XEOS MEDICAL AURA 10 PET-CT

INSTRUCTIONS FOR USE

DOCUMENT NUMBER: IFU EN 20220301
VERSION: 2
DATE OF LAST ISSUE: 20220520

xeos

Legal notice



XEOS MEDICAL
Ottergemsesteenweg-Zuid 808 Bus 358
Gent 9000 BELGIUM
+32 9 277 77 94

For more information on XEOS Medical products, please visit www.XEOS.care

© 2022 XEOS Medical

All rights reserved.

No parts of this work may be reproduced, copied, adapted or transmitted in any form or by any means without the written permission of XEOS Medical.

XEOS Medical and the AURA 10 PET-CT are trademarks of XEOS Medical. All other trademarks are held by their respective owners and are used in an editorial fashion with no intention of infringement.

Products and services may not be available for your local area. Please contact your local sales representative for availability of information. XEOS Medical diligently strives to provide as accurate information as possible, but shall not be responsible for any typographical error. XEOS Medical shall under no circumstances be liable for any loss of profit or any other commercial damage arising or allegedly caused by the use or inability to use any information, apparatus, method or process disclosed in this document. Consult national authorities to determine any local operational requirements.

Any serious incident that has occurred in relation to the device shall be reported to the XEOS Medical and the competent authority of the country in which the user and/or the patient is established.

XEOS Medical reserves the right to make changes to this document without prior notice. The original version of this document is in English.

XEOS Medical assumes no liability for use of this document if any unauthorized changes to the content or format have been made.

Foreword

This manual was created by XEOS Medical. It is intended to guide the user on how to setup and use the AURA 10 PET-CT, developed by XEOS Medical. XEOS Medical or its authorized agent will install the AURA 10 PET-CT.

After installation, the user must turn the system on and login to initiate the software. Please review the required setup procedures in SECTION 3 of this manual before continuing.

Intended Use

The AURA 10 PET-CT is a cabinet PET-CT system. It is a compact and mobile specimen imaging system that combines positron emission tomography (PET) with X-ray computed tomography (CT) to respectively measure the amount of radiotracer in a tissue specimen and visualize the density of that tissue specimen. The CT image is a 3-dimensional structural density image. The PET image shows the 3-dimensional distribution of a radiotracer, administered to the patient before resection. The PET, CT or co-registered PET-CT images are visualized by the AURA 10 PET-CT. The PET and CT portions of the system may be used independently or in combination. The PET and CT images may be transferred to other systems for storage and review.

The AURA 10 PET-CT is for In Vitro Diagnostic Use. The device is intended for near-patient use. The AURA 10 PET-CT is not intended to detect a specific disorder, condition or risk factor. The AURA 10 PET-CT is not validated for performing margin assessment.



The AURA 10 PET-CT is automated and semi-quantitative (the visualization of structure and radiotracer distribution is qualitative and the density (Hounsfield units) and radiotracer uptake (Bq/mL) is quantitative).

The AURA 10 PET-CT is to be used with a specimen container, which is a single-use consumable component which has the purpose of holding the resected tissue specimen and keeping track of the orientation of the specimen. The specimen is placed in the specimen container. The specimen container is placed on the scanner platform and is (automatically) moved inside the scanner for the acquisition. After the acquisition is done, the specimen container is automatically moved outside the scanner.

The testing population of the AURA 10 PET-CT is any patient over 18 years old undergoing resective surgery, excluding pregnant woman.

The test principle is as follows. The AURA 10 PET-CT acquires two 3-dimensional images of the specimen: an X-ray computed tomography and a positron emission tomography image. The solution then visualizes these images on a display. The CT image is reconstructed by acquiring planar X-ray projections of the specimen in different angles and using back projection techniques to reconstruct an image of the density distribution of the specimen. This represents the anatomical structure of the specimen. To obtain a PET image, the patient is injected with a radiotracer. During PET image acquisition, the gamma rays emitted by the decaying radiotracer are detected by the PET detectors. Based on millions of these detections, iterative reconstruction techniques can distill the original radiotracer distribution within the specimen. The PET and CT images are then displayed in a fused format, so they are geometrically overlaid and a specific point in the PET and CT image refer to the same physical point in space.

The intended users of the AURA 10 PET-CT are healthcare professionals such as surgeons, nurses, radiologists, nuclear medicine professionals, physicians and pathologists.

The intended use environment of the AURA 10 PET-CT is the hospital. Apart from the space occupied by the system and an ambient temperature and humidity that are within common limits, there are no other requirements for the environment.

The type of specimen required is resected tissue from a patient undergoing resective surgery.

The system can operate as a stand-alone device. If connected to a network, it is critical that measures are implemented on the host network to reduce the risk to patients by decreasing the likelihood that device

functionality is intentionally or unintentionally compromised by inadequate cybersecurity. By default, the AURA 10 PET-CT rejects all outside network connections to maintain secure operation.

The AURA 10 PET-CT should be stored between acquisitions. It should be taken out of storage before use, plugged into a power socket, connected to a wireless or local area network and switched on. Brief calibration and/or quality control measurements are necessary for PET and CT, which can be performed automatically. Periodic calibration is required and requires phantom measurements. Yearly preventive maintenance is required.

1. INTRODUCTION

This manual was created by XEOS Medical. It is intended to guide the user on how to receive and use the AURA 10 PET-CT hardware and software, developed by XEOS Medical.

After installation, the user must turn the system on and login. At a minimum, please review the required setup and safety procedures in this manual before attempting to operate the system.

1.1 ADDITIONAL INFORMATION

For further technical assistance, please contact:

XEOS Medical
Ottergemsesteenweg-Zuid 808 Bus 358
Gent 9000 BELGIUM
+32 9 277 77 94
www.XEOS.care
support@xeos.care

1.2 SYMBOLS

1.2.1 WARNING AND CAUTION SYMBOLS

The following symbols show how warnings, cautions, instructions and notes appear in this document. The text explains their intended use.



ELECTRICITY HAZARD
Warns the reader of potential electrocution should the reader ignore the warning and deliberately use specialized tools to open a sealed electrical cabinet and handle its contents (ISO 7010, W012).

Note: no tools are provided by XEOS Medical.



DANGER/WARNING/CAUTION
The manual shall be consulted in all cases where this symbol is marked, in order to find out the nature of the potential hazards and any actions which have to be taken to avoid them (ISO 7010, W001).

DANGER: A danger safety notice indicates a hazardous situation of direct, immediate danger for a potential serious injury to a user, engineer, patient or any other person.

WARNING: A warning safety notice indicates a hazardous situation which can lead to a potential serious injury to a user, engineer, patient or any other person.

CAUTION: A caution safety notice indicates a hazardous situation which can lead to a potential minor injury to a user, engineer, patient or any other person.



REFER TO INSTRUCTION MANUAL/BOOKLET
An instruction is a direction which, if it is not followed, can cause damage to the equipment described in this document or any other equipment or goods and can cause environmental pollution (ISO 7010, M002).



LIFTING HAZARD
Cautions the reader to use care in lifting heavy equipment to avoid personal injury and damage to the equipment (ISO 3864-2, LB-0017).



RADIOACTIVE MATERIALS OR IONIZING RADIATION
Warns the reader that ionized radiation is emitted into the labelled area when the x-ray beam is energized. The AURA 10 PET-CT has safety interlocks to prevent the labelled area from being accessed while the x-ray beam is energized (ISO 7010, W003).



BIOLOGICAL HAZARD
Warns the reader to use appropriate protection (such as surgical gloves or an approved specimen container) to avoid exposure to potentially infections materials such as patient tissue samples (ISO 7010, W009).



FLAMMABILITY HAZARD
Warns the reader against the risk of fire (ISO 7010, W021).



GENERAL PROHIBITION SIGN
A prohibition is a direction which, if it is not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution (ISO 7010, P001).

1.3 PRODUCT LABELS

1.3.1 X-RAY HIGH VOLTAGE POWER SUPPLY



Figure 01 – Label with warning for X-ray high voltage power supply

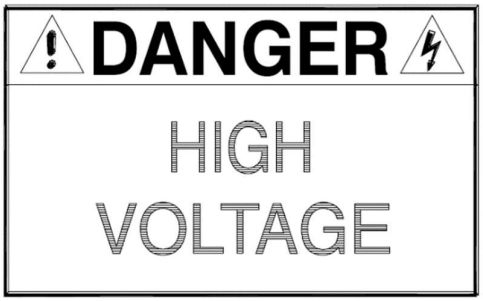


Figure 02 – Label with warning for X-ray high voltage power supply

1.3.2 X-RAY DETECTOR



Figure 03 – Label example detector

1.3.3 X-RAY TUBE

CAUTION RADIATION

THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED

Figure 04 – Label example Caution Radiation

CAUTION
BERYLLIUM
X-RAY
WINDOW

Figure 05 – Label example Caution Beryllium X-ray Window

Manufactured by Micro X-Ray Inc.	
Part Number: 18132	Max Voltage: 60 kV
Serial Number: 06604	Max Current: 1mA
Target Material: W	Max Power: 50W
Mfg Date: 4/29/2021	Max Fil. Current : 1.7A
Warranty Exp: 4/29/2022	Max Temp: 55°C

Figure 06 – Label example type label

1.3.4 MONITOR

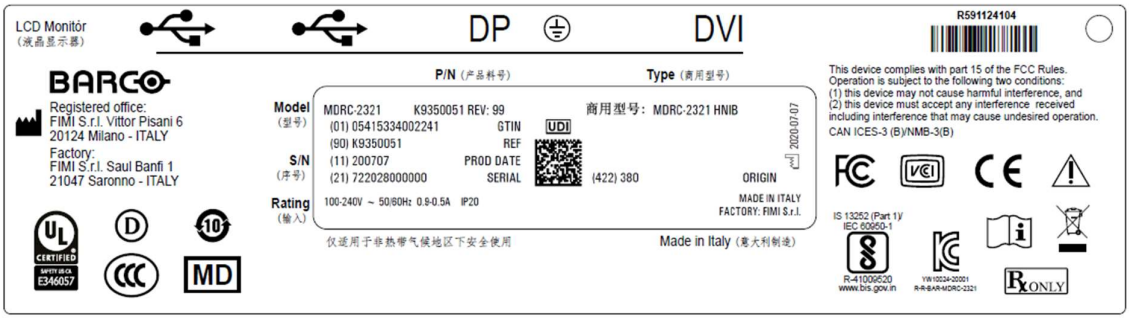


Figure 07 – Label example monitor

1.3.5 SYSTEM TYPE LABEL

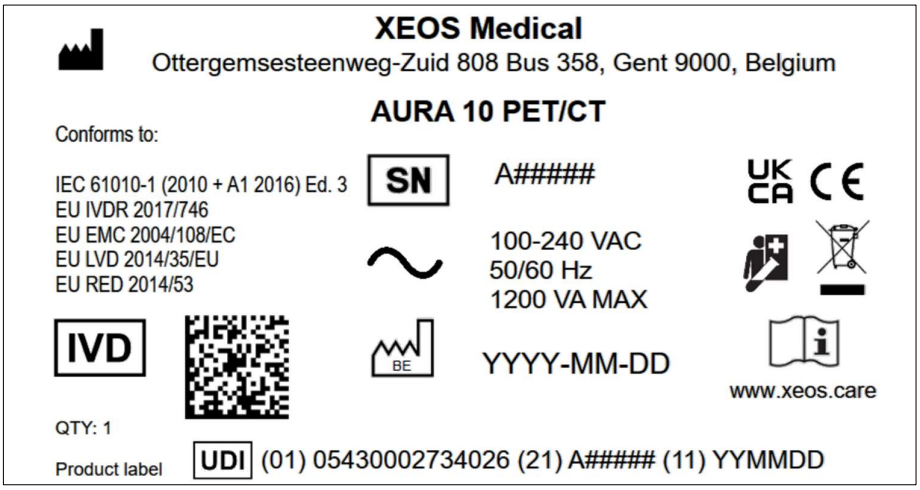


Figure 08 – Type label, for illustration purposes only

1.3.6 FUSE



Figure 09 – Fuse label

1.3.7 PRODUCT LABEL



MANUFACTURER
Indicates the natural or legal person with responsibility for design and/or manufacture of a medical device (ISO 7000, 3082).



