English

Technical Reference Guide

Incisive CT

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PHILIPS

Revision History

Revision	Date	Reason for Change
459801855481_A	2020/8	Initial Release
459801855481_B	2020/12	Update Information
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1 Introduction

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

1.1 About this 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 of System and Data** 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.

Note

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

1.2 Caution

The Philips system should not be used if any of the following conditions exist or are thought to exist:

- The image performance quality assurance checks (**Image performance quality assurance**) have not been satisfactorily completed.
- The preventative maintenance program is not up-to-date.

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- If any part of the equipment or system is known (or suspected to be) operating improperly.

1.3 Compatibility

Equipment described in this manual should not be used in combination with other equipment or components unless such other equipment or components are recognized as compatible.

Changes and/or additions to the equipment should only be carried out by Philips Healthcare or by third parties expressly authorized by Philips Healthcare to do so. Such changes and/or additions must comply with all applicable laws and regulations that have the force of law within the jurisdiction(s) concerned, and with best engineering practice.

Changes and/or additions to the equipment that are carried out by persons without the appropriate training and/or using unapproved spare parts may lead to the Philips Healthcare warranty being voided. As with all complex technical equipment, maintenance by persons not appropriately qualified and/or using unapproved spare parts carries serious risks of damage to the equipment and of personal injury.

Warning

Authorization from the manufacturer must be obtained before modifying this equipment. After modification, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

1.4 Compliance

The Philips CT system complies with relevant international and national standards and laws. Information on compliance will be supplied on request by your local Philips representative, or by:
Philips Medical Systems, Nederland B.V.
Veenpluis 6
5684 PC Best
The Netherlands

The Philips systems comply with relevant international and national laws and standards on EMC (electro-magnetic compatibility) for this type of equipment when used as intended. Such laws and standards define both

the permissible electromagnetic emission levels from equipment and its required immunity to electromagnetic interference from external sources.

The Schedule of quality assurance checks identifies the procedures and frequency of their performance, necessary to ensure (continued) compliance with the Federal Performance Standards for Diagnostics X-Ray Equipment, 21 CFR Subchapter J, Radiological Health Section 1020.30 and 1020.33.
Reference IEC 60601-1 Clause 7.9.2.15.

This symbol appears on components on your CT scanner system. It indicates separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. The system should be disposed by qualified agency. Please dispose of the system in accordance with your local regulations to protect the environment.

California

In compliance with California's Best Management Practices for Perchlorate Materials (California Code of Regulations, title 22, division 4.5, chapter 33, article 1), the following warning applies to all Philips Healthcare CT scanners and workstations due to Panasonic CR (button) batteries that are mounted on printed circuit boards in various parts of the system:

Warning

Perchlorate Material – special handling may apply. For more information, see www.dtsc.ca.gov/hazardouswaste/perchlorate/index.cfm.

Vermont

In compliance with the labeling requirements of the Vermont labeling law V.S.A. 10, Chapter 159, §6621(d) and Section 6-803 of the Vermont Solid Waste Management Rules, this product consists of devices that may contain mercury, which must be recycled or disposed of in accordance with local, state, or federal laws. (Within this system, the backlight lamps in the monitor contain mercury.)

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REACH

REACH (Registration, Evaluation, Authorization and Restriction of Chemical substances) requires Philips Healthcare (PH) to provide chemical content information for Substances of Very High Concern (SVHC) if they are present above 0.1% of the article weight. Components within electric and electronic equipment may contain phthalates above the threshold. The SVHC list is updated on a regular basis. Refer to the following Philips REACH website for the most up-to-date list of products containing SVHC above the threshold: https://www.philips.com/a-w/about/sustainability/sustainable-planet/green-operations/reach.html

REACH Declaration related to substances in articles

The table indicates which substances of very high concern (SVHC) may be present in Philips products above the threshold level of 0.1% by weight of the listed article. Based on our current knowledge and current supplier information, no other SVHC are present in our articles.

Philips Product category	Substance of Very High Concern	CAS Number	Comments
Cables and other PVC-based components of electric and electronic equipment	DEHP, bis(2-ethyl(hexyl)phthalate DIBP, diisobutyl phthalate	117-81-7 84-69-5	This substance may be present in separately sold PVC cables and PVC cables or parts along with the appliances
Components of electric and electronic equipment	Lead	7439-92-1	This substance may be present in e.g., lead solders, as an alloying element in steel and aluminium, in galvanised steel components and in copper alloys (applications exempted by the EU RoHS Directive 2011/65/EU, Annexes III and IV). For example, lead in X-ray shielding.

1.5 IEC-60601 Classification

Reference IEC 60601-1 Clause 7.9.2.1 and 7.9.2.5.

Type of protection against electric shock	Class I equipment
Degree of protection against electric shock	Type B applied part (patient table) Type CF applied part (PIM)
Degree of protection against harmful ingress of water	Ordinary equipment (IPX0) 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 with short time loading (per IEC 60601-1)

1.6 IEC Statement of Compliance

Reference IEC 60601-2-44 Clause 201.4.3 and IEC 60601-1 Clause 4.3.

This CT equipment is compliant to the following standards:

IEC 60601-1: 2005/A1:2012

IEC 60601-1-2: 2014

IEC 62304: 2015

IEC 60601-1-6: 2010/A1:2013

IEC 60601-2-44: 2009/AMD1:2012/AMD2:2016

IEC 62366-1:2015

This CT equipment with radiation protection in accordance with IEC 60601-1-3:2013.

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1.7 Electromagnetic Emissions

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.

Reference IEC 60601-1-2 clause 5.2.2.1 a.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions, CISPR 11	Group1 Class A	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals. 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 IEC 61000-3-2	Not Applicable	CT 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	

1.8 Essential performance

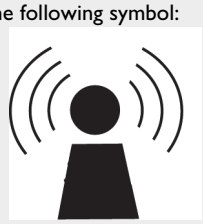
The Incisive CT essential performance:

- Accuracy of length, area and volume value on images shall be assured. Measure length, area, volume and scale on images of phantom with known size
- Continuous CT for interventional procedure
  - CCT Single (Interventional Guidance Single): scan each time the X-ray pedal is depressed.
  - CCT Continuous (Interventional Guidance Continuous): sequential axial scans as long as the pedal is being pressed.

1.9 Electromagnetic Immunity

Reference IEC 60601-1-2 clause 5.2.2.1, 5.2.2.5 a and 5.2.2.5 c.

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.

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. power and signal ports 150 kHz to 80 MHz 6 Vrms on a.c power and signal ports in ISM bands 150 kHz to 80 MHz See Note 3 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 80% AM at 1 kHz	Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity fields from RF wireless communications equipment IE61000-4-3	380 MHz – 5800 MHz	380 MHz - 5800 MHz see Notes 4“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.			

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Note 2 Only the equipment specified in the CT Installation Manual may be used inside the gantry and patient table room.
Note 3 The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 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.
Note 4 See the table Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment.
Note 5 Incisive CT is a PERMANENTLY INSTALLED LARGE ME SYSTEM, the tested for radiated RF IMMUNITY over the entire frequency range 80 MHz to 6 000 MHz can be exempt.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment.

Test frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM± 5 kHz deviation 1 kHz sine[c]	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the Incisive CT may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 35% non-condensing per the CT planning reference data (PRD).
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 100kHz repetition frequency	Main's power quality must comply with the CT planning reference data (PRD).
Surge IEC 61000-4-5	±1 kV lines to lines ±2 kV lines to earth	±1 kV differential ±2 kV common mode	Main's power quality must comply with the CT planning reference data (PRD).
Voltage dips, 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.
Voltage interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% *U*T; 250/300 cycle	0% *U*T; 250/300 cycle *U*T is the AC mains voltage prior to application of the test level.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	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.

Reference IEC 60601-1-2 Clause 5.2.2.5 b.

Warning

This equipment has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation.

1.10 Equipment Cable Requirement

Reference IEC 60601-2-44 Clause 201.4.10.2, IEC 60601-1 Clause 7.9.3.1, and IEC 60601-1-2 Clause 5.2.1.1 d.

Power cable						
No.	Name	Length (m)	Shielding	Note		
1	Power cable	16.6	No	Three-phase Fve-wire, 16mm^2		
Signal cable, interconnection cables or patient coupling cables.						
No.	Name	Length (m)	Shielding	From	To	Note
2	Gantry to Console PE cable	23	No	Gantry	Console	
3	UPS power cable	23	No	Gantry	Console	
4	optical fiber gantry to console	27	No	Gantry	Console	Signal cable
5	Network cable gantry to console	23	Yes	Gantry	Console	Signal cable
6	Gantry interface board to DRC card	23	Yes	Gantry	Console	Signal cable
7	Gantry to console interface board	23	Yes	Gantry	Console	Signal cable
8	Mobile monitor power cable	15	No	Gantry	Mobile monitor	2 cables
9	Camare power cable	15	No	Gantry	Camera Kit	
10	IVC controller to Gantry cable	6	Yes	Gantry	IVC controller	Signal cable
11	Power cable of mobile monitor on ceiling	23	No	Gantry	Mobile monitor	
12	PE cable of mobile monitor on ceiling	23	No	Gantry	Mobile monitor cart	
13	Camera USB3.0 cable	25	Yes	Console	Camera Kit	Signal cable
14	DP monitor optical fiber cable	30	No	Console	Mobile monitor	Signal cable
15	CT Box control cable	2.9	Yes	Console	CT Box	Signal cable
16	PIMdata cable	3.5	Yes	Gantry	PIM	Signal cable
17	CCT foot switch cable	5	Yes	Gantry	CCT foot switch	Signal cable
18	USB cable for IVC interface board to Console	30	Yes	Gantry	Console	Signal cable
19	UPS output line	2	No	UPS	Monitor	3 cables

Cables and component should be replaced by Customer Service.

1.11 Electrical Ratings

Reference IEC 60601-1 Clause 7.9.2.3.

Power supply type	380/400 VAC, 3-phase
Power capacity	115 kVA
Frequency	50/60 Hz
Rated voltage	380/400 V
Maximum voltage fluctuation	90% ~ 110%

1.12 Technical Data

Reference IEC 60601-2-44 Clause 201.7.9.2.9.

55 kW

The corresponding nominal X-ray tube voltage together with the highest X-ray tube current obtainable from the high voltage generator when operated at that X-ray tube voltage.	80 kV, 667mA
The corresponding highest X-ray tube current together with the highest X-ray tube voltage obtainable from the high voltage generator when operated at that X-ray tube current.	140 kV, 392 mA
The corresponding combination of X-ray tube voltage and X-ray tube current which results in the highest electric output power.	140 kV, 392 mA@55 kW 120 kV, 458 mA@55 kW 100 kV, 550 mA@55 kW
The nominal electric power given as the highest constant electric output power in kilowatts which the high-voltage generator can deliver, for a loading time of 4 s at an X-ray tube voltage of 120 kV, 458mA.	55 kW

72 kW

The corresponding nominal X-ray tube voltage together with the highest X-ray tube current obtainable from the high voltage generator when operated at that X-ray tube voltage.	100 kV, 667mA
The corresponding highest X-ray tube current together with the highest X-ray tube voltage obtainable from the high voltage generator when operated at that X-ray tube current.	140 kV, 514 mA
The corresponding combination of X-ray tube voltage and X-ray tube current which results in the highest electric output power.	140 kV, 514 mA@72 kW 120 kV, 600 mA@72 kW
The nominal electric power given as the highest constant electric output power in kilowatts which the high-voltage generator can deliver, for a loading time of 4 s at an X-ray tube voltage of 120 kV, 600mA.	72 kW

80 kW

The corresponding nominal X-ray tube voltage together with the highest X-ray tube current obtainable from the high voltage generator when operated at that X-ray tube voltage.	120 kV, 667mA
The corresponding highest X-ray tube current together with the highest X-ray tube voltage obtainable from the high voltage generator when operated at that X-ray tube current.	140 kV, 571 mA
The corresponding combination of X-ray tube voltage and X-ray tube current which results in the highest electric output power.	140 kV, 571 mA@80 kW 120 kV, 667 mA@80 kW
The nominal electric power given as the highest constant electric output power in kilowatts which the high-voltage generator can deliver, for a loading time of 4 s at an X-ray tube voltage of 120 kV, 667 mA.	80 kW

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2 Safety

2.1 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 information given in the **Introduction** section of this **Technical Reference Guide** and **Instructions for Use**.

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.

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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** headings.

Warning

Do not use the CT system for any application until you have read, understood 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.

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 **Instructions for Use.**

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 purpose of the CT system is described under the heading **Intended purpose** in the **Introduction** section of **Instructions for Use**. Compatibility is discussed under the heading **Compatibility** in the **Introduction** section of this **Technical Reference Guide**.

Reference IEC 60601-1 Clause 7.9.3.1.

Warning

- **Do not modify this equipment without authorization from the manufacturer.**
- **No modification of this equipment is allowed.**
- **If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.**

2.2 Emergency Procedures

2.2.1 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.

2.2.2 Reset from Emergency Stop

Use this procedure to reset from emergency stop:

1. Locate the button that was pressed to initiate the stop.
2. Press the button to disengage it from the stop position.
3. Restart the gantry.
4. Relaunch the host application.

Warning

After the Stop button is pressed, the table is locked in place for two seconds before it is movable. You must maintain control of the table.

Warning

During all movements of the gantry (automatic and manual) and the patient table, keep the patient under continuous observation to avoid patient falling and 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.

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2.2.3 Emergency Patient Release

Reference IEC 60601-2-44 Clause 201.9.2.5.101.

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 legs.

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**, use one of the following procedures:

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.

Note

- **In the event of a power failure or emergency stop, the patient table does not move vertically. Be prepared to help the patient from the table.**
- **When the emergency stop button is pressed, the tilt angle of gantry would be less than 0.5 degree and table stopped in 10 mm (when patient weight is 135kg). (Reference IEC 60601-2-44 Clause 201.9.2.3.1.102.)**

2.3 Electrical Safety and Grounding

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.**
- **To avoid risk of electric shock, do not cut cables.**
- **To avoid risk of electric shock, make sure that there is no movement run over the cables.**
- **Visual inspection of cables before use is necessary to avoid risk of electric shock, if any defects are found please contact Customer Service.**
- **Be careful of cables on the floor to avoid tripping of personnel.**

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

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

The equipment must be grounded to an earth ground by a separate conductor. The neutral side of the line is not to be considered the earth ground. On equipment provided with a line cord, the equipment must be connected to a properly grounded, three-pin receptacle. Do not use a three-to-two pin adapter.

Warning

Reference IEC 60601-1 Clause 7.9.2.2.
To avoid risk of electric shock, this equipment must be connected to a supply mains with protective earth. The neutral side of the line is not to be considered the earth ground. An additional MULTIPLE SOCKET-OUTLET or extension cord shall not be connected to the system.

2.4 Mechanical Safety

Warning

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

- **Operate this equipment carefully to avoid injury to the patient, table cover, and gantry cover.**

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

2.5 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.

2.6 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.

2.7 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 electric shock and/or 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.

2.8 Electromagnetic Compatibility

The Philips CT system complies with the requirements of applicable EMC standards (Refer to **Electromagnetic Emissions**, on page 1-6 and **Electromagnetic Immunity**, on page 1-7).

Warning

Reference IEC 60601-1-2 clause 5.2.1.1 c.

- **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**

Reference IEC 60601-1-2 clause 5.2.1.1 e.

- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**

Note

Reference IEC 60601-1-2 clause 5.2.1.2

- **The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.**

2.8.1 Mobile Telephones and Similar Products

Other electronic equipment exceeding the limits defined in such EMC standards, such as certain mobile telephones, could affect the operation of the CT system.

Warning

Reference IEC 60601-1-2 clause 5.2.1.1 F.

- **Portable RF communications equipment (including accessories such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Incisive CT, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

2.8.2 Electronic and Implanted Stimulators

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 FDA recommendations (summarized below) should be followed.

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.
   - Ask patient with a neurostimulator to shut off the device temporarily while the scan is performed.
   - 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.

Note

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.

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.

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2.9 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.

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 leakage radiation from within the source housing or to scattered radiation resulting from passage of radiation through matter.

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.

