Helianthus SERIES

Operator's manual

Helianthus

Helianthus C

Helianthus DBT

METALTRONICA

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DECLARATION ACCORDING TO IEC 60601-1 STANDARD

Metaltronica S.p.A. declares its responsibility concerning safety, reliability and equipment features included in this manual only if the following items are fully satisfied:

1) - Installation;
   - room temperature and humidity;
   - updates;
   - recalibrations;
   - repairs and/or modifications carried out by technical personnel officially authorized from Metaltronica S.p.A.
2) Electrical pre-installation performed in the site where the system has to be put into operation, carried out according to prescription given by IEC rules concerning Medical Application.
3) Service personnel must ensure that they receive training on the equipment with Metaltronica S.p.A. training programs prior to service the Unit.
4) Use of the equipment according to instruction in this manual. In case of difficulties concerning interpretation, English translation **shall prevail.**

WARNING

Using and keeping X-Ray equipment and device must conform the local Regulations and national laws concerning Medical X-Ray handling.

NOTE

According to 2017/745 EU MDR Regulation concerning product traceability, Metaltronica S.p.A. must be informed of any owner or installation address change.
Medical Devices traceability is prerequisite to assure their safety and reliability over the time.

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Section I:
General Information

1.1 INTRODUCTION

Proper use of this equipment requires that the operating personnel is thoroughly familiar with the operating instruction, in particular with functions, safety, and Protective Measures and capable to use Personal Computers and their applications.

If legally-binding regulations govern the installation and/or the operation of the above equipment, it is responsibility of the installer or the operator to observe these regulations.
This Operator's Manual is intended to give a detailed overview on Functions, Specifications, Safety and all other important issues to know to get maximum utilization of mammography device.
This Operator's Manual is related to HELIANTHUS series.
HELIANTHUS series includes the following models:

- **HELIANTHUS C**
- **HELIANTHUS**
- **HELIANTHUS DBT**

For dedicated configuration of each model, please refer to par.1.29.
Where the considerations are extended to the models indifferently we will always talk about HELIANTHUS series, in order to include them all

1.2 INTENDED USE

HELIANTHUS series is a medical device intended to produce digital mammographic images of the breast for diagnosis of breast cancer. Its intended use is for two-dimensional diagnosis, screening, three-dimensional tomosynthesis exams or for needle localization in case of stereotactic biopsy.

PRIMARY FUNCTIONS
To finalize its intended use the medical device must perform the following principle functions:

- Exposure by means X-ray
- Move C-arm and Tube for correct positioning of the patient
- Compression of Breast in order to avoid movements artifacts and increase image quality,
- Coming in contact with Breast Tissue to perform compression

1.3 SCOPE AND INDICATIONS

The device is to be used in a radiology or clinic exam room environment in a hospital, outpatient clinic, a breast imaging center or other facilities. Mammography technologists operate the equipment for the production of mammograms. The device may also be used for quality control purposes and other clinical or research related activities by medical physicists and radiologists certified in accordance with local standards.

Reading a mammogram a doctor will be looking for different types of breast changes, such as:

- small white spots called calcifications (micro/macrocalcifications),
- larger abnormal areas called masses/lumps,
- and other suspicious areas that could be signs of cancer
- X-ray pictures of each breast are taken, typically from 2 different angles.

Calcifications:

Calcifications are tiny calcium deposits within the breast tissue. They look like small white spots on a mammogram. They may or may not be caused by cancer. There are 2 types of calcifications.

Macrocalcifications:

Macrocalcifications are larger calcium deposits that are most likely due to changes caused by aging of the breast arteries, old injuries, or inflammation. These deposits are typically related to non-cancerous conditions and don't need to be checked for cancer with a biopsy. Macrocalcifications become more common as women get older (especially after age 50).

Microcalcifications:

Microcalcifications are tiny specks of calcium in the breast. When seen on a mammogram, they are more of a concern than macrocalcifications, but they don't always mean that cancer is present. The shape and layout of microcalcifications help the radiologist judge how likely it is that the change is due to cancer. In most cases, microcalcifications don't need to be checked with a biopsy. But if they have a suspicious look and pattern, a biopsy will be recommended to check for cancer.

Masses:

A mass is an area of dense breast tissue with a shape and edges that make it look different than the rest of the breast tissue. With or without calcifications, it's another important change seen on a mammogram. Masses can be many things, including cysts (non-cancerous, fluid-filled sacs) and non-cancerous solid tumors (such s fibroadenomas), but they may also be a sign of cancer. Cysts are fluid-filled sacs. Simple cysts (fluid-filled sacs with thin walls) are not

cancer and don’t need to be checked with a biopsy. If a mass is not a simple cyst, it’s of more concern, so a biopsy might be needed to be sure it isn’t cancer.

Solid masses:

can be more concerning, but most breast masses are not cancer.

A cyst and a solid mass can feel the same. They can also look the same on a mammogram. The doctor must be sure it’s a cyst to know it’s not cancer. To be sure, a breast ultrasound is often done because it is a better tool to see fluid-filled sacs. Another option is to use a thin, hollow needle to remove (aspirate) fluid from the area.

If a mass is not a simple cyst (that is, if it’s at least partly solid, or it has other concerning features), more imaging tests might be needed to decide if it could be cancer. Some masses can be watched over time with regular mammograms or ultrasound to see if they change, but others may need to be checked with a biopsy. The size, shape, and margins (edges) of the mass can help the radiologist decide how likely it is to be cancer.

Breast density:

A mammogram report will also contain an assessment of patient’s breast density. Breast density is based on how fibrous and glandular tissues are distributed in patient’s breast, compared to how much of patient’s breast is made up of fatty tissue. Dense breasts are not abnormal, but they are linked to a higher risk of breast cancer. Dense breast tissue can also make it harder to find cancers on a mammogram. Still, experts don’t agree what other tests, if any, should be done along with mammograms in women with dense breasts who aren’t otherwise at higher risk for breast cancer (based on gene mutations, breast cancer in the family, or other factors).

1.4 CONTRAINDICATIONS AND LIMITATIONS

No absolute contraindications are given for mammography. Due to the nature of X-ray procedures the patient is exposed to radiation and adverse health effects exist and are known. Specifically Limitations of Mammograms are: Mammograms don't prevent breast cancer, but they can save lives by finding breast cancer as early as possible.
They aren't perfect and 100% accurate in showing if a woman has breast cancer, so they could generate:

- **False negative**:

mammogram could looks normal even if breast cancer is present and it can give women a false sense of security, thinking that they don't have breast cancer when in fact they do

- **False positive**

a mammogram looks abnormal even if there's no cancer in the breast :can give anxiety, requiring extra testing (diagnostic mammograms, ultrasound, and sometimes MRI or even a breast biopsy) to find out if the change is cancer which cost time, money, discomfort and in any case additional xray radiation

- **overdiagnosis and overtreatment**

Whats more some breast cancers that are found by mammograms are so slow-growing that they would not have caused any health problems for women in their lifetime. Overdiagnosis leads to some women getting treatment that's not really needed (overtreatment), because the cancer never would have caused any problems.

- **Radiations**

While repeated X-rays can increase the risk of breast cancer over time, the risk is very small. Studies show the benefits of receiving a mammogram outweigh the risks of radiation exposure for most women. In fact, a mammogram is the single most effective method of early breast cancer detection. Because mammograms are x-ray tests, they expose the breasts to radiation. The amount of radiation from each mammogram is low.The scientific unit of measurement for radiation dose, commonly referred to effective dose, is the millisievert (mSv). On average the total dose for a typical mammogram with 2 views of each breast is about 0.4 /0.7 millisieverts, or mSv. (A mSv is a measure of radiation dose.) The radiation dose from 3D mammograms can range from slightly lower to slightly higher than that from standard mammograms.To put these doses into perspective, people in the US are normally exposed to an average of about 3 mSv of radiation each year just from their natural surroundings (occurring radioactive materials and cosmic radiation from outer space.). (This is called background radiation.) The dose of radiation used for a screening mammogram of both breasts is about the same amount of

radiation a woman would get from her natural surroundings over about 7 weeks/3 months. As with other medical procedures, x-rays are safe when used with care. Radiologists and technologists have been trained to use the minimum amount of radiation necessary to obtain the needed results.

1.5 POTENTIAL ADVERSE EVENTS

The following is a list of potential effects applicable to the mammography:

- Excessive breast compression
- Excessive X-ray exposure
- Infection
- Skin irritation, abrasions or puncture wounds.

1.6 USER SKILLS

To use the equipment, you must know working principles and how to use the following:

- Touchscreen devices;
- Windows menu / drop-down lists;
- keyboard/mouse and its function (e.g. click, drag, select / deselect);
- Personal computer

Metaltronica S.p.A. declines each responsibility for injury or damage cause by incorrect system operation. Metaltronica S.p.A. usually holds training for mammography technologist, specialist and technicians. Metaltronica S.p.A. technical service complete trainings during and after equipment installation.

The mammo unit may be operated by medical staff with dedicated profession in radiology (technician, technologists, etc) or specifically educated nurses. The user/operator must physically be able to operate the system. It includes sufficient capabilities in hearing, vision and mobility. Minimum education required:

- Basic principles in anatomy of the breast;
- Knowledge in radiation protection
- Basic knowledge in hygiene

TRAINING REQUIREMENTS

Metaltronica S.p.A. usually holds training for mammography technologist, specialist and technicians. Metaltronica S.p.A. Technical service complete trainings during and after equipment installation. Make sure to receive training on the mammo unit before use on patients. Read and refer to this operative manual for direction about use of device.

Please, contact Metaltronica S.p.A. for local training program oriented to a safe and effective manner use of device.

DISCLAIMER

Metaltronica S.p.A. declines each responsibility for injury or damage caused by incorrect system operation.

1.7 QUALITY CONTROLS

All quality control tests must be performed following the dedicated Quality Control Manual (MCQHELIDMD_Uxx) provided with the Mammo Unit.

1.8 PRODUCT COMPLAINTS

Report any compliant or product problems using the specific modules "*FAILURE REPORT*" " at the end of this manual.

WARNING

In the event of serious accidents relating to the medical device covered by this manual, notify Metaltronica S.p.A. and the competent authority of the Member State in which the user and/or patient is established.

1.9 POPULATION

The digital mammography system is intended to support examinations of the human breast of patients (women/men).

Typically, patients are mobile or in a wheelchair. So examinations shall be performed:

- in an upright standing or sitting, including wheel chair position;
- recumbent, lying on a stretcher position.

Patients might be handicapped, immobile or frightened.

Patients invited for screening are usually in the age of 40 to 70, depending on the local regulations. Patients coming for diagnostic examinations are of any adult age.

Regarding particular patient categories these are the principle recommendations, as demonstrated by literature:

- **Breast feeding**
  - Mammograms do not harm breastmilk; therefore, the procedure does not pose a risk to patient or her infant.

- **Pregnant Patient**
  - As with any aspect of medical care, knowing that a patient is or could be pregnant provides important information. Pregnancy, for example, might explain certain symptoms or medical findings. While the vast majority of medical x-rays do not pose a critical risk to the developing fetus, there may be a small likelihood of causing a serious illness or other complication. The actual risk depends on how far along the pregnancy is and on the type and amount of radiation. X-ray studies of the head, neck, arms, legs and chest do not usually expose the baby directly to radiation and typically the technologist who takes the x-rays will implement special precautions to ensure that the baby of a pregnant patient is not directly exposed.
  - The amount of radiation needed for a mammogram is small, and the radiation is focused on the breasts, so that most of it doesn't reach other parts of the body

    Although the risk to the fetus is very small, and mammograms are generally thought to be safe during pregnancy, screening mammograms aren’t routinely done in pregnant women who aren't at increased risk for breast cancer.

- **Prostheses**
  - If patient has implants, a regular breast cancer screening is needed. Film or digital mammograms are recommended.
  - Technician should know if patient has implants prior to the procedure. They might need to take extra images because implants can hide some breast tissue.
  - The radiologist who reads the images will need to know, too.

It's rare, but a breast implant can rupture during a mammogram. Ultrasound or MRI could be advisable under doctor indications.

1.10 PRECAUTIONS

To improve performance/efficiency avoiding the risk of new exams these are the important precautions/contraindications

- **DON'T apply deodorant before mammogram.**

  Patients should also refrain from using perfume, lotion, creams, and any other substance on and around their breast, including under arms! These can show up in the mammogram screenings as white spots, causing inaccurate readings.
- **DON'T wear a dress or one-piece outfit.**

  It's best to wear two pieces (pants/skirt with a top) so to keep bottoms on during the exam.
- **DON'T go right before or during own period.**

  Women breasts may be more tender/swollen around this time, which can cause extra discomfort during the mammogram. If patient is premenopausal, the best time to go is about a week after her period (The breast tissue may be less dense during this week, so mammograms conducted at this time may be more accurate for some women) and avoid **the week just before her period**

1.11 COMPLIANCE STATEMENT

Metaltronica S.p.A. declares that the medical equipment is developed following technical standards below:

IEC 60601-1 (Ed. 3.1)	Medical electrical equipment - Part.1 - General requirements for basic safety and essential performance.
IEC 60601-1-3 (Ed. 2.1)	Medical electrical equipment - Part.1 – General requirement for basic safety and essential performance – collateral standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-2 (Ed. 4)	Medical electrical equipment - Part.1-2: General requirements for basic safety and essential performance – collateral standard: Electromagnetic disturbances – requirements and tests
IEC 60601-1-6 (Ed. 3.1)	Medical electrical equipment - Part.1: General requirements for basic safety and essential performance – collateral standard: Usability
IEC 60601-2-28 (Ed. 3)	Medical electrical equipment - Part.2-28: Particular requirements for basic safety and essential performances of X-ray tube assemblies for medical diagnosis
IEC 60601-2-45 (Ed. 3.1)	Medical electrical equipment - Part.2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
IEC 62366-1 (Ed.1)	Medical devices – part.1: Application of usability engineering to medical devices
IEC 62304 (Ed.1.1)	Medical device software – Software life-cycle processes
IEC 62471 (Ed. 1)	Photobiological safety of lamps and lamp systems
ISO 10993-1(Ed. 5.0)	Evaluation and testing within a risk management process
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes

Metaltronica S.p.A. has the responsibility for safety, performance and reliability for the equipment if following provisions are observed by the user:

- Installation satisfies requirement reported into Planning Guide;
- Electrical installation meets requirement of safety and standard IEC 60364 (sec. 710)
- The equipment is used according to the current Operator’s manual
- The maintenance operation is performed only by authorized and trained persons
- The network and communication system are installed following IEC standards
- Medical equipment shall be installed following special EMC requirements, reported into detailed paragraph “ELECTROMAGNETIC INFORMATION ACCORDING TO IEC 60601-1-2”

1.12 GENERAL DESCRIPTION

The HELIANTHUS is a modular mammography solution for different exam types, optimized for digital imaging. The equipment provides a specific user interface to perform screening and diagnostic mammograms. It allows to perform three different exam types according to its configuration:

- Conventional mammography (2D) with flat field digital detector;
- Tomosynthesis scan with flat field digital detector;
- Conventional mammography and tomosynthesis mixed scan with a single compression.

Flat field digital detector could be provided in two different versions:

- Indirect Conversion Amorphous (a-Si) or crystalline Silicon Detector (SOLO DM) usually for conventional mammography (2D), also usable for Stereo Biopsy with stereo biopsy device (optionally) and for Tomosynthesis exams;
- Amorphous Selenium (a-Se): option both for conventional mammography and Tomosynthesis scan also usable for Stereo Biopsy with stereo biopsy device (optionally).

The Amorphous Selenium produces a highest signal/noise ratio and greater efficiency than other well-known technologies. With the Amorphous Selenium X-ray beam is transformed directly into an electric signal without relying on an intermediate step. Direct detection avoids light diffusion that degrades image quality, produces a precise signal profile and preserves the image sharpness. Indirect conversion Amorphous Silicon detector (a-Si) is strictly recommended for specific environments where temperature ranges are large and easily of use is required such as **mobile** environment.

HELIANTHUS s*eries is a* medical equipment solution*,* an optional review station may be provided on request of which Metaltronica S.p.A. is not Metaltronica S.p.A. (Review station is not as a part of mammograph).

Mammo unit architecture is characterized by:

- C-Arm also usable for Stereotactic biopsy in combination with BYM 3D DMD biopsy device;
- Acquisition workstation embedded on stand or (optional) separated with integrated X-ray barrier;
- A digital flat field detector.

1.13 HELIANTHUS series: MAIN components:

- High voltage X-Ray generator:
  - 100 kHz ripple
  - 20 ÷ 35 kV / 20 ÷ 49 kV (optional) - (0.5 kV step allowed)
  - 1 ÷ 640 mAs (1 mAs step allowed) / (R'20) – optional
- C-Arm with motorized vertical movement and motorized rotation for patient positioning;
- Motorized rotation for breast tomosynthesis (if provided) with three scan angles:
  - ±7.5° (15°) - NARROW angle;
  - ±12° (24°) - INTERMEDIATE angle;
  - ±25° (50°) - WIDE angle
- Motorized rotation for biopsy projections ±15° (only with BYM 3D DMD). Fixed focus-detector (S.I.D.) distance of 66 cm;
- X-Ray tube with tungsten biangular anode:
  - 0,1 and 0,3 focal spots
  - 3.000 rpm (optionally 10.000 rpm)
  - 300 kHU maximum anode heat storage capacity
  - Automatic filter (50 µm Rhodium/50 µm Silver/500 µm Aluminium-specific for TOMO exams).

    Optionally 700 µm Aluminium may be provided for particular requests;

    Optionally 300 µm Copper predisposition for future implementation.
- Dynamic collimation device with automatic recognition of format and position of compression paddle;
- Automatic selection of anode/filter combination with Automatic exposure mode;
- Indirect Conversion flat field Detector:
  - Format: 24x30;
  - Sensor Physical dimension: 23.9 x 30.5 cm
  - Technology: Amorphous Silicon (a-Si)
  - ADC bit Depth: 16 bit
  - Pixel Pitch: 85x85 µm
  - Active area: 2816x3584 pixels
  - Read time: <1.1 s (24x30 cm format)

  - Fill factor: 80% geometric
  - Alternatively, the following detectors could be provided in replacement of the previous one

- flat field Detector (SOLO DM), optional:
  - Format: 24x30;
  - Conversion Screen: Direct Deposited CsI or Hi-Res GadOx
  - Sensor Physical dimension: 22.8 x 29.2
  - Technology: Crystalline Silicon with CsI conversion screen
  - A/D Conversion (bits): 14bit (standard); 16 bit (extended)
  - Pixel Pitch: 49.5x49.5 µm
  - Active area: 4608x5888 pixels
  - Read time: <1.13 s (24x30 cm format)
  - Fill factor: 79% geometric
- Direct Conversion Full Field Flat Panel Detector (optional):
  - Format: 24x30 cm
  - Sensor Physical dimension: 23.9x30.5 cm
  - Technology: Amorphous Selenium (a-Se)
  - ADC bit Depth: 16 bit
  - Pixel Pitch: 85x85 µm
  - Pixel Pitch in tomosynthesis: 85x85 µm (full resolution)
  - Pixel Pitch in reconstructed slices: 85x85 µm
  - Active area: 2816x3584 pixels
  - Read time: <1.1 s (24x30 cm format)
  - Fill factor: 88% geometric
- Removable Potter-Bucky with anti-scatter grid (Ratio 5:1, 102 lp/cm for 3D exams; Ratio 6:1, 36 lp/cm for 2D exams);
- “SensROI” Automatic Exposure Control (AEC) with full automatic kV/mAs, manual kV/auto mAs in function of effective Breast Density evaluated by pre-exposure X-Ray pulse or breast thickness for fast operation and/or special cases with silicone prosthesis. Dose limits according to European Protocol for Dosimetry and EUREF protocol;
- AGD (Average Glandular Dose) calculator;

-
- ”**Smart µPress**” compression system:
  - Motor-driven adjustable force with safety release compression with fine adjustment by double manual rotating controllers
  - Manual release/compression
  - Descending paddle speed proportionally reduced with increasing compression force
  - Fast unlock of compression paddles
  - Compression paddles with softly curved and smooth lines for higher patient comfort
- **Compression paddles** format:
  - 24x30 cm format compression paddle
  - 24x30 cm format compression paddle (tomo exam)
  - 18x24 cm format compression paddle with lateral shifting
  - 10x24 cm format compression paddle
  - 9x21 cm format compression paddle for magnification
  - 18x24 cm format spot d75 compression paddle
  - 18x24 cm format compression paddle for 2d biopsy
  - Φ 7.5 cm format spot compression paddle for magnification
  - 9x9 cm format spot compression paddle for magnification
  - 10x24 cm format compression paddle for prostheses
  - 18x24 cm format square spot compression paddle
  - 14x17 cm format compression paddle
  - 14x17 cm format compression paddle (two interchangeable plans)
- Fast lock protective screen to keep patient’s face out of X-ray beam during two-dimensional exams;
- Extended protective screen to keep patient’s face out of X-ray beam during tomosynthesis exams;
- Double 7” touch screen colour displays on both sides of C-Arm showing information like: compression force, compressed breast thickness, patient name, projection angle, breast laterality, ACR code, collimation format, magnification factor, messages to the operator in several languages;
- Foot control (for vertical movement of compression paddle) or Multifunction Foot control (for vertical movement of C-Arm and compression paddle)

- Optional kit for geometric magnification (variable 1,5x/1,8x/2x):
  - platform without anti-scatter grid interchangeable with Potter-Bucky;
  - Spot compression paddle for magnification (Φ 7,5 cm format).
- Calculator with removable hard disks (one SSD for operating system and acquisition software and one (or two) HDD for images storage):
  - 2 MPixel LCD Display System (24" viewable size);
  - Optionally 3 or 5 Mpixel LCD Display System (21,3"viewable size) may be provided;
- Two emergency push-buttons;
- Integrated UPS (24 Vdc), 5÷10 minutes typically;

Acquisition software complete of:

- Off-line images display and viewing
- Local operational mode
- Patient information local DataBase
- Tools to make following operations:
  - Local opening of new studies (i.e. not from the worklist)
  - Local studies storing (i.e. in the internal memory of the Acquisition Work Station)
  - Local studies reloading (i.e. from internal memory of the Acquisition Work Station)
  - Local database managing
- "**POEt**" Post-processing algorithm specific for mammography to optimize the quality of the acquired images. Dedicated filters for geometric magnification and in case of prosthesis, metallic clips, surgical markers, clusters of micro calcifications, breast specimens and surgical anatomical parts
- Image tools:
  - Selection and positioning of images to display
  - Display protocol with ACR predefined views
  - Current session loaded images
  - Fit to window, Zoom, Pan, Magnification lens
  - 1:1, Effective size
  - DICOM W/L, High/Very High/Skin contrast
  - Histograms
  - Override ACR settings

  - Mirroring operations on ACR standard views (CC, MLO)
  - Geometric transformations (Invert, Mirror, Flip, 90° rotation) and measurement (ruler, oval, freehand)
- DICOM tools:
  - Worklist studies opening and closing
  - Sending of locally stored studies to the appropriate RIS server
  - Studies printing
  - Studies recording on CD/DVD
  - QC tools based on EUREF protocol
  - Adding annotations and markers (arrow, oval, freehand)

- HIS-RIS-PACS Interface
- Conformities:
  - DICOM 3.0 MG:

<u>The optional separated Acquisition Work Station (AWS) is inclusive of:</u>

- Transparent anti-X protective barrier for operator;
- Monitor Touchscreen 15” or 17” (viewable size);
- Emergency push-button;
- X-ray push buttons.

Additional separate Anti-x barrier for operator protection may be provided in case of local AWS or for other needs, as well as an x-ray foot control can be added.

A compatible Viewing/Reporting Station is also available as option (not part of this Medical Device).

NOTE

This manual describes all the available and certified options, not necessarily all the configurations which are commercially or available in individual markets

1.14 SAFETY SYMBOLS

WARNING

Indicates a risk of danger that may lead to serious physical injury or death.

CAUTION

Indicates a risk of danger that if disregarded leads to slight or moderate physical injury and/ or property damage.