DATE OF MANUFACTURE
Indicates when the medical device was manufactured (ISO 15223-1, 5.1.3).

'BE' indicates that the device is manufactured in Belgium. (ISO 15223-1, 5.1.11)



SERIAL NUMBER
Indicates the manufacturer's serial number so that a specific medical device can be identified (ISO 15223-1, 5.1.7).



ALTERNATING CURRENT
Indicates that the device operates with alternating current indifferently (IEC 61010-1, Table 1, Symbol 2).



CONSULT INSTRUCTIONS FOR USE
Indicates the need for the user to consult the instructions for use (ISO 7000, 1051; ISO 15223-1, 5.4.3).



WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT
Indicates waste electrical and electronic equipment (WEEE Directive 2012/19/EU).



CE MARKING OF CONFORMITY
Indicates compliance of the device with EU IVD Regulation 2016/746, EU EMC Directive 2004/108/EC, EU LVD 2014/35/EU and EU RED 2014/53.



UK CONFORMITY ASSESSED
Indicates compliance of the device with UK regulations.



IN VITRO DIAGNOSTIC MEDICAL DEVICE
Indicates a medical device that is intended to be used as an in vitro diagnostic medical device or its accessories (ISO 15223-1, 5.5.1).



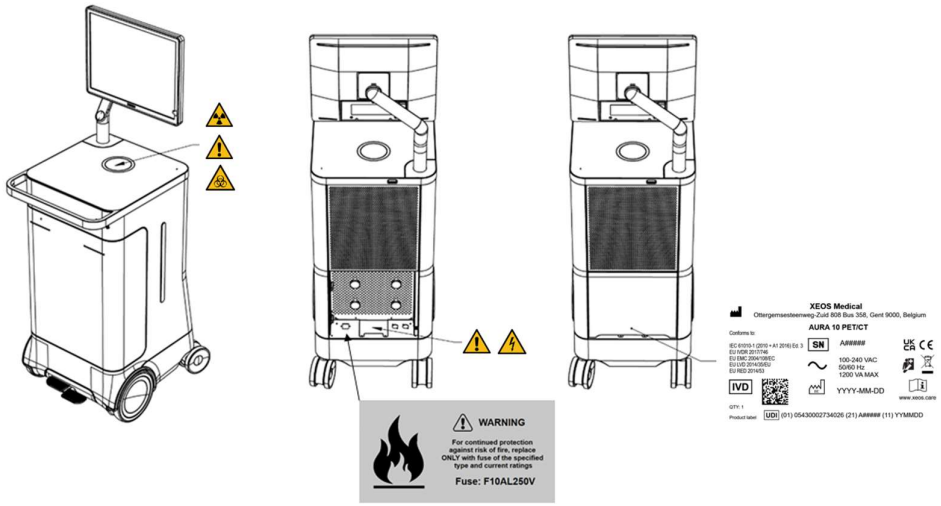
UNIQUE DEVICE IDENTIFIER
Indicates a carrier that contains Unique Device Identifier information (ISO 15223-1, 5.7.10).



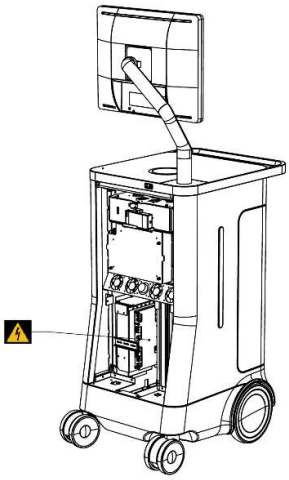
FOR NEAR PATIENT TESTING
Indicates that the device is to be used in a near patient setting by a health professional (self-defined).

1.4 ARCHITECTURE DRAWING WITH LABEL LOCATIONS

1.4.1 EXTERIOR LABEL LOCATIONS



1.4.2 SERVICE-ONLY-ACCESSIBLE LABEL LOCATIONS



1.4.3 SOFTWARE LABELS

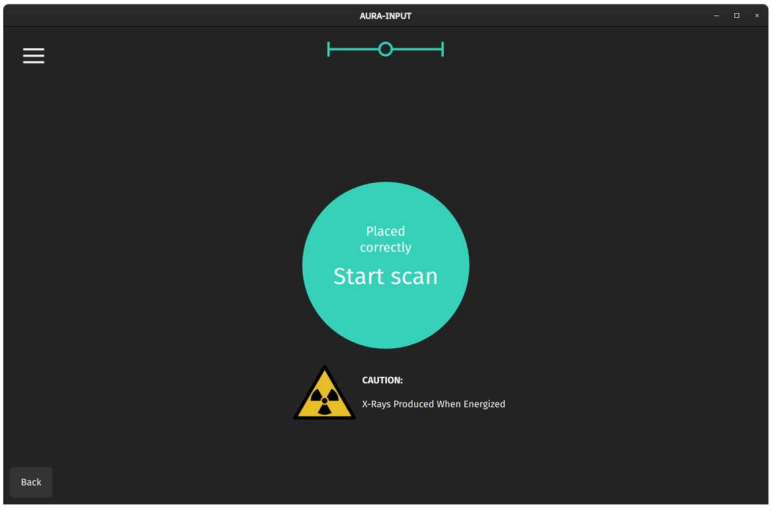


Figure 10 – X-Rays Produced When Energized

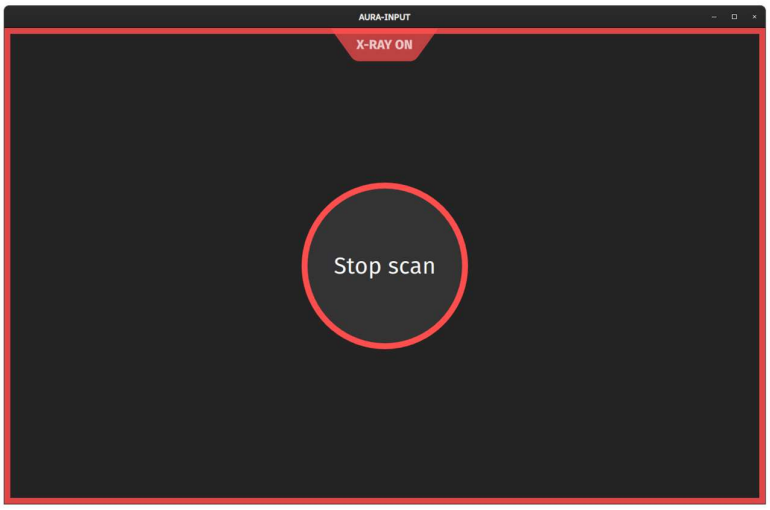


Figure 11 – X-RAY ON and ‘Stop scan’

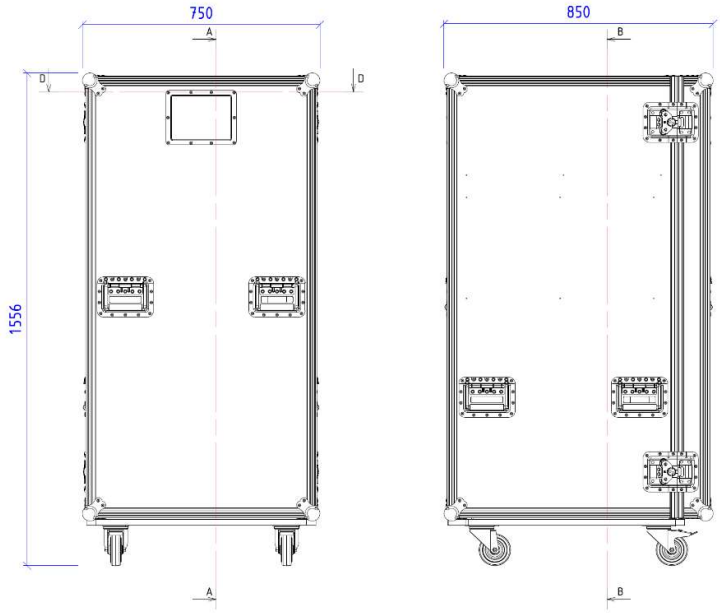
2. RECEIVING, MOVING, STORING, INSTALLATION AND CONFIGURATION

Installation and configuration are performed by a XEOS Medical trained and authorized service engineer. Contact XEOS Medical for more information.

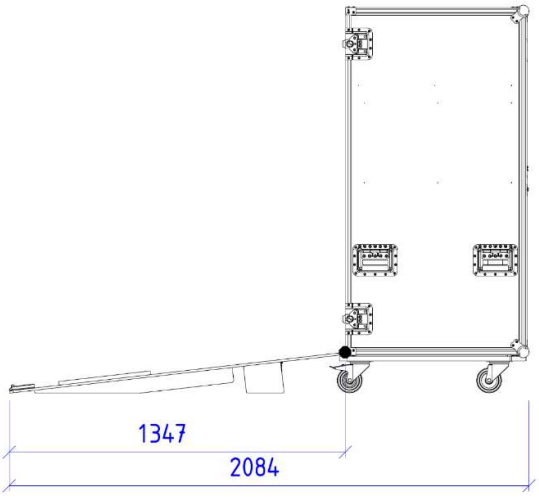


2.1 Preparation for arrival

The AURA 10 PET-CT arrives in a custom designed shipping case. The shipping case weighs 250 kilograms when loaded and 100 kilograms when empty. The case has the dimensions shown below. Please make sure your facility has adequate space for intake and receival.



For unloading, a ramp in the shipping case must be lowered. The space requirements to lower the ramp and unload the system are shown below. Please make sure adequate space is available to open the case and lower the ramp so that XEOS or their representative can unpack and install the system.



2.2 Inspecting the shipping case on arrival

The AURA 10 PET-CT arrives in a reusable wheeled shipping case. Have the shipping agent transport the case to an area where it can be kept safe from theft, damage, and environmental extremes until the authorized representative of XEOS Medical can install the system.

Check the shipping case for any damage. If it appears to be damaged, contact XEOS Medical at +32 (0)9 277 77 94 or support@xeos.care.

The shipping case is 156 cm (61 in) tall. It contains the device, the device's display monitor and support arm, the device's region-specific power cable, the AURA 10 Calibration Phantom, and the device manual(s).

2.3 Setting/unsetting the shipping case brake

The AURA 10 PET-CT shipping case is wheeled and has brakes on all four wheels which may be set to keep the case from rolling. At least 2 of the wheel brakes should always be set when the case is not being moved manually.

2.4 Lifting and transporting the shipping case



CAUTION: The case weighs maximally 250 kilograms (550 lbs) loaded and 100 kilograms (220 lbs) unloaded. The packaged system should be kept upright as indicated on the shipping case.

CAUTION: The shipping case should not be moved up or down an incline by a single person.

The shipping case is wheeled and may be transported by pushing or pulling the case by one person on a flat surface. The case may also be moved by pallet jack or forklift by a *qualified* forklift operator.

2.5 Storing the shipping case

The shipping case whether loaded or unloaded should be stored between 0-40°C at a relative humidity of less than 75% (non-condensing).

2.6 Unpacking and installing the device



The AURA 10 PET-CT will be unpacked and assembled on site by an authorized representative of XEOS Medical. Please contact XEOS Medical at +32 (0)9 277 77 94 or support@xeos.care or your local representative when your system arrives to arrange for system setup if it has not already been arranged.

2.7 Location of the device

The AURA 10 PET-CT has ventilation and the power entry connector at the rear of the cabinet.

When preparing a location for its install or while relocating the AURA 10 PET-CT during regular use, be sure to leave at least 30 centimeters (12 in) of clear space behind the unit to allow proper air flow and to allow access to disconnect the power cord.