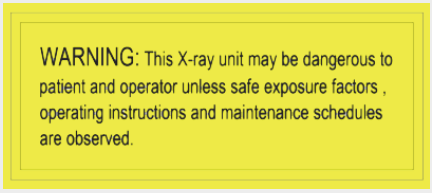
- ICRP, Pergamon Press, Oxford, New York, Beijing, Frankfurt, Sao Paulo, Sydney, Tokyo, Toronto
- NCRP, Suite 800, 7910 Woodmont Avenue, Bethesda, Maryland 20814, USA

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.

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.



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

2.9.1 Radiation Indicators

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

If a radiation indicator 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.

2.9.2 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.

2.10 Oil Leaks

The X-ray tube and high-voltage generator are cooled by oil. This is a closed-circuit system that is sealed.

Caution

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

2.11 Laser Safety

Warning

- **Laser radiation.**
- **Do not stare into laser beam when you use of optical instruments, such as eyeglasses with large diopter or mirrors. The laser light can cause eye damage.**
- **1M laser production.**

Label / Symbol	Description
	CAUTION: Radiation hazard.
	Laser Radiation Do not expose users of telescopic optics class 1M laser product <0.39mW, output: λ=650nm Acc.IEC 60825-1:2014 Complies with FDA 21 CFR1040.10&1040.11 except for deviation pursuant to laser notice NO.50 dated June 24,2007

2.12 Protection Measures

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

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.

- Always use a gonadal shield, if possible.
- Use the applicable protocols for children.

Recommendation for the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures.

Specific area gonad shielding covers an area slightly larger than the region of the gonads. Such shielding should be provided when the following conditions exist:

- The gonads will lie within the primary x-ray field, or within close proximity (about 5 centimeters), despite proper beam limitation.
  - Specific area testicular shielding should always be used during those examinations in which the testes usually are in the primary x-ray field, such as examinations of the pelvis, hip, and upper femur;
  - Specific area testicular shielding may also be warranted during other examinations of the abdominal region in which the testes may lie within or in close proximity to the primary x-ray field, depending upon the size of the patient and the examination techniques and equipment employed.
  - Specific area gonad shielding should never be used as a substitute for careful patient positioning, the use of correct technique factors and film processing, or proper beam limitation (confinement of the x-ray field to the area of diagnostic interest).
  - Specific area gonad shielding should provide attenuation of x-rays at least equivalent to that afforded by 0.25 millimeter of lead.
- The clinical objectives of the examination will not be compromised.
  - Specific area testicular shielding usually does not obscure needed information except in a few cases such as oblique views of the hip, retrograde urethrograms and voiding cystourethrograms, visualization of the rectum and, occasionally, the pubic symphysis.
  - The use of specific area ovarian shielding is frequently impractical at present because the exact location of the ovaries is difficult to

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estimate, and the shield may obscure visualization of portions of adjacent structures such as the spine, ureters, and small and large bowels.

- The patient has a reasonable reproductive potential.
  - Specific area shielding need not be used on patients who cannot or are not likely to have children in the future.
  - The following table of statistical data regarding the average number of children expected by potential parents in various age categories during their remaining lifetimes is provided for x-ray facilities that wish to use it as a basis for judging reproductive potential:

Age	Male parent	Female parent
Fetus	2.6	2.6
0 to 4	2.6	2.5
5 to 9	2.7	2.5
10 to 14	2.7	2.6
15 to 19	2.7	2.6
20 to 24	2.6	2.2
25 to 29	2.0	1.4
30 to 34	1.1	.6
35 to 39	.5	.2
40 to 44	.2	.04
45 to 49	.07	0
50 to 54	.03	0
55 to 64	.01	0
Over 65	0	0

2.13 System symbols and labels

Reference IEC 60601-1 Clause 7.9.3.1.

These symbols may be included on system labeling:

Fragile Content

Upwards positioning


Waterproof Package

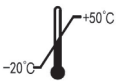

Center of gravity

Stack Limiter/Layer Limitation


Do not stack


Lift from here

Atmospheric pressure limitation



Temperature limitation

Humidity limitation

Serial number


Manufacturer

Gantry front

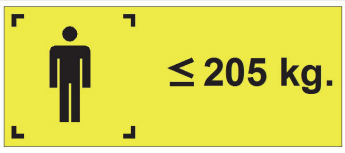
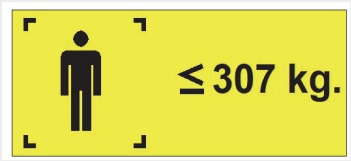
Couch head

These labels may be included on the system components:

Follow all warnings included on product labeling as well as those included in this manual.


Refer to user instructions


Refer to user instructions

	Reference IEC 60601-2-44 Clause 201.7.9.2.2. Caution: Crushing hazard (hand)
	Caution: Crushing hazard (foot)
	Caution: Crushing hazard (hand). Do not grasp side of the cradle.
	Caution: Sitting prohibited. Weight limit.
	ESD (electrostatic discharge): The product is marker with this symbol to warn the user not to touch exposed pins. Touching exposed pins can cause electrostatic discharge, which can damage the product.
	Table: Maximum weight capacity is less than or equal to 205 kg.
	Table: Maximum weight capacity is less than or equal to 307 kg.

Extension: Maximum load capacity is less than or equal to 24 kg (53 lb).

Caution: Keep screen dry and clean.

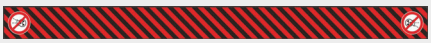
WARNING: Do not scan this area.

This side up. Remove arm rest before scanning.

Left and right side of therapy top.
WARNING: Be aware of possible pinch points between the therapy top and the gantry. Two person lift required.

Maximum load capacity is less than or equal to 285 kg

CAUTION: Hand pinch point or crush hazard.

	End of therapy top. WARNING: Do not scan this area.
	
	Caution: Crushing hazard (Leg)
	
	Warning: Do not lean against the floating sensors which are located at the rear end of both table sides and rear handle, to avoid unintentional activation of the floating mode.

Warning

- **Make sure the system and the scan room comply with operational requirements before initiating the system.**
- **Take care to avoid fingers, arms, clothing, infusion or life support devices drawn into moving parts of couch, and cause serious injury to patient.**
- **To avoid people injury, which are caused by table and extension breakage/disconnection, please pay attention to the maximum table weight and maximum foot extension load capacity.**

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

	ISO 7000-0434A	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	ISO 7000-1641	Operator's manual; operating instructions	To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.
	IEC 60417-6042	Caution, risk of electric shock	Identifies equipment that has risk of electric shock, for example the power source.
	IEC 60417-5638	Emergency stop	Identifies an emergency stop control device. Found on the red buttons located on the gantry and the System Scan Control Box.
	N/A	Electronic Instructions for Use	Identifies the website address to access the electronic version of the instructions for use (eIFU).
	ISO 7010-M002	Refer to instruction manual/booklet	Signifies that the instruction manual/booklet must be read and the warnings and instructions therein followed.

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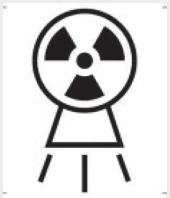
	IEC 60417-5840	Type B applied part	Identifies a type B applied part complying with IEC 60601-1.
	ISO 7000-5390	Patient, normal; person, general	Indicates a reference to a normal patient, or to indicate a person and human body.
	IEC 60417-5335	Type CF applied part	Identifies a type CF applied part complying with IEC 60601-1.
	IEC60825-1	Laser Warning label	Indicates potential harm from the presence of a laser beam or radiation from the laser apparatus.
	ISO 7000-5339	Emitting X-ray source assembly	Indicates the emission or the imminent emission of X-radiation.
	ISO 7000-2497	Date of manufacture	The date when the medical device was manufactured. The associated date is presented in YYYY-MM-DD format.
	ISO 7000-3082	Manufacturer	Indicates the medical device manufacturer (i.e. the entity placing the medical device on the market).

	IEC 60417-6049 IEC TR 60878-6049	Country of manufacture	Identifies the country of manufacture using the two letter country code defined in ISO 3166-1 represented by “CN” in this example.
	ISO15223-1	Authorized representative in the European Community	Indicates the authorized representative in the European Community
	N/A	Medical Device	Indicates that the item is a medical device.
	IEC 60417-6050	Model	Indicates the product model.
	ISO 7000-2498	Serial number	Indicates the manufacturer's serial number so a specific medical device can be identified.
	ISO 7000-2493	Catalogue number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	N/A	Unique Device Identifier	Indicates the Unique Device Identifier Information

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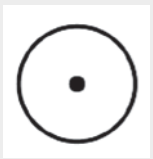
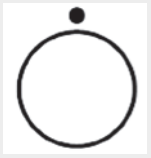
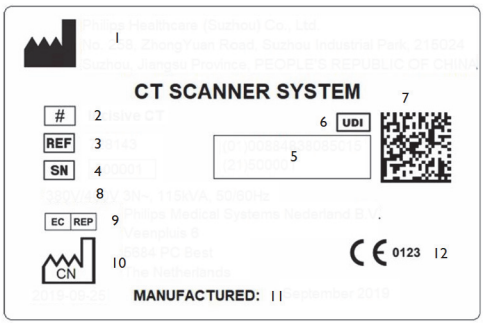
	ISO 7010-P019	No stepping on surface	Indicates the surface is unsuitable for stepping onto.
	ISO 7010 - W024	Warning; Crushing of hands	Take care to avoid injury to hands when in the vicinity of equipment with closing mechanical parts.
	IEC 60417 - 5019	Protective earth (ground)	Identifies any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.
	IEC 60417 - 5017	Earth; ground	Identifies an earth (ground) terminal in cases where neither the symbol 5018 nor 5019 is explicitly required.
	IEC 60417 - 5140	Non-ionizing electromagnetic radiation	Indicates medical electrical equipment or systems that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment; or to indicate elevated, potentially hazardous, levels of non-ionizing radiation.
	IEC 60417-5264	ON (Power)	To indicate the “ON” condition.
	IEC 60417-5265	OFF (Power)	To indicate the “OFF” condition.

CE 0123	N/A	Product complies with the requirements of the applicable European Union directives.
C SA® US	CSA certification	This product complies with standards of CSA certification in United States and Canada.
Rx ONLY	N/A	This product is available by Prescription only.
CCC	China Compliance Certification	Product complies with the requirements of the applicable China Compliance Certification.
	ANSI Z535.2-2011	Radiation.

Unique Device Identification Label



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Number	Description
1	Manufacturer address
2	Model
3	Reference or catalog number
4	Serial number
5	Global Trade Identification Number (GTIN) as Device Identifier (DI) and Production Identifier (PI).
6	Unique Device Identifier
7	Unique Device Identification GS1 2D DataMatrix barcode (contains information from 5).
8	Electrical rating specific to system
9	Authorized representative in the European Community
10	Country of manufacture
11	Month and year of device manufacture as per 21 CFR.
12	Product complies with the requirements of the applicable European Union directives.

2.14 Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2.15 Storage and Transportation

	Temperature	Relative humidity	Air pressure
Storage	-15°C ~ 45°C (Max. Gradient: 10 °C/ Hour)	20% ~ 80% (no condensing)	50 - 106 kPa
Transportation	-20°C ~ 50°C	20% ~ 80% (no condensing)	50 - 106 kPa

3 Security of System and Data

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 computer-based 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 defences are essential to good security practice.

This chapter provides guidelines to help the operator and owner understand 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 offices at their location:

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

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3.1 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.

Note

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

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.

3.2 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.

3.2.1 Network Security

The CT 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 and virus scanners. Clinical data transferred across the network is not encrypted.

- The Host system time can be configured to synchronize with an Internet time server.

3.2.2 Hard Drive Encryption

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

Note

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.

3.2.3 Remote Service

Philips Healthcare has a global, web-based 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 technologies. The remote service function is a secure connection through explicit authorization and authentication control with encryption of all data.

3.3 Access Control

3.3.1 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.

When the CT is not in use, please click **Exit Console** in **Service** interface to log out, and keep it in a locked room.

3.3.2 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.

3.3.3 User Account Roles

The following user account roles are supported by the system:

- Clinical
- Local Administrator
- O-level Service
- Philips Service

The ability to install or update the software/firmware is available only to Philips authorized service personnel.

3.3.4 User Logging

The system logs the user login/logout and system operation, the Service Engineer can find the file in Logs folder.

3.3.5 User Account Backup and Restore

User account information can be backed up and restored by Philips Service Representative.

3.3.6 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.

See "**22.6.15 Security Setting**" in **Instructions for Use** for more information.

3.3.7 Manual Blanking Display

When you leave the console monitor, please manually blank the display.

1. Click **Screen Lock** at the bottom of the interface.
2. Click **Yes** to lock the screen.
3. Click **Unlock** to activate the screen.

3.3.8 Positioning of Display Monitors

Unauthorized visual access to protected information can be minimized by positioning the system's display monitor so it faces a wall, 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.

3.3.9 Manage User Accounts

The clinical user, O-level service user, and default administrator user account login password will require change upon first login, and the new login information should be stored in a secure location.

3.3.10 User Login and Logout Protections

A consistent user login process (user names and passwords) provides good security of protected information. Minimum login standards include:

- Implementing strong passwords. This is the easiest and most effective method to increase security. Strong passwords consist of at least eight alphanumeric, mixed case characters, digits and special characters like '@' or '*'. Never use words that can be found in the dictionary
- Never post or share user names and passwords
- Change passwords periodically

See "**22.6.13 User management**" in **Instructions for Use** for more information.

Emergency Login

To enable Emergency Login, click **Service** from the Workflow bar, click **System Setting**, then click **Security Setting** and select **Enable Emergency Account**.

To log in to the system:

1 Select **Emergency login**

2 In order to use the emergency login option, a temporary operator name must be entered in the **Operator Name** field.

3 Enter the password, if needed.

The operator name and password may consist of letters, numbers, and underscores.

4 Click **Login**.

After using the emergency login, the console will display **Warning: Emergency Mode** at the bottom 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 procedure.

Note

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

3.3.11 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.

The system hard drive is sealed to protect against tampering, only Philips Service can open it.

3.3.12 Personal Data Storage Location

Personal data is stored in the hard drive, in logical disk D and Y drive.

3.3.13 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.

3.3.14 Removable and Portable Media

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

- Inserting removable media can introduce a virus to the medical device. Check removable media for viruses before using them.
- Removing media containing patient data can allow access to the data by unauthorized individuals.
- 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.

Caution

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

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.

3.3.15 Audit Trail

When any of the following events occur, the system logs the event in an ePHI (Electronic Protected Health Information) audit log:

- Application Activity
- Audit Log Used
- Begin Transferring DICOM Instances
- DICOM Instances Accessed/ Study deleted
- DICOM Instances Transferred
- Patient-record-event
- PHI-export
- PHI-import
- Query Information
- 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 at least 8 months from the initial date of the log. Logs older than 8 months may be deleted from the archive. ePHI audit logs can be backed up and restored.

It is recommended to backup the audit trail logs in a secure location.

See "**22.10 Audit Trails**" in **Instructions for Use** for more information.

3.3.16 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

3.4 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.

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 whitelist 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.

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3.5 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.

Note

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 and select it.
2. Select **Secure Erase**.
3. Select the desired drive.
4. There is a message shown.
5. Select **Continue**.
6. The estimated time to complete Secure Erase is displayed.

7 Select **Continue**. The elapsed time will be displayed until "Secure Erase Complete" is displayed.

8 Select **Continue** to return to the drive selection menu.

Repeat step 3 to step 7 to Secure Erase additional drives.

9 Select the **Main** menu, click **Save Changes and Exit** to exit BIOS Setup, if done.

Note

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.

3.6 3rd party software

Incisive CT includes the following 3rd party software.