NOTE

Should be understood as a tip. You should not observe these instructions. However, there will be advantages if you follow notes.

1.15 OTHER SYMBOLS

ESD

Warning symbol denoting a device's susceptibility to electrostatic discharge.

1.16 SAFETY INFORMATION

CAUTION Please pay attention to the following notes!

1. *HELIANTHUS series has not to be used by unskilled or untrained personnel.* Metaltronica S.p.A. *does not accept responsibility for injury or damage associated with improper or unsafe system operation. The user should refer to this operator manual for* HELIANTHUS *series's use.*

2. *A correct use of the equipment assumes that operators (technicians and radiologists) hold the necessary technical and specialist knowledge and they have been properly trained for Good Clinical Practice.*

3. *It is supposed that the reader of this manual is used to the general operations of the windows® operating system; it is also assumed that the concepts of PACS, RIS, DICOM, server etc. are well-known.*

4. *This machine must be used only for mammography.*

5. *This machine must be used only in a controlled area inside a dedicated room provided with x-ray protection that meets local standards and regulation.*

6. *This equipment used in the presence of flammable anesthetic or enriched oxygen may cause an explosion*

7. *The equipment is classified as permanently installed according to IEC 60601-1 international standard. This means that it must be electrically connected by means of permanent connections. In particular, for the maximum electrical safety, the protective earth conductor must be fixed and permanently installed.*

8. *To guarantee the electrical insulation of the mammo unit circuits from supply mains, a locking mechanism has to be provided by the responsible organization (e.g. Thermal-magnetic circuit breaker) capable of being locked in the off position.*

9. *HELIANTHUS series can be used by all categories of patient. For disable patients (on wheel chair) be always careful to all automatic movements of c-arm (especially up/down movement).*

10. *Patients with disabilities or temporary disablement must remain seated during the positioning and the mammographic examination.*

11. *Keep away foot controls from the patient's feet and/or exam chair, especially for disable patient on wheel chair and with disability in general. Metaltronica S.p.A. recommends to keep foot controls in a safe area outside the patient ambient (approximately 1,5 m, as defined by IEC 60601-1).*

12. *Before using, check always perfect state of all parts of unit.*

13. *Frequently verify the wear of the compression paddles to prevent damages as cracks and tears, and consequent risks for the patient.*

14. *Do not modify this equipment without authorization of Metaltronica S.p.A..*

15. *Use only original components and spare parts.*

16. *Do not remove plastic coverings of mammography unit that give a protection against the electrical, thermal and mechanical hazards.*

17. *Do not insert in the x-ray beam devices other than compression paddles or magnification device.*

18. *Use lead apron for patient protection, if necessary.*

19. *During x-ray emission, operator must be behind anti-X protective barrier and in position where it is possible to watch patient and unit.*

20. *The detector has a very strict range of temperature for correct operation. It must be operated between 20° and 25 °C (for a-Se detector), between 5° and 40 (for a-Si detector) and between 10° and 40 °C (for SOLO DM detector). Using the mammography unit outside this range can result in bad quality images.*

21. *Respect the storage conditions to avoid irreversible detector damage. Actually this component is very sensitive to the sudden changes of temperature (maximum rate of temperature change: 10°C in 20 minutes) and it must be maintained between 5° and 40°C (for a-Se detector), between -15°C and 65°C (for a-Si detector), between -5° and 55°C (for SOLO DM).*

22. *Pay attention to the LCD monitor of mammography unit and touch screen of Acquisition Work Station (if provided) that are the most fragile parts of the device.*

23. *Use the mammography unit, the Acquisition Work Station and its software according to the instruction given in this manual. Do not try to install unauthorized software, access to operating system configuration or perform other potentially dangerous operations.*

24. *Do not use other equipment or network/data couplings (to which a signal input/output part may be connected), other than those forming part of HELIANTHUS series.*

25. *This is a medical equipment and it should not be considered to be a general-purpose computer: when operating the Acquisition Work Station, do not attempt to make any change to system software and do not use it as a personal internal PC. Any modification or attempt to modify the operating system software will make the unit unsuitable for its intended use.*

26. *If install an Anti-virus Software on the calculator where main device processes work, exclude object storage folders (C:\DMD" and "C:\UTILS) from scan by adding folders to exception on the Anti-virus software. Anti-virus protection and network security are exclusively under the responsibility of the user.*

27. *The device incorporates a LED (Risk Group 2 at 20 cm) for light beam centering device (according to IEC EN CEI 62471). Possibly hazardous optical radiation emitted from this product. Do not stare at operating lamp. May be harmful to the eyes. This LED belongs to low risk (risk group 1 at 50 cm according to IEC EN CEI 62471)*

28. *Never leave unsolved problems that may affect the safety of the product.*

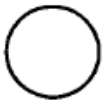
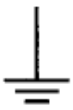
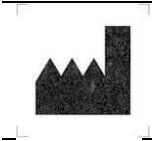
29. *The pictures present in this manual are only indicative and may be subjected to changes (for example the background color) which are not significant for the procedure described.*

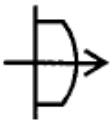
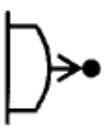
30. *If mammograph is installed in a mobile environment such as a VAN or Truck, it is necessary remove any component from unit before cruise. Lock the C-arm to the lowest position using its special support.*

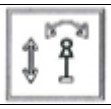
1.17 INTERNATIONAL SYMBOLS

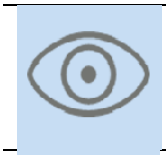
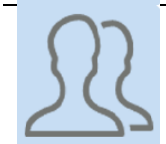
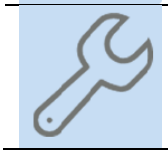
The meaning of symbols appearing on the plate and on some components of the machine is specified in the following Table 1:

Table 1

SYMBOLS	*CEI–IECSTANDARD DEFINITION*
	***ISO 7000-0434A*** ***Caution***
5008 	***IEC 60417-5008*** ***"OFF" Power***
5010 	***IEC 60417-5010*** ***"ON"/ "OFF" (push-push) Power***
5840 	***IEC 60417-5840*** ***Type B Applied Part***
5032 	***IEC 60417-5032*** ***Alternating Current***
5019 	***IEC 60417-5019*** ***Protective Earth (ground)***
5017 	***IEC 60417-5017*** ***Earth (ground)***
	***ISO 15223-1*** ***Manufacturer***
	***ISO 15223-1*** ***Date of Manufacture***

	***ISO 15223-1*** ***Serial Number***
	***ISO 15223-1*** ***Indicates temperature the medical device can be exposed***
	***ISO 7010-M002*** ***Refer to instruction manual/booklet*** ***NOTE On ME EQUIPMENT "Follow instructions for use"***
5036 	***IEC 60417-5036*** ***Dangerous Voltage***
	***WEEE (Waste Electrical and Electronic Equipment)***
5638 	***IEC 60417-5638*** ***Emergency Stop***
5326 	***IEC 60417-5326*** ***Large Focal spot***
5325 	***IEC 60417-5325*** ***Small Focal spot***
5384 	***IEC 60417-5384*** ***Indication of radiation field by light***
5349 	***IEC 60417-5349*** ***Radiodiagnostic compression device, movement***
5350 	***IEC 60417-5350*** ***Radiodiagnostic compression device, pressure applied***

	***IEC 60417-5351*** ***Radiodiagnostic compression device, parked***
	***IEC 60417-5339*** ***X-ray source assembly, emitting***
	***IEC 60417-5570*** ***Unlocking or unlock***
	***C-arm rotation angle***
	***IEC 60417-5367*** ***C-arm position***
	***C-Arm rotation angle and up/down (for Biopsy device)***
	***Compressed Breast THICKNESS***
	***ERROR MESSAGE***
	***Focal Spot***
	***Xray tube***
	***Z axis increase and decrease (for Biopsy device)***
	***Medical Device***
	***Unique Device Identification***
	***Electronic Instruction For Use***
	***Nearby Model Name***

	***Acquisition software icon (user)***
	***Icon to access to software maintenance tools***
	***Area to set or modify device users***
	***Access to manufacturer reserved area***

1.18 ACRONYMS

The meaning of acronyms appearing on this manual are specified in the following Table 2

Table 2

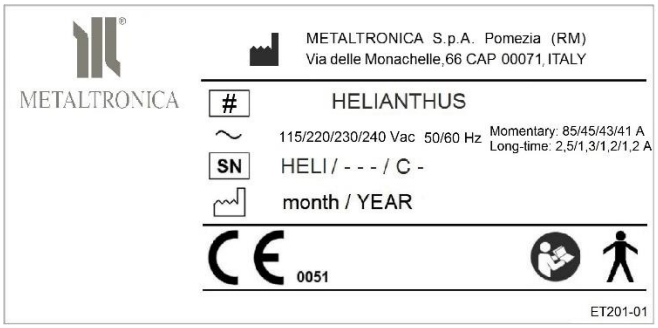
ACR	American College of Radiology
AEC	Automatic Exposure Control
AGD	Average Glandular Dose
AOI	Area of Interest
AWS	Acquisition Work Station
CB	Core Biopsy
DBT:	Digital Breast Tomosynthesis
DICOM	Digital Imaging and Communications in Medicine
DMD	Digital Mammography Device
DME	Digital Mammography Equipment
DSP	Service display (Pop-up service window)
FFDM	Full Field Digital Mammography

FTSE	Function of Tissue Strength Evaluation
GUI	Graphical User Interface
HRD	High Resolution Display
MG	Needle Safety Margin
MMD	Manufacturer Mammography Devices
MMI	Man-Machine Interface (it has the same meaning of GUI)
NPU	Needle Position Unit
OD	Optical density
PACS	Picture Archiving and Communications Systems
RIS	Radiology Information System
ROI	Region of Interest
TSD	Touch Screen display
UDI	Unique Device identifier

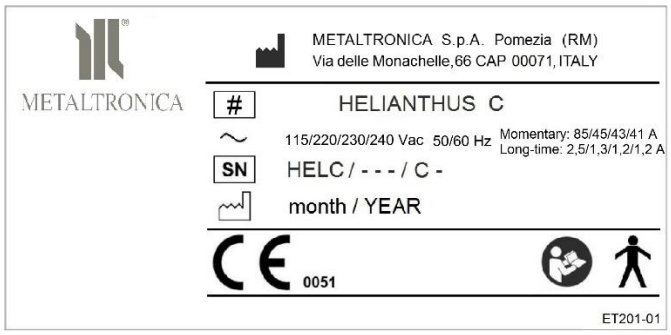
1.19 DEVICE CLASSIFICATION

The identification label and additional UDI label are placed on the back of the device and a true copy of it is also placed inside the gantry

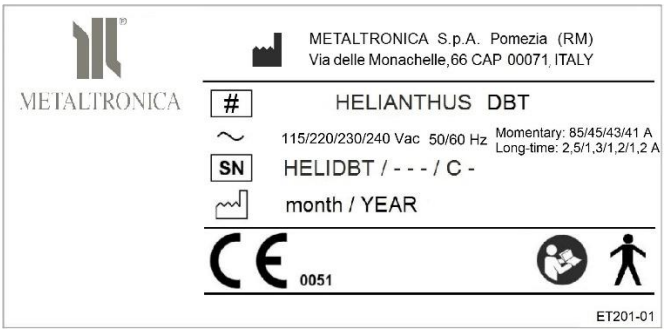
HELIANTHUS 115/220/230/240 Vac MAINS *(50/60 Hz)*



HELIANTHUS C 115/220/230/240 Vac MAINS *(50/60 Hz)*



HELIANTHUS DBT 115/220/230/240 Vac MAINS *(50/60 Hz)*



HELIANTHUS series belongs to Class I type B applied parts.

HELIANTHUS series belongs to Class IIb.

NOTE

The images depicting the mammographic unit or part of it are illustrative or schematic. The images where assembly instructions are given are faithful to the actual configuration of the mammography unit.

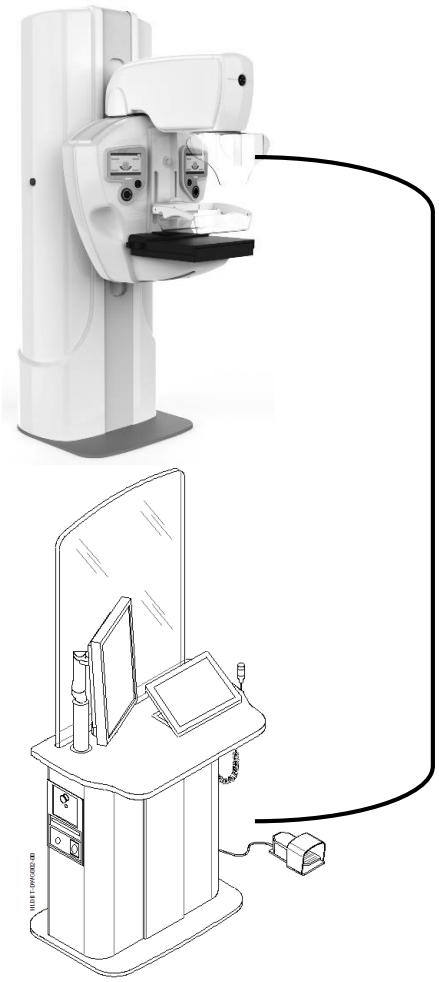
1.20 ACQUISITION WORK STATION (AWS) CONFIGURATIONs

CAUTION

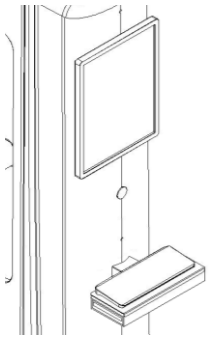
Acquisition Workstation is not intended for reviewing and long term archiving scope.

NOTE

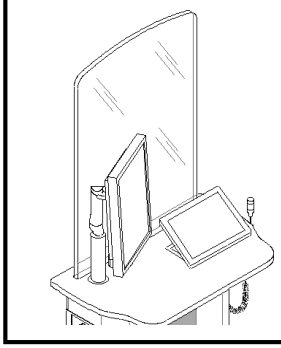
The configurations available depend on the option chosen. See paragraph “configurations available” in section VIII: Auxiliary components & optional parts, for more details



Mammograph



Acquisition work station



NOTE

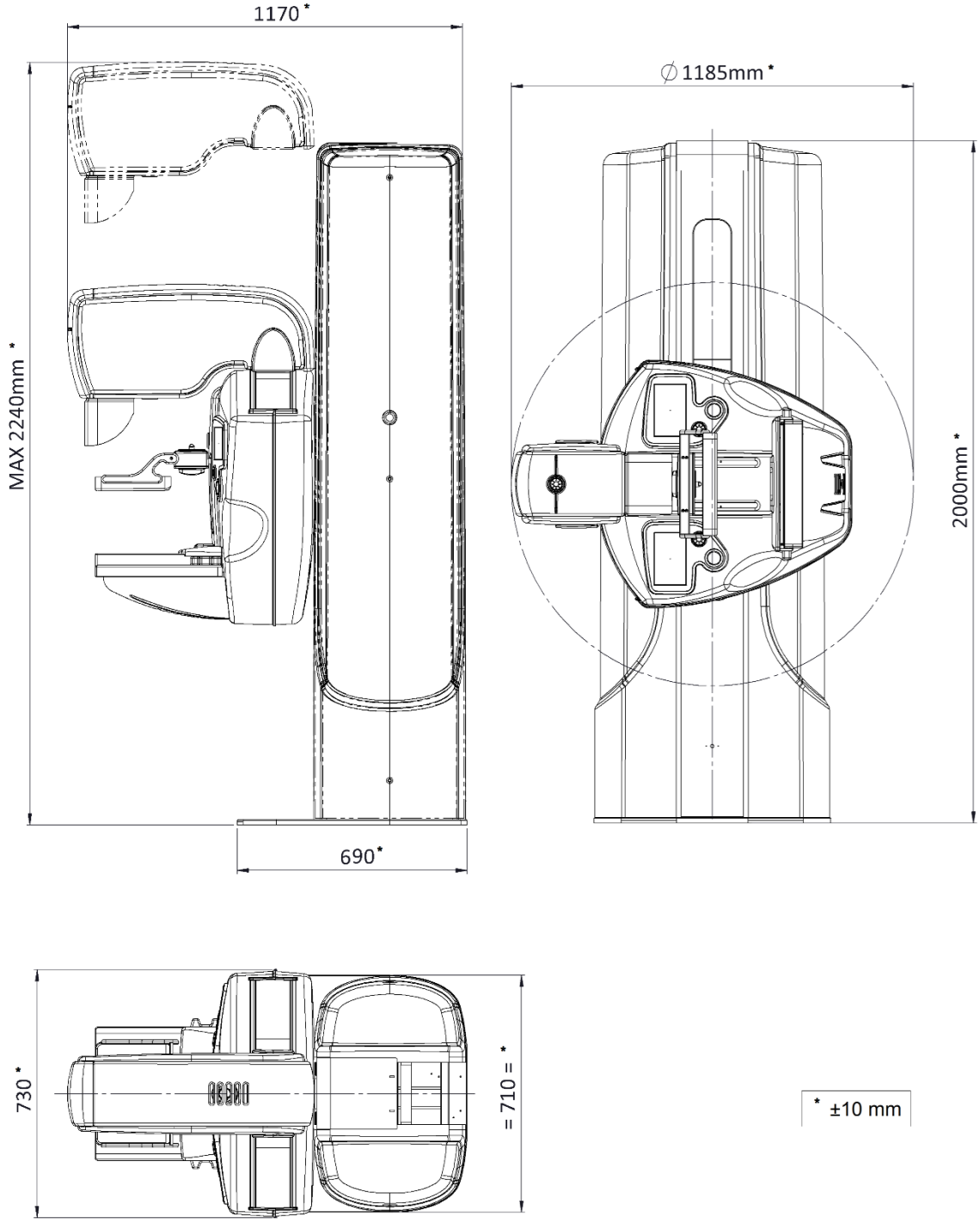
Double AWS Configuration (Mammograph with Acquisition Workstation) could be available for dedicated countries

1.21 DIMENSIONAL DRAWINGS

CAUTION

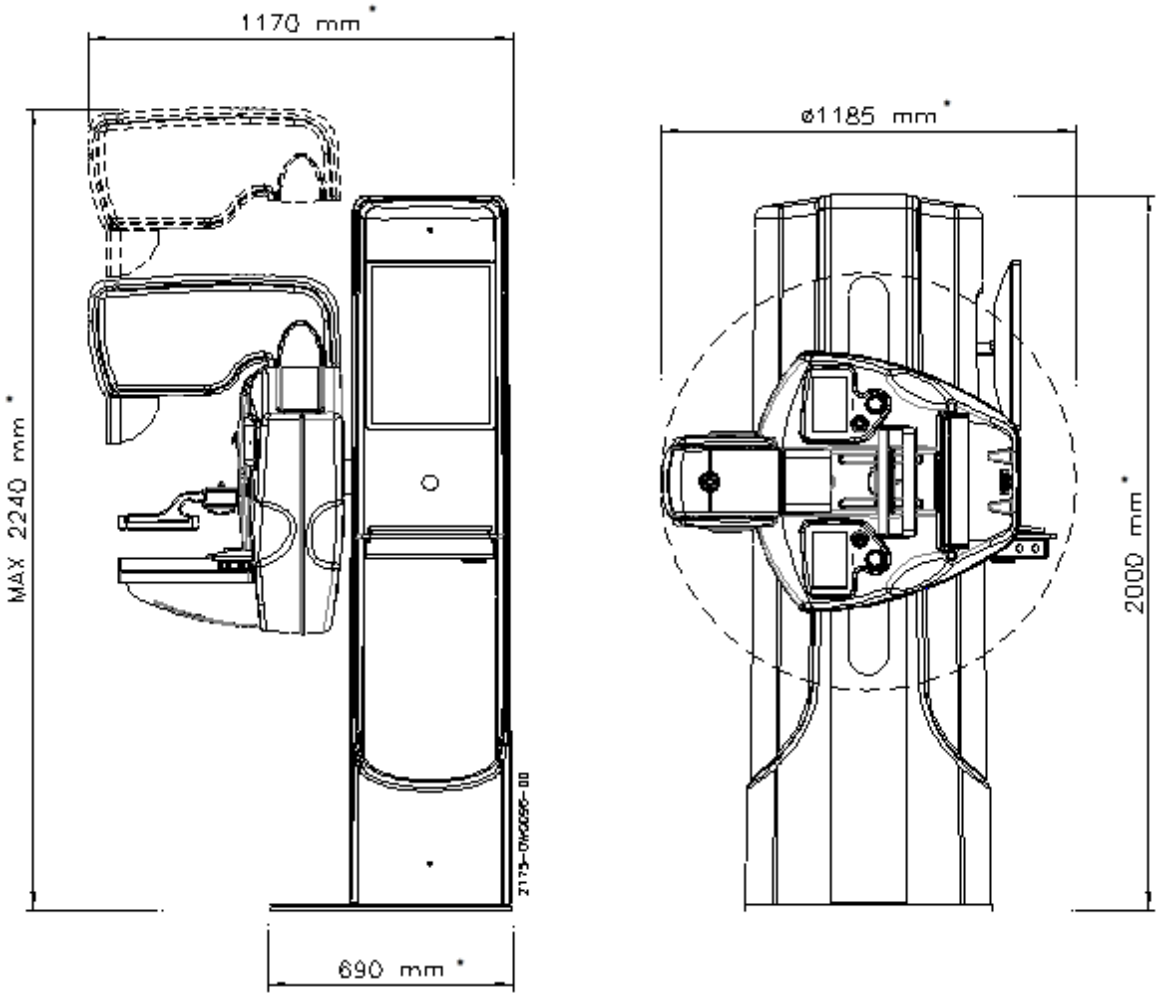
When carrying out the necessary support calculation, weight of patient and operator must be considered.