2.8 Warnings



- Please read the instructions for use carefully before using the system.
- Do not use the system in any other way than its intended use as described in these instructions for use. Otherwise, the protection provided by the AURA 10 PET-CT may be impaired. If in doubt, contact XEOS Medical.
- Do NOT use the system with any other specimen container than that provided by XEOS Medical.
- Not all power cords have the same rating. Do not use any other power cord with this system other than the one provided. Do not use the power cord from the AURA 10 PET-CT on any other equipment.
- Do not access the interior of the device.
- The AURA 10 PET-CT is tested to the highest international standards. However, it is recommended that you contact your national authorities regarding any local operational requirements.
- The AURA 10 PET-CT is not intended for public use. It must be located in an area where the general public cannot access the AURA 10 PET-CT without an operator being present.

2.9 General precautions



The following precautions must be taken to prevent damage to the AURA 10 PET-CT.

- Never connect or disconnect communication and/or power cables, while the system power is on. Damage to the system electronics or hard drives may occur if the cables are connected / disconnected while the power is on.
- The camera system is fragile and care should be taken to prevent camera damage. The camera system must never be mishandled, hit, knocked or dropped.
- The AURA 10 PET-CT has an image calibration mode. Image calibration must be completed daily on days in which the system is used to ensure proper system function. Please refer to the Calibration Procedure in these instructions for use.
- Caution – Use of controls or adjustments to performance of procedures other than those specified in these instructions for use may result in hazardous radiation exposure.
- XEOS Medical suggest the device use should include discussion with a nuclear medicine professional.

2.10 Radiation protection

X-ray radiation can cause serious damage to health. Always observe care operating x-ray equipment, even if shielded. Some of the effects of x-ray radiation are cumulative and may extend over a period of time. Therefore, the X-ray operator should minimize x-ray exposure as much as possible. Do not use the system in any other way than its intended use as described in these instructions for use. Otherwise, the protection provided by the AURA 10 PET-CT may be impaired.

The AURA 10 PET-CT provides shielding of its own internally generated x-rays. The shielding blocks x-ray exposure to less than 5 µSv/hr. In addition, the door provides 2 interlocks meeting “FDA X-ray cabinet” (CFR 1020.40) specifications. All service access points are also interlocked.

Physical damage to the system could potentially damage the internal x-ray shielding. Therefore, the system should be observed for damage at each use. If serious damage is observed, contact support@xeos.care and do not operate the system.

The user is instructed to notify the person in charge of radiation safety at the installation facility to advise staff who will use the AURA 10 PET-CT on applicable radiation safety procedures for their location.

2.11 Monitoring of personnel

Individual radiation monitoring tracks the amount of ionizing radiation a person has been exposed to. It monitors the safety of the operators and it helps check that safety measures regarding ionizing radiation are adequate. Inadequate or improper protection can lead to serious damage to health.

To measure radiation, personal radiation dosimeters are typically used. They provide an indication of the amount of radiation the operator was exposed to. XEOS Medical recommends following the radiation monitoring policies of your institution and consult the responsible for radiation protection at your institution regarding the need to wear a radiation dosimeter.

2.12 Configuration of the device

The AURA 10 PET-CT will be configured for you on installation by an authorized representative of XEOS Medical. This representative will make sure the system is properly configured before leaving. To determine yourself if the system is properly configured, note that the “breathing” animation lights will come on when the main power switch is turned to the on position, and that the log-in screen becomes available when the standby switch (see Section 10) is pressed for at least 3 seconds.

2.13 Cybersecurity

Device security is a shared responsibility between XEOS Medical and the installation facility. Failure to maintain cybersecurity can result in compromised device functionality, loss of data (medical or personal) availability or integrity, or exposure of other connected devices or networks to security threats.

XEOS Medical maintains a set of cybersecurity controls to improve the cybersecurity of its units and to maintain their functionality and safety. The AURA 10 PET-CT implements the following measures to reduce the attack surface exposed by the system to the outside world:

- Password-protected login: any user must provide the correct credentials to use the functions of the system or access its data.
- Limited user environment: once logged in, the user is only allowed access to the AURA FLOW software in order to operate the AURA 10 PET-CT, retrieve scheduled procedures from a worklist server, and transfer data to a remote and trusted PACS. It is NOT possible for the user to access any other common but potentially risky computer features such as a web browser, OS and network settings, system configuration files, software installers, text editors, productivity apps, media players, web or app stores, social media apps, file-sharing programs, cloud storage apps, or other executables.
- Whitelist-only connection policy: only IP addresses and ports specifically listed on the system’s firewall whitelist are allowed to make incoming connections to the system. By default, the whitelist is setup such that the AURA 10 PET-CT only responds to requests it initiates. Access to the whitelist is protected by credentials known only to XEOS service personnel. Only XEOS service personnel may update the whitelist at customer request and subject to XEOS’ discretion.
- Rejection of USB mass-storage devices: the system is configured to not recognize and not mount any USB mass-storage devices physically connected to it in order to prevent unauthorized copying of data out of the system. All data transfer should be done through use of the AURA FLOW software DICOM PACS capabilities to a trusted PACS on a closed, professionally managed network.

- Compartmentalization of read, write, and execute privileges: the AURA 10 PET-CT uses the time-tested read, write, and execute privileges underpinning the Linux operating system family to compartmentalize the privileges of different processes on the system and their access to data to reduce the impact of unknown or new but unpatched security vulnerabilities.

Despite efforts to reduce the attack surface of the AURA 10 PET-CT system, the installation facility should never connect the system directly to the Internet. The system should always be operated on a closed, professionally managed network. In particular, the installation facility should make every effort to protect against man-in-the-middle attacks between the AURA 10 PET-CT and any DICOM nodes it might be connected to such as a scheduled procedure worklist or PACS system.

In case of a cybersecurity event, disconnect the system from the network and contact XEOS Medical immediately.

3. PERFORMANCE SPECIFICATIONS



WARNING: The AURA 10 PET-CT is not validated for margin assessment.

WARNING: The AURA 10 PET-CT is not intended to be used with pregnant women and minors.

WARNING: Specimen PET-CT cannot substitute interpretation of a specimen by an anatomical pathologist. Evaluation of the imaged specimen by standard anatomical pathology is always required after use of the device.

3.1 Analytical performance

Analytical performance of the AURA 10 PET-CT was evaluated regarding accuracy of measurement (trueness and precision), as well as different imaging characteristics relevant for PET and CT imaging.

As the system provides two three dimensional (3D) images (PET + CT), the accuracy of measurement needs to be demonstrated for both images. Accuracy of imaging entails that the reconstructed image is an accurate representation of the 3D distribution of the relevant parameter (density for CT and radiotracer concentration for PET) in the object that was imaged. This was validated for both PET and CT imaging by demonstrating that the reconstructed PET and CT images of a phantom adequately represent the phantom that was imaged. This was done with the following boundary conditions:

- CT: density trueness was validated by demonstrating that the average Hounsfield Units (HU) of several regions within a phantom was within 50 HU of their known HU value. The standard deviation was less than 100 HU within each of these regions. Spatial mapping trueness was validated by assuring that the distance between specific landmarks in the CT image was within 0.5mm of their known distance. These measurements were repeated to validate precision.
- PET: radiotracer concentration trueness was validated by demonstrating that the reconstructed radiotracer concentration in the PET image (in kBq/cc) was within 10% of the known radiotracer concentration. The measurements were repeated to validate precision.
- PET-CT coregistration: spatial coregistration of PET and CT images was validated by demonstrating that the distance between a known feature on PET and CT images was no more than 1mm. This measurement was repeated to validate precision.

The following PET imaging characteristics were validated through phantom measurements:

- The measuring range is from 0 to 50 kBq/cc.
- Spatial resolution: is below 1mm.
- Count rate performance: the PET system supports activities of up to 4MBq in the specimen.
- Detection sensitivity: in the center of the field of view is at least 6%.
- Attenuation and scatter correction accuracy is validated by demonstrating that the spill-over into cold regions is below 20%.

The following CT imaging characteristics were validated through phantom measurements:

- The measuring range is from -1000 HU to +2500 HU.
- Modulation transfer function: is at least 10% at 4 lp/mm.
- Noise power spectrum: is below 30 HU2 mm3.
- Signal-to-noise ratio: is at least 10.
- Degree of cupping: is below 20HU per mm.

- Metal artefact correction: is validated by demonstrating that no streak artefacts occur around metal objects.

4. SPECIMEN INTERACTION



The AURA 10 PET-CT should only be used with XEOS Medical's specimen container and specimen needles. The specimen container and specimen needles are designed to: keep the specimen secure, maintain the cleanliness of the inside of the system, and to provide good image quality. Imaging specimens without XEOS Medical's specimen container may lead to system contamination and sub-optimal imaging performance. If the interior of the system is contaminated due to failure to use XEOS Medical's specimen container, contact service (support@xeos.care) immediately and do not use the system until advised it is OK to do so.

4.1 Warnings and precautions



WARNING: Only use a XEOS approved specimen container and specimen needles in combination with the AURA 10 PET-CT. This is required to ensure proper orientation of the specimen container in the device.

WARNING: Take care not to spill biohazardous material.

WARNING: Take care that nothing blocks the door of the loading zone when closing.

5. CLEANING & DISINFECTION

For general cleaning of e.g. dust from the exterior, a damp cloth may be used. However, for normal use of the system in a hospital environment the system should be regularly disinfected according to the following guidelines.

5.1 Warnings



WARNING: All appropriate policies and procedures should be followed to avoid contamination of the staff, patients and equipment. All existing universal precautions should be extended to avoid potential contamination. The user is responsible for selecting a disinfection procedure.

WARNING: Unplug the power cable from the mains power input before cleaning the device.

CAUTION: Take care not to damage or scratch the glass components. Be careful with rings or other jewelry and do not apply excessive pressure on the glass components.

CAUTION: Do not apply or spray liquid directly on the device as excess liquid may cause damage to internal electronics. Instead, apply the liquid to a cleaning cloth.

5.2 General guidelines for cleanliness

Samples containing biological specimens can harbor infectious agents that are hazardous to your health. Follow appropriate biosafety procedures; wear gloves when handling tissue specimens or any materials which they come in contact with.

The AURA 10 PET-CT MUST be used with the specimen container provided by XEOS. The specimen container is designed to keep the interior of the imager clean without user intervention.

5.3 Cleaning directions

Clean the display(s) using a sponge, cleaning cloth or soft tissue, lightly moistened with a recognized cleaning product for medical equipment. Read and follow all label instructions on the cleaning product. In case of doubt about a certain cleaning product, use plain water.

Possible cleaning solutions are:

- 70% isopropyl alcohol;
- 1.6% aqueous ammonia,
- Cidex® (2.4% glutaraldehyde solution);
- Sodium hypochlorite (bleach) 10%;
- “Green soap” (USP);
- 0.5% chlorehexidine in 70% isopropyl alcohol;
- Like Cleansafe® optical cleaning liquid.



Do not use following products:

- Alcohol/solvents at higher concentration > 70%;
- Acetone
- Strong alkalis lye, strong solvents;
- Acid;
- Detergents with fluoride;
- Detergents with ammonia at higher concentration > 1.6%;
- Detergents with abrasives;
- Steel wool;
- Sponge with abrasives;
- Steel blades;
- Cloth with steel thread.

5.4 Disinfection safety directions



WARNING: Using a disinfectant that can form an explosive or flammable gas mixtures is hazardous to life and health because of explosion risk. Switch the equipment off before disinfecting. Allow the gas mixture to evaporate before switching the system back on.

WARNING: Use gloves where there could be contact with the skin when handling potentially infectious substances or surfaces (such as human samples).