Name	Version
Adobe Reader	9.1
McAfee Corporate Virus Scan Command Line	6.0
COPSSH	5.4
UltraVNC	1.0.8.2
Microsoft® SQL Server® 2014 Service Pack 2 (SP2) Express	12.0.5000.0
Windows 10 OS	NA
OpenCV	2.4.10
ITK	5.0
Azure Kinect Sensor SDK	1.4.0
TensorFlow	1.11.0(for camera) 1.14.0(for post-processing algorithm)
IPP	IPP8
DCMTK354	3.5.4
CUDA	10.0

Name	Version
CUDNN	7.6
OpenCV	2.4.10
Azure Kinect Sensor SDK	1.4.0
libpng	1.6.37
PCL	1.11.0
prima	NA
TensorRT	7.0.0.11
zlib	1.2.11

3.7 De-Identified Items

The following items are blanked:

- Accession Number
- Image Comment
- Institution Name
- Institutional Department Name
- Operators' Name
- Patient Comments
- Patient's Birth Date
- Patient's Sex
- Performed Procedure Code Sequence
- Protocol Name
- Referenced Request Sequence >Requested Procedure Code Sequence
- Referring Physician's Name
- Requested Procedure Description
- Station Name

The following items are removed:

- Admitting Diagnoses Code Sequence
- Institution Address
- Patient's Age
- Patient's Size
- Patient's Weight
- Performed Procedure Step Description
- Performed Procedure Step ID
- Performed Procedure Step Start Date

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- Performed Procedure Step Start Time
- Procedure Code Sequence
- Reason for the Requested Procedure
- Referenced Performed Procedure Step Sequence
- Referenced Request Sequence>Reason for Requested Procedure Code Sequence
- Referenced Study Sequence
- Request Attributes Sequence
- Requested Procedure ID
- Scheduled Procedure Step Description
- Series Description
- Study Description

The following items are modified to “dummystring”:

- Contrast/Bolus Agent
- Device Serial Number
- Study ID

The following item is modified to time string (yyyymmddhhmmssSSS, such as 20201126093325340):

- PatientID

The following items are modified to new UID:

- Irradiation Event UID
- Referenced Image Sequence>Referenced SOP Instance UID
- SOP Instance UID
- Frame of Reference UID

The following item is modified to Anonymous:

- Patient’s Name

The following items are modified to 19000101:

- Series Date
- Acquisition Date
- Content Date
- Instance Creation Date
- Study Date

The following items are modified to 000000:

- Acquisition Time
- Content Time
- Instance Creation Time

- Series Time
- Study Time

The following item is modified to 19000101000000:

- Acquisition DateTime

The following items are newly generated:

- PatientIdentifyRemoved: Yes
- De-identification Method Code Sequence: Basic Application Confidentiality Profile, Clean Descriptors Option, Retain Safe Private Option

3.8 Software Distribution

Software Distribution option allows you to download and install software patches released by Philips. The software patches can be automatically or manually downloaded which are depending on the patches types, when the system is connected to Philips Remote Service (PRS).The download happens only when the scanner is not in use. 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.

When the **New Software Available**  icon appears, it means there is a package waiting for downloading or already downloaded.

Log off the console software, then log in **Software Distribution**, when the patch needs to be downloaded manually, select the desired patch and click **Accept**.

After the patch is download, click **Install** to Install the selected patch.

Note

- **The automatic download of software patches may affect the system performance.**
- **Once the download is complete, the clinical users will receive a patch availability notification after login. Philips Service Personnel, Third Party Service or Local Administrator can install the downloaded software patches.**
- **Any failed software patch installation prevents clinical user login with a notification on the screen.**

4 Image performance quality assurance

4.1 Overview

Imaging performance of the scanner is checked by scanning head and body system phantoms.

When testing image quality, the system should be properly calibrated.

This chapter covers information on these areas:

- Head and body phantom.
- Quality assurance checks-daily and monthly.

Read this section carefully and follow all instructions regarding scheduling and performance of quality assurance checks.

Note

- **These instructions represent the manufacturer's required QA performance checks. If additional testing is required by your national or local authorities, please contact your service representative.**
- **Imaging performance of the scanner must use the same version of Incisive CT phantoms which correspond to the system version.**
- **Observe table position range when executing QA checks, incorrect table position can cause Non-Diagnostic Image.**

Warning

- **Follow Image performance quality assurance instructions to avoid Image quality degradation.**
- **Do not perform the IQ check when there is a person in the scanning room, to avoid people receive unwanted ionizing radiation.**

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4.2 Head & body system performance phantom

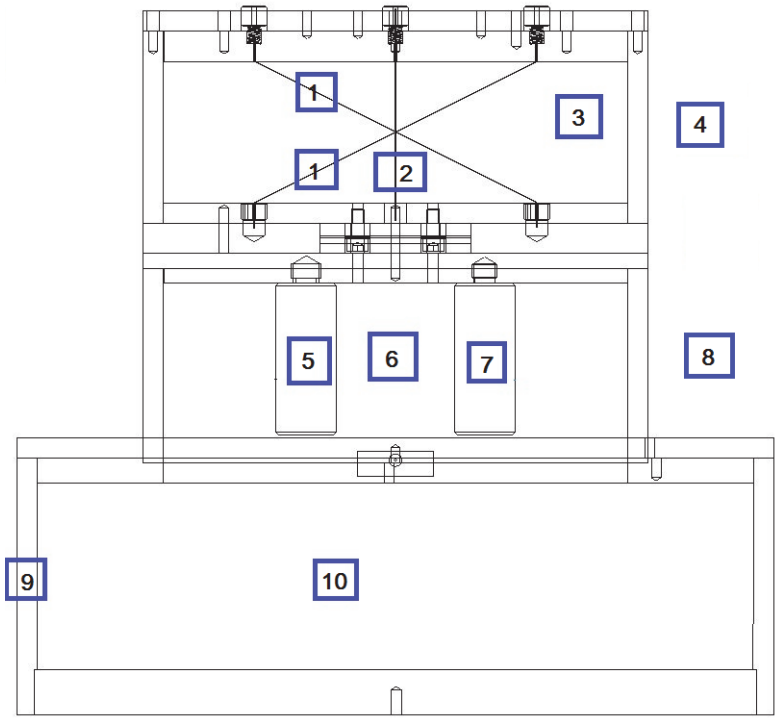
The phantom consists of two portions which cover the aspects of head and body scans. The out shell of phantom is made of PMMA. This section covers the specifications of both the head and body portions of the phantom. Familiarize yourself with this information before you scan either portion.

There are two kinds of system phantom:

- Acrylic material+PE material
- LEXAN material+PE material

Please refer to the description and tech data for the phantom type shipped with your system.

The illustration below shows the entire phantom.



Item	Description
1	Metal Wire for Slice Thickness Test
2	Metal Wire for Impulse Response Measurement
3	Air
4	Physics Layer

5	PE
6	Water
7	LEXAN/Acrylic
8	Head Water Layer
9	Body Water Layer
10	Water

4.2.1 Head phantom

The head phantom is a PMMA shell filled with water. It is 200 mm in diameter and consists of two layers:

- Physics layer for impulse response and tomographic section thickness (slice width) measurements.
- Head Water Layer for measuring noise, CT numbers and Uniformity. The cylinder made of PE material and the cylinder made of LEXAN/Acrylic material in head water layer is used for measuring CT numbers linearity.

4.2.2 Body phantom

The body phantom is a PMMA shell filled with water. It is 300 mm in diameter. Only one layer is used for measuring noise, CT numbers and Uniformity.

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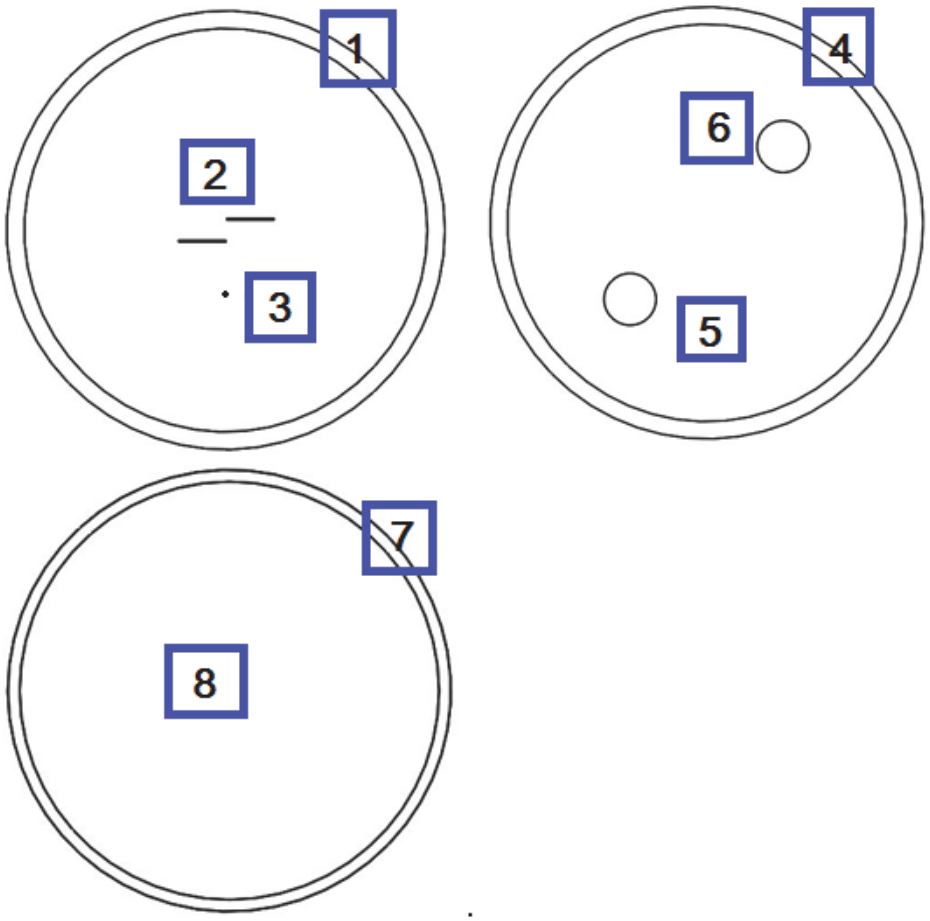
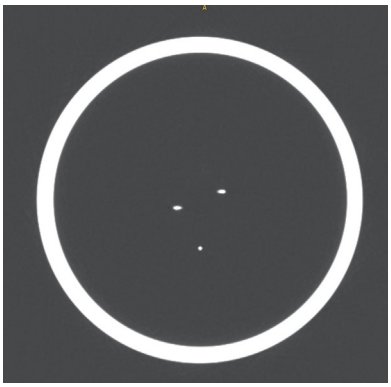
4.2.3 Phantom composition

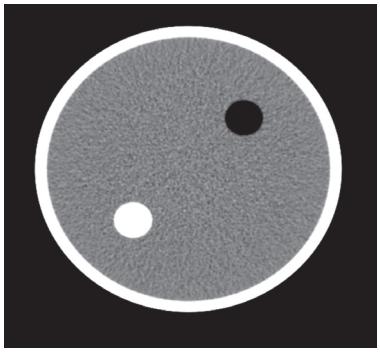


Item	Description
1	Physics Layer
2	Metal Wire for Slice Thickness Test
3	Metal Wire for Impulse Response Measurement
4	Head Water Layer
5	LEXAN/Acrylic
6	PE
7	Body Water Layer
8	Water

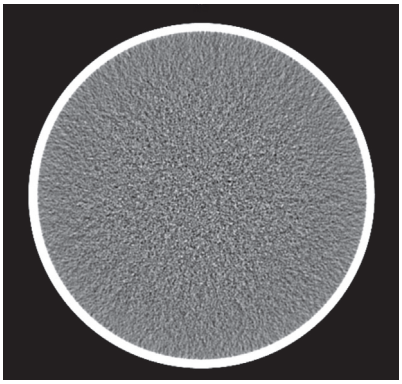
4.3 Representative quality assurance images



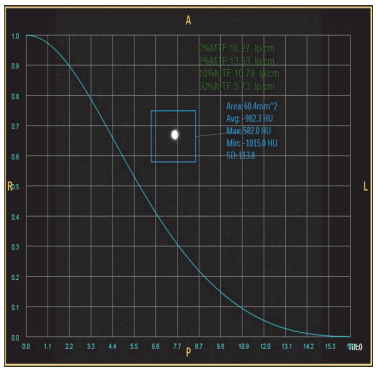
Physics layer using Head STD-QA



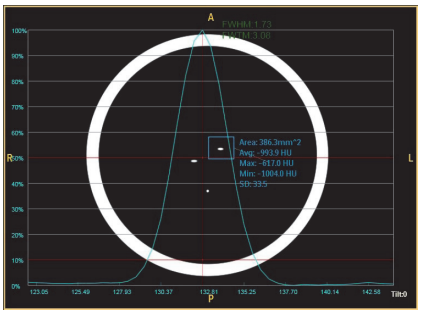
Water layer using Head STD-QA



Body layer using Head STD-QA



Impulse Response FOV= 50



Slice sensitivity profile test using head scanning protocol

4.4 Schedule of quality assurance checks

Daily checks

Daily checks should be done to ensure the best possible image quality from your scanner. The procedures for daily checks cover these areas:

- Noise-water layer of the head phantom and the body phantom.
- Uniformity-water layer of the head phantom and the body phantom.
- Low contrast resolution-the body phantom.
- MeanCT-water layer of the head phantom and the body phantom.

Monthly checks

Use your facility's recommended schedule for monthly checks. You should check at least once a month.

- Spatial resolution-the physical layer of the head phantom.
- Slice thickness-the physical layer of the head phantom.

Note

You can save QA data and recall at a later date for marking and measuring. You can save marked images on the system CD or removable disk.

Warning

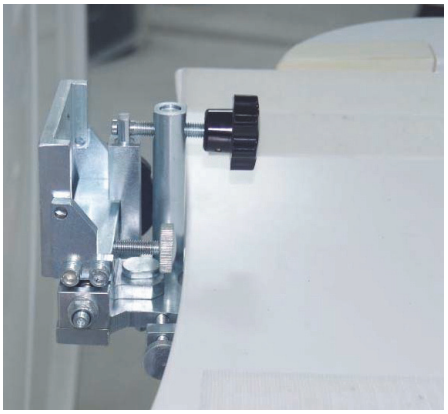
Daily and monthly checks should be done to ensure the best possible image quality and avoid patient receiving unwanted ionizing radiation.

4.4.1 Daily checks

Automatic daily image quality checks

Use the water layer of the head and body phantom for these automatic checks:

1 Install the phantom holder.



Standard Table

Bariatric Table

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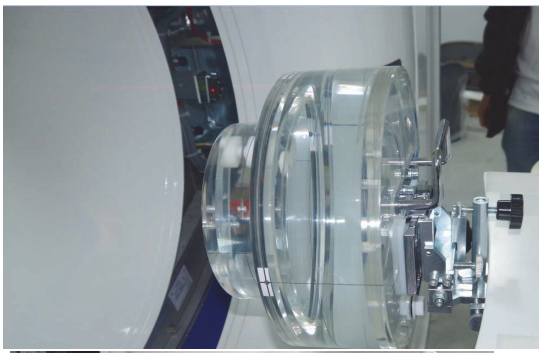
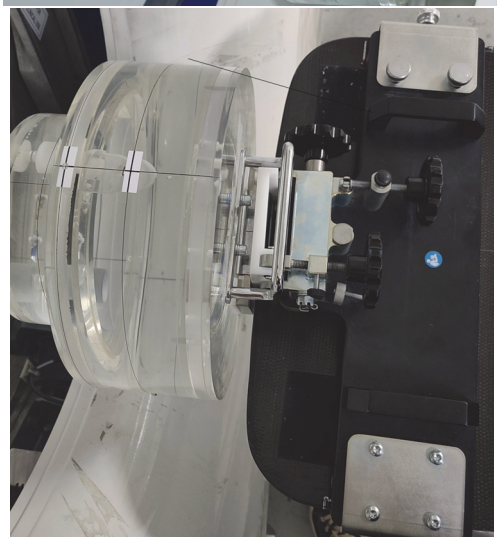
2 Position the System Phantom on the phantom holder.



