

Technical Reference Guide

English

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Vereos PET/CT System

PHILIPS

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1 Introduction

The Philips Vereos PET/CT system is a diagnostic imaging device that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT subsystem images anatomical cross-sections by computer reconstruction of X-ray transmission data. The PET subsystem images the distribution of PET anatomy-specific radiopharmaceuticals in the patient.

About this guide

This manual is intended to provide guidance to users in the safe and effective operation of the system. This manual is intended to assist physicians, physicists, operators, and other personnel in the quality assurance testing of the scanner. It includes physics instruction 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.

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NOTICE

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

There are features and accessories described in this manual that are optional and may not be included or available with your system.

Warnings, cautions, and notes

Before attempting to operate the system, it is imperative that you read the *Safety* chapter in this manual in its entirety and comply with all safety and emergency measures contained therein. Furthermore, you must strictly observe all Cautions and Warnings that appear in the manual.

The following conventions are used to describe potential hazards to the patient or operator, potential damage to the equipment, potential loss of data, or call your attention to important supplemental information.



WARNING

Directions, which if not followed, could cause fatal or serious injury to an operator, patient or any other person, or could lead to a misdiagnosis or mistreatment.

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CAUTION

Directions, which if not followed, could cause damage to the equipment described in this manual, and/or any other equipment or goods, and/or cause environmental pollution.

NOTICE

A Notice provides important supplemental information that may enhance your understanding of the topic or performance of the procedure.

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) 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 with short time loading (per IEC 60601-1) Long time operation with momentary loading (per UL/ANSI/AAMI 60601-1 and NFPA 70)

IEC/EN Statement of Compliance

This equipment is compliant to the following standards:

IEC 62304:2006

EN 62366:2008

EN 62304:2006 + Cor.:2008

EN 60601-1-6:2010

IEC 60601-1-6:2010

EN 60601-2-28:2010

IEC 60601-2-28:2010

IEC 60601-2-44:2009+A1:2012+Corr1:2010

IEC 60601-1:2012

EN 60601-1:2006+C:2010+A1:2013

IEC 60601-1-3:2008+A1: 2013

EN 60825-1:2014

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IEC 62366:2007/A1:2014

IEC 60601-1-2: 2014

IEC 60825-1:2014

EN 60601-1-2:2015

EN 60601-1-3:2008 + A11:2016

EN 60601-2-44:2009/A11:2011 + A1:2012 + A2:2016

Electromagnetic Immunity

The 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 system should be used.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	**See Note 2 below** Interference may occur in the vicinity of equipment marked with the following symbol: 

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: The system 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 Installation Manual may be used inside the gantry and patient table room.

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Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
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	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 35% non-condensing per the system's planning reference data (PRD).
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power mains input ±1 kV for signal ports with 100kHz repetition frequency	Main's power quality must comply with the system's planning reference data (PRD).
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 system's planning reference data (PRD).
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 5 s	0 % U_T for 5 s	Main's power quality must comply with the system's planning reference data (PRD). If the user of the system requires continued operation during power mains interruptions, it is recommended that the system is powered from an uninterruptible power supply (UPS).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m, 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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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.

Electromagnetic Emissions

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

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

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.	The system 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 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	

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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 scanner should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the 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 scanner.

Electrical Ratings

Voltage (VAC)	Phase	Frequency (Hz)	Power consumption (kVA)	
			Continuous (IEC) long time (UL/NFPA 70)	Short time (IEC) momentary (UL/NFPA 70)
200	3	50/60	15	110
208	3	50/60	15	110
240	3	50/60	15	110
380	3	50/60	15	110
400	3	50/60	15	110
415	3	50/60	15	110
440	3	50/60	15	110
480	3	50/60	15	110
500	3	50/60	15	110

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 scanner in which part of the high voltage generator is integrated with the X-ray tube assembly.

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1) NOMINAL X-RAY TUBE VOLTAGE and highest X-RAY TUBE CURRENT obtainable from the HIGH-VOLTAGE GENERATOR when operated at that X-RAY TUBE VOLTAGE	+60kV, -60kV; 665mA
2) Highest X-RAY TUBE CURRENT and the highest X-RAY TUBE VOLTAGE obtainable from the HIGH-VOLTAGE GENERATOR when operated at that X-RAY TUBE CURRENT	655mA; +60kV, -60kV
3) Combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which results in the highest electric output power	+60kV, -60kV at 665mA = 80kW Or +75kV, -75kV at 571mA = 80kW
4) NOMINAL ELECTRIC POWER given as the highest constant electric output power (kW) which the HIGH-VOLTAGE GENERATOR can deliver for a LOADING TIME of 4 seconds at an X-RAY TUBE VOLTAGE of 120 kV, or nearest to 120 kV and the value of LOADING TIME nearest to but not less than 4 seconds	80kW
5) NOMINAL ELECTRIC POWER given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME, which are used in the CT scanner	80 kW, +75kV/-75kV, 571mA, 4.1 sec

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WARNING

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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.

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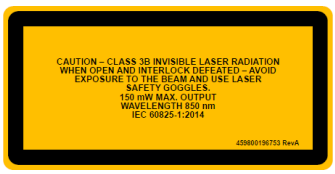
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2 Labels on the System

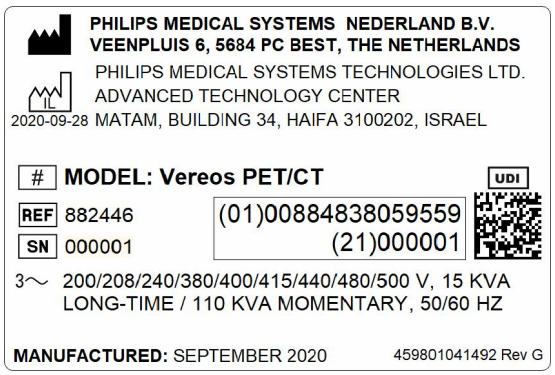
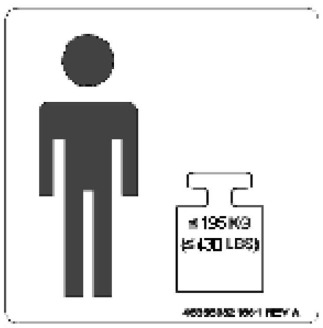
Philips Healthcare products are designed to meet stringent safety standards. It is imperative that you strictly observe all danger notices and safety markings on the system.

The following labels are attached to the system in accordance with 21 CFR 1040.10, IEC 60825-1, and other applicable standards and regulations. The purpose and location of each of these labels is described below.

	Warning: Electrical Shock High voltage is present beneath the covers. Do not remove covers. Location: On covers of the gantry.
	Warning: Pinch Point Location: Patient table, flat pallet, and table catcher.
	Emergency Stop - Halts all scanner and table motions and X-ray generation. Location: on the gantry and Scan Control box. (IEC 60601-1, 3rd Edition)
	CAUTION Class 2 patient positioning lasers. 1.0 mW maximum output, wavelength 650 nm. IEC 60825-1:2014.
	CAUTION Class 3B invisible laser radiation when open and interlocks defeated. Avoid exposure to the beam and use laser safety goggles. 150 mW MAX. OUTPUT WAVELENGTH 850 nm IEC 60825-1:2014.
	Caution Location: Various locations on the gantry and table to advise operator of special attention needed.

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	Unique Device Identification (UDI) label. See below for full description.
	Consult user manual for more information. Location: Various locations on the gantry and table to advise operator of special attention needed.
	Warning: Body Weight Limit Do not exceed maximum weight of 430 lbs. (195 Kg) on the patient table. See user manual for additional information regarding patient weight. Location: On the handle of the patient table.
	Do Not Step Here Location: Base of the table catcher.

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Warning to service representatives: See service manual for additional information regarding the Suite Annunciator.

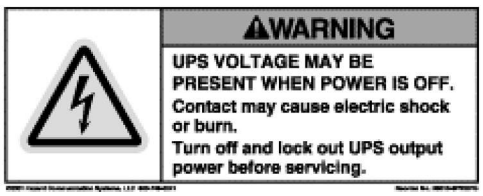
Hazardous voltages may be on the annunciator connections after power is removed from the system. Disconnect customer's annunciator power before servicing the gantry.

Non-compliance can cause injury or death.

Contact Rating:

- 24 to 250v~
- 2A RMS max.

Location: On the back of the gantry.



Warning: Hazardous Voltage.

Contact may cause electric shock or burn.

Turn off and lock out UPS output power before servicing.

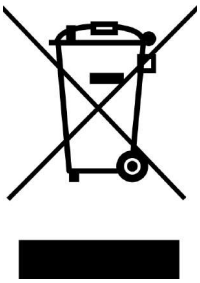
Location: On the inside of the Gantry Power Protection cabinet door and dehumidifier UPS cabinet door.

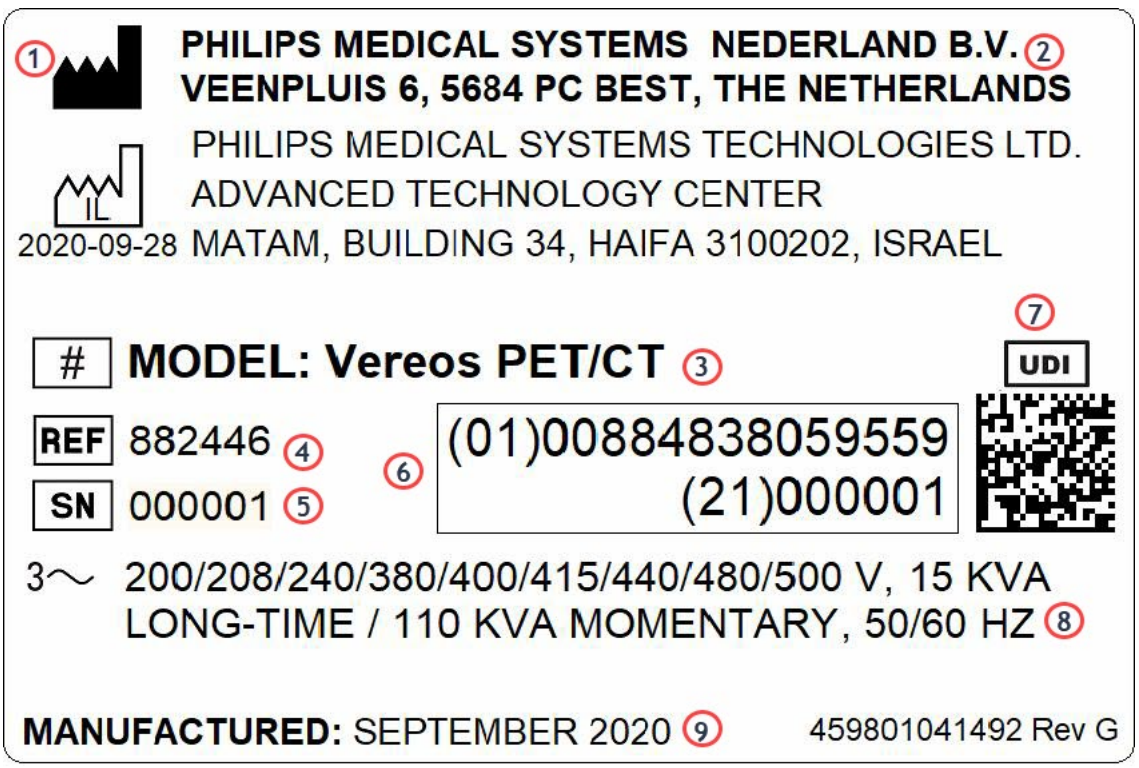


Date of Manufacturing

Location: Serial Label

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	Factory of Manufacture Location: Serial Label
	Dispose of in accordance with your country's requirements. This label indicates that there is material in the system that you must separately collect and recycle in accordance with the requirements of the European Waste Electrical and Electronic Equipment (WEEE) Directive. Please contact your Philips distributor or your municipal waste collection facility for information on proper disposal. Location: On the patient table and back gantry cover.



Number	Description
1	Manufacturing site of the finished device.
2	Site of legal manufacturer, the entity responsible for placing the device on the market.

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Number	Description
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.

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3 Safety

Important Safety Directions

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

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

It is vital that you strictly follow all safety directions described in this chapter and all **Warnings** and **Cautions** throughout all operator manuals provided to help ensure the safety of both patients and operators.

In particular, you must read, understand and know the chapter “Emergency Procedures” on page 26 described in the Safety chapter of this manual before attempting to use the equipment for any patient examination. You should also note the following information given in the *Introduction* of the Reference Manual:

- Intended purpose of the Philips CT system (Refer to the Instructions For Use)
- Training for operators of the Philips CT system (Refer to the Instructions For Use)



WARNING

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



WARNING

Do not use the system for any application until you are sure that the 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 chapter “Quality Assurance” on page 47 and chapter “ Information for the CT User” on page 91 of this document.

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WARNING

Do not use the 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* of the Reference Manual.

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 system for any purpose other than those for which it is intended. Operation of the system for unintended purposes, or with incompatible equipment, could lead to fatal or other serious injury. It could also lead to clinical misdiagnosis.

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Safety Precautions During a Scanning Procedure

Observe the following safety recommendations while performing a scanning procedure on a patient:

General Safety Precautions

- Never leave a patient unobserved before, during, or after a procedure.
- When moving a patient using the Gantry Control Panel, advise the patient not to move as they may be temporarily out of your line of view.
- Close all doors to the scan room before a CT scan procedure is started. Unless given permission by the physician in charge, do not allow anyone to enter the scan room during a CT scanning procedure.

WARNING

To avoid injury, never leave the patient unobserved in the scan room. Be aware that the flashing displays can cause seizures in epileptic patients. Be prepared to summon assistance if there is an unexpected event.

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- Advise the patient not to move during scanning procedures.
- With the exception of head and neck scans, instruct the patient to keep their arms above their head. If this position is too uncomfortable, instruct the patient to position their arms at their side with hands straight and fingers relaxed.

NOTICE

Use a hook and loop immobilization strap to secure the patient's arms tightly at their sides. This position helps minimize scan truncation and/or artifacts in the areas of the body near the edge of the Field of View (FOV).

- For larger patients, if it is uncomfortable for them to keep their arms above their head, ask them to lay their hands on their chest. This position helps minimize scan truncation and/or artifacts in the areas of the body near the edge of the Field of View (FOV).
- Advise the patients not to touch any external apparatus, such as infusion and resuscitation equipment.
- Ensure that the patient or operator fingers, hair, clothing, or sheets do not get caught in the patient table during patient positioning.



WARNING

Do not secure intravenous tubing, solutions or poles to the patient table or to the gantry. The intravenous therapy equipment could become detached, dislodged, or entangled in the moving parts of the patient table and the gantry.

- Use caution when scanning a patient receiving intravenous therapy. The intravenous lines could become detached, dislodged, or entangled in the moving parts of the patient table and the gantry.



WARNING

The polycarbonate armrests provide temporary support to allow you to begin an intravenous line for contrast while the patient is on the table.

Make sure that the armrests are removed before beginning a scan. Failure to do so can result in damage to the armrests or may interrupt the scan and cause overexpose to an area on the patient

- After you have completed the line, remove the armrests to begin your scan.

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WARNING

Verify that all scans are complete and that all data is acquired without error before allowing the patient to leave. If the patient leaves before valid data is acquired, the patient may need to return for another study.

- Unapproved accessories can cause artifacts in images, injuries to the patient and operating personnel, and damage to the equipment. Only use accessories approved by Philips. Immediately replace defective accessories with new, approved accessories.
- Accessories can cause artifacts in images, injuries to the patient and operating personnel, and damage to the equipment. The site is responsible for selecting safe and effective accessories and using them appropriately.
- Verify that all patient-support accessories such as head holders, table mattress, or arm supports are not damaged. Verify that the supports are secured to the patient table.
- Always examine the system for damage or defects. Using a system with damaged or defective components compromises patient and operator safety. If any damage or defects are detected, repair or replace the component immediately.
- Use caution to avoid tripping on the power cables to the system

Patient Table Safety Precautions

WARNING

During scanning procedures, the patient table movements are automatic.

- **If you utilize an automatic scan sequence, then the motion of the patient table is automatic, and without pressing the enable button. Advise the patient that the table motions occur automatically.**
- **Before starting a procedure, verify there is enough clearance between the patient and the gantry. If necessary, perform manual table movements to verify clearance.**

- The table supports a maximum patient weight of 195 kg (430 lbs).
- The patient table is designed to support the patient in the prone or supine position. Do not scan a patient in the sitting position.
- Do not secure intravenous lines, solutions, or poles to the patient table or to the gantry.
- Do not Home the patient table with a patient on the table. Perform all table homing procedures with an empty table.
- Do not allow the patient or patient positioning accessories to extend beyond the end of the patient pallet.
- Auto scan means that automatic motions are expected without using the enable button. Ensure the patient table does not collide with the gantry during movement.

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Immobilizing the Patient

Advise the patient to remain motionless while on the patient pallet. Involuntary or unexpected movement by the patient during the scanning procedure can cause motion artifacts in the images or potentially result in a fall or injury to the patient.



WARNING

Make sure the patient is placed securely on the patient table and is not in danger of falling. If necessary, use immobilization straps to secure the patient. Be sure to avoid dangling of the hands.

If it is necessary to immobilize the patient with one or more immobilization straps:

1. Place the straps underneath the mattress pad and secure them on top of the patient with the hook-and-loop fastener ensuring:
   - the patient is positioned symmetrically and his or her arms are fixed.
   - the patient's arms do not hang down over the sides of the table and cannot be crushed between the table and the gantry.
2. Fold all sheets, blankets, and clothes around the patient so that they do not hang over the edge of the patient table.
   - Gather all loose materials and place under the restraining straps. Verify that the patient table is free of any loose objects that may become entangled with it.
   - While moving the patient table, maintain continuous observation of the patient to avoid any collisions with the gantry and to avoid accidental disconnection of the intravenous therapy or resuscitation equipment.
3. Keep intravenous lines and other equipment that are attached to the patient clear of the edges of the patient table.

   When not in use, fold the restraining straps over the patient table so they do not hang over the sides and become caught in the moving parts of the table.

Scanner Suite

Familiarize yourself with the scanner suite at your site:

- Become aware of the location of all Emergency stop buttons on the system. When you press an emergency stop button, all 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.
- The door-switch interlock helps avoid unnecessary radiation.

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WARNING

Do not use the 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 system without a proper awareness of how to use it safely could lead to fatal or other serious personal injury.

Main Power Supply

The main power supply, in most installations, is located on the wall of the scan room. Familiarize yourself with the location of this switch and how to use it. In an extreme emergency, use the circuit breaker at the main power supply to remove all power and turn the system off, then remove the patient from the system.

NOTICE

If your site is equipped with a UPS (uninterruptible power supply) system, the main power supply may not be located on the wall of the scan room. It is important that you know where the main power supply switch is located so that you can turn the system off in an emergency.

Emergency Procedures

The system is equipped with safety devices to stop all movements in the event of patient contact with the gantry or if it is necessary to quickly remove the patient from the system.

Emergency Stop

To bring scanner, patient table movements and X-ray production to an immediate halt, press one of the red Emergency Stop buttons. The system has five red Emergency Stop buttons:

- one on each Gantry Control Panel on the front of the gantry
- one on each side on the back of the gantry
- one on the Scan Control Box at the Operator's Console

Familiarize yourself with the location of these buttons.

NOTICE

The Emergency Stop buttons do not remove power from the system.

Reset from Emergency Stop

Use this procedure to reset the system after an emergency stop is activated.

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After you press an Emergency Stop button, the operator's console displays a Keyswitch Prompt window:

1. Locate the button that was pressed to activate the emergency 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

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.

When restarting the system after an Emergency Stop, several minutes may pass before the system is ready for use. Allow the system adequate time to restart after an Emergency Stop before initiating troubleshooting. For more information on the system status indicator, refer to *Status Area and Pausing a CT Scan* in the Reference Manual.

Emergency Patient Release

If a medical emergency arises, it may become necessary to interrupt a scan and remove a patient from the patient table. While the system power is on, the mechanical drive to the patient table is engaged and you cannot manually move the patient table. To manually move the patient table, you must press an Emergency Stop button and then use the following procedure to remove the patient.

If a medical emergency occurs and power is not lost, you can also quickly retract the patient table using the Patient Release button on the Gantry Control Panel.

