459801063624_F/728 * MAR 2020

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Infant Scan Protocols	Head	Body
Rotation Time	0.75	0.4
Reconstruction Filter	UB	C
FOV (mm)	200	180
Storage	Local	Local
Thickness (mm)	2.5	3
Increment (mm)	2.5	1.5
Pitch	N/A	1.297
kVp	100	120
mAs	300	120
Number of Scans	1	1

Monitor Calibration test

This procedure is for use with both standard and Deutsche Industrie-Norm (DIN) 6868-157 standard Acceptance Test for Image Display Systems with diagnostic quality only.

If you are unsure if your monitor follows DIN 6868-157 standard, contact your local Philips service representative.

1. On the left monitor, click the wrench icon on the top-right corner.
2. From the panel opened on left side of the monitor, select **Monitor Calibration**.
3. Select the desired image type or pattern type.
4. Select the image position as center, clinical or full screen.
5. Click on the required test pattern.
6. Follow the DIN 6868-157 procedure for the Acceptance Test for Image Display Systems (For DIN monitors only).
7. Select **Close** button to terminate the **Monitor Calibration** application.

NOTICE

Monitor Calibration is not available during active scan.

WARNING

If an error occurs during the test, the system displays a red X. Contact Philips Service for assistance.

459801063624_F/728 * MAR 2020

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459801063624_F/728 * MAR 2020

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6 User Information

Technique Factors - Maximum Deviations

Peak X-ray Tube Voltage

The peak X-ray voltage displays on the Operator workstation screen. The actual x-ray voltage during scan is within ±5% of the displayed value.

Peak X-ray Voltage
80, 120, or 140 kVp (100 kVp optional)

The peak X-ray voltage is measured on a resistive divider, which is calibrated during the manufacturing process.

Tube Current Exposure Time Product

The actual current exposure time product (in mAs) during a scan is within ±22% of the value displayed on the Operator console. The tube current exposure time product is measured by a dosimeter calibrated in mAs. The dosimeter is calibrated by measuring the tube anode current on an accurate resistor between X-ray on and off during a long exposure.

Linearity of Radiation

The maximum deviation of linearity of radiation is ±10%.

Gantry Laser Alignment Lights

The Gantry has two sets of laser alignment lights. One set is on the outside surface of the gantry, and the other on the inside, on the scan plane.

The outside laser lights are useful for positioning the patient with respect to the axis of rotation. The inside laser alignment light is useful for defining the position of the actual X-ray beam.

The alignment light inside the gantry bisects the width of the proposed X-ray beam scan plane during patient set-up. During the scan initialization, the table moves so that the middle of the first image slice coincides with the laser line (within 2.0 mm). Isocenter is within ±3 mm of the indication from the Sagittal and Coronal lasers.

NOTICE

For more details, refer to the "Table and Gantry Movements" section in "Chapter 3 (Preparing for an Exam)" in the Instructions For Use.

459801063624_F/728 * MAR 2020

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Preventive Maintenance

Routine preventive maintenance for the whole CT system is scheduled every six months and should be performed by qualified Philips personnel.

As part of routine maintenance, the Service Engineer will use a diagnostic program to check these items:

- Cathode voltage
- Emission current
- Exposure time

Cleaning and Disinfection of the System

Cleaning and disinfection are critical to minimize the risks of transmission of infectious agents. Cleaning is the removal of contaminants. It consists of the removal, usually with detergent and water, of adherent soil (e.g. blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of a medical device. Disinfection is the process to reduce the number of viable microorganisms. This product is classified as non-critical device that is intended to contact with intact skin, therefore low to intermediate level disinfection is required. Cleaning and disinfection should follow recommendations for low to intermediate level disinfection as defined by the government agencies, e.g. CDC, using the products approved and registered with your governing authorities, e.g. EPA and VAH.

CAUTION

Wear proper Personal Protective Equipment (PPE), e.g. gloves and glasses, for cleaning and disinfection.

CAUTION

Follow the cleaner/disinfectants manufacturer's instructions for cleaning and disinfection.

The following can be used for cleaning the system including the console, gantry, table, and accessories:

- Distilled water
- Methylated spirit
- Bleach and water solution or disinfectant wipes at ratios of up to 1:10

The following disinfectants can be used for disinfecting the system including the console, gantry, table, and accessories. Only the products approved and registered with the governing authorities, e.g. EPA and VAH, should be used.

- 1:10 bleach equivalent spray cleaner or wipes

459801063624_F/728 * MAR 2020

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- Low- or intermediate-level disinfectant Germicidal Wipes or liquid
- 3% Hydrogen Peroxide
- Ethanol
- Quaternary ammonium compounds
- Benzyl-C12-18-alkyldimethyl

Based on how the parts are exposed to the patients, the extent of the exposures and the frequency of the exposures, the following cleaning/disinfection frequencies are recommended:

- Parts that the patients make direct contact with during normal scans shall be cleaned/disinfected for every patient;
- Parts the patients could touch or the patient body fluid (blood or other potentially infectious materials) couch reach shall be cleaned/disinfected daily
- Noncritical environmental parts that the patients do not touch or the patient fluid (blood or other potentially infectious materials) is not expected to reach, shall be cleaned/disinfected weekly or as needed

CAUTION

After each occurrence of spill of contrast medium or patient body fluid (blood or other potentially infectious materials), immediately remove any residual contrast medium and/or patient body fluid, followed by cleaning and disinfection. Contact service engineers if the contrast medium or patient body fluid get inside the equipment.

CAUTION

Blood and contrast medium are health risks. Take appropriate health and safety precautions when removing blood or residual contrast medium.

Tips:

- After cleaning and disinfection, inspect for any damages to the parts, e.g. cracks on the covers, degraded labels, or torn/broken parts etc. Contact Philips Service Representative immediately if any parts are damaged.
- Clean and disinfect the system after installation and before first clinical use.
- When cleaning the front and rear covers on the scanners, cover the microphones to avoid leaking the cleaning solution inside.
- When cleaning the buttons, mouse and the inside of the Gantry opening, take care to avoid leaking the cleaning solution inside.
- When cleaning the monitor screens, use soft cloth, if necessary, moistened with water or LCD cleaner. Do not use any corrosive agents or abrasive agents. Damp cloth can be used but never use wet cloth.

459801063624_F/728 * MAR 2020

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- Activate the clean screen function when cleaning the touch panels (if equipped). Use soft cloth, if necessary, moistened with water or LCD cleaner. Do not use any corrosive agents or abrasive agents. Damp cloth can be used but never use wet cloth.
- The patient restraints can be machine washed or dry-cleaned. Wash the restraints closed to protect the Velcro parts. Remove contaminations with wet cloth. On site cleaning can be performed using specified cleaners/disinfectants, followed by cleaning with water as needed. Make sure the patient restraints are completely dry before using or storing them.
- Apply solution on lint-free wipes if solutions are used. Do not apply solutions directly on the device.
- Rinsing, when needed, should be done with a damp lint-free wipes. Wipes can be damped with distilled water.
- Drying, when needed, should be done with lint-free wipe.

CAUTION

Do not use detergents or organic solvents to clean the system. Strong detergents, alcohol, and organic cleaners may damage the finish and also cause structural weakening.

X-ray System Specifications

X-ray Tube

The X-ray tube, mounted on the gantry, has a 8.0 MHU rotating anode with a variable focal spot size of 0.5 x 1.0 mm^2 and 1.0 x 1.0 mm^2.

Leakage

The tube housing assembly together with the beam limiting device:

Leakage
≤ 80 mR/hr @1 meter

Filtration

Minimum tube housing filtration:

Filtration
1.0 mm Al equivalent

The beam-limiting device includes additional filtration to achieve a half value layer of Aluminum Quality Equivalent Filtration:

459801063624_F/728 * MAR 2020

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kVp HVL
80 kVp 6.4 ± 0.5 mm Al
100 kVp 7.8 ± 0.5 mm Al
120 kVp 8.9 ± 0.5 mm Al
140 kVp 9.9 ± 0.5 mm Al

Cooling Curves

See chapter “X-ray Tube Housing Assembly Information” on page 84.

Power Rating Charts

See chapter “Tube Power Ratings - Brilliance CT” on page 85.

Maximum Continuous Heat Dissipation

4.1 KW power average over an hour.

X-ray Power Supply

Line Voltage and Regulation

Power supply input voltage is 480 VAC +10% and -15%. The change in the output high voltage is ±1.5% at all line conditions.

Maximum Line Current

110 A RMS

Maximum Power

60 kW

X-ray System Loading Factors

The following system loading factors are applicable to Brilliance CT per IEC 60601-2-44 SEC 6.8.2.

- **Nominal X-ray tube voltage**: 140 kV at 428 mA X-ray tube current
- X-ray tube voltage corresponding to highest obtainable X-ray tube current:
  - 80 kV at 500 mA
  - 100 kV at 500 mA (if 100 kV option is installed)
  - 120 kV at 500 mA
- **Highest electric output power**: 120 kV X-ray tube voltage and 500 mA X-ray tube current.
- **Nominal Electric Power for 4.0 second loading**: 60 kW at 120 kV X-ray tube voltage and 500 mA X-ray tube current.