Standard Table

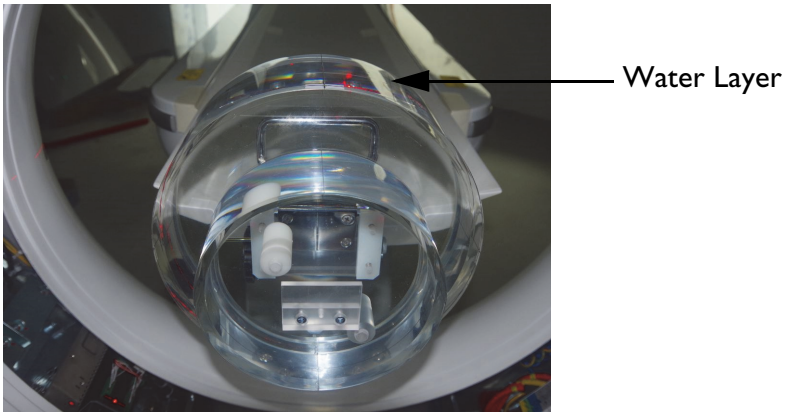


Bariatric Table

3 Open laser light.

4 Manually control the height of the System Phantom Bracket, center the laser beam on the center of the phantom.

5 Manually move the Patient Support Top so that the Laser Marker set to center of phantom.



6 Select **QA** from the **Service**. Follow the on-screen prompts for viewing and reporting the results.

Manual daily image quality checks (optional)

Use the water layer of the head and body phantom for these manual checks.

Head scan

1 Position the water layer of the head phantom in the center of the scan circle.

2 Perform a scan using the Head STD-QA 2D protocol with scan and reconstruction parameter values in the following tables:

Scan parameters	
Scan Type	Axial
Voltage (kV)	120 kV
Current (mA)	380 mA
Rot Time (s)	1.0 s
Collimation (mm)	32 x 0.625
Resolution	Standard

Reconstruction parameters	
Slice thickness (mm)	5

Reconstruction parameters	
FOV (mm)	250
Matrix	512
Filter	UB
iDose[4]	3

3 Check the resulting images to ensure they are free of artifacts.

Note

- **If the images display with artifacts, check that the water phantom is the only item contained within the scan field, and repeat the procedure.**
- **If the problem continues, contact your service specialist.**

4 Select one from these images.

5 Place around the center of the phantom image a ROI with an area of 3000 ± 1000 mm^2.

6 Check these items:

AV (Average Value)	0 ± 4.0 HU
SD (Standard Deviation)	2.05 ± 0.75

Body scans

1 Position the body phantom in the center of the scan circle.

2 Perform a scan using the Body STD-QA Helical protocol (under Abdomen) with scan and reconstruction parameter values in the following tables:

Scan parameters	
Scan Type	Helical
Voltage (kV)	120 kV
Current (mA)	293 mA
Pitch	1.0
Rot Time (s)	0.75 s
Collimation (mm)	32 x 0.625
Resolution	Standard

Reconstruction parameters	
Slice thickness (mm)	3
FOV (mm)	350
Matrix	512
Filter	B
iDose[4]	3

3 Check the resulting images to ensure they are free of artifacts.

Note

- **If the images display with artifacts, check that the body phantom is the only item contained within the scan field, and repeat the procedure.**
- **If there is still a problem, contact your service specialist.**

4 From these images, select one to conduct the remainder of the checks.

5 Check the CT number of the body water layer. It should be as follows:

AV (average)	0 ± 4 HU
SD (Standard Deviation)	11.5 ± 1.70

Warning

Screw down the phantom holder screws. The water phantom must be stably fixed on the phantom holder. If phantom holder or water phantom is not engaged securely, it can come loose causing injury to the patient.

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4.4.2 Monthly checks

Use the multi-pin layer of your phantom for monthly checks.

Note

- **If the images display with artifacts, check that the phantom is the only item contained within the scan field, and repeat the procedure.**
- **If there is still a problem, contact your service specialist.**

Automatic constancy check

During this procedure, you will move the phantom up, down and to the right or left in accordance with the on-screen prompts.

1 Position the system phantom.

2 Select **Constancy** from the Service menu.

3 Click **Next** to begin.

4 When the test is complete, click **Report** to view the results.

Head scan

1 Position the water layer of the head phantom in the center of the scan circle.

2 Perform a scan using the Head protocol with these scan and reconstruction parameter values:

Scan parameters	
Scan Type	Axial
Voltage (kV)	120 kV
Current (mA)	300 mA
Rot Time (s)	1.0 s
Collimation (mm)	32 x 0.625
Resolution	Standard

Reconstruction parameters	
Slice Thickness (mm)	10
FOV (mm)	250
Matrix	512
Filter	UB

Absorption readings

The readings for the absorption of the different pins must be as follows (values in CT numbers):

Water	0 ± 4 HU
PE	-60 ± 40 HU
LEXAN	120 ± 40 HU
Acrylic	120 ± 40 HU

Warning

All measurements should be made by positioning a small ROI well within each of the checked pins and regions. Because the phantom is comprised of a variety of materials, you may need to refer to the phantom label for specific values.

Image performance parameters

Reference IEC 60601-2-44 Clause 203.6.7.2.

									Min.	Max.
CT Number	Adult	Head	120 kV	380 mA	32*0.625	Normal	UB	FOV 250	-4 HU	4 HU
		Body	120 kV	300 mA	32*0.625	Normal	B	FOV 350	-4 HU	4 HU
			70 kV	600 mA	32*0.625	Normal	B	FOV 350	-6 HU	6 HU
			80 kV	500 mA	32*0.625	Normal	B	FOV 350	-6 HU	6 HU
			100 kV	400 mA	32*0.625	Normal	B	FOV 350	-6 HU	6 HU
			140 kV	300 mA	32*0.625	Normal	B	FOV 350	-6 HU	6 HU
	Pediatric	Head	100 kV	433 mA	32*0.625	Normal	UB	FOV 250	-4 HU	4 HU
		Body	120 kV	300 mA	32*0.625	Normal	B	FOV 250	-4 HU	4 HU
			70 kV	600 mA	32*0.625	Normal	B	FOV 250	-6 HU	6 HU
			80 kV	500 mA	32*0.625	Normal	B	FOV 250	-6 HU	6 HU
			100 kV	400 mA	32*0.625	Normal	B	FOV 250	-6 HU	6 HU
			140 kV	300 mA	32*0.625	Normal	B	FOV 250	-6 HU	6 HU

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Uniformity	Adult	Head	120 kV	380 mA	32*0.625	Normal	UB	FOV 250	-4 HU	4 HU
		Body	120 kV	300 mA	32*0.625	Normal	B	FOV 350	-8 HU	8 HU
			70 kV	600 mA	32*0.625	Normal	B	FOV 350	-8 HU	8 HU
			80 kV	500 mA	32*0.625	Normal	B	FOV 350	-8 HU	8 HU
			100 kV	400 mA	32*0.625	Normal	B	FOV 350	-8 HU	8 HU
			140 kV	300 mA	32*0.625	Normal	B	FOV 350	-8 HU	8 HU
	Pediatric	Head	100 kV	433 mA	32*0.625	Normal	UB	FOV 250	-4 HU	4 HU
		Body	120 kV	300 mA	32*0.625	Normal	B	FOV 250	-4 HU	4 HU
			70 kV	600 mA	32*0.625	Normal	B	FOV 250	-8 HU	8 HU
			80 kV	500 mA	32*0.625	Normal	B	FOV 250	-8 HU	8 HU
			100 kV	400 mA	32*0.625	Normal	B	FOV 250	-8 HU	8 HU
			140 kV	300 mA	32*0.625	Normal	B	FOV 250	-8 HU	8 HU
Noise	Adult	Head	120 kV	380 mA	32*0.625	Normal	UB	FOV 250	1.3	2.8
		Body	120 kV	300 mA	32*0.625	Normal	B	FOV 350	6.7	9
			70 kV	600 mA	32*0.625	Normal	B	FOV 350	11.2	15.0
			80 kV	500 mA	32*0.625	Normal	B	FOV 350	8.5	11.3
			100 kV	400 mA	32*0.625	Normal	B	FOV 350	5.9	7.9
			140 kV	300 mA	32*0.625	Normal	B	FOV 350	4.05	5.55
	Pediatric	Head	100 kV	433 mA	32*0.625	Normal	UB	FOV 250	3.3	4.8
		Body	120 kV	300 mA	32*0.625	Normal	B	FOV 250	2.85	4.35
			70 kV	600 mA	32*0.625	Normal	B	FOV 250	4.9	6.5
			80 kV	500 mA	32*0.625	Normal	B	FOV 250	3.75	5.25
			100 kV	400 mA	32*0.625	Normal	B	FOV 250	2.65	4.15
			140 kV	300 mA	32*0.625	Normal	B	FOV 250	1.75	3.25

MTF	Adult	Head	10% MTF	120 kV	380 mA	32*0.625	Normal	UB	FOV 50	4.67 lp/cm	6.32 lp/cm
			50% MTF	120 kV	380 mA	32*0.625	Normal	UB	FOV 50	2.72 lp/cm	3.68 lp/cm
		Body	10% MTF	120 kV	100 mA	4*0.625	High	YC	FOV 50	8.1 lp/cm	10.9 lp/cm
			50% MTF	120 kV	100 mA	4*0.625	High	YC	FOV 50	4.8 lp/cm	6.4 lp/cm
	Pediatric	Head	10% MTF	100 kV	433 mA	32*0.625	Normal	UB	FOV 50	4.67 lp/cm	6.32 lp/cm
			50% MTF	100 kV	433 mA	32*0.625	Normal	UB	FOV 50	2.63 lp/cm	3.56 lp/cm
		Body	10% MTF	120 kV	150 mA	4*0.625	High	YC	FOV 50	8.1 lp/cm	10.9 lp/cm
			50% MTF	120 kV	150 mA	4*0.625	High	YC	FOV 50	4.8 lp/cm	6.4 lp/cm

4.4.3 Advanced quality assurance checks

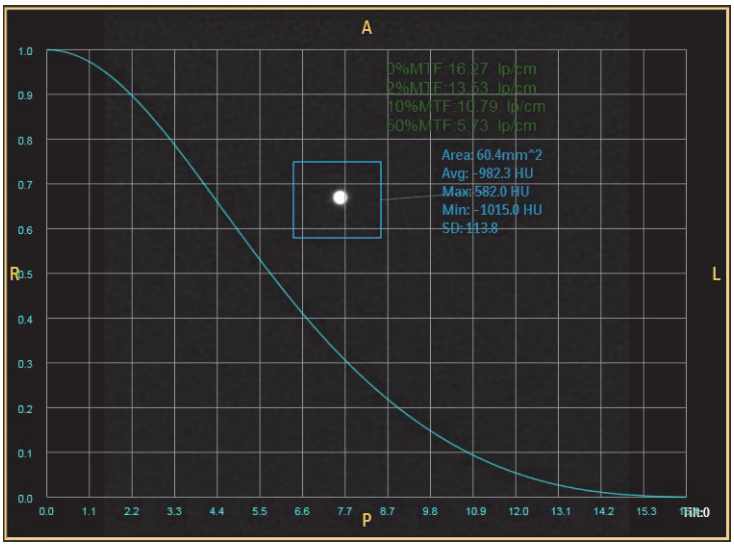
These procedures can be useful for resolving problems revealed by the daily checks. They are intended for use as advanced applications for Physicists and your service specialist.

Impulse response measurements

1. Position the physics layer of the head phantom in the center of the scan circle, taking care to make sure the 0.2 mm copper wire (in the center of the layer) is perpendicular to the scan direction.
2. Perform a scan using the Head Std (SB) protocol, with the parameter values listed in the Daily Checks section.
3. Click **Service**.
4. Select **Advanced**.
5. Click **Image Evaluation**. The system displays a window.
6. Select an image.
7. Select **Spatial Resolution**
8. Scroll through the images to access the copper wire.
9. Click **Show** to display the MTF.

Reference IEC 60601-2-44 Clause 203.6.7.2.

MTF graphs evaluation



Tomographic section thickness (slice width) measurements

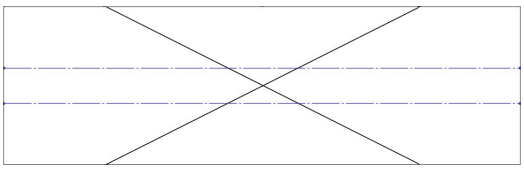
Reference IEC 60601-2-44 Clause 203.6.7.2.

This function is used to check the Slice Thickness (width) of the scanner during monthly tests. Available protocols depend on your scanner type.

1 Install the system phantom used for slice width measurements.

2 Perform a lateral scan.

3 Plan an axial slice on the image as shown in the example below. The dotted line indicates the planned scan:



If it is necessary, adjust phantom holder angle to ensure axis of the phantom is perpendicular to the rotating plane.

4 Adjust In/Out position of phantom to obtain better precision.

5 Perform a scan using the Brain STD-QA protocol, with the parameter values listed in the Daily Checks section.

6 Click **Service**.

7 Select **Advanced**.

8 Click **Image Evaluation**. The system displays a window.

9 Select an image.

10 Select **Slice Thickness**.

11 Draw ROI in the area of copper wire.

12 Click **Evaluate** to measure the thickness

13 Repeat the procedure for these slice thicknesses and tolerances:

Slice thickness	FWHM value
0.625 mm	0.625 mm ± 0.5 mm
0.67 mm	0.67 mm ± 0.5 mm
0.8 mm	0.8 mm ± 0.5 mm
0.9 mm	0.9 mm ± 0.5 mm
1.0 mm	1.0 mm ± 0.5 mm
1.25 mm	1.25 mm ± 0.625 mm
1.5 mm	1.5 mm ± 0.75 mm
2.0 mm	2.0 mm ± 1.0 mm
2.5 mm	2.5 mm ± 1.0 mm
3 mm	3 mm ± 1.0 mm
3.5 mm	3.5 mm ± 1.0 mm
4 mm	4 mm ± 1.0 mm
4.5 mm	4.5 mm ± 1.0 mm
5.0 mm	5.0 mm ± 1.0 mm
10.0 mm	10.0 mm ± 1.0 mm

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5 User information

5.1 Overview

The following chapter contains information about preventative maintenance, physics details, dose analysis, and system specifications.

Be sure to familiarize yourself with this information before conducting any scan procedures.

5.2 Technique factors-maximum deviations

5.2.1 Peak x-ray tube voltage

Reference IEC 60601-2-44 Clause 201.12.1.101.

The peak X-ray voltage displays on the console. The actual X-ray voltage during scan is within ±10% of the displayed value, which is in the range of 70 to 140 kV.

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

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5.2.2 Tube current

Reference IEC 60601-2-44 Clause 201.12.1.101.

The tube current displays on the console. The actual tube current during scan is within ±20% of the displayed value, which is in the range of 5 to 667mA.

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

5.2.3 Scan Time

The scan time displays on the console. The actual scan time during scan is within ±10% of the displayed value.

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

5.2.4 Tube current-exposure time product

The actual current-exposure time product (in mAs) during a scan is within -28% to 32% of the value displayed on the console. The tube current-exposure time product is measured on a equipment, which is calibrated during the manufacturing process.

5.3 Gantry laser localizer

The Incisive CT gantry system contains two internal laser localizers, located on the top left and right side of the gantry, perpendicular to Z direction. The Laser light button turns the lasers on and off.

When the lasers are on, the slice plane is marked by a long, thin light-beam. The laser light field indicates the central slice of the entire scan range. The center of the gantry opening is marked by shorter and thicker perpendicular beams on the top and sides of the body.

Note

Reference IEC 60601-2-44 Clause 203.115.

- **The precision of the internal laser localizer is ± 2mm.**
- **The accuracy of the location of the isocentre with respect to the laser markers marking the sagittal positioning is ±14.5mm and marking the coronal positioning is ±12mm.**

Warning

- **Laser radiation.**
- **Do not stare into laser beam when you use of optical instruments, such as eyeglasses with large diopter or mirrors.**
- **1M laser production.**

5.4 Preventive maintenance

Reference IEC 60601-1 Clause 7.9.2.13.

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:

- Anode voltage
- Cathode voltage
- Emission current
- Exposure time

5.4.1 Cleaning and Disinfection of the System

Reference IEC 60601-1 Clause 7.9.2.12.

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.**
- **Follow the cleaning/disinfection product manufacturer's instructions for cleaning and disinfection.**

Warning

Use of inappropriate cleaning materials can cause skin irritation, allergic reaction and poisoning.

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
- 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) could 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.**

- **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, to avoid risk of electric shock.
- 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.
- 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.

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5.5 X-Ray system specifications

5.5.1 X-ray tube

Reference IEC 60601-2-44 Clause 201.7.2.15.

- **Leakage radiation factor**: 140kV and 43 mA.
- **Filtration**: Minimum tube housing filtration is 1.1mm aluminum using a 1.1 mm filter plate at 75 kV.
- **Maximum Heat Dissipation**: 6.6 kW.

