

Spectral CT

Version 5.0.1

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1 Introduction

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

Intended User

Philips systems may be used by a trained healthcare professional.

There are three types of personnel involved in the operation of the CT and/or PET/CT scanners. The Operator interacts directly with the system, and performs the scans. The physician provides clinical interpretation of the scans and/or performs interventional imaging. The physicist is responsible for onsite quality assurance of the system, including calibrations.

About this Reference Guide

This manual is intended to assist users in the safe and secure operation of the equipment described.

This guide is intended to assist with quality assurance testing of the CT scanner. It includes physics information critical to understanding dose, sensitivity, and other scan information subjects. This document also includes classifications, ratings, and the hazard labels and symbols included on your system. You must pay special attention to all the information given, and procedures described in the SAFETY and SECURITY sections.

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

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

NOTICE

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

Product Family

| Product | 6 NC |
|----------------------------|--------|
| Spectral CT | 728333 |
| Spectral CT System Upgrade | 728335 |

Product Family additional information:

Spectral CT - 728333 - 8 CM, 128 detector rows, 256 slices

Intended Purpose/Intended Use/Indications for Use

Intended Purpose

The Spectral CT is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

Intended Use

The Spectral CT is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

Indications for Use

The Spectral CT system acquires one CT dataset – composed of data from a higher-energy detected x-ray spectrum and a lower- energy detected x-ray spectrum. The two spectra may be used to analyze the differences in the energy dependence of the attenuation coefficient of different materials. This allows for the generation of images at energies selected from the available spectrum and to provide information about the chemical composition of the body materials and/or contrast agents. Additionally, materials analysis provides for the quantification and graphical display of attenuation, material density, and effective atomic number.

This information may be used by a trained healthcare professional as a diagnostic tool for the visualization and analysis of anatomical and pathological structures in patients of all ages, and to be used for diagnostic imaging in radiology, interventional radiology, and cardiology and in oncology as part of treatment preparation and radiation therapy planning.

USA Only Indications for Use

The Spectral CT is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

The Spectral CT system acquires one CT dataset – composed of data from a higher-energy detected x-ray spectrum and a lower- energy detected x-ray spectrum. The two spectra may be used to analyze the differences in the energy dependence of the attenuation coefficient of different materials. This allows for the generation of images at energies selected from the available spectrum and to provide information about the chemical composition of the body materials and/or contrast agents. Additionally, materials analysis provides for the quantification and graphical display of attenuation, material density, and effective atomic number.

This information may be used by a trained healthcare professional as a diagnostic tool for the visualization and analysis of anatomical and pathological structures in patients of all ages, and to be used for diagnostic imaging in radiology, interventional radiology, and cardiology and in oncology as part of treatment preparation and radiation therapy planning.

The system is also intended to be used for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer*. The screening must be performed within the established inclusion criteria of programs / protocols that have been approved and published by either a governmental body or professional medical society.

*Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl. J Med 2011; 365:395-409) and subsequent literature, for further information.

Contraindications

There are no contraindications for Spectral CT System.

Intended Users

Philips systems may be used by a trained healthcare professional. There are three types of personnel involved in the operation of the CT and/or PET/CT scanners. The Operator interacts directly with the system, and performs the scans. The physician provides clinical interpretation of the scans and/or performs interventional imaging. The physicist is responsible for onsite quality assurance of the system, including calibrations.

Target Population

The patient age may range from a newborn to an elderly patient. The patient may be conscious, unconscious, or sedated. In addition to external medical devices, the patient may have internal medical devices (e.g. pacemaker, orthopedic implants). The scan may be either scheduled or unscheduled (e.g. trauma). The patient generally does not interact with the system.

Radiation exposure is a concern in people of all ages; however, pediatric patients are more sensitive to radiation exposure because they have more rapidly dividing cells than adults. The younger the patient, the more sensitive they are to the detrimental effects of radiation exposure. In order to get vital diagnostic information for the patient this concern has to be weighed against medical necessity.

Clinical Benefits

The Computed Tomography X-Ray System is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

The main clinical benefits of CT include:

- The ability to view single and/or progressive cross-sectional images of the body.
- Images and measurements of physical/physiological parameters obtained by a CT scan may, when interpreted by a trained physician, provide information that may assist patient diagnosis and therapy planning.
- Images can be obtained in multiple planes without repositioning the patient.
- Three-dimensional representations of anatomical structures can be obtained.
- Visual feedback can be obtained during interventional procedures.

IEC-60601 Classification



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

NOTICE

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.

IEC/EN Statement of Compliance

This equipment is compliant to the standards mentioned in below table:

| International | European |
|----------------|-------------------|
| IEC 60601-1 | EN IEC 60601-1 |
| IEC 60601-1-2 | EN IEC 60601-1-2 |
| IEC 60601-1-3 | EN IEC 60601-1-3 |
| IEC 60601-1-6 | EN IEC 60601-1-6 |
| IEC 60601-2-28 | EN IEC 60601-2-28 |
| IEC 60601-2-44 | EN IEC 60601-2-44 |
| IEC 60825-1 | EN IEC 60825-1 |
| IEC 62366-1 | EN IEC 62366-1 |
| IEC 62304 | EN IEC 62304 |
| IEC 63000 | EN IEC 63000 |

For the exact revision of the standards, please refer to the declaration of conformity.

Electromagnetic Emissions

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

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

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



WARNING

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

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

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

Electromagnetic Immunity

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

| Immunity Test | IEC 60601 test level | Compliance level | Electromagnetic environment-guidance |
|--|--|--|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms on a.c. and d.c. power and signal ports 150 kHz to 80 MHz 6 Vrms on a.c. and d.c. power and signal ports in ISM bands 150 kHz to 80 MHz See Note 4 for list of ISM bands | Only those cables supplied with the CT system should be used. |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.7 GHz | 3 V/m 80 MHz to 2.7 GHz | See Note 2 below Interference may occur in the vicinity of equipment marked with the following symbol: <div data-bbox="1107 842 1286 1020" data-label="Image"> </div> |
| Proximity fields from RF wireless communications equipment RF IEC 61000-4-3 | 380 MHz - 5800 MHz | 380 MHz - 5800 MHz 9-28 V/m | IEC 60601-1-2, Table - 9 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment |
| Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| Note 2: CT has not been tested for radiated RF immunity over the entire frequency range of 80 MHz to 5.8 GHz. It was step tested at the selected frequencies 88 to 108, 144 to 148, 151, 185, 380 to 390, 425, 430 to 470, 468, 704 to 787, 800 to 960, 902 to 928, 939, 1700 to 1990, 2400 to 2570, and 5100 to 5800 MHz respectively, at minimum of 3 V/m field strength. Test signal was either 80% modulated AM, at 2Hz, 1000 Hz modulation frequencies or Pulse modulation at 18 Hz or 217 Hz. | | | |
| Note 3: Only the equipment specified in the CT Installation Manual may be used inside the gantry and patient table room. | | | |
| Note 4: The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6765 MHz to 6795 MHz; 13553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz. | | | |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact ±15 kV air | ±8 kV contact ±15 kV air | |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines ±1 kV for input/output lines | ±2 kV for power mains input ±1 kV for signal ports with 100kHz repetition frequency | Main's power quality must comply with the CT planning reference data (PRD). |

| Immunity Test | IEC 60601 test level | Compliance level | Electromagnetic environment-guidance |
|--|--|--|--|
| Surge IEC 61000-4-5 | ±1 kV lines to lines ±2 kV to earth | ±1 kV lines to lines ±2 kV to earth | Main's power quality must comply with the CT planning reference data (PRD). |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | N/A 0 % U _r for 5 s N/A | N/A 0 % U _r for 5 s N/A | Main's power quality must comply with the CT planning reference data (PRD). If the user of the CT requires continued operation during power mains interruptions, it is recommended that the CT be powered from an uninterruptible power supply (UPS). |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m, 50/60 Hz | 30 A/m, 50/60 Hz | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

**WARNING**

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

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

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

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

Electrical Ratings

| Voltage (VAC) | Phase | Frequency (Hz) | Power consumption (kVA) | |
|---------------|-------|----------------|---|---|
| | | | Continuous (IEC) long time (UL/NFPA 70) | Short time (IEC) momentary (UL/NFPA 70) |
| 380 | 3 | 50/60 | 25 | 175 |

| Voltage (VAC) | Phase | Frequency (Hz) | Power consumption (kVA) | |
|---------------|-------|----------------|---|---|
| | | | Continuous (IEC) long time (UL/NFPA 70) | Short time (IEC) momentary (UL/NFPA 70) |
| 400 | 3 | 50/60 | 25 | 175 |
| 415 | 3 | 50/60 | 25 | 175 |
| 440 | 3 | 50/60 | 25 | 175 |
| 460 | 3 | 50/60 | 25 | 175 |
| 480 | 3 | 50/60 | 25 | 175 |

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



WARNING

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

Electric Output Data, per IEC 60601-2-44

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

| | |
|--|--------------------------------------|
| NOMINAL X-RAY TUBE VOLTAGE and highest X-RAY TUBE CURRENT obtainable from the HIGH-VOLTAGE GENERATOR when operated at that X-RAY TUBE VOLTAGE | 140kV/, 750mA or 120kV, 1000mA |
| Highest X-RAY TUBE CURRENT and the highest X-RAY TUBE VOLTAGE obtainable from the HIGH-VOLTAGE GENERATOR when operated at that X-RAY TUBE CURRENT | 120kV, 1000mA |
| Combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which results in the highest electric output power | 120kV, 1000mA, 120kW |
| NOMINAL ELECTRIC POWER given as the highest constant electric output power (kW) which the HIGH-VOLTAGE GENERATOR can deliver for a LOADING TIME of 4 seconds at an X-RAY TUBE VOLTAGE of 120 kV, or nearest to 120 kV and the value of LOADING TIME nearest to but not less than 4 seconds | 105kW |

2 Labels and Symbols

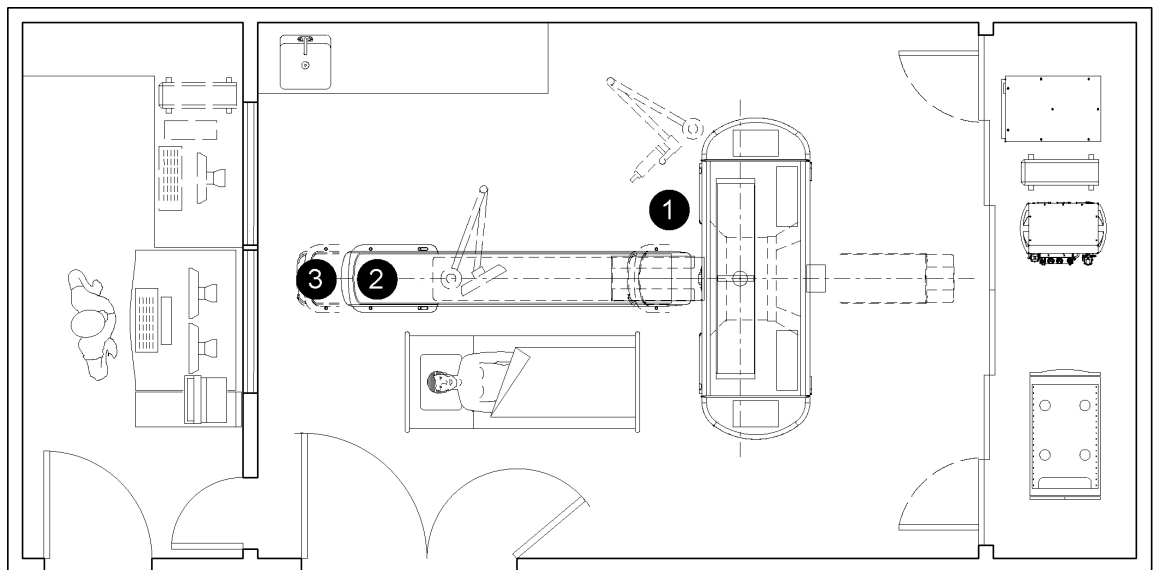
System Labels

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

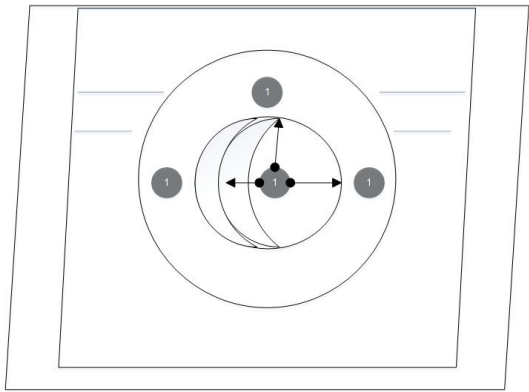
NOTICE

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

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



6 class 2 laser warning labels are applied on the gantry: 3 labels on the front cover and 3 labels in the cone (not on the Lexan ring) as displayed in the diagram below. The label is the item 1 in the table below.




| Number | Label/Sign | Location | Description |
|--------|------------|---|---|
| 1 | | Front of the Gantry and in the cone per Diagram | <p>CAUTION</p> <p>Class 2 patient positioning lasers.</p> <p>1.0 mW maximum output - wavelength 650 nm. EN/IEC 60825-1:2014.</p> <p>Note: The beam divergence is 90 Deg</p> |
| 2 | | End of Patient Table | <p>WARNING: Maximum patient table load is 307 kg, 676 lb</p> |

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Philips


Unique Device Identification Label

1



PHILIPS MEDICAL SYSTEMS NEDERLAND B.V. 2

VEENPLUIS 6, 5684 PC BEST, THE NETHERLANDS



PHILIPS MEDICAL SYSTEMS TECHNOLOGIES LTD.

ADVANCED TECHNOLOGY CENTER

2022-11-01 MATAM, BUILDING 34, HAIFA 3100202, ISRAEL

#

MODEL: Spectral CT 3

REF

728333 4

6

(01)00884838101111


SN

000001 5

(21)000001

7

UDI



3~ 380/400/415/480 V , 50/60Hz, Momentary: 175 kVA

, Continuous: 25kVA 8

MANUFACTURED: NOVEMBER 2022 9

459801041492 Rev I

| Number | Description |
|--------|---|
| 1 | Manufacturing site of the finished device. |
| 2 | Site of legal manufacturer, the entity responsible for placing the device on the market. |
| 3 | Model name of the system. |
| 4 | Reference or catalog number. |
| 5 | Serial number. |
| 6 | Global Trade Identification Number (GTIN) as Device Identifier (DI) and Production Identifier (PI). |
| 7 | Unique Device Identification GS1 2D DataMatrix barcode (contains information from 7). |
| 8 | Electrical rating specific to system. |
| 9 | Month and year of device manufacture as per 21 CFR. |






Symbols


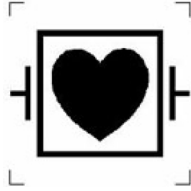





Use the following information to interpret the symbols used on the system and accessories.





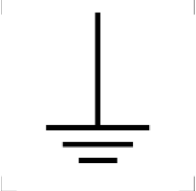

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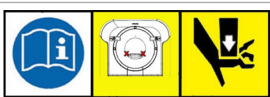



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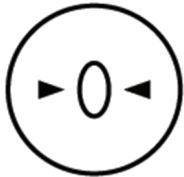



IEC 60601-1, 3rd Edition Symbols For each symbol, the table below describes the standard in which the symbol is defined — ISO 15223-1:2012 and ISO 15223-1:2016 "Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements.




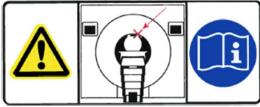
| Symbol | Symbol Reference | Symbol Title | Description |
|---|-------------------------|---|--|
|  | ISO 7010 - W012 | Warning; Electricity | Warns of electricity. |
|  | IEC 60417 - 5638 | Emergency stop | Identifies an emergency stop control device. Found on the red buttons located on the gantry and the System Scan Control Box. |
|  | ISO 7000 - 0434B | Caution | Indicates that caution is necessary when operating the device or control close to where the symbol is placed or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. |
|  | ISO 7000-1641, ISO 3864 | Operator's manual; operating instructions | Mandatory action. Identifies the location where the operator's manual is stored or identifies information that relates to the operating instructions. Indicates that the operating instructions should be considered when operating the device or control close to where the symbol is placed. |
|  | ISO 7010-M002 | Refer to instruction manual/booklet | Signifies that the instruction manual/booklet must be read and the warnings and instructions therein followed. |

| Symbol | Symbol Reference | Symbol Title | Description |
|---|------------------|---|--|
|  | IEC 60417 - 5840 | Type B applied part | Identifies a type B applied part complying with IEC 60601-1. |
|  | IEC 60417 - 5336 | Defibrillation-proof type CF applied part | Identifies a defibrillation-proof type CF applied part complying with IEC 60601-1. |
|  | IEC 60417 - 5390 | Patient, normal; person, general | Indicates a reference to a person or human body. On medical equipment this graphical symbol is used to indicate a reference to a normal patient. |
|  | ISO 7000-1329 | Laser beam; radiation of laser apparatus | Identifies the radiation of laser products. Indicates that the equipment generates a laser beam. |
|  | IEC 60417 - 5339 | X-ray source assembly, emitting | 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). |

| Symbol | Symbol Reference | Symbol Title | Description |
|---|------------------|---------------------------|---|
|  | IEC 60417 - 5665 | Body weight | Identifies the control or the indicator to enter or call up the body weight of a person. |
|  | N/A | European Union directives | Product complies with the requirements of the applicable European Union directives. |
|  | N/A | CSA certification | This product complies with standards of CSA certification in United States and Canada. |
|  | 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. |
|  | N/A | WEEE directive symbol | Waste electrical and electronic equipment (WEEE). |

| Symbol | Symbol Reference | Symbol Title | Description |
|---|-----------------------------------|---|--|
|  | 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. |
| Rx ONLY | N/A | Prescription Device only | Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. |
|  | ISO 3864-1, ISO 7000-5339 | Do not scan this area. | Do not scan this area. |
|  | ANSIZ535, ISO 7000-1641, ISO 3864 | Therapy top pinch point. Keep clear during operation. | CAUTION: Pinch point. Keep hands clear during operation, reference to instruction manual is mandatory. |
|  | N/A | Laser light ON/OFF | Turns on and off both the internal and external laser markers, used for positioning the patient in the slice plane. |
|  | N/A | Breathing lights: Breathe In, Hold, Breathe Out | Provides the patient visual cues coordinated with scan breath hold. |
|  | N/A | Scan control box volume control | Volume for scan control box. |

| Symbol | Symbol Reference | Symbol Title | Description |
|---|-----------------------|--|---|
|  | N/A | Scan control box volume control for gantry speaker | Volume for gantry speaker. |
|  | N/A | Patient intercom microphone control | Allows the operator to speak to the patient. |
|  | N/A | Zero Screen | Resets the table in/out indicator to zero. |
|  | N/A | Temporarily disable touch screen | Deactivates touch screen buttons, so that the touch screen can be cleaned. |
|  | N/A | Patient breathing lights demonstration | Demonstrates the first acquisition breathing light sequence. Any acquisition that occurs after the current one is ignored for breathing light demonstration purposes. |
|  | EC definition: #3 PVC | Polyvinyl chloride | Material is Polyvinyl chloride (type 3 plastic). |

| Symbol | Symbol Reference | Symbol Title | Description |
|---|------------------|------------------|--|
|  | ISO 7000-2492 | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified. The symbol may be shown without the enclosure. |
|  | ISO 7000-2493 | Catalogue number | Indicates the manufacturer's catalogue number so that the medical device can be identified. The symbol may be shown without the enclosure. |
|  | ISO 7000- 2498 | Serial number | Indicates the manufacturer's serial number so that a specific medical device can be identified. The symbol may be shown without the enclosure. |
|  | N/A | N/A | CAUTION: Do not raise the system table to its maximum vertical height when the head or body phantom is mounted to it. The phantoms may collide with the gantry covers. |
| | N/A | N/A | Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed. |

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Philips

3 Safety

Important Safety Directions

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

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

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

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

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



WARNING

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



WARNING

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



WARNING

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

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

**WARNING**

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

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

**WARNING**

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

**WARNING**

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

Intended use of the CT system is described under the heading **Indications for Use Statement** in the **Introduction** section of the **Instructions for Use** document. Compatibility is discussed under the heading **Compatibility** in the **Introduction** section of the **Instructions for Use** document.

Scanner Suite

Familiarize yourself with the scanner suite at your site:

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

**WARNING**

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

Emergency Procedures

Emergency Stop

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

Reset from Emergency Stop

Use this procedure to reset from emergency stop:

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

**WARNING**

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

**WARNING**

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

**WARNING**

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

**WARNING**

One of the possible sources of ESTOP may be the couch user area. If this is the source, ensure no high voltage RF emission is in place, before initiating any new patient scans.

Emergency Patient Release

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

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

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

NOTICE

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

Pulling the Patient Out

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

Pushing the Patient In

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

Rapid release of the patient table can also be achieved by grabbing the floating switches along either side of the table, or by grasping the handle at the end of the patient table, or by pressing one of the foot switches. This triggers the force assistance function of the patient table and help to release the patient with low manual force.

Emergency release unlocks the table from its driving mechanism and allows it to be manually extended or retracted..

NOTICE

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

Electrical Safety & Grounding

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

**WARNING**

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

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

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

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

Mechanical Safety

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

**WARNING**

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

Explosion Safety

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

**WARNING**

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

Implosion Hazard

**WARNING**

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

Fire Safety

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

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

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

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

**WARNING**

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

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

Electromagnetic Compatibility

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

Mobile Telephones and Similar Products

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



WARNING

You should not allow portable radio transmitting devices (such as mobile telephones) into the examination room - whether switched on or off. Such devices could exceed EMC radiation standards could interfere with the proper functioning of the CT system. This could, in extreme cases, lead to fatal or other serious personal injury or to clinical mis-diagnosis. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CT system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electronic and Implanted Stimulators

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

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

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

Recommendations prior to scan:

1. Ask the patient if he/she has any implanted or external electronic medical devices.
2. Use CT Surview scans to determine if implanted or externally worn electronic medical devices are present and if so, their location relative to the programmed scan range.
3. For CT procedures in which the medical device is in, or immediately adjacent to, the planned scan range, make these adjustments:
 - Determine the device type.
 - If practical, try to move external devices out of the scan range.
 - Minimize X-ray exposure to the implanted or externally worn electronic medical device by using the lowest possible X-ray tube current consistent with obtaining the required image quality, and making sure that the X-ray beam scans over the device for less than a few seconds.

**WARNING**

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

Recommendations after scan:

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

Radiation Safety

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

**WARNING**

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

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

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

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

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

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

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

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

Radiation Warning Lamps

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

If the radiation warning lamps do not light up:

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

Installation and Environment

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

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



WARNING

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

Coolant Leaks

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

**CAUTION**

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

Laser Safety

**WARNING**

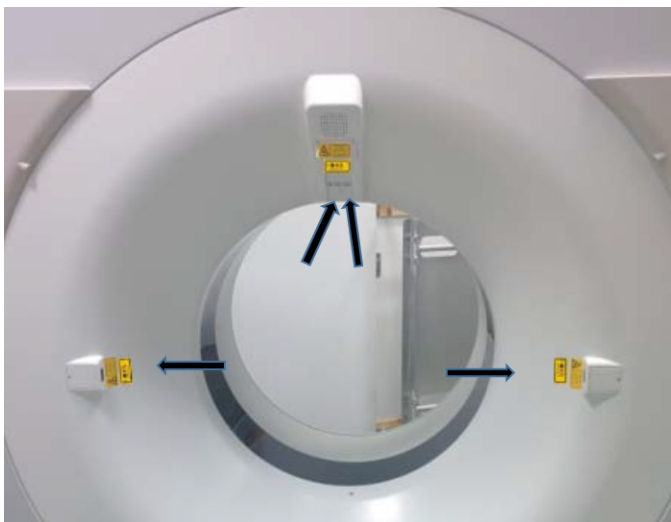
Follow these Laser Safety warning instructions:

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

**CAUTION**

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

The gantry includes 8 lasers all of the same model. 4 positioning lasers are located on the front of the gantry and 4 lasers are located on the rotor. The aperture of the lasers on the gantry front cover is displayed below.



Protection Measures

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

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

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

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

Phantom Handling

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



WARNING

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

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

Residual Risks to be Considered

Residual Thermal Hazards

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

- When covers are removed, service personnel may be exposed to thermal hazards. The system complies with the IEC60601-1 clauses for internal markings and service manuals have warning instructions for these hazards which should be followed by service personnel to ensure their safety.

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

Residual Risks Related to Moving Parts

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

- For patients connected to life support systems, extra care should be taken by the operator to ensure that the all connections are positioned in a manner to avoid pulling or disconnecting during the scan. During all movements of the gantry (automatic and manual) and the patient table, keep the patient under continuous observation to avoid pressing the patient against the gantry or between table parts.
- Make sure that the motion of the table is in the direction that will ensure that the patient can be easily released and will not get pressed against the gantry covers.
- For all patient table types, take care when using attachments (such as the head and foot holders) to avoid collision with the gantry. Non-original patient supports may cause danger for the patient through collisions with the gantry. Positioning aids must be used exclusively for their intended purpose: head holder only for positioning the head, table top extension only for positioning the feet.
- Be aware of possible pinch points between the foot extension and the gantry
- Make sure that the patient is strapped securely to avoid dangling of the hands.
- When using the radiation Therapy Table Top, users should be aware of possible pinch points
- During studies, the patient table and gantry movements (if applicable) are automatic. Ensure enough clearance between the patient and the gantry. Before initiating the scan, perform manual movements to check the clearance. Auto scan means that automatic motions are expected without using the enable button.
- While moving the table or Gantry, avoid placing your feet under the table side covers or between the Gantry and Patient table. Avoid inserting your fingers between the table top and the table carriage. Avoid placement of ancillary equipment (such as wheelchairs, IV pumps or beds) under the table. The table could collide with these items during movement.

- Use caution when opening or closing the front cover. When lifting the front cover make sure to stand aside and let the cover lift to the fully open position. The locking pins **MUST** be engaged whenever the front cover is fully opened for servicing. Failure to comply may result in serious injury to service personnel.
- There are multiple pinch points underneath the gantry covers. Pay attention to all safety labels and follow service instructions to minimize risk of injury.
- Verify that the rotor is not spinning, by viewing through the gantry cone before opening the covers. Use caution when opening or servicing the scanners. Never service the rotating frame when or if rotational movement is enabled. In case of a power failure or fault condition the rotor can spin (approximately 25 minutes or longer) after the power is removed from the system. Wait until the rotor stops before opening covers. Failure to comply may result in equipment damage, serious injury or death to service personnel.
- Check for rotational interference between rotor and cones (by hand rotation). Be aware and careful of pinch points during service operations.
- The Rotor contains heavy parts, such as the X-ray Tube, DMS, etc., and is perfectly balanced. When this balance is disturbed by removing a part from it, it will start an uncontrolled mechanical rotational motion to reach a new equilibrium point. This motion cannot be stopped and may injure the service engineer.
- Wear proper clothing to reduce the risk of injury due to hair, clothing or jewelry getting caught in parts of the system during servicing.
- Install the vertical safety support brace whenever personnel are working under the table. It is especially **CRITICAL** when performing repair or replacement on the vertical drive system. If the motor/brake assembly is removed without it, the patient support will free fall to the ground. The patient support scissors support a weight of ~600 pounds (272 kg); a fall may result in personnel injury or death.

Residual Laser Radiation Risks

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

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

Residual Mechanical Gravity Related Hazards

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

- If coolant leaks are detected, shut down the scanner and immediately contact the nearest Philips field service office. The floor may be slippery and present a risk of slipping or tripping.
- During maintenance procedures, check the entire X-segment cooling circuit for any obvious leakage
- All cables should be routed between the injector, the patient, the table and the CT scanner so they do not impede the free movement of personnel. Route all cables between the PIM, IVC (where applicable) the patient, the patient table, and the CT scanner so that they do not impede the free movement of personnel. Route cables in existing troughs, ducts, or adjacent to system components to prevent obstructions that can cause personnel to trip and fall
- If the monitor is located on a cart, make sure that the cables connected to the device are not in the way of the patient or the personnel in the scan room. The additional monitor cart inside the scanner room should not be used to hold anything but the original monitor. The 21-inch monitor-base should always be on top of the stand and secured properly. When not in use, the cart and its cables should be moved to a corner of the room so they do not interfere with routine activities in the scanner room. Care must be taken not to collide with the monitor stand or trip on the monitor cables.
- Make sure that the patient is strapped securely to avoid dangling of the hands. Ensure that the patient is placed securely on the patient table and is not in danger of falling. During all movements of the gantry and the patient table (automatic and manual), keep the patient under continuous observation to ensure safety of the patient.
- If a head holder or support is not engaged securely, it can come loose causing injury to the patient. Positioning aids must be used exclusively for their intended purpose: head holder only for positioning the head, table top extension only for positioning the feet.
- Follow all service instructions when installing or servicing the system. Pay attention to clearance requirements to prevent excessive strain on wheel castors to minimize the risk of rollover and toppling. Minimize the clearance between the Gantry/Patient Table/CIRS Rack base and the floor when transporting these components.. Use assistance wherever specified (e.g. CIRS rack removal from pallet). Wheel castors should be secured to minimize tipping hazard. Ensure components are attached to floor as specified during service and replacement procedures. Failure to comply may result in serious injury or death to service personnel.
- Handling equipment without proper tools, training, and adherence to all warning labels, etc., can cause damage to equipment or harm to personal.
- Make sure the gantry and other system components are on level ground. The system may move/roll on uneven ground. Block/brace the wheels on gantry as instructed to avoid undesired movement

Residual Lifting and Ergonomics Related Risks

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

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

Residual Loss of Communication and Noise Related Risks

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

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

Residual Risks Related to Mechanical Expelled Parts

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

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

Residual Risk of Accidental Radiation

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

- All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection.
- The radiation warning lamps on the gantry panels, on the scan control panel, as well as site radiation warning lamps, must light up if scanning has been triggered. If the radiation warning lamps do not light up shut down the system immediately and contact Customer Service. Press the Emergency Stop button if there is danger to you or the patient.
- If there is any indication that X-rays are not turned off after releasing the foot pedal switch, press one of the STOP buttons on the gantry control panels or the Pause button on the scan control box. This stops the generation of X-rays, scanner rotation, and patient table motion.

- Only the patient should be in the scan room for scanning. When occupancy of the scanner room is unavoidable, attention should be paid to the zones of occupancy as documented in the Technical Reference Guide. Anyone who has to be near the patient during scanning must wear protective clothing (lead apron), wear a PEN dosimeter and/or film badge, and stay in the zone shielded by the system (to the side of the gantry or behind a mobile protective wall). The physician is responsible for protecting the patient from unnecessary radiation. Use protective shielding whenever appropriate to minimize dose to sensitive organs.
- Use the applicable exams for children. Use pediatric exams based on the age, weight, and indications to avoid over exposure. Philips recommends the use of the infant mode for newborns up to 18 months of age
- When performing Advanced Interventional procedures, prepare the appropriate radiation shielding equipment and materials to avoid accidental radiation exposure.
- For CT procedures that require scanning over the medical device for more than a few continuous seconds (as with CT perfusion or interventional exams) users should prepare to treat possible adverse reactions.
- Properly center all patients in the gantry. Patients not properly centered may be under or over exposed to radiation if the table height is set too high or too low
- To avoid overexposure to radiation, ensure the scan room is clear of personnel during servicing and related service scanning. Follow the procedures established for your site.
- The useful and scattered beams can produce injuries to patients and persons in the surrounding area if used by an unskilled operator. Adequate precautions must always be taken to avoid exposure to the useful beam, as well as to indirect radiation including scattered radiation from within the scanner as well as anything in the path of the beam.
- Follow Safety warning instructions when refilling or transporting phantoms

Residual Risk of Potential Electrical Hazards

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

- Compliance with standards for design combined with planned maintenance and inspection of the system according to service instructions are designed to detect any problems with the system that might lead to potential electrical hazards, such as damaged couch or gantry covers exposing electrical components or improper system grounding. However, hazardous voltages are still present within the system that can cause serious injury. The operator should not remove covers or override safety locks present on the system. If covers are damaged or removed, the operator should not operate the system until repaired by a qualified service personnel.
- Before installing and prior to any service or maintenance activity, make sure to switch off the system at the main power supply and the UPS (ensure no power is applied to the Ghost) as a precaution against electrical hazards.
- Never remove or connect the Gantry cone cables with power ON to the rotor and/or stator as a precaution against electrical hazards.