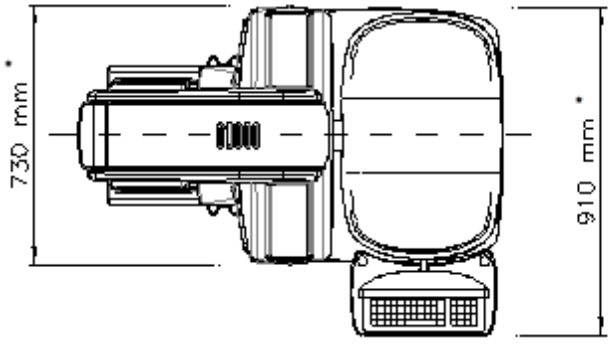
1.2.1 MAMMO UNIT WITHOUT LOCAL AWS



Weight: 300 kg

MAMMO UNIT WITH LOCAL AWS



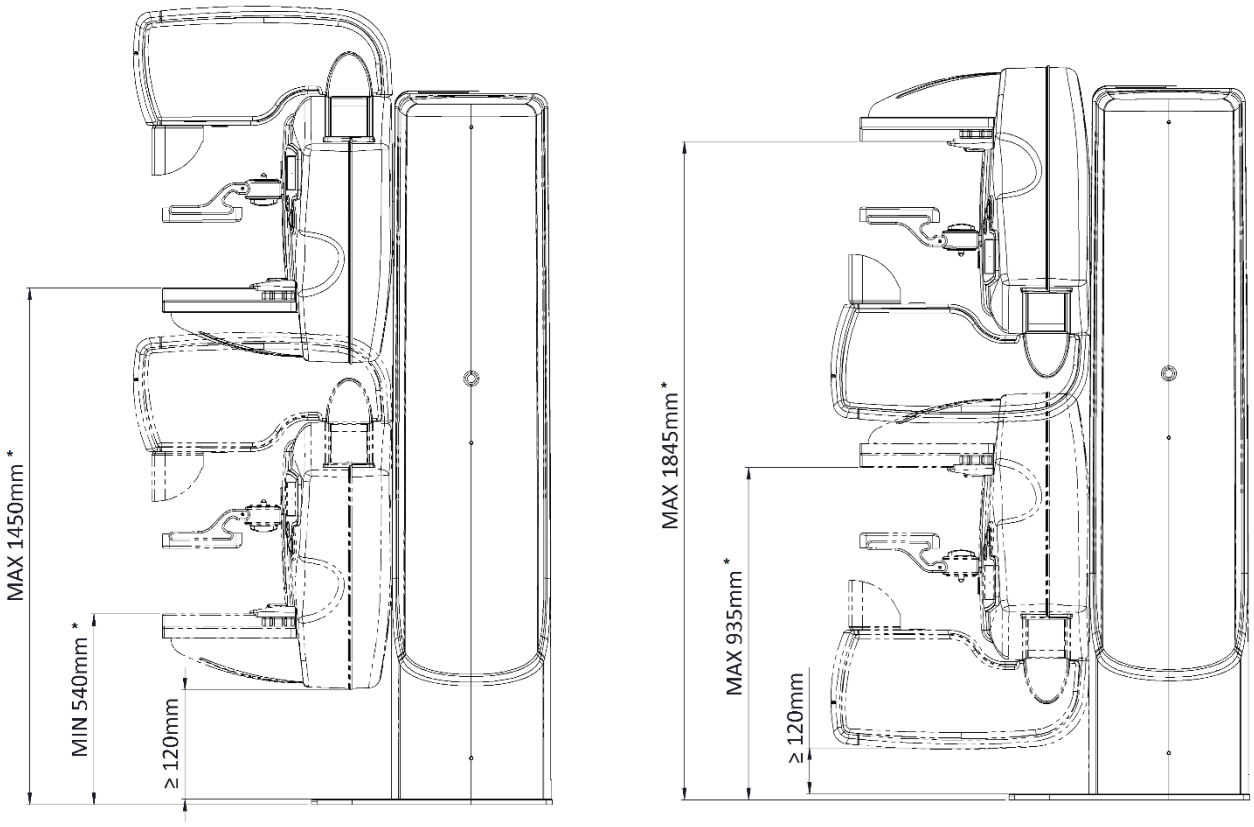


* ±10 mm

Weight: 300 kg

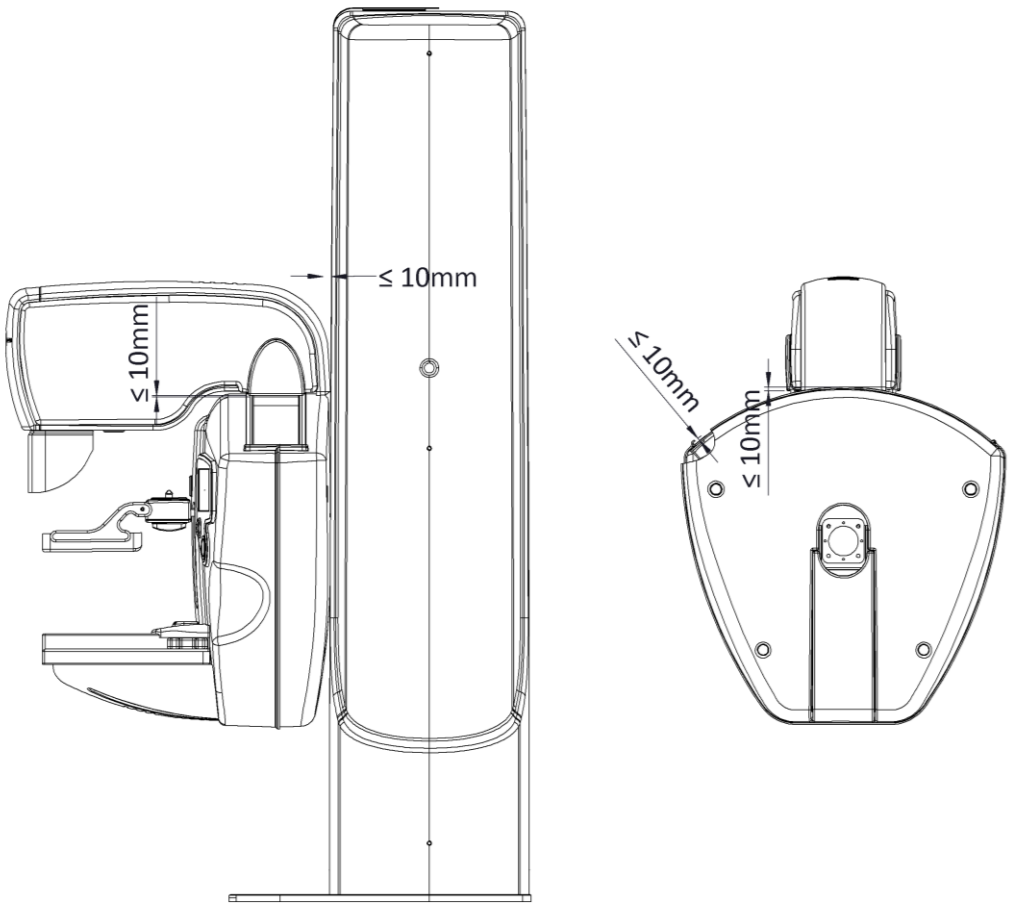
NOTE

The choice regarding the right or left positioning of the local AWS can be made during the purchase phase.



NOTE

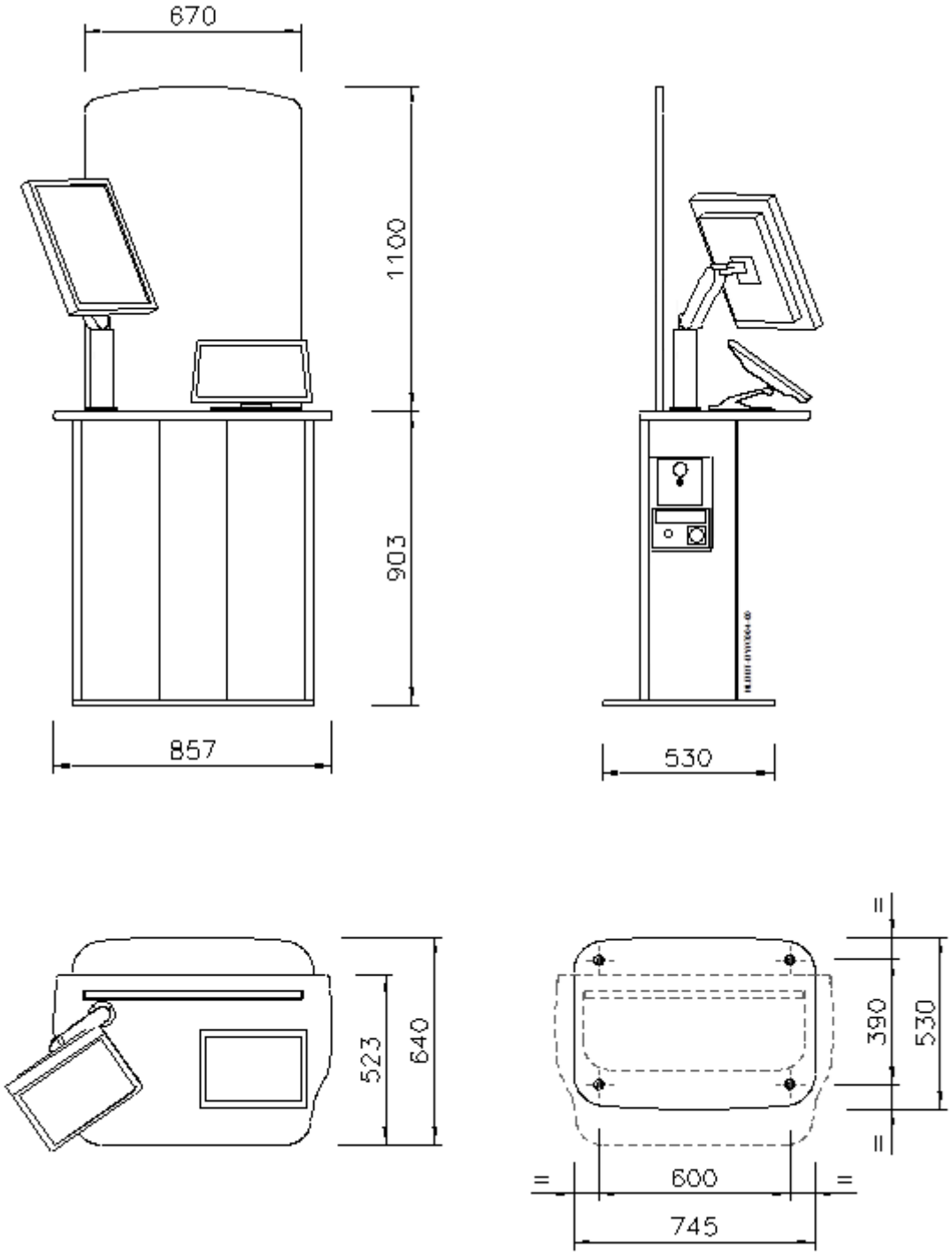
This indication (*) for the drawing above may have a tolerance of ±5mm due to the sum of overall tolerance during assembling .



NOTE

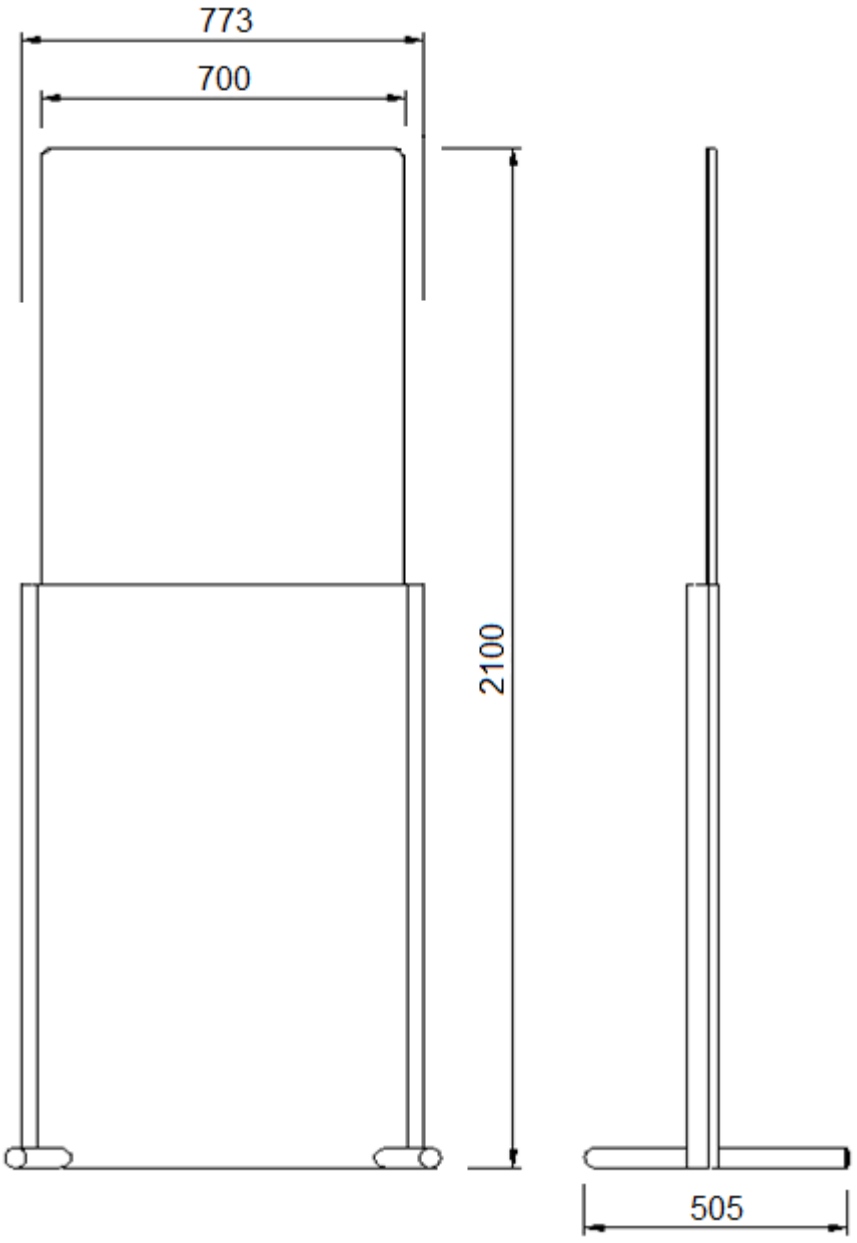
When the stereotactic biopsy device BYM 3D DMD is installed on HELIANTHUS series, the C-Arm maximum rotation is limited to ± 90°.

1.22 ACQUISITION WORK STATION (AWS) DIMENSIONAL DRAWINGS



Weight:
90 kg (0,34mm Eq. Pb, thickness 20 mm)
56 kg (0,50mm Eq. Pb thickness 11 mm)

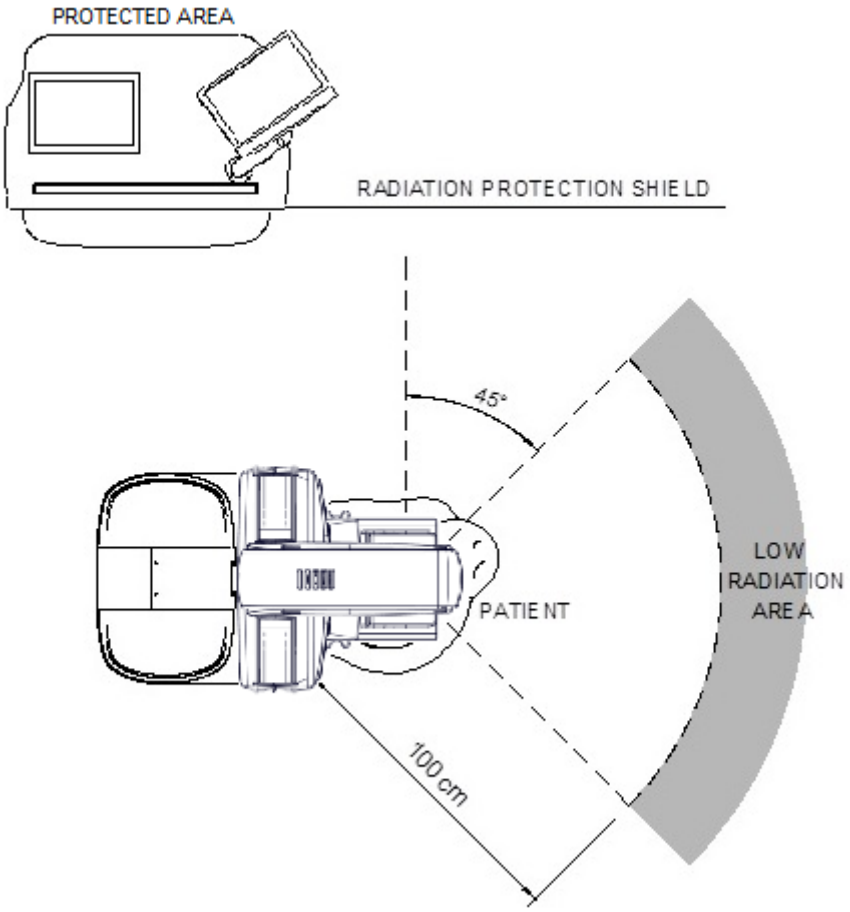
1.23 ANTI-X BARRIER DIMENSIONAL DRAWINGS



Weight: 77 kg (0,34mm Eq. Pb, thickness 20 mm)
50 kg (0,50mm Eq. Pb thickness 11 mm)

1.24 PROTECTION AGAINST STRAY RADIATION

The HELIANTHUS series incorporates a barrier to protect the operator against stray radiation. The control of x-ray equipment must be implemented from the protected area placed behind the Acquisition Work Station (International Standard IEC 60601-1-3 point 13.2).

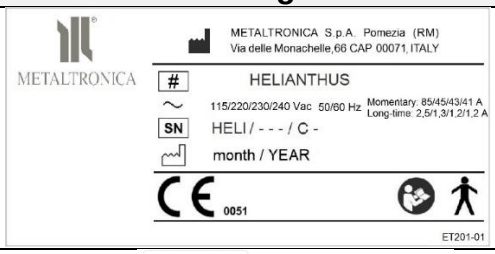
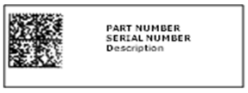
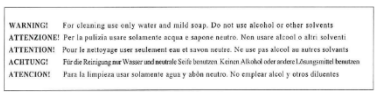


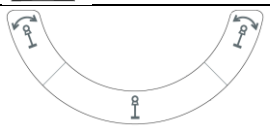
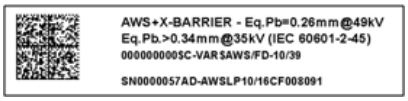
According to local regulation for radiological protection, the access to the equipment and to the protected area must be restricted to the authorized personnel only.

CAUTION

If the Anti-X Barrier is already available and not directly provided by Manufacturer, please follow the same above indication for radiation protection

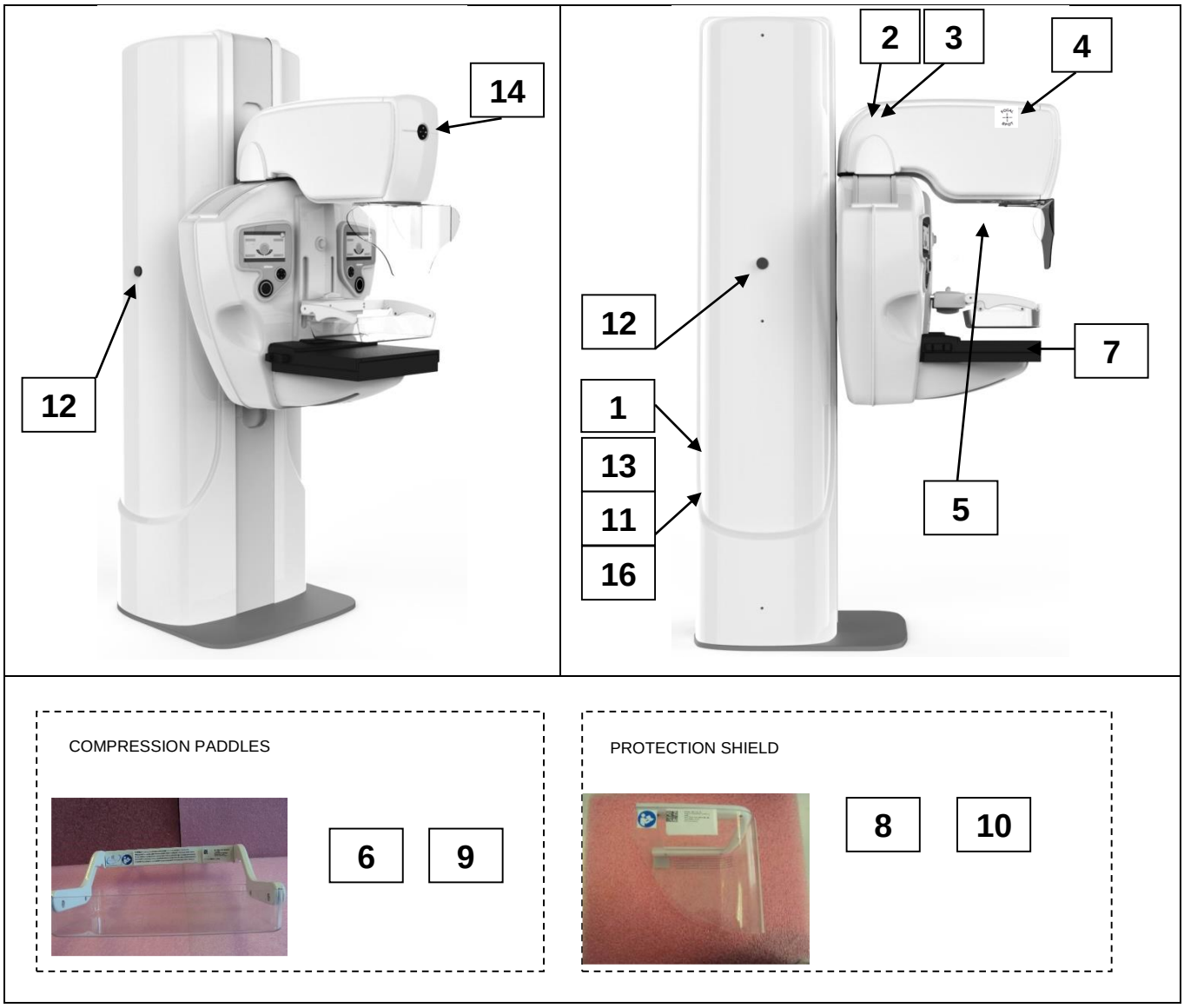
1.25 MAMMO UNIT EXTERNAL LABELS

External Labels or symbols		Placement	Ref
Meaning	**Image**	**Description**	**#**
ID label		**Back panel of Mammo unit**	**1**
UDI label			
Medical Device label			
Model	 Nearby Model Name		
X-ray Tube identification	 **Optional tubes:** 	**Back Xray tube Cover on C-arm**	**2**
X-ray Tube Characteristics		**Back Xray tube Cover on C-arm**	**3**
X-ray Tube identification		On the Xray lateral cover of C-arm jn correspondence of real focal spot	4
Led indication		On the lower panel of C-arm near the collimation window	5
Indications on auxiliary components: • Refer to manuals • Applied Parts • Logo Brand • Part Number • SN Mammo Unit	    	On the Internal Metallic Frame of compression paddles	6
		On the Edge of Tables/Magn Device/Detector and on the lower panels	7
		On the Upper Part of protection screen	8
Cleaning Indications		On the Internal Metallic Frame of compression paddle	9
		On the Upper part of protection shield	10

External Labels or symbols		Placement	Ref
Meaning	**Image**	**Description**	**#**
Safety protection		On the Back Panel of Mammo Units and on the Cover near the opening screws	11
Emergency unlock		Below the Emergency controls (on lateral covers and remote AWS if available)	12
WEEE waste bin,		On the back panel of Mammo Gantry	13
C-arm movements		On up/down rotation controller	14
X-ray Protection		On Metallic frame of AntiX Barrier or Back Panel of remote AWS if provided	15
eIFU		On the back panel of Mammo Gantry	16

NOTE The X-ray tube labels shown in the figure above are representative. The data shown on them depend on the model installed on the mammography unit.

1.26 MAMMO UNIT IDENTIFICATION LABELS



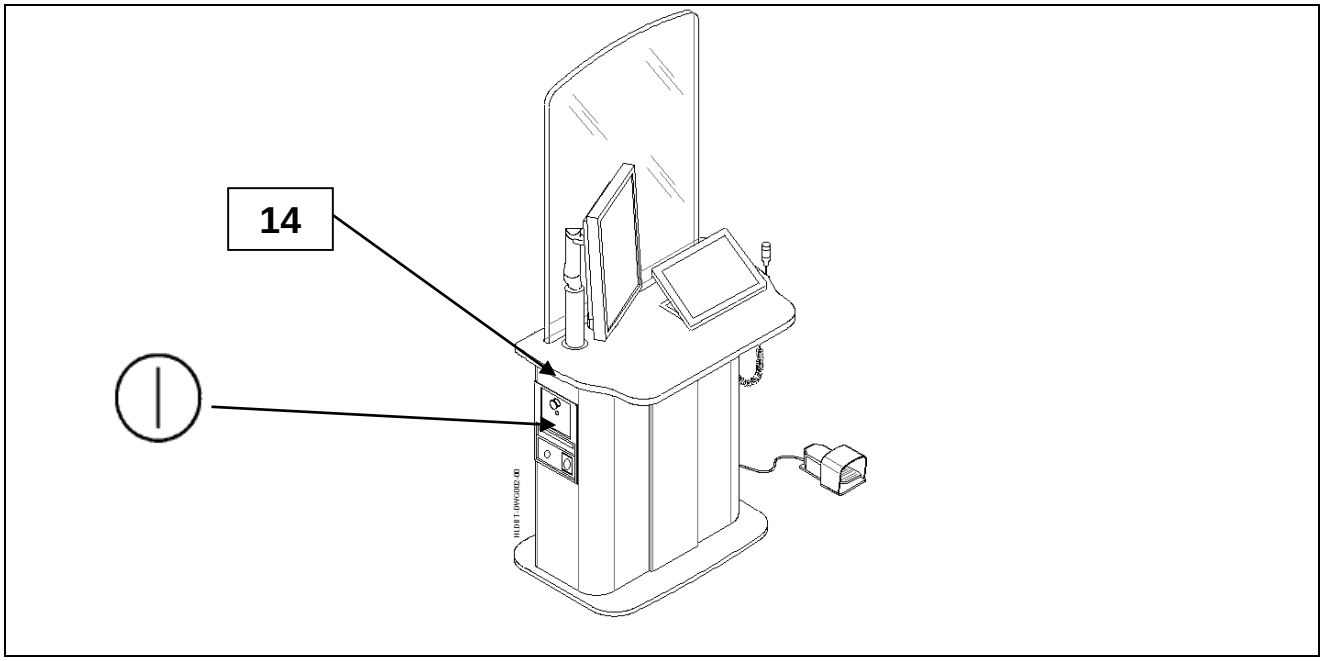
NOTE

This medical device is intended for professional use.
For this reason, English easy to be understood by user is applied for some external labels.