To remove a patient after pressing an emergency stop button:

1. Evaluate the location of the patient table and the position of the patient to make sure you can safely remove the patient.
   - Make sure the patient’s head will not touch the top of the gantry opening. If necessary, lower the head by removing the head support or the pillow and turning the patient’s head to the side.
   - Make sure the patient’s arms and legs are on the table and can pass freely through the gantry openings.

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2. When you have determined that you can safely remove the patient, grasp the handle on the end of the patient pallet and pull the pallet out.
3. Help the patient off the table.
   – In the event of a power failure or an emergency stop, you cannot move the patient table down. Keep a stool or stepladder nearby to assist the patient down from the table.
   – If necessary, summon assistance to remove the patient from the table.
   – It may be necessary to home the patient table before resuming scanning. The system displays a prompt when it is necessary to home the table.

NOTICE

Do not home the patient table with a patient on the table. Perform all table homing procedures with an empty table.

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 main power supply and grounding connections must conform to the power requirements, site planning and installation documents for this product.



WARNING

To avoid risk of electric shock, do not connect accessory cables while touching patient.

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

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WARNING

Do not connect any ancillary device to the system that does not meet the requirements of IEC 60601. Using a device on the system that does not meet the requirements of IEC 60601 can lead to serious personal injury or death.

Only qualified service personnel are authorized to replace fuses.

Mechanical Safety

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

WARNING

Do not remove the covers from the system. Removing covers on the equipment could expose mechanical operating systems that could cause serious or fatal personal injury. Operate the system only with all covers in place.

Do not operate the system with any covers open or removed. Operating the system with open or removed covers could expose mechanical operating systems that could cause serious or fatal personal injury to you or the patient. Only qualified and authorized service personnel should remove covers from the system.

Carefully observe the patient during the scanning procedure to ensure that when the patient table moves, the table does not cause the patient to collide with the gantry or other equipment. If required, use restraints to prevent the patient from grabbing or holding any part of the system or nearby equipment.

WARNING

Before initiating a movement of the patient table or gantry, ensure that the area is free of obstructions such as tools, boxes, chairs, and step stools. Physical injury or damage to the system can occur.

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.

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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. When performing procedures on patients receiving intravenous therapy, use care to ensure the tubing for the intravenous solutions does not become disconnected and allow the intravenous solution to seep into the system components. 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.

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Electromagnetic Compatibility

The system complies with the requirements of applicable Electro-Magnetic Compatibility (EMC) standards.

Mobile Telephones and Similar Products

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

WARNING

Do 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 system. This could, in extreme cases, lead to fatal or other serious personal injury or to clinical misdiagnosis.

Electronic and Implanted Stimulators

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

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

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

Recommendations prior to scan:

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

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

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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

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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 Control Panels and the Scan Control Box, as well as site radiation warning lamps, must light up if CT scanning has been triggered.

- If the lamps do not function properly, shut down the system immediately and contact Customer Service.
- Press the **Emergency Stop** button if there is danger to you or the patient.

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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 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 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.

X-ray Protection Measures

Take the following X-ray 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 X-ray 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 X-ray radiation.

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

Always follow local radiation protection guidelines.

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Hazardous Substances

REACH

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

REACH Declaration related to substances in articles

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

Philips Product category	SVHCs which may be present	CAS Number
Cables and other PVC-based components of electric and electronic equipment	DEHP, bis(2-ethyl(hexyl)phthalate	117-81-7
		84-69-5
Foam-based packaging such as EPS	Hexabromocyclododecane (HBCDD)	5637-99-4
		3194-55-6

Lu-176

The detector in this system uses LTS (Lutetium Scintillator) as the scintillation material and, as in any system using a LTS detector, it includes a small amount of Lu-176, a naturally occurring radioactive material. Lu-176 has an abundance of 2.6% and the activity concentration of Lu-176 in the scintillator is approximately 30 Bq/g. The density of the scintillator is 7.3 g/cc and there is less than 10,000 cc of scintillator in the detector. This calculates out to be less than 100 µCi (microCurie) of Lu-176 in a complete scanner.

Your facility may require a license amendment to possess and use the Lu-176 in the system. Contact your local regulatory agency to determine your facility's license requirements.

Perchlorate

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

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WARNING

Perchlorate Material

This product contains a chemical known to the State of California to cause cancer.

Special handling may apply. For more information, see www.dtsc.ca.gov/hazardouswaste/perchlorate/index.cfm.

Mercury

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

Handling of CT Phantoms

The liquid-filled phantoms used on the CT scanner 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 CT scanners which requires personal protection.

WARNING

The phantom solution is a strong eye irritant and may be harmful to skin.

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

- **Handle an opened or damaged phantom with care.**
- **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.**

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 for CT/AMI are as follows:

- Radiation Effects.

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*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

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4 System and Data Security

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

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

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

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

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

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 Reference Manual for more information.

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(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 system 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 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.

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.

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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 system 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.

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Manage Clinical User Accounts

Use the Local Administrator account to create and manage clinical users. The Local Administrator does not have permissions to perform scans, reviews, analysis, and other standard 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 should be stored in a secure location.

Create User

When creating user accounts, it is recommended that you disable the default clinical user account and create a unique user account for each person using the system.

To create a user account:

1. Enter the Local Administrator user name and password on the login screen.
2. Select **Add User**.
3. Enter the clinical user name, password, and security question/answer.
4. Click **OK** and then **Exit**.

NOTICE

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

Manage Users

Once logged on as the Local Administrator, you can remove users, reset a user password, and disable the default user account.

NOTICE

The "User Sharing" and "View Logs" features are unavailable.

To:	Do the following:
Remove a user	Select a user from the Users list. Click **Remove User** and confirm the permanent deletion of the account.
Reset a user password	Select a user from the Users list. Click **Reset Password**. Give and confirm the new password and update the security question if necessary. It is recommended to regularly change user passwords.
Disable user (default) login	Check the box to disable the factory-set, default clinical user account. To reactivate the account, deselect the checkbox.

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NOTICE

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

Clinical User Password Rules

- Password cannot contain the user's user ID.
- New password should not be the same as old password.
- Password must contain at least 8 characters and must include:
  - uppercase letter
  - 1 lowercase letter
  - 1 number;
  - 1 special character: **!@#$%&*().**
- Password is case sensitive
- Passwords must be reset every 90 days.
- After 5 consecutive failed login attempts, the account is locked.

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.

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 display monitor automatically goes blank after a set period of time.

Emergency Access

A special emergency access user account may be created by the Local Administrator. The login credentials may then be placed in a “break glass” environment. See chapter “Create User” on page 42.

Automatic 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.

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System Hard Drive

Clinical images that reside in the system hard drive are not encrypted; therefore the importance of local access controls to only authorized users is critical.

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.

User Logging and Audit Trails

- The system does not support clinical user activity event logging nor user audit trails that track user access to clinical data.
- The system does support a number of system-level event logs to assist with system troubleshooting and repair, including successful and unsuccessful user log in.

Data Integrity Checks

- The system supports basic system level data and database integrity checks.

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- If you suspect improperly altered or destroyed clinical data, notify your local IT security office or notify Philips service.

System Application Control

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



CAUTION

Whenever media is inserted into the system, make 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, the whitelist prevents it from execution. The system will display an error detailing the disallowed file activity and log this information. If you notice unfamiliar system behavior or performance changes, especially after the system is restarted, contact a Philips Field Service Engineer to have the system checked.

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5 Quality Assurance

To ensure high quality images and to verify that the system is performing to specification, it is essential that the system is at proper operating temperature, calibrated, and tested prior to use on any patient.

The procedures for Tube Conditioning and Air Calibration prepare the scanner for use, and Quality Control testing verifies that the system is producing images that are capable of identifying the anatomic structures and physiologic functions required to assist a physician in making a clinical decision. Collectively, these procedures are referred to as the calibration and quality assurance procedures. These procedures are performed on both the PET and CT components of the system.

System operators are expected to perform tube conditioning, air calibration, and the daily and periodic quality assurance procedures. Your Philips representative performs additional calibration and advanced quality assurance procedures.

NOTICE

The instructions for quality control and calibration represent the manufacturer's required performance checks. If additional testing is required by your national or local authorities, contact your Philips representative for assistance.

Schedule for Quality Assurance and Calibration Testing

The following tables describe the required frequency of Quality assurance and calibration testing required on the system by modality. Your facility or governing authority may require more frequent testing.

CT Scanning System

Procedure	Frequency
Short Tube Conditioning	Daily, or after 8 to 10 hours of scanner inactivity.
Air Calibration	Weekly
Head IQ Check	Weekly
Body IQ Check	Monthly
Constancy Check	Monthly

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PET Scanning System

Procedure	Frequency
Daily PET QC	• Daily • After power to the system is recycled
Monthly Image Calibration and Uniformity QC	• Monthly
SUV Calibration	• When the SUV validation fails • When the system is recalibrated • When you change your dose calibrator

CT Scanner Quality Assurance

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

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

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.

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Daily Short Tube Conditioning

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

WARNING

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

1. Check the scan room to ensure no people are present.
2. Move the table up to a position in the scannable range.

   For example, at 185 mm.

3. Click the **Tool** icon.
4. Click **Quality Assurance**.
5. 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).
6. Click **Next** and follow the screen prompts.
7. Click **Start** when ready.
8. After procedure is complete, click **Exit** to close the program.

Weekly Air Calibration

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

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

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

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NOTICE

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

WARNING

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

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

WARNING

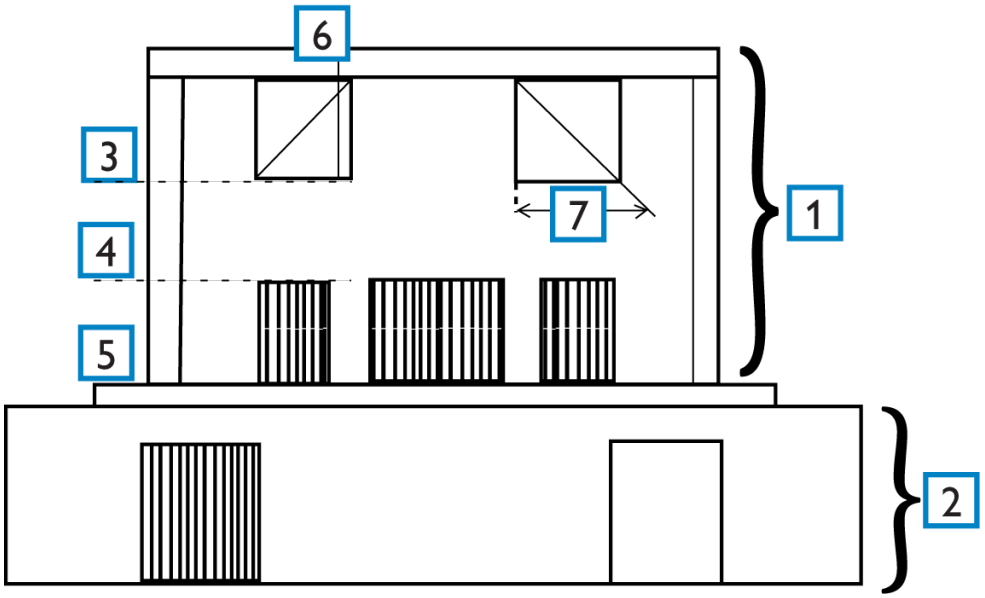
If ring artifacts are observed in the acquired images, perform Air Calibration. If ring artifacts persist, contact your Philips Service Representative.

System Performance Phantom

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

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

Head Section

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

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

Body Section

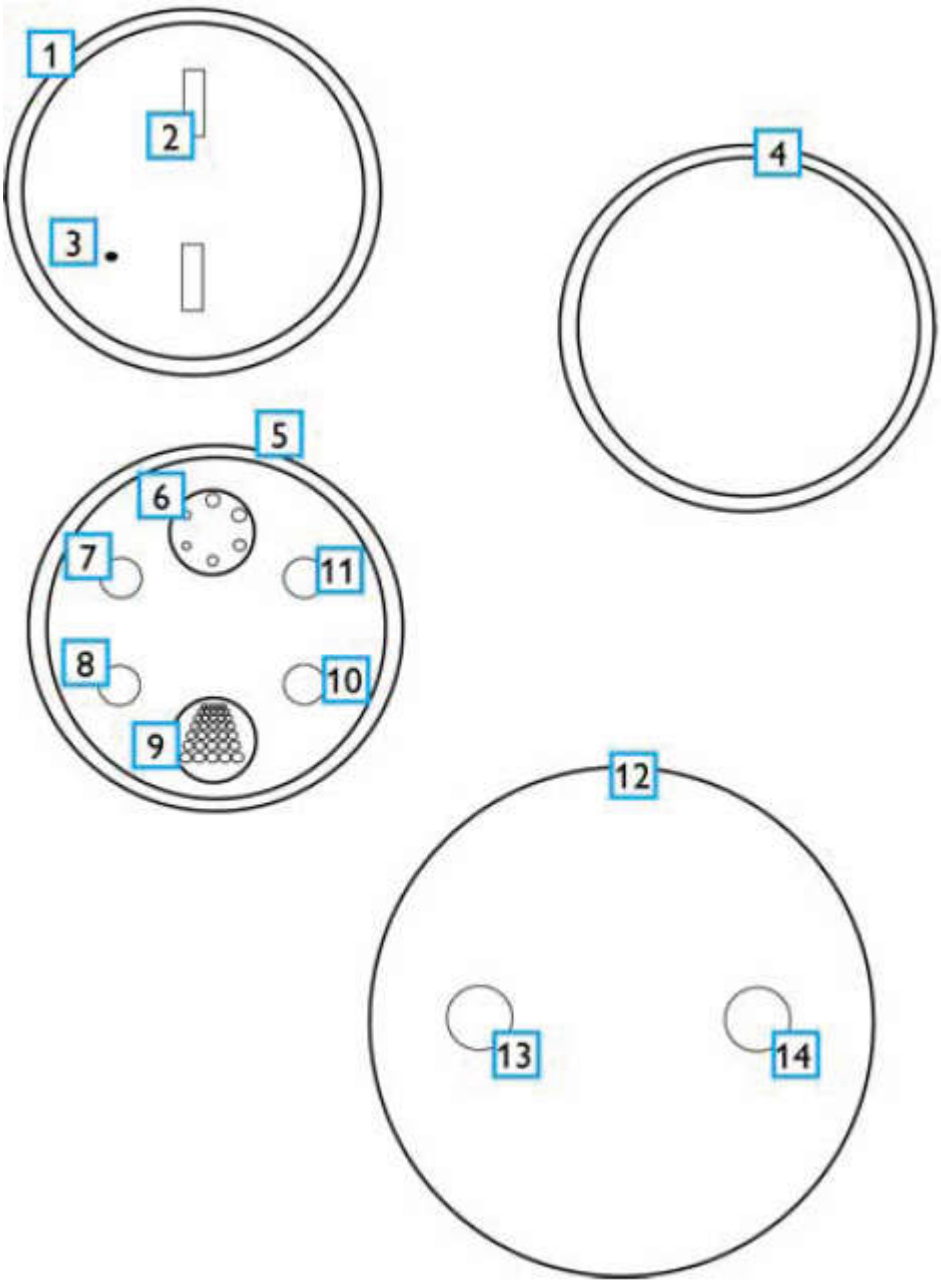
The body phantom is a nylon cylinder 300 mm outer diameter. It includes these features:

- Teflon pin
- Water (phantom liquid) pin

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Phantom Composition



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

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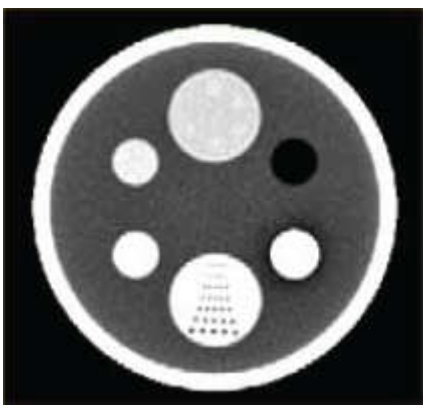
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Item	Description
6*	Nylon (Aculon) body with six smaller Lexan pins of 3 mm, 4 mm, 5 mm, 6mm, 7 mm and 8 mm respectively
7	Lexan pin
8	Acrylic pin
9	Acrylic with seven rows of holes of different diameters. Each row has five equidistant holes of the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

Representative Quality Assurance Images

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

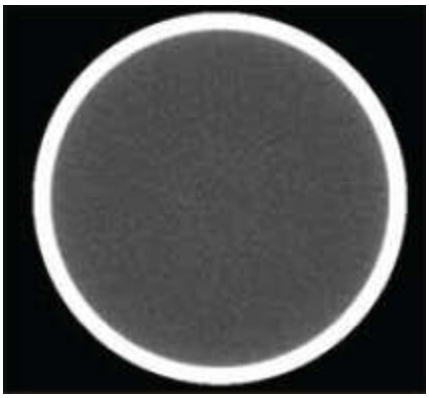
Multi-pin layer, QA Axial Head 2D



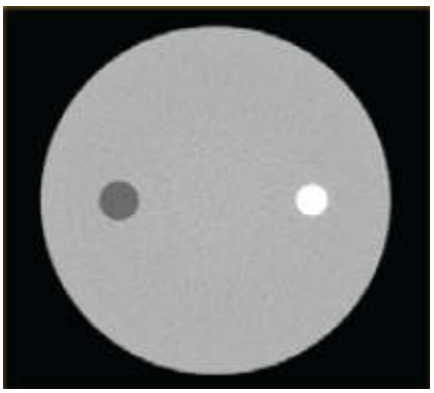
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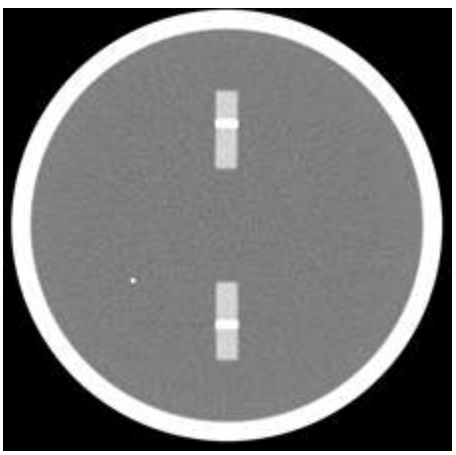
Water (phantom liquid) layer, QA Axial Head 2D



Body layer, QA Axial Body 2D



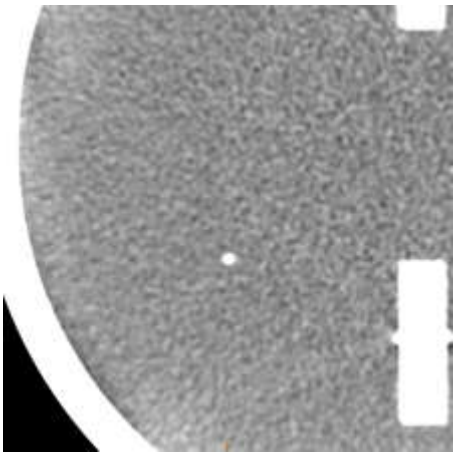
Physics layer (slice width image, QA Axial Head 2D)



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Impulse response (modified-100 FOV, QA Axial Head 2D)



Weekly Head IQ Check

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

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

WARNING

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

1. Attach phantom holder to the end of the patient table.
2. Check the scan room to ensure no people are present.
3. Place the system Head and Body phantom on the holder.
4. Click the **Tool** icon to open the System Utilities.
5. From the System Utilities 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.

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8. Click **Next**. Follow the on-screen instructions for all the tests, including phantom placement. After completing the steps, click **Start** to automatically move the table and begin the check.

NOTICE

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

In case the phantom is not found during the IQ test, exit the test and perform chapter “Manual Centering for System Phantom” on page 77. Afterwards, return to the test and skip the Automatic Centering step.

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

NOTICE

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

If any Test Failed



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

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

NOTICE

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

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

Monthly Constancy Test



WARNING

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

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The following test should be performed once a month:

1. Attach phantom holder to the end of the patient table.
2. Check the scan room to ensure no people are present.
3. Place the system Head and Body phantom in the holder.
4. Click the **Tools** icon and then select **Quality Assurance**.



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

NOTICE

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

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

NOTICE

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

In case the phantom is not found during the IQ test, exit the test and perform chapter “Manual Centering for System Phantom” on page 77. Afterwards, return to the test and skip the Automatic Centering step.