459801063624_F/728 * MAR 2020

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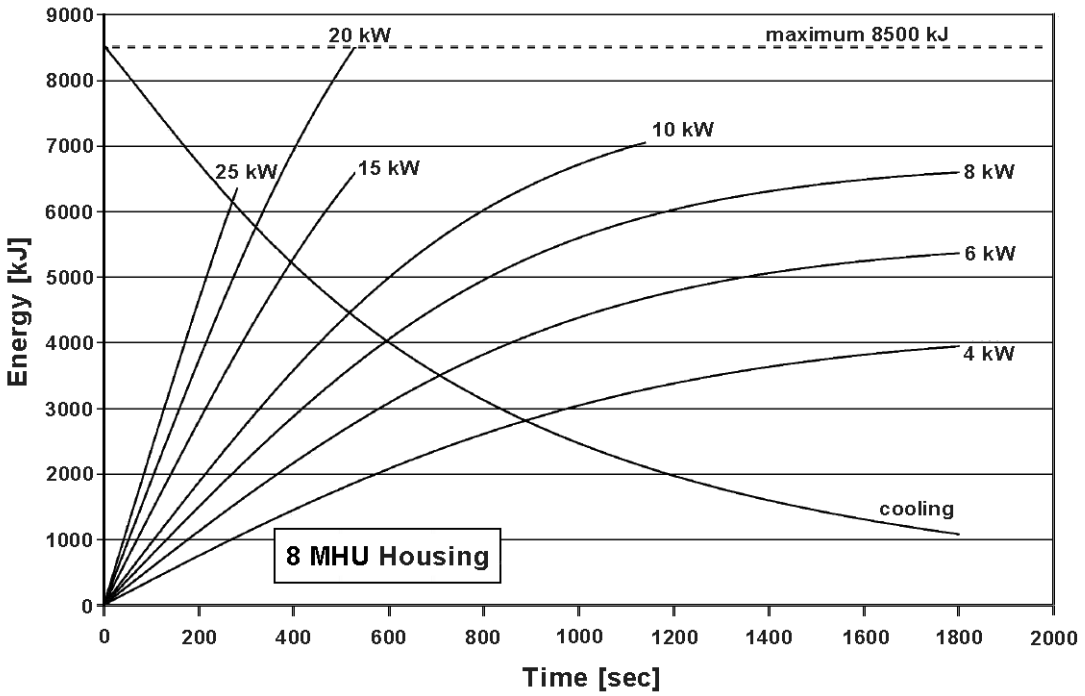
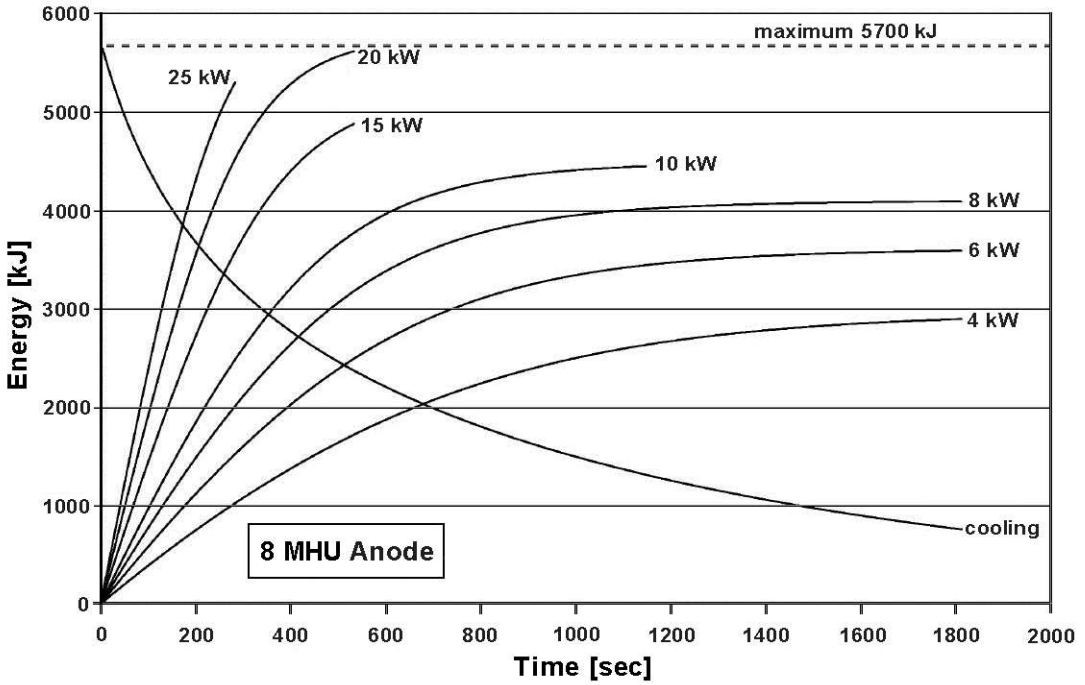
X-ray Tube Housing Assembly Information

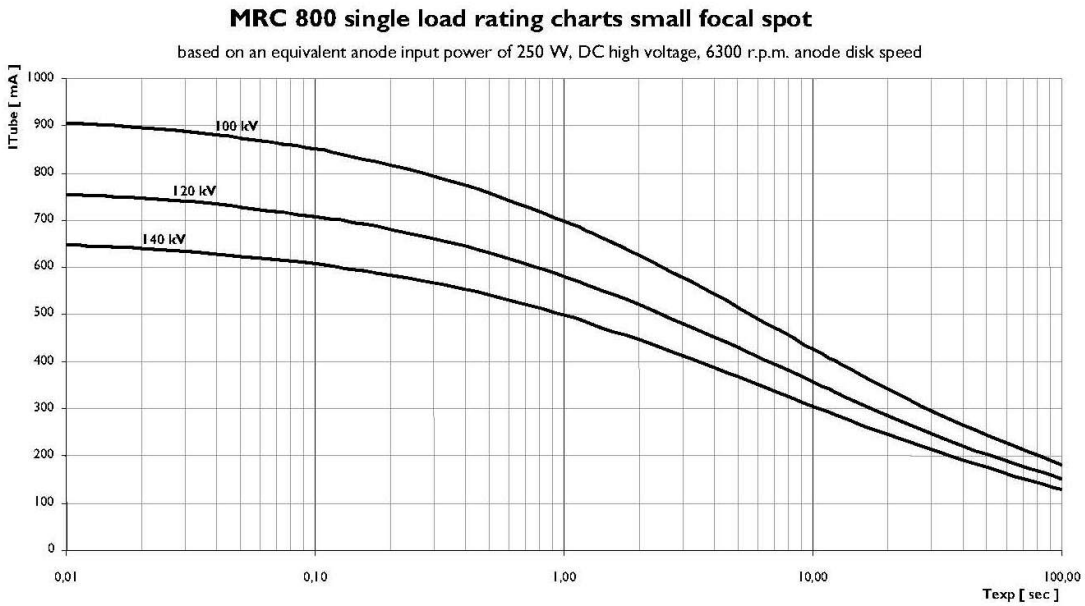
The following are graphs of the MRC 600, 800 and 880 tube housing assembly heating and cooling curves, and the anode heating and cooling curves.



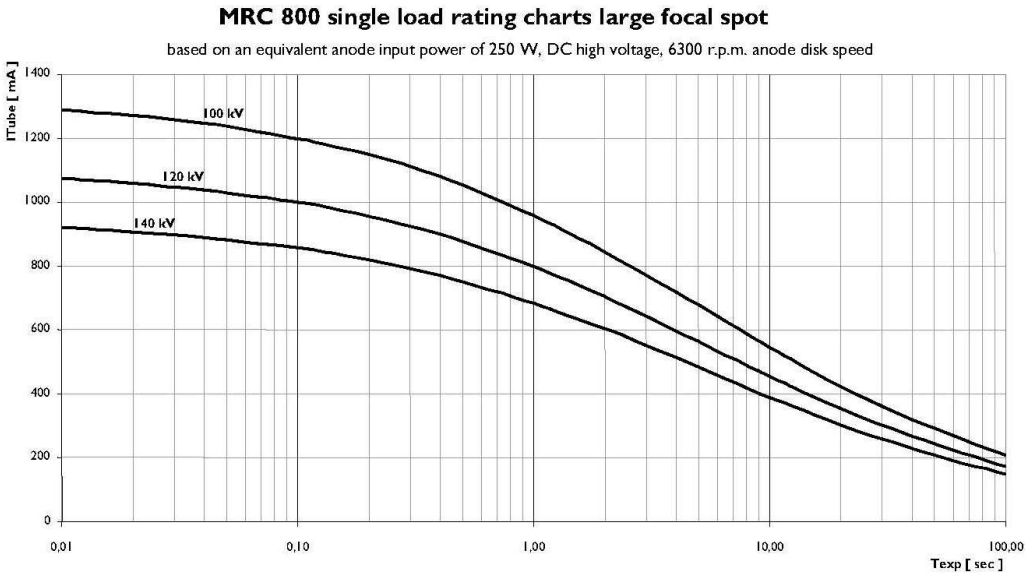


459801063624_F/728 * MAR 2020

Tube Power Ratings - Brilliance CT



The max. input power is limited at 60 kW due to the HVPS CRX 500 (Spellman).



User Dose & Imaging Information

The scanner is designed for scanning the head and the body. Therefore, dose and image quality information are provided separately for head and body scans according to the Code of Federal Regulations (21 CFR).

459801063624_F/728 * MAR 2020

NOTICE

This information is provided as required by the US DHHS, pursuant to 21CFR, Chapter 1, Subchapter J, paragraph 1020.30 and 1020.33.

Phantoms & Measurement Methods

Dose Phantoms

The CT Dosimetry Phantom is the phantom used for determining the dose delivered by a CT X-ray system. The phantoms are right circular cylinders of polymethyl methacrylate, at least 14 cm long. Their density is 1.19 ± 0.01 grams/cc. The phantom for testing CT imaging of the body has a diameter of 32 cm, and the phantom for the head has a diameter of 16 cm.

The phantom provides means for the placement of dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation, 1.0 cm from the outer surface and within the phantom.

Dose Profiles & Dose Measurements

The dose profiles were measured using an X-ray sensitive, film-type media. Actual dose values were measured with a 10 cm long, pencil-shaped ionization chamber.

CTDI Definition

Computed Tomography Dose Index (CTDI) is the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomography section thickness and the number of tomograms produced in a single scan, as follows:

$$CTDI_{100} = \frac{1}{nT}\int_{-50mm}^{+50mm} D(z)dz$$

with these definitions:

- D(z) = Dose to Air ($CTDI_{100}$) at position z
- T = Nominal tomographic section thickness
- n = Number of tomograms produced in a single scan

The CTDI definition assumes that, for a multiple tomogram system, the scan increment between adjacent slices is nT.

The $CTDI_w$ is computed from $CTDI_{100}$ as follows:

$CTDI_w = [1/3\ CTDI_{100\ (center)} + 2/3\ CTDI_{100\ (periphery)}]$

OR

$CTDI_w = 1/3[CTDI_{100\ (center)} + 2\ CTDI_{100\ (periphery)}]$

459801063624_F/728 * MAR 2020

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The volume CTDI ($CTDI_{vol}$) describes the average dose over the total volume scanned for the selected CT conditions of operation. The $CTDI_{vol}$ is defined as follows:

- for axial scanning

$$CTDI_{vol} = \frac{N \cdot T}{\Delta d} CTDI_w$$

  with these definitions:
  - N = the number of tomographic sections produced in a single axial scan of the X-ray source
  - T = the nominal tomographic thickness
  - Δd = the patient support travel in z-direction between consecutive scans.
- for helical scanning

$$CTDI_{vol} = \frac{CTDI_w}{CT_{pitch\ factor}}$$

- for scanning without movement of the patient support

  $CTDI_{vol}$ = n x $CTDI_w$
  - n = the maximum number of pre-programmed rotations

  The value for $CTDI_{vol}$ is expressed in milligrays (mGy).

Image Noise - System Performance Phantom

There are two sections of the system phantom used for noise measurement:

- The Head phantom is 200 mm outer diameter, water-filled (phantom-liquid filled) with a PVC shell (8 mm wall thickness).
  - The CT number of water (phantom liquid) is 0 ± 4.
  - The CT number of PVC shell is +1200 ± 200.
- The body phantom is 300 mm outer diameter and made of Nylon (Aculon).
- The CT number is 102 ± 18.

Noise is measured using these ROIs:

- 5024 ± 500 mm^2 area for head section.
- 11300 ± 1000 mm^2 area for body section.

NOTICE

See the ROI information in the Graphics section of the Instructions for Use.

459801063624_F/728 * MAR 2020

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The SD as displayed on the screen is divided by [average CT number + 1000] and multiplied by 100 to obtain the percent noise.

The maximum deviation from the stated noise is 10%.