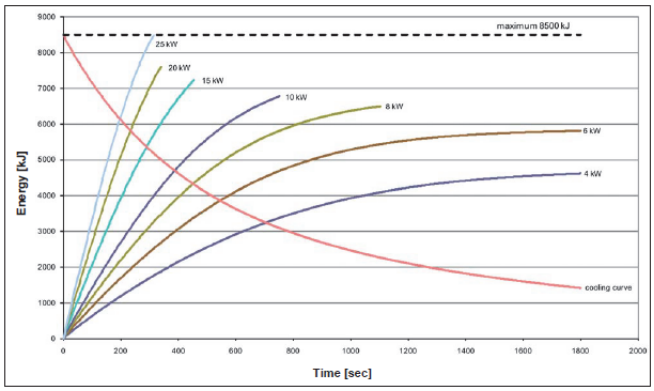
Continuous anode input power

Reference IEC 60601-2-44 Clause 203.12.3.

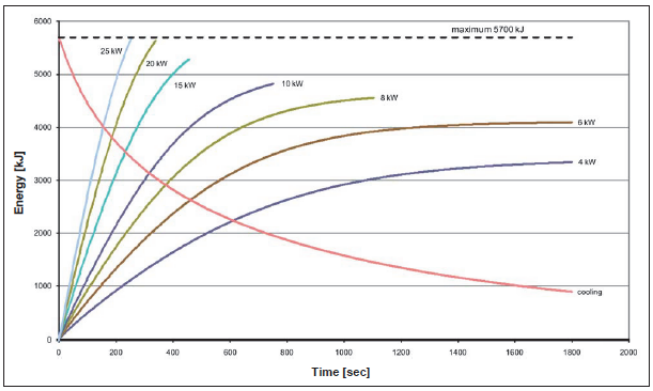
Continuous anode input power: 5.5 kW

kV	mA
70	5 through 667
80	5 through 667
100	5 through 667
120	5 through 667
140	5 through 571

Cooling curve and Power rating

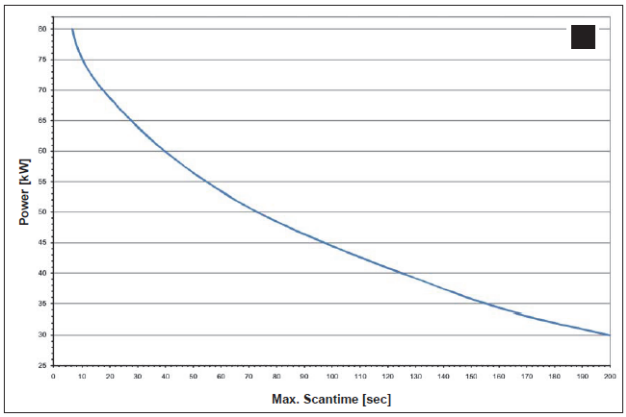


The heating and cooling curves include the heat capacity of the cooling unit. They show the maximum heat content of the X-ray tube assembly.

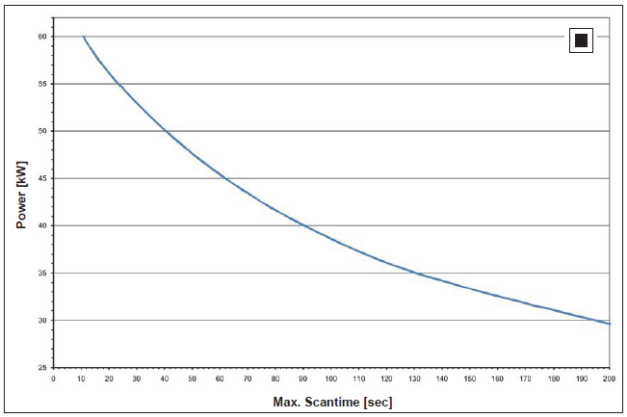


The anode heating and cooling curves show the maximum heat content of the X-ray tube.

Power rating chart



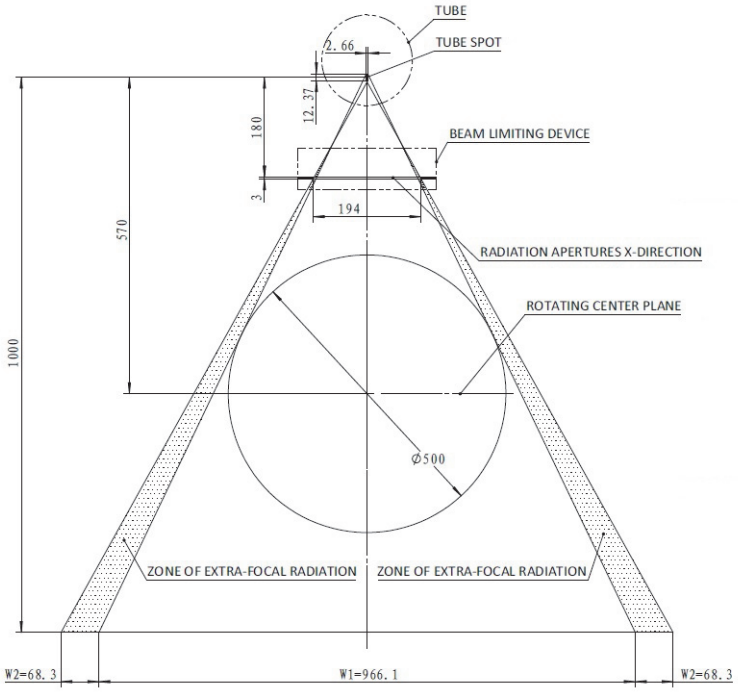
Large focus rating chart



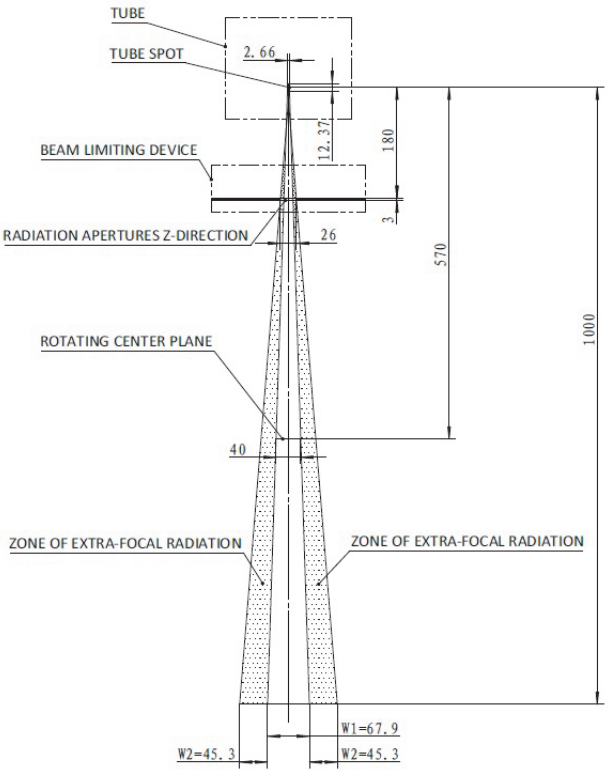
Small focus rating chart

5.5.2 Focal spot and dimensional data

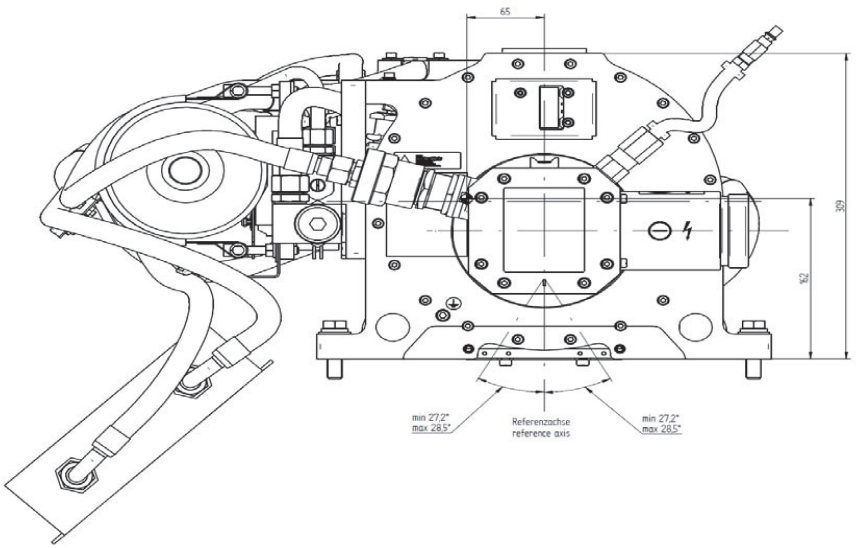
Zone of extra-focal radiation (X-Y plane, mm)



Zone of extra-focal radiation (Z-Y plane, mm)



General dimensional data (mm)



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5.5.3 X-ray power supply

- **Line Voltage and Regulation**: Power supply input voltage is 3 Phase, 380/400 VAC ±10%, nominal line-to-line, 50/60 Hz.
- **Line Current**: Maximum line current is 200 A/phase at 400 V input voltage, output the maximum voltage 140 kV(571 mA), maximum current 667 mA (120 kV).
- **Measurement Criteria**: Peak x-ray tube voltage is calculated by averaging samples that are 90% of the peak value. Time starts the first time the dose rate waveform reaches 50% of peak, and ends the last time it drops below 50%. Intermediate readings are time since start trig; mA Measurement: Measure the effective values after the radiation is on for over 1s (stabilization time >=20ms)

5.5.4 Generator rating and duty cycle

- Generator: Octavia
- Duty cycle: 4s scan time, 0.67% duty cycle @80kW and 60s scan time, 10% duty cycle @40kW
- Maximum input line voltage: 3 Phase, 380/400 VAC ± 10%, 50/60 Hz
- Maximum output voltage: 140 kV
- Maximum output current: 667 mA
- Maximum output power: 80 kW

5.5.5 Leakage radiation

The leakage radiation of the tube housing assembly together with the beam limiting device is less than 0.88mGy/h from a distance of 1 meter to the focal spot at 140kV and 43 mA.

5.6 CT mean and standard deviation

You can view information for an ROI using the ROI tools in the common tools box. The system displays the CT number which is calculated from the average CT value of all the pixels in the ROI. Standard deviation (SD) is calculated from the CT value of all the pixels in the ROI.

Contrast scale = $\frac{\mu_X - \mu_W}{(CT)_X - (CT)_W}$

Where:

μ_w = Linear attenuation coefficient of water

μ_x = Linear attenuation coefficient of material of interest

$(CT)_w$ = CT number of water

$(CT)_x$ = CT number of material of interest

Note

Percent noise: The SD as displayed on the screen is divided by [AV + 1000] and multiplied by 100 to obtain the percent noise.

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5.7 Dose and imaging information

5.7.1 Filtration information

Reference IEC 60601-2-44 Clause 203.7.3.

Tube inherent filtration	1.1 mm Al 75kV
Slab filter outside the tube	1.0 mm Ti, equivalent to 3.63 mm Al 75 kV
Wedge filter outside the tube	The thinnest in the mid is 2.11 mm Al
Minimum permanently filtration	6.84 mm Al 75 kV
Collimation total filtration	5.74 mm Al 75 kV

5.7.2 Half value layer

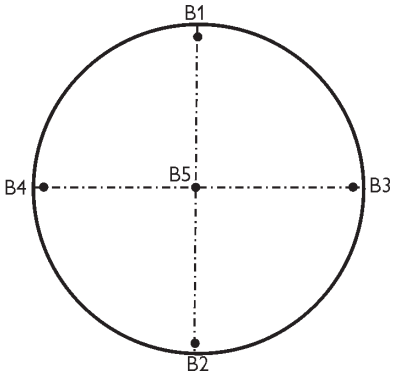
Reference IEC 60601-2-44 Clause 203.7.1.

Half value relative to voltage	
	16 x 0.625 mm
70 kV	Hvl 5.46 mm Al
80 kV	Hvl 6.20 mm Al
100 kV	Hvl 7.40 mm Al
120 kV	Hvl 8.33 mm Al
140 kV	Hvl 9.11 mm Al

5.7.3 Dosimetry Phantoms and measurement methods

Reference IEC 60601-2-44 Clause 203.5.2.4.2 and 203.108.

- The phantom is PMMA.
- The diameter of head phantom is 16 cm. Head phantom is placed on the head holder.
- The diameter of body phantom is 32 cm. Body phantom is placed on patient table.
- The distance between the hole center of B1,B2,B3, and B4, to the outer surface is 10 mm.
- The length of the dosimetry phantom is 145 mm.



5.7.4 CTDI and dose analysis information

Reference IEC 60601-2-44 Clause 203.109, and 201.3.212.

The table below displays typical CT conditions of operation for dosage testing.

Voltage	120 kV
Slice Thickness	32 x 0.625 mm
Scan Time	1 s
mA	300 mA

$$CTDI_{100} = \int_{-50\,mm}^{50\,mm} \frac{D(z)}{N \times T} dz$$

$$CTDI_{W} = \frac{1}{3} CTDI_{100} \text{ (center)} + \frac{2}{3} CTDI_{100} \text{ (peripheral)}$$

For axial scanning:

$$CTDI_{vol} = \frac{N \times T}{\Delta d} CTDI_{W}$$

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.

Reference IEC 60601-1-3 Clause 6.4.5.

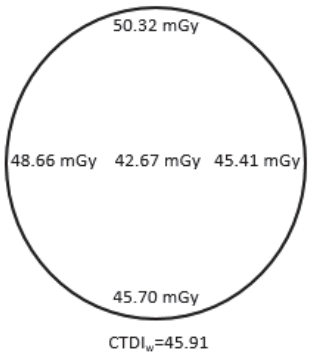
Maximum deviation from the values shown below is ± 20% or 1mGy. (take the larger one as standard).

CTDIw of CTDI Head= 45.9 mGy.

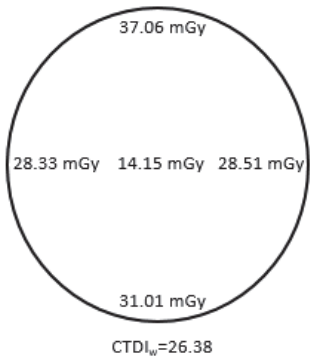
CTDIw of CTDI Body= 25.54 mGy.

The maximum deviation from the reported CTDIw for 2 x 0.625 is ± 20%.

CTDI Head



CTDI Body



The maximum dose is delivered at the 12 o'clock position on each figure above. The following tables show dosage value (CTDI) of the phantom in different positions (120 kV, 300 mA, 1s, 32 x 0.625 mm) under typical parameter conditions. All measurements are in mGy.

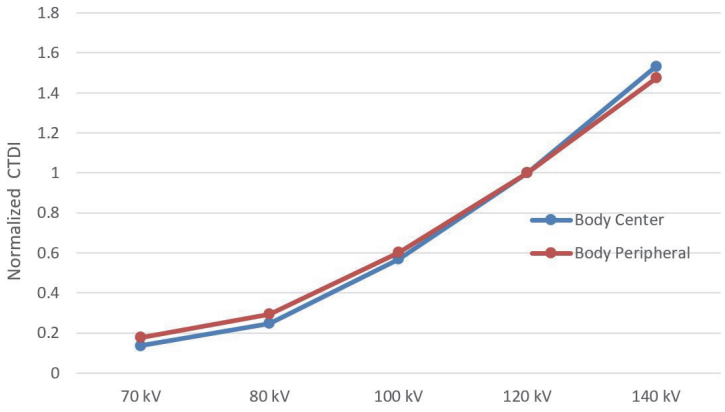
$CTDI_{100}$	B1	B2	B3	B4	B5	CTDI peripheral	CTDIw
Head	50.32	45.70	45.41	48.66	42.67	47.52	45.91
Body	37.06	31.01	28.51	28.33	14.45	32.33	26.38

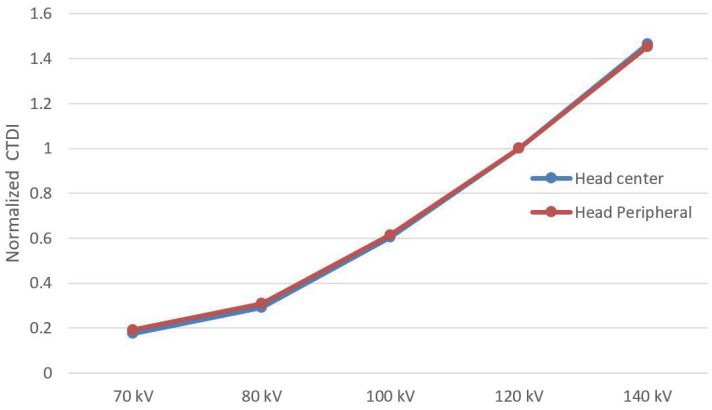
Reference IEC 60601-2-44 Clause 203.109.1.