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

   Click **Start**. If a temperature stabilization message displays, click **Close** to proceed.
10. When the test is complete, the **Quality Assurance** dialog box displays.

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NOTICE

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

If any Test Failed



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

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

NOTICE

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

When prompted: **Do you want to continue the last attempt and perform only the failed modes?** Click **No**. Repeat the test.

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.

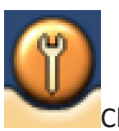
Monthly Body IQ Check

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 end of the patient table.
2. Check the scan room to ensure no people are present.
3. Place the system Head and Body phantom in the holder.
4. Click the **Tools** icon to open the system utilities.

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

NOTICE

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

In case the phantom is not found during the IQ test, exit the test and perform chapter “Manual Centering for System Phantom” on page 77. Afterwards, return to the test and skip the Automatic Centering step.

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

NOTICE

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

If any Test Failed



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

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

NOTICE

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

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

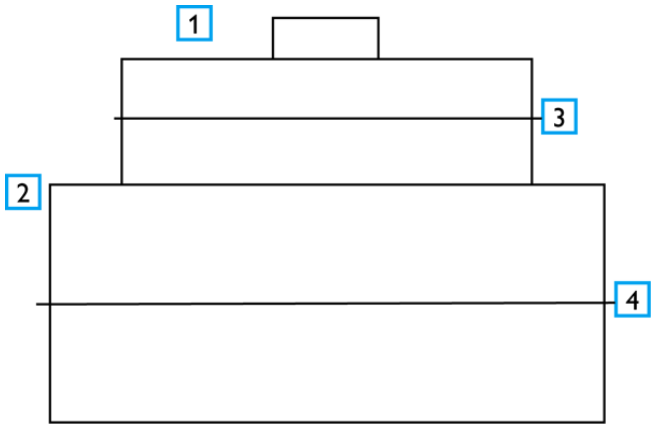
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Infant Phantom Testing

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

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



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

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

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

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

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. Attach phantom holder to the end of the table.
2. Move the patient table away from the gantry (OUT).
3. Remove the Head phantom, if present.
4. Check the mounting bracket to ensure it is tightly attached.
5. Insert the infant phantom by sliding its hooks onto the bracket.
6. Turn on the laser markers.
7. Move the patient table to position the phantom in isocenter.
8. Move the patient table towards the gantry (IN).
9. Position the table so that the laser markers line up with the centerline on the phantom holder. Zero the table.
10. Click **Patient**. Enter the demographic information. Select **Infant** from the Age Group.
11. Click **Reference Exam Cards**.

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- Click the **Head** exam card group. Select the **Brain 0-18m** exam card.
- Click the **Abdomen** exam card group. Select the **Abd/Pel 0-10 kg** exam card.
- Click **OK**.

12. Set the Surview to scan the entire Infant Phantom.
13. Using the Surview, plan the Infant Brain Helical scan to (at minimum) cover the Head part of the Infant phantom (see the parameters in the table). Perform the scan.
14. Using the same Surview, plan the Infant Body Helical scan to (at minimum) cover the Body part of the Infant phantom (see the parameters in the table). Perform the scan.
15. The phantom liquid (water) CT values should yield these results:
    - For the Head Section, using an ROI of 100 ± 20 mm^2, the CT number should measure 0 ± 4 CT numbers.
    - For the Body Section, using an ROI of 195 ± 30 mm^2, the CT number should measure 0 ± 6 CT numbers.

NOTICE

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

You can also use the phantom immediately before imaging infant heads to accurately correct the CT number of infant brains for quantitative results. For example, if the phantom image produces a CT number of -2.0 before the brain exam and then the infant brain image measures +26.0, then the infant brain result can be corrected to give +28.0 CT numbers. This procedure permits a more quantitative infant head examination for those who can benefit from greater CT number accuracy.

Infant Scan Protocols		
	Head	**Body**
Resolution	Standard	Standard
Collimation	64 x 0.625	64 x 0.625
Scan Angle	360°	360°
Rotation Time	0.4	0.4
Reconstruction Filter	UB	C
FOV (mm)	200	180
Storage	Local	Local
Thickness (mm)	2.5	3
Increment (mm)	2.5	1.5
kVp	100	100

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Infant Scan Protocols	Head	Body
mAs	300	125
Number of Scans	1	1

PET Scanner Quality Assurance

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

Daily PET QC

The PET Daily QC program is a semi-automated program that performs calibration and quality control testing to optimize the performance and image quality of the PET imaging system. The PET Daily QC process requires approximately 20 minutes to complete and includes:

Test Name	Description
System Initialization	The system initialization program restarts the hardware and firmware on the system and performs a series of self diagnostics. The program stops if the system initialization fails. System initialization requires less than two minutes to complete.
Check Sensors	The hardware sensors test verifies that voltages, currents, and temperatures are correct for PET gantry electronics.
Source Centering	The source centering test checks activity and source position. If the offset in any direction is more than: • 1 mm in the axial (Z) plane, or • 2 mm in the transverse (X,Y) plane the system shows a warning and gives guidance for relocating the source.

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Test Name	Description
VBias calibration	The VBias test varies the offset voltages to the photo-diodes in the digital detectors to determine the voltage needed to optimize event detection. No source is required. When performing Daily QC, the system first determines if a valid VBias calibration file is available. If one is available, the system does not perform another calibration. If a valid VBias calibration file is not available, the system then performs the calibration.
Acquiring Data	The system performs a five-minute acquisition of the sodium or F-18 source that is used in subsequent steps.
Timing Test	The timing test compares the system timing against the calibration settings. If this test fails, call your Philips service representative to perform a calibration.
Energy Test	The energy test and analysis calculates the energy centroids and the resolution of the collected data. The system displays an error message if the energy centroids are not approximately 100 or if the resolution is greater than the threshold. If this test fails, call your Philips service representative to perform a calibration.
Detector Uniformity Test	The system checks to ensure that all crystals are detecting approximately the same number of events. This test indicates an error if excessive quantities of crystals are not reporting the expected number of events.

NOTICE

To ensure optimal system performance, Philips recommends that you replace the ^{22}Na source every two years. Not replacing the source within this time could negatively affect QC time and image quality.

Daily PET QC Results

The system displays a message when each test completes:

- **PASSED** or **SUCCESS** — The system is fully functional.
- **NOTICE** — The system is fully functional, however a minor change is detected and you should consider contacting Philips for preventative maintenance to eliminate or reduce potential down time in the future.

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- **WARNING** — The system is meeting requirements, however action is required soon. You may continue using the scanner but call your Philips representative.
- **FAILURE** — The measured values are outside the allowed range. Do not use the scanner and call your Philips representative immediately.

PET and CT Status Indicators

There are status indicators for the PET and CT systems. These indicators only appear within the status display while under the Tool icon when there is a system issue or warning. A message appears with the status indicator detailing the system problem. You must click on the status indicator to view the message. The indicators can display the following two states:

- Yellow indicates system is busy
- Red indicates system is not ready for use

The PET and CT status indicators may remain yellow or red for some time while the system cools down to operating temperature and the computers start up and establish connections.

- The CT status indicator will remain yellow if more than 12 hours have elapsed since the last scan and a Short Tube Conditioning is recommended.
- The PET status indicator will remain red if more than 24 hours have elapsed since the last Daily PET QC was performed. Daily PET QC will be mandatory after a Full System Shutdown regardless of the amount of time that has passed.
- Allow adequate time for the system to reach operating temperature and for the startup and connections to complete before initiating Daily PET QC or troubleshooting procedures. If the system displays an error message, note the error message and contact your Philips service representative.

Performing Daily PET QC

NOTICE

Performing a retrospective reconstruction while daily QC is running may delay the completion of daily QC. Therefore it is recommended to defer any retrospective reconstructions while daily QC is running.

Ensure any current exams are completed before performing the PET Daily QC procedure. To perform the PET Daily QC procedure with ^{22}NA solid rod source or as an alternative an F-18 source contained in a 1 mL syringe with an attached extension.

1. Obtain the source to perform PET Daily QC.

   Acceptable sources include:

   – 100 µCi ^{22}Na rod

   – 400 µCi ^{22}Na rod

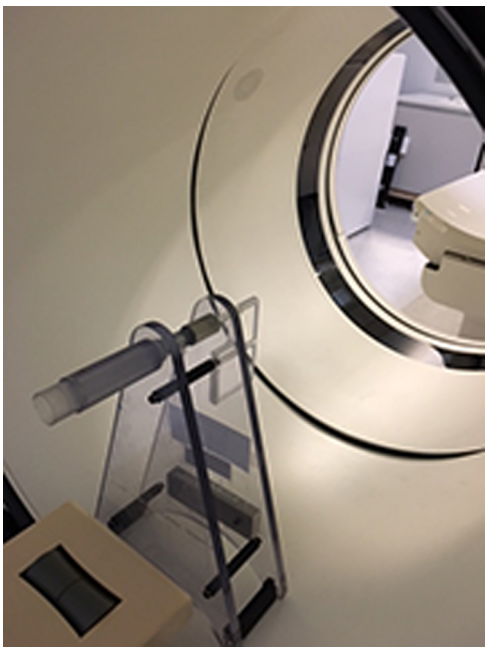
   – 175 ±85 µL of 400 ± 100 µCi F-18 solution in a 1 mL syringe

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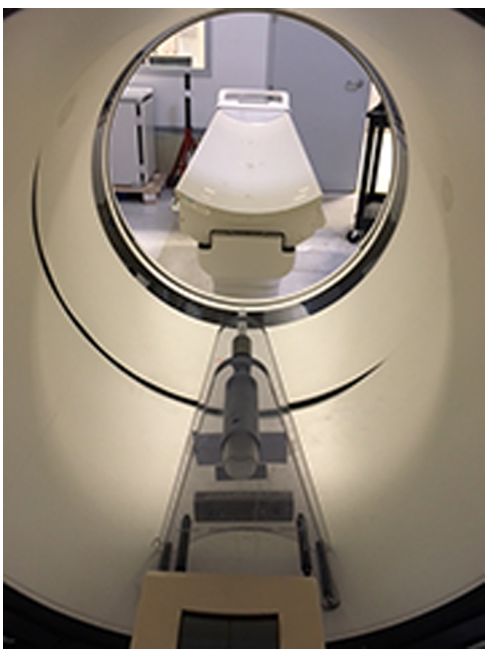
2. Obtain the source holder and insert the source inside the hole at the top of the holder.

   Be sure to insert the source all the way into the cylinder hole until it stops.



3. Place the source holder so as to position the source in the field of view of the PET detectors within the gantry.

   You can align the source from the front or the rear (shown in picture) of the gantry.



4. From the Console,  click the **Tool** icon, then select **PET Quality Assurance**.

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The PET Daily QC window opens.

NOTICE

If you need to perform PET QC more than once on the same day, the system may prompt you to run the Quick PET QC. Quick PET QC is not enabled unless the system has completed a successful Daily PET QC procedure that day. Refer to chapter “Performing Quick PET QC” on page 66.

5. Click **Start** to continue.

   The system performs a check to verify that the point source is centered in the field of view. If the point source is not centered, the system prompts you to center the source, providing the distance in millimeters to do so. Click **OK** after you reposition the source.

   When the system has verified that the source is centered, the system performs the PET Daily QC tests.

   At the end of each test, the system displays a **PASSED**, **SUCCESS**, **NOTICE**, **WARNING**, or **FAILURE** message.

NOTICE

Do not cancel or stop the QC tests before they are completed.

6. Close the dialog box when the PET Daily QC procedures are complete.
7. Remove the source and holder.

Viewing the Daily Quality Control Results Log

You can view the daily quality control files if you receive a failure or warning for a test, or if you want to view a specific result, such as the timing number or energy number.

1. From the Patient Directory window, select the PET QC file.
2. Select the **Reports** tab.
3. Select the most recent report from the list of available reports.
4. Right-click on the report and select **View Report** from the menu.

Performing Quick PET QC

If you need to perform PET QC more than once on the same day, the system may prompt you to run the Quick PET QC. Quick PET QC, which consists of energy and timing tests, is a subset of the Daily PET QC procedure. Quick PET QC is not enabled unless the system has completed a successful Daily PET QC procedure that day.

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When you run PET QC more than once on the same day, the system displays the following message:

Quick PET QC is available since PET QC has already been run today. Press any key to run Quick PET QC.
Time remaining (seconds): 10

Press any key before the counter reaches zero to run Quick PET QC. If you choose to run Quick PET QC, the message **Running Quick PET QC...** displays.

If you do not press a key before the counter reaches zero, the system performs the full daily PET QC procedure.

If you perform Quick PET QC but the tests fail, you must perform the full Daily PET QC procedure.

Preparing the F-18 Source for Daily QC

You can use F-18 in a disposable syringe as the point source for daily PET QC. Daily PET QC requires less than 260 µL of 400 ± 100 µCi F-18. You should prepare the F-18 according to your facility's procedures.

To prepare the F-18 for use with the Daily PET QC procedure:

1. Using the 1 mL Luer Lock syringe, aspirate 175 ± 85 µL of the 400 ± 100 µCi F-18 solution.

   Remove any air bubbles in the syringe.
2. Remove the needle from the syringe.
3. Replace the needle with the Blunt-Tip Dispensing Needle provided by Philips.
4. Proceed to perform the Daily PET QC procedure.

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Monthly SUV and Uniformity QC

Monthly SUV and Uniformity QC includes the following:	
Image Uniformity Check	The Image Uniformity Check procedure is used to verify the uniformity of the PET image. Perform the Image Uniformity Check procedure on the PET scanner at least once a month, or more frequently, if required by the Quality Control schedule for your facility.
SUV Validation	The Standardized Uptake Value (SUV) is the ratio of the concentration of activity in a structure to the average concentration in an entire body. To obtain and use the SUVs, you must periodically calibrate and validate the calibration on the scanner to convert counts per pixel into activity concentrations. The SUV is calculated for a specific part of the image based on patient weight and height and the amount of activity injected. SUV Validation confirms that the SUV calibration was properly completed and that the scanner is ready for clinical SUV computation. • For monthly QC, performing SUV Validation for the 576 FOV is sufficient for both 576 FOV and 256 FOV. • If SUV is re-calibrated, both 576 FOV and 256 FOV SUV validation should be performed.

Procedure to Acquire Data for the Monthly SUV and Uniformity QC (576 FOV SUV validation)

NOTICE

Use the same 30 cm uniform cylinder phantom for both the SUV Calibration procedure and Monthly SUV and Uniformity QC procedure.

1. Prepare a syringe containing an aqueous solution of ^{18}F in the uniform phantom.
   – Add a sufficient quantity of ^{18}F to ensure there will be 1-3 mCi activity at the start of the acquisition.

     NOTE: SUV validation is count based acquisition, so if you plan to continue with 256 FOV SUV validation using the same phantom, 2mCi+/-10% activity at acquisition start is recommended. If the activity at the acquisition start is too low, the acquisition time will be very long.
   – Record the activity and measurement time. Flush the syringe into the phantom multiple times to ensure that no residual activity remains in the syringe.

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- Shake the phantom to thoroughly mix the solution and ensure that the isotope is completely mixed in the phantom.
- Leave a small air bubble after filling the phantom with water and adding the isotope. The bubble is helpful for leveling the phantom prior to beginning the acquisition.

NOTICE

Do not mount the phantom holder unless the patient table is completely retracted. If you mount the phantom holder and do not completely retract both the patient pallet and subpallet, you may affect the image alignment of scans.

2. Mount the phantom holder on the patient table.
3. Mount the phantom on the phantom holder.

   Position the phantom so that the air bubble is at the middle of the phantom
4. On the console, select **Patient**.
5. Enter a Patient Name and ID to uniquely identify the Monthly QC study.
6. Select **Other** as the patient gender.
7. Enter the phantom weight from the label on the phantom as the patient weight.

   If using an older phantom without the label, enter **9.366 kg** (**20.65 lbs**) as patient weight.
8. Enter **30 cm** (**1 ft 0 in**) as the patient height.
9. Select Feet First Supine as the patient position.
10. Select the Reference Exam Cards tab and then click the IQ exam card group.
11. Select **PET/CT SUV Validation**.
12. Click **OK**.
13. Move the table to the CT position.
14. Click **Go**.
15. After the scan initializes, press Manual on the Scan Control Panel.

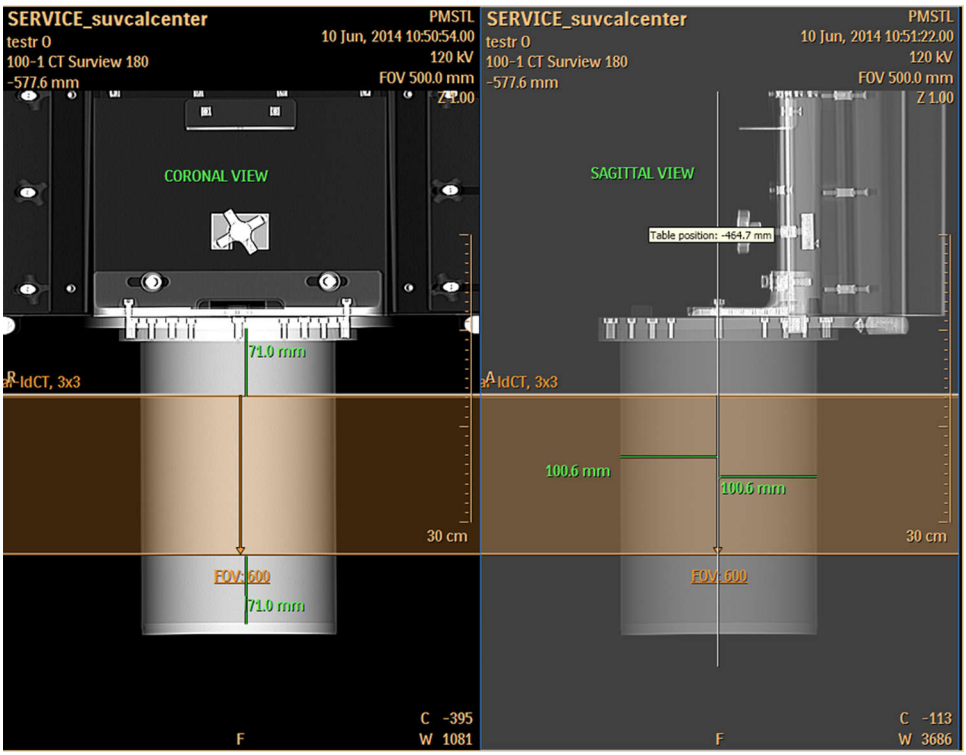
    A Surview image is acquired.
16. Position the ldCT and PET scan planning lines exactly in the center of the phantom.

    A ruler tool is available to precisely set the scan planning window in the center of the phantom.
    - Adjust the table height as necessary to center the phantom in the sagittal view to set the scan planning lines 100 ± 4 mm from the side edges of the phantom.
    - Adjust the scan planning lines as necessary to center of the phantom in the coronal view to set the scan planning lines 71 ± 4 mm from the top and bottom edges of the phantom.

      NOTE: The PET scan planning lines should be within the CT scan planning lines.

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17. Click **Go**.
18. Press Manual on the Scan Control Panel.
19. To display the PET Exam Card Parameters Field:
    - In the Scan Planning panel, select the PET series.
    - In the Scan Parameters panel, Enter the activity measured and the time it was measured. Enter the time in hh:mm:ss format. This step assumes that the clock on the Console is synchronized with the clock used to record the time the dose used to fill the phantom was measured.

NOTICE

1 mCi = 37 MBq.

Be as accurate as possible when entering Admin time. Refer to the clock on the Console when drawing and administering the dose.

20. When all planning is complete, click **Go**.
21. When prompted, press the Enable button.
22. After the CT Scan is complete, click **Next Series** on the Exam Flow window.

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NOTICE

A prompt for the Next Series appears only if it is set within Preferences.

23. Press the Enable button to position the table and start the PET acquisition.
    - This is a count based acquisition that requires about 30 minutes with 1 - 3 mCi in the phantom to complete. 100 million counts are acquired in total in this test.
    - Concurrent reconstruction runs automatically.
24. When the scan is complete, click **End Exam**.
25. Remove the phantom holder from the patient table.



WARNING

When you remove the phantom holder, make sure the patient table is completely retracted. If you do not completely retract the patient table and then remove the phantom holder, you may affect the image alignment of scans performed.