Image Noise - System Performance Harmonized Phantom

There are two sections of the system phantom used for noise measurement:

- The Head phantom is 187 mm in diameter, water-filled (phantom-liquid filled) with an acrylic shell (8 mm wall thickness).
  - The CT number of water (phantom liquid) is 0 ± 4 HU.
- The body phantom is 284 mm in diameter, water-filled (phantom-liquid filled) with an acrylic shell (8 mm) wall thickness.
- The CT number is 0 ± 6 HU.

Noise is measured using these ROIs:

- 5024 ± 500 mm^2 area for head section.
- 11300 ± 1000 mm^2 area for body section.

NOTICE

See the ROI information in the Graphics section of the Instructions for Use.

The SD as displayed on the screen is divided by [average CT number + 1000] and multiplied by 100 to obtain the percent noise.

The maximum deviation from the stated noise is 10%.

Modulation Transfer Function

The impulse response and the tomographic thickness (slice thickness) are not dependent upon the phantom dimensions. They are therefore, measured on the physics layer of the system phantom (see chapter “Quality Assurance” on page 57).

The phantom physics layer diameter is 200 mm (184 mm diameter of water [phantom liquid] in a 8 mm PVC shell).

The impulse response and associated MTF curve is measured on a 0.2 mm copper wire using the **Impulse QA** head or body exam card and the **Resolution Test** Image Tests program (in the Analysis options, accessible from the Directory window).

The maximum deviation of the MTF curve is 15%.

Tomographic Thickness Measurement

The phantom contains two aluminum strips at 45° which give projections of the sensitivity profile in the image plane.

459801063624_F/728 * MAR 2020

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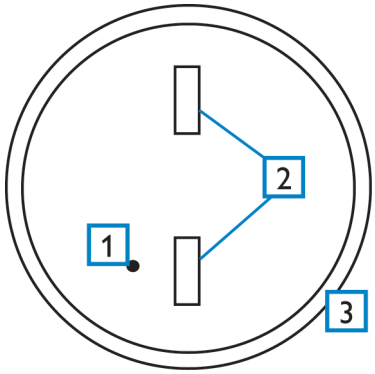

1. 0.2 mm copper wire for impulse response measurement
2. aluminum strips embedded at 45 degrees
3. PVC shell

The profiles of the projections are equivalent to the sensitivity profiles and the FWHM (full width at half maximum) of the profile is the nominal tomographic thickness.

The profile can be measured using the **Slice Thickness** Image Tests program (in the Analysis options, accessible from the Directory window).

The maximum deviation of the derived thickness should be as follows:

Thickness≥ 2 mm	± 1 mm
Thickness >1 to <2 mm	± 50%
Thickness < 1 mm	± 0.5 mm

NOTICE

The 0.625 mm and 1.25 mm results appear wider due to the limited resolution of the image and the thickness of the measuring ramp.

Display CTDI Phantom Size

The 16 cm diameter CTDI phantom is used for head scans. The 32 cm diameter CTDI phantom is used for body scans.

The $CTDI_{vol}$ for Infant Body is reported with the 32 cm diameter phantom placed in the center of the Gantry opening, on the patient table. To approximate the comparable dose index with a 16 cm diameter phantom, multiply the posted $CTDI_{vol}$ by 2.

The phantom size used for reporting $CTDI_{vol}$ or DLP displays in the Main Parameters.

The phantom size is also listed on the Dose information page displayed after the end of the study.

System Imaging Geometric Accuracy

The system imaging geometric accuracy is better than ±1 mm in the gantry plane across 50 mm and is better than ±5 mm at 500 mm in both X and Y directions.

459801063624_F/728 * MAR 2020
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Head-scan Information

Head dose - typical head CT scan conditions of operation:

Main	
FOV	250
Storage	Local

Scan	
Collimation	32 x 1.25
Thickness	5
Increment	0
Rot Time	0.75
Voltage	120
mAs	250

Recon	
Filter	UB
SP Filter	No

459801063624_F/728 * MAR 2020

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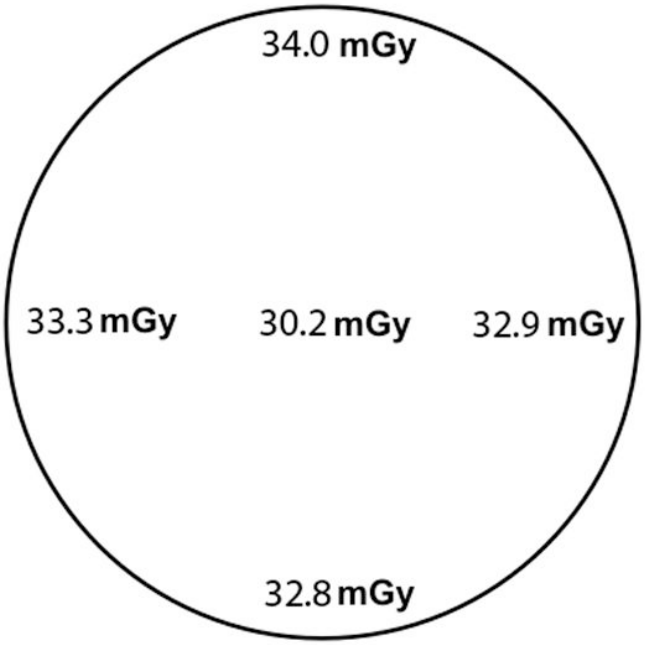
CTDI100 Head



The maximum dose is delivered at the 12 o'clock position.
The 16 cm diameter phantom is placed in the center of the Gantry opening, on the head holder.
Maximum deviation from the values shown below is ±25%. $CTDI_{VOL}$ = 32.3 mGy.
The $CTDI_{100}$ is not dependent on the scan diameter.
The maximum deviation from the reported $CTDI_{vol}$ for 2 x 0.625 and 2 x 0.5 is ±30%.

Tube Current - Exposure Time Product (mAs) Dependence

The dose increases linearly with the tube current - exposure time product. The $CTDI_{100}$ in the center location of the head phantom, normalized to the $CTDI_{100}$ in the center location from the values shown in the $CTDI_{100}$ Head section, depends on the mAs for the minimum, maximum, and mid-range values as shown by the ratios below. The maximum deviations of these ratios are also provided.

	$CTDI_{100}$	
Minimum $CTDI_{100}$ (at 15.0 mAs)	0.06 ± 20%	...times the $CTDI_{100}$ at 250 mAs
Mid-range $CTDI_{100}$ (at 495 mAs)	1.98 ± 20%	...times the $CTDI_{100}$ at 250 mAs
Maximum $CTDI_{100}$ (at 1100 mAs)	4.40 ± 20%	...times the $CTDI_{100}$ at 250 mAs

Collimation Setting Dependence

Several collimation settings are available. The $CTDI_{100}$ in the center of the head phantom depends on the collimation setting, as shown below.

	$CTDI_{100}$	
The $CTDI_{100}$ of the 16 x 2.5 mm collimation is...	1.00 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 64 x 0.625 mm collimation is...	1.00 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.

459801063624_F/728 * MAR 2020

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	$CTDI_{100}$	
The $CTDI_{100}$ of the 40 x 0.625 mm collimation is...	1.04 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 16 x 0.625 mm collimation is...	1.23 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 12 x 1.25 mm collimation is...	1.13 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 12 x 0.625 mm collimation is...	1.33 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 20 x 0.625 mm (UHR) collimation is...	1.17 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 2 x 0.5 mm (UHR) collimation is...	2.42 ± 20%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 2 x 0.625 mm (HR) collimation is...	1.93 ± 20%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.

Voltage Dependence - Center

The X-ray voltage can be varied between 80 and 140 kV. The $CTDI_{100}$ in the center of the head phantom depends on the X-ray voltage as shown below.

	$CTDI_{100}$	
With 80 kV, the $CTDI_{100}$ is...	0.29 ± 15%	... of the $CTDI_{100}$ at 120 kV
With 100 kV, the $CTDI_{100}$ is...	0.61 ± 15%	... of the $CTDI_{100}$ at 120 kV
With 140 kV, the $CTDI_{100}$ is...	1.47 ± 15%	... of the $CTDI_{100}$ at 120 kV

Voltage Dependence - Edge

The $CTDI_{100}$ at the peripheral or edge dose position in the head phantom depends on the X-ray voltage as shown below:

	$CTDI_{100}$	
With 80 kV, the $CTDI_{100}$ is...	0.31 ± 15%	... of the $CTDI_{100}$ at 120 kV
With 100 kV, the $CTDI_{100}$ is...	0.61 ± 15%	... of the $CTDI_{100}$ at 120 kV
With 140 kV, the $CTDI_{100}$ is...	1.45 ± 15%	... of the $CTDI_{100}$ at 120 kV

Dose and Sensitivity Profiles - Head Scan

The dose profiles at the center of the phantom superimposed on the sensitivity profiles are presented in the following sections. The maximum deviations from the drawn curves are ±20%.

459801063624_F/728 * MAR 2020

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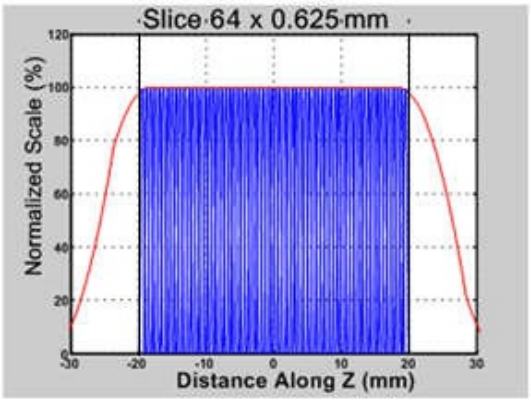
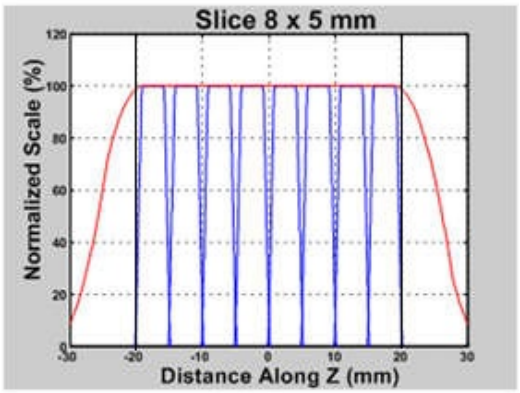
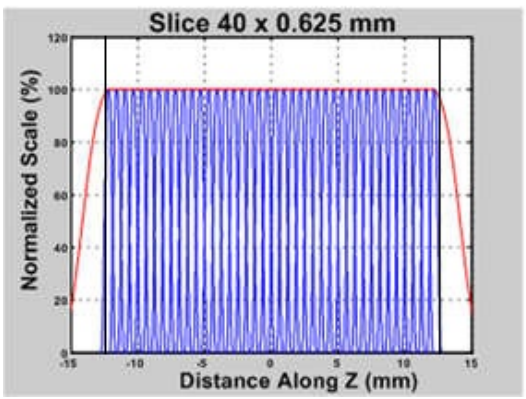
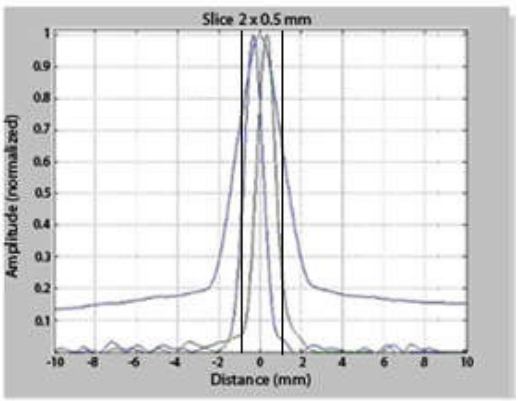
NOTICE