- Front end electronics is energized through the slip rings even when you Power OFF the system. Therefore, before you remove the rear cover, to avoid any electrical danger, switch off all circuit breakers on the gantry left column, and on the main power supply to the scanner, and wait at least ten minutes for energy to be discharged as a precaution against electrical hazards.
- Batteries can present a risk of electrical shock or burn from high short circuit current. Observe proper precautions. Servicing should be performed by qualified service personnel knowledgeable of batteries and required precautions. Keep unauthorized personnel away from batteries. When servicing the battery, wear rubber gloves, electrically insulated footwear, and insulated tools
- The Philips CT system complies with the requirements of applicable EMC standards. Emissions from the CT system may affect other electronic equipment that does not meet the EMC immunity limits. There is a possibility that the X-rays or other electromagnetic radiation from the CT may cause some implanted and external electronic medical devices (pacemakers, defibrillators, neurostimulators, and drug infusion pumps) to malfunction. Philips recommends that users check the device manufacturer's recommendations/ precautions regarding use in a CT scanner prior to exposing a patient to a scan.
- Touch current can reach the patient in the patient area by any chance contact through various paths (i.e. operator touching the patient and accidentally coming into contact with exposed electrical components of the system). The patient area is defined as any area less than 15ft away from the table. The operator should not make contact with potential voltage sources and the patient at the same time in the patient area to avoid potential electromagnetic harms to a patient from leakage current.

Residual Risk of Misrepresentation

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

- The system is intended for use is by trained users that understand the technological limitations and the types of artifacts that can be caused inherently by the CT scanner technology and by impacts from techniques used to generate images.
- User are expected to perform image analysis to verify that measurement results when making critical measurements are correct
- The system requires routine calibration and maintenance. Users are expected to perform daily image quality checks and periodic calibrations and maintenance as specified in the user manuals. Failure to do so can result in image artifacts or inaccurate measurements.
- Errors in RTP may occur when there are problems with geometrical accuracy of the system for RTP (e.g., table sag over distance while table is loaded, image perpendicularity). The overall treatment planning accuracy is dependant on a quality assurance plan by the clinician that takes into account the accuracy of the CT Scan data.
- Spatial positioning errors in RTP and final treatment may occur if the user does not use the oncology radiation therapy flat table top ("Therapy Table Top") and its compatible accessories. To reduce these errors in final treatment, offsets between the lasers and CT center should be measured by scanning a phantom designed for this specific purpose, and

then the measured values should be entered into the RTP system. The overall treatment planning accuracy is dependant on the quantification of any geometric inputs used by the system.

- Errors in RTP may occur if positional accuracy is compromised. In order to maintain positional accuracy, users should evaluate Therapy Table Top alignment immediately following any possible events which could cause misalignment (e.g. forceful table contact, system service). Any malfunction or damage should be evaluated by qualified Philips service personnel, and quality assurance procedures should be repeated after any subsequent repairs or adjustments.
- Patient positioning lasers should not be used for absolute marking in RTP as they are not designed for this purpose and may compromise accuracy. Instead, high accuracy external lasers (supplied by a third party) designed for marking patients for therapy should be used for this purpose.
- RTP accuracy may be compromised if the system is used for RTP prior to completion of both Image Performance QA procedures and any preventive maintenance to be conducted in accordance with the maintenance schedule provided for the system. The system is intended for use by trained personnel. Errors in geometric accuracy can impact the treatment location targeted by the RTP system, which could then potentially harm surrounding healthy tissue. Additionally, errors in determining the CT tissue density can impact the calculations used for therapy beam strength, which can thereby reduce the effectiveness of the treatment.
- Systems used for radiation therapy planning are expected to be maintained and calibrated consistent with AAPM Report No. 083 - Quality assurance for computed-tomography simulators and the computed-tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66.
- List of Commonly Recognized CT Artifacts and their Causes:
 - Patient-based artifacts: motion artifact, transient interruption of contrast, clothing artifact, and jewelry artifact.
 - Physics-based artifacts: beam hardening, cupping artifact, streak and dark bands, metal artifact/high-density foreign material artifact, partial volume averaging, quantum mottle (noise), photon starvation, and aliasing in CT.
 - Hardware-based artifacts: ring artifact, tube arcing, out of field artifact, and air bubble artifact.
 - Helical and multichannel artifacts: windmill artifact, cone beam effect, multiplanar reconstruction (MPR) artifact, zebra artifact, and stair step artifact.

Residual Risks Related to Biocompatibility

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

- The clinical suite may include one (or several) third-party UPS devices. When UPS batteries are not properly maintained, or if they are held in service beyond their usable service life, failure can result in the leaking of electrolyte (sulfuric acid), overheating, and/or the emission of fumes. To ensure continued safe and reliable performance from these devices,

periodic maintenance is required, including possible battery replacement. Based on industry standards, the typical useable service life of a UPS battery is less than five years. You may consult your local Philips Service representative for help in identifying the specific model of your UPS device(s) and available service provider options in your geography.

- Blood and bodily fluids from patients may leak onto surfaces of the system which present potential health risks. Take appropriate health and safety precautions when cleaning and disinfecting the system to minimize the risk of cross contamination. To prevent transmission of biological infection hazard and to prevent damage to the system, cleaning should be performed using materials and methods as described in the system instructions for use. Cleaning should be done using a commercial biocide approved by your governing authority to clean the surface of the system and should ensure that no remnants of cleaning materials remain on the system surface including the console, gantry, table, and accessories.
- Applied parts, which patients and users, may come into contact with during normal operation are designed for biocompatibility according to ISO 10993, however an individual may still have a reaction to such contact. Service personnel may be exposed to additional internal parts and surfaces during their normal duties and should follow all instructions and precautions to minimize their exposure to possible irritants.
- Coolant or other substances that leak from the system may cause harm. Field service should be contacted immediately upon detection
- Service personnel may be exposed to chemical substances during service operations and should take proper precautions to avoid risk.
- The system contains hazardous materials. Incorrect disposal of any of these materials may lead to serious environmental pollution. This system may contain devices that contain mercury, which must be recycled or disposed of in accordance to local, state, or federal laws. Within this system, the backlights in the monitor display contain mercury.

Residual Risk of Sharp Edges

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

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

Undesirable Side Effects

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

Undesirable side effects identified are as follows:

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

Compatibility with Other Devices

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

Safe De-Installation of the CT System

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

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

Customer Service Contact Information

local Philips Healthcare representative. Alternatively, contact:

Philips Healthcare

PO Box 10 000

5680 DA BEST

The Netherlands

Facsimile: +31 40 276 2205

4 System and Data Security

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

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

The practical implementation of technical security elements varies by site and may employ a number of technologies, including firewalls, virus scanning software, authentication technologies, etc. As with any 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 defenses are essential to good security practice.

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

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

Regulatory Controls

Protect Patient's Health Information

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

NOTICE

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

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

Prevent Unauthorized Device Modification

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

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



CAUTION

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

Security Issues and Guidelines

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

Network Security

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

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



CAUTION

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

Hard Drive Encryption

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

NOTICE

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

If encryption is enabled, the system shall encrypt ePHI data at rest.

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

NOTICE

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

Remote Service

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

Data Disaster and Recovery Planning

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

- system and patient-data backup plan
- safeguards in place to store protected health information and backup data
- procedures for restoring system and patient data in the event of a local disaster

Access Control

Room Access Control

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

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

Individual Access Control/User Accounts

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

NOTICE

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

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

Positioning of Display Monitors

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

Emergency Login

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

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

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

The name can be between 2-53 characters long consisting of alphabets, numbers and special characters "_" and ".".

3. Click **Emergency Login**.
4. Follow the on screen prompts.

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

1. Enter the user name as **Emergency**.

2. Enter the password that the Local Administrator provided you. The Emergency login password can be changed only by using the Reset Password option.
3. Enter your user name in the **Emergency User** field. The user name may consist of letters, numbers, and underscores only.
The name can be between 2-53 characters long consisting of alphabets, numbers and special characters "_" and ".".
4. Click **Emergency Login**.
5. Follow the on screen prompts.

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

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

System Logoff

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

Automatic Screen Blanking

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

System Backup Media

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

Removable and Portable Media

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

- Inserting removable media (such as a USB drive or CD-ROM) can introduce a virus to the medical device. Be certain to scan the portable media for malware before inserting the media into the scanner.
- Patient data that is transferred to removable media is not encrypted, handle and store media according to your privacy protection policies.
- If the media is to be discarded it must be destroyed or disabled so that the data can no longer be accessed.

- If removable media is used to store patient data, protect the information from media and technical obsolescence by planning and performing data migrations to newer storage technologies.
- If the removable media is to be stored for safekeeping, protect the data from “fading” loss by storing it in a suitable environment and performing media renewal as recommended by the media manufacturer.

**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.

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.

Physical Locks

The Host Rack includes front door lock and the rear door lock. Two keys (one is a backup key) are provided for these locks.

Local Administrator

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

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

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

When the clinical user is assigned with protocol management privilege by the local administrator, you can edit, create and import clinical protocols.

Manage Clinical User Accounts

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

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

Create Clinical User Account

When creating user accounts, it is recommended that:

- the default clinical user account be disabled (see chapter “Manage Users” on page 53)
- a unique clinical user account is created for each person using the system.

To create a user:

1. Enter the Local Administrator user name and password on the login screen.
2. Select **Create User**.
3. Enter the clinical user name, select **Clinical** from the dropdown list, then enter and re-enter password. See chapter “Password Complexity Rules” on page 54.
4. If required for the user, select **Access to Exam Card Manager**.
5. Click **OK** and then **Logoff**.

NOTICE

Record all clinical user logon information and store it in a secure place.

Manage Users

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

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

Remove a user

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

Reset a user password

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

It is recommended to regularly change user passwords. See chapter “Password Complexity Rules” on page 54.

Enable or Disable a user account

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

Grant or remove access to Audit Trail Logs

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

Grant or remove access to the Exam Card Manager

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

Grant or remove access to the Dose Management

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

NOTICE

Record all clinical user logon information and store it in a secure place.

Password Complexity Rules

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

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

Change the Password Policy

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

NOTICE

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

To change the default password policy:

1. Login as local administrator user.

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

NOTICE

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

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.

User Logging and Audit Trails

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

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

ePHI audit logs are accessible only to the Local administrator through the use of a special viewer. The Local administrator can, however, provide this privilege to another Local Administrator that he or she has created on a case by case basis.

ePHI audit logs are available up to 8 months from the initial date of the log. Logs older than 8 months are deleted from the archive. ePHI audit logs can be backed up and restored.

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

The ePHI audit log message shall contain the following:

- Event Identification
- Active Participants
- Audit Source Identification
- Participant Object Identification according to the audit message format.

User Account Backup and Restore

User account information (excludes the password) can be backed up and restored to any of the Philips CT systems running software version 5.0 by the Local Administrator or Philips Service Representative.

Local Area Network Access

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

User Account Roles

The following user account roles are supported by the system:

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

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

The system supports application level audit logs that identify log-on and log-off events of the users.

Automatic Screen Blanking Setting

The Local Administrator can enable or disable this feature, or change the time period.

Third-Party Viewer Compatibility

The Local Administrator should perform this check to verify that third-party viewers used at the site are compatible with results produced by the system.

1. Click **Preferences** on the **Directory** screen.

2. In **Spectral** preferences, temporarily remove all restrictions on spectral images (allow images to be created without burn-in annotation and allow measurements on images).
3. Use the scanner utilities to create examples of each spectral image type. For this step, use either the Spectral CT Viewer or offline reconstruction. See the **Spectral CT Viewer** and **Creating Spectral Results** sections in the **Instructions for Use** document for more information.
4. Take sample measurements on each example spectral result type.
5. Load the created example spectral results into the third-party viewer that you wish to check.
6. Compare the displayed results to the expected appearance as achieved using the scanner utilities, and verify that appearance and measurements match.
7. Repeat Steps 5 and 6 for each third-party viewer used at the site.
8. Return all settings in **Spectral** preferences to their previous state.

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/digitally signed 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.

Performing Data Sanitization on Hard Drive

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

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

NOTICE

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

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

NOTICE

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

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

Third Party Software used with the System

- Adobe Acrobat Reader DC 19.012.20034
- McAfee Solidifier 8.2.1.143
- Microsoft Windows 10 Enterprise 2016 LTSB (64-bit) Version: 10.0.14393
- Techsmith Snagit 19.1.6
- Tevfik Karagulle CopSSH 6.4.0
- Wind River Systems VxWorks 5.4.2

Open Source Software used with the System

- 7-Zip 4.57
- 7-Zip 64-bit 9.2
- Access Runtime 16.0.4288.1001
- ALogic CeasarFTP 0.99

- Boost C++ library and templates 1.65.1
- CLIPS 6.3
- Free Software Foundation GNU zip 1.2.4
- ICSharpCode.SharpZipLib.dll (#ZipLibrary) 0.85.5
- Joe Richards CPAU.exe-CPAU 01.10.00cpp
- Json.net 10.0.1.2
- Log4net 1.2.10.0
- NPlot Charting Library for .NET 9.9.2
- OpenCV 2.0 2
- Philippe Jounin TFTP32 3.03
- Prism 6.3.0
- RedHat Cygwin (Support Telnet Commands over SSH) 2.87
- SharpZipLib (ICSharpCode.SharpZipLib) 0.85.5
- TightVNC 2.8.11.0
- WeifenLuo.WinFormsUI.Docking 2.7.0.0

ePHI De-Identified Items

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

- INSTANCE CREATOR UID
- ACCESSION NUMBER
- INSTITUTION NAME
- INSTITUTION ADDRESS
- REFERRING PHYSICIANS NAME
- REFERRING PHYSICIANS ADDRESS
- REFERRING PHYSICIANS TELEPHONE NUMBERS
- STATION NAME
- STUDY DESCRIPTION
- INSTITUTIONAL DEPARTMENT NAME
- PHYSICIANS OF RECORD
- PERFORMING PHYSICIANS NAME
- NAME OF PHYSICIANS READING STUDY
- OPERATORS NAME
- ADMITTING DIAGNOSES DESCRIPTION
- DERIVATION DESCRIPTION

- OTHER PATIENT IDS
- OTHER PATIENT NAMES
- MEDICAL RECORD LOCATOR
- MEDICAL ALERTS
- ETHNIC GROUP
- OCCUPATION
- ADDITIONAL PATIENTS HISTORY
- PREGNANCY STATUS
- PATIENT COMMENTS
- DEVICE SERIAL NUMBER
- PROTOCOL NAME
- IMAGE COMMENTS
- REQUESTING PHYSICIAN
- REQUESTING SERVICE
- REQUESTED PROCEDURE DESCRIPTION
- ADMISSION ID
- SPECIAL NEEDS
- CURRENT PATIENT LOCATION
- PATIENT STATE
- SCHEDULED PROCEDURE STEP DESCRIPTION
- REQUESTED PROCEDURE ID
- NAMES OF INTENDED RECIPIENTS OF RESULTS
- REQUESTED PROCEDURE COMMENTS
- IMAGING SERVICE REQUEST COMMENTS
- STORAGE MEDIA FILE SET UID
- ELSCINT1_PATIENT_LANGUAGE
- REFERENCED FRAME OF REFERENCE UID
- RELATED FRAME OF REFERENCE UID
- Main Header (Imagio) structure
- Sub-header (Imagio) structure
- Worklist Blob File

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

- REFERENCED STUDY SEQUENCE
- REFERENCED PATIENT SEQUENCE
- REQUESTED PROCEDURE CODE SEQUENCE

- SCHEDULED PROCEDURE STEP SEQUENCE
- REQUEST ATTRIBUTES SEQUENCE
- CONCEPT_SEQUENCE

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

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

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

- PATIENTS AGE

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

- PATIENTS BIRTH TIME

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

- PATIENTS NAME
- PATIENT ID

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

- PATIENTS SIZE

The rounding is according to the following guidance:

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

Tab. 1: Metric:

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

Tab. 2: English:

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

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

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

- PATIENTS SEX

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

- STUDY INSTANCE UID
- SERIES INSTANCE UID
- ELSCINT1_PATIENT_DATA_MODIFIED

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

- PATIENT_IDENTITY_REMOVED

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

- DE_IDENTIFICATION_METHOD

Software Distribution

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

Third Party Service users. For the hospitals not connected to PRS, the software patches can be downloaded from Philips site and copied on the scanner using removable media by Philips Service, Third Party Service users.

Notes:

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

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Philips

5 Quality Assurance

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

- **Short Tube Conditioning** brings the tube to normal operating temperature. This process is required after 4 hours of scanner inactivity, such as in the morning before any scans are performed on patients.
- **Air Calibration** is part of normal system maintenance. The calibration should be performed once a week.
- **Head IQ Check** should be run at least once a week (follow local regulations).
- **Body IQ Check** should be run at least once a month (follow local regulations).
- **Constancy Test** should be run at least once a month and is used for both Head and Body Quality Assurance upon local regulations.
- The infant phantom is used to check the performance in the infant scanning mode. It is optional and used for Infant Head IQ test.
- **Monitor Calibration** must be run daily if the DIN 6868-157 standard is followed.

NOTICE

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

NOTICE

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

Long Tube Conditioning

After a period of inactivity lasting a week or more, Long Tube Conditioning may be necessary. For more information, contact your Philips Service Representative.

System Performance Harmonized Phantom

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

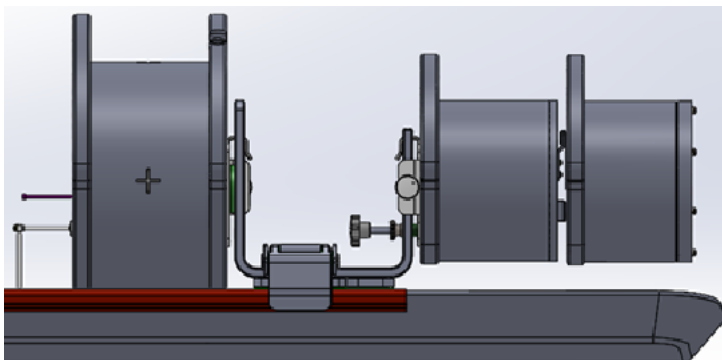
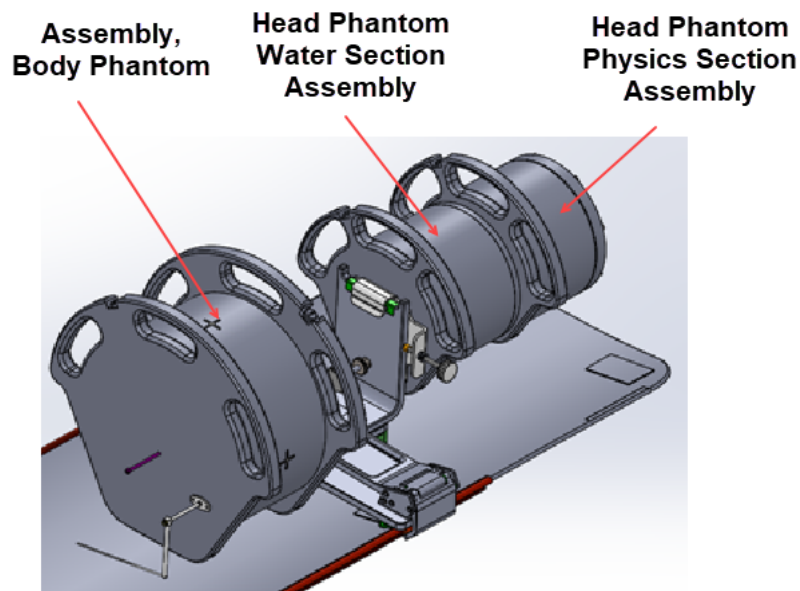
The phantom kit consists of the following parts:

- Harmonized phantom - Head section
- Harmonized phantom - Body section

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

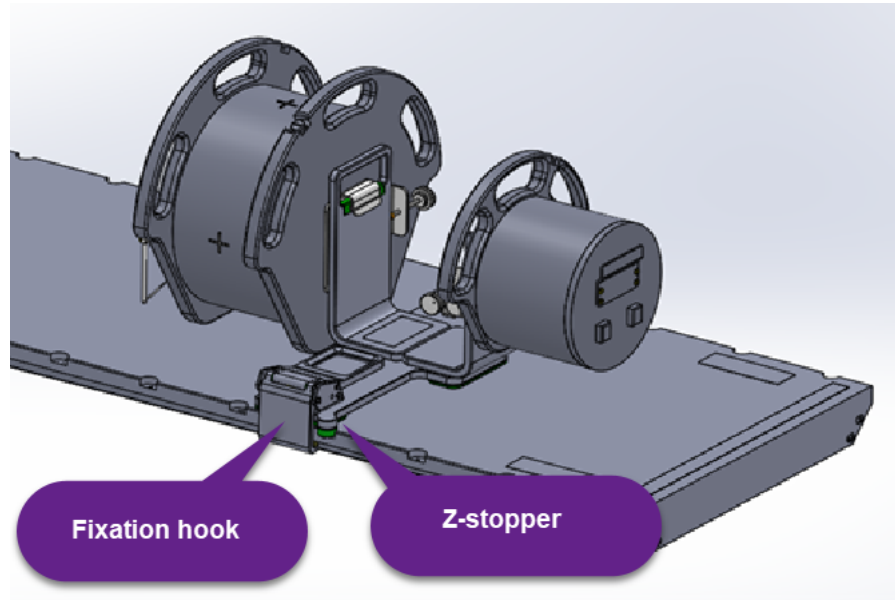
The system phantom is used for the image quality tests and calibrations which can be accessed from the Quality Assurance menu including the automatic phantom centering.

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



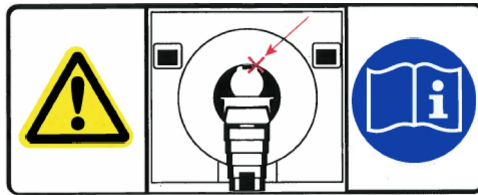
Using Phantom with the Therapy Top

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



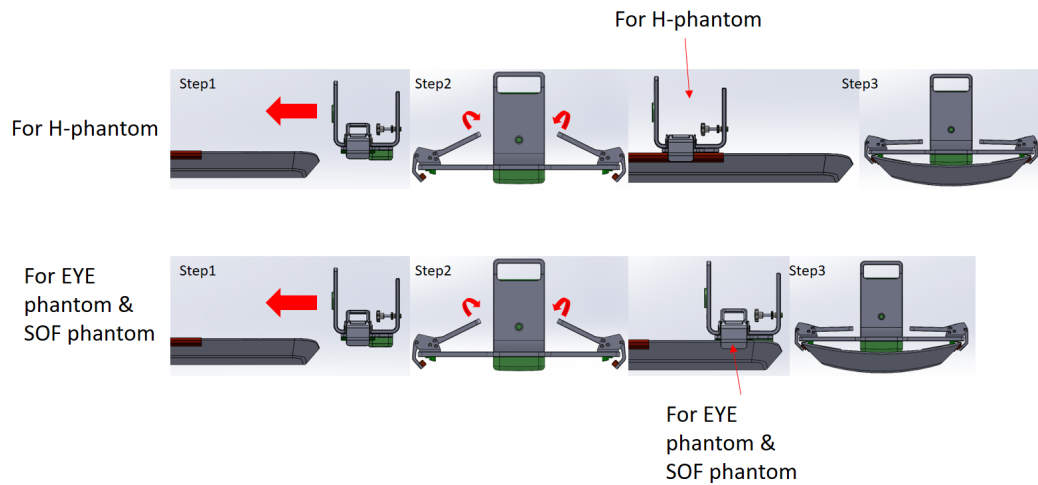
CAUTION

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

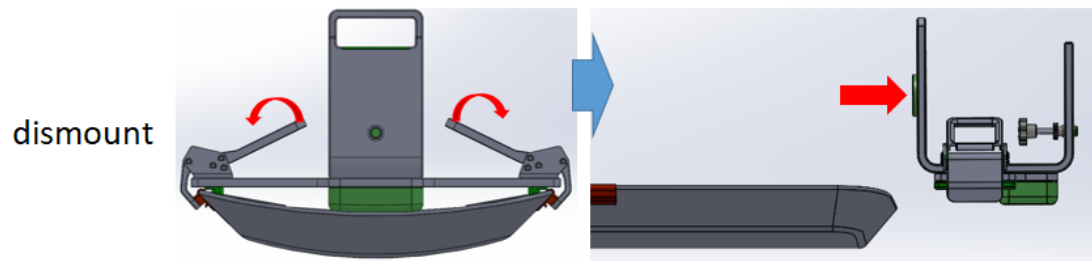


Instructions for Phantom Installation

1. Lift the Phantom Holder on table top with handles in front of the Table top by hands.
2. Slide Phantom Holder on table top along the Table Top, and then push both handles.
3. The Phantom Holder on table top is fixed to the Table Top.
 - Attach phantom holder to the table top over the white line furthest from the gantry.
 - For the therapy top, the z stopper slides into the notch H2, etc.,



4. Remove Phantom Holder on table top from Table Top at any couch height while the table top is out of the gantry bore:
 - Pull the Phantom Holder on table top handles.
 - Lift the Phantom Holder on table top away from the Table Top.



Instructions to center the system phantom using Therapy Top option

The automatic centering is available for this option.

NOTICE

1. Do not skip the Automatic Centering step. This vertically aligns the phantom and correctly positions the table for the scan.
2. Once the right-left phantom centering were performed lock the adjustment screws by its locking nut. This will assure that if phantom section were removed and reinstalled again the Right- Left and Head tilt alignment will remain the same and only Up-Down and Z-position adjustment will be required.
3. The body section is not required for Constancy test according to latest IEC standard: it references the Acceptance test made by service.

Instructions to run HCOR calibrations using Therapy Top option

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

Harmonized Phantom - Head Section

Harmonized Head phantom has only one layer.

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

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

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

NOTICE

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

Harmonized Phantom - Body Section

The body phantom is a single 300 mm outer diameter PMMA shell, filled with phantom liquid.

The body section is used for Body HCOR calibration and IQ tests measuring noise, uniformity and CT accuracy.

Harmonized Phantom - Physics Section

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

It contains:

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

Harmonized Phantom - Infant Section (Optional)

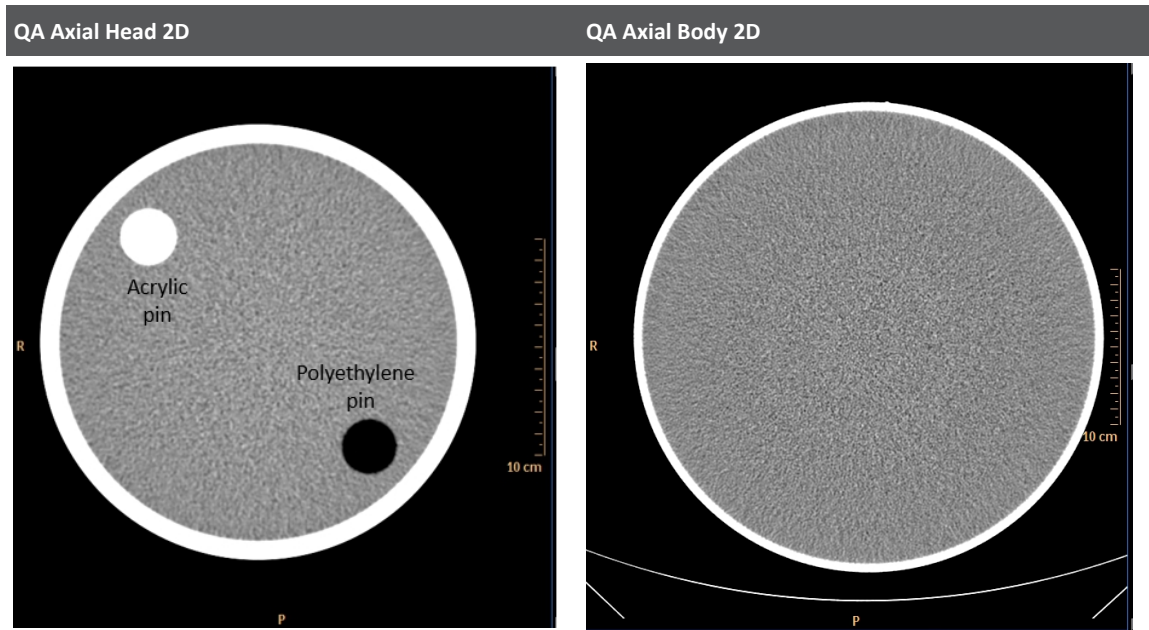
The Infant phantom is a single 110 mm outer diameter PMMA shell, filled with phantom liquid.

The Infant Body IQ can be done on Adult Head section and IQ tests measuring uniformity and CT accuracy.

The Infant head and body HCOR calibrations are scaled for Adult calibrations.

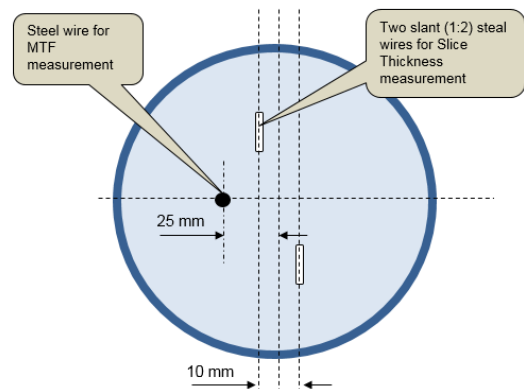
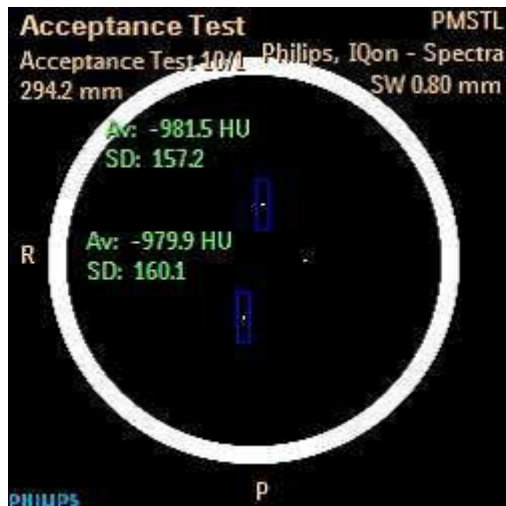
Representative Quality Assurance Images

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



Physics layer for Resolution and Slice Thickness measurement

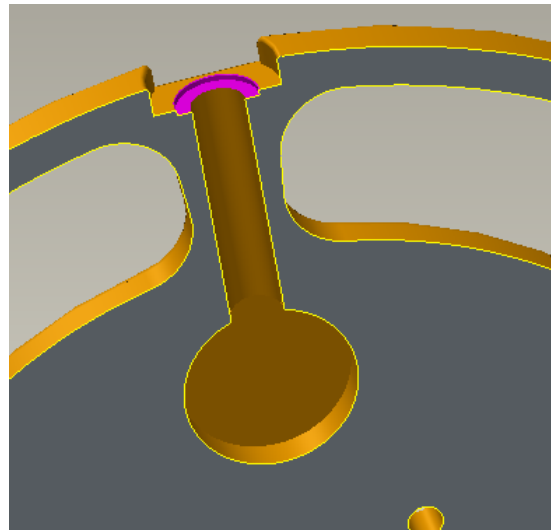
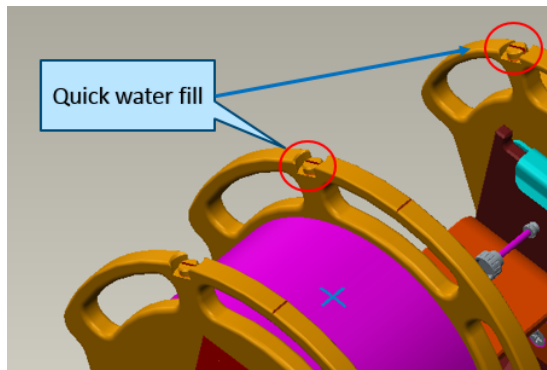
(QA Axial Head 2D)



Phantom Maintenance

The system phantom is certified during scanner manufacturing process and does not require routine calibrations. Adding phantom liquid (water) solution will possibly be needed because of air outgassing. Before use, verify the cylindrical volumes of the phantom are filled with

phantom liquid. Take care to allow small air bubbles to escape to the bubble trap chamber by tilting slightly the phantom. The scanned areas should be free of bubbles not to interfere with measurements. Adding water is performed using specially designed opening on the phantom handle.