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NOTICE

If concurrent reconstruction fails, use the PET Recon Application to manually perform the reconstruction post-acquisition using the SUV-Val protocol. Select the SUV-Val.xml protocol under the Service protocol type.

Do not perform any acquisitions or other reconstructions until the 576 FOV SUV Validation reconstruction completes.

26. When the reconstruction is complete:
    - Visually inspect the phantom image for non-uniformities

      If you notice any significant deviation in uniformity, call your Philips service representative.
    - Validate the results using the Uniformity Analyzer.
    - See chapter “Using the Uniformity Analyzer to Validate the Acquired Data” on page 71.

Using the Uniformity Analyzer to Validate the Acquired Data

After the reconstruction is complete, you can validate the data acquired using the Uniformity Analyzer.

1. Select a CTAC image from the patient directory. For the 576 SUV validation or monthly QC, select the [SUVVAL_CTAC] validation image. For the 256 FOV SUV validation, select the [BR_CTAC] validation image.

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2. Select the Uniformity Analyzer tool from the **Analysis** tab.
3. To view the %Axial Variation and volume-averaged SUV, select **Single ROI** in the **ROI Set** field.
4. Select **SUV** in the **Unit** field.
5. Select the check box for **Auto Center per Slice**.
6. Use the default values for the remaining options.
7. Check the value of %Axial Variation and Volume-averaged SUV (mean SUV). Verify that the **%Axial variation** is less than 5%. For 576 mm FOV SUV validation, the volume-averaged SUV should be 1.00 +/-5%. For 256 FOV SUV validation, the volume-averaged SUV should be 1.00+/-10%.

   If the %Axial variation is greater than 5%, repeat the data acquisition.
8. Click **Capture Screen** and then click **Save Result** and then **Finish**.
9. To view the %IU, select the **Seven ROIs** in the **ROI Set** field.
10. Select **SUV** in the **Unit** field.
11. Select the check box for **Auto Center per Slice**.
12. Use the default values for the remaining options.
13. Verify that the **%IU** is less than 2.5%.

    If it is greater than 2.5%, repeat the data acquisition.
14. Click **Capture Screen** and then click **Save Result** and then **Finish**.

    See expected results in the table below.

Measurement Parameter	Expected Results
% Axial Variation	< 5%
% Integral Uniformity (IU)	< 2.5%
Uniformity Analyzer mean SUV for 576 mm FOV	0.95 ≤ mean ≤ 1.05
Uniformity Analyzer mean SUV for 256 mm FOV	0.90 ≤ mean ≤ 1.10

If any of the results fall outside of the expected range listed in the table above, contact your Philips service representative.

A result with the %IU greater than 2.5% could indicate a Normalization problem.

256 Field of View (FOV) SUV Validation

NOTICE

Perform the 256 FOV SUV Validation procedure after a SUV Calibration procedure is performed. You do not need to perform the 256 FOV SUV Validation as part of the Monthly SUV and Uniformity QC testing.

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The procedure is the same as for 576 SUV validation except you must run the PET/CT SUV256 Validation Exam Card for 256 FOV SUV validation.

Keys to Success

- You are responsible for calibration and validation scans. You must use the same reconstruction protocol parameters (such as Decay, Deadtime, and Attenuation Correction) for calibration, validation, and patient scanning.
- If concurrent reconstruction for the SUV calibration acquisition fails, manually perform a reconstruction post acquisition using the **SUV-Cal.xml** protocol.
- If concurrent reconstruction for the SUV validation (576 FOV) acquisition fails, manually perform the reconstruction post acquisition using the **SUV-Val.xml** protocol. For SUV256 validation, use the **Brain-2mm.xml** protocol.

SUV Calibration

You must perform the SUV calibration:

- When the SUV validation fails
- When the system is recalibrated
- When you change your dose calibrator

SUV calibration includes:

- Preparing and positioning the phantom for an SUV calibration scan
- Acquiring a 24-frame dynamic scan that takes approximately 9.5 hours
- Calculating and installing the calibration
- Validating the SUV calibration using the Monthly Image Calibration and Uniformity QC procedure

Performing the SUV Calibration

The SUV calibration acquisition takes approximately 9.5 hours to complete and acquires 24 dynamic frames.

1. Prepare a syringe containing an aqueous solution of ^{18}F.
2. Add a sufficient quantity of ^{18}F to the phantom to ensure there is 30 ± 10% mCi activity in the phantom at the start of the PET acquisition.
   - Flush the syringe into the phantom multiple times to ensure that no residual activity remains in the syringe.
   - Shake the phantom to thoroughly mix the solution and ensure that the isotope is completely mixed in the phantom.
   - Leave a small air bubble after filling the phantom with water and adding the isotope. The bubble is helpful for leveling the phantom prior to beginning the acquisition.
3. Record the activity and measurement time.

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NOTICE

Do not mount the phantom holder unless the patient table is completely retracted. If you mount the phantom holder and do not completely retract both the patient pallet and subpallet, you may affect the image alignment of scans.

4. Mount the phantom holder on the patient table.
5. Mount the phantom on the phantom holder.

   Position the phantom so that the air bubble is at the middle of the phantom
6. On the console, select **Patient**.
7. On the Patient Data screen, enter “SUV-yyyymmdd" in the **Last Name** field, "Cal” in the **First Name** field, and “SUV-hhmm” as the **Patient ID** to uniquely identify the SUV calibration study.

   For example, an SUV calibration performed on March 10, 2009 at 3:42pm is named “SUV-20090310, Cal” with an ID of “SUV-1542.”
8. Select **Other** as the patient gender.
9. Enter the phantom weight from the label on the phantom as the patient weight.

   If using an older phantom without the label, enter **9.366 kg** (**20.65 lbs**) as patient weight.
10. Enter **30 cm** (**1 ft 0 in**) as patient height.
11. Select Feet First Supine as the patient position.
12. Select the Reference Exam Cards tab and then click the IQ exam card group.
13. Select **PET/CT SUV Cal**.
14. Click **OK**.
15. Move the table to the CT position.
16. Click **Go**.
17. After the scan initializes, press Manual on the Scan Control Panel.

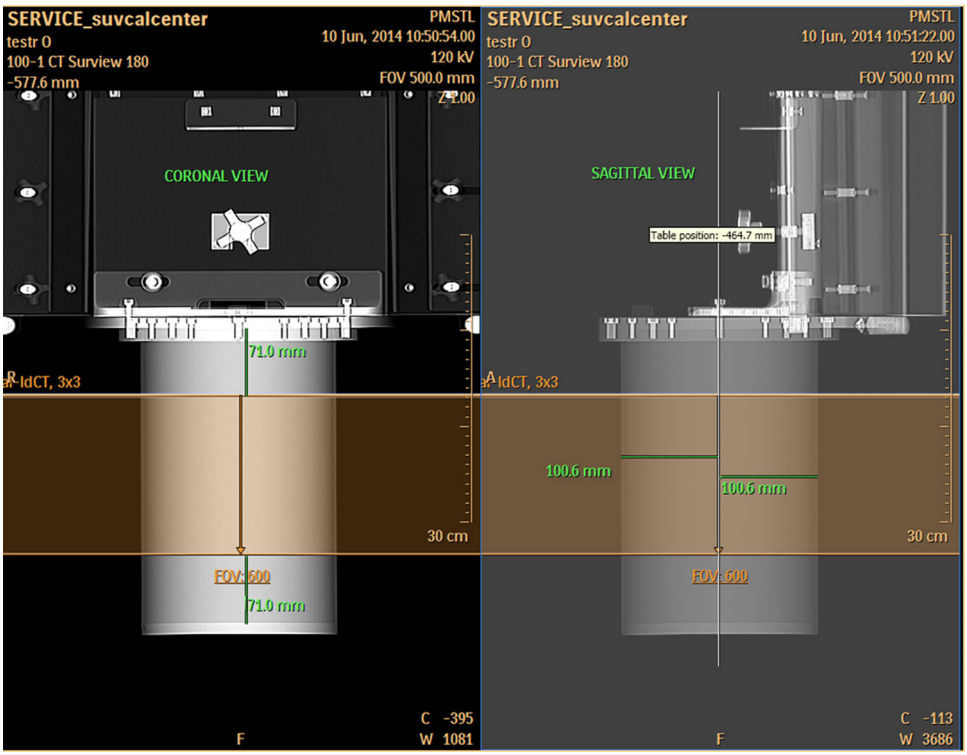
    A Dual Surview image is acquired. Make sure that the entire phantom is clearly visible in the Surview image.
18. Position the ldCT and PET scan planning lines exactly in the center of the phantom.

    A ruler tool is available to precisely set the scan planning window in the center of the phantom.
    - Adjust the table height as necessary to center the phantom in the sagittal view to set the scan planning lines 100 ± 4 mm from the side edges of the phantom.
    - Adjust the scan planning lines as necessary to center of the phantom in the coronal view to set the scan planning lines 71 ± 4 mm from the top and bottom edges of the phantom.

      NOTE: The PET scan planning lines should be within the CT scan planning lines.

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19. In the Plan window, position the CT plan lines so that they are centered on the phantom.
20. Click **Go**.
21. Press Manual on the Scan Control Panel.
22. To display the PET Exam Card Parameters Field:
    - In the Scan Planning panel, select the PET series.
    - In the Scan Parameters panel, Enter the activity measured and the time it was measured. Enter the time in hh:mm:ss format. This step assumes that the clock on the Console is synchronized with the clock used to record the time the dose used to fill the phantom was measured.

NOTICE

1 mCi = 37 MBq.

Be as accurate as possible when entering Admin time. Refer to the clock on the Console when drawing and administering the dose.

23. When all planning is complete, click **Go**.
24. When prompted, press the Enable button.
25. After the CT Scan is complete, click **Next Series** on the Exam Flow window.

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NOTICE

A prompt for the Next Series appears only if it is set within Preferences.

26. Press the Enable button to position the table and start the PET acquisition.
27. When the scan is complete, click **End Exam**.

After the SUV Calibration is completed, perform the procedure including the .

Archiving Raw Data

Before starting the archive process, ensure a minimum of 120 GB of free space is available in the archive device .

If automatic raw data archiving is not enabled, then you must manually copy the SUV calibration raw data from the NMRS to the console after the SUV calibration acquisition is completed.

1. On the operating console, open the NMRS device.
2. Select the SUV Calibration patient.
3. Open the Raw Data tab and select the raw data series.
4. On the tool panel, select **Copy To**.
5. Select the Local device or other archive device that supports PET raw data and click **OK**.
6. Use the queue manager to verify when the transfer is complete.

SUV Calibration or Validation Errors

If an SUV calibration fails to complete or an SUV validation produces values that are outside of the acceptance range, verify that the activity, measure time, and weight information entered for the acquisition is correct. You can check these values in the Recon application under the **Admin Parameters** tab.

If any of the entered information is incorrect, use the Recon application to correct the parameters.

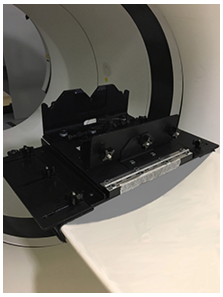
If the information is correct and the warning or error persists, contact your Philips representative for further assistance.

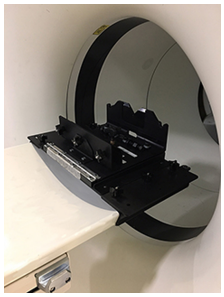
Mounting the Phantom Holder

The phantom holder is a device used to mount the 20-cm CT head and body phantom and the 30-cm uniform PET phantom to the patient pallet. The phantom holder works with both the flat and curved pallets.

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WARNING

Do not mount the phantom holder unless the patient table is completely retracted. If you mount the phantom holder and did not completely retract both the patient pallet and subpallet, you may affect the image alignment of scans performed.

1. Move the patient table to the fully retracted position.
2. Loosen the thumbscrews to open the adjustable clamp on the side of the phantom holder.
   - For the curved pallet, replace the U-shaped bracket with the angled bracket.
   - For the flat pallet, use the U-shaped bracket. The U shaped bracket must be on the left side if you are facing the gantry.
3. Slide the phantom holder over the end of the patient pallet.

   Ensure the holder is completely inserted onto the pallet.
4. Slide the adjustable clamp toward the pallet to secure the holder to the pallet and then tighten the thumbscrews.
   - If necessary, you can adjust phantom holder angle using the large thumbscrew in the center of the holder.
   - The phantom holder for the flat pallet has a nodule on the clamp that fits into the second indexing notch (H3) on the pallet.
5. Secure the phantom holder to the couch by tightening the holder adjustment screws (three screws on each side of the holder).

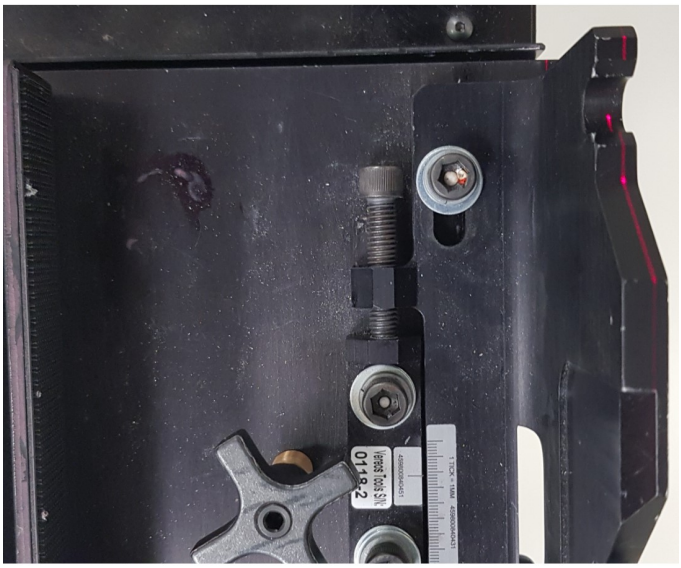
Manual Centering for System Phantom

In case phantom not found during the IQ test, perform the following steps:

1. Activate CT internal Laser.
2. Manual adjust the pallet until the laser is set on the edge of the holder.

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3. Perform Zero offset per marker from panel.
4. Perform Surview with phantom.
5. Correct phantom position in order to align with grid.

Extended Accessory Mode

When the patient table is placed in Extended Accessory Mode, the table extends approximately 33 cm less into the bore for scanning to allow sufficient scan length with the accessory and to allow the patient pallet to retract far enough for patient marking.

Use the Extended Accessory Mode:

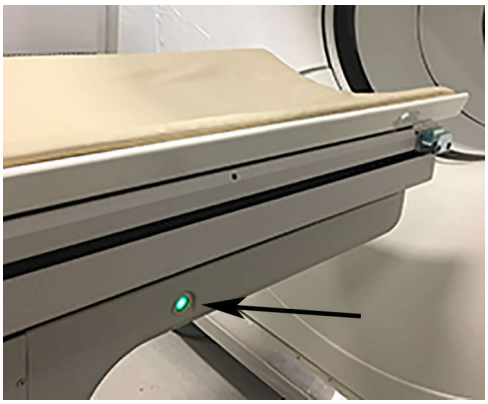
- when using the QC phantom holder
- when marking a patient with external lasers near the end of the patient pallet

To enter or exit Extended Accessory Mode:

1. Move the table into the Home position
2. Attach the phantom holder to the table.
   – The table base push button illuminates, indicating that you have entered Extended Accessory Mode.

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– If the table base push button does not illuminate when the phantom holder is attached to the table, manually press the table base push button once to turn it on.

It is recommended to call Service if the table base push button does not illuminate when the phantom holder is attached as this may indicate a problem with the phantom sensor on the table.

3. When QC testing is completed, remove the phantom holder from the table.
   – The table base push button turns off, indicating that you have exited Extended Accessory Mode.
   – If the table base push button does not turn off once the phantom holder has been removed from the table, manually press the table base push button once to turn it off.

NOTICE

If you press the table base push button when the table is not in the Home position or when the phantom holder is attached, the button flashes three times and the table does not change Modes.

Uniformity Analyzer

The Uniformity Analyzer analyzes data for verification of scan uniformity. You can use the Uniformity Analyzer to help your facility comply with test criteria for the Centers of Quantitative Imaging Excellence (CQIE) and satisfy accreditation requirements for the American College of Radiology.

NOTICE

The Uniformity Analyzer only supports analysis of PET data.

The Uniformity Analyzer does the following:

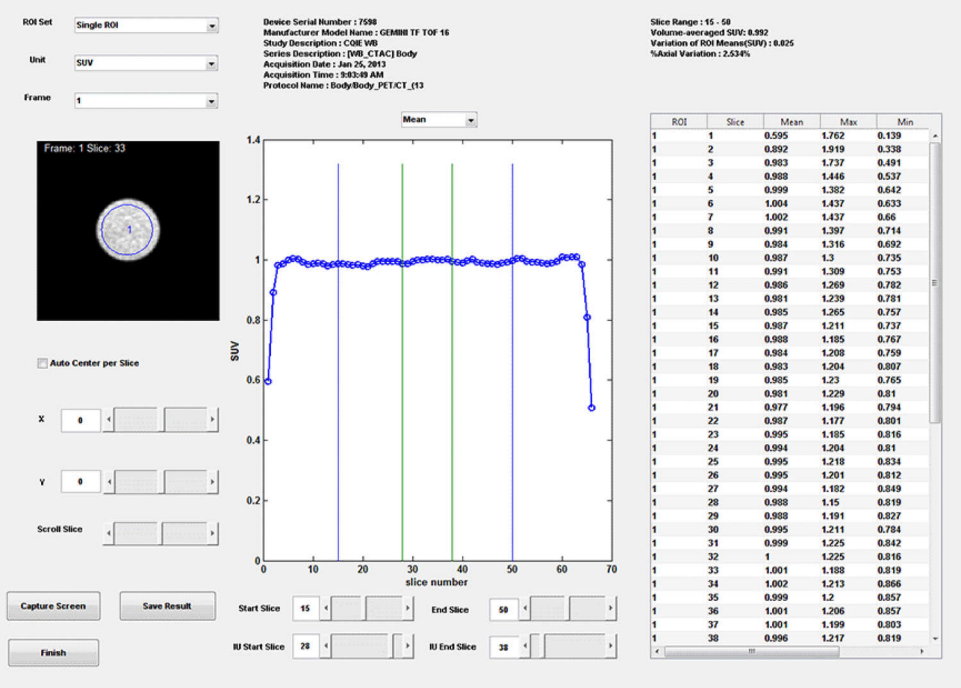
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- Applies a single region of interest (ROI) or a series of regions of interest to every slice in an image series containing one static PET frame or one or more dynamic PET frames
- Creates a graph displaying ROI results in relation to slice number for the selected frame
- Creates a table displaying all ROI statistics for the selected frame
- Calculates summary results, such as % Axial Variation and % IU
- Produces a report containing the ROI results, which is output as a .csv file

You can only analyze one series at a time, and you can only analyze an entire series.

Uniformity Analyzer Interface



ROI Set

ROI Set specifies the ROI sets for analysis.

- **Single ROI**: Measures actual uniformity. One region, 160 mm in diameter, that covers most of the phantom in a single area.
- **Seven ROIs**: Captures varying uniformity with localized specificity. Seven circular regions, each 60 mm in diameter, that create a contiguous set of smaller regions of interest.

Unit

Unit specifies which PET unit to use for analysis. The system fills this field automatically. You can choose alternative PET unit provided that the parameters required for conversion exist in your data set. For example, if you select a series that does not have Standard Uptake Values (SUV) scale factor, the system automatically selects the default unit that is available for that series.