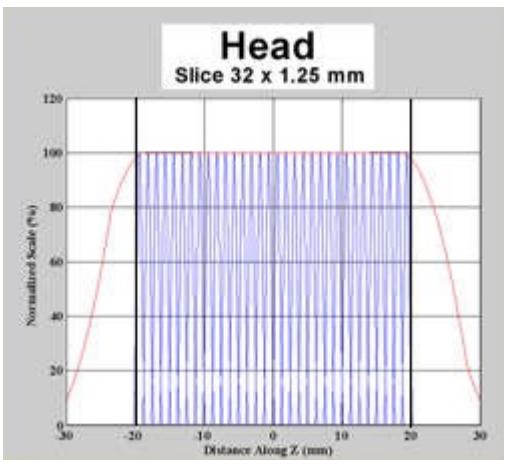
The sensitivity profiles were simulated under the typical conditions of operation presented in the Head Scan Information section, while changing the slice thickness only. The limited resolution of the image causes the thin slice thicknesses to appear thicker than they really are.











459801063624_F/728 * MAR 2020

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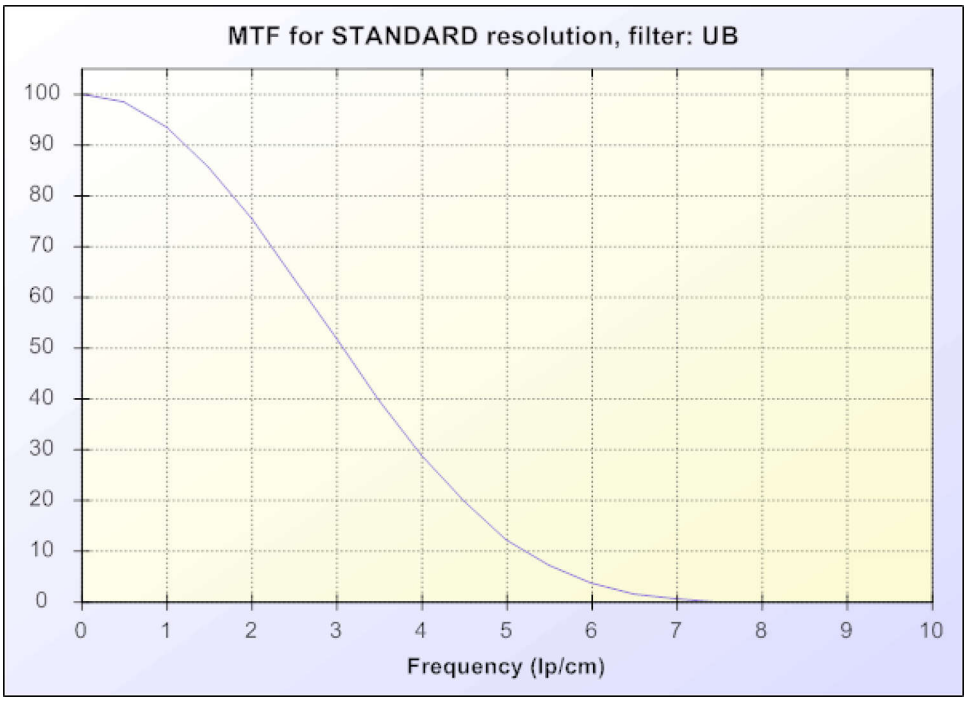
Image Quality - Head

The mean noise on a 200 mm diameter system phantom is 0.41% ± 0.06 (32 x 1.25 mm scan mode, 120 kV, 250 mAs, 5 mm thickness, 0.75 sec rotation time, STD resolution, filter = UB).

The phantom and measurement method are described earlier (See chapter “Image Noise - System Performance Phantom” on page 87 and chapter “Modulation Transfer Function” on page 88).



The maximum deviation of the MTF curve is ±15%.

These are the nominal tomographic section thicknesses:

- 0.5 mm ± 0.5 mm
- 0.625 mm ± 0.5 mm
- 1.25 mm ± 0.625 mm
- 2.5 mm ± 1.0 mm
- 5 mm ± 1.0 mm
- 10 mm ± 1.0 mm

The sensitivity profiles are drawn in Dose and Sensitivity Profiles - Head Scan.

CT Number Uniformity

The system CT Number uniformity is 0 ± 8 Hounsfield Units for Head scans on a system phantom.

459801063624_F/728 * MAR 2020

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CT Number Accuracy

The CT number accuracy for water as measured on the system phantom is typically in the following range:

Phantom Type	Phantom Area	Hounsfield Units Accuracy			
		80kVp	100kVp	120kVp	140kVp
Adult	Head	±6 HU	±4 HU	±4 HU	±6 HU
Infant	Head	±4 HU	±4 HU	±4 HU	--

Body-scan Information

Body dose - typical body CT scan conditions of operation:

Main	
FOV	350
Storage	Local

Scan	
Collimation	32 x 1.25
Rot Time	0.75
Voltage	120
mAs	250

Recon	
Filter	B
Thickness	5
Increment	0

459801063624_F/728 * MAR 2020

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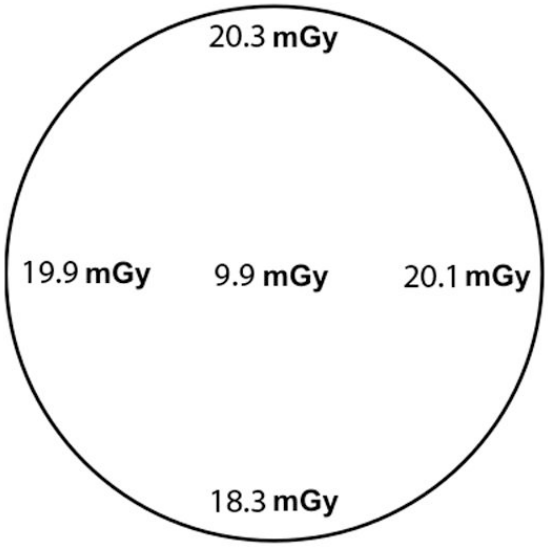
CTDI100 Body



The maximum dose is delivered at the 12 o'clock position.

The 32 cm diameter phantom is placed in the center of the Gantry opening on the table with one of the dosimeters at the maximum dose position.

Maximum deviation from the values shown below is ±25%. $CTDI_{VOL}$ = 16.4 mGy.

The $CTDI_{100}$ is not dependent on the scan diameter.

The maximum deviation from the reported $CTDI_{Vol}$ for 2 x 0.625 and 2 x 0.5 is ±30%.

Tube Current - Exposure Time Product (mAs) Dependence

The dose increases linearly with the tube current - exposure time product. The $CTDI_{100}$ in the center of the body phantom depends on the mAs, as shown below.

	$CTDI_{100}$	
Minimum $CTDI_{100}$ (at 15.0 mAs)	0.06 ± 20%	...times the $CTDI_{100}$ at 250 mAs
Mid-range $CTDI_{100}$ (at 600 mAs)	2.40 ± 20%	...times the $CTDI_{100}$ at 250 mAs
Maximum $CTDI_{100}$ (at 1200 mAs)	4.80 ± 20%	...times the $CTDI_{100}$ at 250 mAs

Collimation Setting Dependence

Several collimation settings are available. The $CTDI_{100}$ in the center of the body phantom depends on the collimation setting, as shown below.

	$CTDI_{100}$	
The $CTDI_{100}$ of the 16 x 2.5 mm collimation is...	1.00 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 64 x 0.625 mm collimation is...	1.00 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 40 x 0.625 mm collimation is...	1.04 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 16 x 0.625 mm collimation is...	1.23 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.

459801063624_F/728 * MAR 2020

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	$CTDI_{100}$	
The $CTDI_{100}$ of the 12 x 1.25 mm collimation is...	1.13 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 12 x 0.625 mm collimation is...	1.33 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 20 x 0.625 mm (UHR) collimation is...	1.17 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 2 x 0.5 mm (UHR) collimation is...	2.25 ± 20%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 2 x 0.625 mm (HR) collimation is...	1.79 ± 20%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.

Voltage Dependence - Center

The X-ray voltage may be varied between 80 and 140 kV. The $CTDI_{100}$ in the center of the body phantom depends on the X-ray voltage as shown below.

	$CTDI_{100}$	
With 80 kV, the $CTDI_{100}$ is...	0.25 ± 15%	... of the $CTDI_{100}$ at 120 kV
With 100 kV, the $CTDI_{100}$ is...	0.57 ± 15%	... of the $CTDI_{100}$ at 120 kV
With 140 kV, the $CTDI_{100}$ is...	1.53 ± 15%	... of the $CTDI_{100}$ at 120 kV

Voltage Dependence - Edge

The $CTDI_{100}$ at the peripheral or edge dose position in the body phantom depends on the X-ray voltage as shown below.

	$CTDI_{100}$	
With 80 kV, the $CTDI_{100}$ is...	0.30 ± 15%	... of the $CTDI_{100}$ at 120 kV
With 100 kV, the $CTDI_{100}$ is...	0.61 ± 15%	... of the $CTDI_{100}$ at 120 kV
With 140 kV, the $CTDI_{100}$ is...	1.47 ± 15%	... of the $CTDI_{100}$ at 120 kV

Dose and Sensitivity Profiles - Body Scan

The dose profiles at the center of the phantom superimposed on the sensitivity profiles are presented on the next page. The maximum deviations from the drawn curves are ±20%.

459801063624_F/728 * MAR 2020

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NOTICE

The sensitivity profiles were simulated under the typical conditions of operation presented in the Body Scan Information section, while changing the slice thickness only. The limited resolution of the image causes the thin slice thicknesses to appear thicker than they really are.