Daily Short Tube Conditioning

Short Tube Conditioning brings the tube to normal operating conditions. This process is required after 4 hours of scanner inactivity, such as in the morning before any scans are performed on patients.



WARNING

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

1. Check the scan room to ensure no people are present, and that the table is at least partially within the gantry.



2. Click the **Tool** icon.
3. Click **Quality Assurance**.
4. From the **Quality Assurance** dialog box, click **Short Tube Conditioning**. The **Procedure** column lists the additional tests that may be performed at the same time (for example, Constancy Test, Air Calibration, and so on).
5. Click **Next** and follow the screen prompts.
6. Click **Start** when ready.

- After procedure is complete, click **Exit** to close the program.

Weekly Tests

Air Calibration and the **Head IQ Check** should be performed at least once a week. If time permits, both tests can be performed at the same time; IQ Check can be run after Air Calibration.

Weekly Air Calibration

It is recommended to clean the plastic protection ring with a damp cloth to clear any possible debris and possible drops of contrast material which are transparent and difficult to see and can cause streak artifacts.

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

- To ensure proper operation of the scanner, conduct this procedure at least once per week.
- Because this procedure should be done at stable operating temperature, perform at midday after a number of patients have been scanned for best results. Allow about 30 minutes for completion.
- Ensure that no objects are in the scan field (in the gantry).

NOTICE

If you discover any objects in the scan field (for example, a blanket) after you begin **Air Calibration**, remove the objects from the scan field and restart the process. Look at the images shown before starting the air calibration to ensure no objects or artifacts are seen on images.



WARNING

The software includes automatic data check of foreign objects in x-ray beam path and warns the user.

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

- It is recommended to check the scan room to ensure no people are present.
- Ensure the table (and/or phantom) does not extend into the gantry.



- Click the **Tools** icon.
- Click **Quality Assurance**.

5. From the **Quality Assurance** dialog box, click **Air Calibration**. The **Recommended In** column lists the additional tests that may be performed at the same time (for example, Short Tube Conditioning, IQ Check, and so on).
6. If necessary, select or deselect individual scan modes to include in the test.
7. Click **Next** and follow the screen prompts.
8. After calibration is complete, click **Exit** to close the program.

Weekly Head IQ Check

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



WARNING

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

1. Attach phantom holder to the table top over the white line furthest from the gantry. For the Radiation Therapy top, attach the phantom holder by placing the z stopper in notch H2.
2. Check the scan room to ensure no people are present.
3. Place the system Head phantom or Harmonized Head Phantom on the holder.



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

NOTICE

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

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

IQ Check report data may be recorded manually or electronically exported to an external USB drive.



WARNING

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

If any Test Failed



Ensure the phantom is properly aligned and level. Check the images for any foreign objects (such as pins from another section of the phantom), ring artifacts, or band artifacts. Perform a full Air Calibration and repeat the test. See chapter “Weekly Air Calibration” on page 72.

Click on the **Report** icon to view the detailed results of the test.

If any test fails again or if ring or band artifacts persist, report the findings to your local Service representative before scanning patients in order to ensure safe operation.

Monthly Constancy Test



WARNING

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

The following test should be performed once a month:

1. Attach phantom holder to the table top over the white line furthest from the gantry. For the Radiation Therapy top, attach the phantom holder by placing the z stopper in notch H2.
2. Check the scan room to ensure no people are present.
3. Place the system Head and Body phantom(s) or Harmonized Head and Body Phantom(s) with Physics layer on the holder.
4. Click the **Tools** icon and then select **Quality Assurance**.



5. Select **Constancy Test**. The **Procedure** column lists additional tests that may be performed at the same time (for example, Short Tube Conditioning, Air Calibration, and so on).
6. Click **Next**.
7. If necessary, select or deselect individual scan modes to include in the test.

8. Click **Next**. Follow the on-screen instructions for all the included tests, including phantom placement. After completing the steps, click **Next** again.

NOTICE

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

9. The **Instructions** page opens, with instructions to correctly set up the phantom. After completing these instructions, click **Start**. Users can press **?** for Help instructions.

NOTICE

Do not skip the Automatic Centering step. This vertically aligns the phantom and correctly positions the table for the scan and warns user if phantom is misaligned in x-direction or tilted.

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

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

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

Constancy Test report data may be recorded manually or electronically exported to an external USB drive.

If any Test Failed



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

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

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

If Any Test Failed a Second Time



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

Monthly Body IQ Check

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

**WARNING**

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

1. Attach phantom holder to the table top over the white line furthest from the gantry. For the Radiation Therapy top, attach the phantom holder by placing the z stopper in notch H2.
2. Place the system Head and Body phantoms or the Harmonized Body Section on the holder.
3. Check the scan room to ensure no people are present.



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

NOTICE

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

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

IQ Check report data may be recorded manually or electronically exported to an external USB drive.

**WARNING**

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

If any Test Failed



Ensure the phantom is properly aligned and level. Check the images for any foreign objects (such as pins from another section of the phantom), ring artifacts, or band artifacts. Perform a full Air Calibration and repeat the test. See chapter “Weekly Air Calibration” on page 72.

Click on the **Report** icon to view the detailed results of the test.

If any test fails again or if ring or band artifacts persist, report the findings to your local Service Representative before scanning patients in order to ensure safe operation.

Stabilizing Detection System

To prevent potential negative impact on image quality, the following steps are recommended for systems following a system power down of over 30 minutes:

1. Following system power up, wait at least 60 minutes (or 30 minutes if the system was kept in controlled temperature and humidity conditions, per product specifications, for the entire power down period).
2. Perform **Short Tube Conditioning** and **Body and Head IQ Checks**.
3. Review images and, if artifacts appear, perform **Air Calibration**.

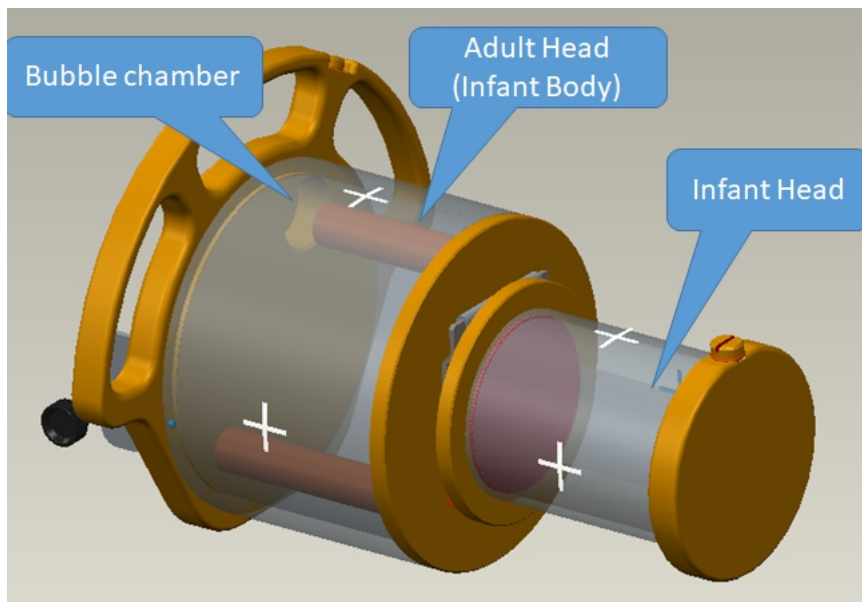
NOTICE

Following a system power down of over 1 week in length, repeat steps 2 and 3 daily for a period of 7 days.

Infant Phantom Testing

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

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



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

Before use, verify the cylindrical volumes of the phantom are filled with phantom liquid. Take care to allow all air bubbles to escape through the bubble chamber. The noted liquid areas should be free of bubbles.

The Harmonized Phantom uses

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

Attach & Scan Phantom

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

1. Move the patient table away from the gantry (OUT).
2. Attach phantom holder to the table top over the white line furthest from the gantry.
3. Check the mounting bracket to ensure it is tightly attached.
4. Insert the infant phantom by sliding its hooks onto the Head Phantom.
5. Turn on the laser markers.
6. Move the patient table to position the phantom in isocenter.
7. Move the patient table towards the gantry (IN).
8. Position the table so that the laser markers line up with the centerline on the phantom holder. Zero the table.
9. Click **Patient**. Enter the demographic information. Select **Infant** from the Age Group.
10. Click **Reference Exam Cards**.
 - Click the **Head** exam card group. Select the **Brain 0-18m** exam card.
 - Click the **Abdomen** exam card group. Select the **Abdomen 0-10Kg** exam card.

- Click **OK**.
- 11. Set the survview to scan the entire Infant Phantom(s).
- 12. Using the survview, plan the Infant Brain Helical scan to (at minimum) cover the Head part of the Infant phantom (see the parameters in the table). Perform the scan.
- 13. Using the same survview, plan the Infant Body Helical scan to (at minimum) cover the head part of the Infant phantom (see the parameters in the table). Perform the scan.
- 14. Set a circular ROI at the phantom image center and note the mean CT value. It should yield the following result.
 - For Infant head section using ROI with a radius of $30\text{ mm} \pm 3\text{ mm}$ the CT number should measure 0 ± 4 CT numbers (or HU)
 - For body section using ROI with a radius of $40\text{ mm} \pm 3\text{ mm}$ the CT number should measure 0 ± 6 CT numbers (or HU)

NOTICE

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

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

| Infant Scan Protocols | Head | Body |
|-----------------------|------------|------------|
| Collimation | 64 x 0.625 | 64 x 0.625 |
| Pitch | 0.296 | 1.390 |
| Rotation Time | 0.4 | 0.33 |
| kV | 100 | 100 |
| mAs | 300 | 125 |
| Thickness (mm) | 2.5 | 3.0 |
| Increment (mm) | 2.5 | 1.5 |
| Filter | UB | C |
| Matrix | 512 | 512 |

Monitor Calibration test

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

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

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

NOTICE

Monitor Calibration is not available during active scan.

**WARNING**

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

6 Harmonized System Phantom



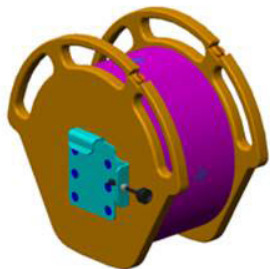
CAUTION

When setting up the harmonized phantom, do not damage any of the phantom components.

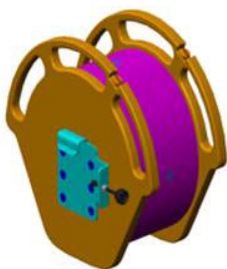
Sections in this help file:

- Harmonized Phantom Configuration Matrix
- Example of Phantom Configurations
- Harmonized System Phantom Holder Setup
- Adjusting the Phantom Left/Right Alignment
- Adjusting the Harmonized Phantom Tilt (Z-direction)
- Harmonized Body Section Installation
- Installing Harmonized Physics Section
- Installing Harmonized Infant Head Section
- Assemble Harmonized Head Phantom to Previously Adjusted Position
- Performing a Manual Scan
- Therapy Top (optional)

Harmonized Phantom Sections



Body 80mm Section



Body 40mm Section



Physics Section



Head Section



Infant Section



Eye phantom for ICT/IQ

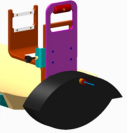
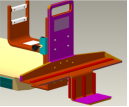
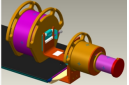
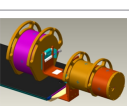



Harmonized Phantom Configuration Matrix



CAUTION
Perform all calibrations and image quality checks with the gantry covers closed.

The following table defines the System Harmonized Phantom usage for different applications:

| Calibration | Eye | SOF | Adult Head | Body | Physics | Infant | Figures |
|-----------------------|-------------------------|-----|------------|------|---------|--------|---------|
| Tube Alignment | ✓ + Slant XRT pin | N/A | N/A | N/A | N/A | N/A | |
| Focal spot X-position | ✓ + Slant XRT pin | N/A | N/A | N/A | N/A | N/A | |

| | | | | | | | |
|---------------------------|-----|-----|-----|-----|-----|-----|---|
| Phantom | ✓ | N/A | N/A | N/A | N/A | N/A |  |
| UHR Comb Align | ✓ | N/A | N/A | N/A | N/A | N/A | |
| + Straight XRT pin | | | | | | | |
| UHR Focal Spot X Position | ✓ | N/A | N/A | N/A | N/A | N/A |  |
| + Straight XRT pin | | | | | | | |
| SFS Position | ✓ | N/A | N/A | N/A | N/A | N/A | |
| + Straight XRT pin | | | | | | |  |
| DFS Position | ✓ | N/A | N/A | N/A | N/A | N/A | |
| + Straight XRT pin | | | | | | | |
| UHR DFS Position | ✓ | N/A | N/A | N/A | N/A | N/A |  |
| + Straight XRT pin | | | | | | | |
| Off-focal | N/A | ✓ | N/A | N/A | N/A | N/A | |
| DDC | N/A | ✓ | N/A | N/A | N/A | N/A |  |
| Steps | N/A | ✓ | N/A | N/A | N/A | N/A | |
| HCOR Basic | N/A | N/A | ✓ | ✓ | N/A | ✓ | |
| HCOR Slice | N/A | N/A | ✓ | ✓ | N/A | ✓ |  |
| Performance | N/A | N/A | ✓ | ✓ | N/A | ✓ | |
| Acceptance | N/A | N/A | ✓ | ✓ | ✓ | N/A | |
| Constancy | N/A | N/A | ✓ | ✓ | ✓ | N/A |  |
| IQ Test, Head only | N/A | N/A | ✓ | N/A | N/A | N/A | |
| IQ Test, Head and Body | N/A | N/A | ✓ | ✓ | N/A | N/A | |

| | | | | | | | |
|-------------------|-----|-----|---|---|-----|-----|---|
| Phantom centering | N/A | N/A | ✓ | ✓ | N/A | N/A |  |
|-------------------|-----|-----|---|---|-----|-----|---|

Example of Phantom Configurations

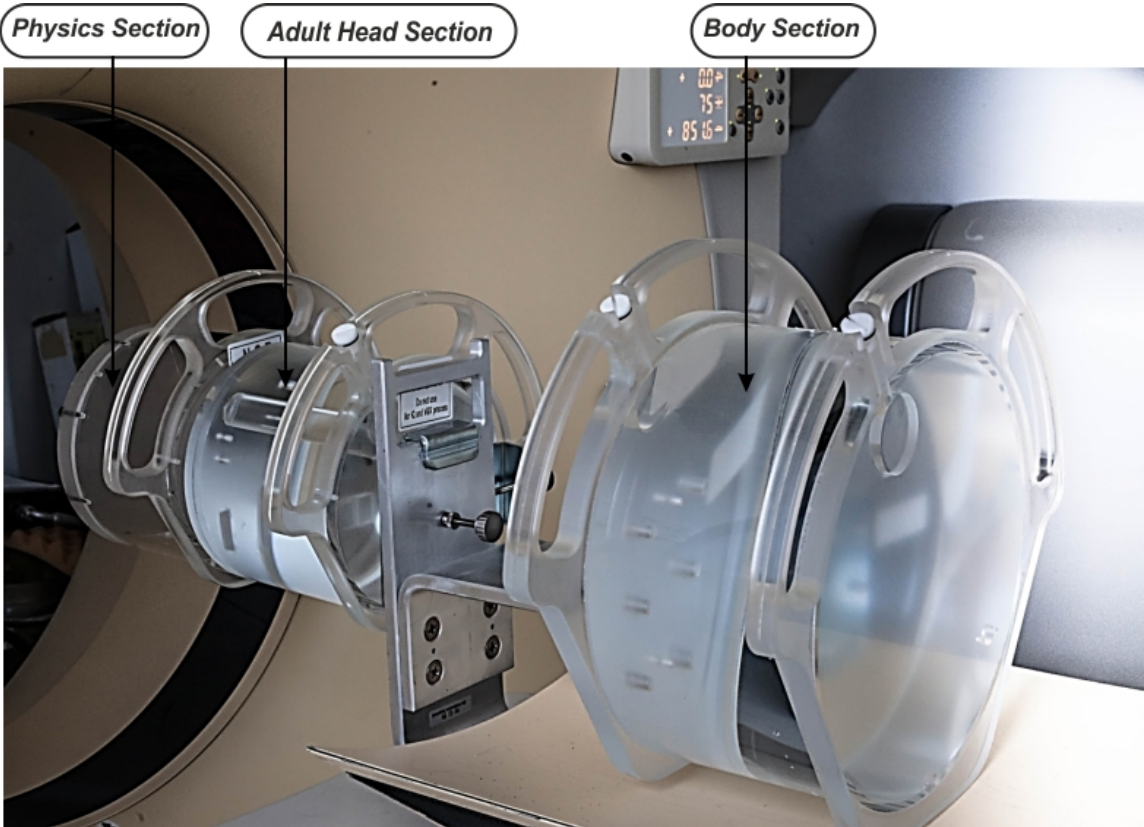


Fig. 1: Harmonized System Phantom Setup for Adult Acceptance and Constancy Test

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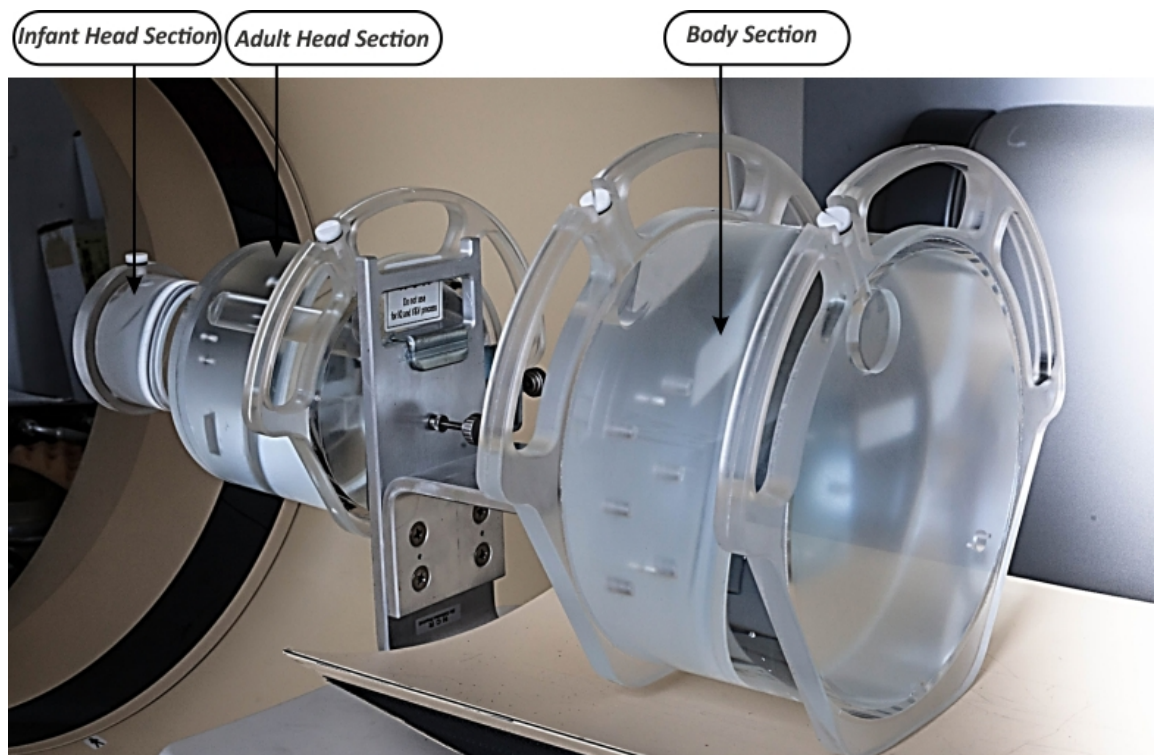


Fig. 2: Harmonized System Phantom Setup for HCOR Slice/Basic and IQ Head Performance Tests

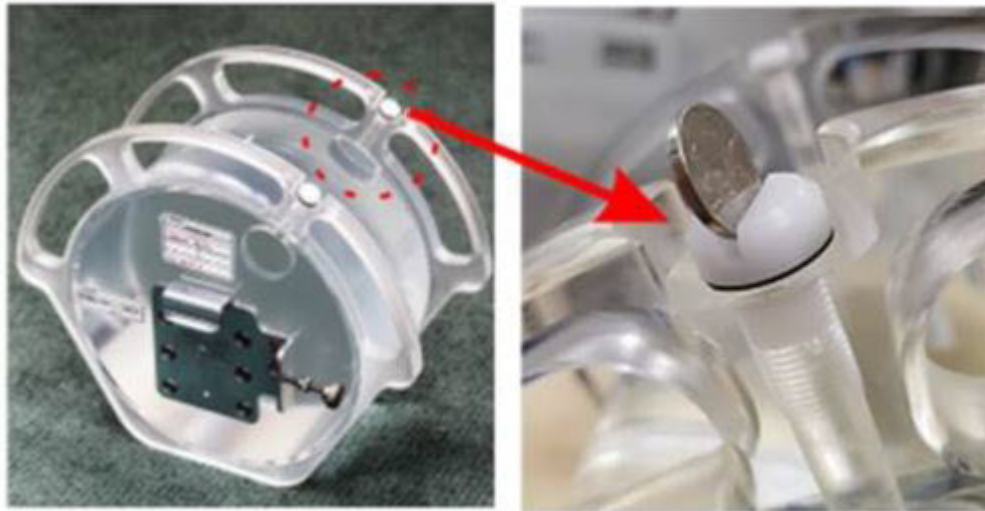
Harmonized System Phantom Holder Setup

1. Perform a visual check of the Harmonized system phantom:
 - No air bubbles larger than 2 mm (refer to the System Installation manual for your system type.)
 - Make sure there are no cracks or water leakage from water filled sections.

Step 1: Check phantom for air bubbles and cracks.

Step 2: If air bubble exist, open the air trap and fill the phantom with phantom water.



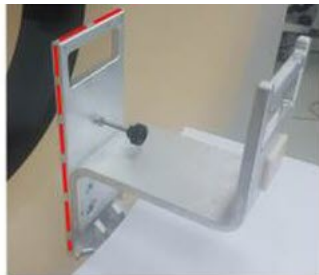


2. Install the phantom holder on the patient table.

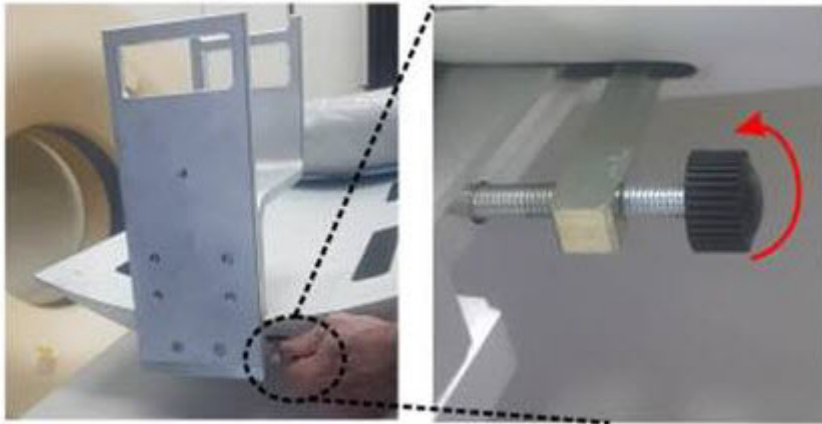
Step 1: Insert the holder into the slot as far as possible.



Step 2: Turn on the lasers and using white alignment lines on the phantom holder.



Step 3: Tighten the locking thumb screw.



Adjusting the Phantom Left/Right Alignment

After starting a test or calibration, if phantom adjustments are needed, instructions appear on the screen with the number of thumb screw turns required to adjust the phantom alignment.

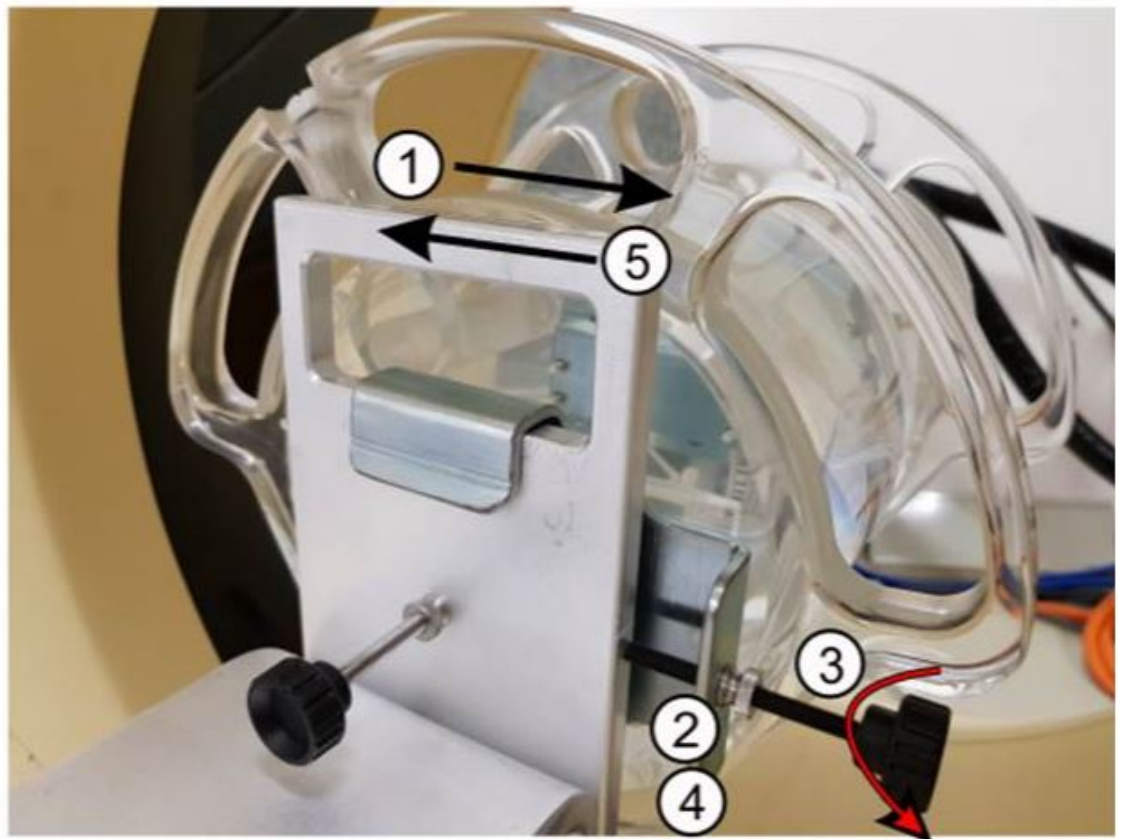


Fig. 3: X-adjustment to Shift Head Section to the Left

1. Shift phantom to the right; more than required.
2. Turn thumb nut to release thumb screw.

3. Turn thumb screw the number of full turns CCW as instructed.
4. Turn the thumb nut to lock the thumb screw.
5. Shift phantom to the left until it is stopped by the screw.

NOTICE

1 turn of thumbscrew = 1 mm

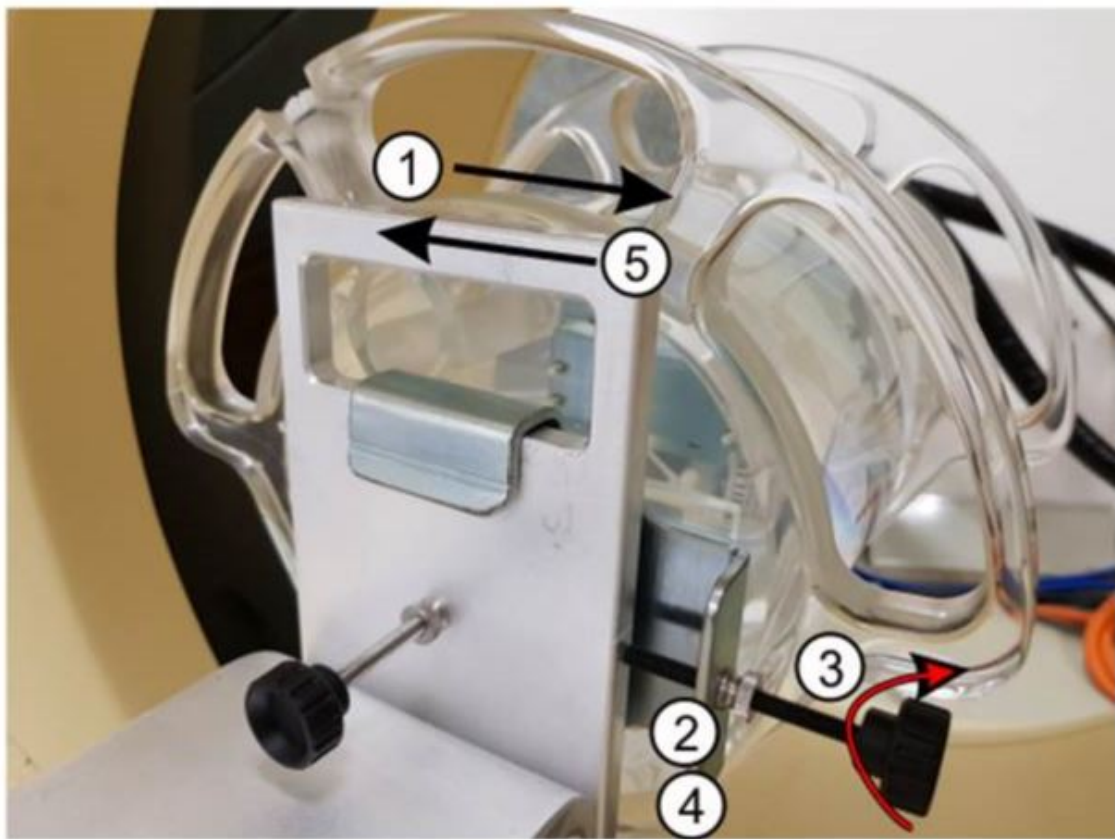


Fig. 4: X-adjustment to Shift Head Section to the Right

1. Shift phantom to the right; more than required.
2. Turn thumb nut to release thumb screw.
3. Turn thumb screw the number of full turns CW as instructed.
4. Turn the thumb nut to lock the thumb screw.
5. Shift phantom to the left until it is stopped by the screw.

NOTICE

1 turn of thumbscrew = 1 mm

Adjusting the Harmonized Phantom Tilt (Z-direction)

1. Release the thumb nut on the adjustment thumb screw.
2. Turn the adjustment screw the number of turns as instructed:
 - Clockwise - to shorten the screw and the phantom will tilt up.
 - Counter-Clockwise - to extend the screw and the phantom will tilt down.
3. Tighten the thumb nut to lock the adjustment screw.
4. Continue with the calibration/test.



When correct tilt is achieved, turn thumb nut CW to lock adjustment screw.