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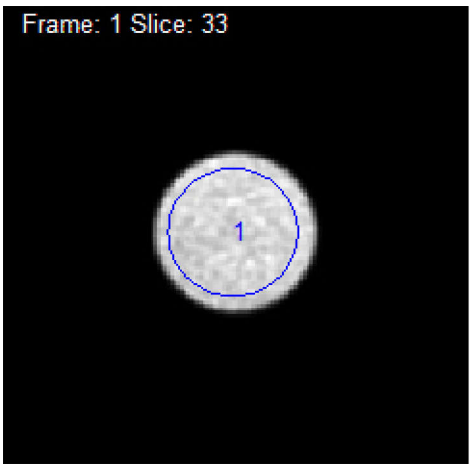
There are three options:

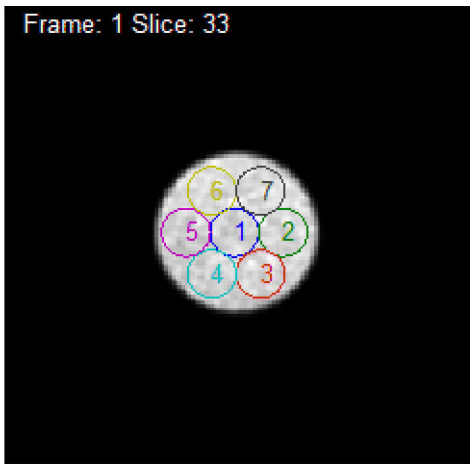
- **SUV**: Standard Uptake Values
- **BQML**: Becquerels/milliliter (Bq/mL)
- **Counts**: Unit that reflects event counts (not proportional to event counts)

Frame

Select the frames to be analyzed. The Uniformity Analyzer lists all frame indices that the selected series contains. When you change the frame, the system removes the previous frame from memory and loads into memory all slices associated with the frame and analyzes them automatically.

A transverse viewer displays a slice of the selected frame and ROI(s). The slice and frame numbers are also displayed. The default displayed slice is the middle slice of the first frame.





Auto Center per Slice

If selected, Auto Center per Slice centers the ROI(s) in the viewer automatically.

Manual ROI Position Controls

Use the following manual ROI position controls to adjust ROI location.

- **X**: Click the left and right arrow buttons, use the slider, or enter a value into the field to adjust the x-axis position of the ROI(s).
- **Y**: Click the left and right arrow buttons, use the slider, or enter a value into the field to adjust the y-axis position of the ROI(s).
- **Scroll Slice**: Click the left and right arrow buttons to scroll through the slices in the frame.

Capture Screen

Capture Screen saves an image of the screen in a temporary folder for further processing. This step is optional. The system does not save the screen captures permanently until you click **Finish**.

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Save Result

Save Result temporarily saves all statistics for all ROIs, all frames, and all slices for further processing. This step is optional. The system saves the results in the database with the series, in an automatically generated file (with the extension .csv). The system does not save the results permanently until you click **Finish**.

Finish

Finish saves all temporary files in the database and exits the program. Files are not permanently saved until you click **Finish**.

Statistical Graph

The Uniformity Analyzer displays the selected statistics, in graph form, in relation to the slices for all ROIs.

- Data points are plotted on the graph, and a curve is drawn between the points.
- The Start Slice and End Slice are represented on the graph as blue vertical lines.
- The Integral Start Slice and Integral End Slice are represented on the graph as green vertical lines.

The graph presents uniformity data in the following views:

- **Mean**: Plots the mean values within each ROI from all the slices.
- **Max**: Plots the maximum values within each ROI from all the slices.
- **Min**: Plots the minimum values within each ROI from all the slices.
- **Std Dev (Standard Deviation)**: Plots standard deviations within each ROI from all the slices.
- **Noise (%)**: Plots noise percentages within each ROI from all selected slices using the following formula: standard deviation/mean * 100%.

Use the drop-down list above the graph to switch between plotted statistics.

Start Slice

Use the slider or the numeric field to indicate the number of slices at the beginning of the frame to exclude from the analysis. The system excludes the number of slices prior to the number you select. For example, if you select 4 as the start, the system excludes the first three slices.

The Start Slice value only affects the values in the result summary.

End Slice

Use the slider or the numeric field to indicate the number of slices at the end of the frame to exclude from the analysis. The system excludes the number of slices after the number you select. (For example, if you select 10 as the end of a 13-slice frame, the system excludes the last three slices.)

The End Slice value only affects the values in the result summary.

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Integral Uniformity (IU) Start Slice

Use the slider or the numeric field to indicate the number of slices at the beginning of the frame to exclude from the integral uniformity analysis. The system excludes the number of slices prior to the number you select.

The IU Start Slice value only affects the values in the integral uniformity part of the result summary.

Integral Uniformity (IU) End Slice

Use the slider or the numeric field to indicate the number of slices at the end of the frame to exclude from the integral uniformity analysis. The system excludes the number of slices after the number you select.

The IU End Slice value only affects the values in the integral uniformity part of the result summary.

A typical IU slice range is selected to cover the middle 44 mm of the object.

System and Data Identifiers

The system shows the following DICOM information related to the system and data:

- Device Serial Number
- Manufacturer Model Name
- Study Description
- Series Description
- Acquisition Date
- Acquisition Time
- Protocol Name

Result Summary

The following table displays the results summary data and indicates which data are displayed when each ROI Set is selected.

Data	Description	Single ROI	Seven ROIs
Slice range	Start and end slice ranges	X	X
Volume-averaged Unit*	Average of all means reported from the indicated ROI on all selected slices displayed in the selected unit	X	

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Data	Description	Single ROI	Seven ROIs
Variation of ROI means (Unit*)	Statistical variation within the means displayed in the selected unit (maximal mean — minimal mean from the indicated ROI on all slices)	X	
% Axial variation	Percentage of the statistical mean variation within the selected slices	X	
% Axial variation of noise	Percentage of noise variation across the axial extent of the object defined by the slice range		X
Mean Noise	A measure for the averaged noise across all ROIs and all the selected slices		X
IU Slice Range	A selected slice range used to calculate the integral uniformity		X
IU%	Percentage of integral uniformity used to measure image non-uniformity in transverse plane		X
*Units can be set as SUV, BQML, or Counts.			

Statistics Table

The Uniformity Analyzer displays a table of all statistics for all ROI slices for the selected frame. The following statistics are presented:

- Mean
- Max
- Min
- Std Dev
- ROI Noise (%)

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Using the Uniformity Analyzer

Open the Uniformity Analyzer

1. Select a PET series acquired on a uniform phantom from the Directory.
2. Click the Uniformity Analyzer icon on the Analysis panel.

   The Uniformity Analyzer window opens.

Select Uniformity Analyzer Settings

1. Select the amount of ROIs placed on the slices from the **ROI Set** drop-down list.
2. Select the unit to be used for the ROI results from the **Unit** drop-down list.
3. Select the frame to analyze from the **Frame** drop-down list.
4. Position the ROI(s) automatically or manually.
   - Select the **Auto Center per Slice** check box to center the ROI(s).
   - Use the **X** and **Y** controls to manually position the ROI(s).

NOTICE

Use the Scroll Slice controls to view ROI placement on slices throughout the frame.

Analyzing and Saving the Results

1. Adjust the following controls:
   - Start Slice
   - End Slice
   - IU Start Slice
   - IU End Slice

NOTICE

Setting the start and end slices defines the Slice Range and associated statistics presented in the results summary.

2. Review the following:
   - Results summary
   - Statistical graph
   - Statistics table

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NOTICE

Adjust the start and end slices, as necessary, to create the desired views of the results summary.

3. Click **Capture Screen**, as necessary, to save an image of the screen in its current state in a temporary folder for further processing.
4. From the drop-down list above the graph, select a different statistical category.
5. Repeat steps 1 - 4, as necessary.

NOTICE

Adjust the **ROI Set**, **Unit**, and **Frame** settings, if necessary, as you repeat this procedure to analyze all available data.

6. Click **Save Result**, If desired, to temporarily save all statistics for all ROIs, frames, and slices for further processing.
7. Click **Finish** to save all screen images and results.

   The Uniformity Analyzer closes.

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6 Maintenance

Perform these routine system checks and maintenance procedures as required to ensure optimal performance and safe operation of the system. Maintain the schedule indicated in this manual to make sure that the system operates to specifications.

CAUTION

Incorrect cleaning may result in equipment damage.

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

WARNING

Blood and contrast medium are potentially infectious.

Use universal safety precautions when removing blood or residual contrast medium.

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:

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- 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) couch reach shall be cleaned/disinfected daily
- Noncritical environmental parts that the patients do not touch or the patient fluid (blood or other potentially infectious materials) is not expected to reach, shall be cleaned/disinfected weekly or as needed

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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.

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- 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.

Weekly Maintenance Procedures

Perform these procedures weekly. After performing the required maintenance, perform the calibration and quality control procedures established by your facility before using the system for patient testing.

Shut Down and Restart the System

Restart the system at least weekly, or more frequently if your site deems it necessary. Do not turn off the main power to the system during these shutdowns.

Test the Safety Devices

Perform the following tests weekly. If any of the tests fail, contact your Philips service representative and do not operate the system until the problem is corrected.

1. Prepare the scanner for a CT acquisition.

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Follow the acquisition procedure until either the Manual or AutoScan indicators on the scan control panel are lighted.

2. Test the Emergency Stop button by pressing an Emergency Stop button.
3. Listen for the sound of the scanner braking to a stop to verify that the Emergency Stop button is functioning.
4. Repeat the steps above for each of the Emergency Stop buttons.
5. After pressing an Emergency Stop button on the gantry panel, manually grasp the handle on the patient table and move the pallet to make sure it moves easily.

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

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7 Information for the CT User

Technique Factors - Maximum Deviations

Peak X-ray Tube Voltage

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

Peak X-ray voltage
80, 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 ±23% of the value displayed on the Operator console. The tube current exposure time product is measured by a dosimeter calibrated in mAs. The dosimeter is calibrated by measuring the tube anode current on an accurate resistor between X-ray on and off during a long exposure.

Linearity of Radiation

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

X-ray System Specifications

X-ray Tube

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

Leakage

The tube housing assembly together with the beam limiting device measured with the aplane blades fully closed and using a 140 kVp 50 mA stationary exposure:

Leakage
≤ 0.88 mGy/hr @1 meter

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Filtration

Minimum tube housing filtration:

Filtration
1.0 mm Al equivalent

The beam-limiting device includes an additional 1.2 mm titanium filter.

Cooling Curves

See chapter “X-ray Tube Housing Assembly Information” on page 93.

Power Rating Charts

See chapter “X-ray Tube Power Ratings - Vereos PET/CT System” on page 94.

Maximum Continuous Heat Dissipation

6.1 kW at 120kV, 40 mA.

X-ray Power Supply

Line Voltage and Regulation

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

Maximum Line Current

160 A RMS

Maximum Power

80 kW

X-ray System Loading Factors

The following system loading factors are applicable to the CT system on the Vereos PET/CT system per IEC 60601-2-44 SEC 6.8.2.

- **Nominal X-ray tube voltage**: 140 kV at 571 mA X-ray tube current
- X-ray tube voltage corresponding to highest obtainable X-ray tube current:
  - 100 kV at 665 mA
  - 120 kV at 665 mA
- **Highest electric output power**: 140 kV X-ray tube voltage and 571 mA X-ray tube current.
- **Nominal Electric Power for 4.0 second loading**: 79.8 kW at 140 kV X-ray tube voltage and 570 mA X-ray tube current.

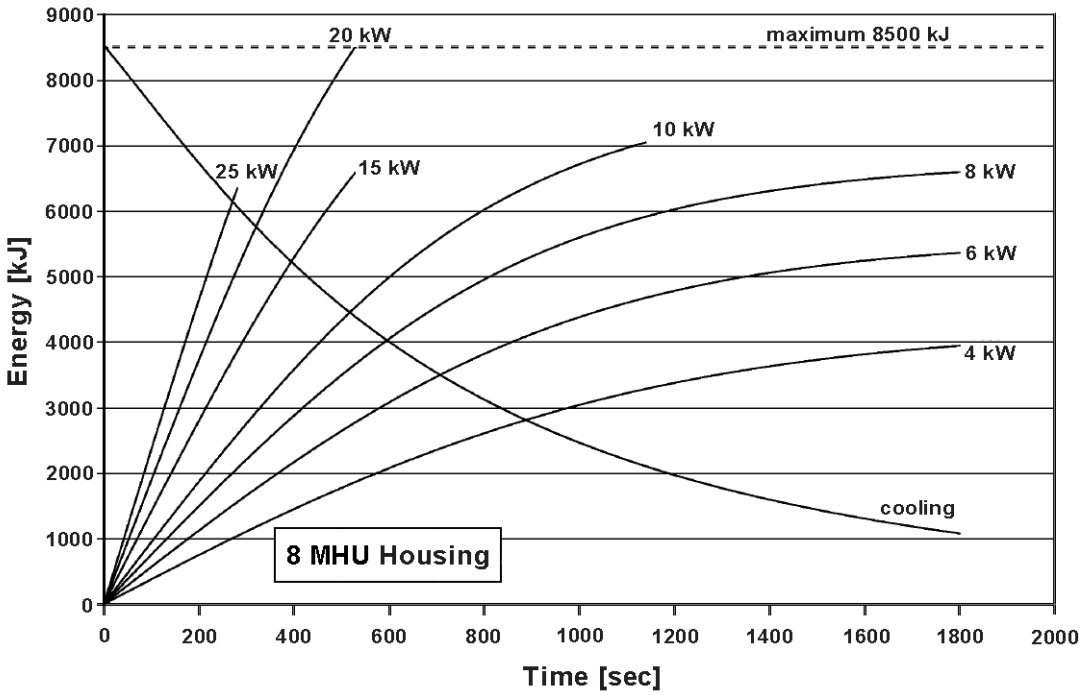
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kV	mA
80	665
100	665
120	665
140	571

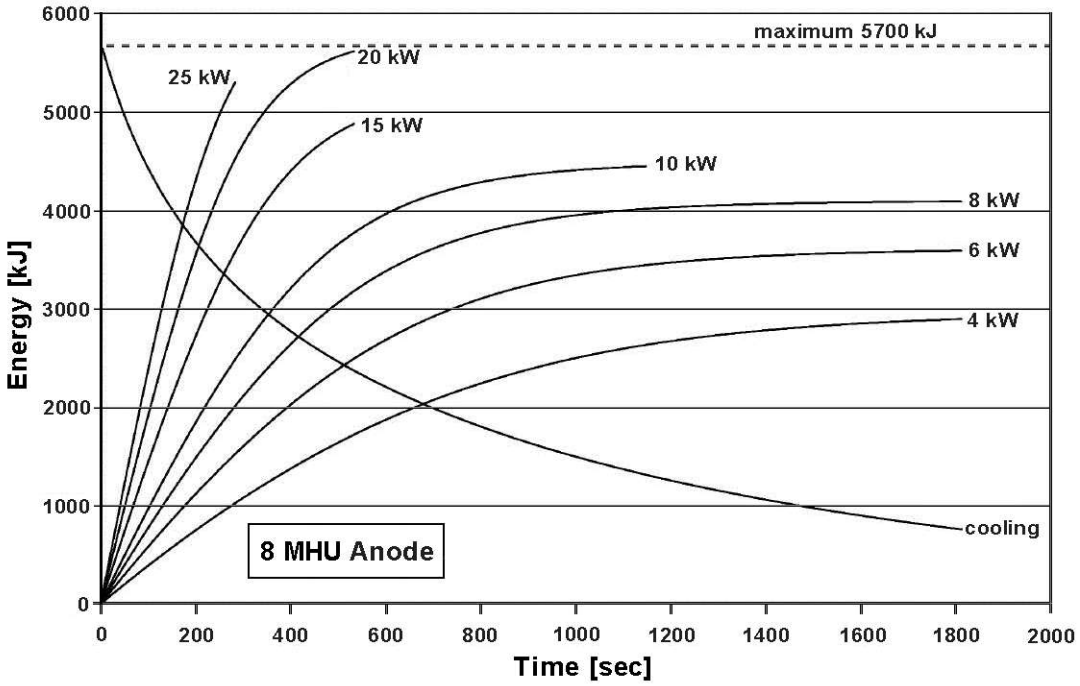
X-ray Tube Housing Assembly Information

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

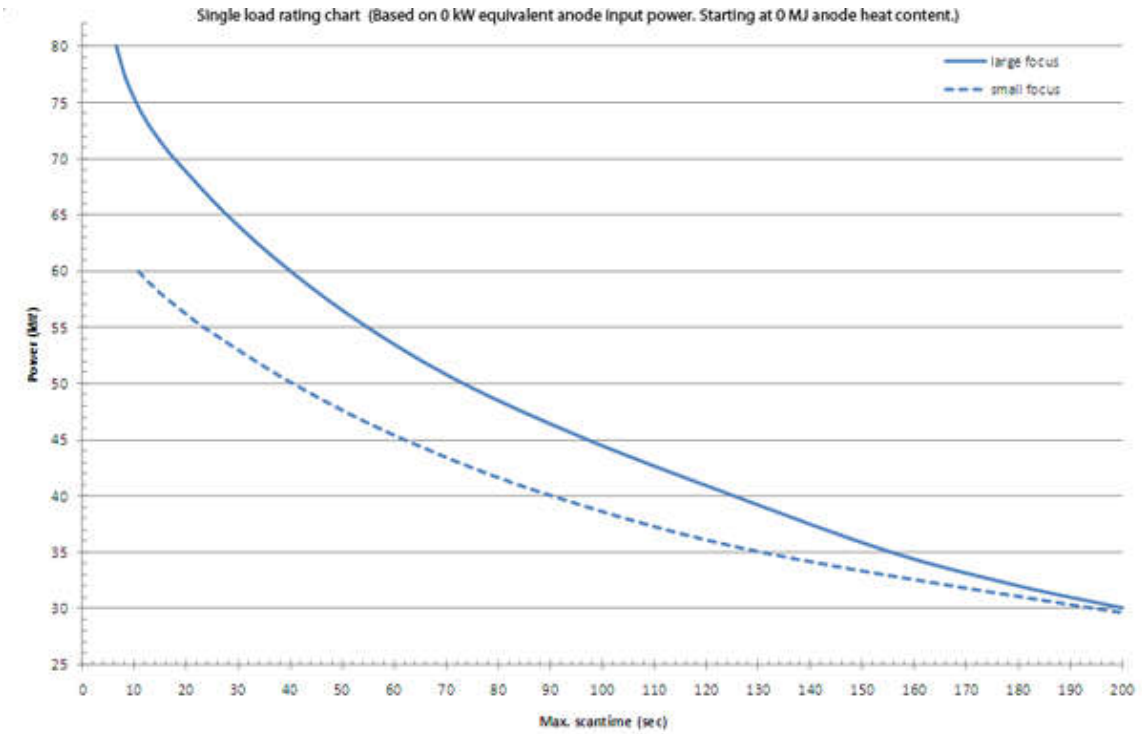


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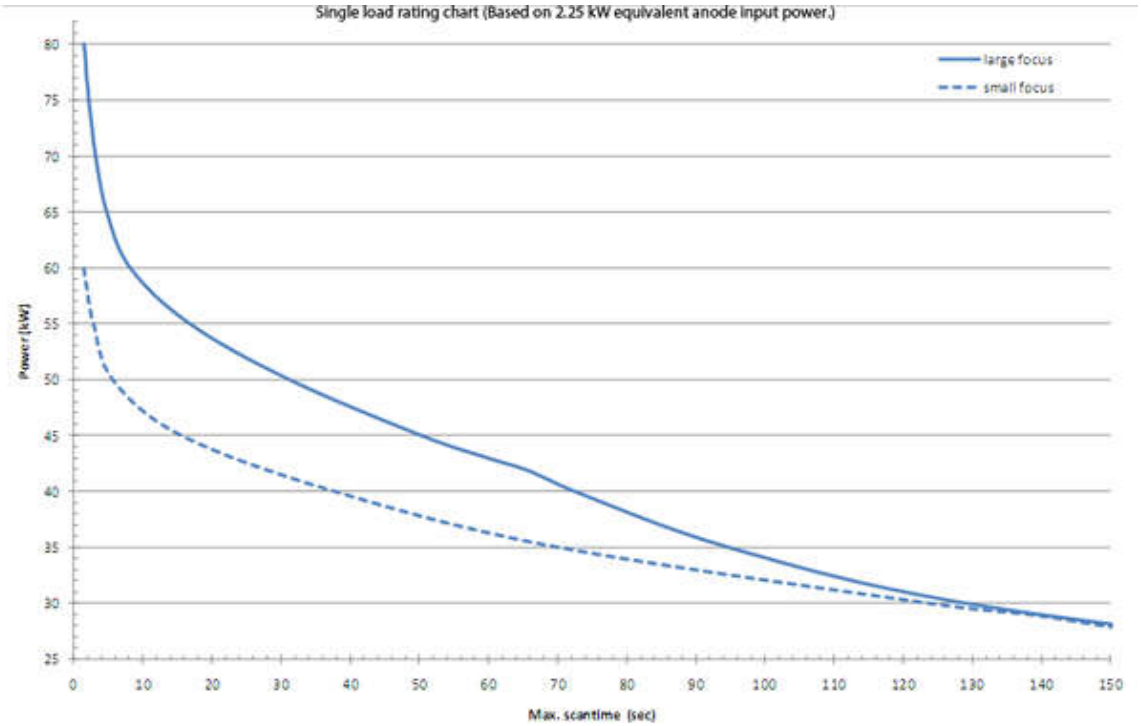


X-ray Tube Power Ratings - Vereos PET/CT System



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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, 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, 15 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.