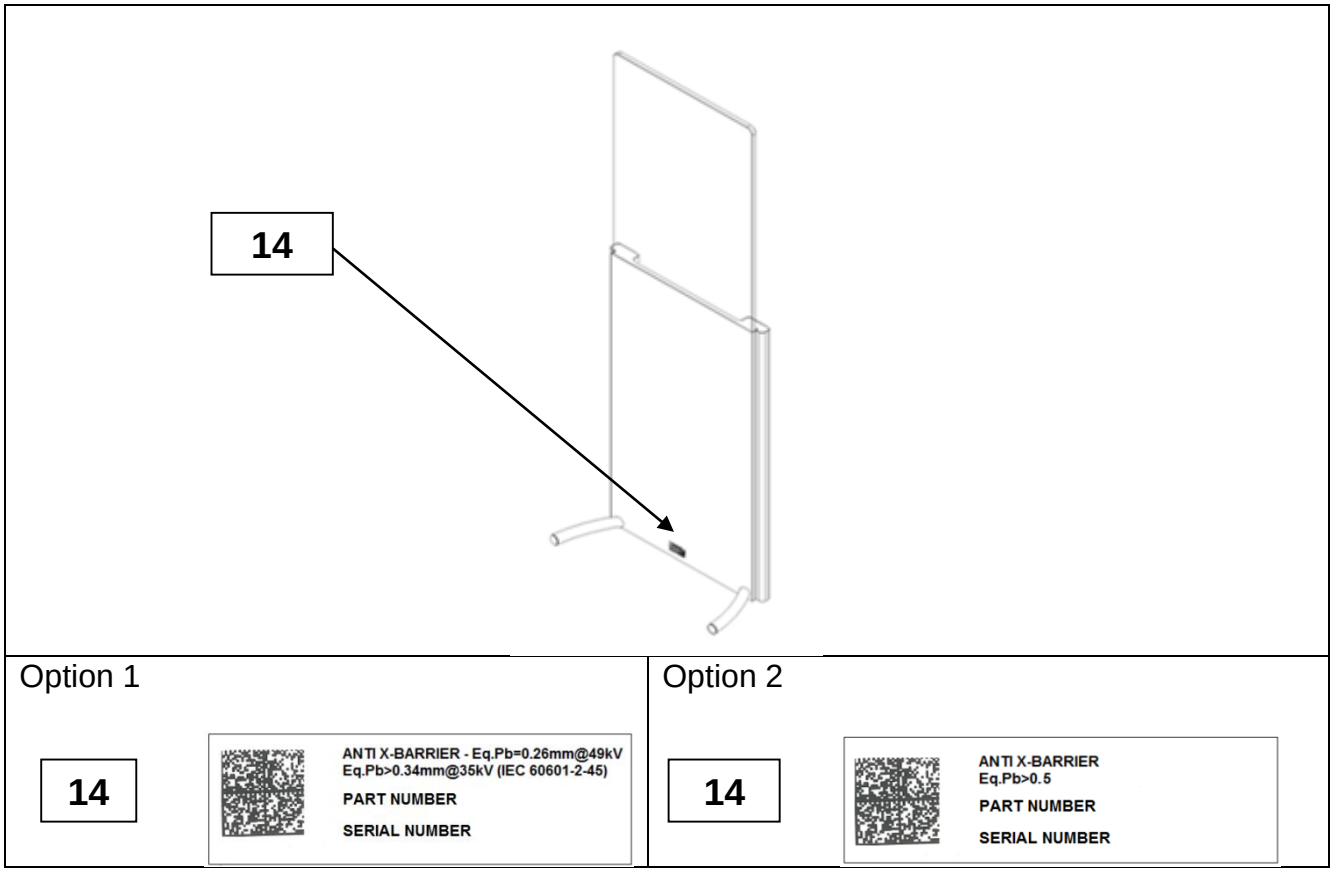
NOTE

Identification labels are important for a safe use of the equipment.

1.27 ACQUISITION WORK STATION (AWS) IDENTIFICATION LABELS



1.28 ANTI-X BARRIER IDENTIFICATION LABELS



Option 1	Option 2
14	14

Anti-x barrier can be optionally provided with local AWS configuration.

1.29 MAMMO UNIT CONFIGURATIONS

FUNCTION	DETAILS	HELIANTHUS C	HELIANTHUS	HELIANTHUS DBT
MOTORIZED ROTATION	NA	O	●	●
HV GENERATOR	20÷35 Kv	●	●	X
	20÷49 Kv	O	O	●
HSS	NA	O	O	●
MAGNIFICATION DEVICE KIT	Including 1. Platform without anti-scatter grid interchangeable with Potter-Bucky, 2. 9x21 cm format compression paddle; 3. Φ 7,5 cm format compression	O	O	O
STEREOTACTIC BIOPSY (Note 1)	Including 1. 14x17 cm format compression paddle	X	O	O
TOMO BIOPSY	NA	X	O	O
LATERAL APPROACH BIOPSY	Including 1. 14x17 cm format compression paddle (two interchangeable plans)	X	O	O
TOMO KIT (3D DIAGNOSTIC)	Including • 24x30 compression paddle for TOMO • Potter-Bucky with vibrating grid specific for 2D and TOMO exams • License Key for Tomo reconstruction • Protective screen for Tomosynthesis exams • Dedicated graphic board • additional 8 GB system RAM	X	O	●
"MVIEW-VI" function	NA	X	O	O
DIGITAL FLAT FIELD DETECTOR	AXS2430FDIV2	●	●	●
	AXS2430screenplus	O	O	O
	AXS2430	O	O	O
	AXS2430FDI	O	O	O
	AXS2430V2	O	O	O
	SOLO DM	O	O	O
XRAY TUBES	IAE XM1016T	●	●	●
	IAE XK1016T	O	O	O
	VAREX M113T	O	O	X

FUNCTION	DETAILS	HELIANTHUS C	HELIANTHUS	HELIANTHUS DBT
PROTECTION SHIELD	2D	●	●	●
	3D	X	O	●
COMPRESSION PADDLES	24x30 cm FORMAT COMPRESSION PADDLE	O	●	●
	24x30 cm FORMAT COMPRESSION PADDLE (TOMO exam)	O	O	O
	18x24 cm FORMAT COMPRESSION PADDLE WITH LATERAL SHIFTING	●	●	●
	10x24 cm FORMAT COMPRESSION PADDLE	O	O	O
	9x21 cm FORMAT COMPRESSION PADDLE FOR MAGNIFICATION	O	O	O
	18x24 cm FORMAT SPOT D75 COMPRESSION PADDLE	O	O	O
	18x24 cm FORMAT COMPRESSION PADDLE FOR 2D BIOPSY	O	O	O
	Φ 7.5 cm FORMAT SPOT COMPRESSION PADDLE FOR MAGNIFICATION	O	O	O
	9X9 cm FORMAT SPOT COMPRESSION PADDLE FOR MAGNIFICATION	O	O	O
	10x24 cm FORMAT COMPRESSION PADDLE FOR PROSTHESES	O	O	O
	18x24 cm FORMAT SQUARE SPOT COMPRESSION PADDLE	O	O	O
DYNAMIC AUTOMATIC COLLIMATION (format/filter)	NA	●	●	●
MOVEMENT FOOT CONTROLS	ONE PAIR	●	●	●
	TWO PAIR	O	O	O
	ONE PAIR MULTIFUNCTIONS	O	O	O
	TWO PAIR MULTIFUNCTIONS	O	O	O
XRAY FOOT CONTROL	NA	O	O	O
DVD BURNER	NA	O	●	●
AUDIO SPEAKER	NA	O	O	●
AWS	NA	O	O	O
MONITOR	2MP	●	●	●
	3MP	O	O	O
	5MP	O	O	O
CALIBRATION TOOLS/ PHANTOMS	periodical system calibration without compression	●	●	●
	AEC / daily check calibration with compression	●	●	●
	Calibration shield	●	●	●
Bearing for compression paddle	NA	O	O	O

FUNCTION	DETAILS	HELIANTHUS C	HELIANTHUS	HELIANTHUS DBT
Mobile Installation KIT	NA	O	O	O
10 kVA (UPS)	NA	O	O	O
Patient bed/chair	NA	O	O	O

●: provided
O: optional
X: Not integrable

Note1: for stereotactic biopsy application this medical device needs to be compatible with components: NEEDLE GUIDES, medical devices manufactured and separately certified by BIOMED INSTRUMENTE & PRODUKTE GMBH (BIP GMBH).

WARNING Use only original components and spare parts.

Section II: Configurations

Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format definition and a network communications protocol. The communication protocol is an application protocol that uses TCP/IP to communicate between systems. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format.

DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a picture archiving and communication system (PACS). DICOM has been widely adopted by hospitals and is making inroads in smaller applications like doctors' offices.

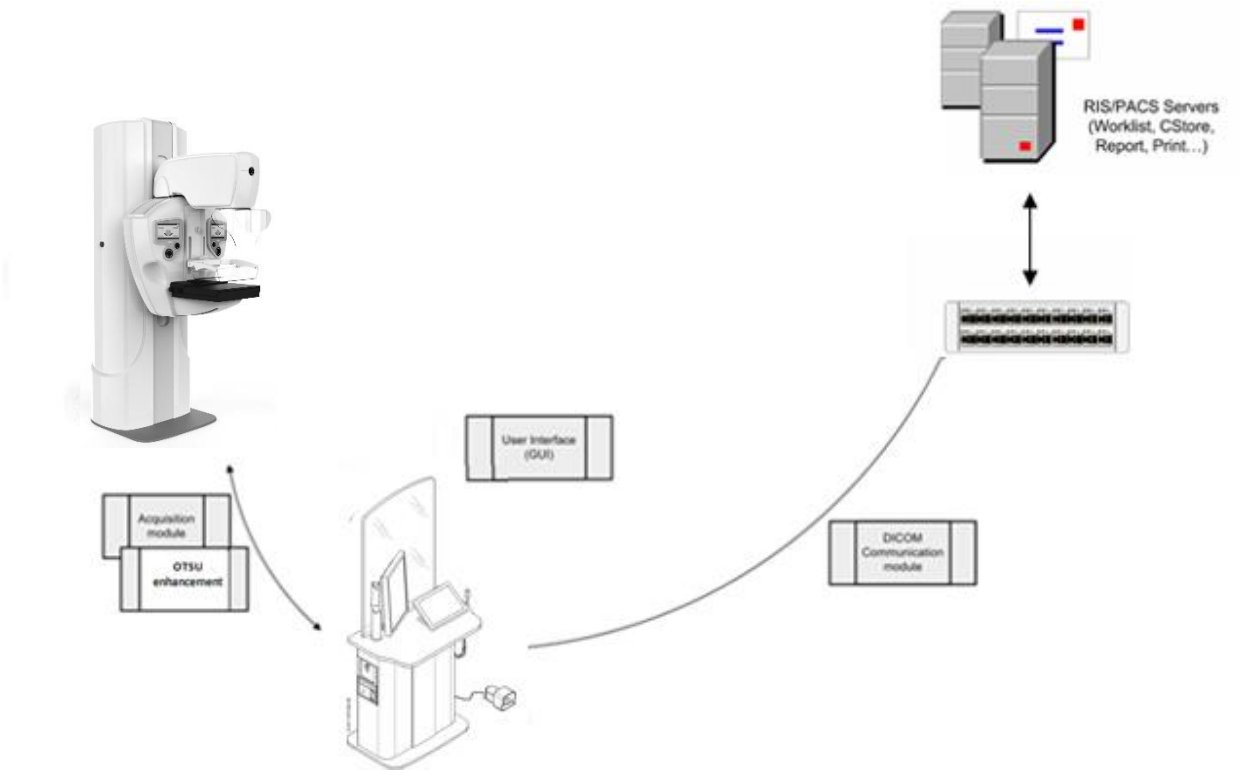
DICOM consists of many different services, most of which involve transmission of data over a network, and the file format below is a later and relatively minor addition to the standard.

HELIANTHUS series is full DICOM 3.0 MG compliant; it means that this device implements the totality of DICOM services provided for mammography.

Depending on the installation site and preferences, HELIANTHUS series can be configured as described in the following pages.

Three different configurations are possible. The differences are based on the presence or not of the DICOM net and on the supplying or not of the Review Station.

2.1. “FULL DICOM” CONFIGURATION

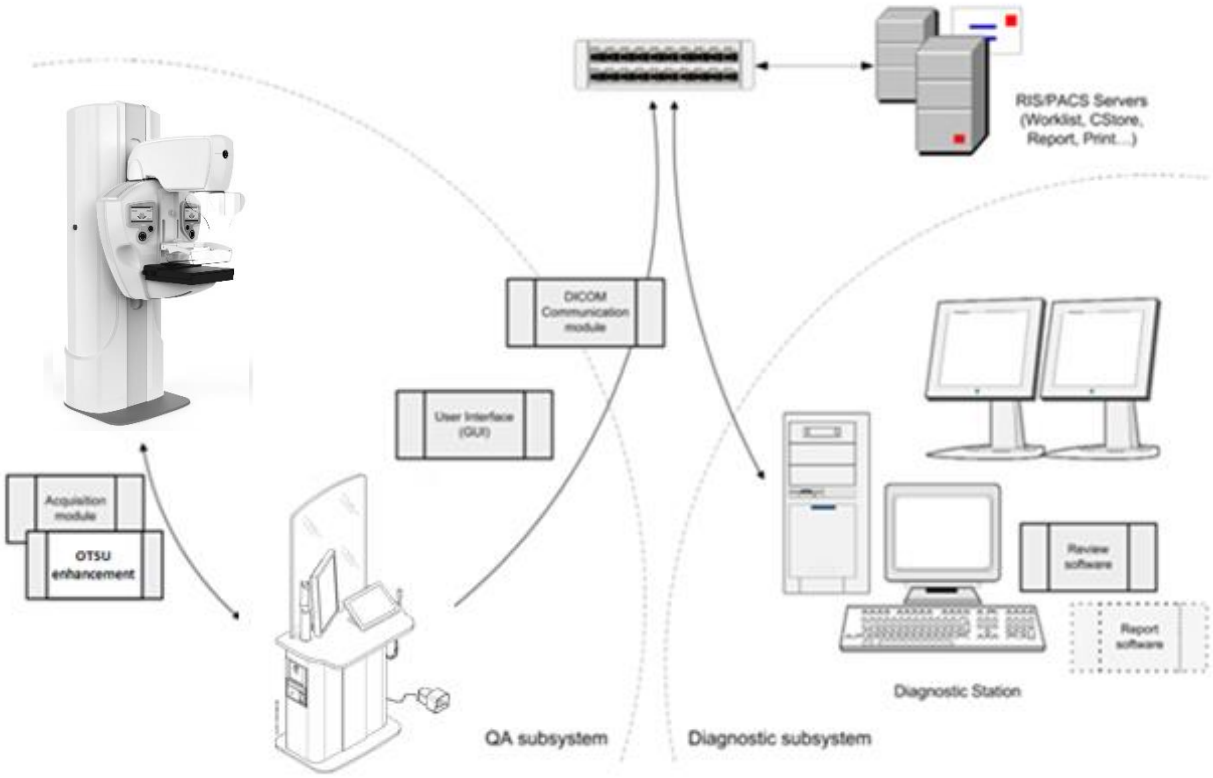


This configuration of the HELIANTHUS series can be used when a DICOM net and a remote Review Station are already available on the installation site.

The mammography system, connected to the PACS, allows to open a study from the Worklist (remotely generated); closing the study, the acquired images and all exam parameters are sent to the PACS, synchronized with the Worklist and stored on the appropriate server of the RIS. Then, the images can be examined and reviewed from remote Review Station.

If the DICOM Worklist server is out of service, the mammography system is anyway able to work. In this case, the images and study data are stored in internal memory of Acquisition Work Station. When the normal functionality of the net is reactivated, the studies are newly synchronized with the Worklist and stored on the server.

2.2. “FULL DICOM” CONFIGURATION + REVIEW STATION



This configuration of the HELIANTHUS series can be used when a DICOM net already exists on the installation site but there is not a remote diagnostic station specific for mammographic review.

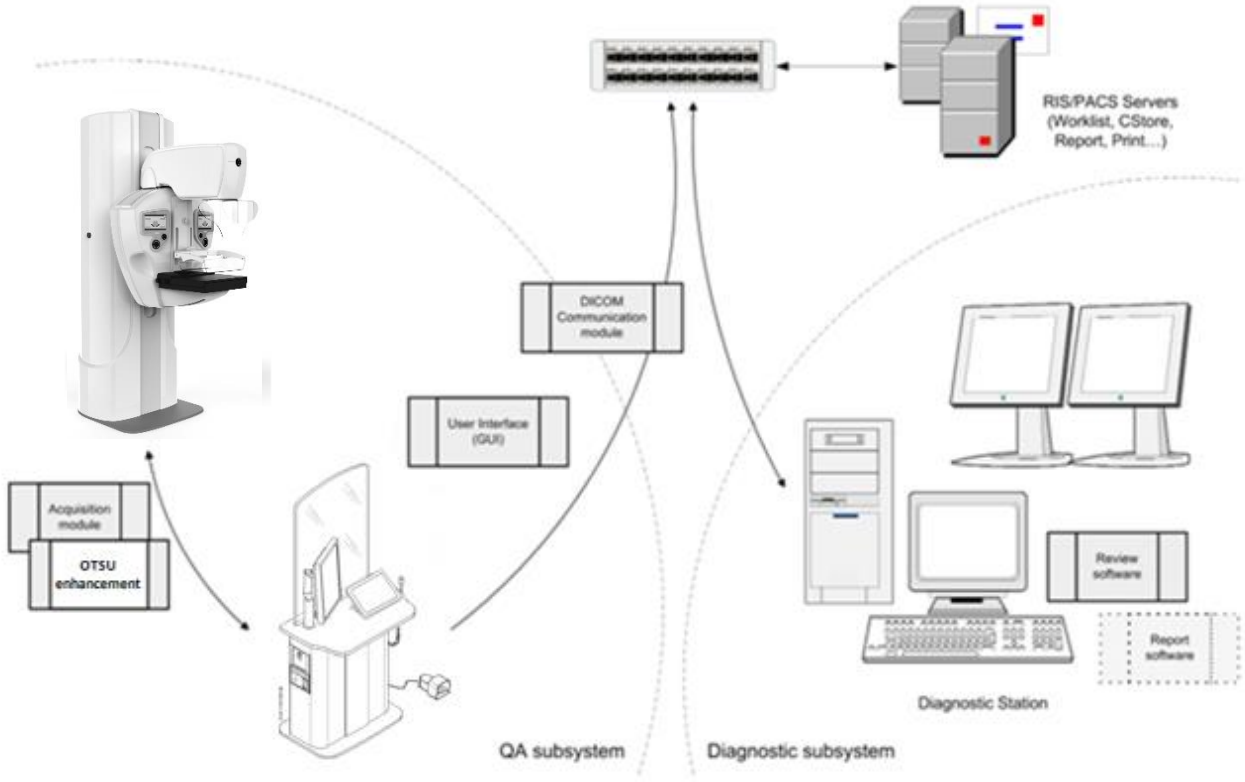
With the mammography system, set up as in the “FULL DICOM” configuration, is supplied also a diagnostic station with a dual headed display system at very high resolution and a review software dedicated to the mammography.

Mammography system and diagnostic station are both connected to the RIS/PACS servers.

The workstation can be configured to use mammographic specific hanging protocol and reading workflow. It displays also images from other modalities (digitized prior mammogram films, breast US, breast MRI, breast NM, breast CT) and allows selection, display, manipulation, markup, print composition and media exchange of breast images.

The software can be integrated with an optional Computer Aided Detection (CAD).

2.3. “mini-PACS” CONFIGURATION



This configuration of the HELIANTHUS series must be used when a DICOM net is not available on the installation site.

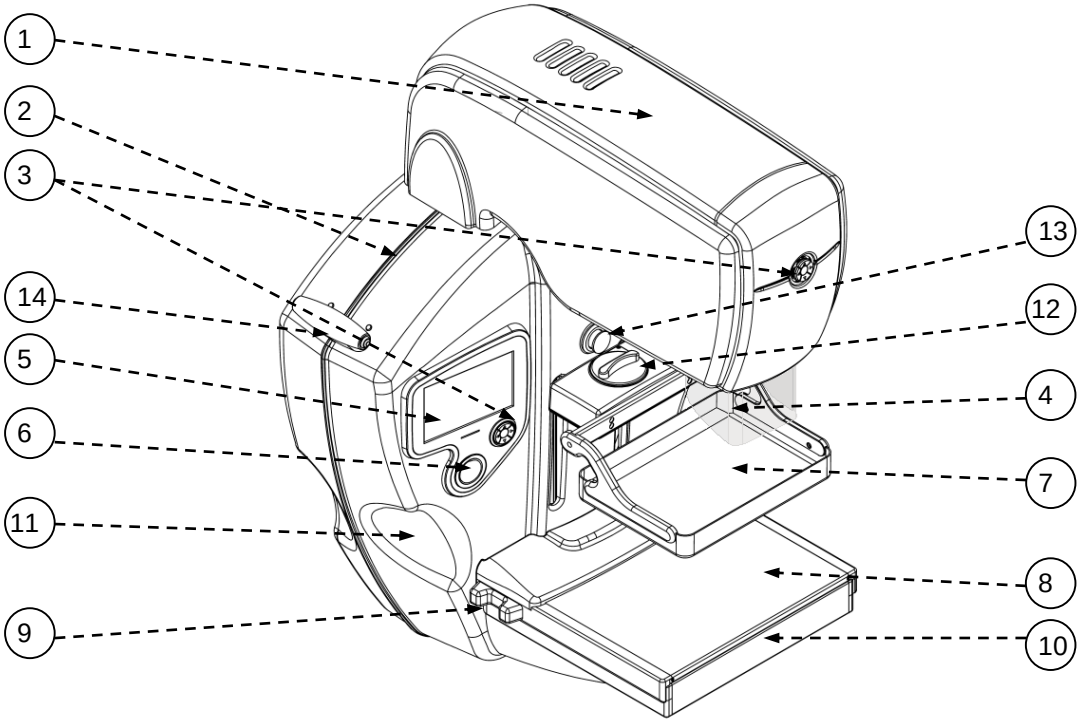
HELIANTHUS series in mini-PACS configuration represents a complete individual island of digital imaging. It has the form of a localized, modality-specific network of modalities and storage directly connected to reading workstations without long-term storage or management. Normally Full Field Digital Mammography (FFDM) requests to manage large image sizes with these highly specialized reading and display requirements.

Also in this case, the mammography system supports connections with all DICOM modalities.