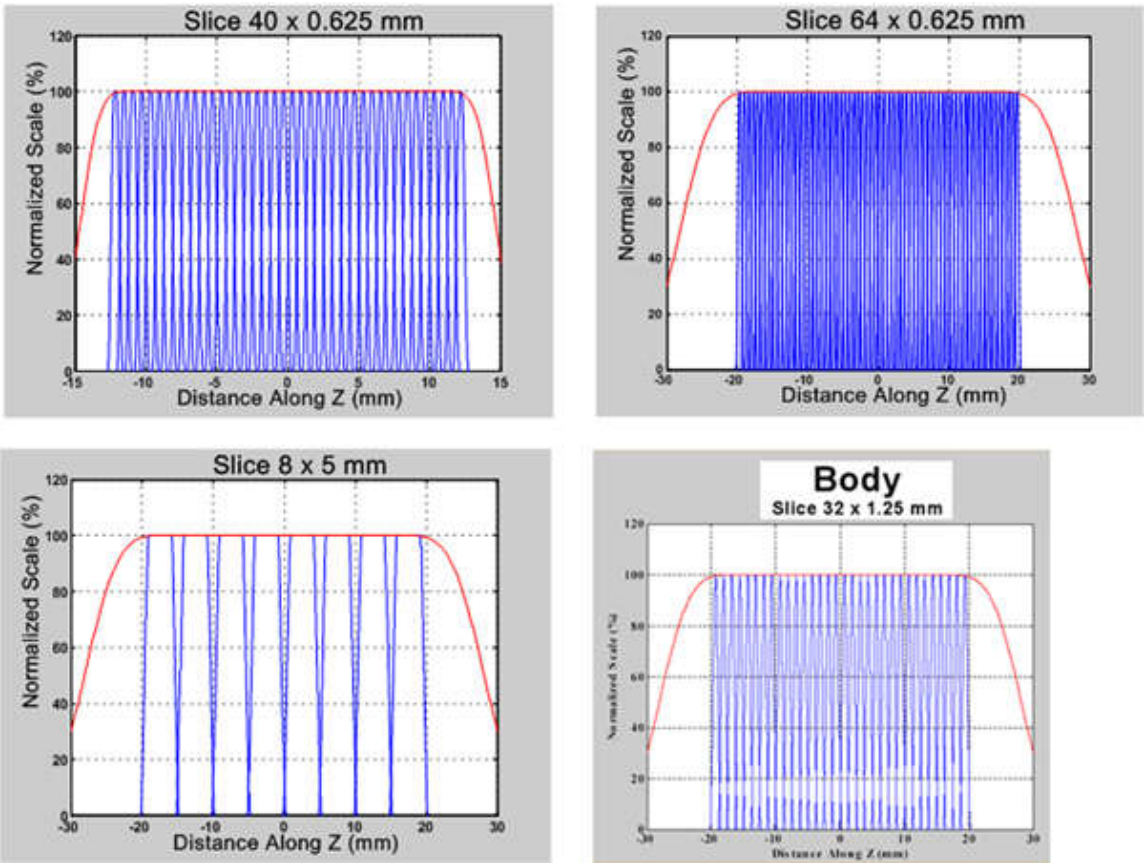
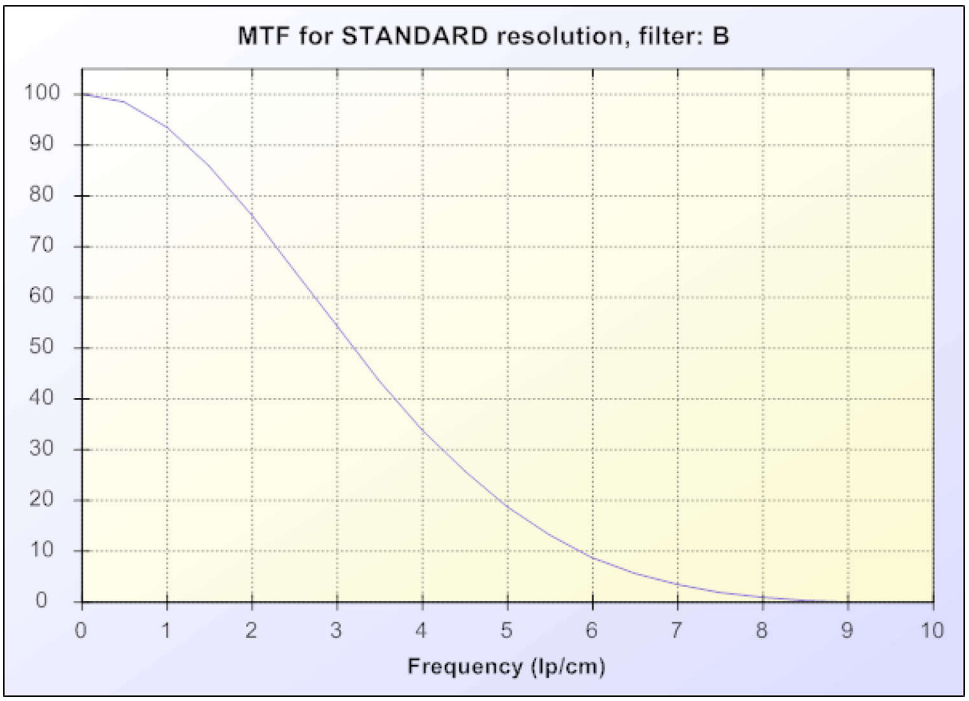


Image Quality - Body

The mean noise on a 300 mm diameter system phantom is 1.35% ± 0.16 (32 x 1.25 mm scan mode, 120 kV, 250 mAs, 5 mm thickness, 0.75 sec rotation time, STD resolution, filter = B).

The phantom and measurement method are described earlier (See chapter “Image Noise - System Performance Phantom” on page 87 and chapter “Modulation Transfer Function” on page 88).

459801063624_F/728 * MAR 2020



The maximum deviation of the MTF curve is ±15%.

These are the nominal tomographic section thicknesses:

- 0.5 mm ± 0.5 mm
- 0.625 mm ± 0.5 mm
- 1.25 mm ± 0.625 mm
- 2.5 mm ± 1.0 mm
- 5 mm ± 1.0 mm
- 10 mm ± 1.0 mm

The sensitivity profiles are drawn in Dose and Sensitivity Profiles - Head Scan.

CT Number Uniformity

The system CT Number uniformity is 0 ± 8 Hounsfield Units for Body scans on a 30-cm water phantom.

CT Number Accuracy

The CT number accuracy for water as measured on the system phantom is typically in the following range:

Phantom Type	Phantom Area	Hounsfield Units Accuracy			
		80kVp	100kVp	120kVp	140kVp
Adult	Body	-4 to 10	-2.5 to 5.5	-1.5 to 6.5	0 to 8
Infant	Body	±4 HU	±4 HU	±4 HU	--

459801063624_F/728 * MAR 2020

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CTDI Free Air

The CTDI Free Air can be found in the following tables. The conditions of operation for Body scans, unless specified in the table, are QA Axial Body 2D, Standard Resolution, 64x0.625, 0.75 seconds, 120 kVp, 200 mAs, 2.5 mm SW.

CTDI Free Air for Body Conditions of Operation

kVp\NxT	4x0.625	8x0.625	16x0.625	12x1.25	40x0.625	64x0.625
80	--	--	--	--	--	10.9 mGy
100	--	--	--	--	--	20.7 mGy
120	58.2 mGy	44.5 mGy	41.1 mGy	37.7 mGy	34.7 mGy	33.5 mGy
140	--	--	--	--	--	48.5 mGy

CTDI Free Air for Other Conditions of Operation

Scan mode	CTDI free air
Adult Head, 64x0.625, 120 kVp, 450 mAs, 2.5 mm SW	75.4 mGy

The maximum deviation from the values shown is ±25%.

If either the Head or Body scans at 64x0.625 collimation and 120 kVp is measured repeatedly, each value should be within ±10% of the mean of a set of 10 measurements.

Conditions to Achieve 1000 mGy CTDIvol (Peripheral)

It is impossible to achieve 1000 mGy in a single axial scan on the Brilliance CT 64-channel. Helical scans cannot achieve 1000 mGy to the same position on the patient, as the table is continuously moving during the scan. It is possible to see 1000 mGy for repeated axial scans in the same location, such as interventional scans or perfusion scans, so those types of scans will be the focus here. Typically, these types of scans are done far below the maximum mAs settings at each kVp.

Adult Head

The maximum peripheral CTDI is seen at the 12:00 o'clock peripheral position. Using the maximum limits on tube mAs for each type of axial scan, the maximum peripheral CTDI which can be achieved for Head Mode can be summarized as follows. If the mAs is lower than the maximum listed here, the number of rotations to exceed 1000 mGy will be increased proportionally.

459801063624_F/728 * MAR 2020

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Head/Brain Perfusion Non-Jog

kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
100	64x0.625	0.75 sec	375	31.1 mGy	33
80	64x0.625	0.75 sec	375	15.8 mGy	64

Brain Axial 2D

This scan is typically done with 10 mm scan increment, but can be manually set to 0 mm scan increment, which will scan the same location repeatedly. This scan can be performed at 420 degree scan, which can increase the mAs even further. If so, then the following maximum 12:00-o'clock-position CTDI values can be achieved.

kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	16x0.625	1.0 sec	580	97.0 mGy	11
140	16x0.625	1.0 sec	465	112.8 mGy	9
100	16x0.625	1.0 sec	580	59.2 mGy	17
80	16x0.625	1.0 sec	580	30.1 mGy	34

Head Axial

Similar to the Brain Axial, this scan is typically done with 10 mm scan increment, but can be manually set to 0 mm scan increment, which will scan the same location repeatedly. This scan can be performed at 420 degree scan, which can increase the mAs even further. If so, then the following maximum 12:00-o'clock-position CTDI values can be achieved. This scan can be done with 1.5 second rotation time, which increases the CTDI per scan.

kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	16x0.625	1.5 sec	875	146.4 mGy	7
140	16x0.625	1.5 sec	700	169.8 mGy	6
100	16x0.625	1.5 sec	875	89.3 mGy	12
80	16x0.625	1.5 sec	875	45.4 mGy	23

Head/Sinus Limited HR

This scan is typically done with 10-15 mm scan increment, but can be manually set to 0 mm scan increment, which will scan the same location repeatedly. This scan can also be performed at 420 degree scan, which can increase the mAs even further. If so, then the following maximum 12:00-o'clock-position CTDI values can be achieved.

459801063624_F/728 * MAR 2020

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kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	2x0.625	0.5 sec	290	70.6 mGy	15
140	2x0.625	0.5 sec	230	81.2 mGy	13
100	2x0.625	0.5 sec	290	43.1 mGy	24
80	2x0.625	0.5 sec	290	21.9 mGy	46

Adult Body Mode

The maximum peripheral CTDI is seen at the 12:00 o'clock peripheral position. Using the maximum limits on tube mAs for each type of axial scan, the maximum peripheral CTDI which can be achieved for Adult Body mode can be summarized as follows. If the mAs is lower than the maximum listed here, the number of rotations to exceed 1000 mGy will be increased proportionally.