To disinfect the device:

- Do not use any corrosive, soluble or gaseous disinfectants.
- Use of spray disinfection can cause malfunctions due to ingress of the disinfectant into the equipment. Disinfect all parts of the unit, including the accessories and connection cables by just wiping them. Switch off the system and cover the cooled system carefully before performing a room disinfection using nebulizer.
- Using unsuitable disinfectants can cause discoloration and damage of the surface of the equipment.

5.5 Disinfection

To disinfect the device, use only disinfectants and disinfection methods that are approved by XEOS Medical and that correspond to national legislation and guidelines as well as explosion protection. If you plan to use other disinfectants, approval of XEOS Medical is needed before use, as most disinfectants can damage the device. UV disinfection is not allowed.

Perform the procedure following the instructions for use, the disposal instructions and the safety instructions of the selected disinfectants and tools and of the hospital.

Items contaminated with blood or body fluids, which may contain blood-borne pathogens, should be cleaned and then receive intermediate level disinfection with a product having an EPA-registered claim for activity against hepatitis B.

5.5.1 Approved disinfectants

XEOS Medical recommends an isopropyl alcohol solution of up to 70% for disinfecting the exterior surfaces of the device.

5.5.2 Internal chamber

The internal chamber is not intended for cleaning by the user due to containing sensitive components. To maintain the cleanliness of the interior of the system it is mandatory that users always use the specimen container provided by XEOS Medical. Using the system without the specimen container provided by XEOS Medical may damage the system and will require servicing.

The entry of the internal chamber may be cleaned and disinfected by the user with an approved disinfectant when the specimen container receptacle is in the loading position.



CAUTION: DO NOT attempt to clean or disinfect any further into the internal chamber than the top of the specimen container receptacle.

CAUTION: Take great care to avoid spills into the internal chamber since a spill of any hazardous substance into the chamber requires a special cleaning by XEOS service.

If a spill should occur into the internal chamber, contact XEOS Medical service (support@xeos.care) before proceeding.

5.5.3 External

Clean and disinfect the external surfaces of the system by wiping all surfaces down with an approved disinfectant. No harsh abrasives, chemicals or cleaners should be used on the system. The device should be cleaned and disinfected after each surgical procedure.

Do not allow any moisture whatsoever to come in contact with the electrical components of the unit.

To clean and disinfect the exterior of the equipment:

1. Stop and turn off the system



WARNING: When the equipment is going to be cleaned, be sure to turn off the main power of the system. Never use anhydrous or very high solvency alcohols, benzine, thinner or any other flammable cleaning agent. Otherwise, this may result in fire or electric shock.

2. Wipe down the exterior of the system with an approved disinfectant.



CAUTION: Make sure no liquid gets in the device.

CAUTION: Clean the equipment with only a little moisture. Do not spray disinfectants or detergents directly on the equipment. Do not pour liquid directly on the equipment. Doing so may damage the interior of the AURA 10 PET-CT and impact performance.

CAUTION: Do not use solvents such as anhydrous or high solvency alcohols, thinner or benzine. Do not use any corrosive, dissolving or abrasive cleaning or polishing detergents.

Doing so may damage the surface of the equipment. Using unsuitable cleaning agents or methods can damage the property when the surface becomes dull and brittle (e.g. by using alcohol-containing agents).

Note: do not open the equipment for cleaning. No components inside the device require cleaning by the user.

3. If needed for further use, start up the system.

6. MAINTENANCE, CONSUMABLES, TOOLS AND ACCESSORIES

This section covers the schedule of maintenance for the system. It also includes instructions to test the system after repairs or maintenance, and how to verify it is in a safe state after repairs or maintenance. It further includes information on consumables for the system, and the tools and accessories either provided with the system or which must be provided by the user.



WARNING: Operation in unsafe conditions include the risk of radiological exposure and injury of the patient and/or the operator. The customer is responsible to ensure the fault-free condition of the equipment.

WARNING: Wear of equipment due to excessively long intervals between service may lead to personal injury and property damage due to worn and unsafe parts.

WARNING: Incorrect or defective spare parts may adversely affect the safety of the system and lead to damages, malfunctions or total failure. Use only original spare parts provided by the manufacturer.

WARNING: Improper changes, additions, maintenance or repair of the equipment or the software can lead to personal injury, electrical shock and damage to the equipment. Safety is only guaranteed when changes, additions, maintenance or repairs are carried out by a XEOS Medical certified field service engineer. A noncertified engineer performing a modification or service intervention on a medical device, acts on his own responsibility and makes the warranty void.

6.1 Lifetime and Schedule of Maintenance, Testing and Calibrations

This section provides a schedule of maintenance - including testing and calibration - for the XEOS Medical AURA 10 PET-CT. It is strongly recommended that the maintenance in this section be performed at the intervals of time indicated to ensure that the system continues to operate at optimal performance.

Note that calibration according to the below schedule constitutes a suitable quality control procedure.



WARNING: If the AURA 10 PET-CT is used in a manner not specified by XEOS Medical, the protection provided by the AURA 10 PET-CT may be impaired.

Table 3: Lifetime and schedule of maintenance

Lifetime	
Expected lifetime for the X-ray tube unit	18 months
Periodic maintenance by XEOS	
The equipment shall have annual maintenance to maintain fault-fee and safe operation.	Every 12 months

Maintenance by the user	
Check ease of movements	Weekly or on each use
Check secure release and locking of brakes	Weekly or on each use
Check functioning of operating controls	Weekly or on each use
Check markers and warning signs	Weekly or on each use
Warm-up of X-ray tube	On each use or monthly, whichever is more frequent
Check all electric cables and connections for damage or broken cables	Weekly or on each use
Image calibration	Daily or on each use, whichever is less frequent
Geometric calibration	Every 6 months, after shipment, collision, or jarring, or as needed.
Hounsfield unit calibration	Every 6 months or as needed
Radiation survey	Every 6 months or as set by your institutions radiation safety policy.



CAUTION: In case of functional defects or other deviations from normal operation behavior the unit must be switched off immediately and XEOS Medical service (support@xeos.care) must be informed. The equipment must only be put back into operation when the fault has been repaired.

6.2 Replaceable Parts

The system has the following user-replaceable parts:

- External fuse: Littelfuse 0217010.MXP

No other parts in the system are user-replaceable.

6.3 Consumables

The AURA 10 PET-CT is compatible with the AURA Specimen Container which is a single-use consumable item. If you need to order more AURA Specimen Containers, please contact sales@xeos.care.

6.4 Tools

Tools to be provided by the user according to scenario

Tool	**Scenario**
Flat-head screwdriver	Fuse replacement
Radiation meter	Radiation survey

Tools to be controlled by the responsible body

As identified also in Section 7, the following tools shall be controlled:



To prevent unauthorized access to the system interior, the installing institution should control access to 2.5mm hex wrenches in the presence of the system.

6.5 Accessories

The following accessories are provided with the system:

Accessory	Description
AURA Calibration phantom	An object or “phantom” used for calibrating the AURA 10 PET-CT. This calibration phantom is suitable for calibrating the AURA 10 PET-CT device only and should not be considered as a calibration object for other devices.
AURA Coregistration phantom	A phantom used for calibrating and checking the coregistration of the AURA 10 PET-CT.

7. SAFETY DIRECTIONS

7.1 General



WARNING: Safety is only guaranteed when a XEOS Medical certified field service engineer has installed the product.

WARNING: The product must only be installed using released components and in released configurations.

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: Ionizing radiation can lead to radiation injuries if handled incorrectly. When radiation is applied, the required protective measures must be complied with.

WARNING: Operating the equipment when it is faulty includes the risk of radiological exposure and injury to the patient and to the operator. Operate the equipment only in safe and fault-free conditions.

WARNING: System unavailability due to hardware or software failure. If the product is used in critical clinical workflows, a backup system has to be foreseen.

WARNING: Strictly observe all warnings, cautions, notes and safety markings within this document and on the product.

WARNING: All XEOS Medical products must be used by trained and qualified personnel.

7.2 X-ray



WARNING: Even if the x-ray generator is switched off, parts on the inside of the generator cabinet and connected controls are still powered! Ensure that only trained service personnel open the generator cabinet and the housing of connected devices! Improper handling may cause a lethal hazard!

CAUTION: Excessive ambient temperature may impact performance of detector electronics and cause permanent damage to the equipment. If ambient temperature and humidity is outside the specified range, do not operate the system or use air conditioning. Warranty will be void if it is obvious that operating conditions are not met.

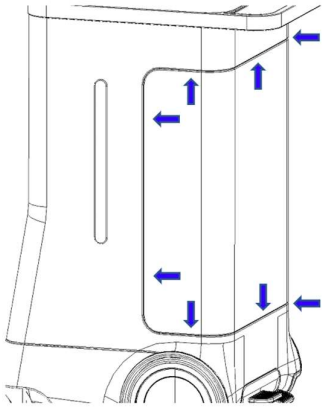
7.3 INSPECTING PROTECTIVE BARRIERS

The system has two service access panels which act as protective barriers. These panels are only intended to be removed by trained service personnel. One access panel is located on the front of the system and one is located on the back.

To inspect these panels to make sure they are in place, check the following.

7.3.1 Front Panel

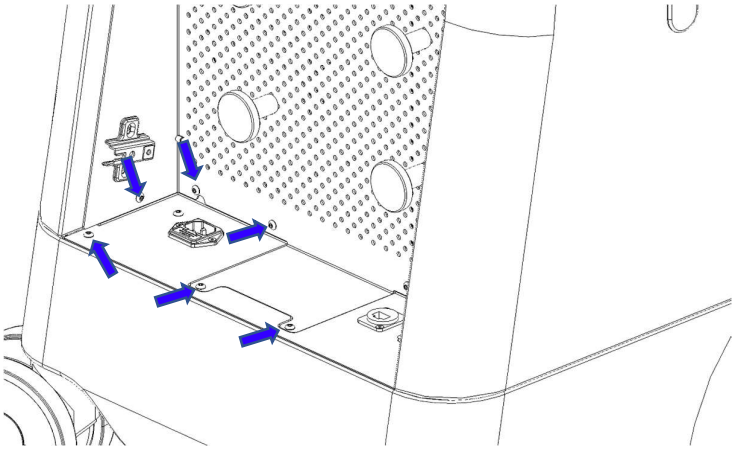
Visually inspect the front panel along the surfaces indicated by the arrows in the figure below. The surfaces of the front panel should be reasonably in-line with the corresponding surfaces of the device. Some small differences due to manufacturing tolerances are okay. A gap of more than 4 millimeters (0.16”) would indicate that the panel is not correctly in place. The front panel cannot be removed directly with any tools and requires removal of the back panel.



7.3.2 Back Panel

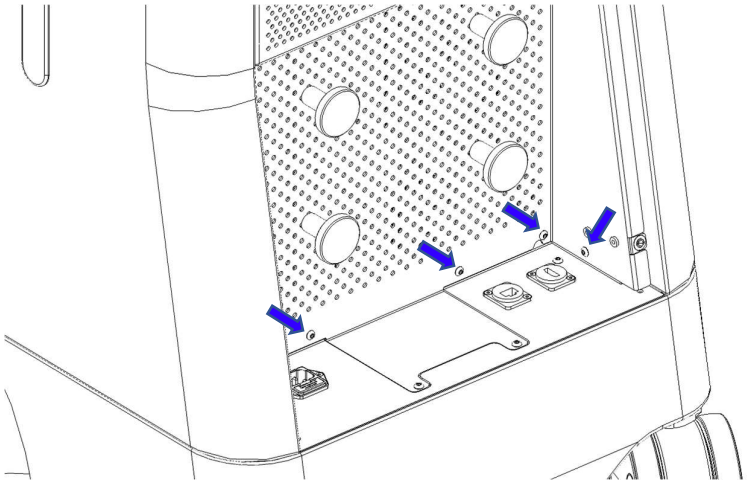
Visually inspect the back panel along the surfaces indicated by the arrows in the figure below. The surfaces of the back panel should be reasonably in-line with the corresponding surfaces of the device. Some small differences due to manufacturing tolerances are okay. A gap of more than 4 millimeters (0.16”) would indicate that the panel is not correctly in place.