Section III:
Main Parts Descriptions

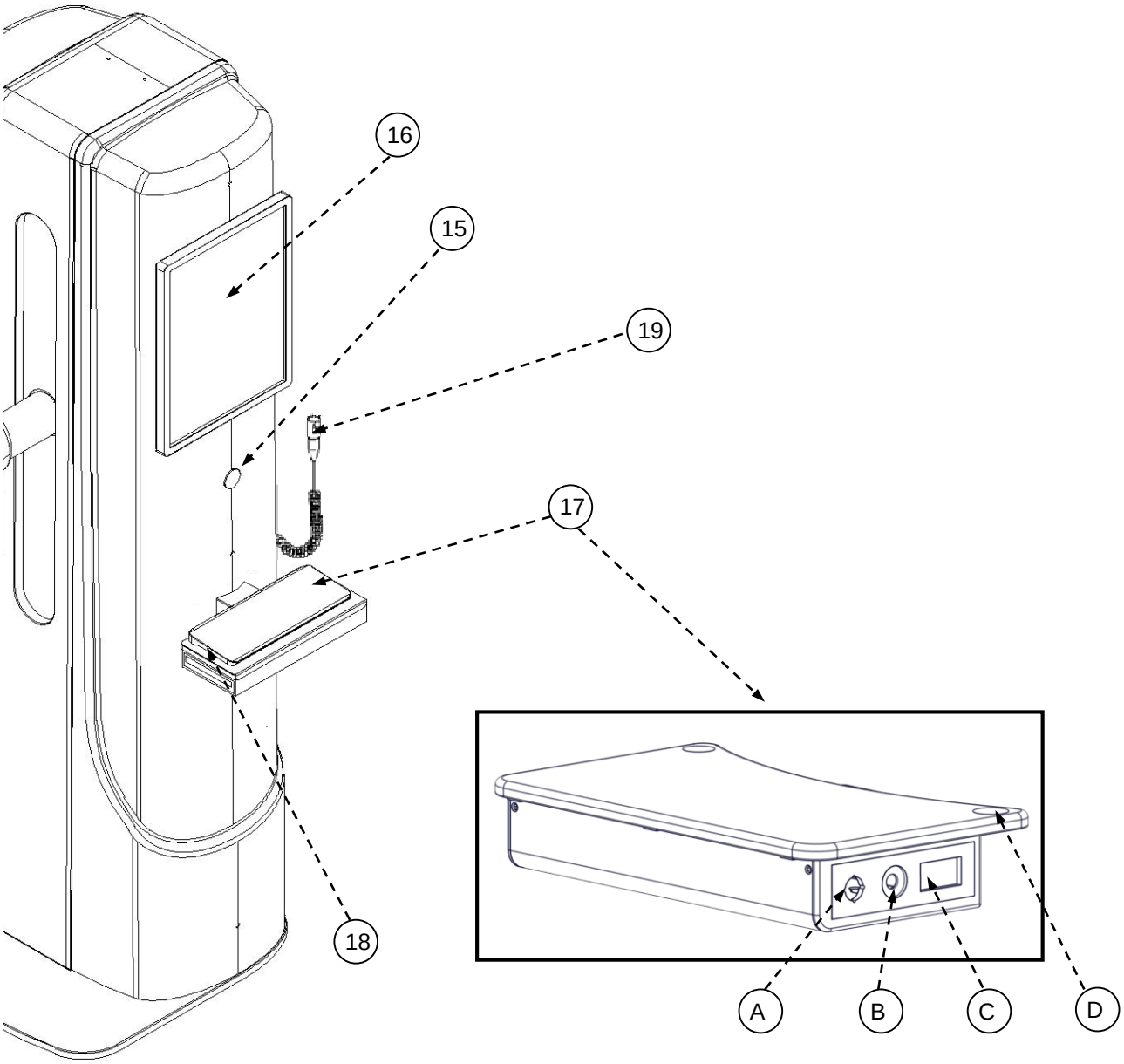
3.1. MAMMOGRAPHY UNIT

C-ARM main parts



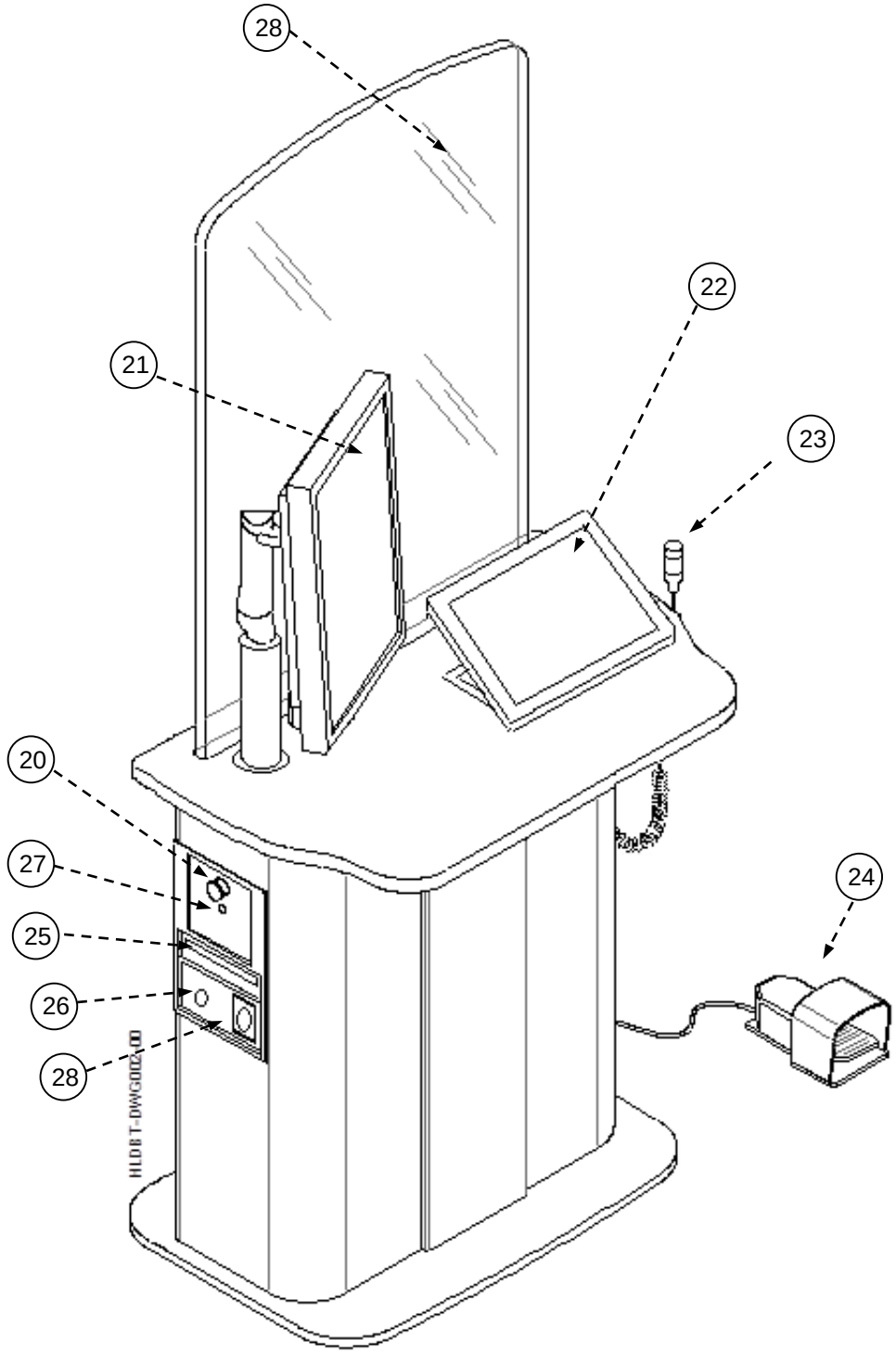
1. X-RAY TUBE COVER
2. TILTING MECHANISM COVER
3. C-ARM MULTI-SWITCH (on both sides and on frontal Tube cover)
4. PROTECTIVE SCREEN
5. MAMMO TSD: TOUCH SCREEN COLOR DISPLAY (on both sides)
6. MANUAL ROTATING CONTROLLER (on both sides)
7. COMPRESSION PADDLE
8. POTTER-BUCKY y
9. PLUNGERS FOR POTTER-BUCKY LOCKING/UNLOCKING
10. FLAT FIELD DIGITAL DETECTOR
11. PATIENT HAND SUPPORT
12. ROTATING KNOB FOR COMPRESSION PADDLE LOCKING/UNLOCKING
13. MANUAL COMPRESSION/RELEASE PUSH-BUTTON
14. HANDLE (for Manual Rotation option, on both sides)

STAND main parts



15. EMERGENCY PUSH BUTTON
16. HIGH RESOLUTION MONITOR
17. KEYBOARD SUPPORT
18. DVD RECORDER
    A. USB 3.1 port
    B. MAIN SWITCH (ON/OFF)
    C. AUDIO SPEAKER
    D. X-RAY PUSH BUTTON HOUSING
19. XRAY-PUSH BUTTON

3.2. ACQUISITION WORK STATION (AWS) with LCD Color display



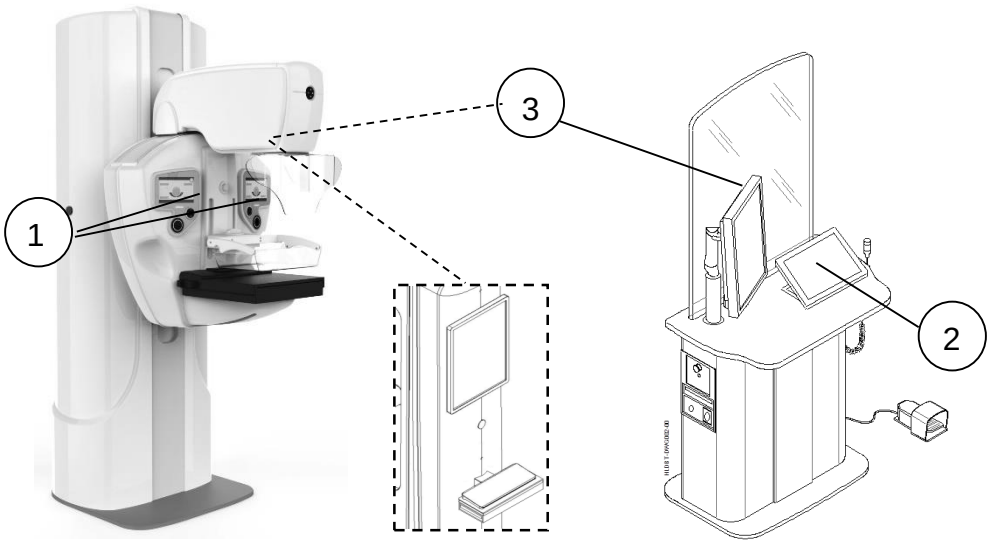
20. EMERGENCY PUSH-BUTTON
21. AWS HRD: HIGH RESOLUTION TOUCH SCREEN COLOR DISPLAY
22. AWS TSD DISPLAY SYSTEM
23. X-RAY PUSH-BUTTON
24. X-RAY FOOT-CONTROL (OPTIONAL)
25. DVD RECORDER
26. 3.1 USB PORT
27. MAIN SWITCH (ON/OFF)
28. AUDIO SPERAKER integrated
29. TRANSPARENT ANTI-X PROTECTIVE BARRIER FOR OPERATOR

As explained in the Mammo Unit Operator's and technical manuals on Mammo unit three different screens may be provided:

1. The double Touch screen color Displays of Mammo Unit (MAMMO TSD) for any operation by Mammo Unit;
2. Monitor LCD 5:4 (15" viewable size) for any operation by AWS or the Touch screen color display of Acquisition Work Station (AWS TSD)
3. The LCD High resolution display system (LCD HRD) to view images

accessPlease take into consideration these names in the following manual:

#	**NAME**	**DESCRIPTION**
1	MAMMO TSD	Double Touch screen color Displays of Mammo Unit
2	AWS TSD	Touch Screen color Display of Acquisition Work Station ("Service monitor")
3	LCD HRD	LCD High resolution Display System



NOTE

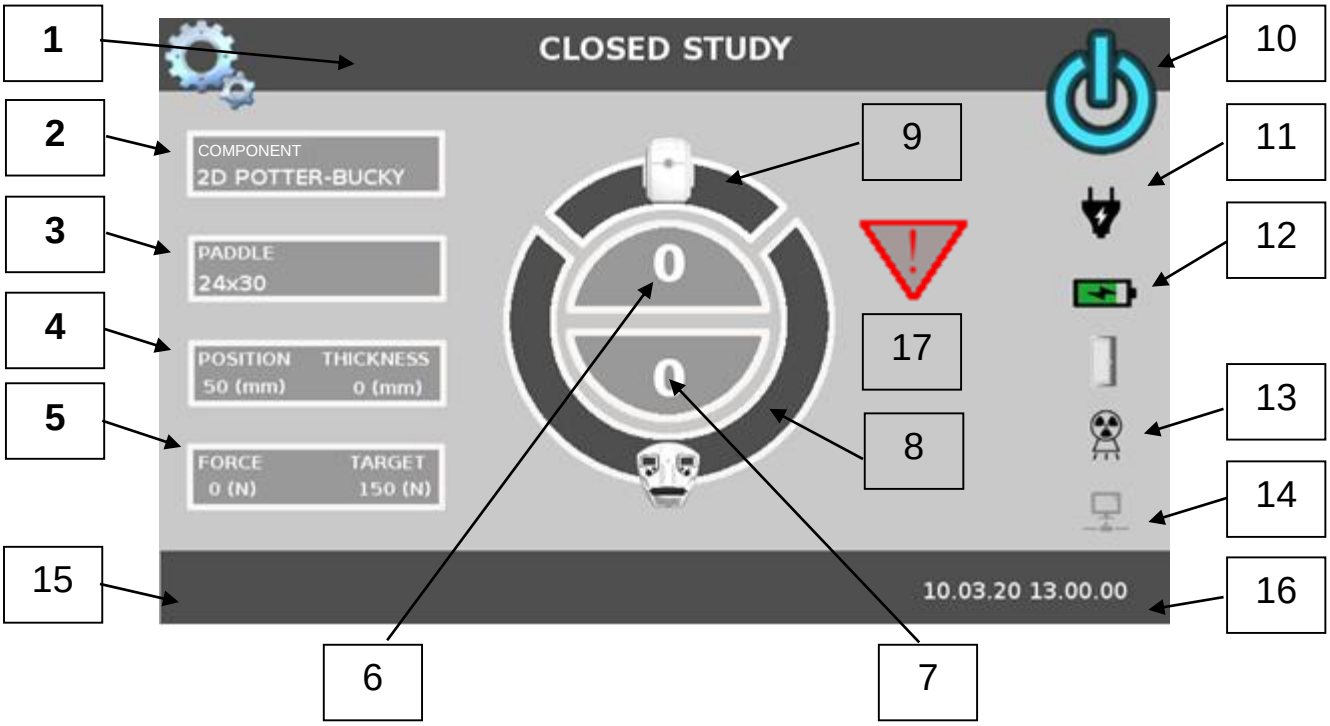
The LCD HRD, according to the configuration chosen, may be provided on the gantry.

NOTE

If the unit is provided without external AWS, LCD HRD works as service monitor. A service pop-up windows appears if necessary and is identified as “Service display (DSP)” in this manual.

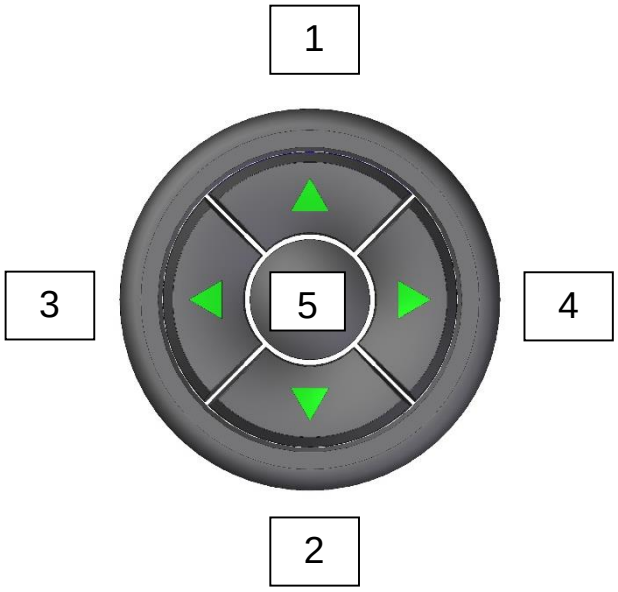
3.3. TOUCH SCREEN COLOR DISPLAY

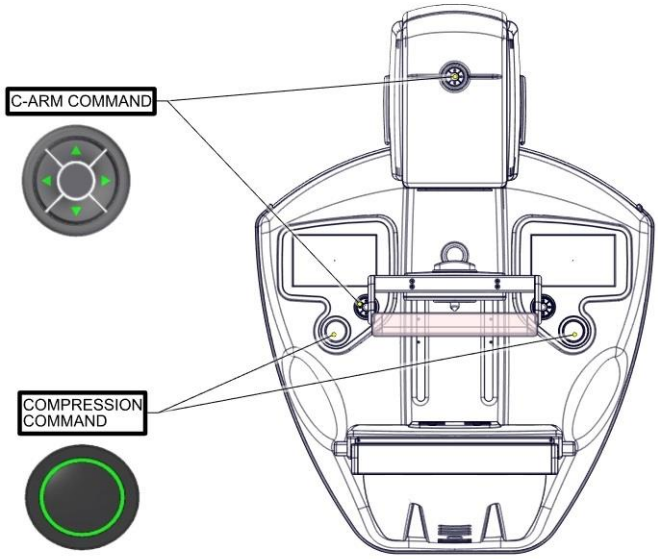
MAMMOGRAPHY UNIT



1. STUDY STATUS AND PATIENT NAME (icon is reserved for technical service)
2. COMPONENTS RECOGNITION
3. COMPRESSION PADDLE (image format)
4. COMPRESSED BREAST THICKNESS (mm); POSITION OF COMPRESSION PADDLE (mm)
5. COMPRESSION FORCE / FORCE TARGET (N)
6. C-ARM ANGLE/INCLINATION (°)
7. X-RAY TUBE ANGLE/RELATIVE INCLINATION (°)
8. MOTORIZED ROTATION BUTTON (PRE-SELECTABLE ROTATION ANGLES – ACR VIEW)
9. X-RAY TUBE TILTING BUTTON (0°; ±15°; ±20°)
10. POWER DOWN BUTTON
11. MAIN SUPPLY ICON (connection status)
12. UPS CHARGE LEVEL
13. DEMO/OPERATIVE MODE
14. AWS CONNECTION (If provided)
15. MANUFACTURER LOGO AND NAME
16. DATE AND HOUR
17. PUSHBUTTON FOR VISUALIZATION OF ERROR DESCRIPTION (if present)

3.4. C-ARM MULTI-SWITCHES



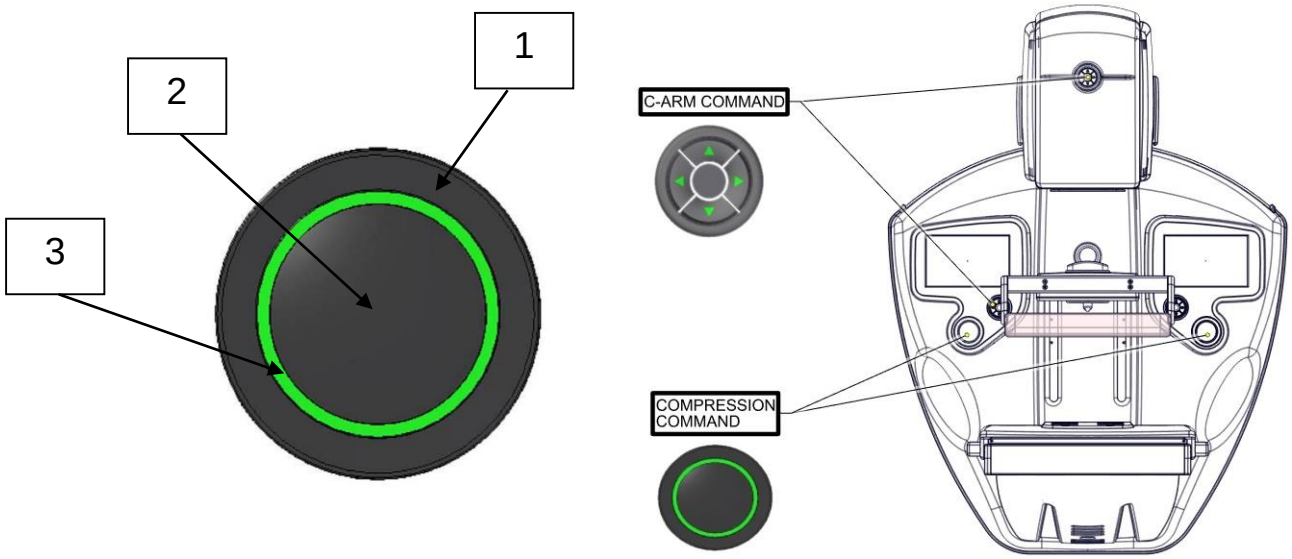


1. UP VERTICAL MOVEMENT
2. DOWN VERTICAL MOVEMENT
3. CONTINOUS ROTATION MOVEMENT (CLOCK WISE, TO THE OPERATOR)
4. CONTINOUS ROTATION MOVEMENT (COUNTER CLOCK WISE TO THE OPERATOR)
5. COLLIMATION LIGHT SWITCH-ON

All the switches are back lighted;

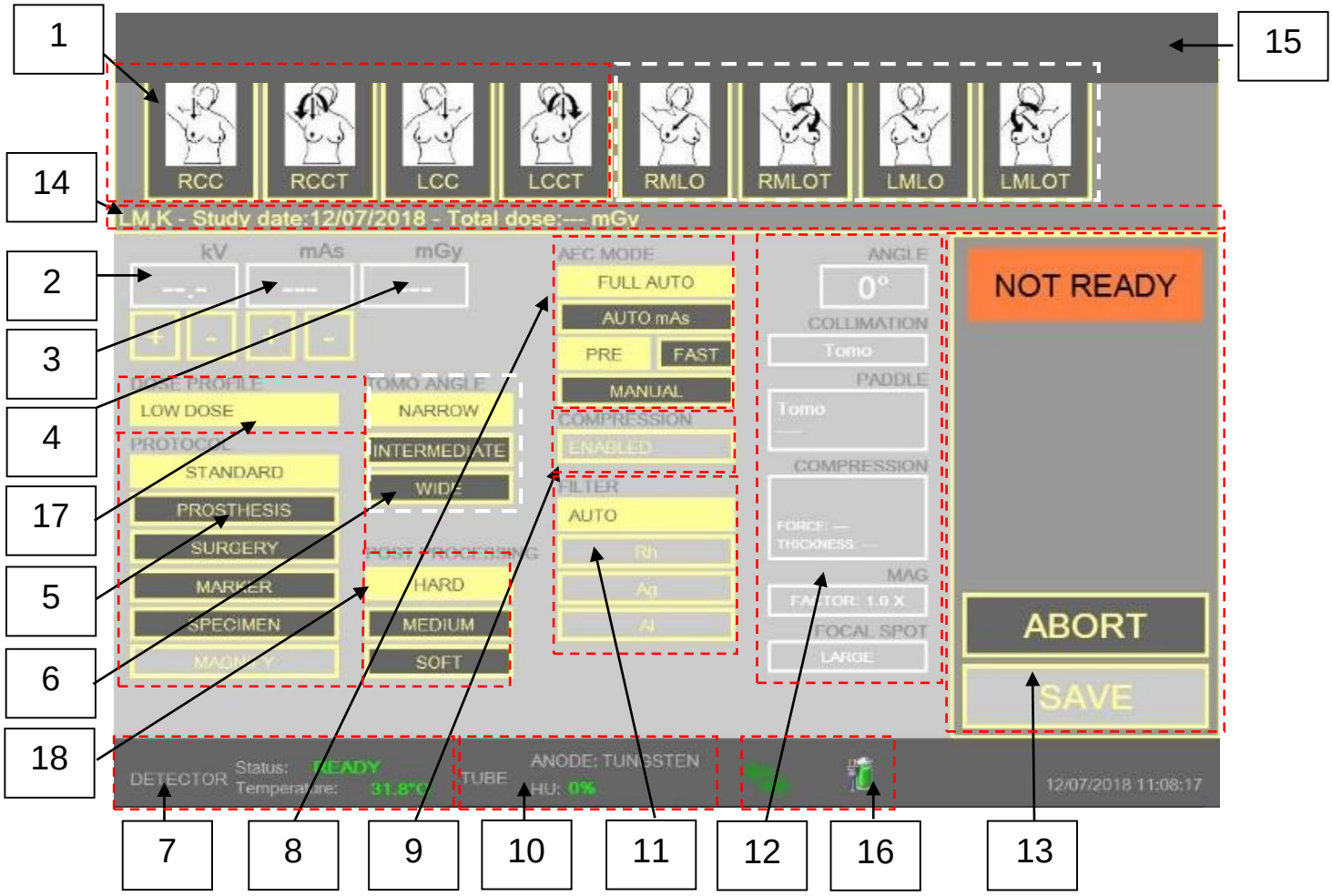
- LIGHT ON: the function is enabled
- LIGHT OFF: the function is disabled (for example in case of compression in progress)