Abdomen/Body Perfusion Axial

kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	64x0.625	0.75 sec	375	30.5 mGy	33
100	64x0.625	0.75 sec	375	18.6 mGy	54
80	64x0.625	0.75 sec	375	9.1 mGy	110

Thorax/High Resolution Axial

This scan is typically done with 10-15 mm scan increment, but can be manually set to 0 mm scan increment, which will scan the same location repeatedly. If so, then the following maximum 12:00-o'clock-position CTDI values can be achieved.

kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	2x0.625	1.0 sec	500	72.7 mGy	14
140	2x0.625	1.0 sec	400	85.5 mGy	12
100	2x0.625	1.0 sec	500	44.3 mGy	23
80	2x0.625	1.0 sec	500	21.8 mGy	46

CCT Mode - Interventional/CCT Single or CCT Continuous

It is possible to achieve high CTDI with CCT modes. Both CCT Single and CCT Continuous use 240 degree reconstruction, which reduces the maximum mAs value. Utilizing similar limits as above, and choosing the collimation which gives this highest peripheral CTDI, results in the following table:

459801063624_F/728 * MAR 2020

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kVp	Scan Coverage	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	2.5 mm	4x0.625	0.75 sec	250	35.3 mGy	29
100	2.5 mm	4x0.625	0.75 sec	250	21.5 mGy	47
80	2.5 mm	4x0.625	0.75 sec	250	10.6 mGy	95

Interventional/CCT Fluoro

CCT Fluoro is a continuous scan mode, and displays CTDI rate in mGy per second (mGy/s). CCT Fluoro uses 240 degree reconstruction, which reduces the maximum mAs value. However, faster rotation times at the same mAs can yield higher CTDI rates. Utilizing similar limits as above, and choosing the collimation which gives this highest peripheral CTDI, results in the table below. Note that the default CCT Fluoro scan is limited to 30 seconds, but it is possible to extend or repeat the scan.

kVp	Scan Coverage	Collimation	Rotation Time	mAs	CTDI rate (12:00 o'clock position)	Number of scan seconds to exceed 1000 mGy
120	2.5 mm	4x0.625	0.4 sec	100	67.3 mGy/s	15
100	2.5 mm	4x0.625	0.4 sec	105	43.1 mGy/s	24
80	2.5 mm	4x0.625	0.4 sec	105	21.2 mGy/s	48

459801063624_F/728 * MAR 2020

Size Specific Dose Estimate (SSDE)

The $CTDI_{vol}$ provided by the scanner is a measure of the absorbed dose, expressed in units of mGy, to either a 32 cm or 16 cm diameter acrylic phantom over the volume scanned with a specific Exam Card. The $CTDI_{vol}$ for a selected Exam Card, therefore, does not represent the absorbed dose to a patient. For infants, the $CTDI_{vol}$ underestimates the absorbed dose to the scan volume by up to a factor of 3. Conversely, the $CTDI_{vol}$ for large patients overestimates absorbed dose to the scan volume; for very large patients $CTDI_{vol}$ can overestimate absorbed dose by as much as 40%.

Through a series of experiments and models, the American Association of Physicists in Medicine devised conversion factors from $CTDI_{vol}$ to a new dose metric, Size Specific Dose Estimate (SSDE) also expressed in units of mGy. The appropriate SSDE conversion factor for a given patient depends on the attenuation of the patient and the top of the couch in the scanned area. The SSDE is the product of this patient attenuation-specific conversion factor and the $CTDI_{vol}$ for the selected Exam Card. For infant head and body scans, the conversion factors are typically larger than 1 because infant heads and bodies are smaller than the 16 cm and 32 cm phantom, respectively, used to calculate $CTDI_{vol}$ for the Exam Card; for these patients, SSDE values are high-

er than $CTDI_{vol}$ values. For adult body scans the conversion factor is typically smaller than 1, since patients are usually larger than the 32 cm phantom used to calculate $CTDI_{vol}$; for these patients, SSDE values are lower than $CTDI_{vol}$ values. For adult head scans, the conversion factors are usually closer to 1 such that SSDE and $CTDI_{vol}$ values are similar.

SSDE provides a better estimate of the average absorbed dose to the patient by taking into account both the radiation output of the CT scanner and the patient's size. Although SSDE is intended to describe dose for patients of all sizes, better estimates of dose are especially important for small pediatric patients since the actual absorbed dose to the patient is higher than indicated by the $CTDI_{vol}$ for a given Exam Card and because radiation exposure is of greatest concern in infants and children.

The IEC is formalizing the calculation of SSDE into a new standard so that all vendors can define and provide this new metric in the same way. When a Surview is performed and DoseRight is enabled, the scanner calculates a Water Equivalent Diameter (WED) for the patient, that is, the diameter of a water equivalent cylinder with the same X-ray attenuation as the patient and the couch top, over the entire Surview. This value is displayed as Patient Size with units of cm on the Surview image. When a shorter scan range is selected for the clinical scan, the Patient Size is still displayed but the scanner also calculates an Average Scan Size in cm, representing the average WED within the scan region only. Average Scan Size is the patient metric used to determine the appropriate conversion factor for SSDE calculation. If DoseRight is not enabled, only Average Scan Size is displayed.

Before each clinical scan, the scanner displays an estimated Average Scan Size and SSDE based on the planned scan region and the planned x-ray output. After a clinical scan, the scanner recalculates Average Scan Size and SSDE based on the actual scan region and the actual x-ray output (estimated and actual values are usually the same). Updated values for Average Scan Size and SSDE are included in the preview display. Final values for all scans are also tabulated in the dose report, compiled at the completion of the exam.

General limitations of the Size Specific Dose Estimate (SSDE) methodology

It is important to recognize that SSDE is still an estimate of the absorbed dose to the scan volume even though it takes into account patient attenuation in the scanned region. The accuracy of this estimate, compared to the actual absorbed dose to the scan volume, is approximately ±20%.

459801063624_F/728 * MAR 2020

Limitations of SSDE in special clinical scenarios

Neck included in scanned anatomy

Additional uncertainty in SSDE of approximately 10% is expected for scans of the head and neck when the scan length in the head and neck region are approximately equal. This is because conversion factors for the head are applied to the entire scan length even though they are not as appropriate for the neck.

Single or bilateral extremities are scanned

In the case of bilateral lower extremity scans or bilateral upper extremity scans where the arms are above the head, patient size estimates from the surview image can be less accurate. This can have a minor impact on the SSDE but any additional uncertainty in the estimate is not expected to exceed 5%.

Patient is not positioned at the center of rotation along the source/detector direction

When patients are not properly centered, patient size estimates from the surview image can be less accurate. Any additional uncertainty in the estimate of SSDE is not expected to exceed 5%.

Patient anatomy outside the scan field of view

Patient anatomy outside the scan FOV will result an underestimation of patient size from the surview and an overestimation of SSDE. However, at large patient sizes, the conversion factors vary slowly with changes in patient size. Except for morbidly obese patients, any additional uncertainty in the estimate of SSDE is not expected to exceed 5%.

Foreign Objects in the Scan Field

When foreign objects (e.g., metal implants, radiation therapy planning hardware, life support devices, bismuth shields) are in the scan FOV, patient size estimates from the surview image can be less accurate. The magnitude of uncertainty in estimation of patient size will depend on the physical size of the foreign object and the attenuation of that material relative to bone and soft tissue. This may result in overestimation of patient size and an underestimation of SSDE causing additional uncertainty in the SSDE that may exceed 5%.

Essential Performance for Interventional Imaging

Image Spatial Accuracy

Spatial Accuracy – XY	+/- 1 mm over a distance of 50 mm in plane
Spatial Accuracy - Z	+/- 1 mm over 300 mm of bed travel

Slice Thickness

The system achieves the following slice thicknesses while scanning with Head Scan Type using 120 kVp, at least 200 mAs, field of view of 250 mm, and 768x768 matrix size:

459801063624_F/728 * MAR 2020

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- For a requested slice thickness of 0.625 mm the measured slice thickness is between 0.6 mm and 1.6 mm using High resolution.
- For a requested slice thickness of 1.25 mm the measured slice thickness is between 0.75 mm and 2.25 mm using Standard resolution.

Low Contrast

The system provides a scanning mode that achieves Low Contrast Resolution so that a 4-mm diameter pin, that is 3-HU different than its background, is distinguishable on the image.

Noise

The system achieves a percent noise of no more than 0.45%, when irradiating with no more than 50 mGy $CTDI_{vol}$.

High Contrast Spatial Resolution

When scanning in Standard Resolution, the system achieves at least 10 lp/cm (measured at 0% MTF) in plane resolution (x-y) within a radius of 100 mm from the iso-center and in the central two slices.

Dose Management

The system computes the accumulated $CTDI_{vol}$ and DLP values for all planned Acquisitions at each anatomic position throughout the exam. If the cumulative $CTDI_{vol}$ or DLP at any anatomic position is expected to exceed the alert value when the next scan is performed, the Dose Alert pop-up message will be displayed. Dose Alerts are associated with complete studies, not individual Acquisitions, and are enabled in Preferences >Dose Management. Use the factory default values or enter values instituted for your site.

Default $CTDI_{vol}$ values have been set at 1000mGy, which is consistent with values suggested by government regulators such as the FDA.

No DLP values are included in the factory settings.

An alert warrants more stringent review before proceeding than a notification and requires a higher level of action by the user. The FDA has suggested an alert value for $CTDI_{vol}$ of 1000 mGy, which would deliver approximately half the dose associated with the onset of skin injury.

NOTICE

For IEC60601-2-44:2016 Compliance the DOSE ALERT Value shall not be set greater than 2000 mGy. $CTDI_{vol}$ values at or above this limit can cause injury to the patient.

459801063624_F/728 * MAR 2020

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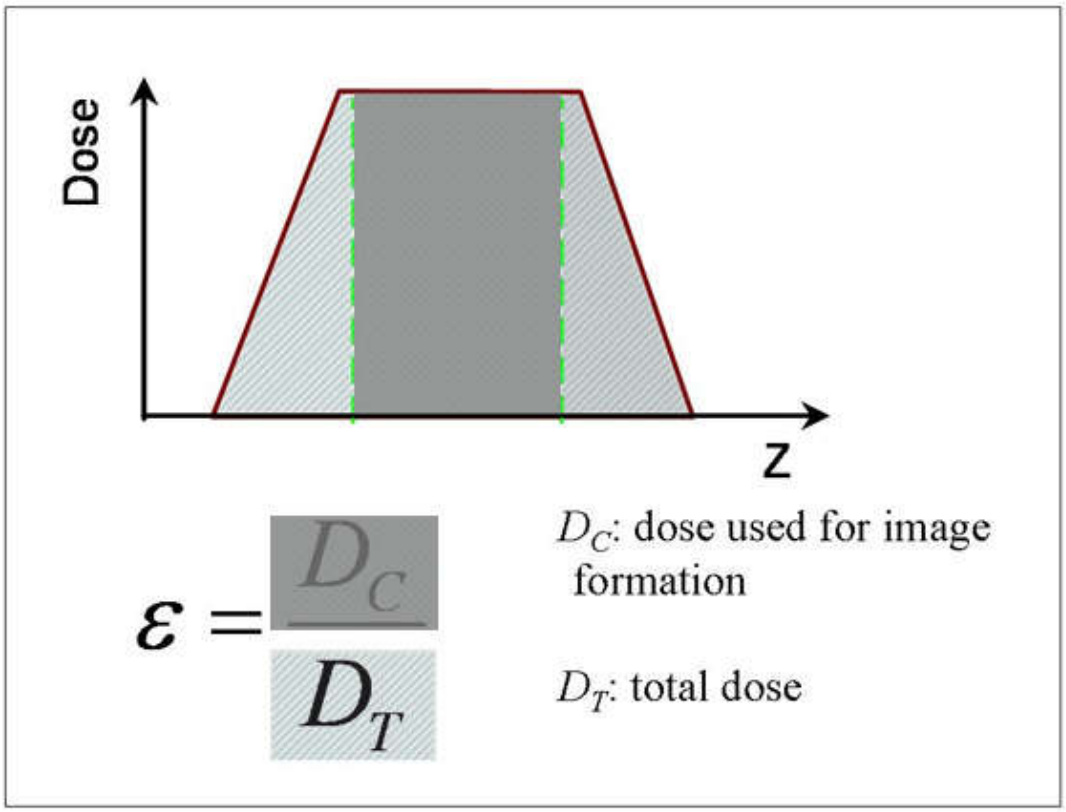
Geometric Efficiency Measurements

The Geometric Efficiency in the Z-Direction is one measure of how efficiently the radiation exposed to the patient is utilized by a scanner. It characterizes the ratio of the radiation that is used to generate images to the total radiation to which the patient is exposed. The Geometric Efficiency in the Z-Direction is expressed as the area of the dose profile in the Z direction subtended by the detector elements used for image generation to the area of the entire dose profile produced at that collimation. This is shown below in an illustrative diagram. The green line denotes the width of the radiation that is used for image generation.