1 turn of thumbscrew = 1 mm

NOTICE

One turn of Tilt Adjustment thumbscrew = **0.8 deg.**

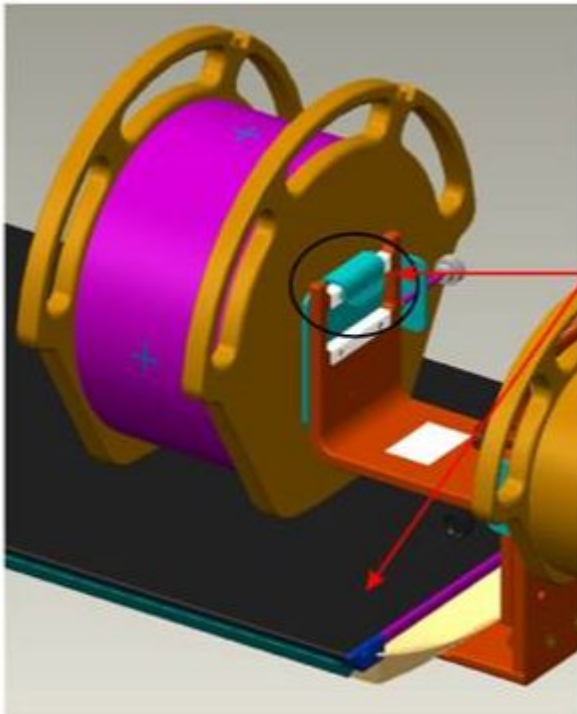
Harmonized Body Section Installation



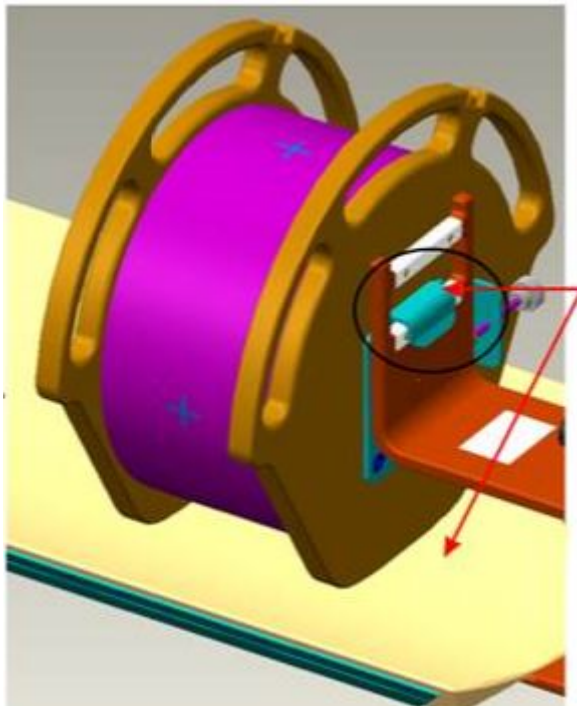
CAUTION

When setting up the harmonized phantom, do not let the adjustment screw hit the phantom holder.

1. Install the Body section on the rear part of the holder in the same manner as the Head phantom:
 - Use the top bar of the rear part of the holder, if the therapeutic top option is installed (see figure below).
 - Use the lower bar of the rear part of the holder, for all other table tops (see figure below).
2. To remove the body section, shift the phantom to the left and lift the body section.



Upper bar with flat top patient table.



Lower bar with curved top patient table.

NOTICE

The Harmonized body section rests on the standard (extended, bariatric) table top and the therapeutic (flat) top.

Installing Harmonized Physics Section

1. Install the Physics section: slide the section's hook bracket over the Head section bracket.
2. Align the Physics section with the Head section using the alignment guides.
3. Make sure both Head and Physics sections are flush and fixed securely.

NOTICE

The brackets on the sections, by design, secure the Head and Physics sections together. The brackets have guides that ensure that the sections are aligned. Additional alignment between sections is not required.

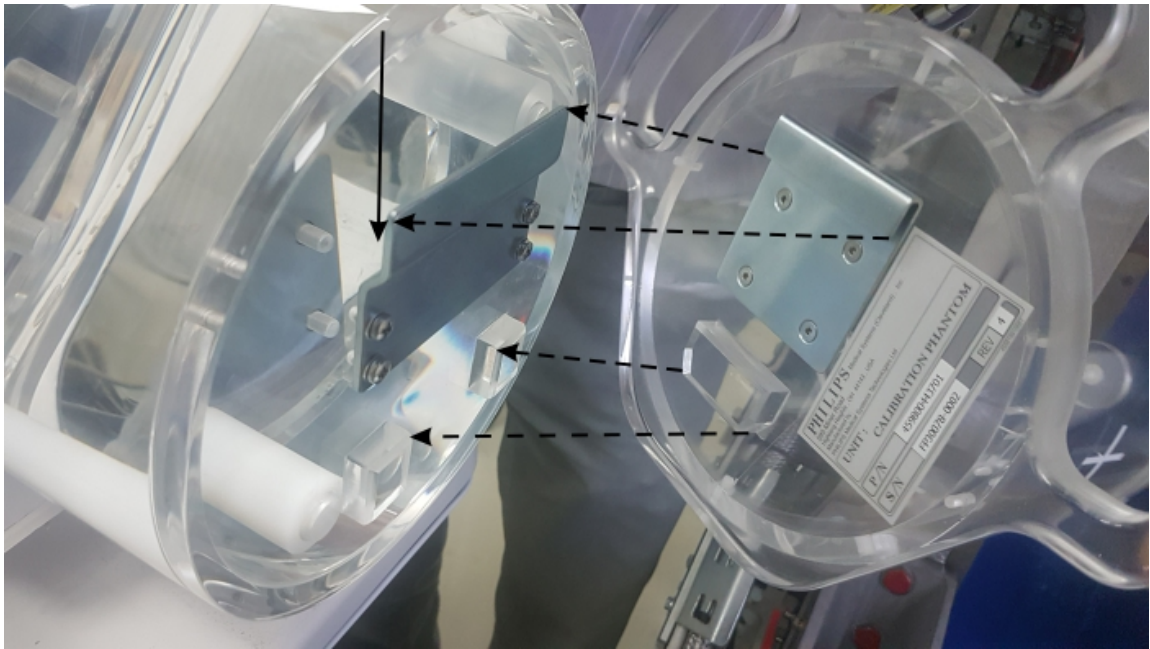


Fig. 5: Physics Section to Harmonized Body Section Assembly Alignment Slot

Installing Harmonized Infant Head Section

1. Remove the Physics section if installed.



CAUTION

When setting up the harmonized phantom, do not let the adjustment screw hit the phantom holder.

2. Install the Adult head section on the Harmonized phantom holder.
3. Slide the Infant Head section hook bracket over the Adult Head section bracket.
4. Make sure both Head and Infant sections are assembled securely together; verify the bracket guides are aligned together.

Assemble Harmonized Head Phantom to Previously Adjusted Position



CAUTION

When setting up the harmonized phantom, do not damage any of the phantom components.

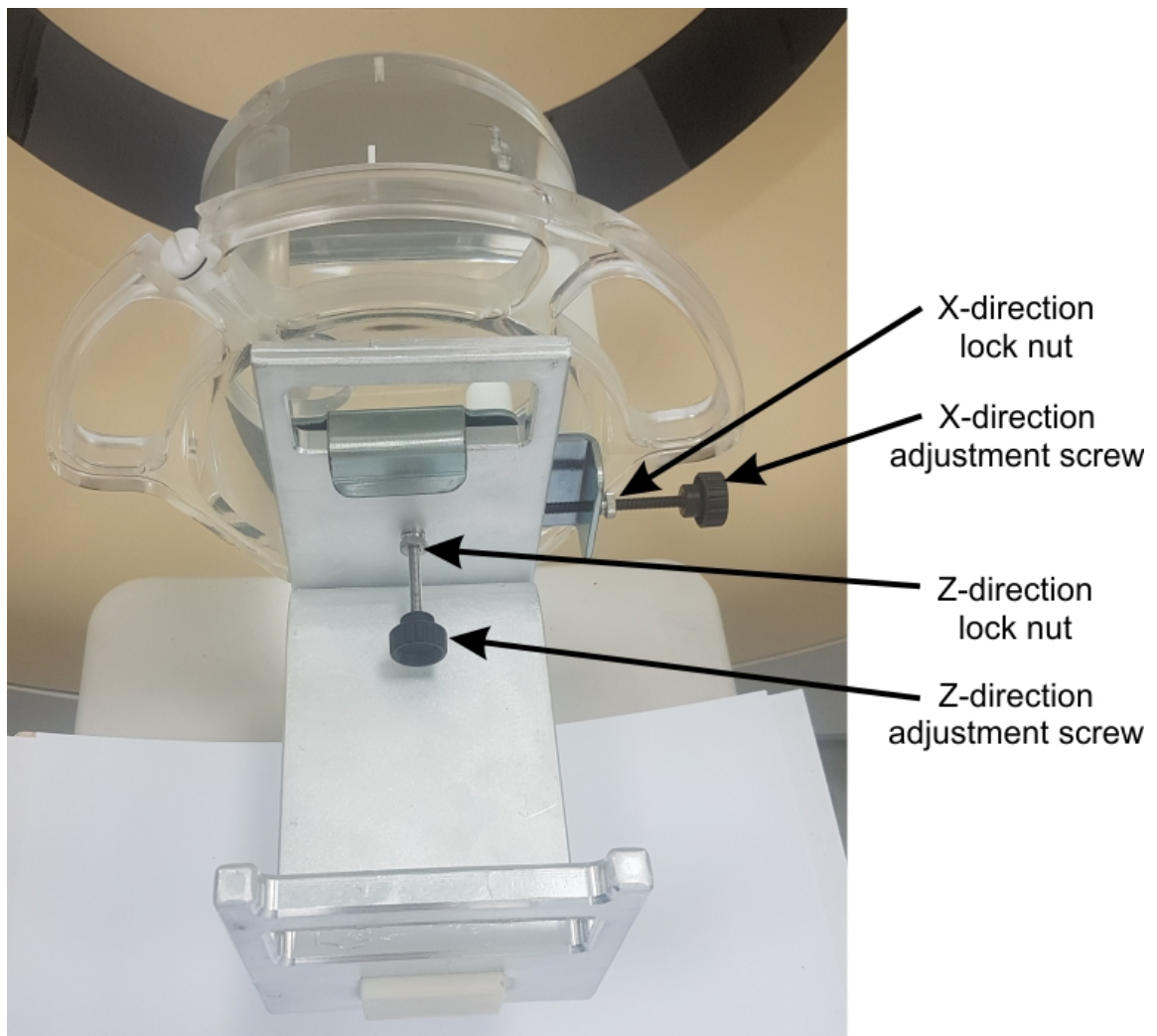
1. Keep the phantom on the right side of the phantom holder and away from the X-adjustment screw.
2. Hook the Head phantom on the phantom holder bar so that the adjustment screw is does not hit the holder.



CAUTION

Do not let the adjustment screw hit the holder. Hook the head phantom on the holder, keeping the phantom off center and to the right.

3. Slide the phantom left until the X-adjustment screw is touching the holder side. This will bring the phantom Z-alignment to the previously adjusted position.
4. To remove the head phantom, shift the phantom to the right and lift the phantom head phantom.



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Performing a Manual Scan

1. Turn On the lasers from the Gantry Control Panel.
2. Adjust the phantom holder Left/Right position on the holder so the sections are exactly aligned.
3. Press the Reset to Zero button on the gantry control panel to reset the PT position to zero.

NOTICE

When using automatic centering, there is no need to press Reset to Zero.

4. Start the test.

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Therapy Top (optional)

If the phantom is installed on the Therapy Top (optional) do the following:

1. Use Slice laser and zero the couch In/Out (Z-position) on the white line on the phantom holder.
2. Use Axial lasers to manually center the Head and Body phantom sections using the Gantry control panel and Head section Tilt using the tilt screw.
3. Click on “Skip centering” checkbox below to skip centering.
4. Click OK to perform scan and check that the phantom is centered Up-Down ± 8 mm and Right-Left within ± 8 mm if not Return to step b.

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Philips

7 User Information

Environmental Requirements

| Temperature | Values |
|-----------------------|-----------------------------------|
| Examination room | 18° to 24° C (64° to 75° F) |
| Control room | 15° to 24° C (59° to 75° F) |
| Technical room | 15° to 28° C (59° to 82° F) |
| Storage and transport | -20° to +50° C (-4° F to +122° F) |

| Humidity | Values |
|-----------------------|---------------------------|
| Examination room | 35% to 70% non-condensing |
| Control room | 35% to 70% non-condensing |
| Technical room | 20-80% non-condensing |
| Storage and transport | 20% to 85% non-condensing |

| Altitude* | Values |
|-----------|--------------------------|
| Operation | maximum 2100m (78kPa) |
| Storage | maximum 3000m (70kPa) |
| Transport | maximum 10000m (30kPa) |

*Please contact your Philips service representative for more information if operating at high altitude.

NOTICE

Short Tube Conditioning brings the tube to normal operating temperature. This process is required daily before any scans are performed on patients, or after 4 hours of scanner inactivity.

It is recommended you perform **Air Calibration** once per week.

Perform **Constancy Checks** monthly.

Complete image quality checks regularly to ensure good image quality.

NOTICE

Before running detectors calibration and once Temperature Notification window is displayed, don't close the Temperature Notification window till temperature stabilization process is successfully complete.

Technique Factors - Maximum Deviations

Peak X-ray Tube Voltage

The peak X-ray voltage displays on the Operator workstation screen. The actual X-ray voltage during scan is within $\pm 8\%$ of the displayed value. Selectable peak values are 80, 100, 120 or 140 kVp.

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

Tube Current Exposure Time Product

The actual current exposure time product (in mAs) during a scan is within $\pm 30\%$ of the value displayed on the Operator console. The tube current exposure time product is measured by a dosimeter calibrated in mAs. The dosimeter is calibrated by measuring the tube anode current on an accurate resistor between X-ray on and off during a long exposure.

Linearity of Radiation

The maximum deviation of linearity of radiation is $\pm 20\%$.

Gantry Laser Alignment Lights

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

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

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

NOTICE

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

Preventive Maintenance

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

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

- Cathode voltage
- Emission current
- Exposure time

Cleaning and Disinfection of the System

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

**CAUTION**

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

**CAUTION**

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

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

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

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

- 1:10 bleach equivalent spray cleaner or wipes
- 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.

**CAUTION**

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

Tips:

- After cleaning and disinfection, inspect for any damages to the parts, e.g. cracks on the covers, degraded labels, or torn/broken parts etc. Contact Philips Service Representative immediately if any parts are damaged.
- Clean and disinfect the system after installation and before first clinical use.
- When cleaning the front and rear covers on the scanners, cover the microphones to avoid leaking the cleaning solution inside.
- When cleaning the buttons, mouse and the inside of the Gantry opening, take care to avoid leaking the cleaning solution inside.
- When cleaning the monitor screens, use soft cloth, if necessary, moistened with water or LCD cleaner. Do not use any corrosive agents or abrasive agents. Damp cloth can be used but never use wet cloth.
- Activate the clean screen function when cleaning the touch panels (if equipped). Use soft cloth, if necessary, moistened with water or LCD cleaner. Do not use any corrosive agents or abrasive agents. Damp cloth can be used but never use wet cloth.
- The patient restraints can be machine washed or dry-cleaned. Wash the restraints closed to protect the Velcro parts. Remove contaminations with wet cloth. On site cleaning can be performed using specified cleaners/disinfectants, followed by cleaning with water as needed. Make sure the patient restraints are completely dry before using or storing them.
- Apply solution on lint-free wipes if solutions are used. Do not apply solutions directly on the device.
- Rinsing, when needed, should be done with a damp lint-free wipes. Wipes can be damped with distilled water.
- Drying, when needed, should be done with lint-free wipe.

**CAUTION**

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

X-ray System Specifications

X-ray Tube

Leakage

X-ray source assembly (including beam limiting device) leakage radiation is less than 0.88 mGy/hr @ 1 meter.

Filtration

Minimum permanent filtration of the X-ray tube assembly is 2.9 mm Al equivalent at 80 kV. The beam-limiting device includes flat and shaped filters.

NOTICE

The Spectral CT X-ray tube has an effective direct cooling system through the bearing in addition to the radiation cooling. Therefore the anode heat capacity concept is not comparable with conventional rotating anode tubes.

X-ray Power Supply

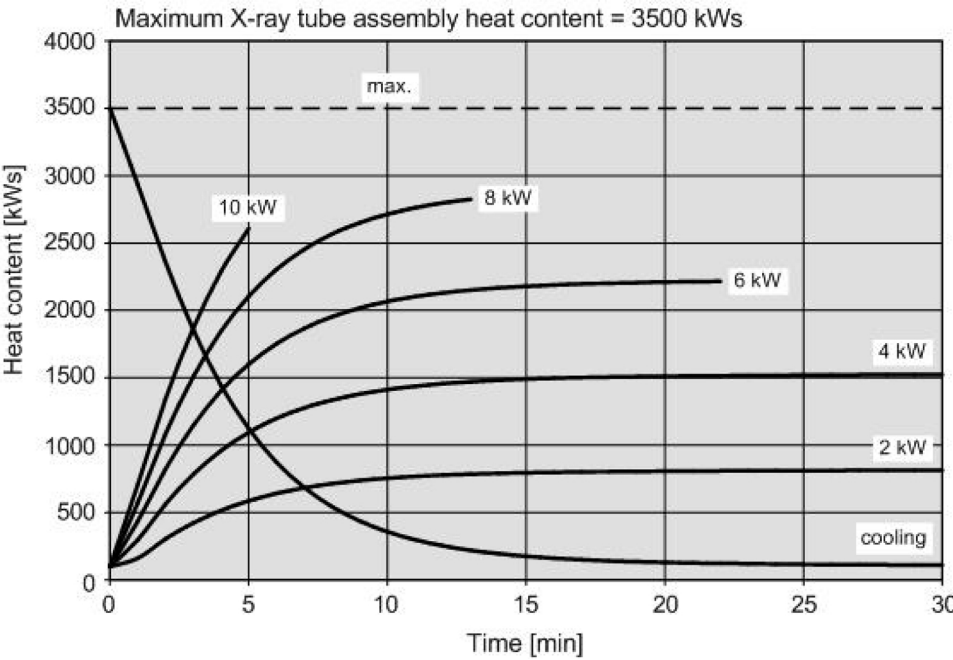
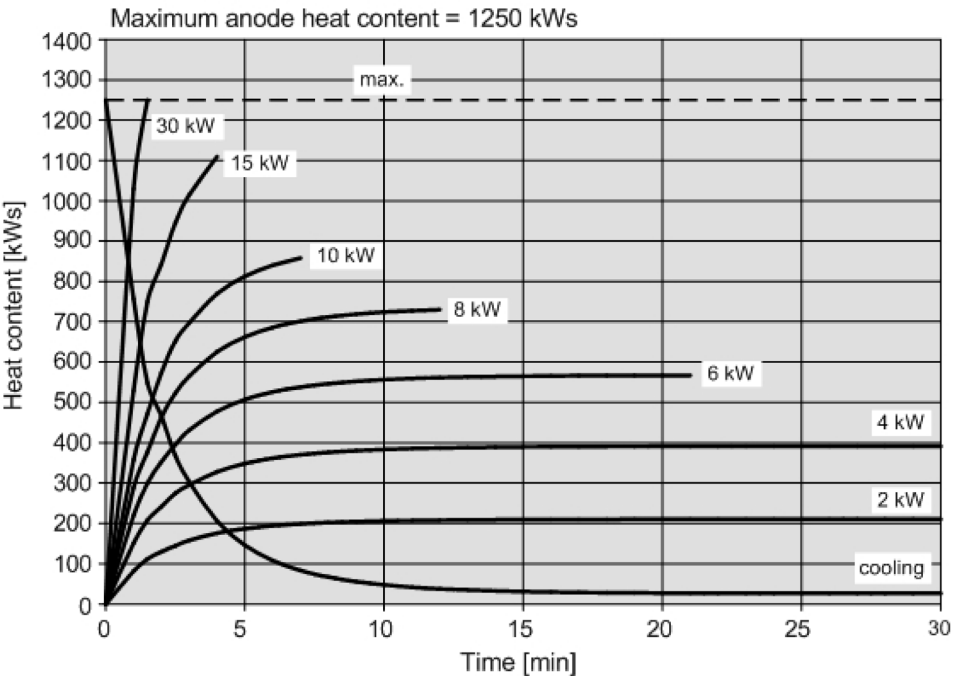
The X-ray Power Supply uses 380 – 480 VAC +/-10%. Change in the output high voltage is +/-1.5% at all line conditions. Maximum line current is 290 A rms at 380VAC, and 230 A rms at 480 VAC. Maximum output power is 120kW, depending on system configuration.

NOTICE

Line current calculated based on 120KW, -10% line voltage, 0.85 power factor, 90% HVG efficiency, 93% AC-DC power chain efficiency.

X-ray Tube Housing Assembly Information

The following graphs are the tube housing assembly heating and cooling curves and the anode heating and cooling curves for your Spectral CT system.

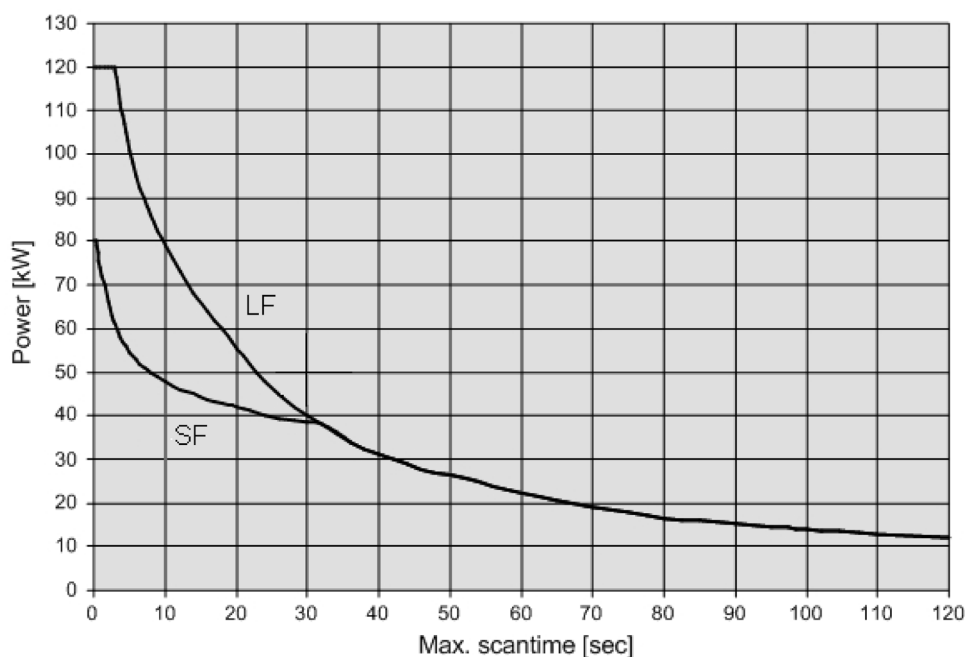


NOTICE

In the graph below, **LF** stands for **Large Focus** (referring to large focal spot size) and **SF** stands for **Small Focus** (referring to small focal spot size).

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Philips



Focal Spot Size Specifications in accordance with IEC 60336 Ed 4.0

- Large focal spot width x length: 1.1 x 1.2
- Small focal spot width x length: 0.6 x 0.7

User Dose & Imaging Information

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

NOTICE

This information is provided as required by the US DHHS, pursuant to 21CFR, Chapter 1, Subchapter J, paragraph 1020.30 and 1020.33 and 2013/59/EURATOM.

Phantoms & Measurement Methods

Dose Phantoms

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

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

Dose Profiles & Dose Measurements

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

CTDI Definition

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

- For $N \times T$ less than or equal to 40 mm

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

- For $N \times T$ greater than 40 mm (all CT conditions of operation except collimation are kept the same for these measurements)

$$CTDI_{100} = \int_{-50mm}^{+50mm} \frac{D_{Ref}(z)}{(N \times T)_{Ref}} dz \times \frac{CTDI_{freeair, N \times T}}{CTDI_{freeair, Ref}}$$

where,

- $D(z)$ is the dose profile representative of a single axial scan along a line z perpendicular to the tomographic plane, where dose is reported as absorbed dose in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry phantom;
- $(N \times T)_{Ref}$ is 20 mm;
- $D_{Ref}(z)$ is the dose profile representative of a single axial scan along a line z perpendicular to the tomographic plane, where dose is reported as absorbed dose in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry phantom for $(N \times T)_{Ref} = 32 \times 0.625$;
- $CTDI_{free air, N \times T}$ is the $CTDI_{free air}$ for a specific value of $N \times T$;
- $CTDI_{free air, Ref}$ is the $CTDI_{free air}$ for $(N \times T)_{Ref} = 32 \times 0.625$;
- N is the number of tomographic sections produced in a single axial scan of the X-ray source;
- T is the nominal tomographic section thickness.

To measure $CTDI_{free air}$ for these wide collimations (e.g. 128×0.625), first center the dose probe in the gantry, zero the couch, and measure the reference $CTDI_{free air}$ (32×0.625). After that, move the couch to position -50mm, and measure the $CTDI_{free air}$ at the wide collimation. Then, move the couch to position +50 mm, and measure again at the wide collimation. Add the two results, and use the sum as $CTDI_{free air, N \times T}$.

- for axial scanning

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

with these definitions:

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

- for helical scanning

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

- for scanning without movement of the patient support

$$CTDI_{vol} = n \times CTDI_w$$

- n = the maximum number of pre-programmed rotations

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

Modulation Transfer Function

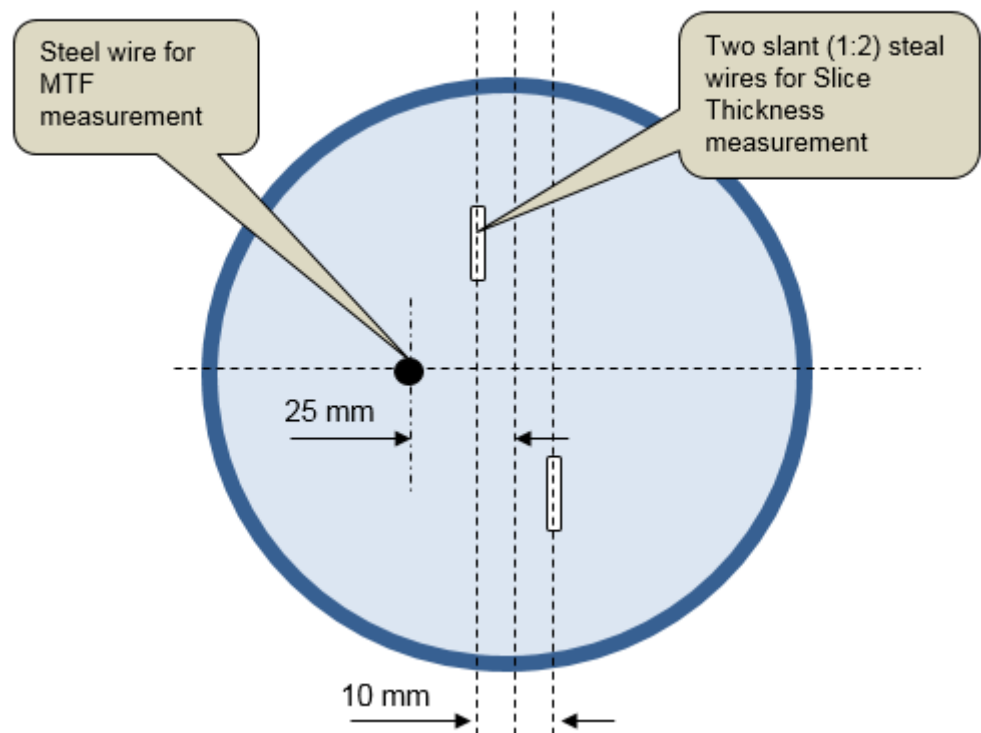
The impulse response and the tomographic thickness (slice thickness) are not dependent upon the phantom dimensions. They are therefore, measured on the physics layer of the system phantom (see chapter “System Performance Harmonized Phantom” on page 65).

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

The maximum deviation of the MTF from the Acceptance baseline is 15%.

Tomographic Thickness Measurement

The phantom contains two steel wires at about 26.6 degrees which give projections of the sensitivity profile in the image plane. The slope of these wires is 1:2.



The profiles of the projections are equivalent to the sensitivity profiles and the FWHM (full width at half maximum) of the profile is the nominal tomographic thickness multiplied by two. The profile can be measured using the **Slice Thickness** Image Tests program (in the Analysis options, accessible from the Directory window).

The maximum deviation of the derived thickness from the Acceptance baseline is as follows:

| | |
|---------------------------------|--------------|
| Thickness ≥ 2 mm | ± 1 mm |
| Thickness $1 \text{ mm} < 2$ mm | $\pm 50\%$ |
| Thickness ≤ 1 mm | ± 0.5 mm |

Display CTDI Phantom Size

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

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

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

To convert a CTD_{vol} measurement which is displayed for a 32 cm (or Body) phantom to a value measured with a 16 cm (or Head) phantom, multiply the 32 cm value by the constants listed in the table below.

| To convert 32 cm CTDI to 16 cm CTDI _{vol} | |
|--|-------|
| 80 kVp | 1.991 |
| 100 kVp | 1.955 |
| 120 kVp | 1.919 |
| 140 kVp | 1.900 |

To convert from 16 cm CTDI_{vol} to 32 cm CTDI, divide the 16 cm CTDI value by the constant value appropriate for the kVp.

The only Head Exam cards are those in the Head, Ear (Inner Ear) Exam Card Groups, and some Standard QA exam cards. All other Exam Cards are considered to be Body Exams on this scanner.

System Imaging Geometric Accuracy

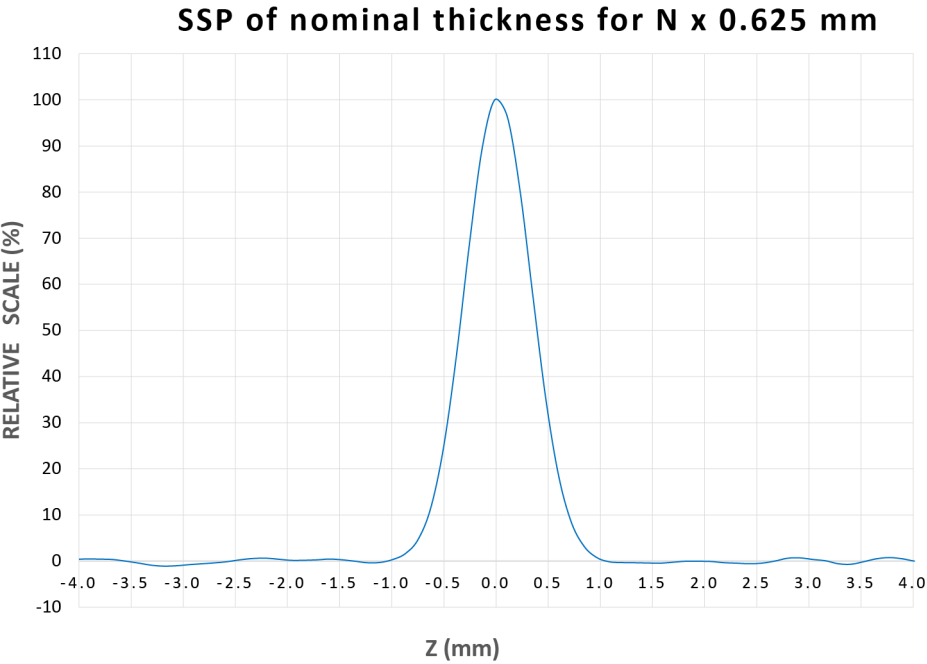
The system imaging geometric accuracy is better than ±1 mm in the gantry plane across 50 mm and is better than ±5 mm at 500 mm in both X and Y directions.

Sensitivity Slice Profile

The following Sensitivity Slice Profile (SSP) is defined according to IEC 60601-2-44. Spectral CT has one basic axial nominal tomographic section N x 0.625. Here N is the number of slices in collimation setup.

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NOTICE

The limited resolution of the image causes the thin slice thickness to appear thicker than it really is.

The FWHM (slice thickness) of the SSP is automatically checked for all collimation setups by running the Constancy Test using the System Performance Phantom.

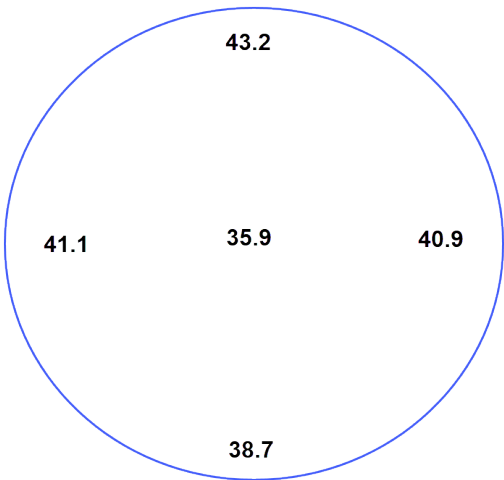
Head Scan Information

Head dose - typical head CT scan conditions of operation:

| Main | |
|-----------------|------------|
| FOV | 250 |
| Storage | Local |
| Number of Scans | 1 |
| Scan | |
| Collimation | 64 x 0.625 |
| Thickness | 5 |
| Increment | 0 |
| Rot Time | 0.75 |

| Scan | |
|-----------|-----|
| Voltage | 120 |
| mAs | 250 |
| Recon | |
| Filter | UB |
| SP Filter | No |

CTDI100 Head



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

The 16 cm diameter phantom is placed in the center of the Gantry opening, on the table.