3.5. ROTATING CONTROLLERS FOR MANUAL COMPRESSION



1. ROTATING CONTROLLER (TO SELECT COMPRESSION FORCE TARGET OR TO ALLOW FINE MANUAL COMPRESSION)
2. PUSH-BUTTON TO ACTIVATE THE FUNCTION:
    - COMPRESSION FORCE TARGET SELECTION (ON)
    - FINE MANUAL COMPRESSION (OFF)
3. BRIGHT RING:
    - OFF: THE CONTROLLER FOR COMPRESSION IS DISABLED
    - ON: THE CONTROLLER FOR COMPRESSION IS ENABLED

3.6. MAIN USER INTERFACE (GUI)



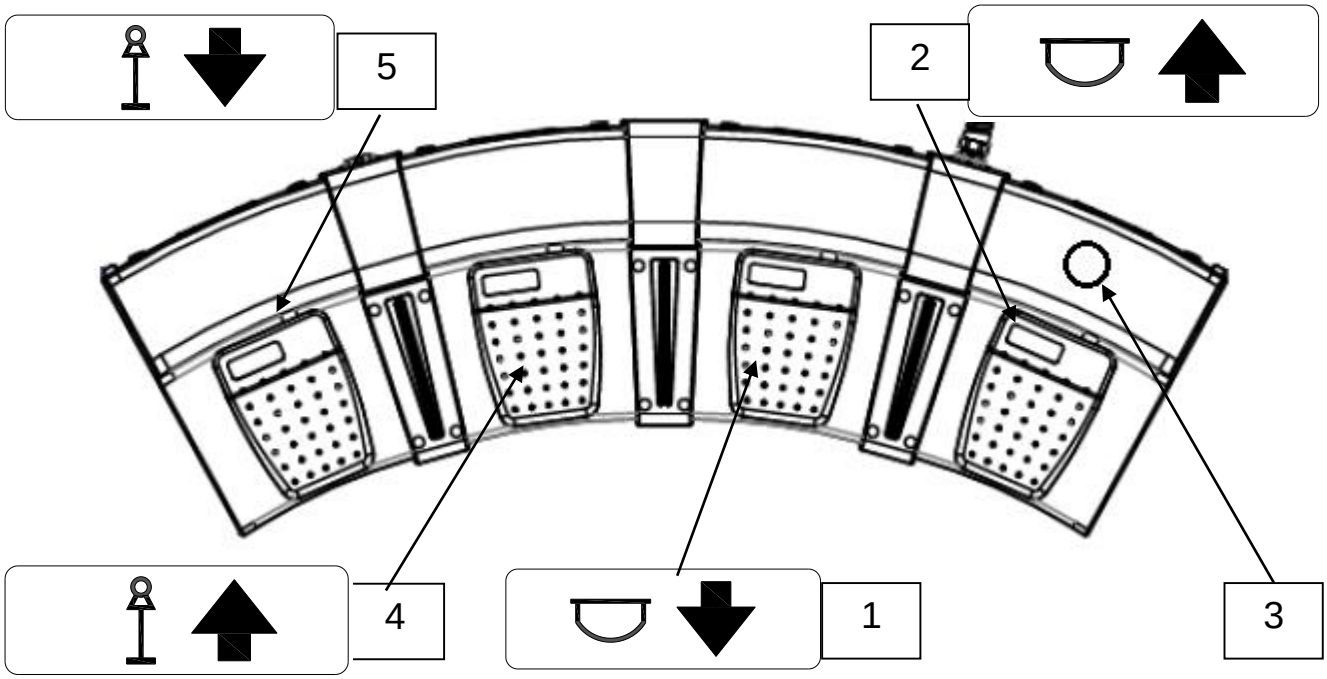
1. EXAM VIEWS AND PROJECTION SELECTION (ACR protocol) (Tomo projection only if available)
2. kV VALUE AND SELECTION
3. mAs VALUE AND SELECTION
4. DOSE INDICATION (Average Glandular Dose)
5. EXAM PROTOCOL SELECTION
6. TOMO ANGLE SELECTION (if availalble)
7. DETECTOR STATUS
8. AEC TECHNIQUE SELECTION
9. COMPRESSION ENABLED / DISABLED
10. TUBE STATUS AND HU HOUSING LEVEL
11. FILTER DEVICE MODE AND MATERIAL SELECTION
12. MAMMOGRAPHY UNIT CONFIGURATION
13. STUDY COMMANDS
14. STUDY INFORMATION
15. LOGO AND NAME (if available)
16. INDICATION OF COMMUNICATION STATE BETWEEN ACQUISITION WORK STATION AND MAMMO UNIT; UPS STATUS INDICATION

17. DOSE PROFILE SELECTION
18. POST-PROCESSING FILTER SELECTION

NOTE

The icons circled in white are functions available only for TOMO options; icons circled in red are standard.

3.7. MULTIFUNCTION FOOT-CONTROLS



1. COMPRESSION PADDLE DOWN
2. COMPRESSION PADDLE UP
3. MOTOR DRIVEN COMPRESSION UNLOCK
4. C-ARM UP
5. C-ARM DOWN

Section IV:
General Operations

4.1. EXAMINATION ROOM

X-Ray units can only be operated inside dedicated room provided with X-ray protection that meets local standards and regulations.

4.2. RELEVANT INSTRUCTIONS BEFORE INITIAL START-UP

The initial start-up must be performed only by the Technical Service of Metaltronica S.p.A. or a person authorized by them. In case of first installation, the Technical Service or the person authorized has to follow the specific instructions contained in the Service Manual.

4.3. SWITCHING ON

CAUTION

Before switching ON the unit, check that all Emergency Push-Buttons are unlocked. See in the following paragraph 4.5 how to check it.

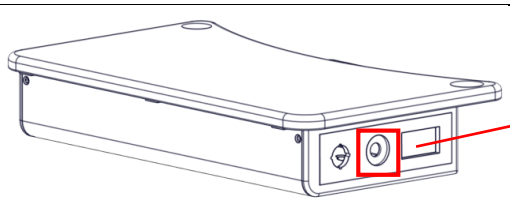
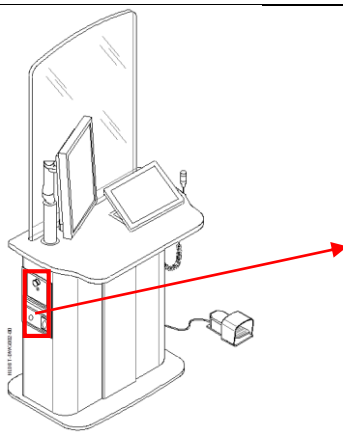
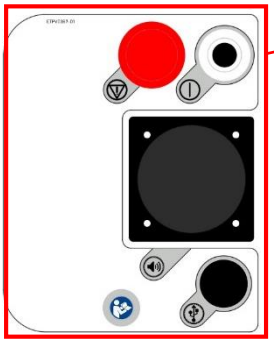
CAUTION

Verify that stand by lamp on mammography unit (on MAMMO TSD cover) is bright, if not or blinking, check thermal-magnetic circuit breaker on the wall and UPS switching (toggle switch in “ON” position) on the rear panel.

Stand-by lamp legend:

- Continuous light: Unit is in stand-by
- Blinking: Device is in stand by supplied by UPS
- Off: Unit is correctly functioning (GUI ON) or disconnected by mains (GUI OFF)

1) Push the ON / OFF button (See “Mains part” paragraph); on Mammo stand or AWS (if available)

PHASE	PROCEDURE	
1*		
1*	 	

*represents the unit power-ON button label. The unit can be switch-on directly from Acquisition workstation (if provided).

The system runs automatically. During initialization, the Acquisition Work Station switches ON detector and mammography unit.

NOTE

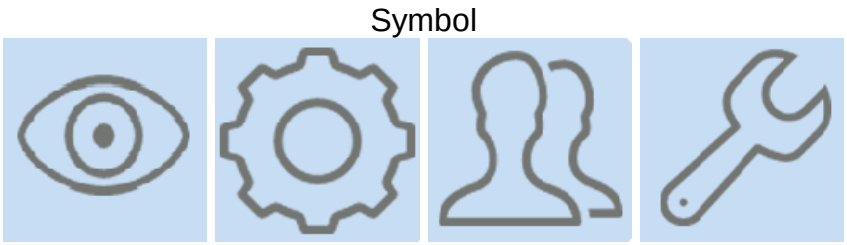
During the start-up phase, it is possible to check on the progress of the system boot by means of the indications visualized on the MAMMO TSD.

The following accounts are pre-installed in the System:

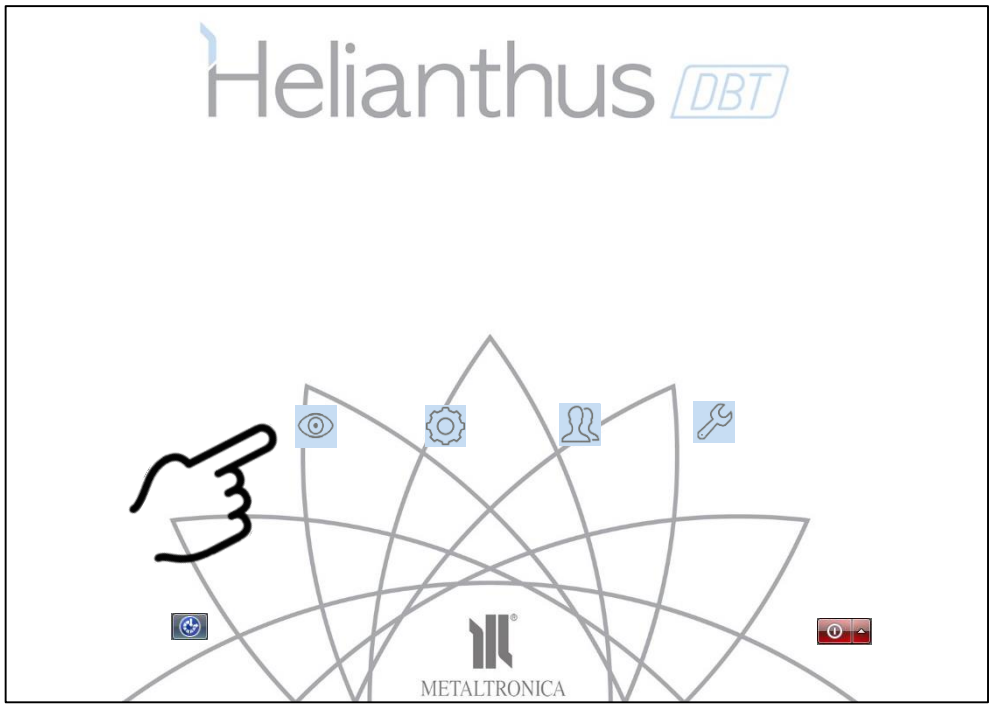
1. “DMDAcquisition”: this is the account for clinical practice. It allows the access to all the main functions of images acquisition and visualization;

2. "DMDToolkit": this is the account for Service activities; it allows the access to all the main functions of calibrations and controls in order to guarantee the correct functioning of the Mammograph.
   Its use is reserved only to the authorized Technical Assistance personnel;
3. "ManageUsers": this is the account for management, creation and configuration of the user's list authorized to access to the DMDAcquisition SW.
   For more information about the use of this Account, contact Metaltronica S.p.A.;
4. "Master": this is an account reserved to Metaltronica S.p.A.

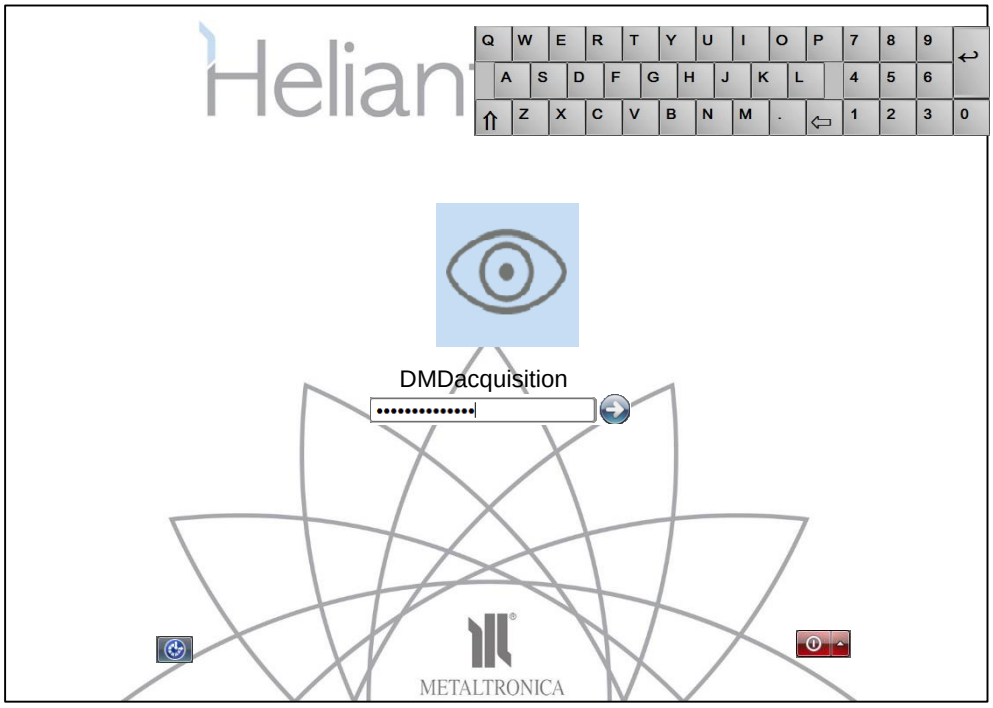
At the end of the initialization, a GUI with four icons appears, as indicated below:



In order to access to DMDAcquisition SW, it is necessary to click on the correspondence icon which appears on the AWS DSP:



Only in case of first access, the operator has to modify the default password (usually the same name that appears below the access icon) using the virtual keyboard at the top-right of the screen:

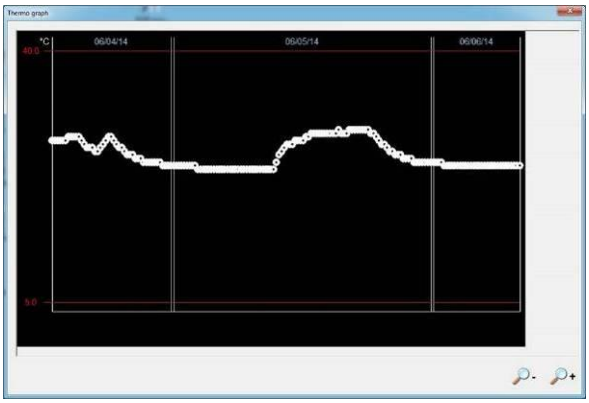


NOTE

In case of virtual keyboard not active, it can be refreshed clicking on the icon located at the bottom left on the AWS DSP.

The chosen password must necessary satisfy the requirement of length (8 character for factory setting) which will have preset duration (90 days for factory setting) after which will be again asked to change it.

At the beginning, a window shows a thermo graph with temperature room trend.
If room temperature exceeded upper or lower limits an error message appears (refer to Section VII: Maintenance).

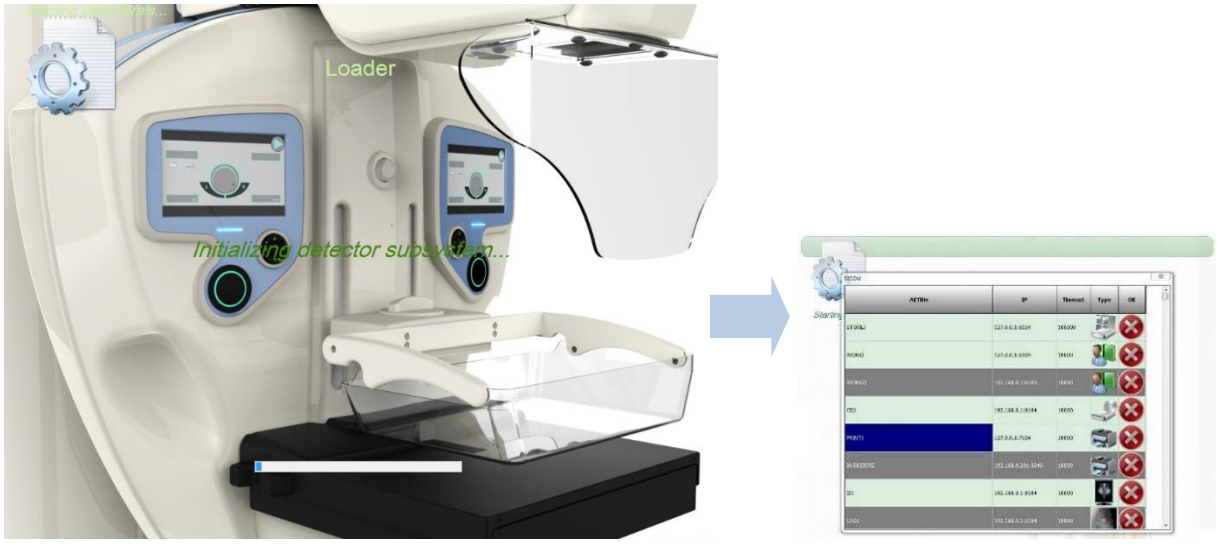


NOTE

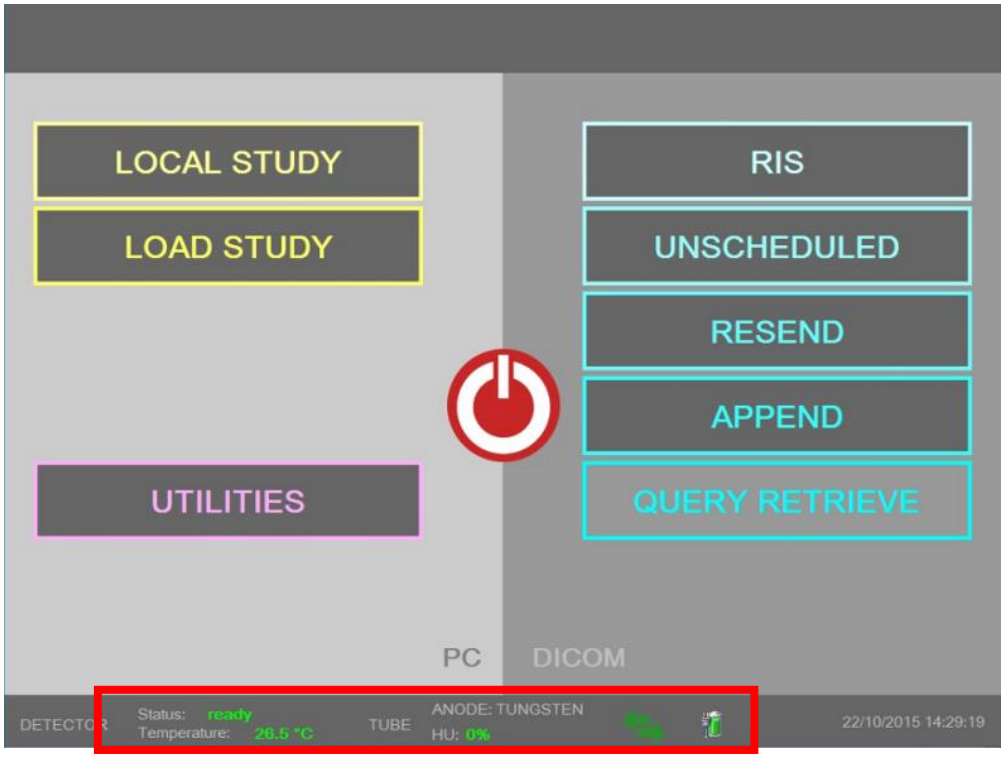
Lens buttons let to the user to zoom in or zoom out the thermo graph. The two red lines in the thermo graph window indicate the operative range of working of FFDM unit

The thermo graph window disappears in few seconds.

After access to DMDAcquisition profile, the initialization of whole system will start. During this phase, the unit checks the presence and the functionality of all devices and components to which is connected



At the end of tuning phase, after about 5 minutes, the User Interface is shown on the AWS DSP and a green message on the down bar reveals that the Mammo Unit and the Acquisition Work Station correctly communicate. Mammograph device is now “ready” to use.


LOCAL STUDY
LOAD STUDY
UTILITIES
RIS
UNSCHEDULED
RESEND
APPEND
QUERY RETRIEVE
PC
DICOM
DETECTOR
Status: ready
Temperature: 26.5 °C
TUBE
ANODE: TUNGSTEN
HU: 0%
22/10/2015 14:29:19

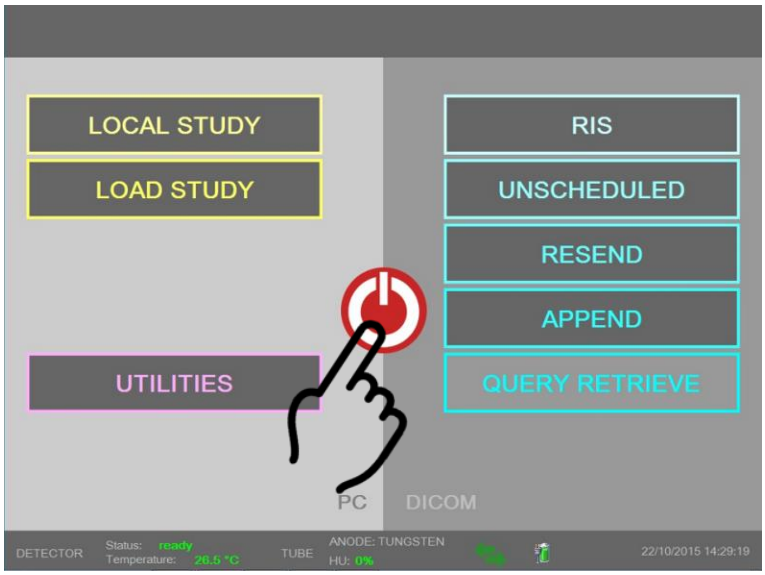
4.4. SWITCHING OFF

CAUTION

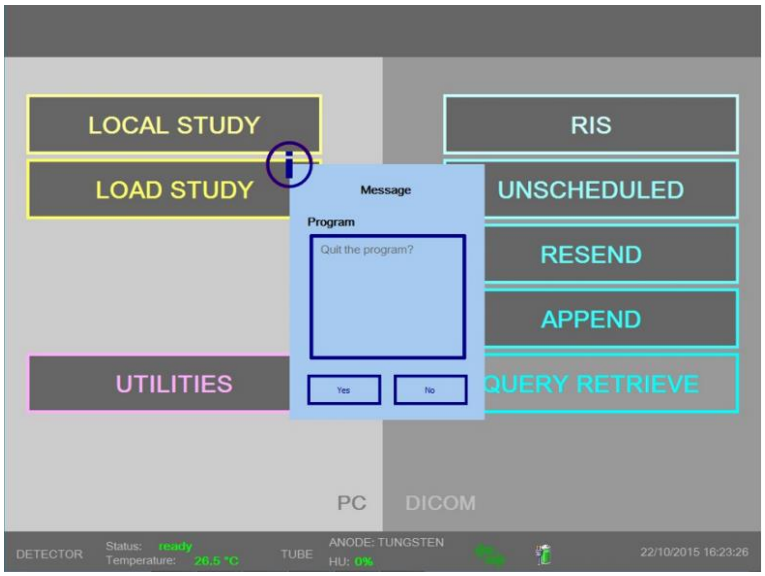
Do not switch OFF the UPS system while mammography unit is switched ON: In case of black out, the system will switch off without autonomy.