The Geometric efficiencies listed here are established according to the techniques listed in the IEC 60601-2-44 standard, Edition 3.0 (2009) Section 203.113. The dose profiles used to establish these efficiencies were measured using GafChromic XRQA2 radiochromic film. The films were digitized using a color flatbed scanner and the profile is extracted from the scan.

The factors that influence Geometric Efficiency in Z-Direction are Collimation Setting, and focal spot size and position. The table below lists the system parameters that influence these factors and the corresponding Geometric Efficiency in Z-Direction for those parameters.

NOTICE

The software displays a notification when the efficiency is lower than 70%.

459801063624_F/728 * MAR 2020

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The scan protocol is as follows: QA Axial Head 2D, variable collimation, 0.75 seconds rot speed, 120 kV, 300 mAs, variable resolution.

Resolution	Collimation	Nominal Beam Width	Efficiency
STD	64 X 0.625 mm	40	91.5
STD	40 X 0.625 mm	25	87.3
STD	32 X 1.25 mm	40	92.2
STD	16 X 0.625 mm	10	72.7
STD	12 X 1.25 mm	15	81.0
STD	8 x 0.625 mm	5	70.3
STD	4 X 0.625 mm	2.5	52.8
High	64 X 0.625 mm	40	91.5
High	40 X 0.625 mm	25	87.3
High	16 X 0.625 mm	10	72.7
High	2 X 0.625 mm	1.25	40.0
UHR	20 X 0.625 mm	12.5	76.1
UHR	2 X 0.5 mm	1.0	32.0

Half Value Layer (HVL)

For all HVL measurements, the CT system operates in a stationary X-ray tube position in the standard resolution mode, at 80, 100, 120 and 140 kVp, 200 mAs, 16 x 0.625 collimation, 10 mm slice width (one slice). Type 1100 aluminum filters of various thicknesses are used.

Aluminum Quality Equivalent filtration for different scan modes and kVps	
Scan Mode	**HVL**
80 kVp	6.4 ± 0.5mm Al
100 kVp	7.8 ± 0.5 mm Al
120 kVp	8.9 ± 0.5 mm Al
140 kVp	9.9 ± 0.5 mm Al

Stray Radiation Dose Maps

The map dose values units are µGy / mAs, calculated from direct measurements of mGy / 570 mAs.

459801063624_F/728 * MAR 2020

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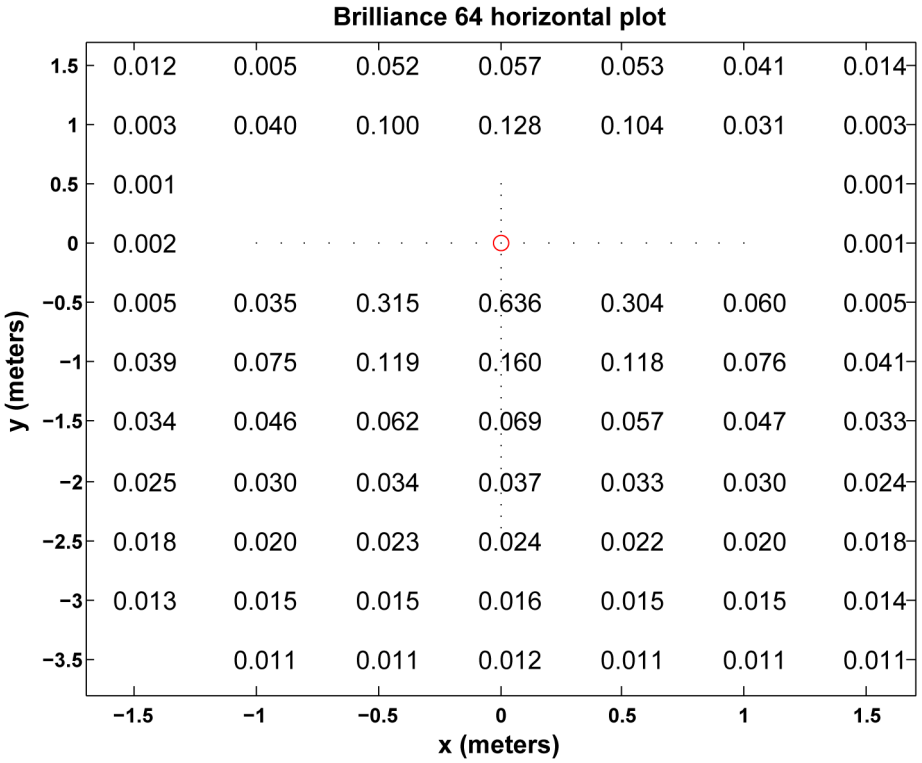
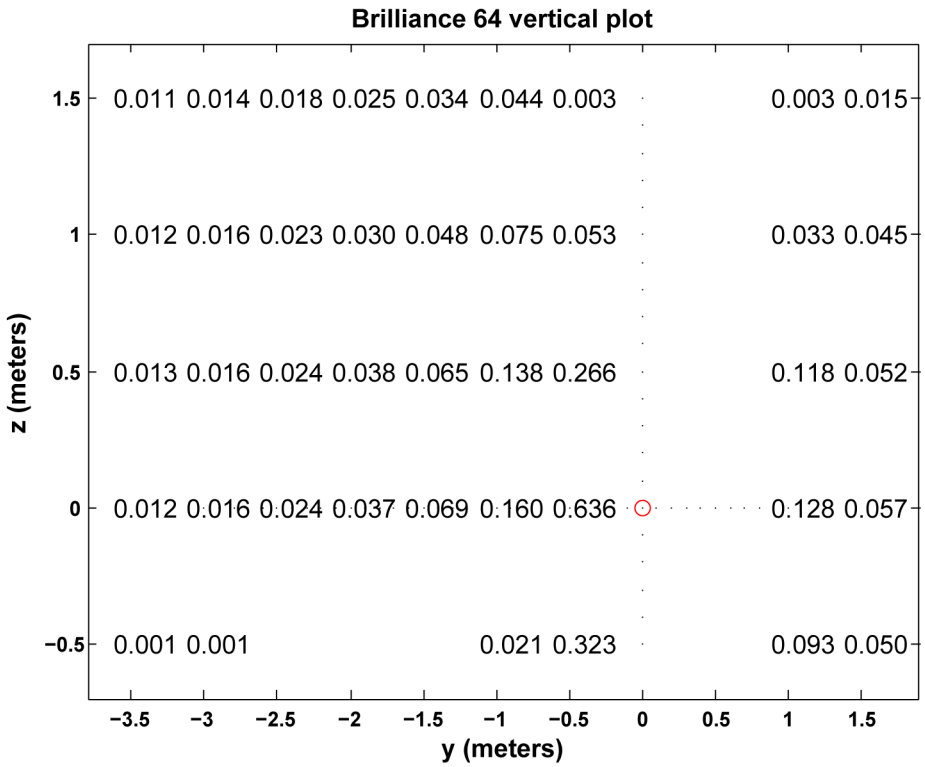
Measurements are made with the QA Axial Body 2D exam card at the maximum collimation of 64 x 0.625 = 40 mm and at 140 kVp, 570 mAs, 2 cycles in the horizontal plane through the system axis and in vertical plane along the system axis. The room dimensions are 6.2 m wide, 5.3 m long with a 3 m high wall and a ceiling that is 5.5 m above the floor.

The body CTDI phantom was centrally positioned in the tomographic scan plane and scanned as indicated to produce the near worst case scatter map values listed. This PMMA material phantom has a cylindrical shape with a diameter of 32 cm and a length of 15 cm. Any missing values on the charts were not measured because the location was not accessible with the measurement probe.

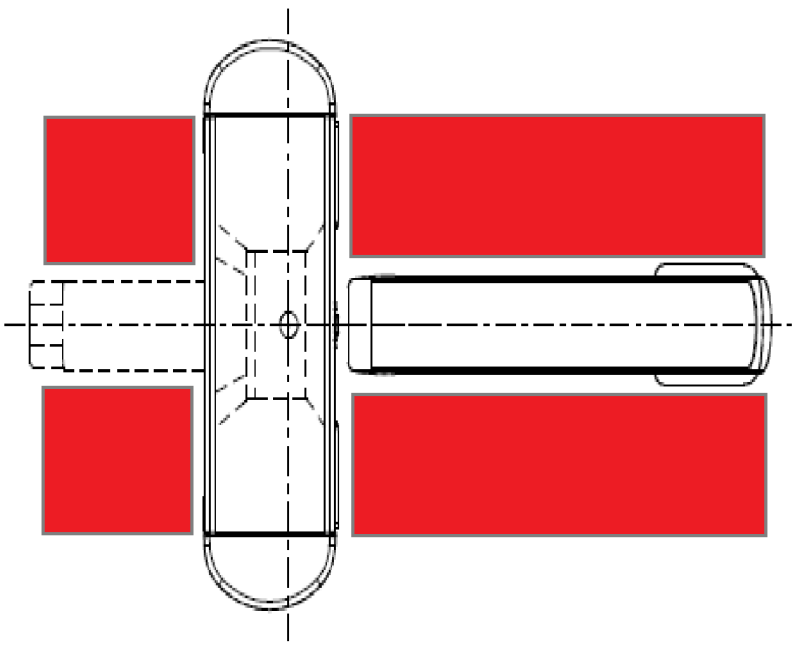


459801063624_F/728 * MAR 2020



Zones of Occupancy

Permitted zones of occupancy shown in red.



The zones of occupancy designated above are to be used for any CT examination where occupancy of the scanner room by medical staff is unavoidable.