Maximum deviation from the values shown is $\pm 35\%$. $CTDI_{100} = 39.3$ mGy.

These $CTDI_{100}$ values are appropriate for Adult and Pediatric Head scans.

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

Tube Current - Exposure Time Product (mAs) Dependence

The dose increases linearly with the tube current - exposure time product. The $CTDI_{100}$ in the center location of the head phantom, normalized to the $CTDI_{100}$ in the center location from the values shown in the CTDI100 Head information, depends on the mAs for the values as shown by the ratios below. The maximum deviations of these ratios are also provided.

| $CTDI_{100}$ | | |
|--|-----------------|--------------------------------------|
| Minimum $CTDI_{100}$ (at 10 mAs) is... | $0.04 \pm 20\%$ | ...times the $CTDI_{100}$ at 250 mAs |
| Maximum $CTDI_{100}$ (at 1500 mAs) is... | $6.0 \pm 20\%$ | ...times the $CTDI_{100}$ at 250 mAs |

Slice Thickness Dependence

The $CTDI_{100}$ in the center location of the head phantom, normalized to the $CTDI_{100}$ in the center location from the values shown in the CTDI100 Head information, depends on the collimation mode and slice thickness as shown by the ratios below. The maximum deviations of these ratios are also provided.

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| Slice Thickness Dependence | | |
|--|-----------|---|
| The CTDI ₁₀₀ of the 128x0.625 mm (80 mm) collimation is ... | 0.94± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation. |
| The CTDI ₁₀₀ of the 112x0.625 mm (70 mm) collimation is ... | 0.95± 15% | ... times the CTDI ₁₀₀ of the 64 x 0.625 mm (40 mm) collimation. |
| The v of the 96x0.625 mm (60 mm) collimation is ... | 0.96± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation |
| The CTDI ₁₀₀ of the 32x0.625 mm (20 mm) collimation is ... | 1.12± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation |
| The CTDI ₁₀₀ of the 16x0.625 mm (10 mm) collimation is ... | 1.39± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation |
| The CTDI ₁₀₀ of the 8x0.625 mm (5 mm) collimation is ... | 1.92± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation |
| The CTDI ₁₀₀ of the 4x0.625 mm (2.5 mm) collimation is ... | 2.61± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation |
| The CTDI ₁₀₀ of the 2x0.625 mm (1.25 mm) collimation is ... | 3.41± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation |

Voltage Dependence - Center

The X-ray voltage can be varied between 80 and 140 kV. The CTDI₁₀₀ in the center location of the head phantom, normalized to the CTDI₁₀₀ in the center location from the values shown in the CTDI100 Head section, depends on the X-ray voltage as shown by the ratios below. The maximum deviations of these ratios are also provided.

| CTDI ₁₀₀ | | |
|--|------------|---|
| With 80 kV, the CTDI ₁₀₀ is... | 0.32 ± 15% | ... times the CTDI ₁₀₀ at 120 kV |
| With 100 kV, the CTDI ₁₀₀ is... | 0.62 ± 15% | ... times the CTDI ₁₀₀ at 120 kV |
| With 140 kV, the CTDI ₁₀₀ is... | 1.45 ± 15% | ... times the CTDI ₁₀₀ at 120 kV |

Voltage Dependence - Edge

The CTDI₁₀₀ in the peripheral location of the head phantom, normalized to the CTDI₁₀₀ in the peripheral locations from the values shown in the CTDI100 Head section, depends on the X-ray voltage as shown by the ratios below. The maximum deviations of these ratios are also provided.

| CTDI ₁₀₀ | | |
|--|------------|--|
| With 80 kV, the CTDI ₁₀₀ is... | 0.34 ± 15% | ... of the CTDI ₁₀₀ at 120 kV |
| With 100 kV, the CTDI ₁₀₀ is... | 0.64 ± 15% | ... of the CTDI ₁₀₀ at 120 kV |
| With 140 kV, the CTDI ₁₀₀ is... | 1.42 ± 15% | ... of the CTDI ₁₀₀ at 120 kV |

Dose Profiles - Head

The dose profiles at the center of the CTDI Head phantom superimposed on the slice sensitivity profiles as well as the nominal sensitivity profile limit lines are presented here. The maximum deviations from the drawn curves are ±20%.

NOTICE

The dose profiles and sensitivity profiles were measured under the typical conditions of operation presented in the Head Scan section, while changing the collimation only.

Head curves were measured in the center hole of 16 cm diameter CTDI phantom (made of PMMA plastic).

X-ray sensitive film Gafchromatic XR-CT2 was used. The measurement is made for 2 x 0.6 (smallest), 128 x 0.625 (largest) and 64 x 0.625 (middle) collimation openings.

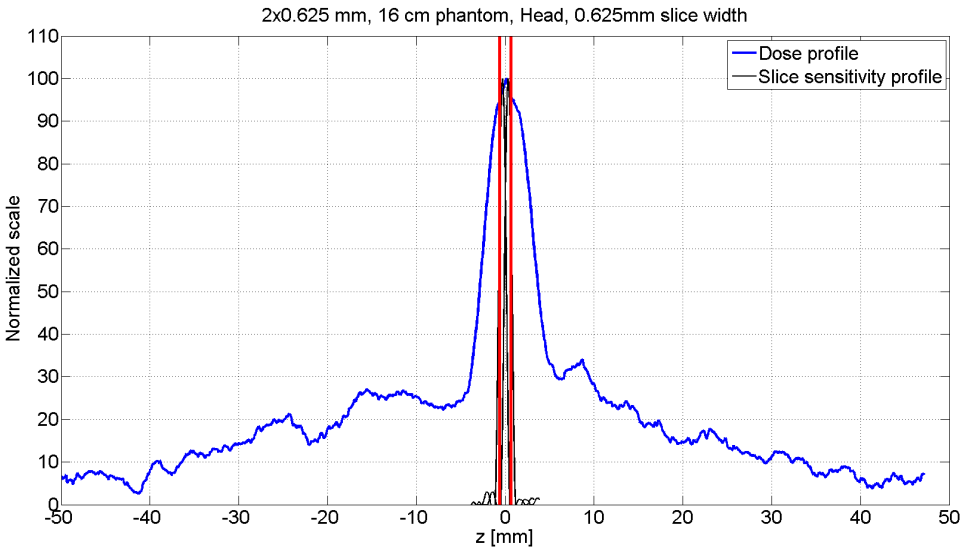
The following are the Dose Profile curves slightly smoothed to reduce the high frequency noise coming from film pixel sensitivity variation.

Head Dose Profiles

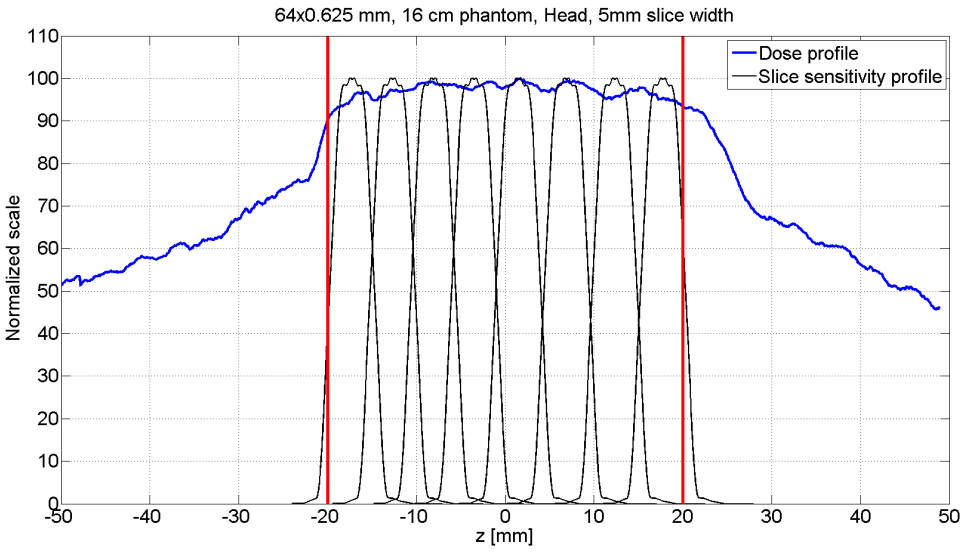
Head, 2 x 0.625 mm collimation, 16 cm phantom

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Head, 64 x .0625 mm collimation, 16 cm phantom



Head, 128 x 0.625 mm collimation, 16 cm phantom

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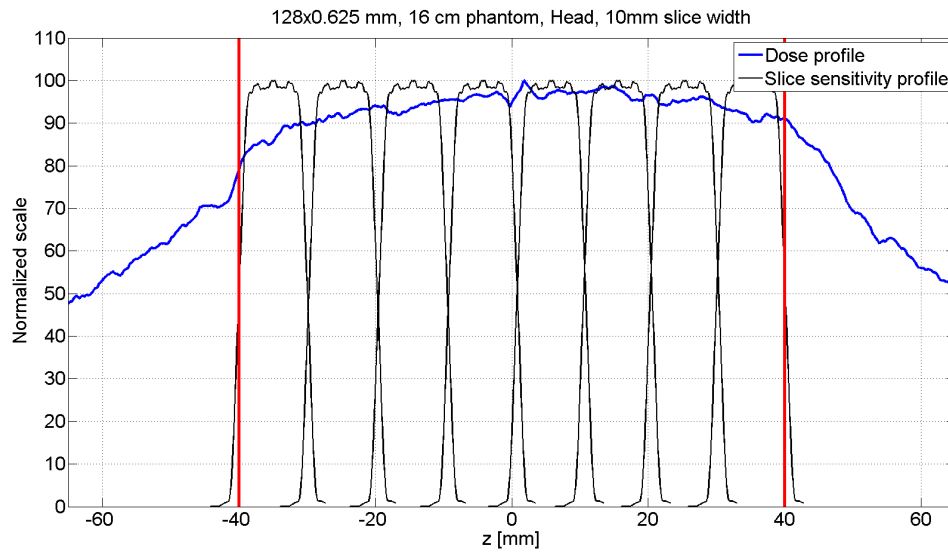
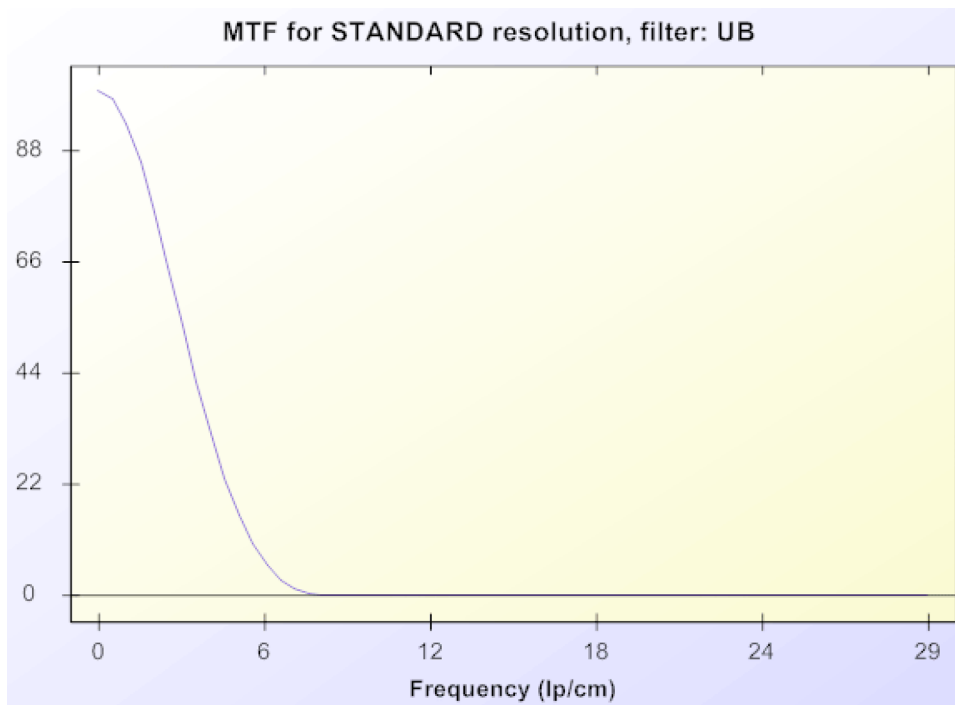


Image Quality

The mean noise on a 200 mm diameter of the water layer (phantom liquid layer) of the system Head phantom is $0.49\% \pm 0.08$ (Axial 3D scan mode, 64x0.625 mm, 120 kV, 160 mAs, filter = UB, slice thickness 3 mm) using Head STD QA Axial 3D exam. Details regarding the phantom and measurement method are described in other related sections. See chapter “Phantoms & Measurement Methods” on page 104 for more information.



You can view the sensitivity profiles in the related Dose and Sensitivity Profiles section.

CT Number Uniformity

The system CT Number uniformity is 0 +/- 8 Hounsfield Units for Head Scans.

CT Number Accuracy

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

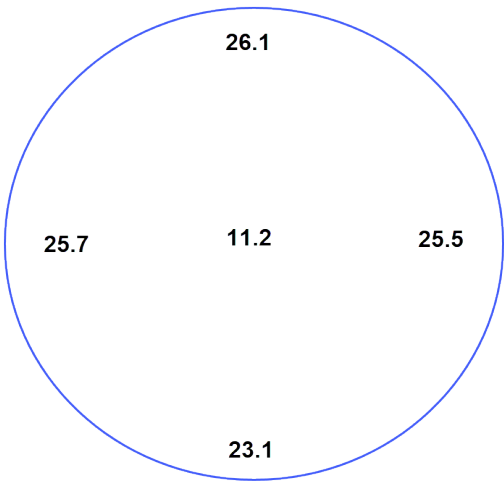
| Phantom Type | Phantom Area | Hounsfield Units Accuracy | | | |
|--------------|--------------|---------------------------|----------|----------|----------|
| | | 80kVp | 100kVp | 120kVp | 140kVp |
| Adult | Head | +/- 4 HU | +/- 4 HU | +/- 4 HU | +/- 4 HU |
| | Body | +/- 8 HU | +/- 6 HU | +/- 6 HU | +/- 6 HU |
| Infant | Head | +/- 5 HU | +/- 4 HU | +/- 4 HU | -- |
| | Body | +/- 6 HU | +/- 4 HU | +/- 4 HU | -- |

Body Scan Information

Body dose - typical body CT scan conditions of operation:

| Main | |
|-----------------|------------|
| FOV | 350 |
| Storage | Local |
| Number of Scans | 1 |
| Scan | |
| Collimation | 64 x 0.625 |
| Thickness | 5 |
| Increment | 0 |
| Rot Time | 0.75 |
| Voltage | 120 |
| mAs | 250 |
| Recon | |
| Filter | B |
| SP Filter | No |

CTDI100 Body



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

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

Maximum deviation from the values shown is $\pm 35\%$. $CTDI_w = 20.5$ mGy.

These CTDI100 values are appropriate for Adult and Pediatric Body scans, and for Cardiac scans.

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

Tube Current - Exposure Time Product (mAs) Dependence

The dose increases linearly with the tube current - exposure time product. The $CTDI_{100}$ in the center location of the body phantom, normalized to the $CTDI_{100}$ in the center location from the values shown in the CTDI100 Body information, depends on the mAs for the values as shown by the ratios below. The maximum deviations of these ratios are also provided.

| CTDI ₁₀₀ | | |
|--|------------|---|
| Minimum CTDI ₁₀₀ (at 10 mAs) is | 0.04 ± 20% | ...times the CTDI ₁₀₀ at 250 mAs |
| Maximum CTDI ₁₀₀ (at 1500 mAs) is | 6.0 ± 20% | ...times the CTDI ₁₀₀ at 250 mAs |

Slice Thickness Dependence

The $CTDI_{100}$ in the center location of the body phantom, normalized to the $CTDI_{100}$ in the center location from the values shown in the CTDI100 Body information, depends on the collimation mode and slice thickness as shown by the ratios below. The maximum deviations of these ratios are also provided.

| Slice Thickness Dependence | | |
|--|-----------|---|
| The CTDI100 of the 128x0.625 mm (80 mm) collimation is ... | 0.94± 15% | ...times the CTDI100 of the 64x0.625 mm (40 mm) collimation |
| The CTDI100 of the 112x0.625 mm (70 mm) collimation is ... | 0.95± 15% | ...times the CTDI100 of the 64x0.625 mm (40 mm) collimation |
| The v of the 96x0.625 mm (60 mm) collimation is ... | 0.96± 15% | ...times the CTDI100 of the 64x0.625 mm (40 mm) collimation |

| Slice Thickness Dependence | | |
|--|------------|---|
| The CTDI ₁₀₀ of the 32x0.625 mm (20 mm) collimation is ... | 1.12 ± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation |
| The CTDI ₁₀₀ of the 16x0.625 mm (10 mm) collimation is ... | 1.39 ± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation |
| The CTDI ₁₀₀ of the 8x0.625 mm (5 mm) collimation is ... | 1.92 ± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation |
| The CTDI ₁₀₀ of the 4x0.625 mm (2.5 mm) collimation is ... | 2.61 ± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation |
| The CTDI ₁₀₀ of the 2x0.625 mm (1.25 mm) collimation is ... | 3.41 ± 15% | ...times the CTDI ₁₀₀ of the 64x0.625 mm (40 mm) collimation |

Voltage Dependence - Center

The X-ray voltage can be varied between 80 and 140 kV. The CTDI₁₀₀ in the center location of the body phantom, normalized to the CTDI₁₀₀ in the center location from the values shown in the CTDI₁₀₀ Body section, depends on the X-ray voltage as shown by the ratios below. The maximum deviations of these ratios are also provided.

| CTDI ₁₀₀ | | |
|--|------------|---|
| With 80 kV, the CTDI ₁₀₀ is... | 0.27 ± 15% | ... times the CTDI ₁₀₀ at 120 kV |
| With 100 kV, the CTDI ₁₀₀ is... | 0.58 ± 15% | ... times the CTDI ₁₀₀ at 120 kV |
| With 140 kV, the CTDI ₁₀₀ is... | 1.52 ± 15% | ... times the CTDI ₁₀₀ at 120 kV |

Voltage Dependence - Edge

The CTDI₁₀₀ in the peripheral location of the body phantom, normalized to the CTDI₁₀₀ in the peripheral locations from the values shown in the CTDI₁₀₀ Body section, depends on the X-ray voltage as shown by the ratios below. The maximum deviations of these ratios are also provided.

| CTDI ₁₀₀ | | |
|--|------------|---|
| With 80 kV, the CTDI ₁₀₀ is... | 0.34 ± 15% | ... times the CTDI ₁₀₀ at 120 kV |
| With 100 kV, the CTDI ₁₀₀ is... | 0.63 ± 15% | ... times the CTDI ₁₀₀ at 120 kV |
| With 140 kV, the CTDI ₁₀₀ is... | 1.43 ± 15% | ... times the CTDI ₁₀₀ at 120 kV |

Dose Profiles - Body

The dose profiles at the center of the CTDI Body phantom superimposed on the slice sensitivity profiles as well as the nominal sensitivity profile limit lines are presented here. The maximum deviations from the drawn curves are $\pm 20\%$.

NOTICE

The dose profiles and sensitivity profiles were measured under the typical conditions of operation presented in the Body Scan section, while changing the collimation only.

Body curves were measured in the center hole of 32 cm diameter CTDI phantom (made of PMMA plastic).

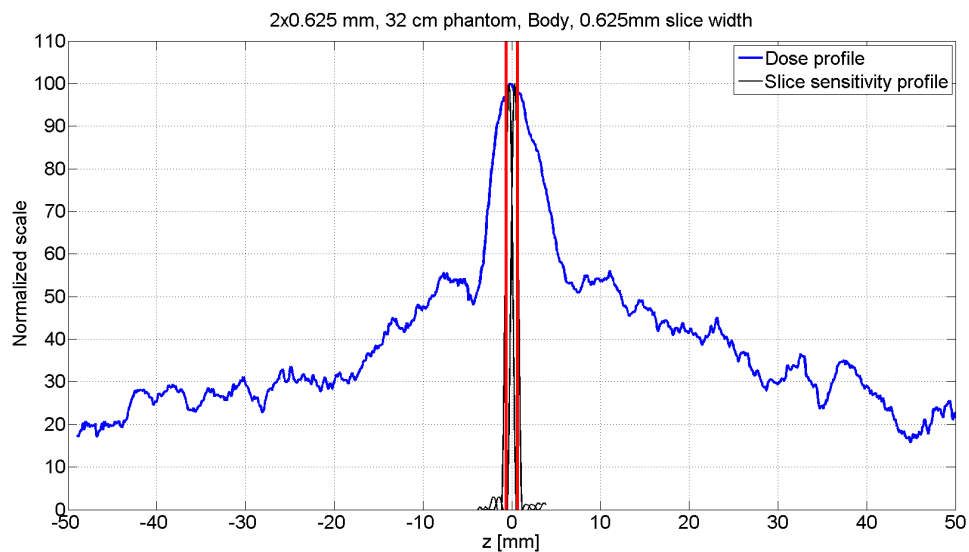
X-ray sensitive film Gafchromatic XR-CT2 was used. The measurement is made for 2×0.625 (smallest), 128×0.625 (largest) and 64×0.625 (middle) collimation openings.

The following are the Dose Profile curves slightly smoothed to reduce the high frequency noise coming from film pixel sensitivity variation.

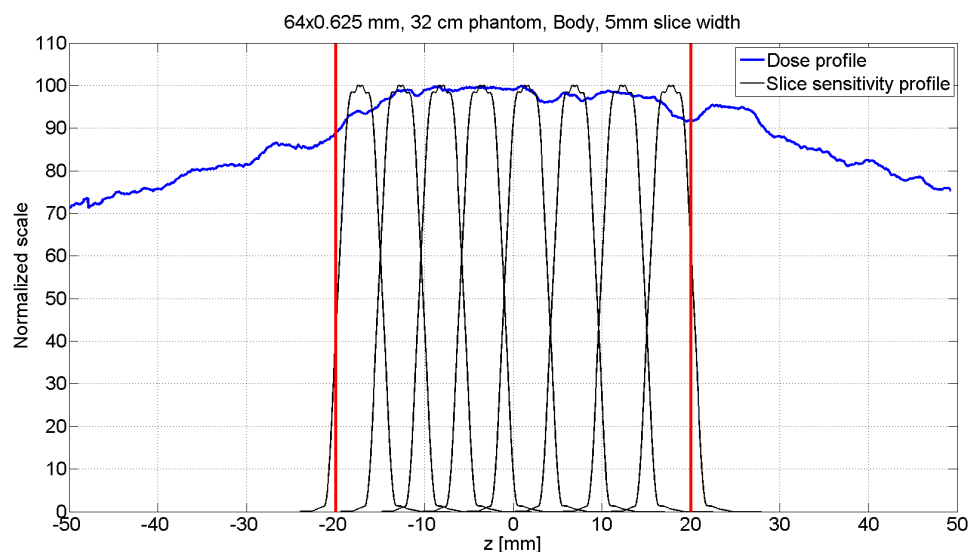
The vertical lines on each graph denote the nominal collimation openings: $2 \times 0.625 = 1.25\text{mm}$, $64 \times 0.625 = 40\text{ mm}$ and $125 \times 0.625 = 80\text{ mm}$ centered on the respective profiles.

Body Dose Profiles

Body, $2 \times 0.625\text{ mm}$ collimation, 32 cm phantom



Body, $64 \times 0.625\text{ mm}$ collimation, 32 cm phantom



Body, 128 x 0.625 mm collimation, 32 cm phantom

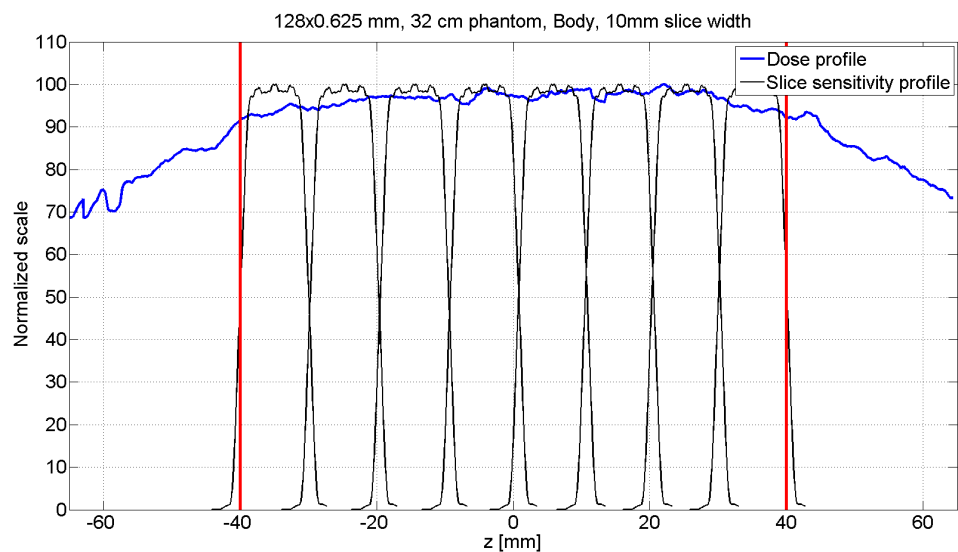
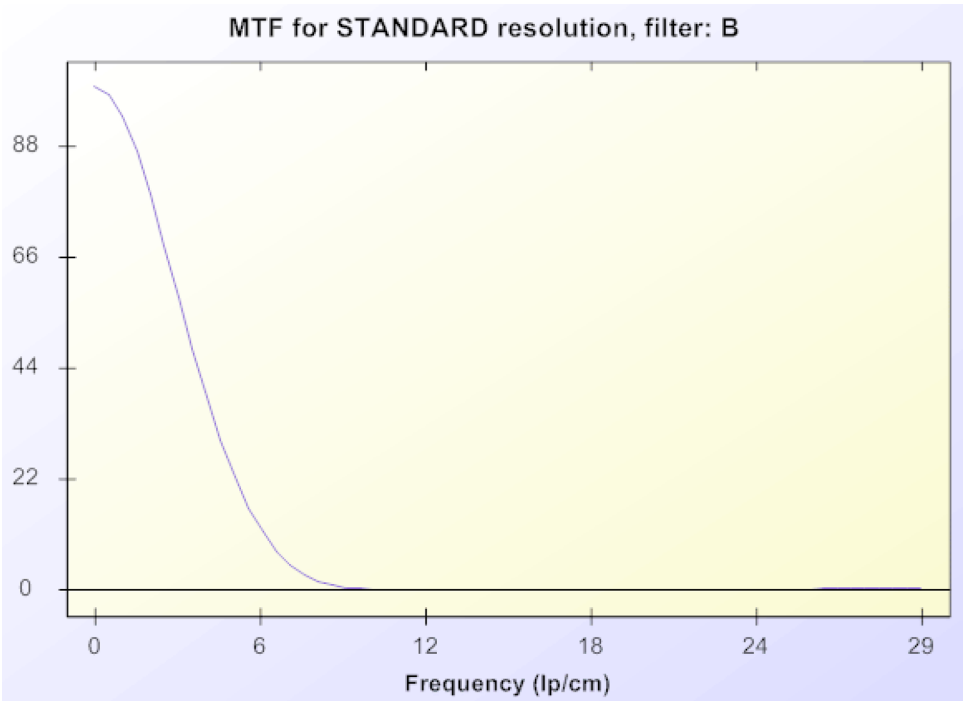


Image Quality

The mean noise on a 300 mm diameter system phantom is $0.825\% \pm 0.125$ (Axial 3D scan mode, 64 x 0.625 mm, 120 kV, 400 mAs, filter = B, slice thickness 5 mm) using Body STD QA Axial 3D exam. Details regarding the phantom and measurement method are described in other related sections. See chapter “Phantoms & Measurement Methods” on page 104 for more information.



CT Number Uniformity

The system CT Number uniformity is 0 +/- 8 Hounsfield Units for Body Scans.

CT Number Accuracy

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

| Phantom Type | Phantom Area | Hounsfield Units Accuracy | | | |
|--------------|--------------|---------------------------|----------|----------|----------|
| | | 80kVp | 100kVp | 120kVp | 140kVp |
| Adult | Head | +/- 4 HU | +/- 4 HU | +/- 4 HU | +/- 4 HU |
| | Body | +/- 8 HU | +/- 6 HU | +/- 6 HU | +/- 6 HU |
| Infant | Head | +/- 5 HU | +/- 4 HU | +/- 4 HU | -- |
| | Body | +/- 6 HU | +/- 4 HU | +/- 4 HU | -- |

CTDI Free Air

The CTDI Free Air for Spectral CT can be found in the following tables. The conditions of operation for Body scans, unless specified in the table, are QA Axial Body 2D, Standard Resolution, 0.75 seconds, 250 mAs, 2.5 mm SW.

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CTDI Free Air for Body Conditions of Operation (mGy)

| kVp\NxT | 2x | 4x | 8x | 16x | 32x | 64x | 96x | 112x | 128x |
|---------|-------|--------|--------|-------|-------|-------|-------|-------|-------|
| 80 | -- | -- | -- | -- | -- | 20.17 | -- | -- | -- |
| 100 | -- | -- | -- | -- | -- | 35.62 | -- | -- | -- |
| 120 | 188.0 | 143.87 | 106.00 | 76.64 | 61.93 | 55.10 | 53.05 | 52.19 | 51.72 |
| 140 | -- | -- | -- | -- | -- | 76.85 | -- | -- | -- |

CTDI Free Air for Other Conditions of Operation

| Scan mode | CTDI free air |
|--|---------------|
| Adult Head, 64x0.625, 120 kVp, 450 mAs, 2.5 mm SW | 99.2 mGy |
| Cardiac, 64x0.625, 0.27 sec, 120 kVp, 155 mAs, 0.8 mm SW | 38.3 mGy |
| Infant Body, 64x0.625, 100 kVp, 32 mAs, 2.5 mm SW | 4.6 mGy |
| Infant Head, 64x0.625, 100 kVp, 265 mAs, 2.5 mm SW | 37.8 mGy |

The maximum deviation from the values shown is $\pm 30\%$.

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

Conditions to Achieve 1000 mGy CTDI100 (Peripheral)

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

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 mAs is lower than the maximum listed here, the number of rotations to exceed 1000 mGy will be increased proportionally.

Brain Perfusion Non-Jog

| kVp | Collimation | Rotation time | mAs | CTDI ₁₀₀ (12:00) | Number of Axial scans to exceed 1000 mGy |
|-----|-------------|---------------|-----|-----------------------------|--|
| 120 | 64x0.625 | 0.75 sec | 750 | 129.80 mGy | 8 |
| 100 | 64x0.625 | 0.75 sec | 750 | 82.68 mGy | 13 |

| kVp | Collimation | Rotation time | mAs | CTDI ₁₀₀ (12:00) | Number of Axial scans to exceed 1000 mGy |
|-----|-------------|---------------|-----|-----------------------------|--|
| 80 | 64x0.625 | 0.75 sec | 690 | 44.65 mGy | 23 |

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. This scan can be performed at 420 degree scan, which can increase the mAs even further. If so, then the following maximum 12:00 CTDI values can be achieved.

| kVp | Collimation | Rotation Time | mAs | CTDI ₁₀₀ (12:00) | Number of Axial scans to exceed 1000 mGy |
|-----|-------------|---------------|-----|-----------------------------|--|
| 120 | 16x0.625 | 0.75 sec | 875 | 210.49 mGy | 5 |
| 140 | 16x0.625 | 0.75 sec | 655 | 224.06 mGy | 5 |
| 100 | 16x0.625 | 0.75 sec | 875 | 134.08 mGy | 8 |
| 80 | 16x0.625 | 0.75 sec | 805 | 66.62 mGy | 16 |

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 ₁₀₀ (12:00) | Number of Axial scans to exceed 1000 mGy |
|-----|-------------|---------------|-----|-----------------------------|--|
| 120 | 2x0.625 | 0.5 sec | 385 | 227.21 mGy | 5 |
| 140 | 2x0.625 | 0.5 sec | 330 | 276.93 mGy | 4 |
| 100 | 2x0.625 | 0.5 sec | 465 | 174.80 mGy | 6 |
| 80 | 2x0.625 | 0.5 sec | 320 | 64.96 mGy | 16 |

Adult and Infant Body 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 mAs is lower than the maximum listed here, the number of rotations to exceed 1000 mGy will be increased proportionally.