Verify that any study, open locally or from worklist (see 6.11 of this manual), is closed.

1) Close DMD Acquisition software clicking on red push-button located at the center of AWS DSP. This action also switches OFF the mammography device.



The following message appears:



Clicking on “YES”, the operator confirms the quit program.

.

CAUTION

In case of disconnection by Mains for more than 4 hours, please switch the circuit breaker (by rocker switch on the back panel) to avoid battery discharges.

NOTE

Do not leave the system permanently ON to avoid a useless dust collection on fans filters and a shortening of detector life (see also Section VII: 7.3).

CAUTION

Please switch off the MAMMO UNIT if you plan not to use it for at least one hour.

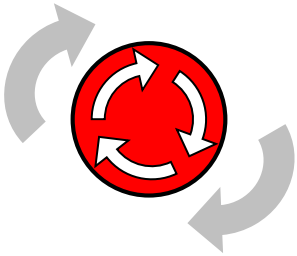
4.5. EMERGENCY PUSH-BUTTONS

There are three Emergency Push-Buttons on the HELIANTHUS series, one on each side of the Mammography Unit and one on Acquisition Work Station (if provided).

In case of emergency, to immediately remove power at the only mammography unit, press any of the pushbuttons.

Once the emergency has been solved, before to re-use the mammography device, it's necessary to follow these steps:

- switch OFF the mammography device with the procedure earlier described;
- turn the Emergency Push-Button (one-quarter rotation) to restore it;

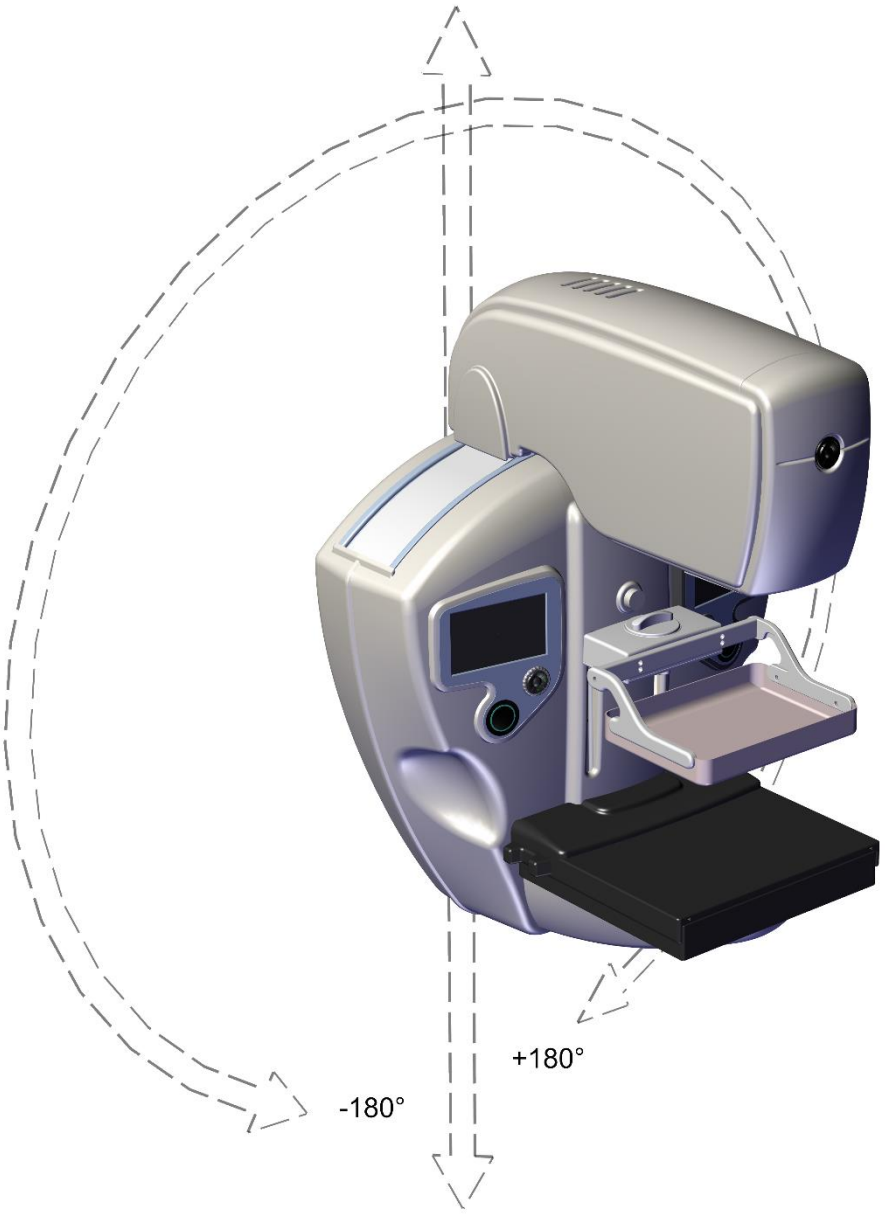


- switch ON newly the mammography device

4.6. C-ARM MOVEMENTS

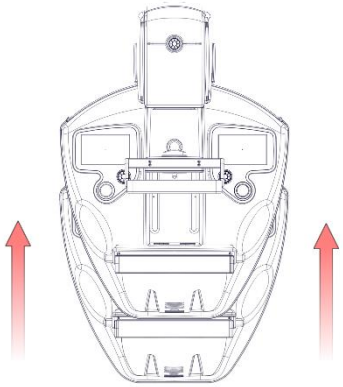
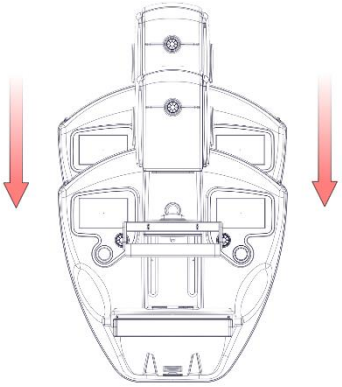
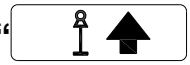
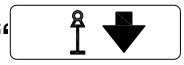
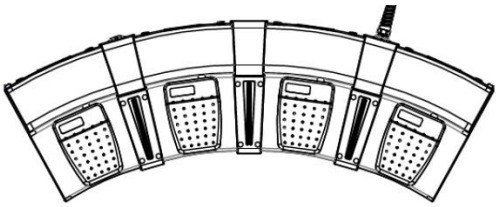
The movements of mammography C-Arm (vertical translation and rotation) are motorized to facilitate and speed up the patient positioning reducing the operator effort.

On the HELIANTHUS series C-Arm allows all breast projections without moving the patient, adjusting the height of its. All movements (including tomosynthesis scan) are disabled when compression force is applied.



4.7. C-ARM VERTICAL TRANSLATION

The operator can move vertically the C-Arm by means of the buttons n° 1 and 2 (paragraph 3.4 “C-arm multi switches”) or the pedals n°4 and 5 (paragraph 3.7 “Multifunction foot-controls”).

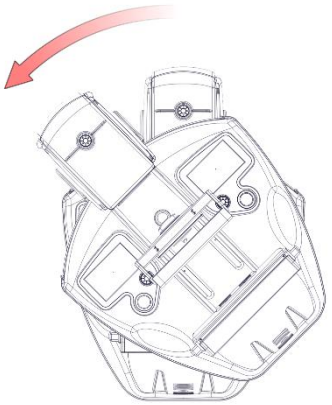
 “ ▲ ” = UP	
 “ ▼ ” = DOWN	
“  ” = UP “  ” = DOWN	

Range of allowed vertical movements and C-arm rotations are shown in Technical specification**.** Movement is possible only if related push button are enabled (LED ON).The C-arm movement ends when:

- The “UP/DOWN” button is released;
- The C-arm travel ends;
- Applying a compression force.

4.8. C-ARM ROTATION

The mammography unit has a safety system to avoid any lesion or damage if C-Arm during rotation runs into a person or an object. Fine adjustment of rotation angle means by buttons n° 3 and 4 - paragraph “C-Arm multi-switches”).
Range of allowed vertical movements and C-arm rotations are shown in technical specification**.**

 **“ ◄ ” = CCW (Counterclockwise rotation)**	
 **“ ► ” = CW (Clockwise rotation)**	

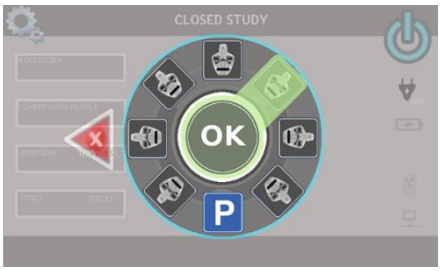
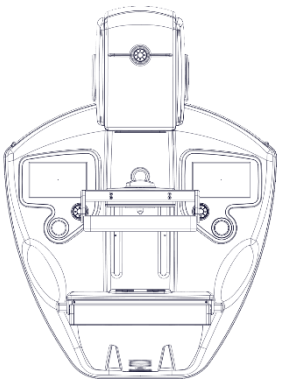
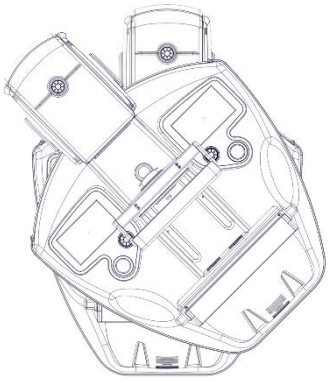
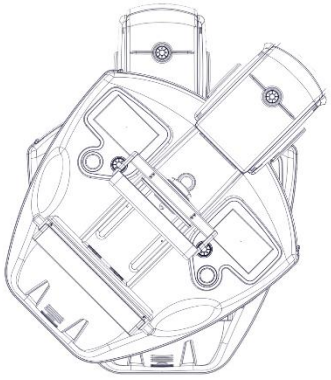
A continuous pressure of “◄” or “►” buttons rotates the C-arm in a range of ±180°**.**

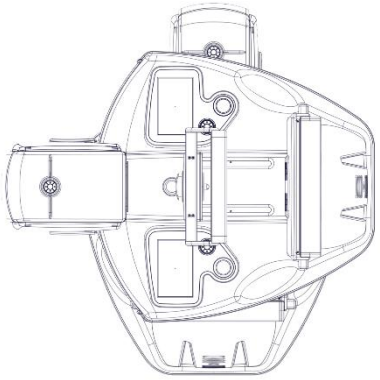
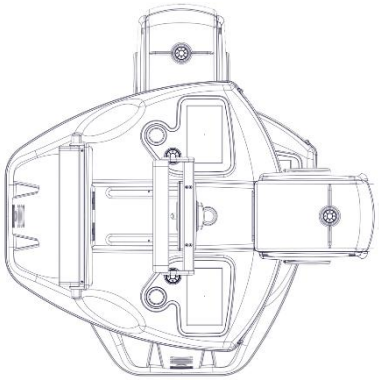
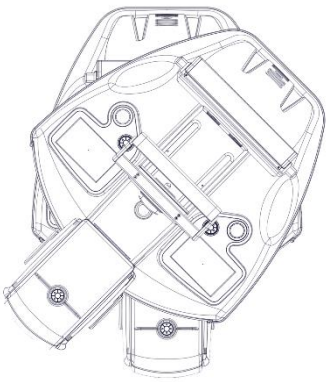
NOTA

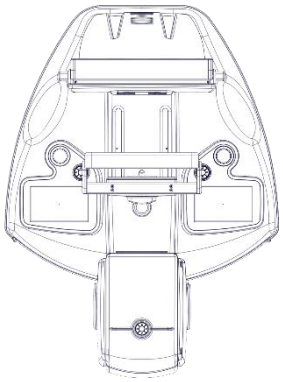
The C-Arm rotation (push buttons “◄” o “►”) is subjected to a restriction: every manual rotation that exceed of ±5° the value selected by the AWS DSP, prevents, during the examination, the X-Ray execution.

The C-arm can rotate to defined positions using Pre-selectable angle (buttons n° 8 - paragraph “Touch screen color display (MAMMO TSD) –Mammography unit”).

The default angular position settings are:

	
“CC”=0°	
“OBL CCW”=-45°	
“OBL CW”=+45°	

“LAT CCW”=-90°	
“LAT CW”=+90°	
+135°	
-135°	

“P”= Parking position	

With a single pressure on icon “CC” the C-Arm rotates automatically to “0°” angular position (factory default). Generally, all the icon pushbuttons of the MAMMO UNIT which allow the rotation of the C-Arm to the pre-selectable angles, are active and usable exclusively with the Study Closed.

In case of Study Open, the operator can control the C-Arm angular position only by GUI commands. Therefore, only in case of the study closed, with a single pressure on “LAT” or “OBL” icon buttons the C-Arm rotates automatically at pre-selected angular positions.

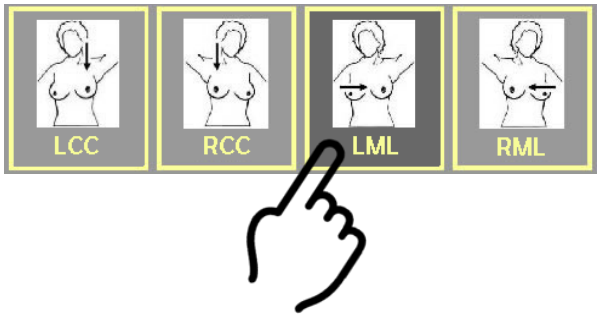
NOTE

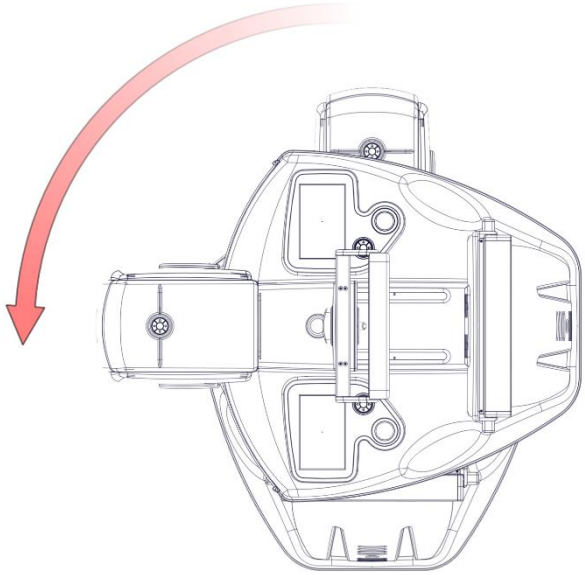
When the C-Arm is being automatically rotated, the movement may be immediately stopped by pressing any “LAT”, “OBL”, “CC” button.

NOTE

Default angle can be modified using the procedure described into Technical manual, before to proceed, contact Metaltronica S.p.A..

When the Study is open, the C-Arm rotation can be controlled by GUI controls. The operator can follow a Standard procedure or a User procedure. In any case, pressing the icon on the AWS DSP, the C-Arm rotates automatically to corresponding angular position.





NOTE

After a rotation movement on a pre-selected angle (“LAT” or “OBL”) the operator can adjust the C-Arm inclination pressing the Fine Adjustment angle buttons”,

NOTE

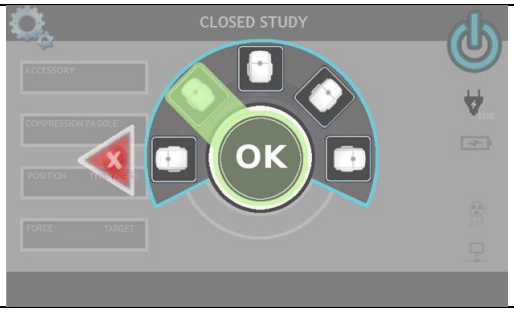
In case of opposite button pressure, the C-ARM rotates to the opposite position respecting the FINE adjustments,

NOTE

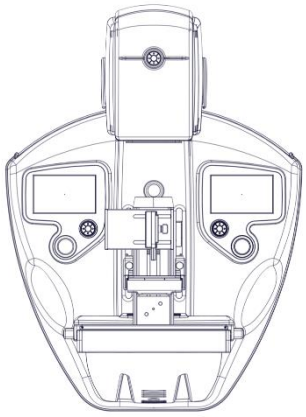
The rotation angle and the standard code of mammography view (according to ACR standard) are shown on all touch screen displays (MAMMO TSD and AWS DSP).

X-RAY TUBE TILTING MOVEMENT:

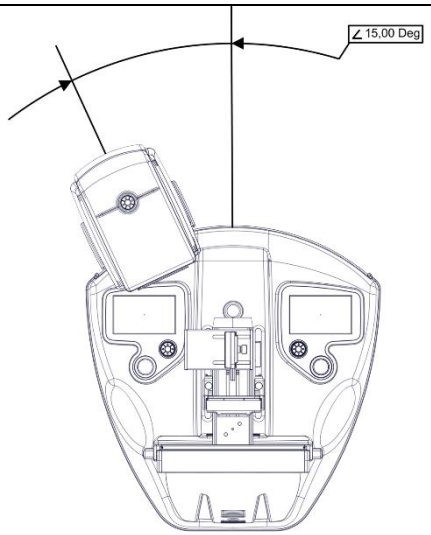
The X-ray tube can tilt respect to the detector plane using Pre-selectable angle (buttons n° 9 - paragraph “Touch screen color display (MAMMO TSD) –Mammography unit”).



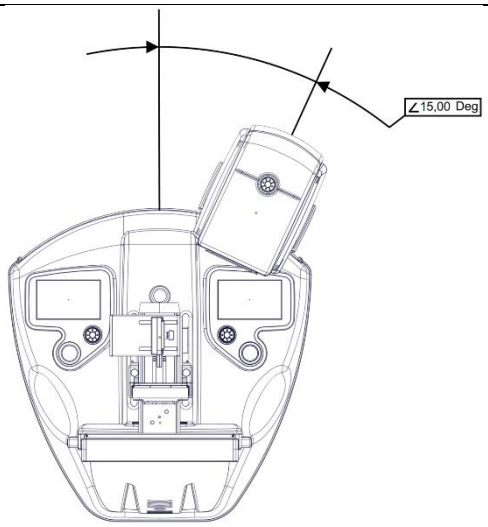
TILT ANGLE: 0°



TILT ANGLE: -15°



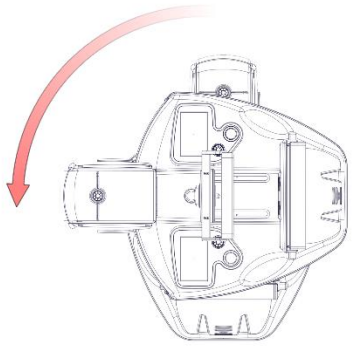
TILT ANGLE: +15°



With a single pressure on icons (pushbuttons) represented in the figure above, X-ray tube tilts automatically over patient plane. Generally, all icon pushbuttons that allow x-ray tube tilting movements are active and usable only with closed study.
When the Study is open, X-RAY tube tilting movement is automatically controlled by GUI during biopsy procedure / TOMO scan according to Biopsy/scan requests.

MANUAL C-ARM ROTATION

HELIANTHUS series can be chosen also without motorized rotation, according to customer needs (See “configurations and options” Paragraph”). Manual rotation is available by means of push button (see “Main parts” paragraph). The system is equipped with an electromagnetic brake to control fine rotation movements of the C-arm.



4.9. C-ARM ROTATION FOR STEREO BIOPSY (only for HELIANTHUS series equipped with BYM 3D DMD)

The HELIANTHUS series may be use for Stereotactic / Tomo guided biopsy procedure, using specific component BYM 3D DMD

NOTE

BYM 3D DMD has a dedicated Operator and Service manual. This manual shows you only general principles. Please refer to that manual for correct use of this auxiliary component.

NOTE

For stereotactic biopsy application this medical device needs to be compatible with Components:
NEEDLE GUIDES by BIOMED INSTRUMENTE & PRODUKTE GMBH (BIP GMBH)
Please refer to dedicated biopsy manual for compatibility details

NOTE

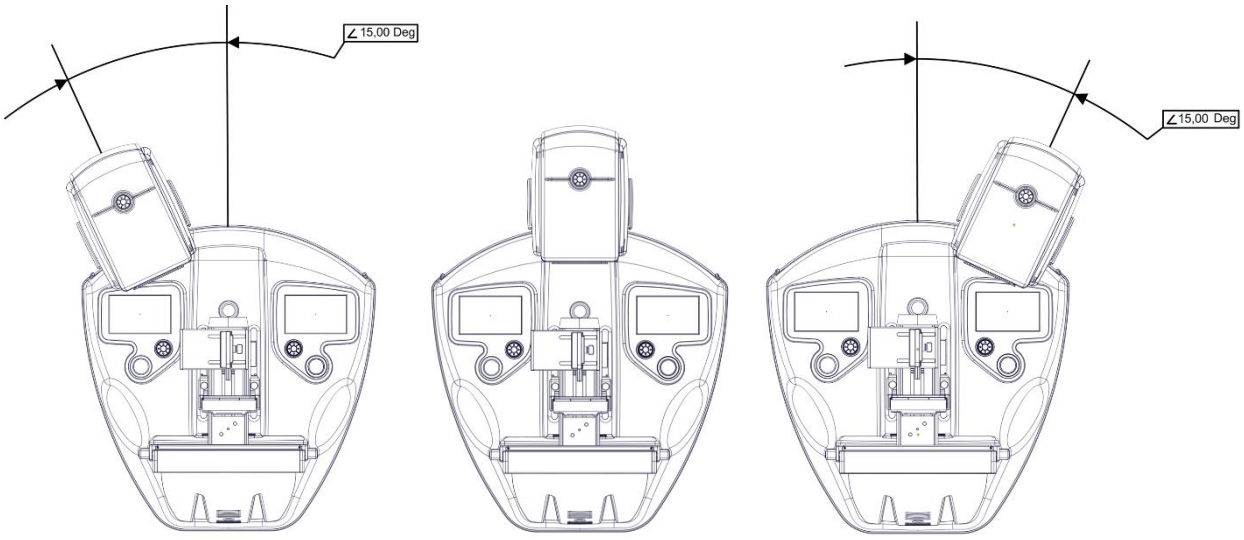
Needle guide bushings are a specific medical device, not part of this Medical Device.
Further information can be found in the dedicated biopsy manual.

The stereographic exam permits to calculate the exact three-dimensional coordinates X, Y, Z of a breast lesion detected with a general diagnostic exam or performing a TOMO exam.
C-Arm can be positioned at the most appropriate inclination and height to reach the lesion inside the breast by means of the UP/DOWN and Rotation push buttons.
After positioning the lesion in correspondence of the window of BYM 3D DMD compression paddle, different procedures (STEREOTACTIC / TOMO GUIDED) are carried out to calculate the coordinates of suspected lesion and reach. The BYM 3D DMD stereotactic biopsy device is easily interchangeable with Potter-Bucky.
In case of stereotactic procedure operator usually performs three exposures at 15° (Left) and -15° (Right) with respect to the reference axis of the system and one at 0° (SCOUT) to position marker in correspondence of each acquired image.

C-ARM tilting positions (±15°), with respect to the reference axis of the system, are motorized and can be operated only with BYM 3D DMD inserted.