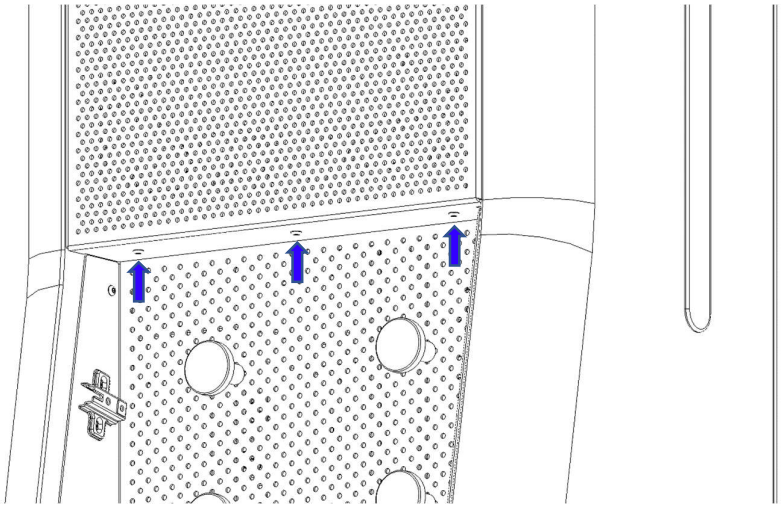
The screws fastening the back panel in place should also be checked. These screws are shown in the below figures, indicated by blue arrows. A *2.5 millimeter hex key is required to remove these screws* and the back panel (protective barrier).

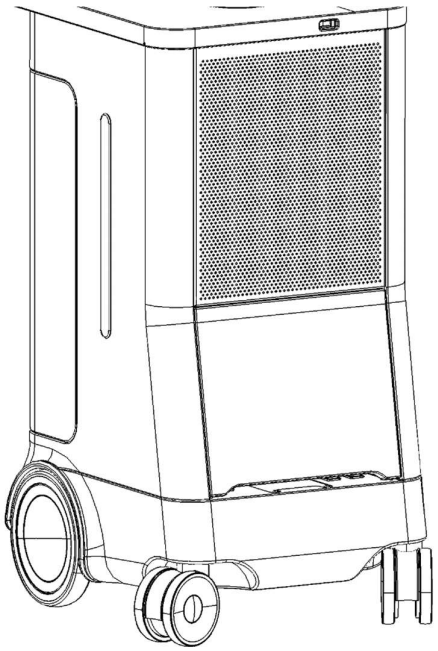




To prevent unauthorized access to the system interior, the installing institution should control access to 2.5mm hex wrenches in the presence of the system.







8. LIFTING AND CARRYING

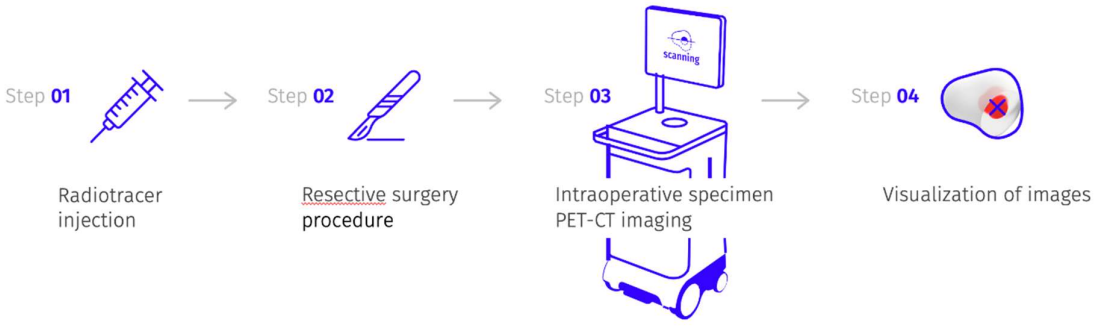


CAUTION: The AURA 10 PET-CT should not be lifted or carried by a person. As a mobile system, it should be wheeled to its destination and the brake should be set when not being moved. For information about moving and storing an AURA 10 PET-CT while in its case, please see Section 4.

9. BASIC WORKFLOW

9.1 Clinical workflow and preparation of the patient

Specimen PET-CT imaging requires adequate preparation of the patient. The basic clinical workflow for specimen PET-CT imaging is shown below.



1. To obtain a relevant PET image of the resected specimen, a positron-emitting radiotracer needs to be present in the specimen. This requires administering (usually via intravenous injection) a radiotracer to the patient before the specimen is resected.



WARNING: The selection of a radiotracer as well as the dose to be administered depends on different factors (e.g. type of resected specimen, duration of surgery, etc.). This determination needs to be made in conjunction with a trained nuclear medicine physician.

WARNING: The use of a non-positron-emitting radiotracer will lead to incorrect images.

2. Surgery is performed and the specimen is resected. After the specimen is removed from the patient, it is placed in the specimen container and fixed with specimen needles. Any other orientation markers can be added to the specimen if needed, as long as they do not interfere with PET-CT imaging (e.g. no metal markers should be used preferably).



WARNING: The specimen container is specifically designed to keep track of the orientation of the specimen by correlating the symbols on the floor to anatomical orientation. It is of the utmost importance that the surgeon or other user keeps track of this correlation until specimen imaging is completed.

3. Specimen PET-CT imaging is performed by entering all necessary patient data and placing the specimen container in the system. After imaging is completed, the specimen container can be removed from the system, and the specimen can be sent for pathological evaluation.

4. The images are visualized by the user on the AURA 10 PET-CT. If a PACS connection is available, the images can also be sent to the PACS for evaluation by personnel not present in the operating theatre.

9.2 Off, Standby, and On states

The system has three power states:

- Off
- Standby
- On

The system may be left in the Off state (main power switch in off position) or in a Standby state in which the main power switch is on but the system electronics and internal computer are off or in low-power mode.

The power state of the system may be determined by the following identifiers.

Off state:

- No system lights or displays are on
- The main rocker power switch on the back side of the system is in the “Off” position
- All components in the system are off

Standby state:

- System lights are in their “breathing” animation, slowly pulsing in intensity
- All displays are off
- The main rocker power switch on the back side of the system is in the “On” position
- Components in the system – including the internal computer – are off or in their low-power mode

On state:

- System lights are on according to present workflow state of the system
- All displays are on
- The main rocker power switch on the back side of the system is in the “On” position
- The standby button on the top of the main work surface is lit in a “solid on” state

9.3 Starting the system



CAUTION: The touch screen on the user interface self-calibrates each time it is turned on. Turning on the system while an object is placed on the touch screen area of the user interface may affect this self-calibration and lead to poor performance of the touch screen. Always make sure the glass above the touchscreen is clear of any objects before turning on the system.

CAUTION: Inspect the exterior power cable prior to each use.

To start the system:

1. If the system is in the Off state, flip the main rocker power switch on the back side of the system from the “Off” to the “On” position. The system lights will come on indicating the system is in the Standby state. If the system is already in the Standby state, continue to the next step.
2. **Make sure no objects are placed on the touch screen of the user interface.**
3. From the Standby state, “press” and hold the standby switch on the top for at least 3 seconds until the icon blinks and release. The system displays will come on and the lighting will change.

4. Once the internal computer has booted, the login screen will appear on the touch display. Select “user” and enter the password provided to you by XEOS Medical or set by your organization.
5. After login you will be at the image acquisition workflow which you may follow to collect image data.

For using the system, the temperature difference between calibration and usage must be within the recommended range of 20°C to 25°C.

9.4 Performing an Acquisition



CAUTION: The system “user” password allows a person to access and generate x-rays. The “user” password should be carefully controlled and only shared with those properly trained to use the XEOS AURA 10 PET-CT.

CAUTION: X-rays will be generated as part of the acquisition.

1. Log into the user account by pressing the “user” icon and then entering the password given to you by XEOS Medical or their representative.
2. Click the “New Acquisition” button.
3. Click the “Enter new patient” button, or select a patient from the modality worklist.
4. Enter the patient data as prompted.
5. When prompted, put the specimen container into the specimen container receiver. Make sure to correctly orient the specimen container. When the specimen container is correctly set into the receiver, the output display will indicate this.
6. Press “Start scan”
7. (If you wish to cancel the scan at any time, press “Stop scan”)
8. Wait for scan to complete.

9.5 Turning off the system

Although the system may be stopped at any time by switching off the main rocker power switch on the back of the system, this “hard” shutdown does not properly shut down the on-board computer. This may lead to loss of data or corruption of the data drives. It also causes a longer startup the next time the system is turned on while the system checks the integrity of the data drives.

Therefore, it is recommended to follow one of the two methods below to turn off the system and assure data integrity. The two methods are equivalent in outcome.

Turning off the system, Method 1:

1. From the On state, press the “hamburger” menu icon in the top-left corner of the touchscreen interface and press the “Power Off” button.
2. When asked to confirm if you want to turn off the system, again press “Power off”. The computer will shut down and the system will go to the Standby state with exterior lighting in its breathing animation.
3. If desired to fully turn off the system, flip the main power rocker switch on the back of the system to the off position.

Turning off the system, Method 2:

1. From the On state, press and hold the standby/sleep button at the top of the system for at least 3 seconds and release.

2. A pop-up will appear on the touchscreen to confirm that you want to shut down. Press shut down to continue. If you do not wish to continue, click anywhere outside the pop-up.
3. The computer will shut down and the system will go to the Standby state with exterior lighting in its breathing animation.
4. If desired to fully turn off the system, flip the main power rocker switch on the back of the system to the off position.

10. PRODUCT INFORMATION

10.1 Compatibility

The system must only be used in combination with other equipment or components that are expressly recognized by XEOS Medical as compatible. A list of such equipment and components is available from XEOS Medical service support on request.

Changes or additions to the equipment must only be carried out by persons authorized to do so by XEOS Medical. Such changes must comply with best engineering practice and all applicable legislation.

10.2 Connectivity

10.2.1 Power

Xeos provides a C14 connector power cable with region-specific plug. Only use your system with the XEOS-provided power cable and observe the following ratings:

- **Minimum rated input voltage:** 100VAC
- **Maximum rated input voltage:** 240VAC
- **Maximum power draw:** 1200W

10.2.2 Signal

The software may optionally connect with other devices in the hospital network using the DICOM protocol.

The software may optionally be connected to a PACS system.

The system may optionally be connected to an external HD-resolution display via an HDMI cable. XEOS Medical does not warrant that all HD displays are compatible with the AURA 10 PET-CT.

10.3 Compliance

The system is compliant with specific legislation and standards.

10.3.1 General

- ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes
- ISO 14971:2019 – Medical devices – Application of risk management to medical devices
- ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
- IEC 62304:2006 – Medical device software – Software life cycle processes
- IEC 62366-1:2015 – Medical devices – Part 1: Application of usability engineering to medical devices

10.3.2 Safety

- IEC 61010-1 (2010 + A1 2016) – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements
- IEC 61010-2-091:2012 – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-091 – Particular requirements for cabinet X-ray systems
- IEC 61010-2-101:2018 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- IEC 61326-2-6:2020 – Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements

10.3.3 European Union

- EU Directive 1907/2006 (REACH)
- EU Directive 2011/65/EU (RoHS 2)
- EU Directive 2012/19/EU (WEEE)
- EU Directive 2004/108/EC (EMC)
- EU Directive 2014/35/EU (LVD)
- EU Directive 2014/53/EU (RED)
- EU Regulation 2017/746 (IVDR)
- The product has been designed in accordance with EU Guidelines regarding In Vitro Diagnostic Medical Devices

11. PRODUCT COMPLAINTS

Any health care professional (for example a customer or a user) who has any complaints or has experienced any dissatisfaction with the quality, durability, reliability, safety, effectiveness, or performance of this product must notify XEOS Medical via support@xeos.care.