Body Perfusion

| kVp | Collimation | Rotation Time | mAs | CTDI ₁₀₀ (12:00) | Number of Axial scans to exceed 1000 mGy |
|-----|-------------|---------------|-----|-----------------------------|--|
| 120 | 64x0.625 | 0.75 sec | 750 | 78.18 mGy | 13 |
| 100 | 64x0.625 | 0.75 sec | 750 | 49.26 mGy | 21 |
| 80 | 64x0.625 | 0.75 sec | 690 | 26.35 mGy | 38 |

CCT Mode

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 ₁₀₀ (12:00) | Number of Axial scans to exceed 1000 mGy |
|-----|-------------|---------------|-----|-----------------------------|--|
| 120 | 4x0.625 | 0.75 sec | 270 | 73.46 mGy | 14 |
| 140 | 4x0.625 | 0.75 sec | 100 | 38.85 mGy | 26 |
| 100 | 4x0.625 | 0.75 sec | 400 | 68.56 mGy | 15 |
| 80 | 4x0.625 | 0.75 sec | 450 | 41.26 mGy | 25 |

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 ₁₀₀ (12:00) | Number of Axial scans to exceed 1000 mGy |
|-----|-------------|---------------|-----|-----------------------------|--|
| 120 | 2x0.625 | 1 sec | 330 | 117.31 mGy | 9 |
| 140 | 2x0.625 | 1 sec | 285 | 144.67 mGy | 7 |
| 100 | 2x0.625 | 1 sec | 400 | 89.58 mGy | 12 |
| 80 | 2x0.625 | 1 sec | 275 | 32.94 mGy | 31 |

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 ₁₀₀ (12:00) | Number of Axial scans to exceed 1000 mGy |
|-----|-------------|---------------|-----|-----------------------------|--|
| 120 | 64x0.625 | 0.33 sec | 250 | 26.06 mGy | 39 |
| 140 | 64x0.625 | 0.33 sec | 185 | 27.54 mGy | 37 |
| 100 | 64x0.625 | 0.33 sec | 250 | 16.42 mGy | 61 |
| 80 | 64x0.625 | 0.33 sec | 230 | 8.08 mGy | 124 |

Cardiac Perfusion

| kVp | Collimation | Rotation Time | mAs | CTDI ₁₀₀ (12:00) | Number of Axial scans to exceed 1000 mGy |
|-----|-------------|---------------|-----|-----------------------------|--|
| 120 | 64x0.625 | 0.33 sec | 330 | 34.40 mGy | 30 |
| 100 | 64x0.625 | 0.33 sec | 330 | 21.67 mGy | 47 |
| 80 | 64x0.625 | 0.33 sec | 210 | 7.38 mGy | 136 |

Size Specific Dose Estimate (SSDE)

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

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

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

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

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

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

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

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

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.

Single or bilateral extremities are scanned

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

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

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

Patient anatomy outside the scan field of view

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

Foreign Objects in the Scan Field

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

Essential Performance for Interventional Imaging

Image Spatial Accuracy

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

Slice Thickness

The system achieves the following slice thicknesses while scanning with Head Scan Type using 120 kVp and at least 250 mAs:

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- For a requested slice thickness of 0.8 mm the measured slice thickness is between 0.5 mm and 1.25 mm using a field of view 250 mm and YB filter.
- For a requested slice thickness of 1.4 mm the measured slice thickness is between 0.7 mm and 2.1 mm using a field of view 250 mm and YA filter.

Low Contrast

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

Noise

The system is able to achieve a percent noise of no more than 0.45%, when irradiating with no more than 50 mGy CTDI_{vol}.

High Contrast Spatial Resolution

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

Dose Management

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

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

No DLP values are included in the factory settings.

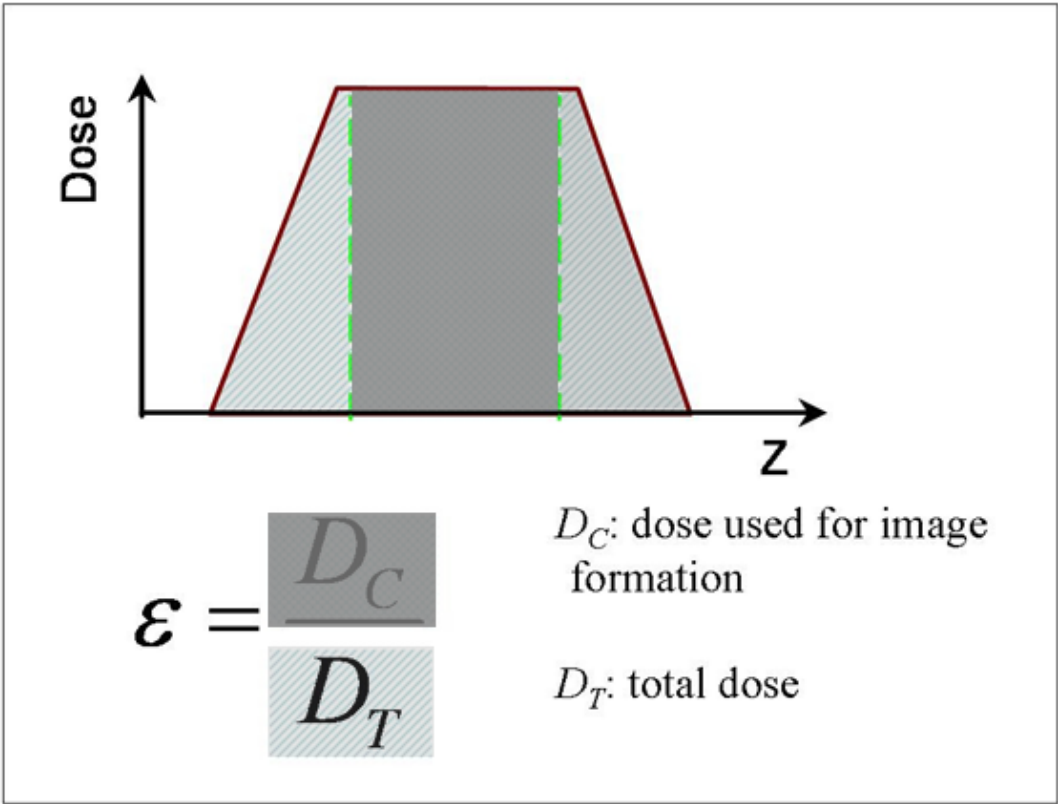
An alert warrants more stringent review before proceeding than a notification and requires a higher level of action by the user. The FDA has suggested an alert value for CTDI_{vol} of 1000 mGy, which would deliver approximately half the dose associated with the onset of skin injury.

NOTICE

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

Geometry Efficiency Measurements

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



The Geometric efficiencies listed here are established according to the techniques listed in the IEC 60601-2-44 standard, Edition 3.2, Section 203.113. The dose profiles used to establish these efficiencies were measured using Gafchromic XR-CT2 film. The films were digitized using a color flatbed scanner and the profile is extracted from the scan .

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

NOTICE

If any protocol results in less than 70% Z axis geometrical dose efficiency, the system displays a warning message.

| Resolution | Collimation | Geometric efficiency (%) | Geometric efficiency range (%) |
|-------------------|----------------|--------------------------|--------------------------------|
| Axial Scan Mode | | | |
| HIGH | 128 X 0.625 mm | 96 | 93-99 |
| HIGH | 112 X 0.625 mm | 94 | 91-97 |
| HIGH | 96 X 0.625 mm | 94 | 91-97 |
| HIGH | 64 X 0.625 mm | 91 | 88-94 |
| HIGH | 32 X 0.625 mm | 84 | 81-87 |
| HIGH | 16 X 0.625 mm | 69 | 66-72 |
| HIGH | 2 X 0.625 mm | 23 | 20-26 |
| STD | 128 X 0.625 mm | 95 | 92-98 |
| STD | 112X 0.625 mm | 95 | 92-98 |
| STD | 96 X 0.625 mm | 94 | 91-97 |
| STD | 64 X 0.625 mm | 92 | 89-95 |
| STD | 32 X 0.625 mm | 82 | 79-85 |
| STD | 16 X 0.625 mm | 66 | 63-69 |
| STD | 8 X 0.625 mm | 47 | 44-50 |
| STD | 4 X 0.625 mm | 34 | 31-37 |
| Helical Scan Mode | | | |
| STD | 128 X 0.625 mm | 94 | 91-97 |
| STD | 112 X 0.625 mm | 92 | 89-95 |
| STD | 96 X 0.625 mm | 91 | 88-94 |
| STD | 64 X 0.625 mm | 85 | 82-88 |
| STD | 32 X 0.625 mm | 77 | 74-80 |
| STD | 16 X 0.625 mm | 57 | 54-60 |

Half Value Layer (HVL)

NOTICE

The filtration is not user accessible.

For all HVL measurements, the CT system operates in a stationary X-ray tube position in the standard resolution mode, at 80, 100, 120 and 140 kVp, 50 mAs, 16 x 0.625 collimation, 10 mm slice width (one slice). Type 1100 aluminum filters of various thicknesses are used.

Aluminum quality equivalent filtration for different scan modes and kVps

| Scan Mode | Infant and Adult Head/ Infant and Adult Body |
|-----------|--|
| 80 kVp | 5.2±0.5 mm Al |
| 100 kVp | 6.4±0.5 mm Al |
| 120 kVp | 7.4±0.5 mm Al |
| 140 kVp | 8.4±0.5 mm Al |

Stray Radiation Dose Map - Spectral CT

The map dose values units are $\mu\text{Gy} / \text{mAs}$, calculated from direct measurements of $\text{mGy} / 500 \text{ mAs}$. All measurements in this section have a tolerance of $\pm 30\%$.

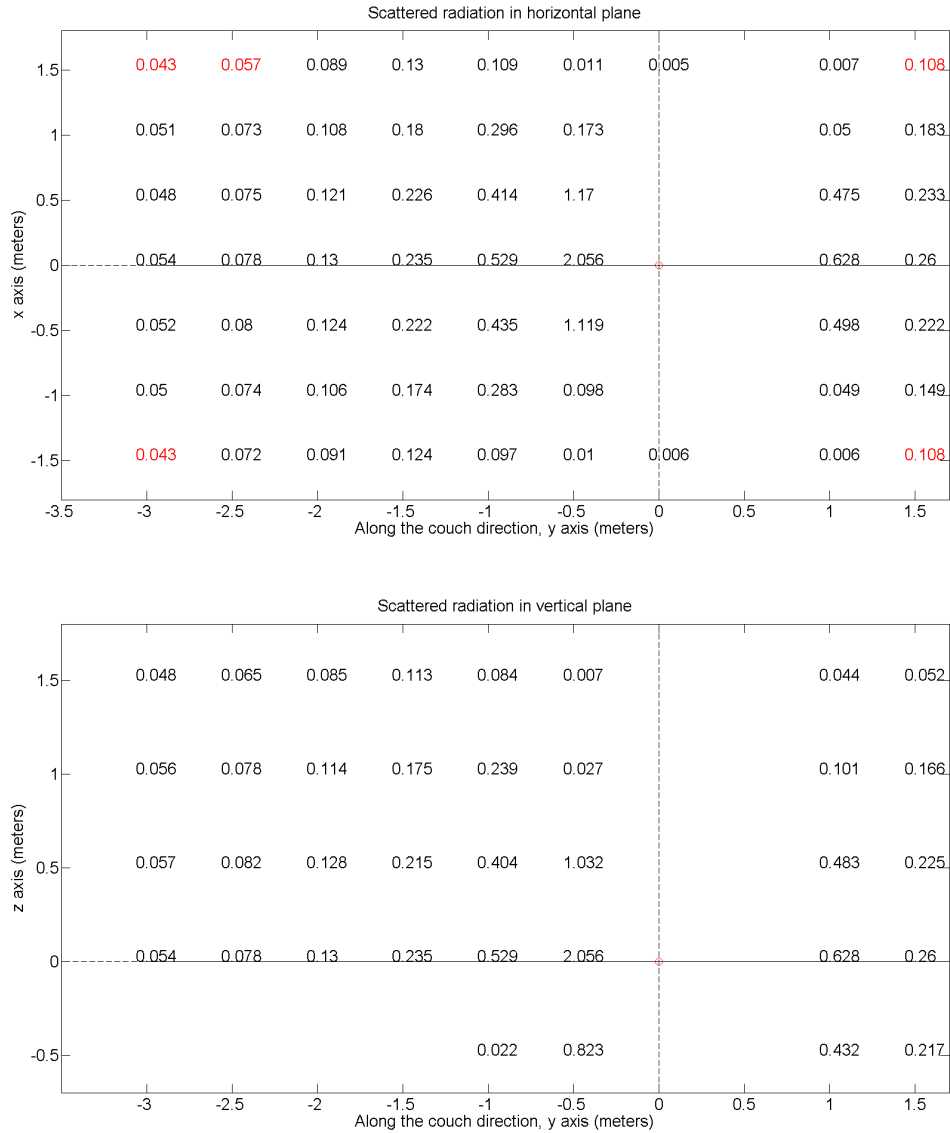
Measurements are made with the QA Axial Body exam card at the maximum collimation of $128 \times 0.625 = 80\text{mm}$ and at 140 kVp in the horizontal plane through the system axis (108.7 cm above the floor).

The body CTDI phantom was centrally positioned in the tomographic scan plane and scanned as indicated to produce the near worst case scatter map values listed. This PMMA material phantom has a cylindrical shape with a diameter of 32 cm and a length of 15cm.

The stray radiation measurements were made with the aid of a Raysafe x2 survey sensor which has an active area of 50 cm^2 and has dimensions of 14 mm X 66 mm X 192 mm. The red measurement values on the dose maps represent stray radiation values at points that were inaccessible for measurement. The stray radiation values at such points were determined by assuming that away from the gantry, the stray radiation decays with a $1/r^2$ dependence, where r represents the distance from that point to the isocenter.

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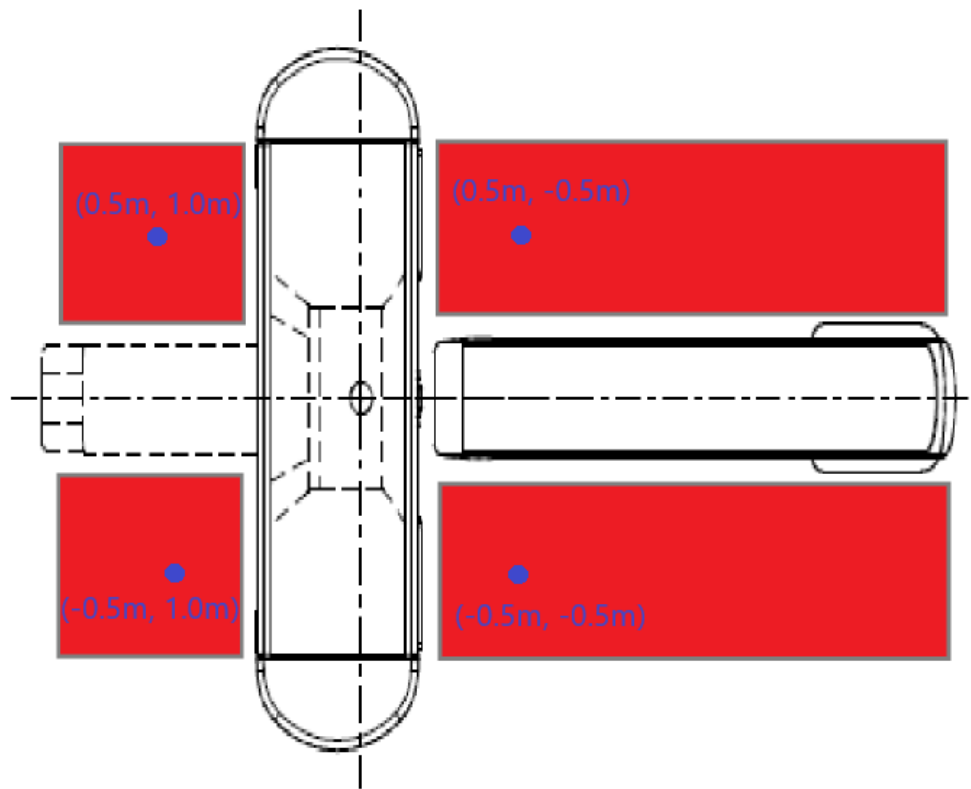
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Zones of Occupancy - Spectral CT

Permitted zones of occupancy shown in red.

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

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

The radiation profiles (shown below) represent the exposure measured in four blue dots demarcated in the above figure. The accessible points within the zone of occupancy in the front of the gantry for which the radiation profiles are provided is closer to the isocenter than the accessible points within the zone of occupancy in the rear of the gantry for which the radiation profiles are attached. Measurements were taken using a 32 cm diameter, 15 cm length PMMA phantom to simulate a large patient centered at isocenter and scanned with the imaging mode with the least beam filtration. The phantom was scanned at 140 kVp to create the worst-case scatter possible.

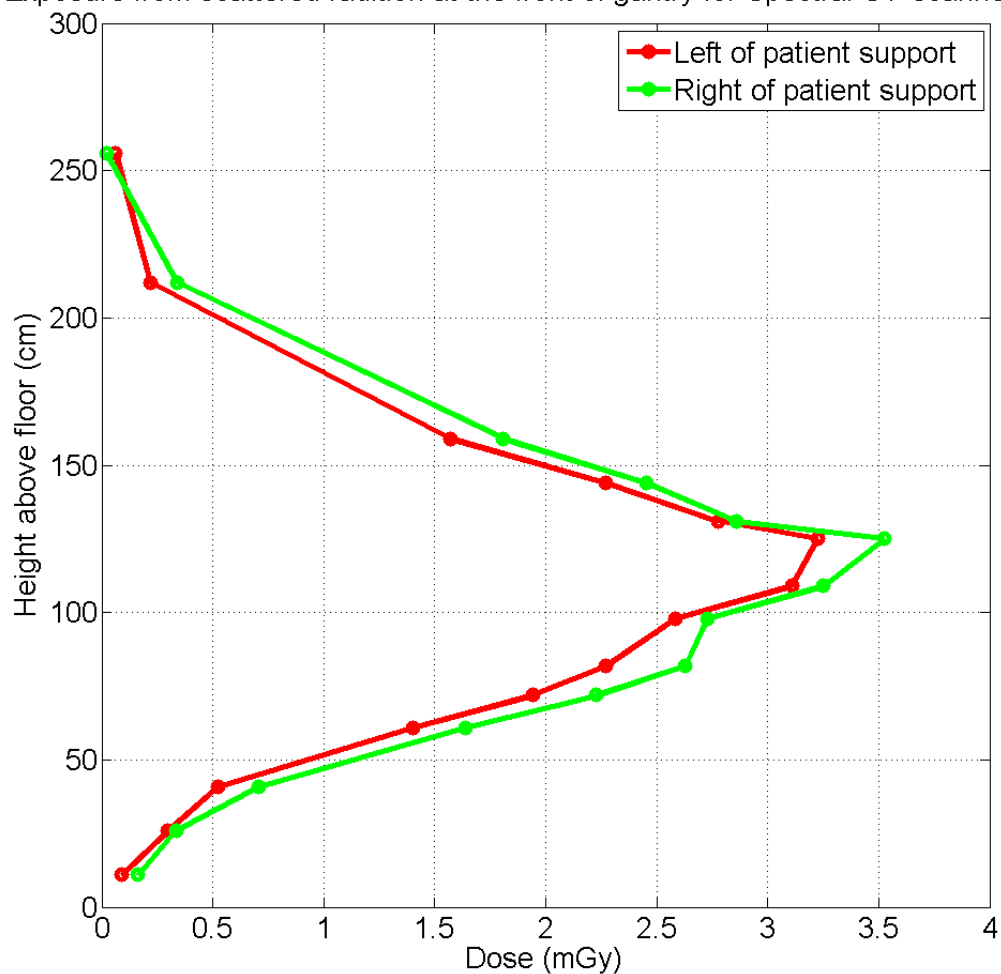
For the profiles, measurements were made with a Raysafe x2 survey sensor with an active area of 50 cm² and has dimensions of 14 mm X 66 mm X 192 mm. The measurements were taken with a 128 x 0.625 mm collimation, 140 kVp, 500 mA, 1.0 second exposure time, 360-degree scan angle. The resulting measurements were scaled to represent air kerma for a 500 cc volume. The profiles were generated with measurements taken at 10-20 cm intervals from floor level to 200 cm above the floor. The profiles shown do not represent the use of any protective devices.

CT is not designed to operate in a continuous mode, so for ease of use the measurements provided represent a single 500 mAs shot. In order to scale these air kerma values to represent one hour at the conditions of loading that achieve the maximum X-ray tube continuous average power of 3.8 kW, the values must be multiplied by 195. The maximum continuous tube power at 140 kV is 3.8 kW which would be a tube current of 27.1 mA for one hour, or 97560 total mAs, which is 195 times the 500 mAs used for the measured values.

Exposure from Scattered Radiation in the Front of the Gantry for Spectral CT

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

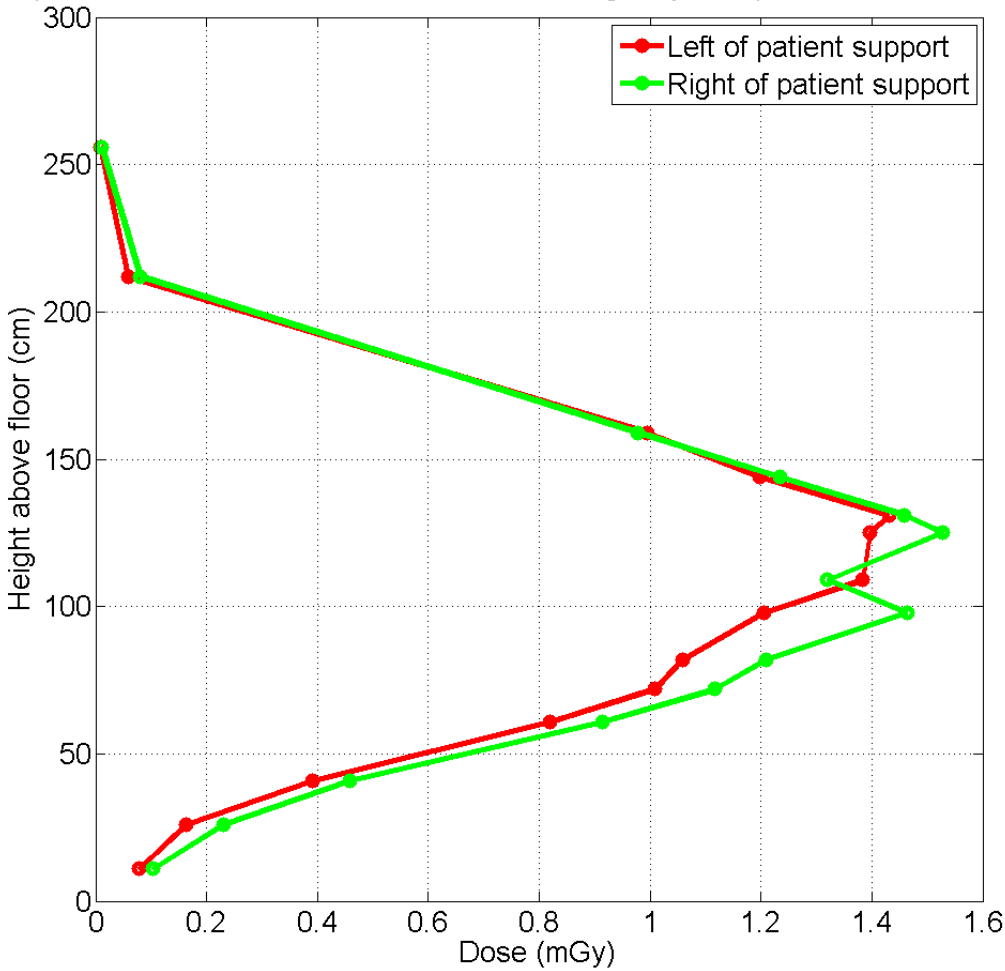
Exposure from scattered radiation at the front of gantry for Spectral CT scanner



Exposure from Scattered Radiation in the Rear of the Gantry for Spectral CT

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

Exposure from scattered radiation at the rear of gantry for Spectral CT scanner



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Tube Continuous Average Power

| Conditions of Operation to Achieve X-Ray Tube Continuous Average Power of 3.8 kW | |
|--|---------|
| 80 kV | 47.5 mA |
| 100 kV | 38 mA |
| 120 kV | 31.6 mA |
| 140 kV | 27.1 mA |

HU-Value Conversion

The Gammex Tissue Characterization Phantom Model 472 from Gammex, Inc. was used to measure the conversion of measured HU-values to electron and mass density values relative to water. The CT number was measured for air, water, two different soft-tissue equivalent materials and two different bone-equivalent materials. For the Gammex Tissue Characterization Phantom Model 472, the air hole and five tissue mimicking material rods were identified for measurement. The CT number conversion factors of six materials for the head scan mode were measured:

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

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

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

| | |
|---------------|-------------------|
| Collimation | 64 x 0.625 = 40mm |
| Rotation Time | 0.4 s |
| Pitch | 0.3 |
| Slice Width | 3 mm |
| Filter | UB |
| FOV | 350 mm |
| kVp | 120 |
| mAs | 450 |
| CTDI | 70.73 mGy |

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

| | |
|---------------|--------------------|
| Collimation | 128 x 0.625 = 80mm |
| Rotation Time | 0.4 s |
| Slice Width | 3 mm |
| Pitch | 0.9 |
| Filter | B |

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| | |
|-------------|-----------|
| FOV | 500 mm |
| kVp | 120 |
| mAs | 250 |
| CTDI | 19.23 mGy |

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

NOTICE

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

Typical relative electron density of materials and the corresponding CT number (in HU) as measured on the Spectral CT scanner for conditions of operations typical of a oncological head scan.

| Materials | Electron Density Relative to Water | HU-Value (HU) |
|---------------------------|------------------------------------|---------------|
| Air | 0.000 | -1009.8 |
| Adipose | 0.93 | -89.0 |
| Water | 1.000 | 1.7 |
| BRN-SR2 Brain | 1.04 | 24.7 |
| CB2-30% CaCO ₃ | 1.28 | 488.5 |
| CB2-50% CaCO ₃ | 1.47 | 888.0 |

Results of the tests for noise, mean CT-number, and uniformity, as measured with the methodology of IEC 61223-3-5, for conditions of operation typical in an oncological head scan.

| Tests | Average |
|---|---------|
| Mean CT-number (HU) | -0.7 |
| Uniformity (HU) | 1.2 |
| Standard deviation, measure of noise (HU) | 3.4 |

Typical relative electron density of materials and the corresponding CT number (in HU) as measured on the Spectral CT scanner for conditions of operation typical in an oncology body scan.

| Materials | Electron Density Relative to Water | HU-Value (HU) |
|-----------|------------------------------------|---------------|
| Air | 0.000 | -1005.4 |
| Adipose | 0.93 | -84.8 |

| Materials | Electron Density Relative to Water | HU-Value (HU) |
|---------------------------|------------------------------------|---------------|
| Solid Water | 0.99 | 6.6 |
| LV1 Liver | 1.06 | 81.1 |
| CB2-30% CaCO ₃ | 1.28 | 510.0 |
| CB2-50% CaCO ₃ | 1.47 | 901.1 |

Results of the tests for noise, mean CT-number, and uniformity, as measured with the methodology of IEC 61223-3-5, for conditions of operation typical in an oncological body scan.

| Tests | Average |
|---|---------|
| Mean CT-number (HU) | -0.4 |
| Uniformity (HU) | 3.8 |
| Standard deviation, measure of noise (HU) | 8.9 |

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

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

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

8 IEC Acceptance Testing for Spectral CT

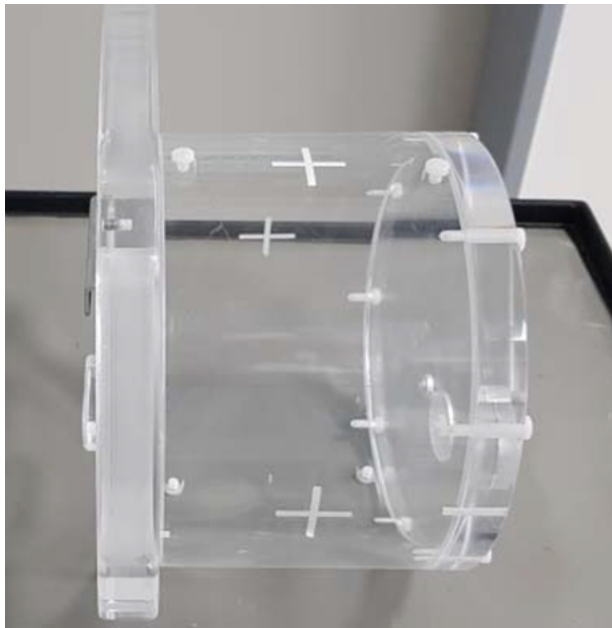
The IEC 61223-3-5 Standard requires sites to perform Acceptance and Constancy testing at regular intervals. This CT scanner has been tested at the factory for the various tests listed in the standard, and again upon installation. The Service Engineer can provide you with the baseline values set at installation at the site. However, if the site prefers to perform the testing independently, and to maintain their own baseline repository, the following test procedures describe the tests and tolerances for this scanner.

Couch Accuracy

The IEC 61223-3-5 standard describes the test for Couch movement accuracy. Please refer to that document, as there are no changes for Philips CT Scanners.

Laser Alignment Accuracy

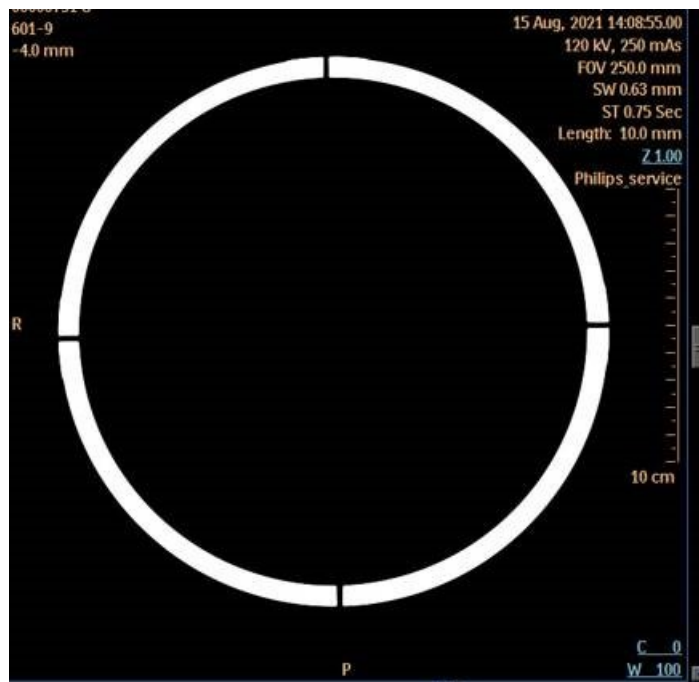
The Physics section of the system phantom has white crosshairs on the sides and the top. Beneath these crosshairs are small (1 mm diameter) holes drilled into the shell, to test laser alignment.



Make sure that the Physics section is level, and then align the lasers on these crosshairs in the center of the bore.

Perform a scan with the parameters: Standard QA Axial Body 2D, Default parameters except 16 x 0.625, Standard Resolution, 0.75 seconds, 120 kVp, 100 mAs, slice thickness 0.625 mm, B Filter.