459801063624_F/728 * MAR 2020

The zones of occupancy are shown in the red outline on the diagram above. The two zones in the rear of the gantry are 120 cm x 120 cm and the zones alongside the table in front of the gantry are 120 cm wide and 280 cm long.

The radiation profiles (shown below) represent the exposure measured in the worst-case scenario for system use. Measurements were taken using a 35 cm diameter, 15 cm high water phantom to simulate a large patient centered at isocenter. The phantom was scanned at 140 kVp to create the worst-case scatter possible.

For the profiles, measurements were made with a 180 cc ion chamber with a 100 cm^2 effective cross section. The measurements were taken with a 64 x 0.625 mm collimation, 140 kVp, 500 mA, 2.0 second exposure time, 360 degree scan angle. The resulting measurements were scaled to represent air kerma for a 500 cc volume. The profiles were generated with measurements taken at 10 cm intervals from floor level to 200 cm above the floor. The profiles shown do not represent the use of any protective devices.

CT is not designed to operate in a continuous mode, so for ease of use the measurements provided represent a single 500 mAs shot. In order to scale these air kerma values to represent one hour at the conditions of loading that achieve the maximum X-ray tube continuous average power of 3.8 kW, the values must be multiplied by 195. The maximum continuous tube power at 140 kV is 3.8 kW which would be a tube current of 27 mA for one hour, or 97200 total mAs, which is 97.2 times the 1000 mAs used for the measured values.

Exposure from Scattered Radiation in the Front of the Gantry

The blue line represents measurements taken on the right side of the patient support. The green line represents measurements taken on the left side of the patient support.

459801063624_F/728 * MAR 2020

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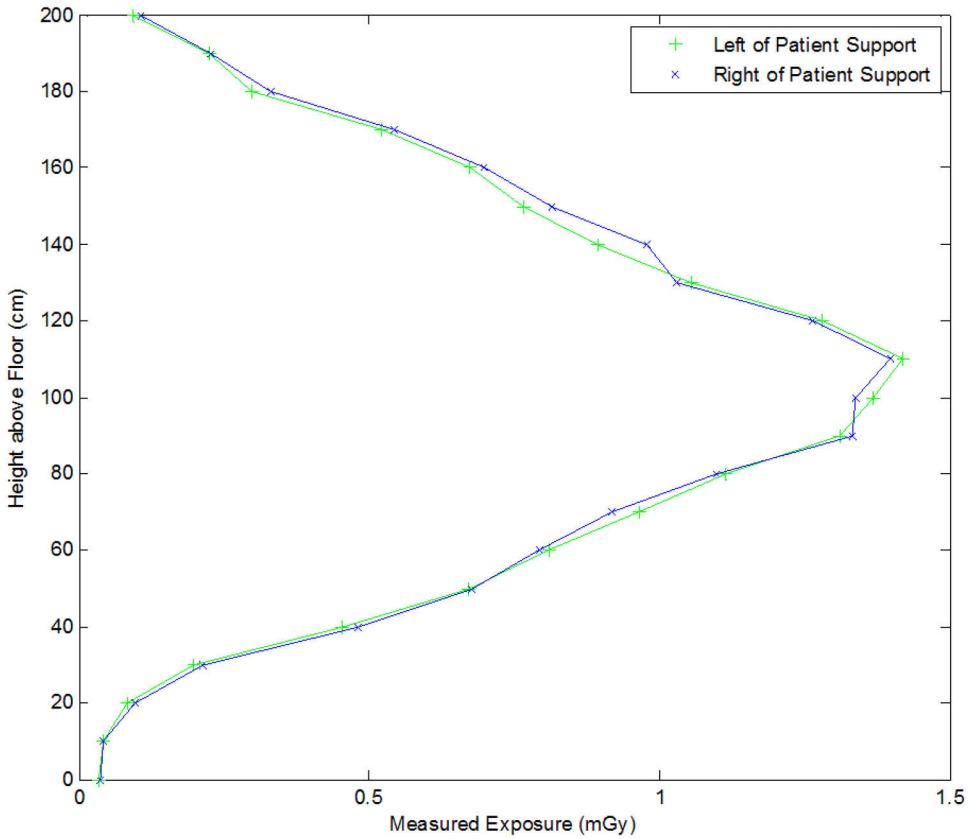

Exposure from Scattered Radiation in the Rear of the Gantry

The blue line represents measurements taken on the right side of the patient support. The green line represents measurements taken on the left side of the patient support.

459801063624_F/728 * MAR 2020

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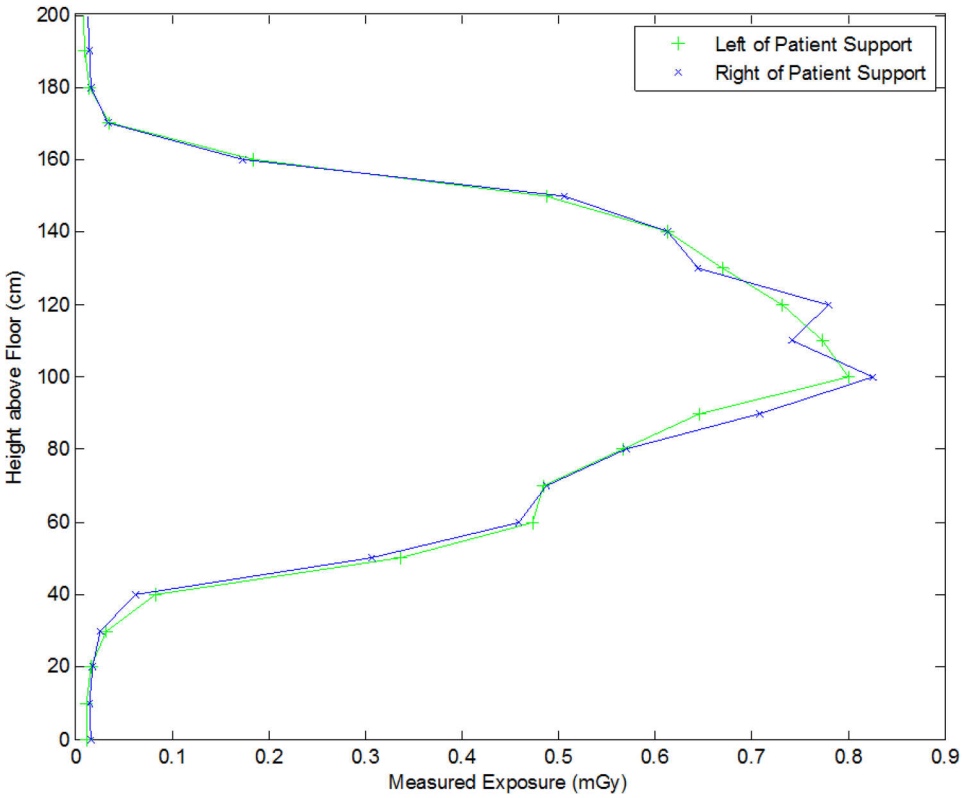

HU-Value Conversion

The Gammex Tissue Characterization Phantom Model 467 from Gammex, Inc. was used to measure the conversion of measured HU-values to electron and mass density values relative to water. The CT number was measured for air, water, two different soft-tissue equivalent materials and two different bone-equivalent materials. For the Gammex Tissue Characterization Phantom Model 467, the air hole and five tissue mimicking material rods were identified for measurement. The CT number conversion factors of six materials for the head scan mode were measured:

- Air
- Solid Water
- BRN-SR2 Brain (soft-tissue-equivalent material)
- AP6-Adipose Tissue (soft-tissue-equivalent material)
- CB2-30% CaCO3 (bone-equivalent material)
- CB2-50% CaCO3 (bone-equivalent material)

For the body scan mode, LV1 Liver (soft-tissue-equivalent material) was measured instead of SR2 Brain (soft-tissue-equivalent material), and the other 5 materials were measured.

The Head measurements were performed with the phantom positioned at iso-center and using *Brain Axial*exam card with the following scan parameters to represent the typical oncology head mode scan:

459801063624_F/728 * MAR 2020

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Collimation	16 x 0.625 = 10mm
Rotation Time	0.75 s
Slice Width	2.5 mm
Filter	UB
FOV	400 mm
kVp	120
mAs	400
CTDI	91.4mGy

The Body measurements were performed with the phantom positioned at iso-center and using *Abdomen* exam card with the following scan parameters to represent the typical oncology body mode scan:

Collimation	16 x 0.625 = 10mm
Rotation Time	0.75 s
Slice Width	2.5 mm
Pitch	0.69
Filter	B
FOV	400 mm
kVp	120
DRI	26 (max mAs 388)
CTDI	46.7 mGy

The tables below represent the relationship between the relative electron density and CT number (in HU) of the six materials for head and body scan mode measured at 120kVp for the IQon CT scanner.

NOTICE

The values shown below are representative numbers based on a limited sample. These values are intended as a reference and not for use as presented.

Typical relative electron density of materials and the corresponding CT number (in HU) as measured on the IQon CT scanner in oncology head scan mode.

Materials	Electron Density Relative to Water	HU-Value (HU)
Air	0.000	-995.8
Adipose	0.935	-93.2
Solid Water	1.003	-2.3

459801063624_F/728 * MAR 2020

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Materials	Electron Density Relative to Water	HU-Value (HU)
BRN-SR2 Brain	1.027	21.4
CB2-30% $CaCO_3$	1.261	477.9
CB2-50% $CaCO_3$	1.453	851.0

Typical relative electron density of materials and the corresponding CT number (in HU) as measured on the IQon CT scanner in oncology body scan mode

Materials	Electron Density Relative to Water	HU-Value (HU)
Air	0.000	-993.5
Adipose	0.935	-92.7
Solid Water	1.003	-2.8
LV1 Liver	1.067	71.5
CB2-30% $CaCO_3$	1.261	477.6
CB2-50% $CaCO_3$	1.453	861.6

The largest available reconstructed field-of-view on the IQon CT scanner is 500 mm, and the true field-of-view is also 500 mm. The IQon CT scanner does not have any inherent accuracy limitations within the 500 mm true field-of-view. CT values within the 500 mm field-of- view are generally accepted to be accurate within scanner specifications, however they may vary due to the specific circumstances such as beam hardening artifacts, etc.

It is important to understand that the conversion factors can be different from scanner to scanner, i.e. the CT number variation may be observed from scanner to scanner. It is important to have scanner-specific HU-value conversion calibrations of each CT-based treatment planning computers. The conversion factors are also subject to change with specific scan parameters that can affect measured HU-values as well, for example kVp changes or changes to certain reconstruction filters. Philips strongly recommends confirmation of all conversion factors before use. Factors to consider when evaluating conversion factors include, but are not limited to:

- Treatment Planning software manufacturer recommendations.
- Industry guidance for treatment planning software and CT simulator commissioning.
- Any other unique considerations for each user's intended use.

The values listed in the tables above are only a representative of the conversion of measured HU-values to electron and mass density values relative to those of water. These CT numbers represent the calibration of a typical scanner and are not intended to be used as calibration data of any other CT scanner.

459801063624_F/728 * MAR 2020

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