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

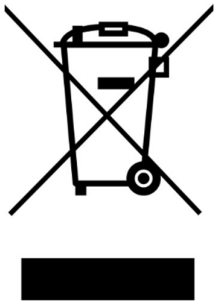


XEOS MEDICAL
Ottergemsesteenweg-Zuid 808 Bus 358
Gent 9000 BELGIUM
+32 9 277 77 94

XEOS Medical Service Support – local support addresses and phone numbers are listed on www.XEOS.care

12. DISPOSAL AFTER USE

12.1 WEEE end user notice



The directive on Waste Electrical and Electronic Equipment (WEEE) aims to prevent the generation of electric and electronic waste and to promote the reuse, recycling and other forms of recovery. It therefore requires the collection of WEEE, recovery and reuse or recycling.

Due to the implementation into national law, specific requirements can be different within the European Member States. The WEEE symbol on the products, and/or accompanying documents means that used electrical and electronic products should not be treated as, or mixed with general household waste. For more detailed information about take-back and recycling of this product please contact your local service organization and/or dealer. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources.

12.2 X-ray components

Decommission and dispose of replaced x-ray tubes in accordance with local legislation.

12.3 Specimen receptacle



Any used specimen container should be disposed of as biohazard waste. The specimen container is intended for single use only.

13. HF EMISSION

The AURA 10 PET-CT complies with the emission and immunity requirements described in IEC 61326-2-6:2020 – Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.



WARNING: The AURA 10 PET-CT is intended for use by healthcare professionals only. This device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.

WARNING: The HF-emission and immunity can be influenced by connected data cables depending on length and the manner of installation.

WARNING: The AURA 10 PET-CT has emission compliance Class A. The AURA 10 PET-CT is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

WARNING: The AURA 10 PET-CT is not intended to be used in a home healthcare environment. The AURA 10 PET-CT is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a home healthcare environment. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

WARNING: Do not use the AURA 10 PET-CT in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.

CAUTION: Cables and accessories which were tested and found to comply with the collateral standard IEC 61326-2-6 (EMC). Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Stacking or placing objects on top of the touch screen during startup may lead to miscalibration of the touch screen until it is powered off again, yielding sub-par performance of the touch screen. If this occurs, remove the object and restart the system.

This device is intended for operation in the electromagnetic environment given below. The user of the device should ensure that it is used in such an environment.

RF Emission Measurements	Agreement	Electromagnetic Environment Guidelines
High frequency RF emissions in accordance with CISPR 11	Group 1	The device uses high frequency energy exclusively for its internal functions. For this reason, its high frequency RF emission is very low and it is improbable that neighboring electronic equipment will be disrupted.
High frequency RF emissions in accordance with CISPR 11	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to

		take mitigation measures, such as relocating or re-orienting the equipment.
Tests of Resistance to Disruption	**Test level of professional medical equipment and basic EMC standards**	**Electromagnetic Environment** Recommended protective distance: N/A
Conducted high frequency disturbance variables in accordance with IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V within ISM bands	
Radiated high frequency disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	
RF communication	Refer to the section “Immunity to RF wireless communication equipment"	

14. DEVICE SPECIFICATIONS



WARNING: If the AURA 10 PET-CT is used in a manner not specified by XEOS Medical, the protection provided by the AURA 10 PET-CT may be impaired.

Environmental conditions

Operational:

Temperature: 18-25°C (64-77°F)
Relative humidity: <75% non-condensing
Pollution Degree: Pollution Degree II

Storage and transport:

Temperature: 0-40°C (32-104°F)
Relative humidity: <75% non-condensing

This equipment is designed for the following conditions:
- Indoor use
- Altitude up to 2000 meters

Radiation safety

For safe operation, the system possesses the following:

- Radiation shielded cabinet.
- Specimen door equipped with dual safety interlocks.
- Service access points equipped with safety interlocks.
- Radiation: Less than 5 µSv/hr at 5 centimeters (2 inches) from any exterior surface at maximum kV.
- Certified to comply with standards set by the US Food and Drug Administration, Center for Devices and Radiological Health, (21 CFR 1020.40) "FDA X-ray Cabinet".
- Designed to comply with standards set forth by Underwriters Laboratory in the US and Canada.

X-ray tube

Focal spot size	< 80 µm
kV range	0 - 50 kV max
mA range	0 - 2 mA max at less than 25 kV, above 25 kV current is power-limited to 50 W maximum.
Max power	50 W max @ 50 kV, 1 mA
Nominal operation power	30 W @ 50 kV, 0.6 mA
X-ray On time	Approximately 60 seconds per acquisition
Beryllium window thickness	127 µm
X-ray beam divergence	40 degrees typical
Maximum x-ray radiation field	45 degrees (full fan angle measurement)
Target material	Tungsten (W)
Filtration	1 mm aluminum

Radiographic magnification: 1.33X

X-ray duty cycle: continuous through CT scan

Power requirements

- 100 – 240 VAC
- Voltage fluctuations: +/-5% from nominal
- 50/60 Hz (+/- 5%)
- 1200 VA Max
- Overvoltage category II
- Connection: Use Xeos-supplied mains power cable only.

User-replaceable Fuses

- Quantity: 2 per system (line and neutral fused)
- Fuse Type: Fast-acting 5x20mm cartridge fuse
- Fuse current: 10A
- Fuse voltage rating VAC: 250VAC
- Breaking capacity current: 35A
- IEC 127 fuse marking: F10AL250V
- Recommended fuse replacement: Littelfuse 0217010.MXP

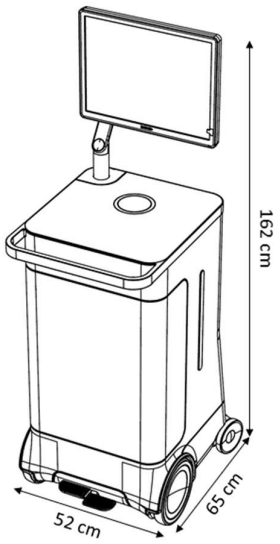
Dimensions

Exterior dimensions

	cm	Inches
Height	162	64
Width	52	21
Depth	65	26

Weight

	Kg	Lbs
Net	150	330
Shipping	250	550



15. SOFTWARE

Refer to Section 10 for turning on/off the system from off or standby.

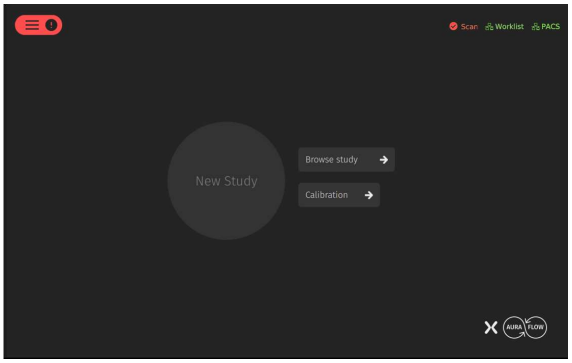
15.1 LOGIN

On the touch screen, click the “user” icon to choose the user to log in as. For patient management and image acquisition the Medical user must be chosen. Enter the “user” password provided to you by XEOS Medical or their representative. Press “Login” button to access the main menu.

15.2 ACQUISITION

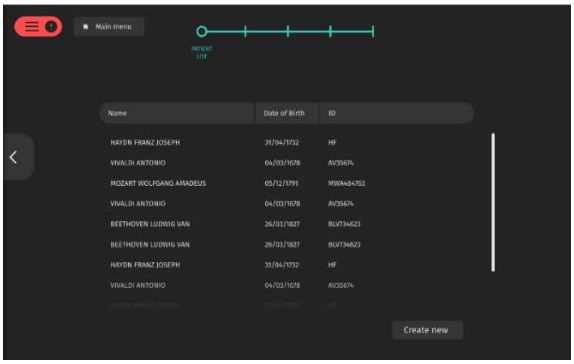
15.2.1 Start a new acquisition

Once logged in, on the touch screen touch the “New Study” button as shown in the picture below.



15.2.2 Enter patient data

Next, a patient can be selected from the loaded list of scheduled procedures (subject to healthy connection to Modality Worklists server). To pursue with the received patient data, press the arrow at the right side of the touch screen.
If the patient data cannot be fulfilled via Modality Worklists, a new patient can be created through the “Create new” button as shown below. This method is discouraged.

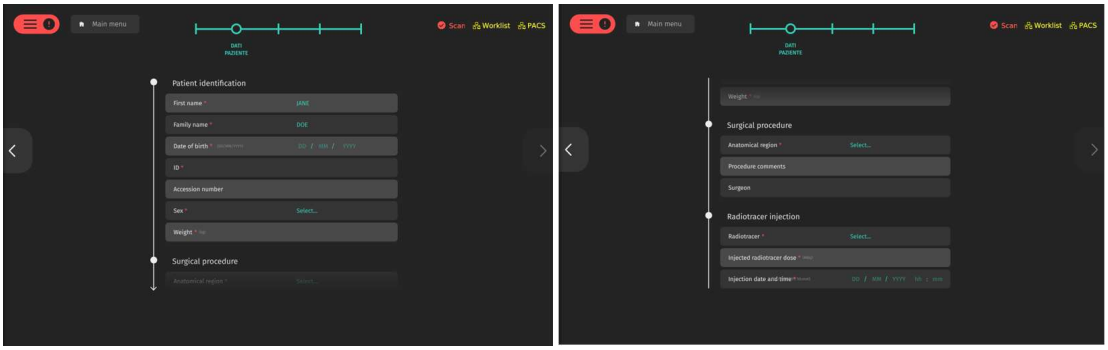


Enter the patient’s identification data in the provided boxes on the touch screen. It is also possible to return to the main menu at this point by touching the “Main menu” button.

Different information about the patient and the procedure needs to be filled in, as shown below. Patient data can be edited using the touchscreen, while the output screen displays an overview of the entered patient data. The mandatory fields are indicated by the asterisk (*) next to the data field description. Once all mandatory fields have been filled with valid values, the “next” button at the right of the screen is enabled to transit towards laterality selection.

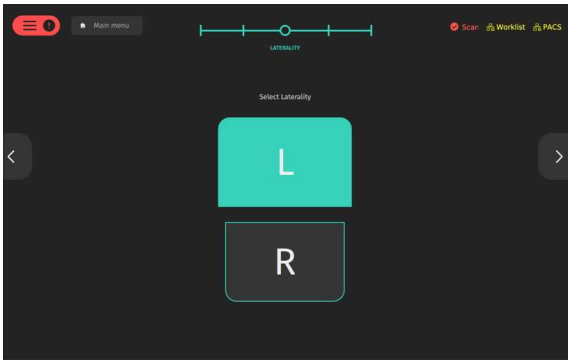
The injected radiotracer dose is entered into the corresponding field. This injected radiotracer dose is the estimated total dose injected into the patient, at the time of injection. This requires subtracting the leftover dose in the syringe after injection from the dose measured in the syringe before injection, and to correct all dose measurements for decay to the time of injection. The time of injection is entered into the field 'Injection Time and Date'.

Note that the field "Procedure Comments" in the "Surgical Procedure" section may be used to put in detailed anatomical information or other comments according to the user's preference and will be available in the DICOM field (0040,0280) "Comments on the performed procedure step" in the DICOM images produced by the scan.