In one of the center four slices (slice 7 through 10), an image of the shell with holes in it should look like the following:



If all four position air holes are not visible in the same slice, adjust the phantom z-position and/or tilt and/or swivel to make them all four visible. The repeat the test with the slice lasers in the middle of the crosshairs.

Note: The phantom swivel should be correct, if the couch is properly adjusted relative to the gantry rotation plane but to make small correction for phantom swivel you can do this using small free play of phantom holder which should be enough.

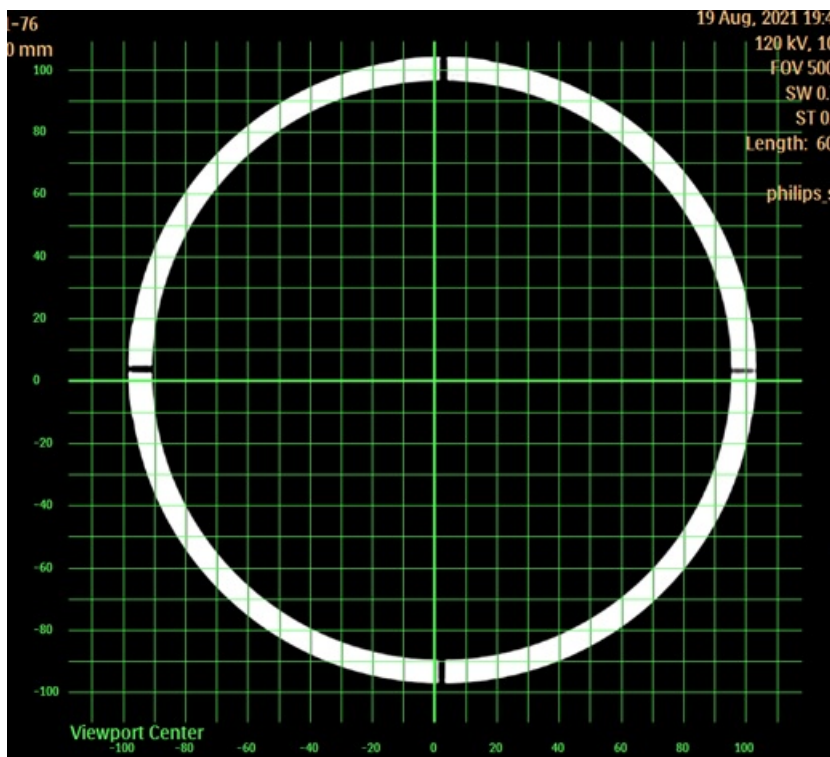
To test the external lasers, align the lasers on the crosshairs of the system phantom away from the bore, as shown below:



When aligned this way, move the phantom into the bore, so that the central laser is aligned on the top crosshair.

Perform a scan with the parameters: Standard QA Axial Body 2D, Default parameters except 16 x 0.625, Standard Resolution, 0.75 seconds, 120 kVp, 100 mAs, slice thickness 0.625 mm, B Filter.

In the same central image as before, the holes at 3:00, 12:00, 6:00 and 9:00 should be aligned with the grid on the image, to within ± 2 mm.

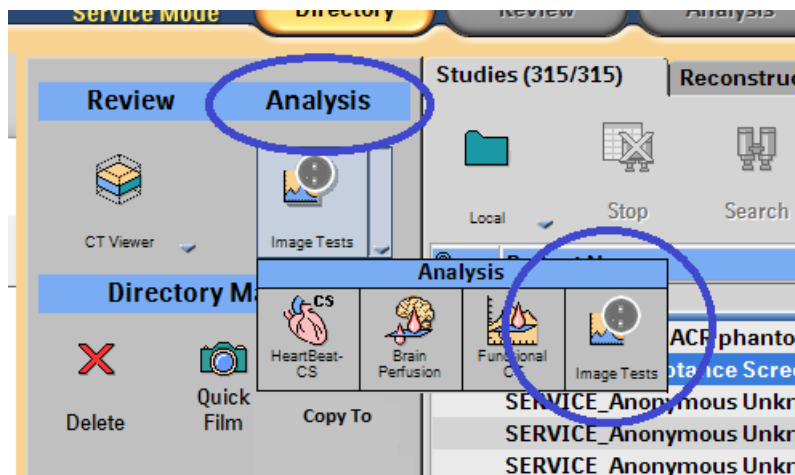


Reconstructed Section Thickness

This test uses the Slice Thickness wires of the Physics Section of the chapter “Harmonized System Phantom” on page 81, and the Slice Thickness tool described below.

To Measure Reconstructed Section Thickness:

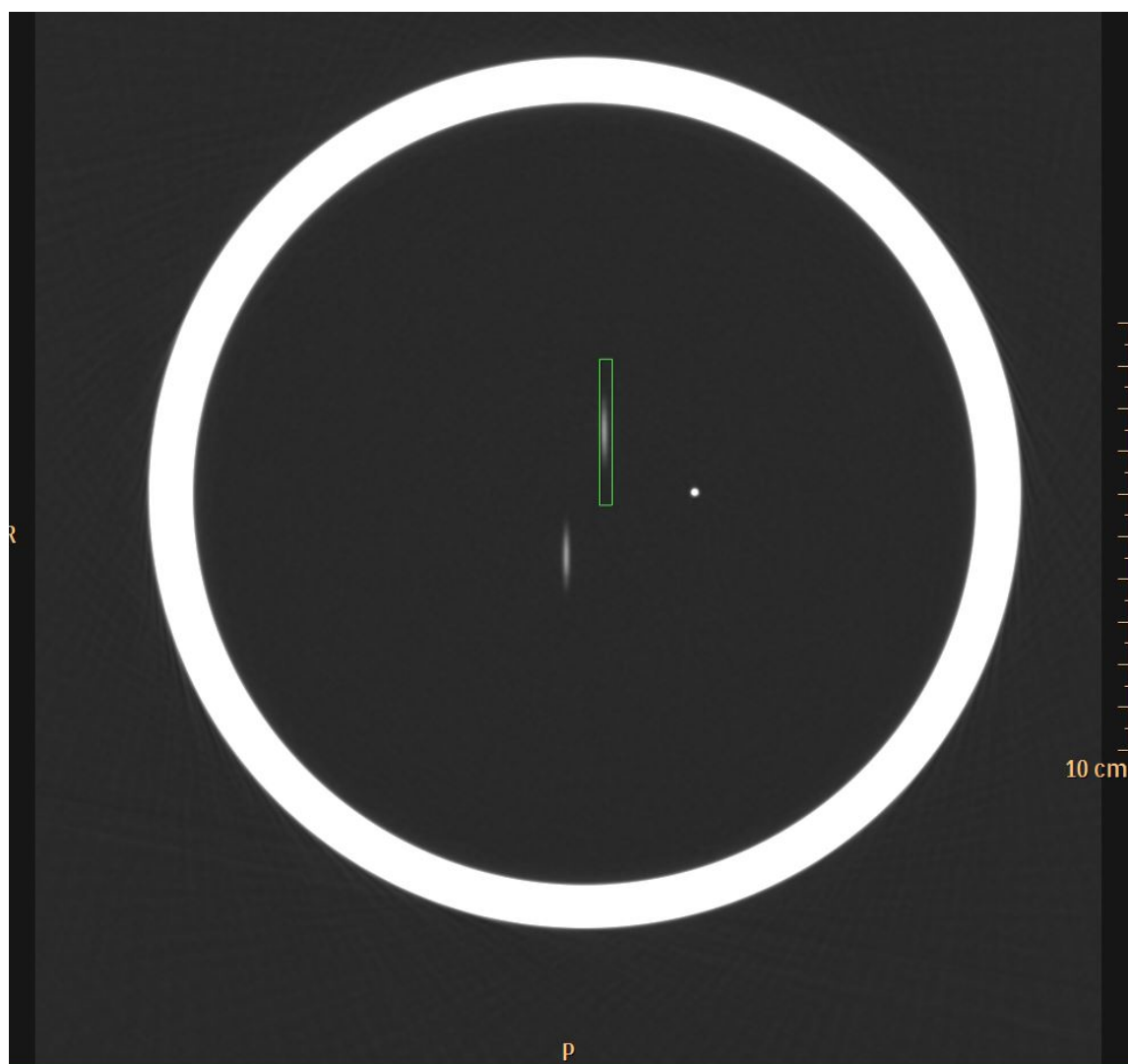
1. Adjust the table so that the phantom physics layer centerline aligns with the laser lights.
2. Set up a standard patient scan (refer the following table for details).
Note: The gantry tilt should be set at zero degrees (perpendicular).
3. Perform the first axial scan using the parameters for first slice width scan (e.g. 16 x 0.625, Axial) from the following table.
4. From the **Directory**, select the scan series.
5. Select **Image Tests** from the **Analysis** options.




6. Select the middle image of the first scan.
7. In the Slice thickness row, select the **Slice Thickness Position Rectangle** to place a rectangle on the image.



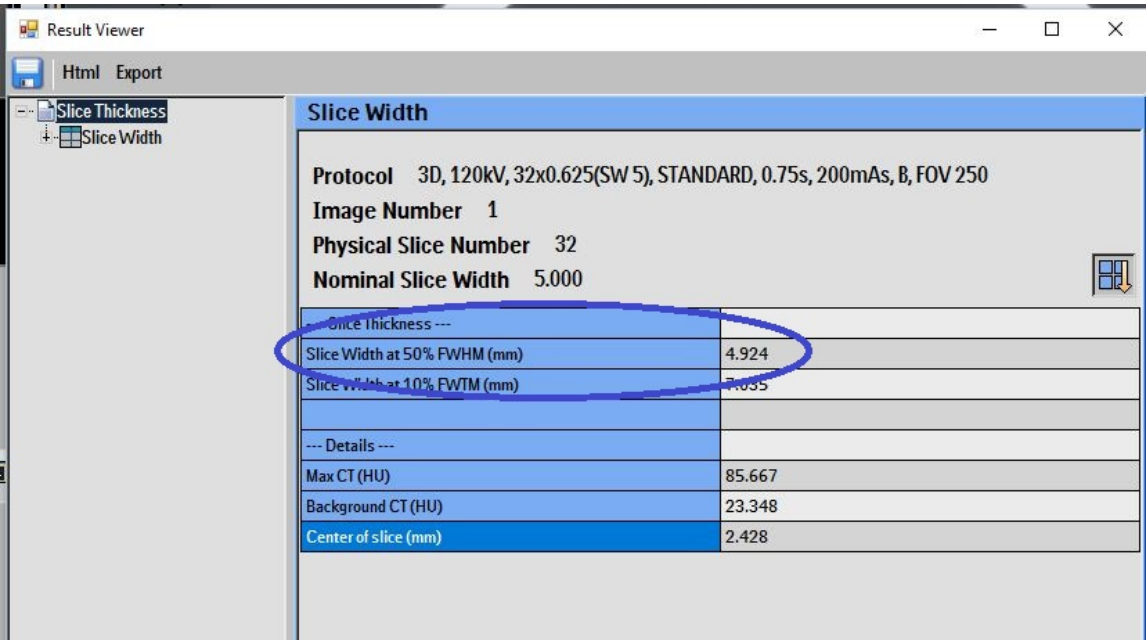
8. Move and resize the **Position Rectangle ROI** to symmetrically position it to surround one image of the wire.



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9. To view the sensitivity profile and calculate slice thickness, click  **Calculate Slice Thickness**. The appropriate measured value is the “Slice Width at 50% FWHM (mm)” value.

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- 10. Repeat steps 7-9 to measure both vertical wires, and average the two results.
- 11. Repeat steps 6-10 using the first slice.
- 12. Verify the results are within the allowed tolerance.
- 13. Exit the **Image Tests** program.

Scan Parameters and Results for Slice Thickness Measurements:

| Measurement Element | Scan parameters | Slices to measure | Low Limit (mm) | Upper limit (mm) | Comments |
|--------------------------|--|-------------------------------------|----------------|------------------|-------------|
| Slice Thickness 1 | Axial 3D, Body, 120kV, 16 x 0.625 (SW 0.8mm), High, 0.75s, 200mAs, E, FOV 250, 1024 x 1024 | 1-st slice and one of middle slices | 0.30 | 1.30 | 0.80 ± 0.50 |
| Slice Thickness 2 | Axial 3D, Body, 120kV, 32 x 0.625 (SW 2.0mm), STD, 0.75s, 200mAs, YA, FOV 250, 512 x 512 | 1-st slice and one of middle slices | 1.00 | 3.00 | 2.00 ± 1.00 |
| Slice Thickness 3 | Axial 3D, Body, 120kV, 32 x 0.625 (SW 5mm), STD, 0.75s, 200mAs, B, FOV 250, 512 x 512 | 1-st slice and one of middle slices | 4.00 | 6.00 | 5.00 ± 1.00 |

Note: Use Window width 600 and Window Center -900 for all three scans.

Dose

Dose can be measured as either CTDI_{vol} with an ion chamber inserted into large phantoms made with PMMA, or by measuring CTDI_{free air} with an ion chamber suspended in air at the isocenter.

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To measure $CTDI_{vol}$, it is important that the CTDI phantoms be centered and leveled to within ± 3 mm in all three axes. Also, with Philips scanners, the system is designed to start generating X-rays within a short time from pressing the **Scan** button, but then the tube can be anywhere in the 360° as it spins. To account for the effect that this has on the peripheral CTDI measurements, we do repeated scans with a fixed cycle time. The intention is to reliably sample the motion around the gantry in a technique sufficient to get good repeatability. For this scanner, we need to measure 8 scans separated by a cycle time of 5.1 seconds. If the Ion chamber is set to accumulate total dose, then divide the measured dose by 8, otherwise write down 8 measurements and average them. $CTDI_{vol}$ is a weighted average of five measurements in the five holes of the CTDI phantoms.

The typical Head and typical Body scan parameters and $CTDI_{100}$ specifications are as listed in and .

To measure $CTDI_{free\ air}$, it is important that the ion chamber be centered in air at the isocenter (within ± 5 mm is usually sufficient), but it must also be level.

After the probe is positioned, the $CTDI_{free\ air}$ is calculated from the measured dose as:

$$CTDI_{free\ air} = \frac{(Measured\ Dose) \times 100}{N \times T}, \text{ Where } N \times T \text{ is Collimation (e.g. } 64 \times 0.625 \text{ is } 40\text{mm)}$$

$CTDI_{free\ air}$ Test and Tolerances:

| Stage # | Scan Parameters Scan type, kV, Collimation, Resolution | Expected Value (mGy) | Maximum deviation |
|---------|---|----------------------|-------------------|
| 1 | Axial 2D: Body, 120kV, 250mAs, 0.75sec, 128x0.625, Standard Resolution | 51.69 | $\pm 25\%$ |
| 2 | Axial 2D: Body, 120kV, 250mAs, 0.75sec, 64x0.625, Standard Resolution | 55.19 | $\pm 25\%$ |
| 3 | Axial 2D: Body, 120kV, 250mAs, 0.75sec, 32x0.625, Standard Resolution | 61.92 | $\pm 25\%$ |
| 4 | Axial 2D: Body, 120kV, 250mAs, 0.75sec, 16x0.625, Standard Resolution | 76.72 | $\pm 25\%$ |
| 5 | Axial 2D: Body, 120kV, 250mAs, 0.75sec, 8x0.625, Standard Resolution | 106.07 | $\pm 25\%$ |
| 6 | Axial 2D: Body, 120kV, 250mAs, 0.75sec, 4x0.625, Standard Resolution | 144.03 | $\pm 25\%$ |
| 7 | Axial 2D: Body, 120kV, 250mAs, 0.75sec, 2x0.625, High Resolution | 188.17 | $\pm 25\%$ |
| 8 | Axial 2D: Body, 140kV, 250mAs, 0.75sec, 64x0.625, Standard Resolution | 76.93 | $\pm 25\%$ |
| 9 | Axial 2D: Body, 100kV, 250mAs, 0.75sec, 64x0.625, Standard Resolution | 35.63 | $\pm 25\%$ |

| Stage # | Scan Parameters Scan type, kV, Collimation, Resolution | Expected Value (mGy) | Maximum deviation |
|---------|---|----------------------|-------------------|
| 10 | Axial 2D: Body, 80kV, 250mAs, 0.75sec, 64x0.625, Standard Resolution | 20.05 | ±25% |
| 11 | Axial 2D: Body, 120kV, 250mAs, 0.75sec, 64x0.625, High Resolution | 46.84 | ±25% |
| 12 | Axial 2D Head: Head, 120kV, 250mAs, 0.75sec, 64x0.625, Standard Resolution | 55.14 | ±25% |
| 13 | Axial 3D: Body, 120kV, 250mAs, 0.75sec, 64x0.625, Standard Resolution | 55.73 | ±25% |
| 14 | Axial 3D: Paediatric Head (Child Age Group), 100kV, 200mAs, 0.5sec, 32x0.625, Standard Resolution | 32.00 | ±25% |
| 15 | Axial 3D: Paediatric Body (Child Age Group), 120kV, 300mAs, 0.5sec, 64x0.625, Standard Resolution | 67.03 | ±25% |

CT number, Uniformity and Noise

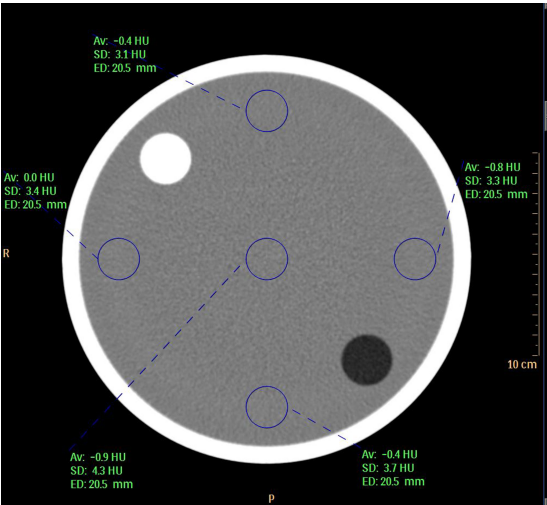
The Mean CT number, CT number Uniformity and Image Noise are measured on the Head or Body sections of the Harmonized System Phantom. Acceptance measures these on the Head Section of the phantom for all modes except Adult Body, 120 kVp, which is also measured on the large Body section. This allows Constancy to run only with the Head Section, for convenience.

Head phantom:

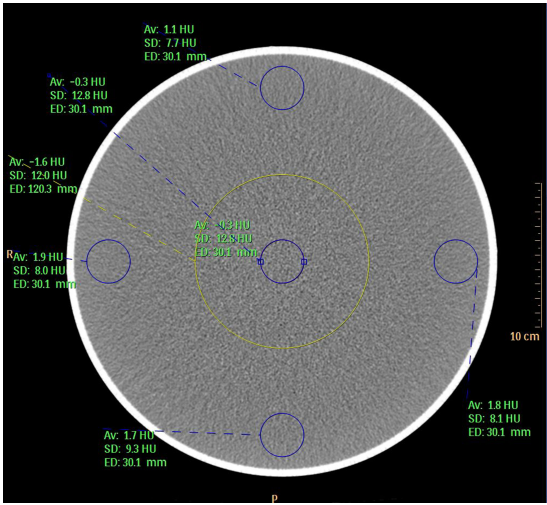
To measure CT number, use an ROI of area $300 \pm 50 \text{ mm}^2$ (effective diameter 20 mm), centered in the phantom. To measure CT number uniformity, use ROI's of the same size, located at approximately 12:00, 3:00, 6:00 and 9:00 in the phantom, 1 cm inside the plastic shell. Image noise uses an ROI of $5000 \pm 50 \text{ mm}^2$ (effective diameter 80 mm), also centered in the phantom.

Body phantom:

To measure CT number, use an ROI of area $700 \pm 75 \text{ mm}^2$ (effective diameter 30 mm), centered in the phantom. To measure CT number uniformity, use ROI's of the same size, located at approximately 12:00, 3:00, 6:00 and 9:00 in the phantom, 1 cm inside the plastic shell. Image noise uses an ROI of $11,300 \pm 100 \text{ mm}^2$ (effective diameter 120 mm), also centered in the phantom.



ROI placement for Uniformity measurements on Head Phantom



ROI placement for Uniformity and Noise measurements on Body Phantom

Scan Parameters and Tolerances for CT number, Uniformity and Noise Measurements:

| Scan | Protocol Element | Scan Parameters | Slices to Measure | Mean CT limits (HU) | Uniformity limits (HU) | Noise Low Limit (HU) | Noise Up Limit (HU) |
|------|--------------------------|---|---|---------------------|------------------------|----------------------|---------------------|
| 1 | Adult Head | Axial 3D Head, 120kV, 64 x 0.625 (SW 3mm), STD, 0.75s, 160mAs, UB, FOV 250, 512 x 512 | Middle slices (all slices except defined below) | [-4.0, 4.0] | [-4.0, 4.0] | 4.5 | 6.1 |
| | | | 1 first and 1 last slices | [-4.0, 4.0] | [-4.0, 4.0] | 4.7 | 6.4 |
| 2 | Adult Body Large phantom | Axial 3D Body, 120kV, 64 x 0.625 (SW 5mm), STD, 0.75s, 400mAs, B, FOV 350, 512 x 512 | Middle slices (all slices except defined below) | [-6.0, +6.0] | [-8.0, +8.0] | 7.1 | 9.6 |
| | | | 1 first and 1 last slices | [-6.0, +6.0] | [-8.0, +8.0] | 8.2 | 11.1 |
| 3 | Adult Body on Head | Axial 3D Body, 120kV, 128 x 0.625 (SW 5mm), STD, 0.75s, 400mAs, B, FOV 350, 512 x 512 | Middle slices (all slices except defined below) | [-6.0, +6.0] | [-4.0, 4.0] | 2.8 | 3.8 |
| | | | 1 first and 1 last slices | [-6.0, +6.0] | [-4.0, 4.0] | 3.2 | 4.4 |

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| Scan | Protocol Element | Scan Parameters | Slices to Measure | Mean CT limits (HU) | Uniformity limits (HU) | Noise Low Limit (HU) | Noise Up Limit (HU) |
|------|-------------------------------------|---|---|---------------------|------------------------|----------------------|---------------------|
| 4 | Adult Body with varied tube voltage | Axial 3D Body, 80kV, 128 x 0.625 (SW 5mm), STD, 0.75s, 400mAs, B, FOV 250, 512 x 512 | Middle slices (all slices except defined below) | [-6.0, +6.0] | [-8.0, 8.0] | 5.4 | 7.3 |
| | | | 1 first and 1 last slices | [-6.0, +6.0] | [-8.0, 8.0] | 6.1 | 8.3 |
| 5 | | Axial 3D, Body, 100kV, 128 x 0.625 (SW 5mm), STD, 0.75s, 400mAs, B, FOV 250, 512 x 512 | Middle slices (all slices except defined below) | [-6.0, +6.0] | [-8.0, 8.0] | 3.7 | 5.0 |
| | | | 1 first and 1 last slices | [-6.0, +6.0] | [-8.0, 8.0] | 4.1 | 5.6 |
| 6 | | Axial 3D, Body, 140kV, 128 x 0.625 (SW 5mm), STD, 0.75s, 400mAs, B, FOV 250, 512 x 512 | Middle slices (all slices except defined below) | [-6.0, +6.0] | [-8.0, 8.0] | 2.4 | 3.2 |
| | | | 1 first and 1 last slices | [-6.0, +6.0] | [-8.0, 8.0] | 2.6 | 3.6 |
| 7 | Pediatric Head | Axial 3D, Head, 100kV, 32 x 0.625 (SW 2.5mm), STD, 0.5s, 200mAs, UB, FOV 250, 512 x 512 | Middle slices (all slices except defined below) | [-4.0, 4.0] | [-4.0, 4.0] | 5.7 | 7.7 |
| | | | 1 first and 1 last slices | [-4.0, 4.0] | [-4.0, 4.0] | 6.4 | 8.7 |
| 8 | Pediatric Body | Axial 2D, Body, 120kV, 32 x 0.625 (SW 2.5mm), STD, 0.5s, 300mAs, B, FOV 250, 512 x 512 | Middle slices (all slices except defined below) | [-4.0, 4.0] | [-8.0, 8.0] | 4.4 | 6.0 |
| | | | 1 first and 1 last slices | [-4.0, 4.0] | [-8.0, 8.0] | 4.9 | 6.6 |

| Scan | Protocol Element | Scan Parameters | Slices to Measure | Mean CT limits (HU) | Uniformity limits (HU) | Noise Low Limit (HU) | Noise Up Limit (HU) |
|------|---|--|---|---------------------|------------------------|----------------------|---------------------|
| 9 | Pediatric Body with varied tube voltage | Axial 3D, Body, 80kV, 64 x 0.625 (SW 2.5mm), STD, 0.5s, 300mAs, B, FOV 250, 512 x 512 | Middle slices (all slices except defined below) | [-6.0, +6.0] | [-8.0, 8.0] | 8.7 | 11.8 |
| | | | 1 first and 1 last slices | [-6.0, +6.0] | [-8.0, 8.0] | 9.5 | 12.9 |
| 10 | | Axial 3D, Body, 100kV, 64 x 0.625 (SW 2.5mm), STD, 0.5s, 300mAs, B, FOV 250, 512 x 512 | Middle slices (all slices except defined below) | [-6.0, +6.0] | [-8.0, 8.0] | 5.8 | 7.8 |
| | | | 1 first and 1 last slices | [-6.0, +6.0] | [-8.0, 8.0] | 6.3 | 8.6 |
| 11 | | Axial 3D, Body, 140kV, 64 x 0.625 (SW 2.5mm), STD, 0.5s, 300mAs, B, FOV 250, 512 x 512 | Middle slices (all slices except defined below) | [-6.0, +6.0] | [-8.0, 8.0] | 3.6 | 4.9 |
| | | | 1 first and 1 last slices | [-6.0, +6.0] | [-8.0, 8.0] | 4.0 | 5.4 |

All slices should meet the CT number, Uniformity and Noise requirements. All scans use the Head Section of the system phantom, except Scan 2. Scan 2 uses the large Body Section of the system phantom.

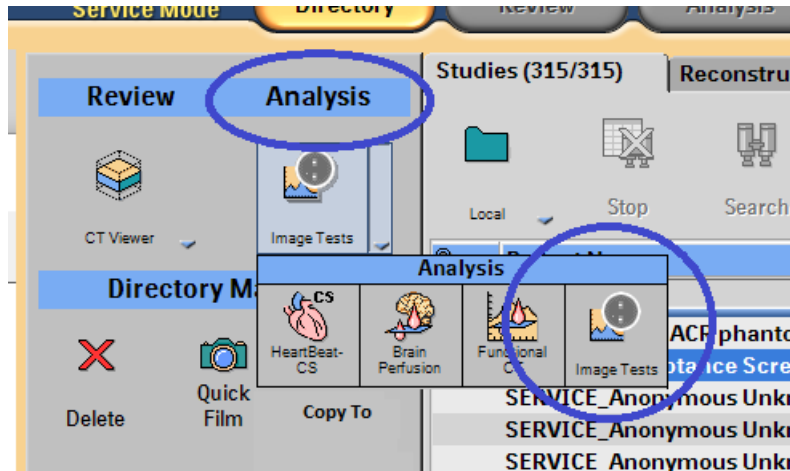
Spatial Resolution

Spatial Resolution is measured with the Modulation Transfer function. This is accessed in the Image Tools menu of the Analysis tab in the Patient Directory view. This test uses the horizontal wire in the Physics Section of the system phantom, which is located approximate 25 mm from the center of the phantom. The Physics Section of the system phantom is described in chapter “Harmonized System Phantom” on page 81.

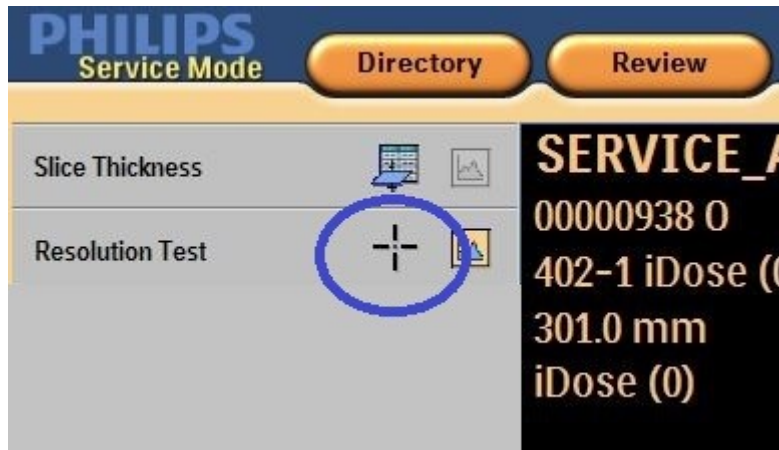
To Measure MTF:


- Scan the physics layer of the system phantom using the protocol and settings specified in the appropriate table.
 - For Head scans, use **Head > Axial > Impulse Response Head Protocol**.

- b. For Body scans, use **Abdomen > Axial > Impulse Response Body Protocol**.
2. From the **Directory**, select the scan series.
3. Select **Image Tests** from the **Analysis** options.



4. Select the middle image of the scan.
5. In the Resolution Test row, select the Position on the pin to place a cursor on the image near the pin.



6. To view the spatial resolution result, click **Calculate Resolution** . The appropriate results are in the lines MTF at 10% (lp/cm) and MTF at 50% (lp/cm).

| Impulse Response Manual Mode | |
|---|---------------|
| Protocol 2D, 120kV, 16x0.625(SW 1.25), HIGH, 0.75s, 150mAs, E, FOV 50 | |
| --- MTF --- | |
| MTF at 10 % (lp/cm) | 10.937 |
| MTF at 50 % (lp/cm) | 5.850 |
| --- Impulse Response --- | |
| Width at 10 % (mm) | 1.346 |
| Width at 50 % (mm) | 0.739 |
| --- Details --- | |
| Max CT at center of pin | 524.000 |
| Background CT | -1000.511 |
| X(c.g) (mm) | {X=181,Y=150} |
| Wire Cor (mm) | -0.014 |

- Repeat steps 5-6 on the other central image.
- Compare each recorded value to the specification provided within the limits listed in the table below.

Scan Parameters and Tolerances for Spatial Resolution Measurements:

| Resolution measurement | | | 10% MTF (lp/cm) | | 50% MTF (lp/cm) | |
|--------------------------------------|--|-------------------|-----------------|-------------|-----------------|-------------|
| Measurement Element | Scan parameters | Slices to measure | Lower Limit | Upper limit | Lower Limit | Upper limit |
| 1. Resolution, Adult Head | Axial 2D, Head, 120kV, 32 x 0.625 (SW 1.25mm), STD, 0.75s, 200mAs, YB, FOV 50, 1024 x 1024 | Two middle slices | 8.90 | 12.90 | 5.30 | 8.30 |
| 2. Resolution, Pediatric Head | Axial 2D, Head, 120kV, 32 x 0.625 (SW 1.25mm), High, 0.75s, 150mAs, E, FOV 50, 1024 x 1024 | Two middle slices | 9.70 | 13.70 | 5.00 | 8.00 |
| 3. Resolution, Adult Body | Axial 2D, Body, 120kV, 32 x 0.625 (SW 1.25mm), STD, 0.75s, 200mAs, YB, FOV 50, 1024 x 1024 | Two middle slices | 8.90 | 12.90 | 5.30 | 8.30 |
| 4. Resolution, Pediatric Body | Axial 2D, Body, 120kV, 32 x 0.625 (SW 1.25mm), STD, 0.75s, 150mAs, YB, FOV 50, 1024 x 1024 | Two middle slices | 8.90 | 12.90 | 5.30 | 8.30 |

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9 Third Party Devices Compatibility Matrix

Philips Medical Systems Nederland B.V. has performed compatibility tests utilizing a limited number of samples of Product. The scope of this compatibility statement is strictly limited to 3rd party devices, upgrades and or accessories as included in CT/AMI Accessories list as presented in appendix 1.