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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 × T less than or equal to 40 mm

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

- For N ×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 $(N \times T)_{Ref}$ =32x0.625;
- $CTDI_{free\ air,N \times T}$ is the $CTDI_{free\ air}$ for a specific value of N × T;
- $CTDI_{free\ air,Ref}$ is the $CTDI_{free\ air}$ for $(N \times T)_{Ref}$ =32x0.625;
- 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. 128x0.625), first center the dose probe in the gantry, zero the couch, and measure the reference $CTDI_{free\ air}$ (32x0.625). 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

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

with these definitions:

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

- for helical scanning

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

- for scanning without movement of the patient support

  $CTDI_{vol}$ = n x $CTDI_w$

  - n = the maximum number of pre-programmed rotations

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

Image Noise

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

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

Noise is measured using these ROIs:

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

NOTICE

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

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

The maximum deviation from the stated noise is 10%.

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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.

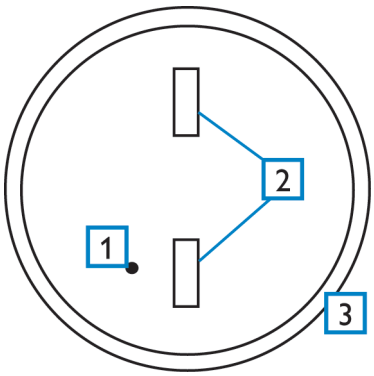
The phantom physics layer diameter is 200 mm (184 mm diameter of water [phantom liquid] in a 8 mm PVC shell).

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

The maximum deviation of the MTF curve is 15%.

Tomographic Thickness Measurement

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



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

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

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

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

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

NOTICE

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

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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	80 kVp	100 kVp	120 kVp	140 kVp
Multiply by:	2.059	1.992	1.965	1.931

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

The only Head Exam cards are Head, IAC (Inner Ear) 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.

Head-scan Information

Head dose - typical head CT scan conditions of operation:

Main	
FOV	250
Storage	Local

Scan	
Collimation	32 x 1.25
Thickness	5
Increment	0
Rot Time	0.75

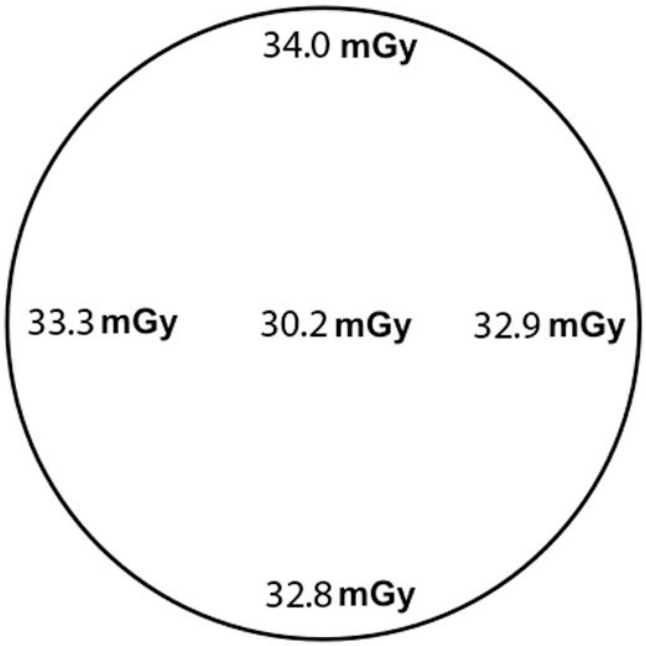
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Scan	
Voltage	120
mAs	250

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 head holder.

Maximum deviation from the values shown below is ±25%. $CTDI_{VOL}$ = 32.3 mGy.

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

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

Tube Current - Exposure Time Product (mAs) Dependence

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

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

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Collimation Setting Dependence

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

	$CTDI_{100}$	
The $CTDI_{100}$ of the 16 x 2.5 mm collimation is...	1.00 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 64 x 0.625 mm collimation is...	1.00 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 40 x 0.625 mm collimation is...	1.04 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 16 x 0.625 mm collimation is...	1.23 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 12 x 1.25 mm collimation is...	1.13 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 12 x 0.625 mm collimation is...	1.33 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 20 x 0.625 mm (UHR) collimation is...	1.17 ± 15%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 2 x 0.5 mm (UHR) collimation is...	2.42 ± 20%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.
The $CTDI_{100}$ of the 2 x 0.625 mm (HR) collimation is...	1.93 ± 20%	... times the $CTDI_{100}$ of the 32 x 1.25 collimation.

Voltage Dependence - Center

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

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

Voltage Dependence - Edge

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

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

Dose and Sensitivity Profiles - Head Scan

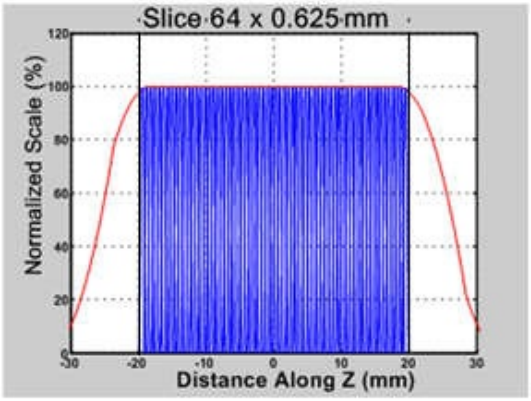
The dose profiles at the center of the phantom superimposed on the sensitivity profiles are presented in the following sections. The maximum deviations from the drawn curves are ±20%.

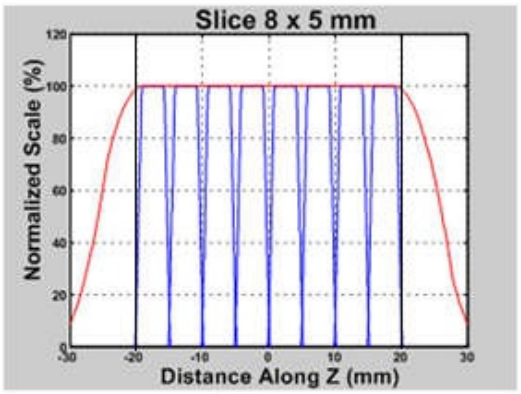
NOTICE

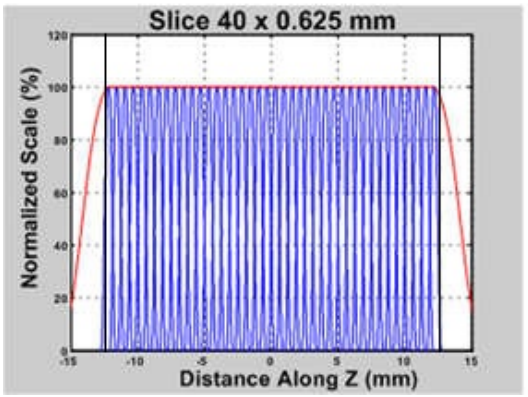
The sensitivity profiles were simulated under the typical conditions of operation presented in the Head Scan Information section, while changing the slice thickness only. The limited resolution of the image causes the thin slice thicknesses to appear thicker than they really are.

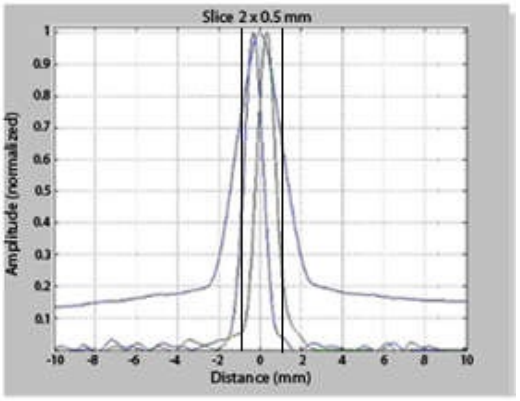
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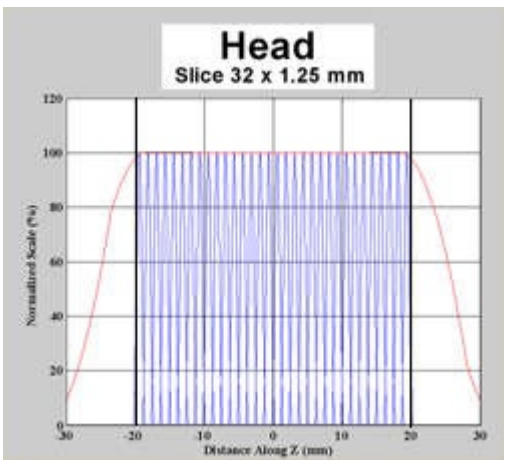


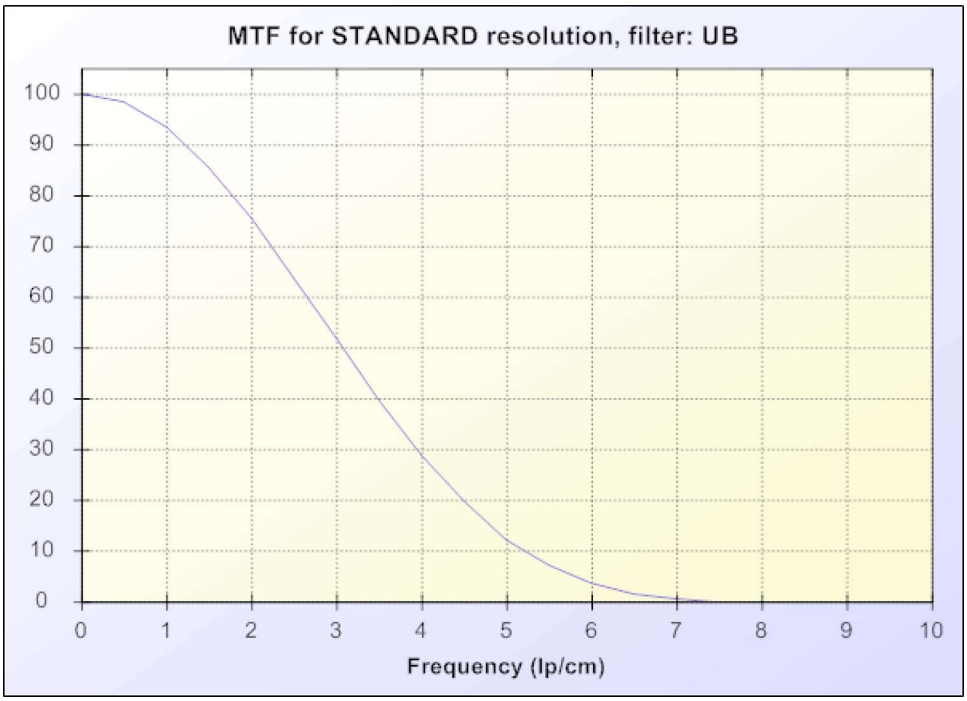
Image Quality - Head

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

The phantom and measurement method are described earlier. See chapter “Image Noise” on page 97 and chapter “Modulation Transfer Function” on page 98.

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

These are the nominal tomographic section thicknesses:

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

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

CT Number Uniformity

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

CT Number Accuracy

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

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

Body-scan Information

Body dose - typical body CT scan conditions of operation:

Main	
FOV	350
Storage	Local

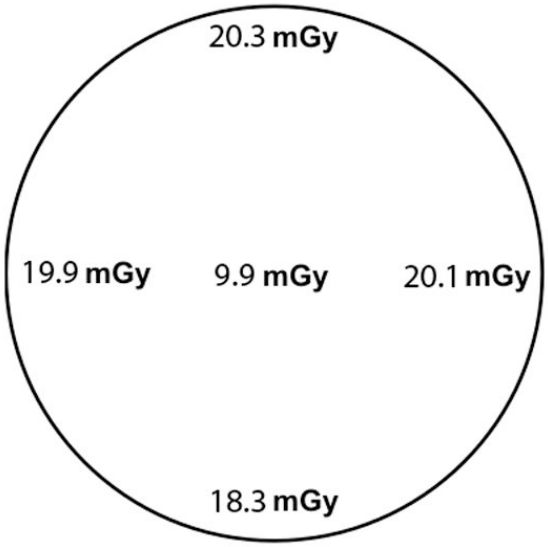
Scan	
Collimation	32 x 1.25
Rot Time	0.75
Voltage	120
mAs	250

Recon	
Filter	B
Thickness	5
Increment	0

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CTDI100 Body



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

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

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

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

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

Tube Current - Exposure Time Product (mAs) Dependence

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

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

Collimation Setting Dependence

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

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

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

Voltage Dependence - Center

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

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

Voltage Dependence - Edge

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

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

Dose and Sensitivity Profiles - Body Scan

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

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NOTICE

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

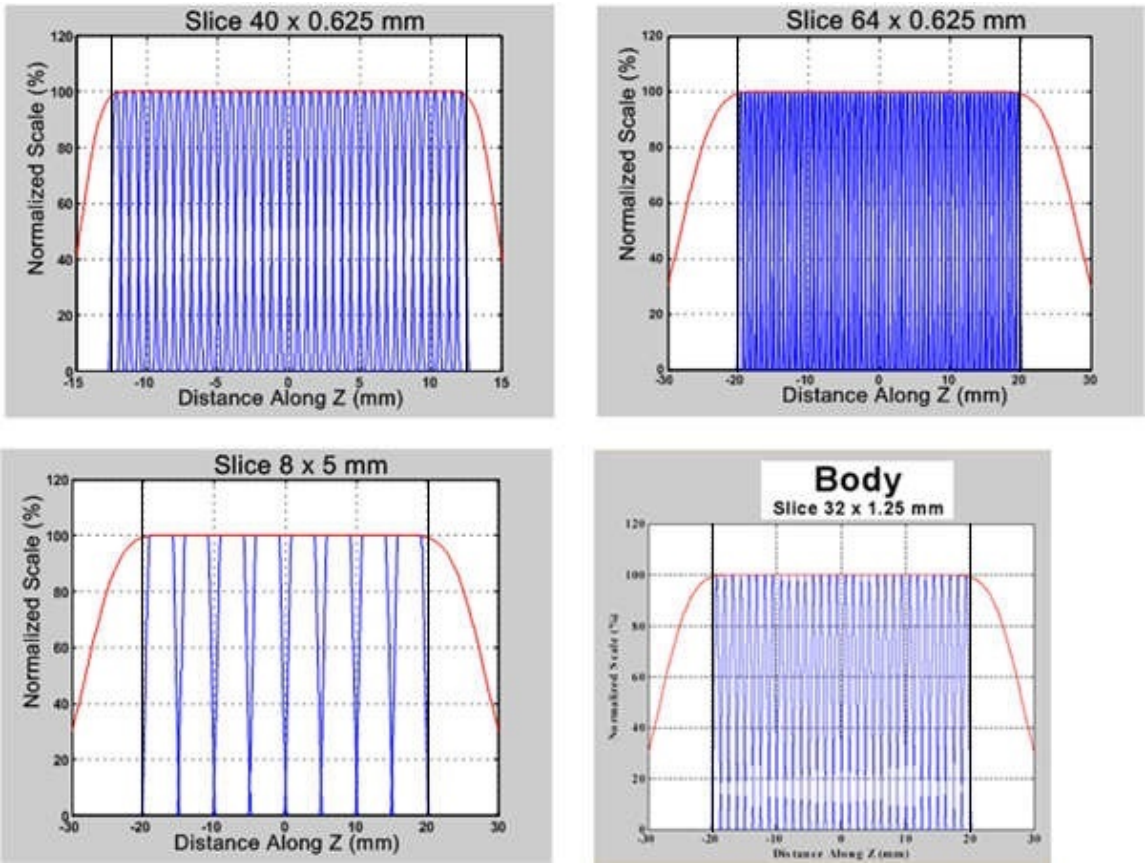


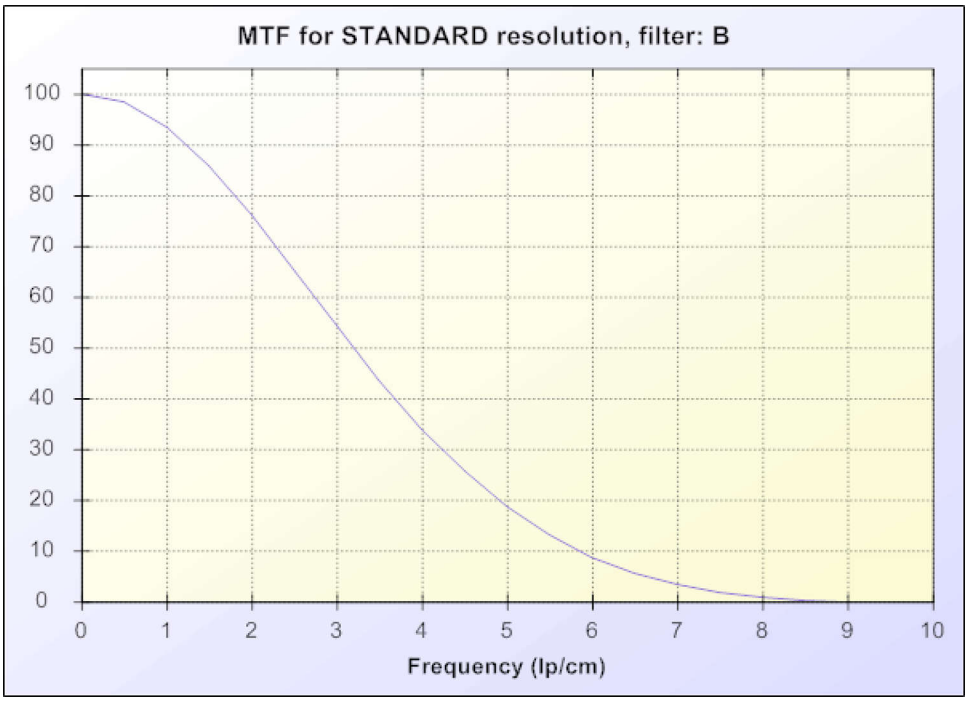
Image Quality - Body

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

The phantom and measurement method are described earlier (See chapter “Image Noise” on page 97 and chapter “Modulation Transfer Function” on page 98.

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

These are the nominal tomographic section thicknesses:

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

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

CT Number Uniformity

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

CT Number Accuracy

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

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

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CTDI Free Air

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

CTDI Free Air for Body Conditions of Operation

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

CTDI Free Air for Other Conditions of Operation

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

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

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

Conditions to Achieve 1000 mGy CTDIvol (Peripheral)

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

Adult Head

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

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Head/Brain Perfusion Non-Jog

kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
100	64x0.625	0.75 sec	495	41.1 mGy	25
80	64x0.625	0.75 sec	450	19.0 mGy	53

Brain Axial 2D

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

kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	16x0.625	1.0 sec	775	129.6 mGy	8
140	16x0.625	1.0 sec	665	161.3 mGy	7
100	16x0.625	1.0 sec	775	79.1 mGy	13
80	16x0.625	1.0 sec	700	36.3 mGy	28

Head Axial

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

kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	16x0.625	1.5 sec	1160	194.0 mGy	6
140	16x0.625	1.5 sec	995	241.3 mGy	5
100	16x0.625	1.5 sec	1160	118.4 mGy	9
80	16x0.625	1.5 sec	1050	54.4 mGy	19

Head/Sinus Limited HR

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

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kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	2x0.625	0.5 sec	290	70.6 mGy	15
140	2x0.625	0.5 sec	245	86.5 mGy	12
100	2x0.625	0.5 sec	290	43.1 mGy	24
80	2x0.625	0.5 sec	290	21.9 mGy	46

Adult Body Mode

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

Abdomen/Body Perfusion Axial

kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	64x0.625	0.75 sec	495	40.2 mGy	25
100	64x0.625	0.75 sec	495	24.5 mGy	41
80	64x0.625	0.75 sec	450	11.0 mGy	92

Thorax/High Resolution Axial

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

kVp	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	2x0.625	1.0 sec	500	72.7 mGy	14
140	2x0.625	1.0 sec	425	90.8 mGy	12
100	2x0.625	1.0 sec	500	44.3 mGy	23
80	2x0.625	1.0 sec	500	21.8 mGy	46

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CCT Mode - Interventional/CCT Single or CCT Continuous

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

kVp	Scan Coverage	Collimation	Rotation Time	mAs	CTDI (12:00 o'clock position)	Number of Axial scans to exceed 1000 mGy
120	2.5 mm	4x0.625	0.75 sec	270	38.1 mGy	27
100	2.5 mm	4x0.625	0.75 sec	330	28.4 mGy	36
80	2.5 mm	4x0.625	0.75 sec	300	12.7 mGy	79

Interventional/CCT Fluoro

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

kVp	Scan Coverage	Collimation	Rotation Time	mAs	CTDI rate (12:00 o'clock position)	Number of scan seconds to exceed 1000 mGy
120	2.5 mm	4x0.625	0.4 sec	105	70.6 mGy/s	15
100	2.5 mm	4x0.625	0.4 sec	125	51.3 mGy/s	20
80	2.5 mm	4x0.625	0.4 sec	125	25.2 mGy/s	40

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.