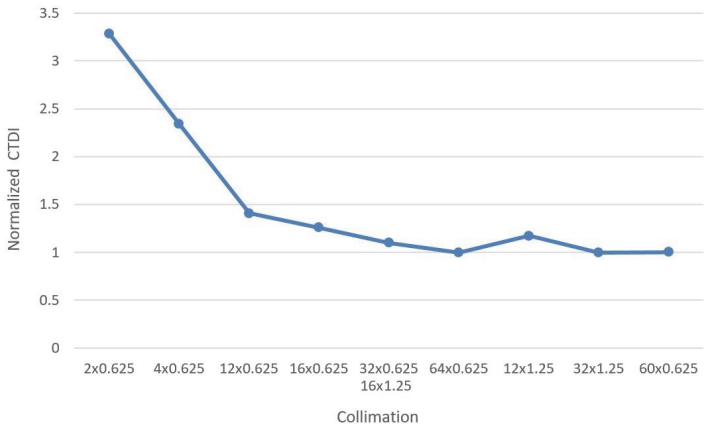
The typical condition is 120 kV, 300 mA, 1 s, 32x0.625 mm, the figures below show radiation relationship among different kV, collimation, mA, and rotation time. Only one parameter can be modified each time. The configuration of other parameters is typical value, all the results are normalized by typical condition. The figures below are the normalized central and peripheral CTDI plots for body and head.

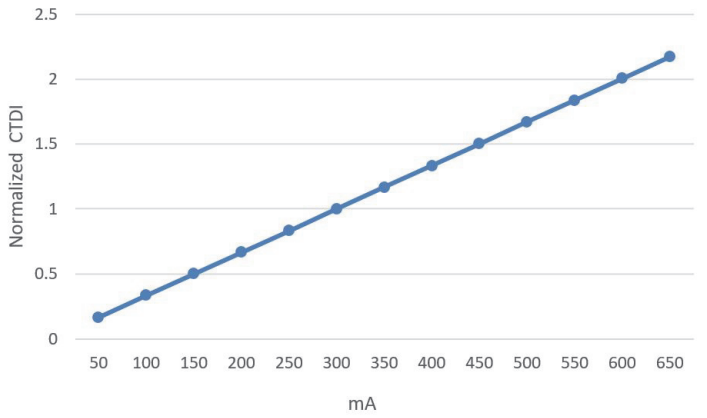
Note

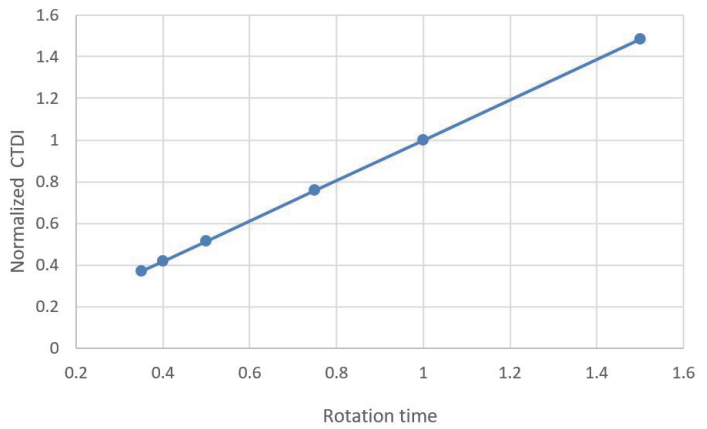
The normalized central and peripheral CTDI plots are same, except kV plot.











The table shows normalized maximum CTDI for head and body.

	$CTDI_{100}$
Maximum $CTDI_{100}$ at 70kV	0.18
Maximum $CTDI_{100}$ at 120kV	1.00
Maximum $CTDI_{100}$ at 140kV	1.47

Reference IEC 60601-2-44 Clause 203.109.2.

	Voltage (kV)	Thickness (mm)	$CTDI_{FREEAIR}$ (50 mA, 1s)
Head	120 kV	64 x 0.625	8.53
	120 kV	32 x 0.625	9.42
Body	70 kV	64 x 0.625	1.76
	80 kV	64 x 0.625	2.75
	100 kV	64 x 0.625	5.29
	120 kV	2 x 0.625	26.86
	120 kV	4 x 0.625	19.40
	120 kV	12 x 0.625	11.85
	120 kV	16 x 0.625	10.71
	120 kV	16 x 1.25	9.42
	120 kV	32 x 0.625	9.42
	120 kV	64 x 0.625	8.53
	120 kV	12 x 1.25	10.04
	120 kV	32 x 1.25	8.53
	140 kV	64 x 0.625	12.53

	Voltage (kV)	Thickness (mm)	$CTDI_{FREEAIR}$ (300mA, 1s)
Head	120 kV	64 x 0.625	51.11
	120 kV	32 x 0.625	56.32

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	Voltage (kV)	Thickness (mm)	$CTDI_{FREEAIR}$ (300mA, 1s)
Body	70 kV	64 x 0.625	10.59
	80 kV	64 x 0.625	16.47
	100 kV	64 x 0.625	31.76
	120 kV	2 x 0.625	161.38
	120 kV	4 x 0.625	116.51
	120 kV	12 x 0.625	71.32
	120 kV	16 x 0.625	64.12
	120 kV	16 x 1.25	56.32
	120 kV	32 x 0.625	56.32
	120 kV	64 x 0.625	51.05
	120 kV	12 x 1.25	60.10
	120 kV	32 x 1.25	51.05
	140 kV	64 x 0.625	74.20

For $CTDI_{FREEAIR}$, each value is within ± 10 percent of the mean of a set of ten measurements.

Maximum $CTDI_{100}$(peripheral) under conditions of operation

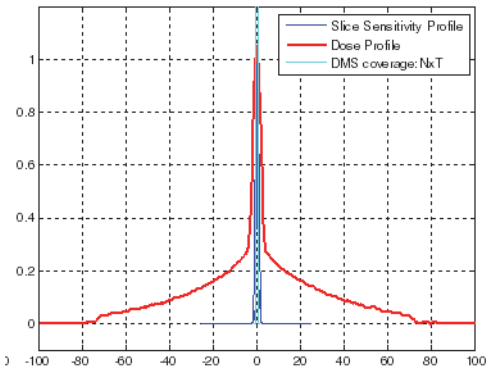
Conditions	Maximum $CTDI_{100}$ (peripheral)
Helical\ Brain\ 140 kV\571 mA\ Rotation time=1 s\Collimation=32 x 0.625\ Pitch=0.2	675.72 mGy

5.7.5 Dose and sensitivity curves

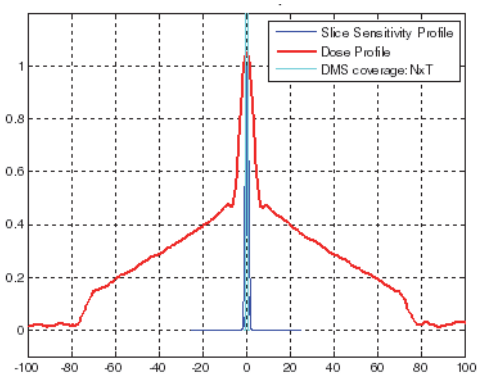
Dose profile and $CTDI_{100}$ SSP

2 x 0.625 mm Slice

Head



Body



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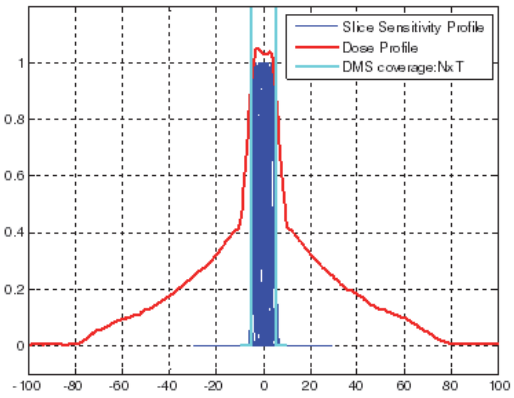
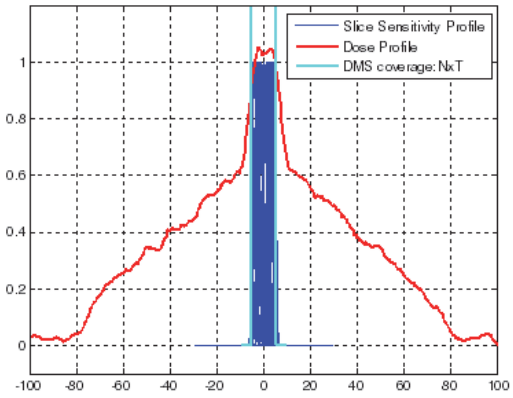
16 x 0.625mm Slice

Head

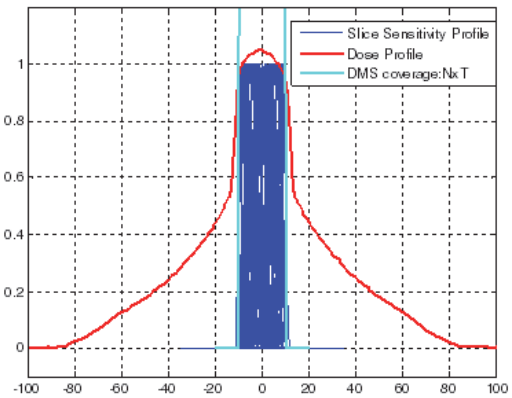


Body

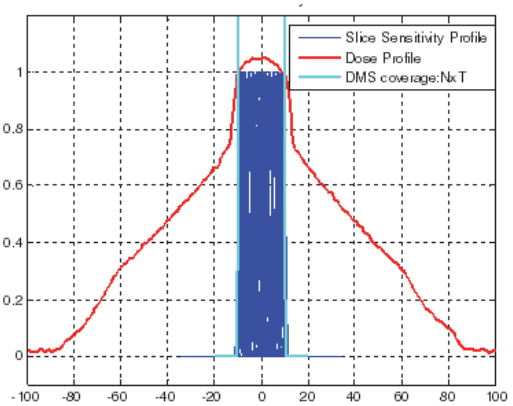


16 x 1.25mm Slice

Head

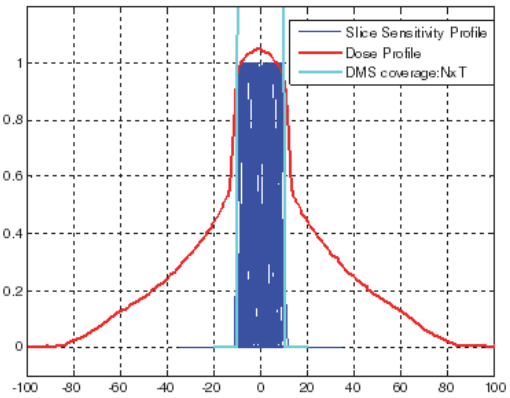


Body

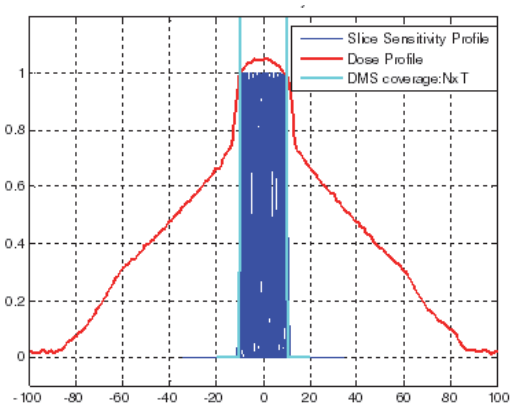


32 x 0.625mm Slice

Head

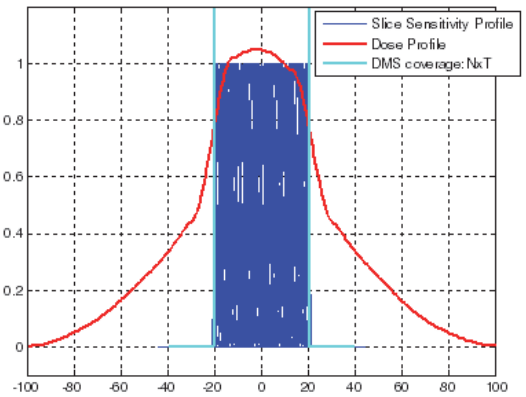


Body

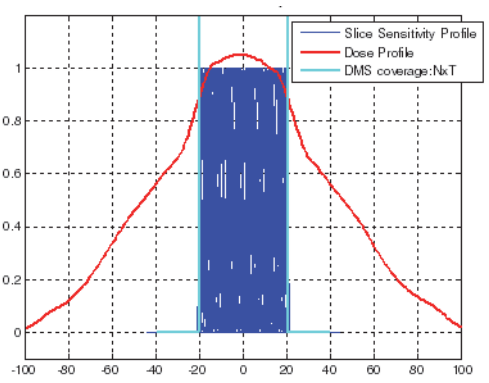


64 x 0.625 mm Slice

Head



Body



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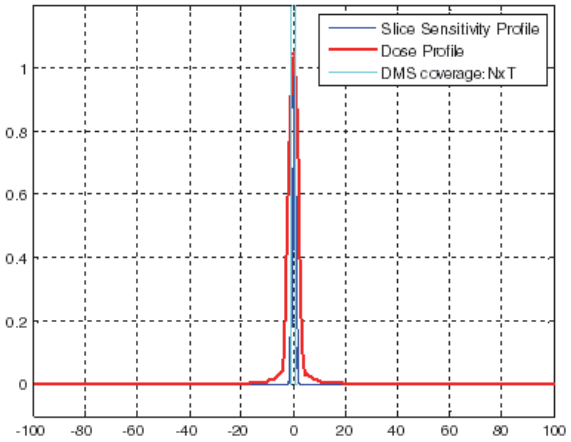
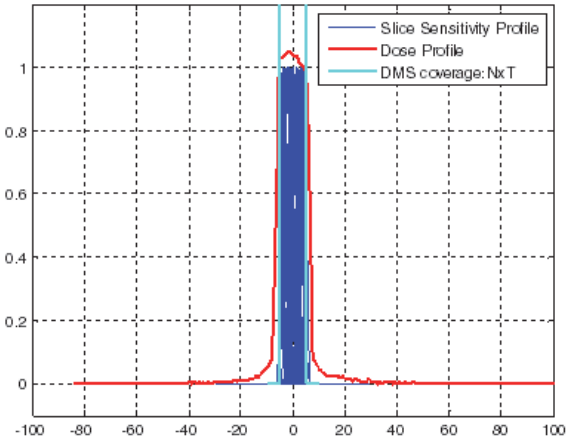
Dose profile and $CTDI_{FREEAIR}$ SSP

Reference IEC 60601-2-44 Clause 203.110 and 203.111.