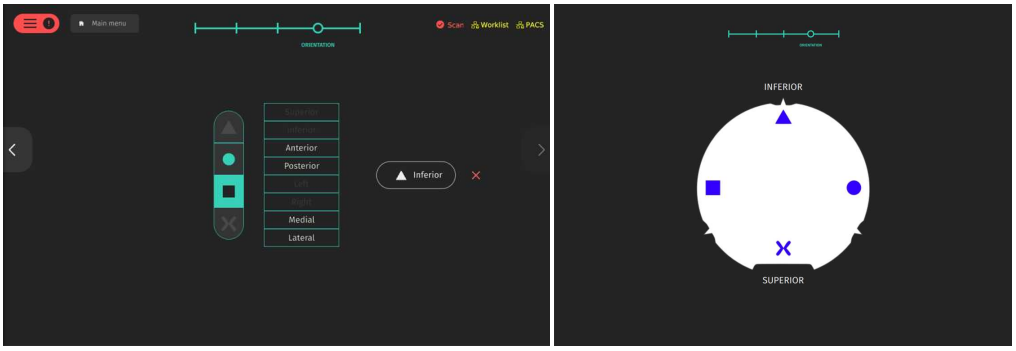
15.2.3 Enter laterality

After the patient information data, the laterality needs to be entered. Once the laterality is selected, the "next" button at the right of the screen is enabled to transition towards orientation selection.



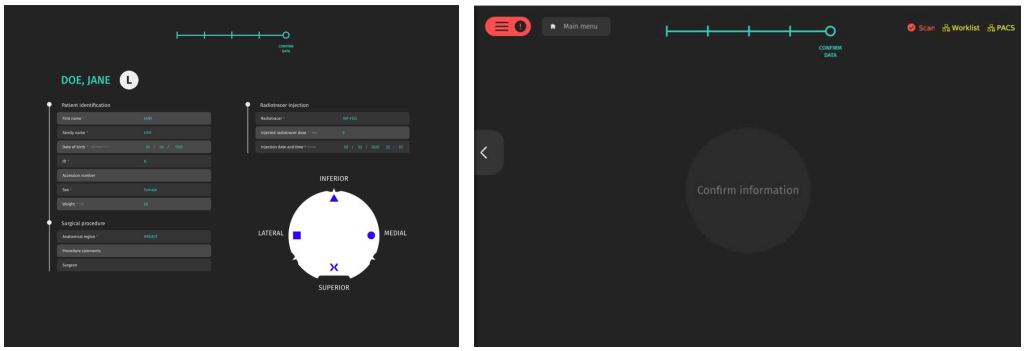
15.2.4 Enter orientation of specimen

Before placing the specimen container into the system, the orientation of the specimen needs to be indicated. The symbols are printed onto the foam at the bottom of the specimen container. The most suitable indications for the orientation of the specimen related to the patient body need to be chosen from the possibilities: anterior, posterior, inferior, superior, left, right, medial, or lateral. Two shape-direction bindings are required to fully define the orientation of the specimen. When the first binding is provided, the opposite direction will automatically be filled in the diagram. For the second binding, only available directions will be selectable. Established bindings are listed and can be undone by pressing the red icon ×. Once two valid bindings have been created, the "next" button at the right of the screen is enabled to transition towards information overview page.



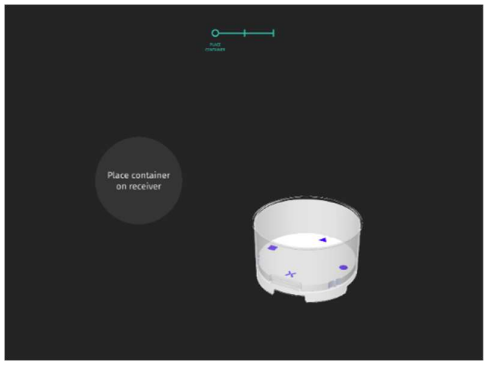
15.2.5 Confirmation of entered data

The next screen will ask for a confirmation of all entered data. Pressing “Confirm information” will engage the motion mechanism to open the door and place the specimen container; do not touch any mechanism meanwhile. This must only be engaged once the specimen container is ready for being loaded.

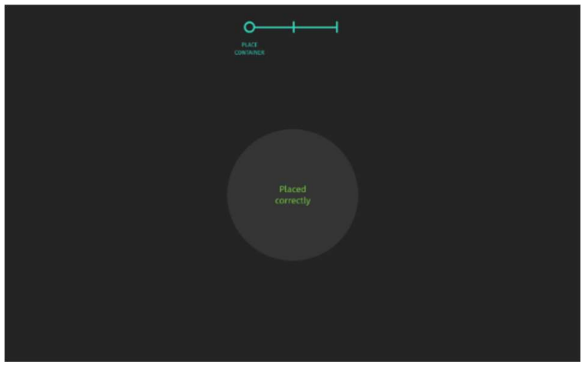


15.2.6 Place the specimen container

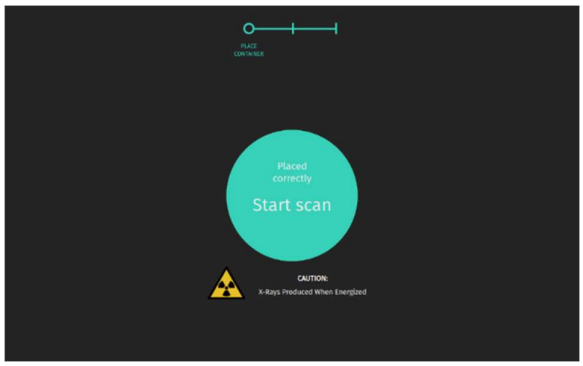
You will be prompted to place the specimen container holding the specimen you intend to scan as shown in the figure below.



When the specimen container is correctly placed a “Placed correctly” message will show on the main display:



And the touch screen will allow for starting the scan:



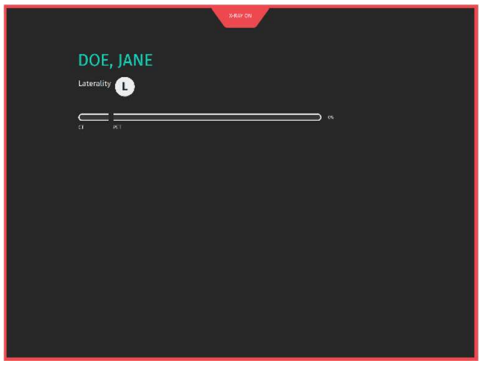
15.2.7 Start the acquisition



CAUTION: X-rays will be generated as part of the acquisition.

You may start the acquisition when ready by touching the “Start scan” button on the touch screen. Motion components will activate, and the door will close; do not touch the specimen meanwhile.

You will see a progress indicator on the main display such as shown in the screen capture below:



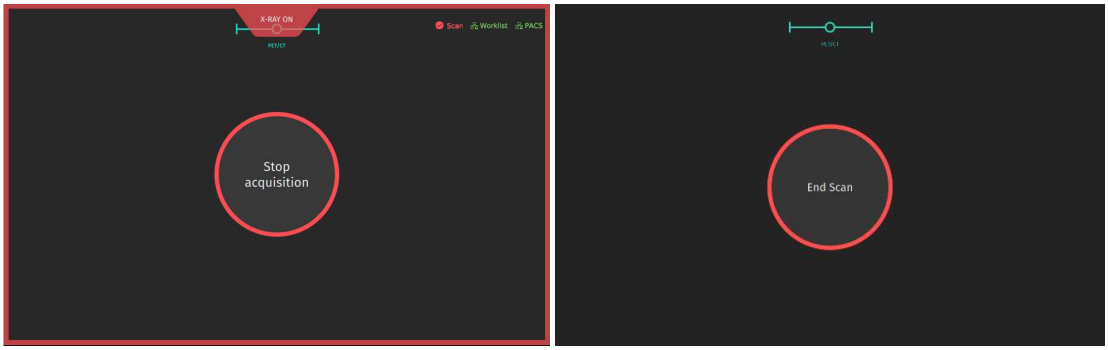
You can determine if and when x-rays are on when the following are observed:

- The main display and touch display will have a red flashing border with red “X-RAY ON” label at the top center.
- The ring around the specimen door is lit in a pulsing red light.
- The two LED indicators on the left and right sides of the system will be lit in a pulsing red light.

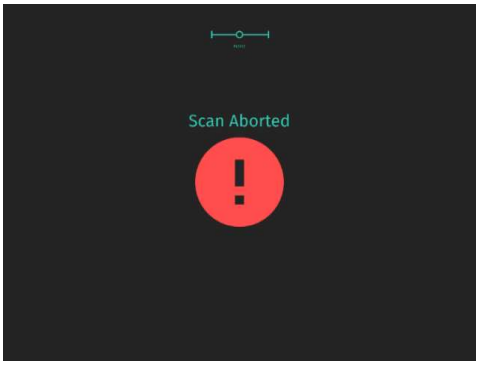
- A periodic beeping noise will be heard.

15.2.8 Stopping x-rays and/or aborting a scan

If x-rays are on, you may stop them by touching the “Stop scan” button in the center of the touchscreen as shown below. This will also abort the scan.



Upon stopping x-rays, you will see the following on the touch screen:

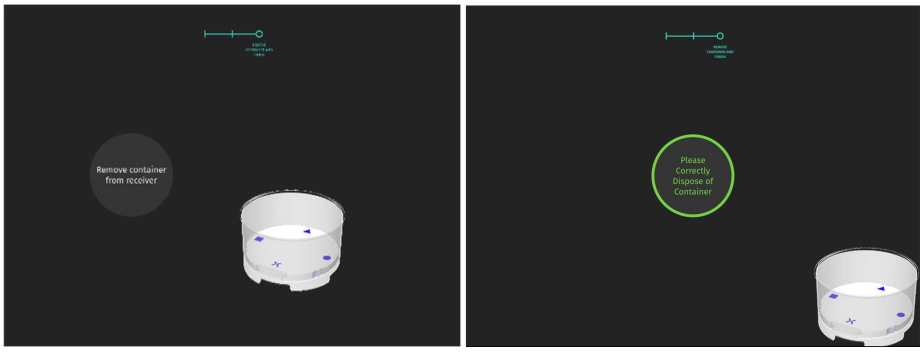


If x-rays are not on, you may still abort a scan by touching the “Stop acquisition” button.

Note that if you abort a scan for any reason, the data will be lost, and you will have to repeat the scan. When a scan is aborted, the specimen container will be returned to the loading position, and you will be prompted to remove it and then close the door. This will engage motion components to close the door; do not touch any mechanisms meanwhile. The patient form with the entered data will be presented, ready for performing another scan in the context of the same study.

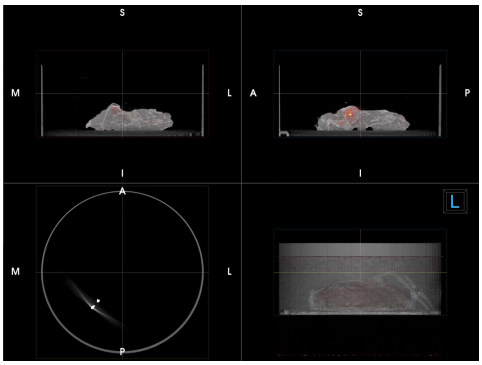
15.2.9 Acquisition completion

When the scan is completed, the specimen container will be returned to the loading position, and you will be prompted to remove it and to dispose of it correctly. You will be asked to select ‘close door’ after you have removed the container. This will engage motion components to close the door; do not touch any mechanisms meanwhile. The software will go to the image viewing stage.



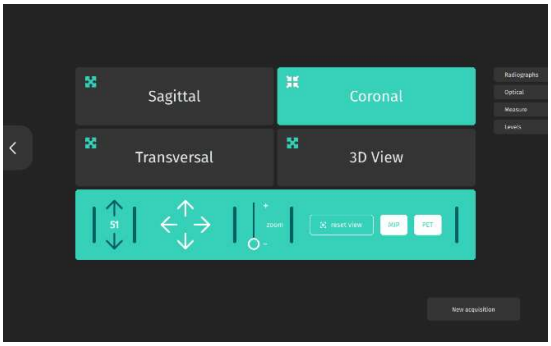
15.3 IMAGE REVIEW

When a scan is finished, the viewing stage is opened automatically. This view contains 4 quadrants of equal size capable of displaying PET/CT co-registered information: three quadrants containing each a 2D sliced CT view, oriented along the three main axes, sampled from three orthogonal planes in a CT volume, and one quadrant containing a 3D CT view, obtained by projection or volume rendering of a CT volume.