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

NOTICE

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

Essential Performance for Interventional Imaging

Image Spatial Accuracy

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

Slice Thickness

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

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

Low Contrast

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

Noise

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

High Contrast Spatial Resolution

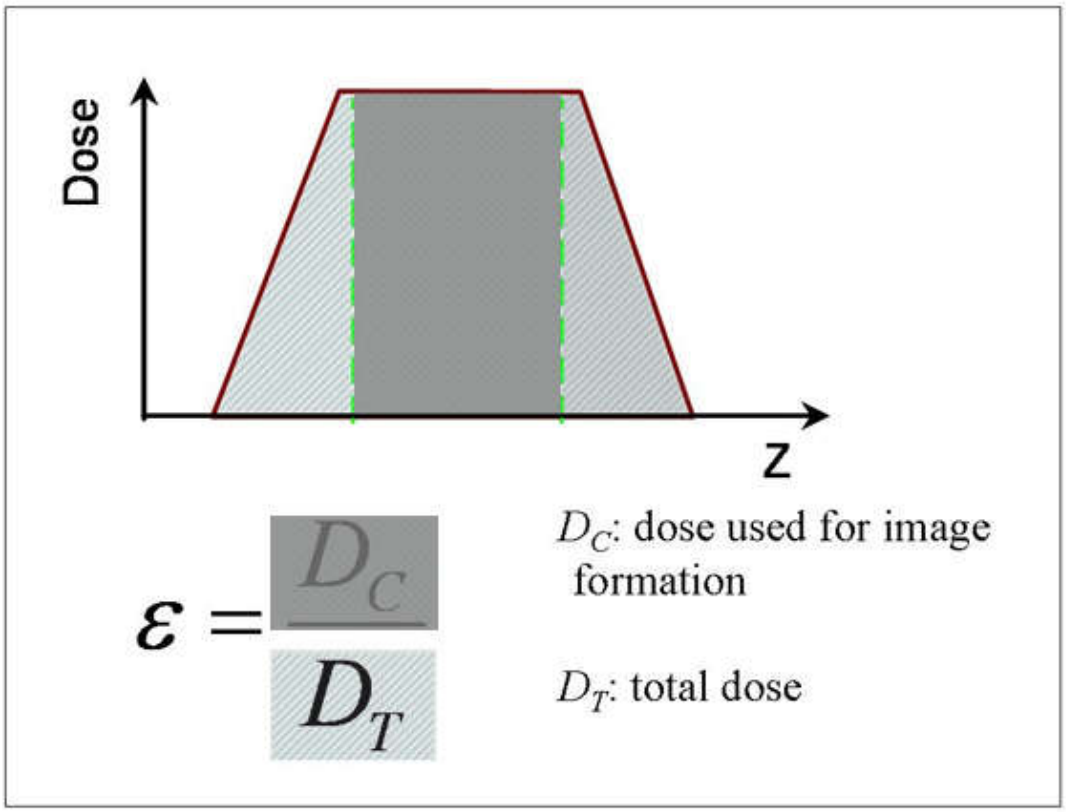
When scanning in Standard Resolution, the system achieves at least 10 lp/cm (measured at 0% MTF) in plane resolution (x-y) within a radius of 100 mm from the iso-center and in the central two slices.

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Geometric Efficiency Measurements

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



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

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

NOTICE

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

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

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

Half Value Layer (HVL)

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

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

Stray Radiation Dose Maps

The map dose values units are µGy / mAs, calculated from direct measurements of mGy / 750 mAs.

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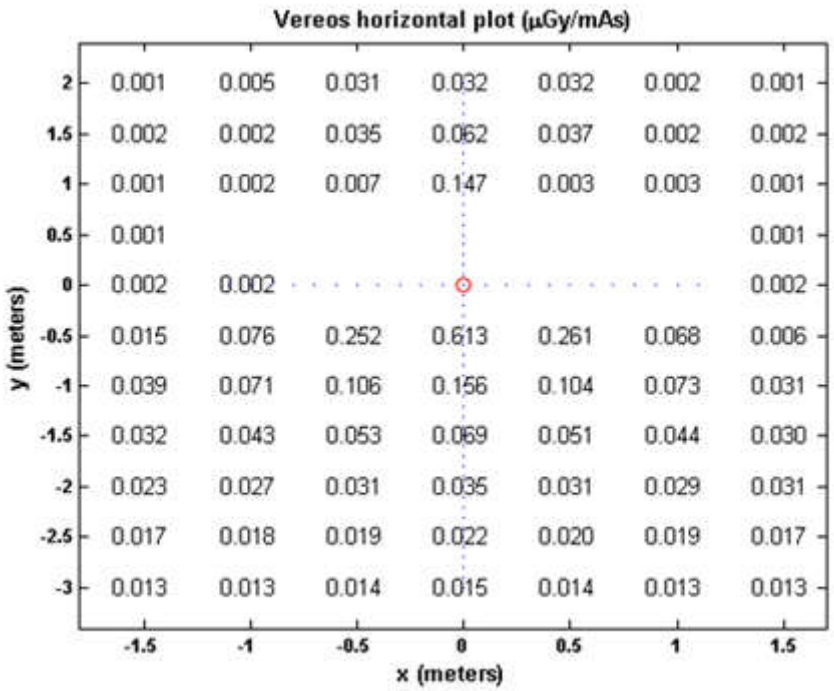
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Measurements were made with the QA Axial Body 2D exam card at the maximum collimation of 64 x 0.625 = 40mm and at 140 kVp in the horizontal plane through the system axis and in vertical plane along the system axis. The room dimensions were 7.9 m wide, 5.7 meters long with a 2.5 m high wall and a ceiling that was 5.5 m above the floor

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

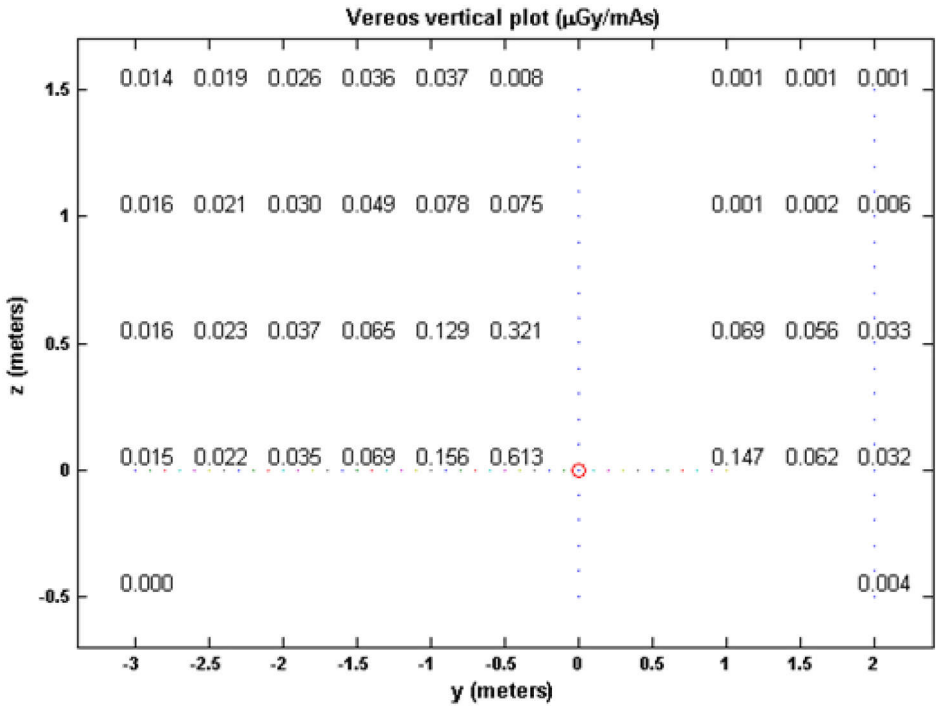
NOTICE

In X-ray radiation environments like CT, Sievert and Gray values are interchangeable; one µSv equals one µGy. By Philips convention, map values are given in µSv/1000 mAs for ease of calculation.



Horizontal stray radiation map for Vereos measured on the horizontal plane containing the axis of rotation, the values shown are in µGy/mAs units from direct measurements.

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Vertical stray radiation map for Vereos. The values shown are in µGy/mAs units from direct measurements.

HU-Value Conversion

The Gammex Tissue Characterization Phantom Model 465 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 465, 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% $CaCO_3$ (bone-equivalent material)
- CB2-50% $CaCO_3$ (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.

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

Collimation	16 x 0.625 = 10mm
Rotation Time	1.0 s
Slice Width	2.5 mm
Filter	UB
FOV	400 mm
kVp	120
mAs	400
CTDI	63.5mGy

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

Collimation	16 x 0.625 = 10mm
Rotation Time	0.75 s
Slice Width	2.5 mm
Pitch	0.69
Filter	B
FOV	400 mm
kVp	120
DRI	26 (max 657 mAs)
CTDI	47.8 mGy

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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 Vereos 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 Vereos PET/CT scanner in oncology head scan mode.

Materials	Electron Density Relative to Water	HU-Value (HU)
Air	0.000	-991.1
Adipose	0.895	-83.0
Water	1.000	6.9
BRN-SR2 Brain	1.039	28.0
CB2-30% $CaCO_3$	1.285	433.6
CB2-50% $CaCO_3$	1.473	791.2

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

Materials	Electron Density Relative to Water	HU-Value (HU)
Air	0.000	-976.7
Adipose	0.895	-85.4
Water	1.000	-2.6
LV1 Liver	1.050	83.5
CB2-30% $CaCO_3$	1.285	446.0
CB2-50% $CaCO_3$	1.473	800.2

The largest available reconstructed field-of-view on the Vereos PET/CT scanner is 700 mm, but the true field-of-view is 500 mm. The Vereos PET/CT scanner does not have any inherent accuracy limitations within the 500 mm true field-of-view. CT values within the 500 mm field-of-view are generally accepted to be accurate within scanner specifications, however they may vary due to the specific circumstances such as beam hardening artifacts, etc. CT numbers between the edge of 500 mm true field-of-view and the edge of the 700 mm extended field-of-view are expected to exhibit large deviations, and are not intended to be used for treatment planning purposes

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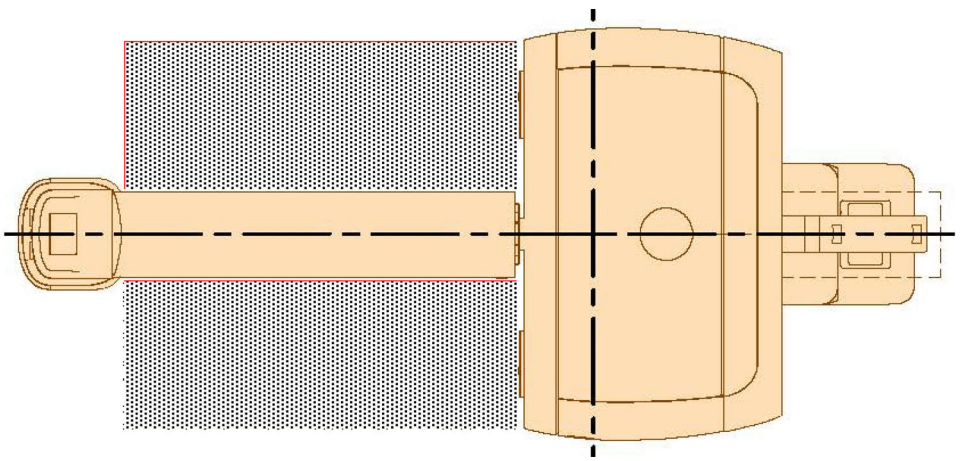
It is important to understand that the conversion factors can be different from scanner to scanner, i.e. the CT number variation may be observed from scanner to scanner. It is important to have scanner-specific HU-value conversion calibrations of each CT-based treatment planning computers. The conversion 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.

Zones of Occupancy

Permitted zones of occupancy are designated in the dotted areas.



The designated zones of occupancy are for use during any CT examination where occupancy of the scanner room by medical staff is unavoidable.

The zones of occupancy are shown in the dotted areas in the figure above. The zones alongside the table in front of the gantry are 80 cm wide and 210 cm long. The corner of the zone closest to the center of the gantry is where the highest exposure occurs and is the location where the measurements were taken.

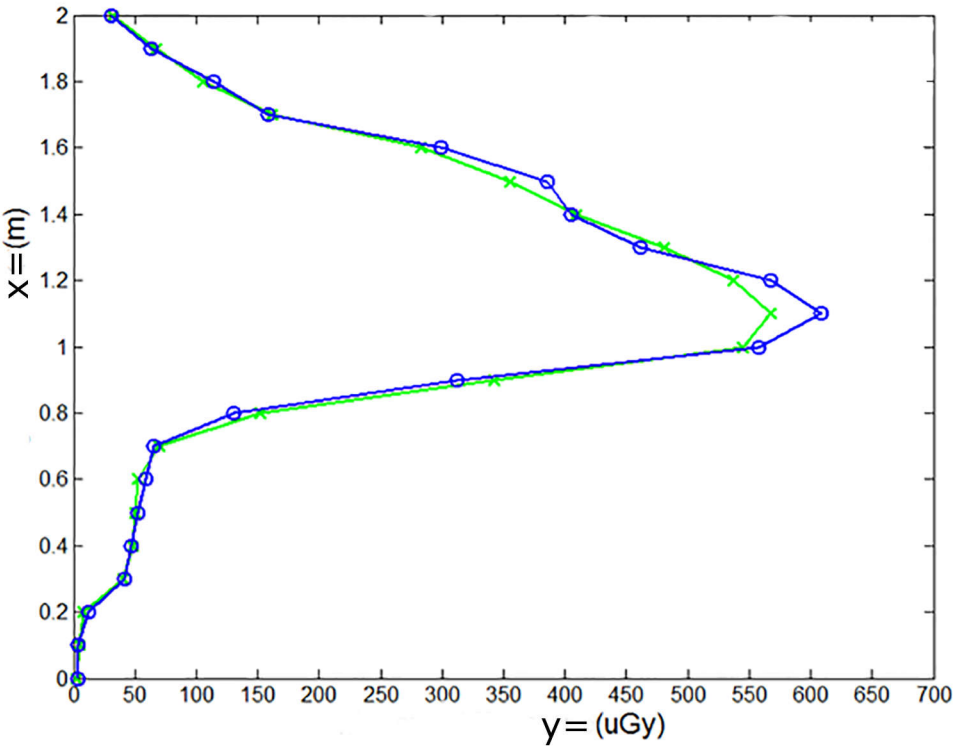
The radiation profiles shown in the figure below represents the exposure measured in the worst-case scenario for system use. Measurements were taken using a Body CTDI phantom with 32 cm diameter and 15 cm length to simulate a large patient centered at iso-center. The phantom was scanned at 140 kVp to create the worst-case scatter possible.

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For the profiles, measurements were made with a 180 cc ion chamber with a 100 cm^2 effective cross section. The measurements were taken with a 64X0.625 mm collimation, 140 kVp, 500 mAs, 1 second rotation time, 360 degree scan angle, and standard resolution with number of cycles set to 2. The resulting measurements were scaled to represent air kerma for a 500 cc volume in the profiles shown. The profiles were generated with measurements taken at 10 cm intervals from floor level to 200 cm above the floor. The profiles shown do not represent the use of any protective devices.

Exposure from Scattered Radiation in the Front of the Gantry



x = height above floor (m)

y = measured exposure (µGy)

= left of the patient table

This line indicates measurements taken on the left side of the patient table in front of the gantry.

= right of the patient table

This line indicates measurements taken on the right side of the patient table in front of the gantry.

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8 Accreditation Guidelines

EARL Accreditation

The European Association of Nuclear Medicine Research Limited (EARL) is an initiative launched to promote multi-center nuclear medicine trials and research activities in Europe. As part of the EARL FDG PET/CT scanner validation program, reconstructed PET images acquired using a modified NEMA NU2 Image quality procedure are submitted to the EARL organization for evaluation. (Refer to the EARL procedure for assessing PET/CT system specific patient FDG activity preparations for quantitative FDG PET/CT studies.) Recovery coefficients in the submitted data sets are measured as a function of sphere size and have to lie within EARL prescribed limits. In practice, some amount of post-filtering of the reconstructed image is required to meet these accreditation specifications.

To achieve this, the factory-default Body reconstruction protocol in the Body Protocol group may be used in conjunction with the 3D-Gaussian post-filter to reconstruct the EARL data sets. Choosing a 3D-Gaussian kernel with a FWHM of 5 mm should suffice in most-cases to meet EARL accreditation specifications. If these settings do not meet EARL specifications, the user has the added flexibility to either increase or decrease the amount of post-filtering. Refer to *Filtering Parameters* in the Reference Manual for information to help achieve these specifications.

* http://earl.eanm.org/cms/website.php?id=/en/projects/fdg_pet_ct_accreditation/guidelines.htm

ACRIN PET/CT Scanner Qualification

The American College of Radiology Imaging Network (ACRIN) PET/CT scanner qualification program is designed to support and standardize PET image acquisitions for clinical trials. The qualification program includes two main categories: Brain and Body Imaging with quantitative requirements for both static and dynamic imaging. Reconstructed images of water filled, uniform cylinder acquisitions injected with ^{18}F are submitted to the ACRIN PET core labs for scanner qualification. Refer to the ACRIN website** for ACRIN PET/CT Qualification Instructions.

For successful scan qualification, the axial variation as well as the volume-averaged SUV values in the uniform cylinder phantom have to be within ACRIN prescribed limits. The uniformity analyzer application can be used to evaluate the ACRIN quantification metrics (Volume-averaged SUV and % Axial Variation) on reconstructed images of the uniform cylinder. Refer to the Uniformity Analyzer section for more information on about the application.

The qualification program includes two main categories: Brain and Body Imaging with quantitative requirements for both static and dynamic imaging of water filled, uniform cylinder acquisitions injected with ^{18}F. Use the Philips supplied 20 cm diameter, 30 cm long uniform cylinder phantom with an interior volume of 9366 ml for acquiring these ACRIN scans. Refer to the ACRIN website** for phantom filling, image acquisition and analysis details.

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When acquiring the uniform cylinder study, ensure that:

- the correct phantom length (30 cm) is entered in the **Height** field.
- the cylindrical phantom is centered axially with respect to the scanned axial extent.

Reconstructed images are submitted to the ACRIN PET core labs for scanner qualification.

- For successful scan qualification, the axial variation as well as the volume-averaged SUV values in the uniform cylinder phantom have to be within ACRIN prescribed limits.
- You can use the uniformity analyzer application to evaluate the ACRIN quantification metrics (Volume-averaged SUV and % Axial Variation) on reconstructed images of the uniform cylinder.

** https://www.acrin.org/CORELABS/PETCORELABORATORY/PETQUALIFICATION.aspx

Performing Uniformity Analysis

1. Select the uniform phantom image volume acquired from the Directory.
2. Click the Uniformity Analyzer icon on the Analysis panel.

   The Uniformity Analyzer window opens.
3. Select **Single ROI** as the ROI set for analysis from the **ROI Set** drop-down list.
4. Select **SUV** as the voxel intensity unit to be used for the ROI results from the **Unit** drop-down list.
5. The selection in the **Frame** field defaults to **1**.