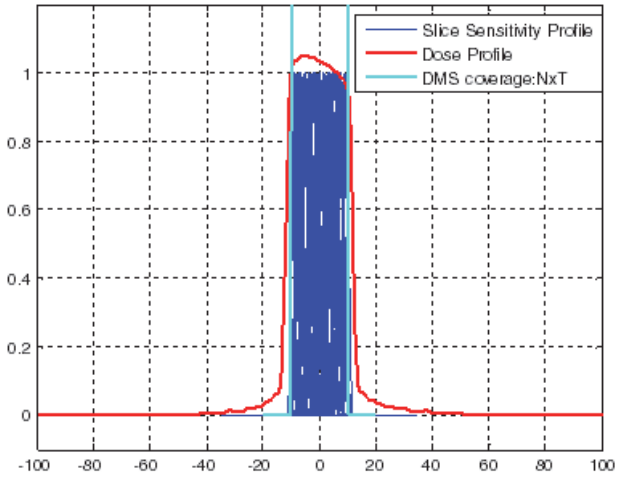
2 x 0.625 mm Slice



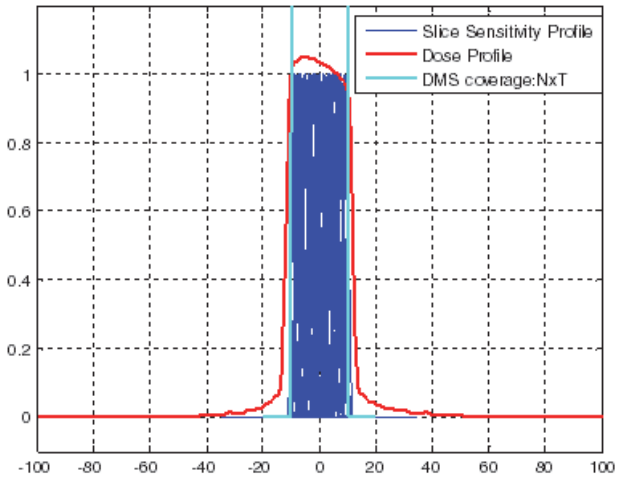
16 x 0.625 mm Slice



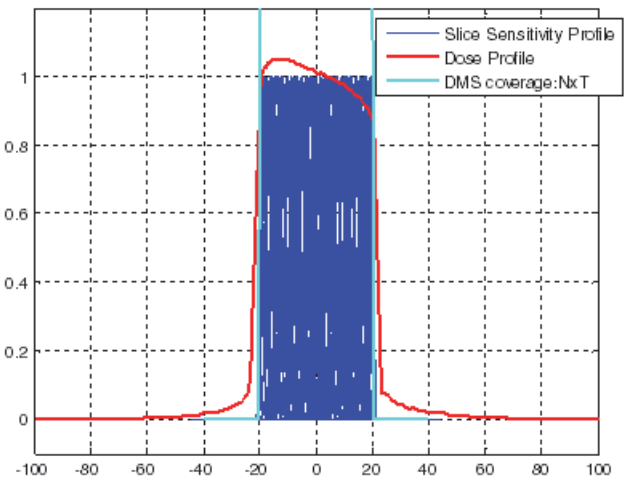
16 x 1.25 mm Slice



32 x 0.625 mm Slice



64 x 0.625 mm Slice



5.8 Geometric efficiency in the Z direction

Reference IEC 60601-2-44 Clause 203.113.

Collimation	Geometric Efficiency (percent)
2 x 0.625	27.19
4 x 0.625	38.07
12 x 0.625	63.46
16 x 0.625	70.15
16 x 1.25	80.44
32 x 0.625	80.44
64 x 0.625	88.72
12 x 1.25	75.42
32 x 1.25	88.72

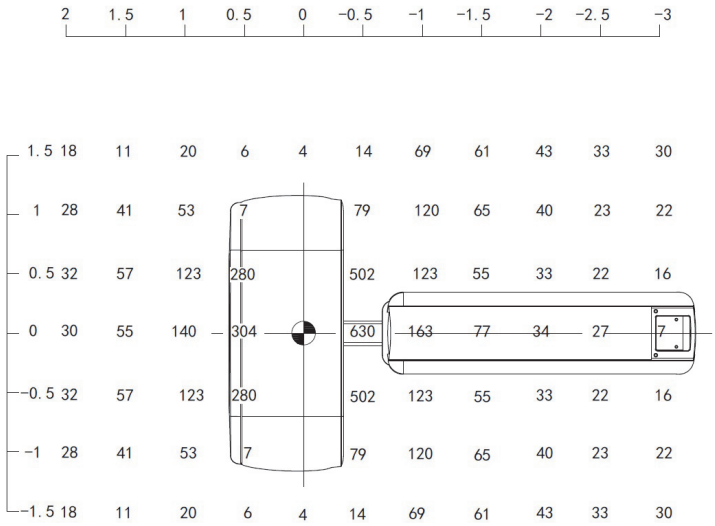
5.9 IEC stray radiation dose map

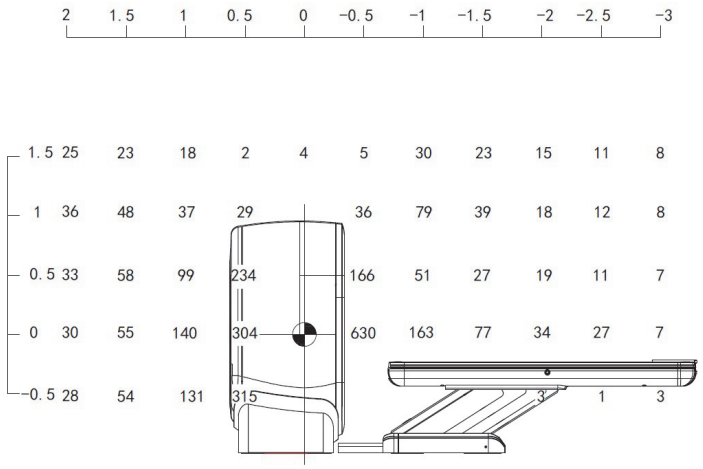
Reference IEC 60601-2-44 Clause 203.13.2.

Only qualified personnel can evaluate shielding in the scan room. These factors must be considered:

- device position
- scan workload
- materials of walls, floor, ceiling, doors and windows

The image below describes the radiation level in the process of scanning a 320 mm (Body Part) polyethylene phantom in the scanning room.





- Scan Condition: 140 kV, 571 x 1.5 mAs
- Proportional Scale: 0.5m
- Dosage Unit: nGy/1 mAs

5.10 Size Specific Dose Estimate (SSDE)

Size Specific Dose Estimate (SSDE)

The CTDIvol 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 CTDIvol for a selected Exam Card, therefore, does not represent the absorbed dose to a patient. For infants, the CTDIvol underestimates the absorbed dose to the scan volume by up to a factor of 3. Conversely, the CTDIvol for large patients overestimates absorbed dose to the scan volume; for very large patients CTDIvol 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 CTDIvol 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 CTDIvol 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 CTDIvol for the Exam Card; for these patients, SSDE values are higher than CTDIvol 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 CTDIvol; for these patients, SSDE values are lower than CTDIvol values. For adult head scans, the conversion factors are usually closer to 1 such that SSDE and CTDIvol 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 CTDIvol 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.

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.

The data used to determine the SSDE conversion factor covered PATIENT diameters ranging from approximately 8 cm to 40 cm. Because the data exhibited smooth behaviour, SSDE is calculated and displayed for PATIENT diameters outside of this range by extrapolation of the SSDE conversion factors.

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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%.

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.

Range of scan projection radiograph exceeded

If the actual scan length exceeds the range of the scan projection radiograph, the manufacturer shall estimate WEB based on attenuation data acquired within the region of the scan projection radiograph, in the majority of clinical cases, the additional uncertainty in the SSDE is not expected to exceed 5 %.

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%.

Wed measurement conditions

Generation of $D_{W,REF}(z)$ for the water PHANTOMS

		Large water phantom	Small water phantom
CT conditions of operation	KVp	120	120
	mAs	200	300
	Pitch	1	0.4
	Rotation Speed	0.75	0.5
	Collimation	32*0.625	32*0.625
	Resolution	Standard	Standard
Reconstruction parameters	Field of view [mm]	350	250
	Reconstruction filter	B	UB
	Slice width [mm]	3	5

Generation of $D_{W,IMP}$ for the water PHANTOMS

	Large water phantom	Small water phantom
X-Ray tube voltage [kVp]	120	120
X-Ray tube current [mA]	30	30
X-Ray tube position	Frontal	Lateral

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Generation of $D_{W,REF}(z)$ for the anthropomorphic PHANTOM

		Torso	Head
CT conditions of operation	kVp	120	120
	mAs	200	300
	Pitch	1	0.4
	Rotation Speed	0.75	0.5
	Collimation	32*0.625	32*0.625
	Resolution	Standard	Standard
Reconstruction parameters	Field of view [mm]	350	250
	Reconstruction filter	B	UB
	Slice width [mm]	3	5

Generation of $D_{W,IMP}(z)$ for the anthropomorphic PHANTOM

	Torso	Head
X-Ray tube voltage [kVp]	120	120
X-Ray tube current [mA]	30	30
X-Ray tube position	Frontal	Lateral

The anthropomorphic phantom model is PH-2B manufactured by Kyoto Kagaku.

5.11 Conditions to Achieve 1000 mGy CTDIvol (Peripheral)

It is impossible to achieve 1000 mGy in a single axial scan on the Incisive CT. 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.

5.11.1 Adult and Infant Head

The maximum peripheral CTDI is seen at the 12:00 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 kVp, collimation, rotation time, and mAs are different with the listed here, the number of rotations to exceed 1000 mGy will be changed proportionally, please refer normalized CTDI plots in **CTDI and dose analysis information**, on page 5-13.

Brain Perfusion Non-Jog

kVp	Collimation	Rotation Time	mAs	CTDI (12:00)	Number of Axial scans to exceed 1000 mGy
120	32x0.625	1s	667	112.1	9

Brain Axial

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

kVp	Collimation	Rotation Time	mAs	CTDI (12:00)	Number of Axial scans to exceed 1000 mGy
120	16x0.625	1s	667	129.1	8

Axial HR Head

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

kVp	Collimation	Rotation Time	mAs	CTDI (12:00)	Number of Axial scans to exceed 1000 mGy
120	2x0.625	0.5s	333	170.3	6

Adult and Infant Mode

The maximum peripheral CTDI is seen at the 12:00 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 kVp, collimation, rotation time, and mAs are different with the listed here, the number of rotations to exceed 1000 mGy will be changed proportionally, please refer normalized CTDI plots in **CTDI and dose analysis information**, on page 5-13.

Body Perfusion

kVp	Collimation	Rotation Time	mAs	CTDI (12:00)	Number of Axial scans to exceed 1000 mGy
120	32x0.625	1s	667	82.9	13

CCT Mode - 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:

kVp	Collimation	Rotation Time	mAs	CTDI (12:00)	Number of Axial scans to exceed 1000 mGy
120	16x0.625	0.75s	270	38.7	26

CCT Fluoro

CCT Fluoro is a continuous scan mode, and displays CTDI rate in mGy per second (mGy/s). 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	Collimation	Rotation Time	mAs	CTDI rate (12:00 o'clock position)	Number of scan seconds to exceed 1000 mGy
120	4x0.625	0.4s	133	89	12

High Resolution Chest

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

kVp	Collimation	Rotation Time	mAs	CTDI (12:00)	Number of Axial scans to exceed 1000 mGy
120	2x0.625	1s	667	252.5	4

Cardiac Step & Shoot

The maximum peripheral CTDI is seen at the 12:00 peripheral position. Cardiac scans can be done with Step & Shoot mode, rescanning the same location as many as three times. Due to the fast rotation speeds, and scanning only 240 degrees for an axial scan, it is impossible to achieve very high mAs values for these scans. Using the maximum mAs values for cardiac mode gives the following results. The number of rotations to exceed 1000 mGy are all much higher than three.

kVp	Collimation	Rotation Time	mAs	CTDI (12:00)	Number of Axial scans to exceed 1000 mGy
120	64x0.625	0.35s	250	27.8	36
120	32x0.625	0.35s	250	31.1	33

Note

Off-center Body Trauma is only available in helical scan mode.

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6 Recycling Passport

Incisive CT Scanner System

Product Name	Incisive CT Scanner System	
Total Weight (in Kg)	2525	
Producer/Manufacturer	Name Company:	Philips Healthcare (Suzhou) Co., Ltd
	Address:	No. 258, ZhongYuan Road, Suzhou Industrial Park Suzhou, Jiangsu Province
	Zip Code:	215024
	Country:	People's Republic of China

Recycle Info	Items	Location
Special attention 	Spring loaded cover	Figure 2 (7), Figure 5 (3), Figure 6 (2), Figure 7 (2)
	Rotor unbalanced when a component is removed	Figure 2 (1)
	Actuators: Unstable when removed, possible rotation of frame.	Figure5 (1), Figure56 (1), Figure7 (1)
Fluids/Gases 	**Items**	**Location**
	Hydrocarbon oil in X-ray tube	Figure 2 (3)
	Hydrocarbon oil in HV generators	Figure 2 (2)
Batteries  **To be removed**	**Type**	**Location**
	NiCd Batteries in console computer	Figure 8 (2)
Hazardous  **To be removed**	**Substances**	**Location**
	Printed circuit boards	Figure 1 (1) (2), Figure2 (4) , Figure2 (5), Figure2 (6), Figure3(1),Figure4 (1), Figure5 (2), Figure6 (3), Figure7 (3), Figure8 (1),
	Collimator-Lead	Figure 2 (4)

Show locations of materials mentioned on the previous sheet.