CT/AMI Accessories list as presented in appendix 1, include 3rd party devices, upgrades and or accessories along with the following information:

- Name of the accessory with reference to 6NC/12 NC
- Classification of the accessories
- Legal Manufacturer name

Through the basic compatibility testing with the Product, Philips found the CT/AMI products performed as intended and specified, with no detrimental degradation of CT/AMI products efficacy or safety when used per the conditions as stated in their Instructions for Use. Basic compatibility testing indicates compatibility of the CT/AMI products along with the 3rd party devices, upgrades and or accessories.

Safety and efficacy of the Product is the sole responsibility of Philips Medical Systems Nederland B.V.

This compatibility statement does not guarantee assurance that compatibility will be maintained with future changes to Product, including incorporated software releases, modifications and upgrades.

| 6NC/ 12NC | Name | Applicable Product | Risk Class | UDI (yes/no) | Legal Manufacturer | Category |
|--------------|-------------------------------------|--------------------------------------|------------|--------------|--|-------------|
| 728272 | Big Bore System Upgrade | Brilliance CT Big Bore | IIb | Yes | Philips Medical Systems Nederland B.V. | Upgrade kit |
| 728327 | Ingenuity CT System Upgrade | Ingenuity CT | IIb | Yes | Philips Medical Systems Nederland B.V. | Upgrade kit |
| 728305 | Brilliance iCT System Upgrade | Brilliance iCT | IIb | Yes | Philips Medical Systems Nederland B.V. | Upgrade kit |
| 45501800105x | ECG MONITOR ENGLISH | Brilliance CT Big Bore, Ingenuity CT | IIb | Yes | PMS Boeblingen | Accessory |
| 45356748489x | ECG Monitor English | Vereos | IIb | Yes | PMS Boeblingen | Accessory |
| 45980158427x | DORADOnova 3 w/ CARINANav, Red Wall | Big Bore, Brilliance CT Big Bore | I | Yes | LAP GmbH Laser Applikationen | Accessory |

| | | | | | | |
|--------------|---|---|-----|-----|------------------------------------|-----------|
| 45980158428x | DORADOnova 3 w/ CARINANav, Red Floor | Big Bore, Brilliance CT Big Bore | I | Yes | LAP GmbH Laser Applikationen | Accessory |
| 45980158431x | DORADOnova3 w/ CARINANav, Red Bridge | Big Bore, Brilliance CT Big Bore | I | Yes | LAP GmbH Laser Applikationen | Accessory |
| 45980158429x | DORADOnova 3 w/ CARINANav, Green Wall | Big Bore, Brilliance CT Big Bore | I | Yes | LAP GmbH Laser Applikationen | Accessory |
| 45980158430x | DORADOnova3 w/ CARINANav, Green Floor | Big Bore, Brilliance CT Big Bore | I | Yes | LAP GmbH Laser Applikationen | Accessory |
| 45980158432x | DORADOnova3 w/ CARINANav, Green Bridge | Big Bore, Ingenuity CT, Brilliance CT Big Bore, Vereos, Brilliance iCT | I | Yes | LAP GmbH Laser Applikationen | Accessory |
| 45980109682x | Certegra SyncRight upgrade kit | Ingenuity CT, Big Bore, Vereos, Brilliance iCT | IIb | Yes | Bayer healthcare LLC | Accessory |
| 98960520105x | SyncRight/ Medrad P3T Cardiac | Ingenuity CT, Brilliance CT Big Bore, Vereos, Brilliance iCT, IQON | IIb | Yes | Bayer healthcare LLC | Accessory |
| 98960520106x | SyncRight/ Medrad P3T Abdomen | Ingenuity CT, Brilliance CT Big Bore, Vereos, Brilliance iCT, IQON | IIb | Yes | Bayer healthcare LLC | Accessory |
| 98960520126x | SyncRight Certegra Injector - Pedestal | Ingenuity CT, Brilliance CT Big Bore, Vereos, Brilliance iCT, IQON | IIb | Yes | Bayer healthcare LLC | Accessory |

| | | | | | | |
|--------------|---|---|---------|-----|-------------------------|-----------|
| 98960520125x | SyncRight Injector – OCS Long | Ingenuity CT, Brilliance CT Big Bore, Vereos, Brilliance iCT, IQON | IIb | Yes | Bayer healthcare LLC | Accessory |
| 98960520124x | SyncRight Injector – OCS Medium | Ingenuity CT, Brilliance CT Big Bore, Vereos, Brilliance iCT, IQON | IIb | Yes | Bayer healthcare LLC | Accessory |
| 98960520123x | SyncRight Injector – OCS Short | Ingenuity CT, Brilliance CT Big Bore, Vereos, Brilliance iCT, IQON | IIb | Yes | Bayer healthcare LLC | Accessory |
| 45980109684x | Certegra SyncRight Kit iCT | Ingenuity CT, Brilliance CT Big Bore, Vereos, Brilliance iCT, IQON | IIb | Yes | Bayer healthcare LLC | Accessory |
| 45980105060x | Tumor LOC | Brilliance CT Big Bore | IIb | Yes | PROS | Accessory |
| 45980053073x | Breath Hold ES, Patient Display | Vereos | Class I | Yes | Medspira | Accessory |
| 45980053072x | Breath Hold ES, Base Unit | Vereos | Class I | Yes | Medspira | Accessory |
| 45980066324x | ASSY, PULMO CHEST BELLOWS, TUBING ES | Vereos | Class I | Yes | Medspira | Accessory |

Tab. 3: APPENDIX 1- CT/AMI Accessories list

10 EURATOM Compliance Statement

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

| | |
|---|---|
| Product Name: | Refer to the System Label. |
| Company Name and Address: | Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands. |
| Contact Information: | Refer to System labels and IFU. |
| Target Users and Training: | Refer to the 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 thru clinical evaluation planning, identify equivalent devices, a comprehensive analysis of available pre- and postmarket 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, this 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.

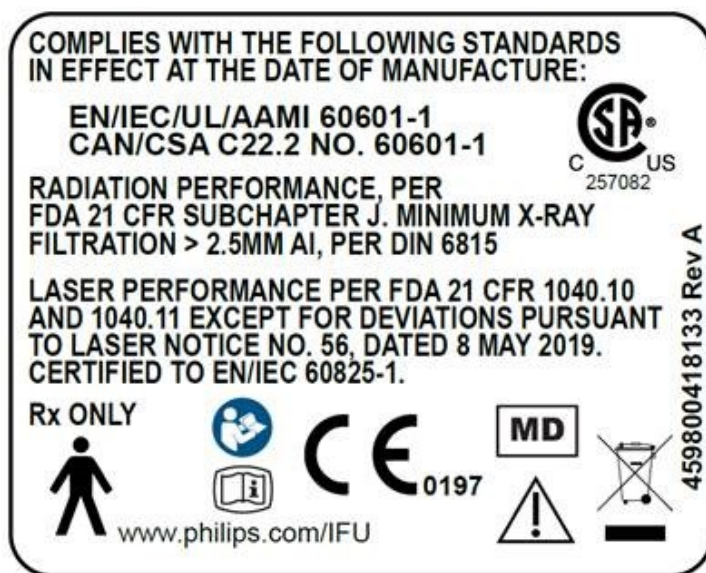
11 CE Mark Information Sheet

See the meaning of the CE mark that is applicable to your system.

| Circumstance | Applicable Mark |
|---|--|
| Where these Instructions for Use (IFUs) have been delivered in association with a device that bears a CE Mark on the system labelling for a device placed on the market on 26 May 2020 or later, or as part of an upgrade where the system being upgraded was placed on the market on 26 May 2020 or later, then the CE Mark indicates that this device complies with the provisions of the Medical Device Directive (93/42/EEC, as amended), the ROHS II Directive (2011/65/EU) and Medical Device Regulations (MDR 2017/745). The Notified Body number adjacent to the CE Mark claims compliance to 93/42/EEC, Annex II, and EU MDR 2017/745, Annex IX Conformity assessment based on a Quality Management System and on assessment of Technical Documentation. |  CE 0197 |
| Where these Instructions for Use (IFUs) have been delivered in association with a device that bears a CE Mark on the system serial tag or regulatory tag (adjacent to the serial tag) and these IFUs are for a device placed on the market on 22 July 2014 or later, or as part of an upgrade where the system being upgraded was placed on the market on 22 July 2014 or later, then the CE Mark indicates that this device complies with the provisions of the Medical Device Directive (93/42/EEC, as amended) and the ROHS II Directive (2011/65/EU). The Notified Body number adjacent to the CE Mark is exclusive to 93/42/EEC, Annex II, and indicates the Notified Body for the system when it was originally placed on the market. |  CE 0197 |
| Where these Instructions for Use have been delivered as part of an upgrade to a system placed on the market prior to 22 July 2014, then the CE Mark shown on the system serial tag or regulatory tag (adjacent to the serial tag) indicates that this device complies with the provisions of the Medical Device Directive (93/42/EEC, as amended). The Notified Body number adjacent to the CE Mark indicates the Notified Body for the system when it was originally placed on the market. The upgraded device is exempt from the RoHS II Directive 2011/65/EU, per Article 4, 4.(b). |  CE 0197 |
| Where these Instructions for Use are associated with a device that does not bear a CE Mark on the system serial tag or regulatory tag (adjacent to the serial tag), then no claim of compliance to either the Medical Device Directive (93/42/EEC, as amended) or the RoHS II Directive (2011/65/EU) is made for the particular device. | No mark |

NOTICE

In the event of a serious incident involving a patient and/or operator during use of the system, immediately report the incident to the manufacturer and the competent authority of the Member State in which the operator and/or patient is established.



The system product label is typically on or near the gantry.

12 Reference Training Checklist

Table and Gantry Controls

☐

I can locate and recognize when and how to use the following gantry and table controls:

☐

Control panels

☐

Gantry covers

☐

Head holder and accessories – positioning and intended use

☐

Foot board (not to be used for any body part other than feet)

☐

Couch pad alignment

☐

Emergency Stops

☐

Table Motion controls and settings

☐

Laser Lights- Internal/External

☐

Load/Unload Foot Pedal

☐

Maximum Patient Load

☐

Scan-able Range

☐

Patient positioning aids

☐

I can locate the following safety devices and recognize when to use them:

☐

Gantry Emergency Stops

☐

Emergency patient releases

☐

Radiation warning lamps on the scanner

☐

I can reset from an Emergency Stop.

☐

I can comply with the following patient safety standards:

☐

Using the foot board for feet only (no other body parts)

☐

Keep the patient under constant observation during all movements of the gantry and patient table

☐

Avoid collision and ensuring patient safety by checking to make sure there is nothing under the table when lowering the patient couch

☐

Instructing patients NOT to stare into the laser beam

☐

I am familiar with the following safety requirements regarding the equipment:

- ☐ *Do not stare into the laser beam.*
- ☐ *Do not remove covers or cables from the equipment.*
- ☐ *Do not use explosive disinfecting sprays while cleaning the CT scanner.*

Power-up and Shutdown

- ☐ **I can perform System Power-up and Shutdown, including the following:**
 - ☐ *Daily Logout/Login*
 - ☐ *Weekly Complete System Shutdown and Power-up*
 - ☐ *Console and System UPS shutdown if applicable*
- ☐ **I will review, understand and follow the system maintenance quick reference, including the following:**
 - ☐ *System Power-up and Shutdown procedures*
 - ☐ *Scanner's Do's and Do not's*
 - ☐ *Appropriate Scanning and Control room conditions*

Quality Assurance – Daily/Monthly

- ☐ **I can perform the following quality assurance functions:**
 - ☐ *Short Tube Conditioning*
 - ☐ *Air Calibrations*
 - ☐ *Phantom Placement*
 - ☐ *Quick IQ Check*
 - ☐ *Constancy*
- ☐ **I am familiar with the following safety advisories:**
 - ☐ *The X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.*
 - ☐ *Do not use the CT scanner for any application until you are sure that the image Performance QA is complete and that the Preventive Maintenance program is up to date.*

User Interface/GUI Overview

- ☐ **I can use the user interface.**
- ☐ *Access the right mouse functions*
 - ☐ *Select folders and devices (verify connection- Free space)*
 - ☐ *Use the Queue Manager*
 - ☐ *Bug Report Submission*
 - ☐ *Monitor Calibration*
 - ☐ *Error Message and Recovery*

Patient Data Entry and Exam Card Selection

- ☐ **I can enter patient data and select exam cards, including:**
- ☐ *Entering or selecting new/current/anonymous/worklist*
 - ☐ *Completing Mandatory Fields*
 - ☐ *Selecting Voice Language*
 - ☐ *Selecting Patient Position*
 - ☐ *Selecting Exam Card (EC)*
 - User EC's
 - Reference EC's
 - Suggested EC's
- ☐ **I am familiar with the following safety advisories:**
- ☐ *Make sure to use radiation protection devices correctly, e.g., adding bismuth shielding after the Surview acquisition and dedicated pediatric protocols to reduce radiation dose.*
 - ☐ *Make sure to enter the patients' age correctly, when using pediatric protocols.*

Exam Card Manager

☐

I can build Exam Cards, and can determine when and how to use the following acquisition and result parameters.

☐

Surview Including:

- Length
- View Angle
- Direction
- Frontal
- Lateral
- Dual

☐

Collimation

☐

Sampled Collimation

☐

DoseRight Index (DRI)

☐

3D Modulation

☐

Z Modulation

☐

Automatic Scan Time

☐

Resolution

☐

kVp

☐

Dose Notification

☐

Slice Thickness

☐

Increment

☐

Filters

☐

Edit before final Recon

☐

Injection Settings

☐

O-MAR

☐

MCR

General Safety Notifications

- ☐ I am familiar with the following safety notifications:
- ☐ Portable radio transmitting devices such as mobile phones should not be used around the CT scanner as they can interfere with proper functioning of the system.
 - ☐ Do not use the CT scanner for any application until you have received adequate and proper training in its safe and effective use.
 - ☐ Never attempt to remove, modify, over-ride or forcibly move any safety device on the equipment.
 - ☐ Do not use the CT scanner for any purpose other than those for which it is intended.
 - ☐ Exposing an implanted medical device such as a pacemaker or neuro-stimulator to medical radiation has the potential to cause the device to malfunction.
 - ☐ Are you familiar with the regulations for radiation safety for your state, province or country?
 - ☐ Philips recommends that when HU measurements are needed, reconstruct the raw data using filters which do not affect the HU numbers, such as the A, B or C filters. Absolute Hounsfield Units should never be used as the sole basis for any diagnosis.
 - ☐ Do NOT use O-MAR in the following instances:
 - External metals
 - Bismuth shields
 - Metal in or near intra-body air spaces
 - Small surgical implanted devices, i.e. screws, pins, clips, etc.
 - ☐ If the following message displays:
 - "A Tube Arc has occurred. You may continue operating the scanner, If the problem persists, contact your service engineer".

Contact the local service engineer immediately for further instructions.

Patient Scanning with Dose Management

- ☐ I can scan patients using the Exam Cards including the following features:
- ☐ Scan Ruler
 - ☐ Result Direction/Acquisition Direction
 - ☐ Auto Enable
- ☐ I can perform the following functions:

- ☐ *End exam*
- ☐ *End exam and continue working*
- ☐ *Work with Recon Queue Manager*
- ☐ **I can scan patients using exam cards that include the following dose management tools:**
 - ☐ *DoseRight*
 - ☐ *DoseRight Index (DRI)*
 - ☐ *3D Modulation*
 - ☐ *Z- Modulation*
 - ☐ *Absolute Min and Max mAs*
 - ☐ *Reference Size*
 - ☐ *Patient Size*
 - ☐ *Head and Liver DoseRight Index*
 - ☐ *Dose Notification – CTDI & DLP*

Scan Control Box

- ☐ **I can explain how and when to use the following Scan Control Box options:**
 - ☐ *Manual-Auto-Pause-Enable*
 - ☐ *Gantry Controls- Up/Down-In/Out*
 - ☐ *Gantry Key On-Off*
 - ☐ *Volume Controls- Console and Gantry Speakers*
 - ☐ *Patient Intercom*

Patient Directory, Archive Manager, and System Preferences

- ☐ **I can explain how and when to use the following Patient Directory tasks:**
 - ☐ *Original vs. Derived Images*
 - ☐ *Sub-selection*

- ☐ *Sort*
- ☐ *Recon*
- ☐ *Queue Manager*
- ☐ *Multimedia Viewer*
- ☐ *Quick Review*

☐**I can perform the following Directory Manager tasks**

- ☐ *Sort*
- ☐ *Copy to*
- ☐ *Recon*
- ☐ *Delete Studies*
- ☐ *Archive notification*
- ☐ *Hard Drive Maintenance*
- ☐ *Burn a CD (CDR)*
- ☐ *View a CD*

☐**I can identify when and how to select Scanning Option Preferences including the following:**

- ☐ *Display overlap warning*
- ☐ *Automatically move to "View" when the last scan is complete*
- ☐ *Enable SyncRight*
- ☐ *Switch to overview layout for editing before final recon*
- ☐ *Automatic Dual Surview*
- ☐ *Play sound along with blue arrow*
- ☐ *Automatically display the mAs profile for each scan*
- ☐ *Bolus Tracking help images*
- ☐ *Restore Default Helper Images*
- ☐ *Enable auto alert before X-Ray*

☐**I can identify when and how to select Reconstruction Preferences, including the following:**

- ☐ *Axial view convention*
- ☐ *Decubitus image view convention*
- ☐ *Automatic matrix*
- ☐ *Remove blank images*

- ☐ *Enable metal reduction*
- ☐ *Plan Geometry Limitations*
- ☐ *Limit Plan Geometry in Exam Card*
 - Force Image Center X,Y to 0,0
 - Force FOV of all results in an acquisition to be equal
 - Disable Result Rotation
- ☐ *Enable Motion Compensation Reconstruction (MCR)*
- ☐ **I can identify when and how to select Exam Summary Preferences:**
 - ☐ *Patient Information*
 - ☐ *Exam Information*
 - ☐ *Results*
 - ☐ *Executed Survey*
 - ☐ *Reference Survey*
 - ☐ *Injection Summary*
 - ☐ *Spectral Images Description*
- ☐ **I can identify when and how to select Cardiac and Pulmonary Preferences**
 - ☐ *Heart-rate dependent phases*
 - ☐ *On-line arrhythmia handling*
 - Coronary CTA
 - Gated CTA
 - ☐ *Always detect wave*
 - ☐ *Automatic retrospective arrhythmia detection*
- ☐ **I can identify when and how to select Dose Management preferences:**
 - ☐ *Dose Alert DLP & CTDI*
 - ☐ *Display Dose Efficiency warning*
 - ☐ *Enable Reference Noise*
 - ☐ *Display mA*
 - ☐ *Enable DoseRight*
 - ☐ *Dose Modulation: enable special Head area DoseRight Index*
 - ☐ *Dose Modulation: enable special Liver area DoseRight Index*
 - ☐ *Enable DoseRight in head for Infant*

☐ *Enable DoseRight in head for Child*☐ *Enable DoseRight in head for Adult*☐ *Create Dose Structured Report*

- Select Devices

☐**I am familiar with the following additional preference options:**☐ *Patient Data*☐ *Connectivity*☐ *Patient Directory*☐ *Windowing Presets*☐ *Image Titles*☐ *Measurements*☐ *Save Images*☐ *Segmentation Preset*☐ *Reporting*☐ *Film Header/Footer*☐ *Viewing Applications*☐ *Institute Information*☐ *Licensing*☐ *Regional Settings*

Bolus Tracking and SyncRight

- ☐ I am comfortable performing Bolus Tracking and SyncRight (if applicable) with patients, including:
- ☐ Building the Injection in the EC
 - ☐ Modifying the injection from the Scan Ruler
 - ☐ Using P3T (if applicable)

Brain Perfusion

- ☐ I can perform perfusion studies. (if applicable)
- ☐ I understand that dose values for brain perfusion should be set at lower values than routine brain imaging.
 - ☐ I understand that there are different collimation options: 6cm, 7cm, 8cm in order to perform a perfusion scan.

Reconstruction Modes, Physics Overview and Workflow Options

- ☐ I can explain how to use the available Recon Modes (iDose4, IMR, Spectral)
- ☐ I can explain the IMR image definitions for brain including:
- ☐ Brain Routine
 - ☐ Sharp
 - ☐ SharpPlus
- ☐ I can explain the IMR image definitions for body including:
- ☐ Soft Tissue
 - ☐ Routine
 - ☐ SharpPlus
- ☐ I can explain the IMR Image definition for cardiac including:
- ☐ Cardiac Routine
 - ☐ Cardiac Sharp

- ☐ *Body Routine*
- ☐ *Body Soft Tissue*
- ☐ *Body SharpPlus*
- ☐ **I can recognize the clinical indications for using Cardiac IMR**
- ☐ **I can select appropriate parameters to customize Exam Cards to include iDose4, IMR and Spectral**
- ☐ **I can determine which parameters to adjust to improve low contrast and spatial resolution**
- ☐ **I can use the IMR worksheet to improve dose optimization**
- ☐ **I can add Auto MPR's, MinIP, MIP and Volume to an Exam Card.**

Administrative Functions

- ☐ **I can recover from errors.**
- ☐ **I can create a bug report.**

IT/CT Administrator Role

- ☐ **The Philips representative has assisted me in doing the following:**
 - ☐ *Establish security requirements*
 - ☐ *Create accounts and passwords for CT users*
- ☐ **I can identify my role as administrator and perform the following user management functions:**
 - ☐ *Lock and unlock accounts*
 - ☐ *Access the Audit Trail*
 - ☐ *Access the ECM*
 - ☐ *Create users*
 - ☐ *Reset passwords*
 - ☐ *Remove users*
- ☐ **I have been informed of the password policy**
 - ☐ *Login attempts settings*
 - ☐ *Password expiry settings*

- ☐ Password complexity requirements
- ☐ I can enable, disable, and configure Screen Blanking
- ☐ I can back up and restore user accounts
- ☐ I can use the audit trail viewer

Spectral Scanning and Results

- ☐ **HU Based Images**
 - ☐ MonoEnergetic (MonoE)
 - ☐ MonoE keV (Equivalent to Conventional CT)
- ☐ **Modified HU based images**
 - ☐ Virtual Non-Contrast (VNC)
 - ☐ Contrast Enhanced Structures
 - ☐ Iodine Removed
 - ☐ Uric Acid
 - ☐ Uric Acid Removed
 - ☐ Calcium Suppression X Index [HU*]
- ☐ **Concentration Value**
 - ☐ Iodine no Water
 - ☐ Iodine Density
- ☐ **Effective Atomic Number Images**
 - ☐ Z-Effective Images
 - ☐ Electron Density [%EDW]
- ☐ **Spectral Base Images**

Spectral Preference Settings

-
- ☐ Burn Spectral label on image pixel data for all Spectral image types when saving images
-
- ☐ Block measurements (which will block windowing as well) when saving non-HU based images
-

☐

Add warning regarding units of measure when saving non-Hu based images.

Build Exam Cards with Spectral Results

☐

I can build Exam Cards with desired Spectral results.

ISP Basics, Spectral CT Viewer, Spectral AVA, Spectral CCA, Tumor Tracking

☐

I can select and use the appropriate spectral viewing mode, and enable the various spectral features and tools to provide additional diagnostic capabilities to the spectral images, including Magic Glass (if available for PACS).

☐

Spectral CT Viewer

☐

I understand that I should always correlate the original CT images to images that have been manipulated in any of the Spectral viewing packages.

☐

Spectral AVA

☐

I am familiar with the AVA warnings including residual bone (skull removal, bone removal), which can mimic calcium plating along vessels. In addition, I understand that I should verify bone removal to ensure that it does not affect vessel completeness. I can correct manually, and use curved MPR to cross reference segmentation and vessel delineation.

☐

Spectral CCA

☐

I am familiar with the need to verify accuracy of automatic segmentation. I will also check cross sectional images created from centerlines and note orientation annotations. I will not use images that do not have annotations displayed. I understand that I should always verify correctness of extracted and labeled vessels.

☐

Tumor Tracking

☐

I understand that I should check that all studies loaded into the tumor tracking application should belong to the same patient.

☐

I understand that I should check the accuracy of the registration when using Automatic registration.

Overview of Remaining CT Viewers and Applications

☐ I can select and use the following viewers:

- ☐ *CT Viewer*
- ☐ *2D*
- ☐ *Slab*
- ☐ *Volume*
- ☐ *Endoscopy*
- ☐ *Brain Perfusion*
- ☐ *Functional CT*
- ☐ *MIP*
- ☐ *Reporting*

Lecture: Interventional/CCT and Perfusion (if applicable)

☐ I can perform interventional/CCT and perfusion.

CCT Tools (if applicable)

☐ I can make the following system adjustments:

- ☐ *1 or 3 image display*
- ☐ *Changing parameters during procedures*
- ☐ *Reference series*
- ☐ *Volume mode*

Interventional Controls

☐ I can explain how and when to use the following Interventional Control options in scan ruler:

- ☐ *Table Controls – In/Out/Move to selected position*
- ☐ *Set movement increment and slice thickness*
- ☐ *Set work/scan position*
- ☐ *Set needle entry/tip point*

- ☐ *Thickness/Increment menu*
- ☐ *Move to Selected Position*

Hardware Interventional Controls

☐ I can explain how and when to use the following Interventional Control options:

- ☐ *Table Controls – Up/Down-In/Out*
- ☐ *Save/Move to saved table position*
- ☐ *Laser controls – On/Off*
- ☐ *Joystick mouse*
- ☐ *Lock/Unlock Screen*
- ☐ *Motion*

- Thickness/increment selection
- Current table location

- ☐ *CCT Acquisition*
 - CCT Mode Selection
 - Image Layout
 - Thickness
 - Coverage
 - GO button
 - Display Reference Image

- ☐ *Image*
 - Save Image
 - Save as Scan Position
 - Automatic windowing
 - Common tools
 - Pointer
 - Scroll

Virtual Tilt Viewer

☐ I can use the following viewers and tools to analyze interventional images:

- ☐ *Oblique Axial/Sagittal*
- ☐ *True Axial/Corona/Sagittal*
- ☐ *Set Entry/Target point*
- ☐ *Auto Launch Virtual Tilt Viewer (VTV)*
- ☐ *Virtual Needle*
- ☐ *Needle Properties*
- ☐ *Adjust Needle Entry Point/Target Point*
- ☐ *Crosshairs On/Off*
- ☐ *Link Viewport Parameters*
- ☐ *Save Plan*
- ☐ *Restore Plan*
- ☐ *User messaging when vertical height is changed*

Cardiac Overview

- ☐ **I can explain the anatomy and functionality of the heart including:**
 - ☐ *Chambers*
 - ☐ *Coronary vessels*
 - ☐ *Heart Rate effect on the Image Quality of Cardiac Scans*

Patient Prep, Skin Prep, and Proper ECG Lead Placement

- ☐ **I can prepare the patient for the exam, including:**
 - ☐ *Explain the cardiac exam*
 - ☐ *Providing breathing instructions*
 - ☐ *Performing skin prep*
 - ☐ *Properly positioning the patient for the for cardiac exam*
 - ☐ *Placing electrodes properly*
 - ☐ *Evaluate the patients HR during Breath hold*

ECG Viewer

- ☐ I can explain and demonstrate how to use the ECG Viewer tools during the scan:
 - ☐ Display ECG wave, HR graph or both on Scan Ruler
 - ☐ Right Side Tools
- ☐ I can explain and demonstrate how to use the ECG Viewer tools after acquisition:
 - ☐ Arrhythmia handling tools
 - ☐ Additional Right Click Menus Options
- ☐ I can explain how to respond to the following warning messages:
 - ☐ ECG Disconnect Warning Message
 - ☐ ECG HR below or above ECG range Warning Message

Calcium Scoring

- ☐ I can perform a Calcium Score
 - ☐ Plan on Calcium Score/Plan on Previous Scan
 - ☐ Set Start/End for the next Cardiac Scan from the Preview images

Retrospective Cardiac

- ☐ I can perform a cardiac helical exam, including:
 - ☐ Expected heart rate (HR)
 - ☐ Auto Pitch and Rotation Time based on HR
 - ☐ Identify Coronary vs. Functional Phases
 - ☐ Use DoseRight and Cardiac DoseRight
 - ☐ Use Phase Tolerance with Cardiac DoseRight
 - ☐ Perform Single Cycle Reconstruction
 - ☐ Handle Irregularities Online

Motion Compensated Reconstruction (MCR)

- ☐ I can perform a Motion Compensated Reconstruction:
- ☐ MCR is for native Coronary arteries only
 - ☐ MCR cannot be used with Retrospective Gated acquisitions in the following scenarios
 - When Single Cycle Reconstruction is selected
 - When the Z Coverage is more than 78cm
 - When there is more than 700 images requested in the result
 - When HR Dependent is selected
 - When a matrix larger than 512 is selected
 - When a cardiac phases below 10% or above 89% is selected
 - ☐ MCR cannot be used with Step and Shoot Gated acquisitions in the following scenarios
 - When a matrix larger than 512 is selected
 - When no Phase Tolerance has been selected
 - When the Z Coverage is more than 78cm
 - When there is more than 700 images requested in the result
 - ☐ MCR can be used in Offline Reconstruction

Cardiac Viewer

- ☐ I can use the following viewers and tools to analyze cardiac images:
- ☐ 2D/Slab
 - ☐ Compare
 - ☐ Link
 - ☐ Paddle Wheel
 - ☐ MIP
 - ☐ Cardiac axes
 - ☐ ECG evaluation
 - ☐ Reset crosshairs
 - ☐ Planar
 - ☐ Area Length Ejection Fraction

- ☐ *Creating Short Axis Series*
- ☐ *Cardiac cine*
- ☐ *Echo views*

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Philips

Step&Shoot Overview

- ☐ I can use the Step&Shoot tools, including:
 - ☐ *Edge correction*
 - ☐ *Phase tolerance*
 - ☐ *Full coverage longer cycle*
 - ☐ *Handle irregularities online*

Arrhythmia Handling

- ☐ I can use arrhythmia handling tools, including:
 - ☐ *Accept an arrhythmia*
 - ☐ *Reject an arrhythmia*

ECG Editing

- ☐ I can do ECG editing, including:
 - ☐ *Add an ECG tag*
 - ☐ *Move an ECG tag*
 - ☐ *Delete an ECG tag*

iDose and IMR for Cardiac

- ☐ I can demonstrate the iDose and IMR for Cardiac, including:
 - ☐ *Set iDose in an Exam Card*
 - ☐ *Set IMR in an Exam Card*
 - ☐ *Compare Results*

Image Quality / Iterative Reconstruction

Time allotted for this topic: 120 minutes

☐

Image Quality

☐

iDose (patient exposure reduction)

☐

iDose (image quality improvements)

☐

IMR (patient exposure reduction)

☐

IMR (image quality improvements)

☐

OMAR (image quality improvements)

☐

Offline Reconstructions with iDose / OMAR/ Phase editing

Sign-In Sheet

Site#:

Site Name:

Training Dates:

Addendum to system configuration:

Yes

No

☐
☐

Off-site training packet received and reviewed?

☐
☐

Attended off-site training?

☐
☐

CEU criteria met?

☐
☐

Continuing Education training materials supplied to the customer?

☐
☐

Clinical Education line discussed with customer?

☐
☐

Service call procedure discussed with customer?

☐
☐

Do you feel the training objectives were met?

"Philips Clinical Education complies with ASRT Accreditation guidelines, and must document that attendees receiving CEUs have received and have been present for at least 80% of this training event. Signatures below acknowledge 80% or greater attendance at this Philips Clinical Education training event."

Customer signature/title:

Date:

Customer comments:

CES signature:

CES comments:

Philips

Spectral CT Version 5.0.1

[illegible]

Body

[illegible]

14 Constancy Test

Enter Pass/Fail for each of the Results Below.

Year: _____

| Month | CT # | | Noise | | Uniformity | | Resolution | | Slice Thickness | |
|-----------|------|------|-------|------|------------|------|------------|------|-----------------|------|
| | Head | Body | Head | Body | Head | Body | Head | Body | Head | Body |
| January | | | | | | | | | | |
| February | | | | | | | | | | |
| March | | | | | | | | | | |
| April | | | | | | | | | | |
| May | | | | | | | | | | |
| June | | | | | | | | | | |
| July | | | | | | | | | | |
| August | | | | | | | | | | |
| September | | | | | | | | | | |
| October | | | | | | | | | | |
| November | | | | | | | | | | |
| December | | | | | | | | | | |

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