   For dynamic data sets, results from the uniformity analysis for each dynamic frame can be displayed by selecting the appropriate frame number from the **Frame** drop-down list.
6. Click the **Auto Center per Slice** box to automatically center the 2D circular ROI in case the uniform phantom volume is not centered along the axial direction.
7. Use the **Scroll Slice** bars to adjust the Start Slice and End Slice so as to skip the edge slices that are affected by low statistics and edge effects.

   For example, 12 mm of edge slices on either end of the phantom may be omitted from the analysis.
8. Record the **Volume-averaged SUV** and **% Axial Variation** values.
9. Click **Save Results** to save all the relevant ROI statistics from all slices as a *csv* file for further processing.

American College of Radiology (ACR) Accreditation

Refer to the instructions in the ACR PET Phantom Instructions† document for phantom preparation and analysis. Scanners that are ACR tested must be calibrated and aligned prior to testing. Phantom data must be acquired with the ACR-approved PET phantom described below. For the acquisition, use your facility's whole body protocol with the same settings that are used for routine clinical studies.

† http://www.acraccreditation.org/Modalities/Nuclear-Medicine-and-PET

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Phantom Description

The phantom is a cylinder with an internal radius of 10.8 cm. The lid comprises 3 fill ports and 1 × 8mm, 1 × 12mm, 1 × 16mm, and 3 × 25mm hollow cylinders. It also contains a 1 × 25mm Teflon cylinder that cannot be filled. An image of the ACR phantom is provided in Figure 1 and a pictorial representation of the phantom lid is provided in Figure 2.

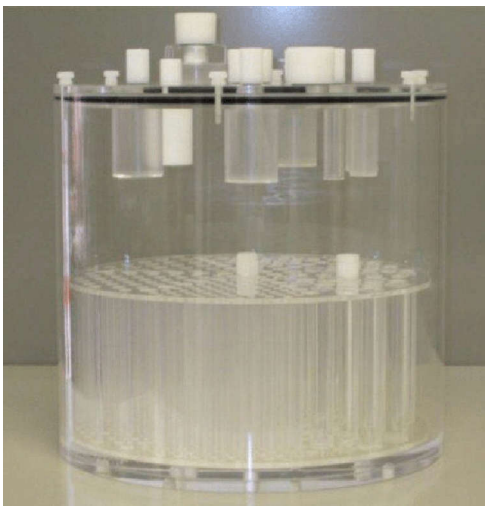


Fig. 1: Figure 1 - ACR Phantom

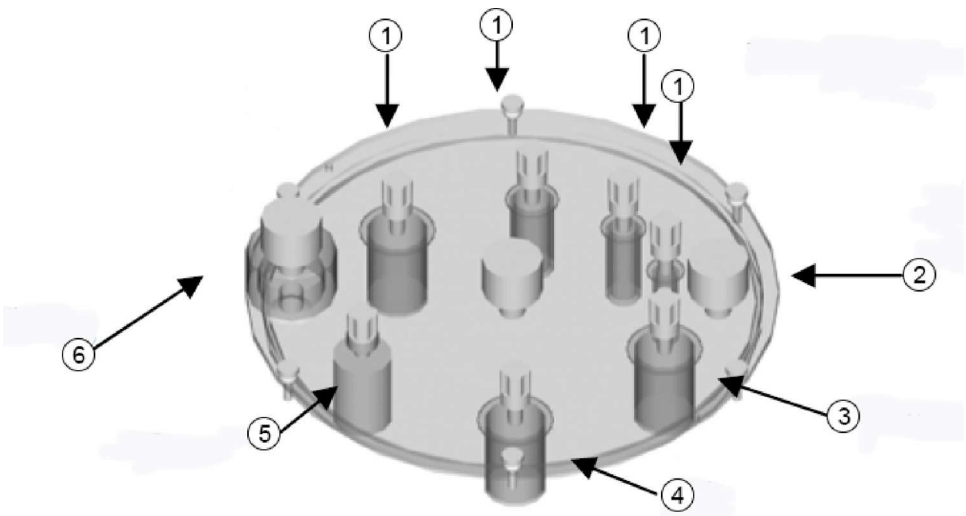


Fig. 2: Figure 2 - ACR Phantom Lid

1 - Hot Cylinders	2 - Secondary Filling Cap
3 - Water	4 - Air
5 - "Bone"	6 - Primary "background" filling cap

Figures courtesy of American College of Radiology *PET Phantom Instructions for Evaluation of PET Image Quality* ACR Nuclear Medicine Accreditation Program, PET Module.

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Materials Required

- ACR PET Phantom
- 1000 mL bottle or bag
- 2 - Tuberculin syringes
- 2 - Large 60 mL syringe
- 2 - Large-bore needles

Phantom Preparation

Prior to filling the phantom, empty all the hollow cylinders and leave the port screws out to allow any residual water to evaporate.

Filling procedure for the ACR phantom

1. Starting at the Teflon cylinder and moving counterclockwise, leave the first hollow cylinder empty (air), and fill the second hollow cylinder with water.
2. Fill the 1000 mL bottle or bag with water or saline, allowing some space for adding and mixing **Dose A**.
3. Fill the entire main compartment with water, allowing some space for adding and mixing **Dose B**.

Preparation of Doses

The following procedures assume the scan occurs one hour after filling the phantom.

1. From the Phantom dose chart below, select the Patient Dose corresponding to the standard dose given to a patient at your location.

   Look up the row with the selected Patient Dose for **Dose A** and **Dose B**.

   For example, if the standard dose provided to a patient at your location is 14 mCi, refer to the row with 'Patient Dose' as 14 mCi.

   – **Dose A** is 0.49 mCi

   – **Dose B** is 1.15 mCi
2. Using a Tuberculin syringe, draw up Dose A with radioactivity specified in the Phantom Dose Chart.
3. Record the activity of the radionuclide and time of measurement in the *ACR Dilution Worksheet*.
4. Using a Tuberculin syringe, draw up Dose B with radioactivity specified in the Phantom Dose Chart.
5. Record the activity of the radionuclide and time of measurement in the *ACR Dilution Worksheet*.

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Patient Dose	Dose A (mCi)	Dose B (mCi)
4 mCi	0.14	0.33
6 mCi	0.21	0.50
8 mCi	0.28	0.66
10 mCi	0.35	0.83
12 mCi	0.42	0.99
14 mCi	0.49	1.15
16 mCi	0.56	1.32
18 mCi	0.63	1.48
20 mCi	0.70	1.65

Tab. 1: Phantom Dose Chart

Dose A

1. Inject Dose A into the 1000 mL bottle or bag.
   Flush the syringe repeatedly to ensure no residual activity.
2. Mix thoroughly.
3. Record the residual activity (in mCi) present in the syringe in the ACR Dilution Worksheet.
4. Discard the syringe used for Dose A.
5. Add water to fill the bottle/bag completely to 1000 mL.
6. Using a 60 mL syringe, withdraw 60 mL from the 1000 mL bottle or bag.
   This is Test Dose 1.
7. Measure the activity of the syringe and note this activity in the ACR Dilution Worksheet under Test Dose 1.
8. Using Test Dose 1, fill the four remaining empty cylinders, in counterclockwise order:
   - 1 × 8 mm
   - 1 × 12 mm
   - 1 × 16 mm
   - 1 × 25 mm

NOTICE

Thus, the cylinders contain, in counterclockwise order, Teflon, Air, Water, Activity from Test Dose 1, Activity from Test Dose 1, Activity from Test Dose 1, and Activity from Test Dose 1.

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Dose B

1. Inject Dose B into the main compartment of the phantom.

   Flush the syringe repeatedly to ensure no residual activity.
2. Mix thoroughly.
3. Record the residual activity (in mCi) present in the syringe in the ACR Dilution Worksheet
4. Discard the syringe used for Dose B.
5. Add water to fill the main compartment of the phantom entirely, with minimal/no air bubbles.
6. Using a 60 mL syringe, withdraw 60 mL from the main compartment of the phantom.

   This is Test Dose 2.
7. Measure the activity of the syringe.

   Note this activity in the ACR Worksheet under Test Dose 2.
8. Inject Test Dose 2 back into the phantom and seal the phantom such that there are minimal or no bubbles and air gaps.

Phantom Position and Orientation

1. Lay the phantom flat on the patient table.

   Some sheets may be used to assist in leveling.

   The long axis of the phantom must be parallel to the axis of the scanner with the fill ports facing towards the gantry.
2. Position the phantom such that the cylinder containing Teflon is at the highest point and the smallest 'Hot' cylinder is at the lowest point.
3. Use a bubble level to ensure a level height in the horizontal plane.
4. Adjust the height of the table such that the phantom is in the center of the transverse FOV.

ACR Phantom Data Acquisition

Scanning is performed exactly one hour after measurement of the first Dose (A). Two acquisitions are expected using this phantom in the order provided below.

1. Select the standard **Body** PET/CT protocol.
2. Enter **ACR PET Phantom Test** as the Patient Name.

   The patient name is not specified in the ACR requirements list.
3. Enter weight as **70 kg**.
4. Enter height as **170 cm**.
5. Use two emission frames for the PET acquisition, and center the two frames such that the phantom is in the middle of the two frames.
6. Enter the patient dose you selected from the Phantom Dose Chart under **Patient Dose**.
7. Enter assay time as the time of measurement of Dose A.

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8. In the series description, enter the series title as **ACR IQ Test Body**.
9. Ensure that PSF is turned off (standard setting: OFF).

   Click the **Show All** button for the PET scan to view and modify the PSF settings .
10. Click **GO**.

Post-Processing Reconstruction and Analysis

Transaxial slices of 1-cm thickness must be generated for the analysis.

Perform an ROI analysis using the fully corrected reconstructed image (*CTAC*)

1. Select the 1 cm slice that best shows the four 'Hot' Cylinders, as shown in the example provided in Figure 3.
2. Draw a 2D circular ROI of diameter 6-7 cm in the center of the transverse slice, avoiding any cylinders, as shown in the example provided in Figure 4.
3. Draw a 2D circular ROI of size large enough to just be inside the boundaries of the largest 'Hot' cylinder of 25 mm.
4. Copy this ROI and place it over all other visible cylinders.

NOTICE

Note that all the ROIs must be of the same size regardless of the cylinder size, as shown in the example provided in Figure 5.

5. Record your SUV measurements as per the ACR instructions.
6. Save a screen capture containing all ROIs in the DICOM Secondary Image Format, to submit with the image set.

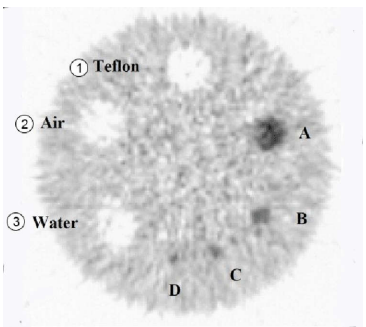


Fig. 3: Figure 3

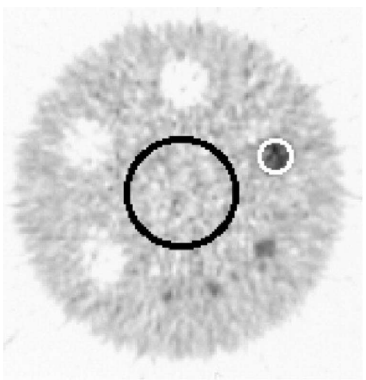


Fig. 4: Figure 4

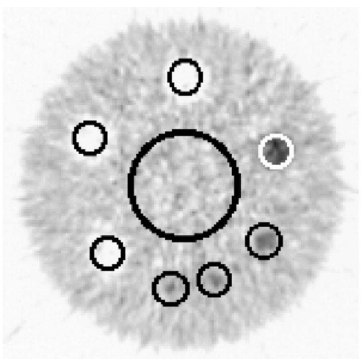


Fig. 5: Figure 5

1 - Teflon
2 - Air

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3 - Water
A, B, C, D - 'Hot' Cylinders

Figures courtesy of American College of Radiology *PET Phantom Instructions for Evaluation of PET Image Quality* ACR Nuclear Medicine Accreditation Program, PET Module.

ACR Phantom Dilution Worksheet

Dose	Time	Dose Ratios
Patient Dose		
FDG Dose (A), mCi:		FDG Doses: B/A (enter ratio value below)
FDG Dose (B), mCi:		
Test Dose #1, µCi:		Test Doses: 1/2 (enter ratio value below)
Test Dose #2, µCi:		
Actual start time of phantom scan:		

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9 Compatibility Statement

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

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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

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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. 2: APPENDIX 1- CT/AMI Accessories list

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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.
Device class:	II b
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.

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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.

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12 Reference Training Checklist

The following checklist is designed to serve as a reference point while training customers on the Vereos PET/CT System. If any sections are not completed, please provide a brief explanation. One copy of the checklist should remain at the site, and the Clinical Education Specialist will keep one copy.

Safety Notifications

_____ I understand the following safety notifications for operating the system in a proper and safe manner and will comply with these safety notifications:

☐	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 scanner for any application until you are sure that the image performance Quality Assurance is completed and the Preventative Maintenance program is up to date.
☐	Do not use the 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 scanner for any purpose other than those for which it is intended.
☐	Know the country, regional, and local safety regulations that govern the use of the system at your site.
☐	Check to make sure covers, cables, floor troughs, or table catchers are not exposed that may harm an individual.
☐	Know the locations of emergency stop buttons and releases
☐	During all movements of the gantry and patient table, keep the patient under constant observation.
☐	Do not remove covers or cables from the equipment.
☐	Do not use explosive disinfecting sprays while cleaning the scanner.
☐	Know where the radiation warning lamps are on the scanner.

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☐	Make sure to use radiation protection devices and dedicated pediatric exam cards to reduce radiation dose. Make sure to enter the patient's age correctly when using pediatric exam cards.
☐	When lowering the patient table, please check to make sure that nothing is under the table in order to avoid collision and to ensure patient safety.
☐	Dose alert and dose notifications for XR-29.
☐	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. Never use absolute HU 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.
☐	Know the "As Low As Reasonably Achievable" (ALARA) principles for radiation safety.
☐	Know the half-life and half-value layers for any radioactive substance in use.
☐	Follow the Nuclear Regulatory Commission, as well as your country, regional, local, and site policies on handling radioactive material.

Notes/Comments:

Table and Gantry Controls

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

☐	Movement of sub pallet and patient pallet
☐	Gantry control panel

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☐	CT laser lights and buttons
☐	Error message recovery
☐	Emergency stop button on scan control box
☐	Phantom holder and placement
☐	Gantry emergency stop buttons
☐	System emergency stop button on wall
☐	Radiation warning lights on scanner and room

Notes/Comments:

Operator's Console Overview

_____ I can perform the following system operations:

☐	System logout & login
☐	System weekly shutdown/start-up
☐	Recover from an emergency stop error
☐	Use scan bar buttons – manual, auto, pause, enable
☐	Voice Manager
☐	Bug Report submission

Notes/Comments:

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Quality Assurance

_____ I can perform the following quality assurance tests:

☐	PET Daily QA
☐	PET monthly uniformity & 576 SUV Validation/256 SUV Validation every 2 months
☐	CT short tube conditioning
☐	CT weekly air calibrations – full, short
☐	CT weekly Head Quick IQ
☐	CT monthly constancy & Body QC

Notes/Comments:

Exam Card Manager

_____ I understand the PET acquisition parameters listed below, as well as, when and how to adjust them:

☐	Measure dose, time, weight, and enter into PET scan parameters
☐	Bed length and overlap
☐	Bed times – constant/variable, by time, by counts
☐	PET reconstruction protocol selections and when to use them (OSEM and AR)
☐	FOV options for CT and PET
☐	CTAC shared planning
☐	Wait for start – dynamic, cardiac

Notes/Comments:

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_____ I understand the CT acquisition parameters listed below as well as when and how to adjust them:

☐	Previous Surview
☐	Surview options – frontal, lateral, dual
☐	Adjust KV
☐	Adjust DRI (mAs) – option to set max & min
☐	DRI liver/brain boost
☐	Injection – manual, timed, bolus tracker
☐	Bolus tracker – locator, tracker, pre and post injection delay, ROI, re-plan
☐	Auto scan time
☐	Procedure – what does this link to
☐	Location – how to link images
☐	Storage devices (CTAC image destination)
☐	Dose modulation – Z modulation, 3D modulation

Notes/Comments:

_____ I am able to build the following exam cards and adjust necessary parameters:

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☐	Exam card groups – save, save as, organize, change name
☐	PET/CT exam card – with ldCT and diagnostic CT
☐	Oncology PET/CT exam card
☐	Neurology PET/CT exam card
☐	Radiation Therapy PET/CT exam card
☐	Exam cards should be built from reference exam cards

Notes/Comments:

Scanning Performance

_____ I can identify the following icons and know their usage for scanning:

☐	Worklists- HIS/RIS – how to pull patients into the Directory page
☐	Data entry required fields (red asterisk, yellow box)
☐	Exam card selection
☐	Patient positioning
☐	Surview – in/out, frontal, lateral, dual
☐	Plan PET/CT scan – planning box
☐	Plan diagnostic CT scan – planning box, difference between PET/CT and diagnostic CT
☐	Scan ruler – extend, repeat, next, injection, bubbles, timer
☐	End exam and continue working
☐	End exam

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☐	Sync Right – P3T protocols (Personalized Patient Protocol Technology)
☐	Dose summary page – what is total dose

Notes/Comments:

Reconstruction

_____ I recognize each of the following PET reconstruction methods and how to perform PET manual reconstructions:

☐	Concurrent reconstruction PET (OSEM vs. AR and single vs. multi)
☐	PET reconstruction selection – group, protocols
☐	Build and save PET reconstruction protocol, delete protocol
☐	PET reconstruction sorter – static, dynamic, cardiac, respiratory gating, injection
☐	Series modifier and when to use it
☐	Point Spread Function – reconstruction filter
☐	PET iterations and subsets
☐	Gaussian filter
☐	Edit PET reconstruction protocol
☐	Recon monitor – how to monitor PET reconstructions
☐	Manually reconstruct a PET scan, how to edit sorter options

Notes/Comments:

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Image Maintenance

_____ I recognize the Preference settings for PET and CT and how to adjust them:

☐	Scanner Preferences
☐	PET preferences
☐	CT preferences

Notes/Comments:

_____ I recognize the following options on the system and what it does:

☐	Directory page/ study files/ series files
☐	Devices – systems devices and remote devices
☐	Sorting study and series options
☐	Right click options for studies and series
☐	Copy to – send items to destinations
☐	Delete a study or series

_____ I recognize the following options on the system and what it does:

☐	Review icon – for all viewers
☐	Analysis icon – for processing packages
☐	Multimedia Viewer – view non-DICOM images

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☐	Quick Review – Parameters page
☐	Burn CD/DVD – Save DVD Ram
☐	Queue Manager – monitor transfers, processing, printing

Notes/Comments:

Viewers

_____ I can launch the CT Viewer and recognize the items listed below:

☐	2D – layout selections, compare
☐	Slab – MIP, MPR, Batch
☐	Volume – clipping tools
☐	Quick Review – viewing options, parameters page

Notes/Comments:

_____ I can launch the NM Viewer/Fusion Viewer and display images:

☐	Loading studies – single, multiple
☐	Add to running application
☐	Display tab – scroll, pan, zoom, color
☐	Registration tab – automatic, manual

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☐	Layouts tab – preference layouts, custom layouts, layout editor
☐	Series tab
☐	3D ROI tab -
☐	SUV methods – obtain auto SUV threshold, % max, manual
☐	Compare studies – load, match and link together
☐	Save- images, display, save all, registered images

Notes/Comments:

Advanced Procedures

_____ I recognize the procedures below and the steps to perform:

☐	Respiratory Gating – PET/CT Prospective
☐	Respiratory Gating – PET/CT Retrospective
☐	Cardiac Acquisition – Rb82, NH3, FDG
☐	Cardiac Reslicing
☐	Cardiac Processing – AutoQuant, ECTB, Corridor 4DM
☐	Neurology Acquisition
☐	Brain Reslicing
☐	NeuroQ
☐	PET/CT Alignment QC
☐	Brain Perfusion
☐	Functional CT
☐	Heartbeat CS

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☐	CCT
☐	Acceptance Testing Q&A with Physicist or responsible party

Notes/Comments:

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