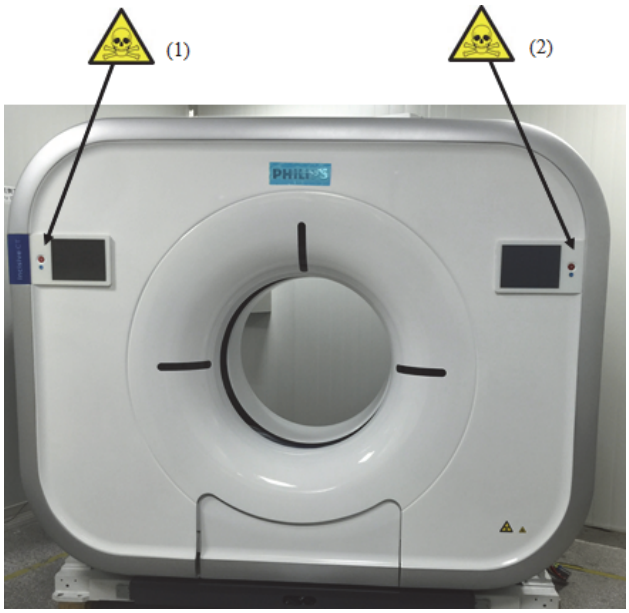

Figure 1: Front View of Gantry with Cover on

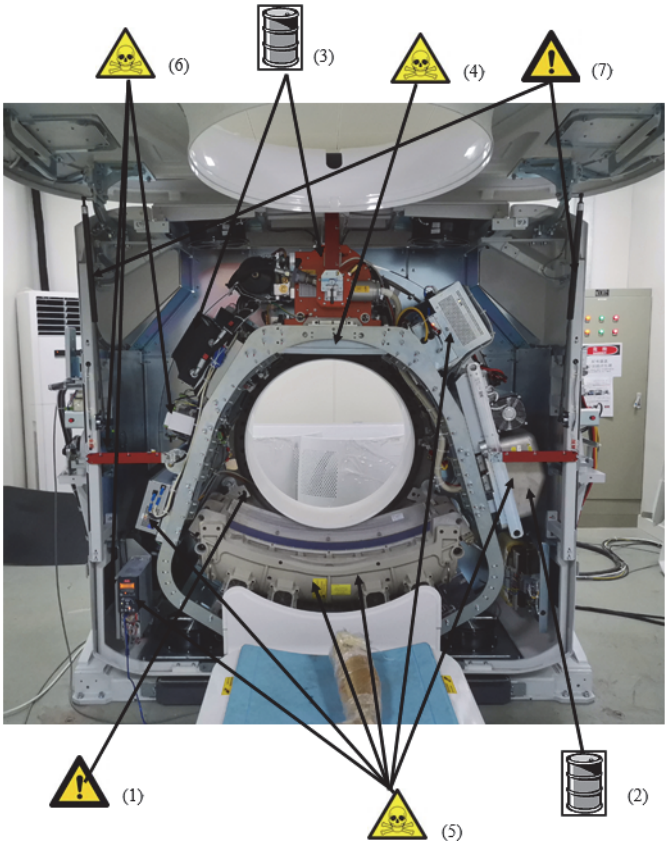

Figure 2: Front View of Gantry with Cover Removed

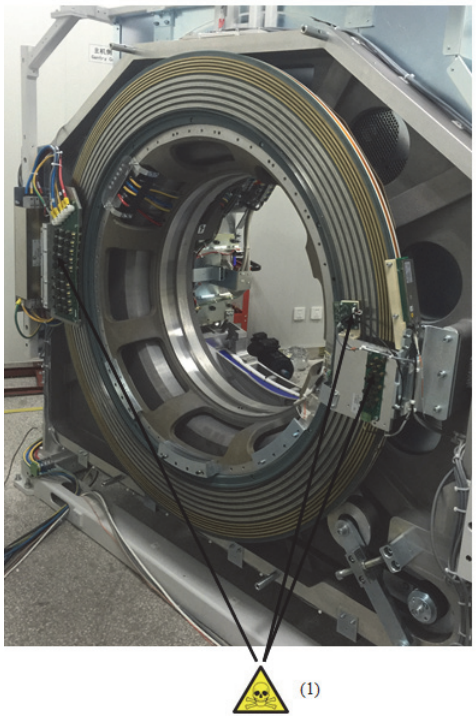

Figure 3: Rear View of Gantry with Cover Removed

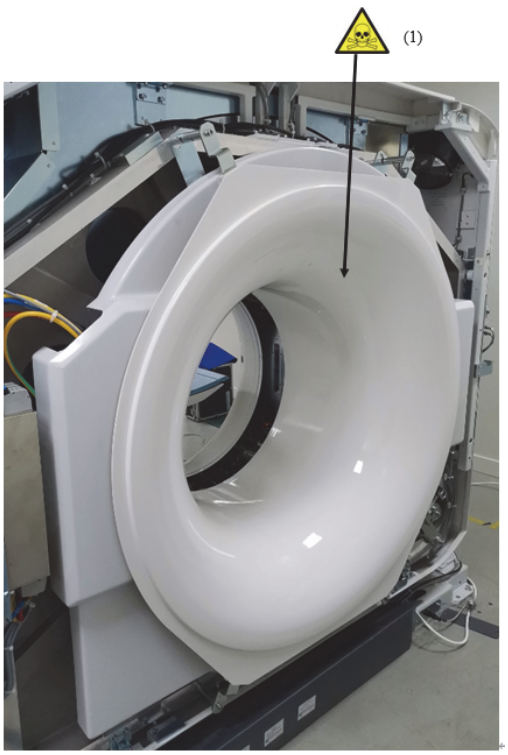

Figure 4: Left Side View of Gantry with Cover Removed

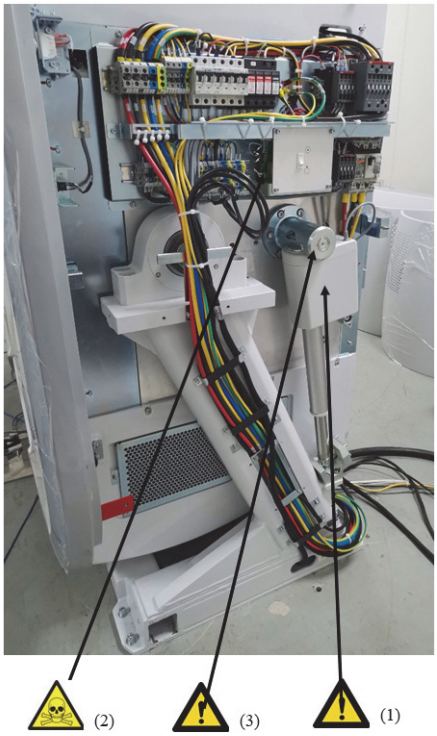

Figure 5: Right Side View of Gantry with Cover Removed

Figure 6: Left Side View of Gantry with Cover Removed

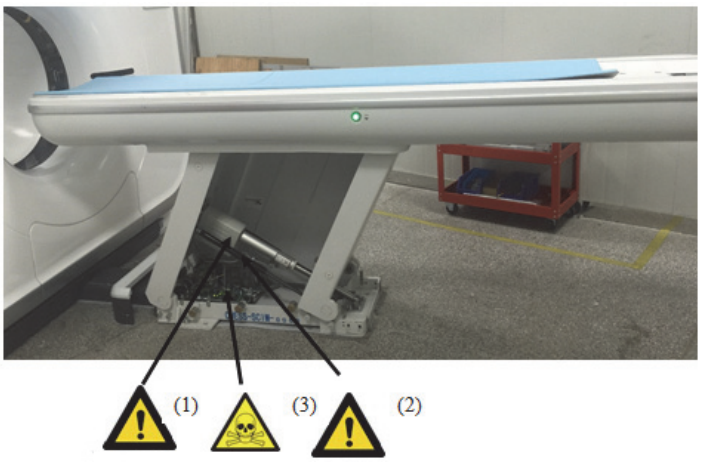

Figure 7: Fixed Couch without Cover

Figure 8: Front View of Console Computer

Bariatric Table (Option)

Product Name	Bariatric Table	
Total Weight (in Kg)	650	
Producer/Manufacturer	Name Company:	Philips Healthcare (Suzhou) Co., Ltd
	Address:	No. 258, ZhongYuan Road, Suzhou Industrial Park Suzhou, Jiangsu Province
	Zip Code:	215024
	Country:	People's Republic of China

Recycle Info	**Items**	**Location**
Special attention 	Removal of Motor & Screw brake & Failsafe: Couch will drop when motor & Screw brake & Failsafe are removed simultaneously.	Figure 10 (2), Figure 12 (1), Figure 13 (1)
Fluids/Gases	**Items**	**Location**
	None	None
Batteries	**Type**	**Location**
 **To be removed**	None	None
Hazardous	**Substances**	**Location**
 **To be removed**	Printed circuit boards	Figure 10 (1), Figure 11 (1), Figure 12 (2), Figure 14 (1)

Show locations of materials mentioned on the previous sheet.

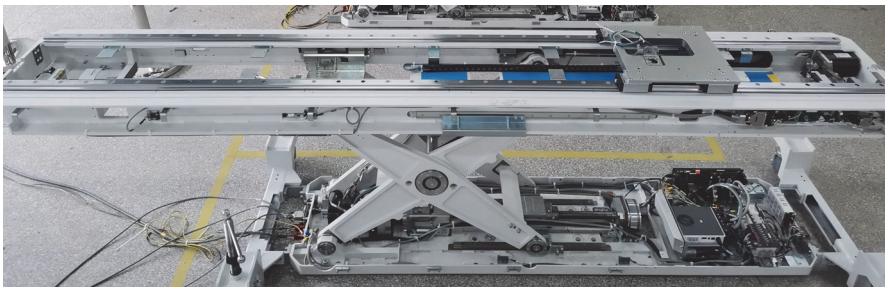

Figure 9: Full view of Patient Support without cover

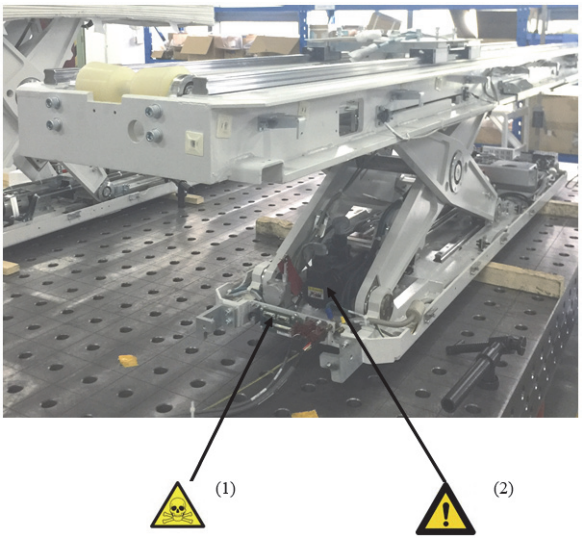

Figure 10: Front view of Patient Support

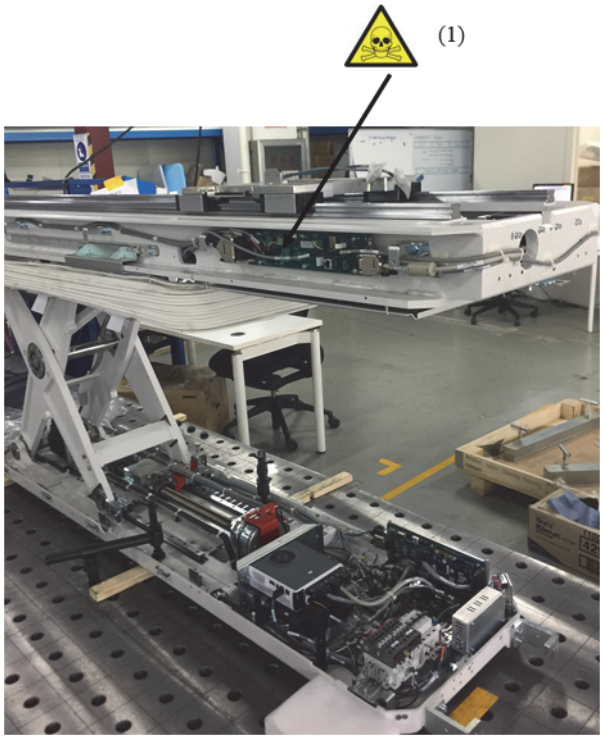

Figure 11: Left side of Patient Support

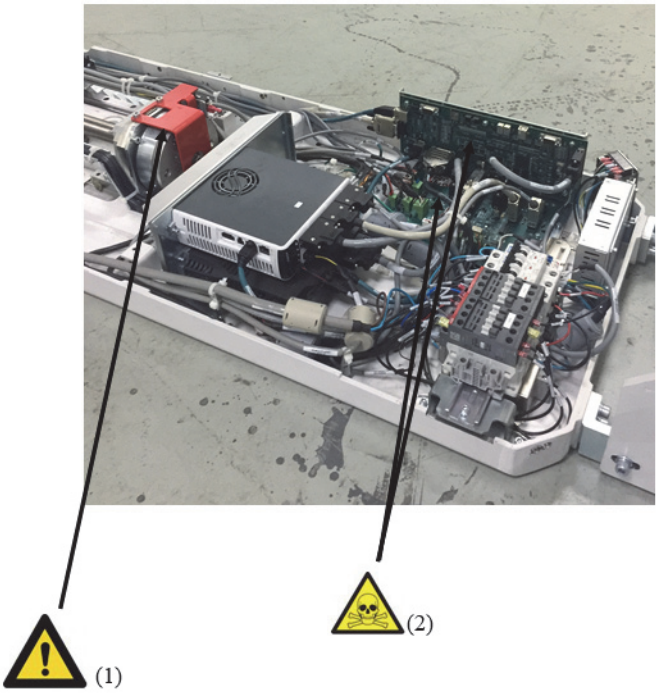

Figure 12: Top View of Patient Support Base

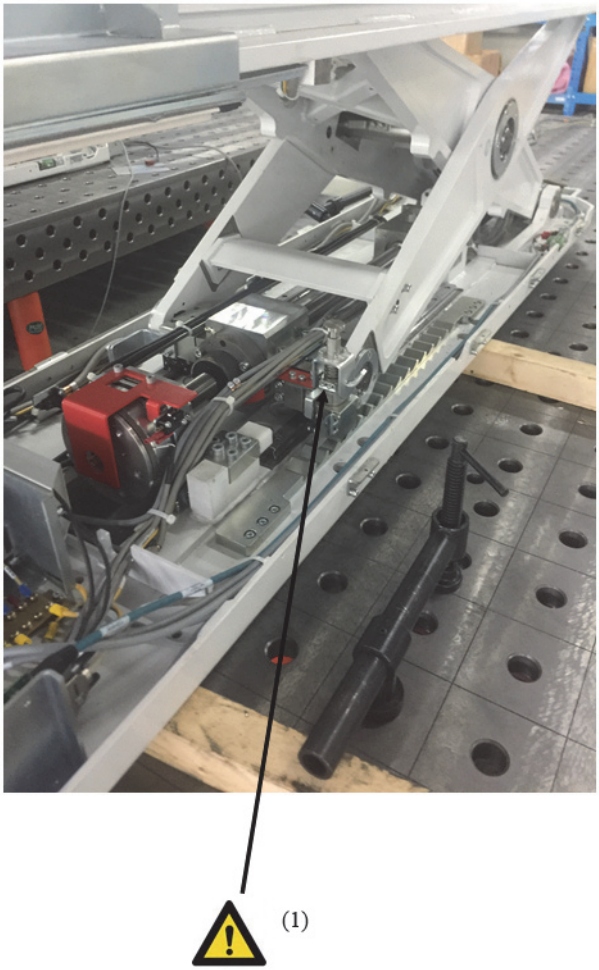

Figure 13: Right side of Patient Support

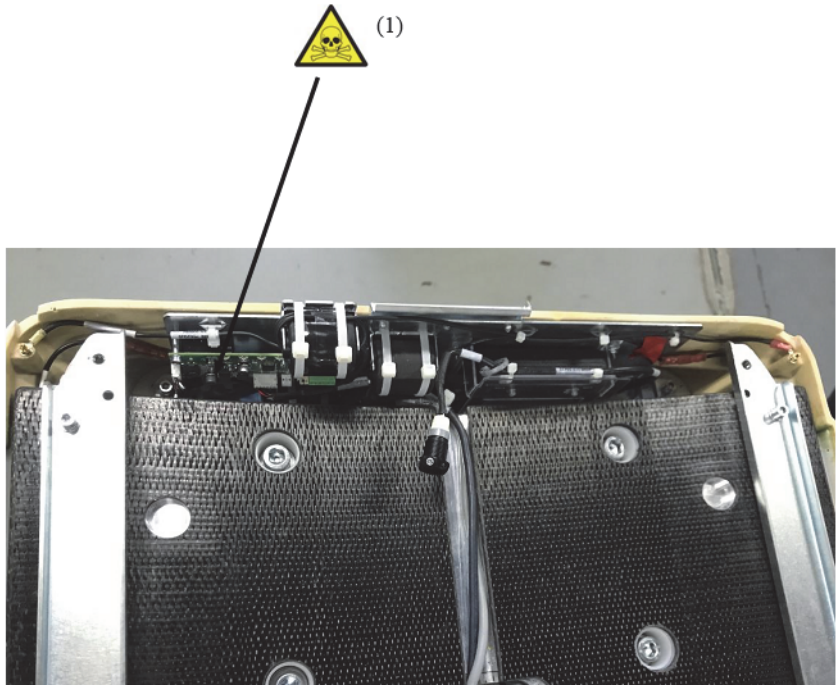

Figure 14: Top View of Patient Support

7 EURATOM Compliance Statement

For basic safety standards for protection against exposure to ionising radiation. (Directive 2013/59/EURATOM)

Product Name: Refer to System label and IFU.

Device class: II b.

Company Name and Address: Refer to System labels and IFU.

Contact Information: Refer to System labels and IFU.

Target Users and Training: Refer to IFU.

Information on the residual risks, any adverse event and precaution for use:

The Philips Risk Management Process comply with ISO 14971 and is applicable to all stages of the life cycle of the device. IFU contains the warnings and precautions for use, applicable to safety of the product. The Risk Management Process recognized hazards associated with the device to estimate and evaluate all the associated risks. Identified risks associated with the use of the device are mitigated and deemed acceptable when weighed against the benefits to the patient. Information pertains to residual risks, adverse events and precautions identified through the instruction for use.

Device description: Refer to IFU.

The summary of the clinical evaluation results as mentioned in article R.5211-36-1:

With respect to safety of the device, Clinical evaluations conducted through clinical evaluation planning, identified equivalent devices, a comprehensive analysis of available pre- and post-market clinical data to ensure the safety and performance of the device intended use. Furthermore, reviewed clinical data did not identify any risks specific to the device, not assessed in the risk analysis. Therefore, the clinical

evaluation concludes that the device will not compromise the clinical condition or the safety of patients, or the safety of the users.

Conclusion:

1. The clinical safety and performance of the device was demonstrated with the clinical evaluation;
2. Conformity with the relevant essential requirements is demonstrated through technical documentation.

With respect to post market clinical follow up, no specific device features or other aspects were identified that require special attention during the post market phase. Post market surveillance monitoring activities (i.e., conducting a search in the literature and clinical experience databases) related to the use of the device in the market are planned to obey our internal processes.

For the list of the applicable Harmonized Standards, you can refer to the Declaration of Conformity

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