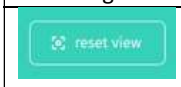
The orientation of the specimen relative to the patient is indicated by displaying the letters P (posterior), A (anterior), I (inferior), S (superior), M (medial) and L (lateral) in every view as appropriate (4 letters in a 2D view, all 6 letters the 3D view). In case of a specimen that has no laterality defined, the letters L (left) and R (right) will be shown instead of M (medial) and L (lateral).

On the input screen the following options are shown:



In this example the ‘coronal’ view is selected, represented by highlighting its button. Each view can be selected to be shown in full-screen size (as indicated with the 4 arrows next to the names of the views; when this consists of 4 inward pointing arrows all 4 views are shown in equal size; when tapping the icon, one view shall be shown in larger size and this icon shall consist of 4 outward pointing arrows).

IMAGE REVIEW TOOL SPECIFICATION	
 Slice selection tool	The number (51 in the sample) indicates the slice which is currently shown in the selected 2D view. Tapping the arrows will allow to move through the slices. This movement can also obtained be by vertically scrolling with 2 fingers on the trackpad. For fine-grade adjustments it is advised to use the arrows instead of the trackpad. This control, as well as its trackpad counterpart, is disabled when in 3D view or when MIP is active.
 Panning tool	The panning tool features 4 arrows that can be used to shift the specimen in the tapped direction in the 2D views (= panning).

 Zooming tool	Zooming can be done by moving the bar from 0 to 400%. Zooming can also be performed by performing a pinch gesture on the trackpad.
 Reset view button	The reset button will reset the view, centering the images on the viewer (undo panning and zooming), window-leveling of CT images and window-leveling of PET images.
 MIP toggle	MIP refers to the 'Maximum intensity projection'. This will show the most intense area of the specimen. This an overlay of all slices and thus it is not possible to scroll through.
 PET toggle	The 'PET' button allows to hide or show the co-registered PET image onto the CT volume and slices.

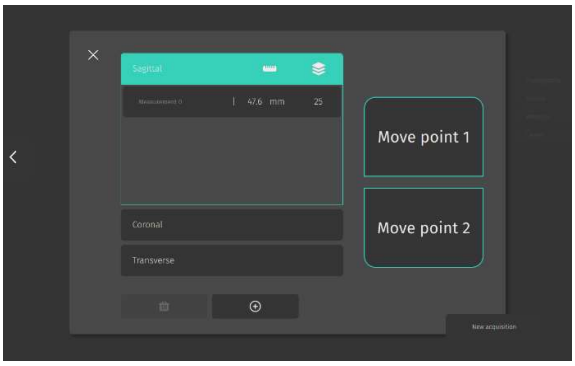
Using a single finger on the trackpad, the 3D view can be rotated. This control is enabled regardless of the selected viewport.

On the right side of the touch screen interface several tools are available:

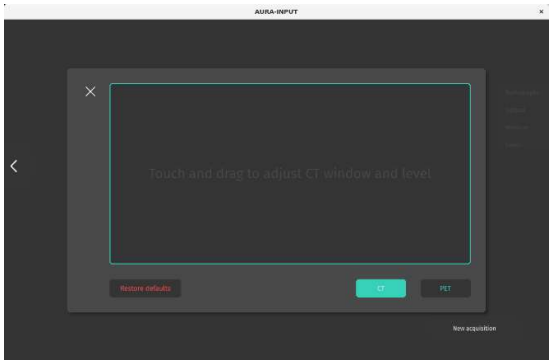
- Radiographs: this will show the 2 radiographs of the specimen that were taken during the acquisition.

- Optical: this will show the optical image of the specimen that was taken during the acquisition. It may be used to visually check the specimen and to verify correct orientation.

- Measurement: This tool allows for placing measurements on 2D slices. When the tool is selected, a new window is opened in which markers can be placed to indicate the two point of interest. Distance between these 2 points will be shown in mm. You may navigate through the available measurements per 2D plane (sagittal, coronal and transverse), and add a new measurement by tapping the + button. The 🗑 button can be used to remove a selected measurement. Measurements are tied to a slice and only visible when the slice is on the view. Tapping a measurement will successfully change the visible slice in the correct viewport to make the measurement visible. Measurements can be named with a friendly name by using the text field in each. To edit a selected measurement, use the toggles to move the points #1 and #2, as visible on the output screen, with the trackpad using a single finger.



- Levels: a new window is opened to adjust the CT or PET window/level settings. This can be performed by touch and drag with one finger. The horizontal axis will modify the window, while the vertical axis will modify the level. The 'Restore defaults' button can be used to restore the default window/level settings of the image series. The default settings are part of the DICOM metadata in each image series, which are as follows:
  - CT: level is 0 HU, window is 2000 HU (resulting in a range from –1000 to 1000 HU)
  - PET: window is 80% of the maximal voxel value in the dataset (rounded to the closest multiple of 1000 Bq/ml) and level is 50% of the window (resulting in a range from 0 to the window value).



WARNING: The default PET and CT window/level settings may not be optimal for interpretation. Therefore, manual adjustment of the window/level settings may be useful. However, adjustment of the settings may also lead to misinterpretation of the images. For the PET images, putting the window too low may lead to the false impression of radiotracer uptake in areas where this is not the case. Conversely, putting the window too high may lead to the false impression of low or no radiotracer uptake where in fact this is the case. For the CT images, adjustment of the window/level settings may lead to the impression of more or less dense regions in the specimen than is the case.

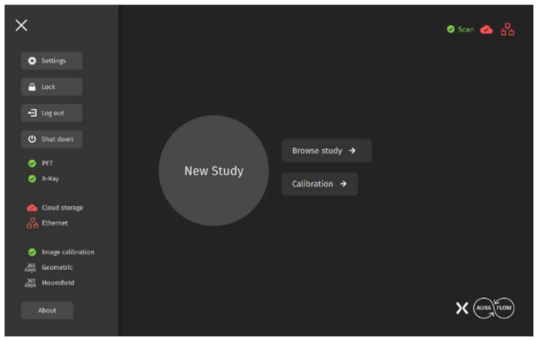
15.4 ABOUT SCREEN

To see more information about the AURA FLOW software, on the touch screen touch the “hamburger” menu button at the top left, then click the “About” button at the button of the opened menu. You will see a window similar to the following:

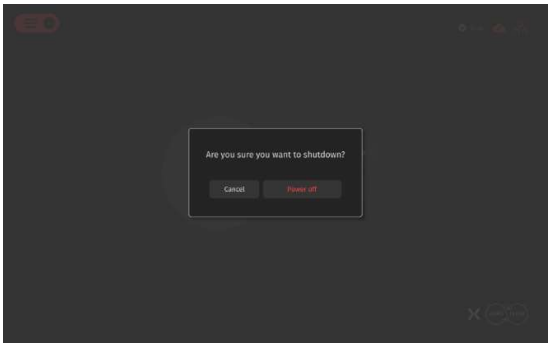


15.5 POWER OFF

To safely power off the system, touch the “hamburger” menu button at the top left of the touch screen and then press the “Shut down” button.



You will be asked to confirm and shown below:



Touch the “Power off” button to continue with shut down or touch “Cancel” to cancel. The system will go into standby mode (“breathing” light animation on door ring and side lights). You may now safely turn off the main power switch.

16. COMPLIANCE REQUIREMENTS AND SAFETY MEASURES

16.1 Requirements | AURA 10 PET-CT Compliance Emission Limits

Limits Radiation emitted from the AURA 10 PET-CT unit does not exceed an exposure of 5 µSv/hr at any point 5 centimeters (cm) outside the external surface.

For countries requiring emission values measured at 10 cm from the external surfaces, the radiation does not exceed 1.0 μSv/hr per hour at 10 cm.

16.2 Safety Interlocks

AURA 10 PET-CT system has two safety interlocks on the specimen door. All service access points have a safety interlock.

16.3 Start Button

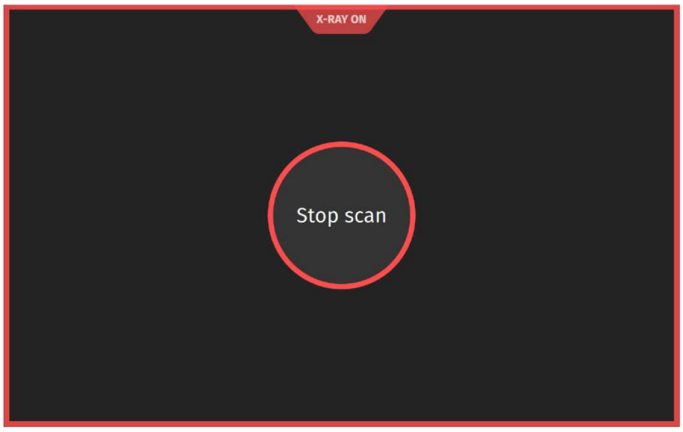
Following interruption of x-ray generation by the safety interlocks during a scan, the scan is canceled and x-rays will not restart. To generate x-rays again, the acquisition must be restarted and the “Start scan” button on the touchscreen interface will resume x-ray generation when ready.

16.4 Password actuated control

To access the x-ray-generating interface of the system, the user password must be entered. This password will be provided to you by XEOS Medical or their representative. It is important to guard the password and only give it to those at your institution whom are authorized to operate x-ray equipment.

16.5 Emergency Stopping of X-rays

At any time when x-rays are on, the “Stop scan” button (shown below) is available on the touchscreen interface to terminate the generation of x-rays at any time. This is in addition to the safety interlocks on the system door and access panels which will interrupt x-ray generation.



16.6 X-Ray Generation Indicators

The AURA 10 PET-CT indicates that x-rays are on through all of the following indicators:

- X-ray On indicator animation on the display and touch screen.
- Pulsing red lighting on ring lighting around the specimen door as well as the indicator light strips on the left and right sides.
- An audible periodic beeping.

16.7 Power Ratings

- 100-240 VAC
- 50/60 Hz
- 1200 VA Max.

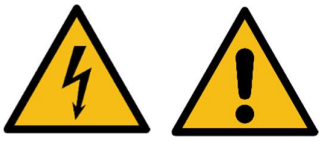
16.8 Tested Standards

Testing carried out by Intertek, a US Nationally Recognized Testing Laboratory and European Notified Body

- IEC 61010-1 (2010 + A1 2016) – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements
- IEC 61010-2-091:2012 – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-091: Particular requirements for cabinet X-ray systems
- IEC 61010-2-101:2018 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- IEC 61326-2-6:2020 – Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
- CE marked as Class A under the EU In Vitro Diagnostic Medical Devices Regulation 2017/746.
- UKCA marked

17. SERVICE AND TROUBLESHOOTING

17.1 Service and Troubleshooting



17.2 Service

Please contact your authorized XEOS Medical representative for servicing.



XEOS MEDICAL
Ottergemsesteenweg-Zuid 808 Bus 358
Gent 9000 BELGIUM
+32 9 277 77 94
E-mail: support@xeos.care
Website: www.xeos.care

17.3 Troubleshooting

17.3.1 Computer or System will not turn on

No power to the computer or X-ray system.

Verify power switch on top back of system is ON and power cable is plugged in.

17.3.2 System appears to be on, but nothing is displayed on either display

The system is in standby mode. Press and hold sleep/wake switch on top surface of unit for 3 seconds and release to move the system from Standby to On.

18. TRAINING

18.1 Level of training, qualifications and/or experience

The user must have received adequate training on the safe and effective use of the system before attempting to work with it. Training requirements may vary from country to country. The user must make sure that training is received in accordance with local laws or regulations that have the force of law.

Training provided by XEOS Medical will include at least an introductive course on instructions for use and specimen PET-CT image interpretation. This could be organized on-site or remote.

19. REVISION HISTORY

Version	Date of last issue	Change description
1	20220301	First version of the instructions for use
2	20220520	Updated for EU IVDR.