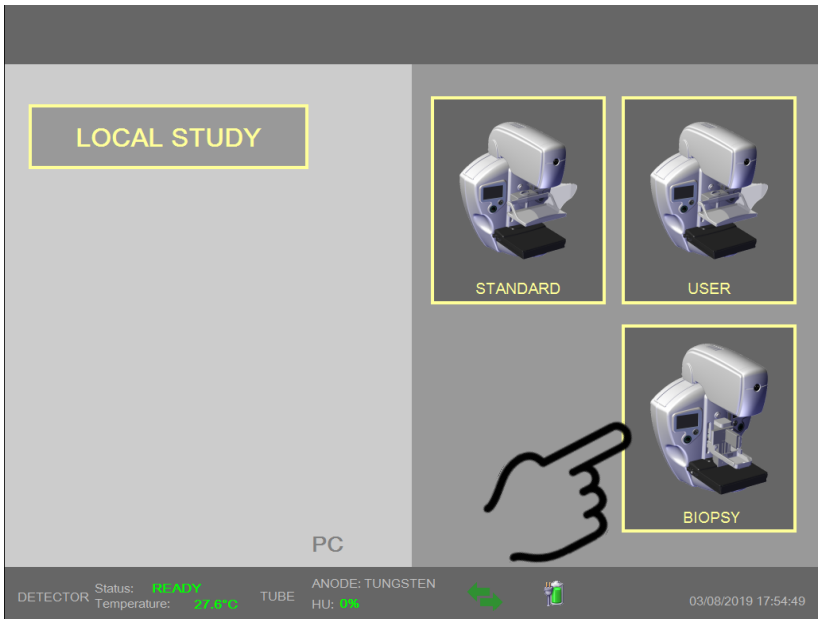
In case of Tomo guided procedure, operator performs a single TOMO scan and system reconstructs suspected lesion positions.

In both case target coordinates are transmitted to Needle positioning unit that reached final position and allows to the operator to reach lesion by means of right needle of gun for tissue sampling. In case of biopsy procedure, C-Arm vertical movement and rotation are disabled and only X-ray tube tilting movement is possible.



RIGHT SCOUT LEFT

In order to access to BYM 3D DMD functions, a Study must be previously open (for this, refer to the “Opening Study”- paragraph). After click on “STEREO” icon on the AWS DSP.



NOTE

During a BIOPSY study is checked the presence of needle adapter. In case of needle absence the systems returns a specific error message (refer to Section VII, Paragraph 7.2)

NOTE

The “STEREO” and “BIOPSY 3D” icons are active only wìth BYM 3D DMD inserted. Regarding the use of this function, refer to “BYM 3D DMD Operator’s Manual”. In other case, a warning message is shown on the AWS DSP.
For further details about the specific and complete procedure, see BYM 3D DMD Operator’s Manual.

If C-Arm position has to be changed, safety interlock switch on board of BYM 3D DMD Needle Positioning Unit has to be activated (for further details see BYM 3D DMD Operator’s Manual).

NOTE

In ordert to allow a easily insertion of the biospy needle, while the BYM 3D DMD moves itself to a define position, tube rotates of -22°.

4.10. COMPRESSION PADDLES INSERTION AND REMOVAL

To install a compression paddle, insert the rear pins into corresponding holes of locking system, then rotate counterclockwise the knob to lock it.

A yellow LED near to rotating knob changes color from yellow to green to confirm the right locking of compression paddle.

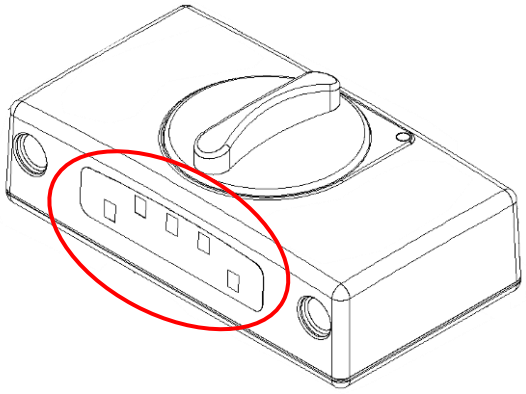
UNLOCKED LOCKED

If the operator selects the compression and does not rotate the knob on the locked position, a warning message appears on both the MAMMO TSD in order to alert the operator to the need of conclude this action. Locking the compression paddle, the warning automatically disappears (refer to Section VII, Paragraph 7.2).

This locking system has also an optical recognition device of compression paddle type able to set automatically the collimation format.

NOTA

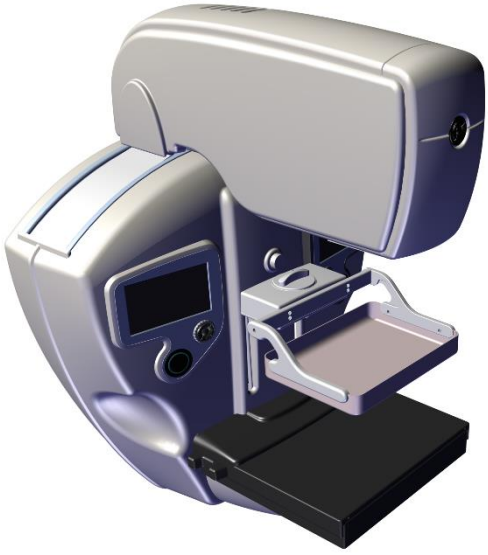
The recognition of the compression paddle depends on the presence of its related auxiliary component. For all information regarding proper coupling between compression paddle and auxiliary component, refer to section IX "Typical Configurations".



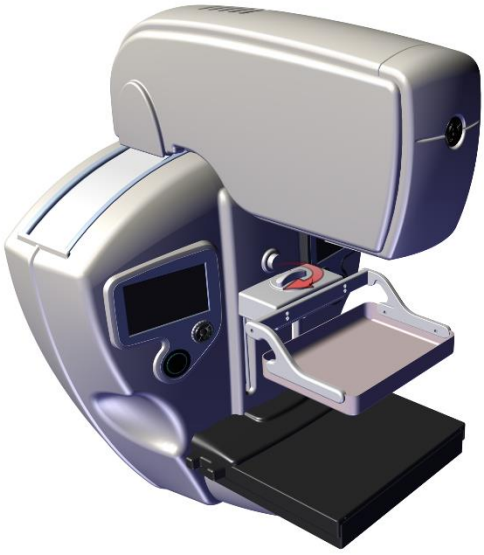
After the recognition, the format will be automatically displayed on the MAMMO TSD.

To remove a compression paddle is enough rotate clockwise the knob to unlock it and pull out the pins from corresponding holes.

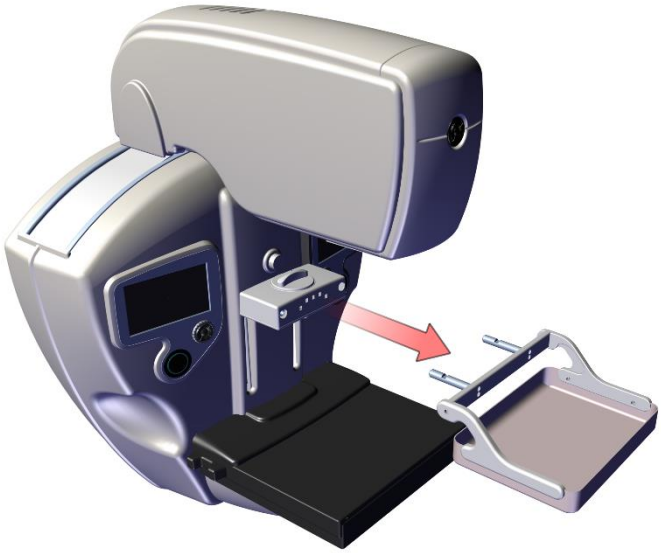
LOCKED UNLOCKED



A



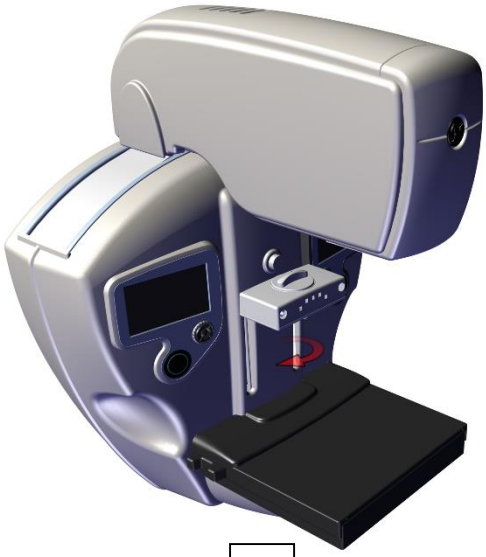
B



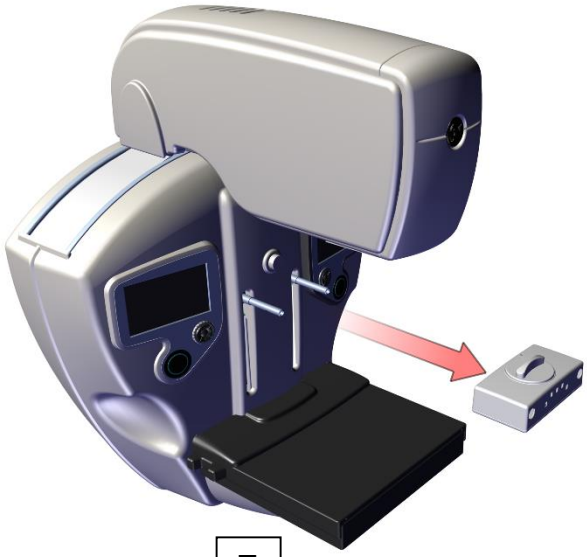
C

A. Compression paddle inserted and locked
B. Unlock the compression paddle rotate clockwise the knob;
C. Remove the compression paddle

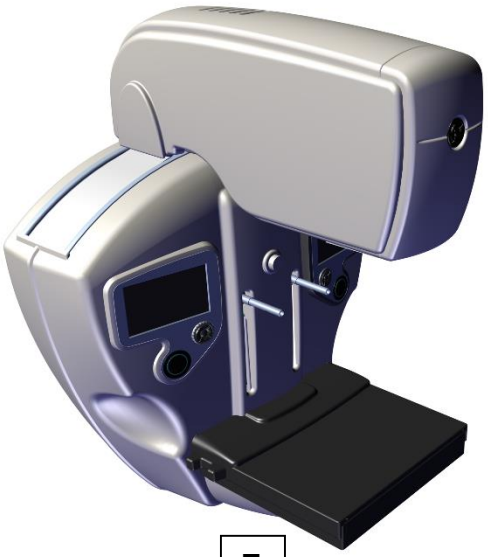
To remove the locking system (Compression paddle holder) rotate clockwise the knob to unlock it and pull out the pins from corresponding holes.



D



E



F

D. Unlock the compression paddle rotate clockwise the knob;
E. Remove the locking system;
F. C-arm with compression paddle and locking system removed

The insertion modality is the same for all the compression paddles available (for the complete list see the “Auxiliary component” section of this manual).

Between all the compression paddles, also a 18x24 cm with lateral shifting compression paddle is available to examine a small/medium breast in lateral projections.
In this specific case, to move the compression paddle with lateral shifting from middle to right or to left push it towards desired direction. The paddle stops into place with an audible click.

4.11. BREAST COMPRESSION SYSTEM

The mammograph is equipped with an advanced compression system.
The breast compression can be motor driven or manual with fine adjustment.
In case of motor driven compression, a function of tissue strength evaluation (FTSE) allows to modulate the force depending on breast density.

Motor driven compression

The compression force can be set rotating the controllers for fine manual compression after having activated the function by means of push-button n°6 (see the paragraph “rotating controllers for fine manual compression”).
The procedure is the following:

1. get free the compression paddle
2. push the button n°2 to activate the function. In this state, the bright ring n°3 will turn on (in flashing mode)
3. rotate the controller n°1 until the desired value
4. push again the button n°2 to confirm the selection. The bright ring n°3 in this state will turn on (not in flashing mode).

The selected value (in N) is shown on all touch screen displays (MAMMO TSD and AWS DSP)

MAMMO TSD

AWS TSD

In particular, the displayed COMPRESSION appears in the following colors:

- yellow/blue: case of no compression detected;
- green: case of compression detected;

The field “COMPRESSION” displays:

- “SET:XX”: case of no compression detected;
- Current force value: case of compression detected.

Also the thickness value (mm) is displayed on the MAMMO TSD and on the AWS DSP:

In particular, it is:

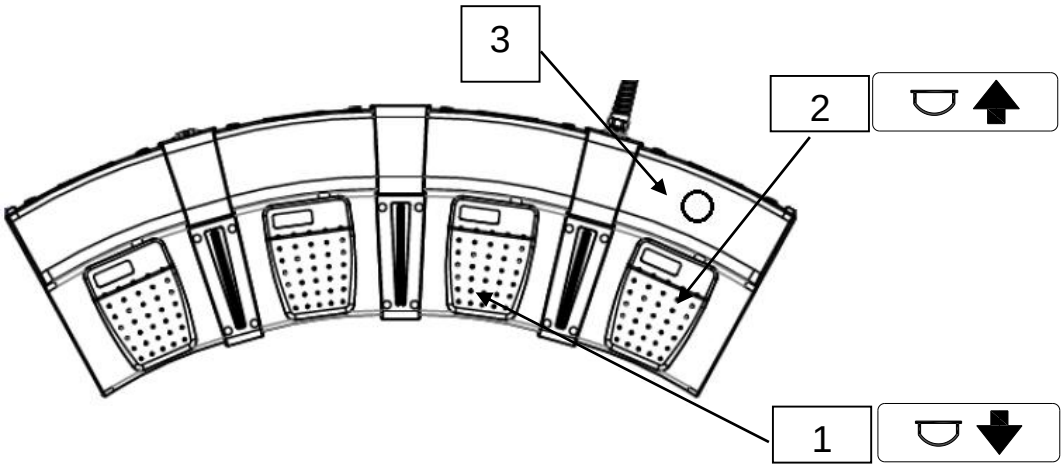
- Calculated and displayed only if a compression is in progress;
- In case of no compression detected and during the compression paddle movement, the value displayed is the following “---“.

NOTE The target will remain selected until the Mammo Unit switch off.

The range of compression can be set from 70 to 200 N means of internal setting.

Motorized compression is operated by the foot control.

Multifunction Foot-Control



In case of Study just open (for the specific procedure, refer to the paragraph “Opening Study” paragraph), pushing the pedal n°1 (see the paragraph “Foot-controls”), the compression paddle goes down with a speed that decreases with height from the Potter-Bucky.

When the compression paddle comes in contact with the breast at a specific force value (30N), it has a very brief stop and start to apply an increasing force.

With the Function of Tissue Strength Evaluation (FTSE), a microprocessor checks the breast tissue strength comparing it with a specific force value (100 N); in this case:

- if the breast is soft, the compression force increases up until value set by the operator;
- if the breast is dense, the compression force stops to 100 N. In this case, the operator can proceed the compression up until the force value set releasing and pushing again the pedal n°1.
  If the operator release and push again the pedal n°1, the compression force increases up to the maximum value set (200 N).

Pushing the pedal n°2, the operator reduces the compression force.

Pushing the pedal n°3 it is operated a fast release of breast compression.
Always using the multi-function controls, the operator can move the compression paddle also with the study closed. In this case, when the system detects a compression, a warning will be shown in order to alert the operator of this state. This message is only a warning and does not prevent the operator to continue with the compression.

Manual compression with fine adjustment

Manual compression is possible acting on the rotating controllers placed on both sides of C-arm.

The continuous rotation of the controller n° 1 in a direction allows to bring down the paddle, touch the breast and press it until to reach the desired force value. The compression force can increase up to maximum value set (200 N).

The continuous rotation of controller n° 1 in the other direction allows to rise the paddle reducing the force.

In any time, the operator can pass from motor driven to manual compression and vice versa. The force really exerted on the breast at the end of compression is shown on the AWS DSP and MAMMO TSD.

Compression release

There are two different operating modes for compression release at the end of the exposure:

- AUTO RELEASE (normal mode)
- MANUAL RELEASE

The operator can choose the release mode on the MAMMO TSD.

The AUTO RELEASE MODE is:

- Available for all the examinations except the biopsy;

- Achievable pushing the dedicated button n°13 of the MAMMO TSD until the appearance of the following symbol:

When the AUTO RELEASE MODE is on, the button is blue rather than gray and the compression automatically get free the patient's breast at the end of the exposure.

NOTE

The AUTO RELEASE MODE, when activated, is saved also after the Mammo Unit switch off.
At the following switch on, it results automatically selected.

The MANUAL RELEASE MODE is:

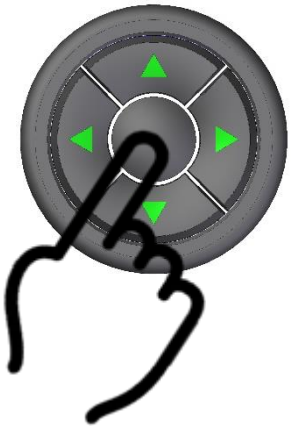
- Always available;
- Achievable pushing the dedicated button n°2 of multifunction foot-controls or rotating continuously the controller n°1 for fine manual compression.

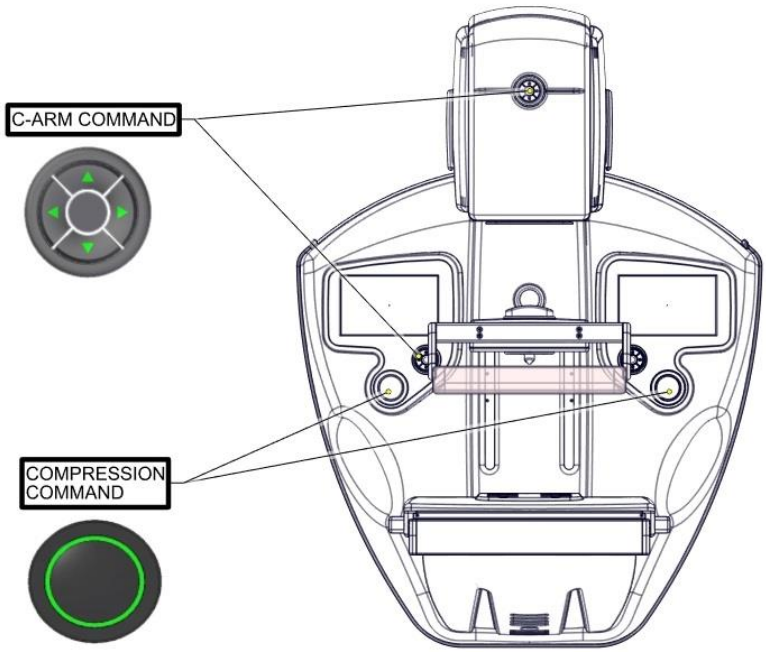
If necessary and for every kind of release modality, it's possible to rise quickly and automatically the compression paddle, pushing the button n° 3 of foot-controls.

In case of power failure: backup battery is provided to maintain the compression of the patient's breast.
The compression release is possible by pushing the n°2 push button (see the paragraph "Rotating controllers for fine manual compression"). This operation will move upwards the compression paddle.
Alternatively, it's possible to release compression by continuously pressing the push button (n°13 in "mains parts description") on the C-arm.

4.12. LIGHT BEAM INDICATOR

Collimation lamp shows X-ray field on the patient support. Collimation lamp can be always switched on by means of push-button n° 5 (see paragraph “C-Arm multi-switches”) on the C-arm. In this case, the light will be turn on for 20 seconds.





CAUTION Do not watch directly the light beam centering system.

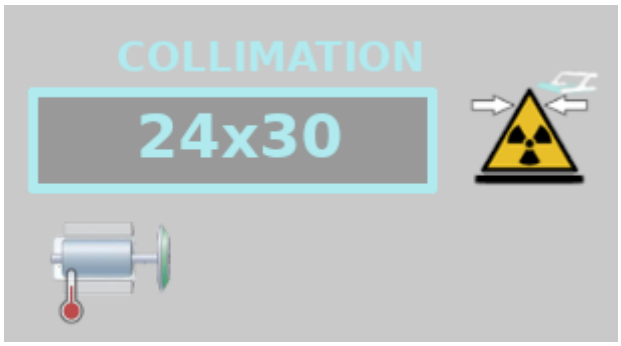
Every time the compression down pedal/manual rotating controller are used, the luminous field indicator light automatically switches on.
The light turns on with a little delay respect the compression movement.
To switch on the light before compression press the button n°5.

4.13. AUTOMATIC COLLIMATION DEVICE

The HELIANTHUS series is provided with an advanced automatic collimation device. An opto-electronic system recognizes the type and the position of compression paddle, then selects the appropriate collimation format and displays it in the area n°2 of the MAMMO TSD.

In case of tomosynthesis exam, a trapezoidal dynamic system change continuously the collimation format during the breast scan to limit the size of the beam to the required region, reducing the scattered radiation.

The following icon can be displayed from the touchscreen displays:



By clicking on the figure, the operator can switch from automatic collimation mode  to manual collimation mode  .

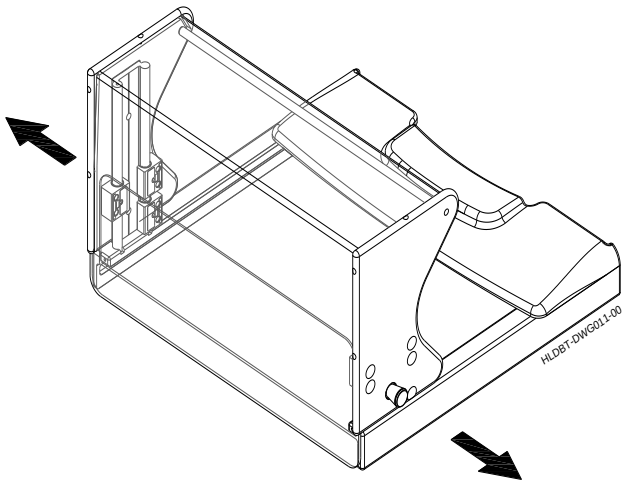
In manual collimation mode, the operator can select the CUSTOM collimation format set in calibration service panel, according to her/his responsibility. This selection is not possible for 3D exam and biopsy exam. Opening a new study, automatic collimation is set according to the type of auxiliary component inserted.

At the end of each exposure, the collimation becomes automatic again.

WARNING When manual collimation is selected, the operator must not select AEC FULL AUTO PRE mode.

4.14. DEVICE FOR GEOMETRIC MAGNIFICATION (VARIABLE FACTOR 1,5x/1.8x/2x)

The grid less device for geometric magnification is easily interchangeable with Potter-Bucky. It's available in three magnification factors: 1,5x, 1.8x and 2x.
To select the magnification factor, pull the two lateral spring-loaded plungers at the same time, and fix table height at requested position. Release the plungers and verify that locator pins lock the device for geometric magnification.

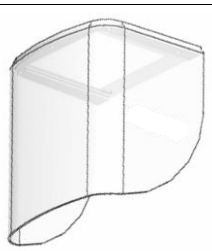


NOTE

After inserting the device for geometric magnification and selecting this mode, the system automatically selects and controls the correct use of focus and collimation field which correspond to the chosen configuration.

4.15. PROTECTIVE SCREENS

HELIANTHUS series is provided of two different protective screens to keep patient's face and extraneous parts (i.e. shoulder, earring, hairs, etc.) out of X-Ray beam. The presence of extraneous parts in the image field may negatively affect the functioning of presentation algorithm, with impact on breast border recognition, worse contrast and dynamic range.
The two different protective screens are alternately available for several and different causes of use (2D, 3D, Combo views) as below described:

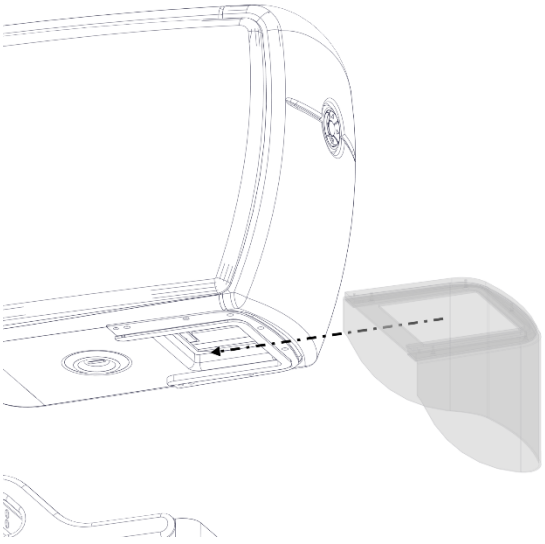
APPLICATION	PROTECTIVE SCREENS	
2D views	Fast lock protective screen only for bi-dimensional exams	
3D and COMBO views	Fast lock protective screen for bi-dimensional and tomosynthesis exams (optional)	

Pay attention to use the correct protective screen when selecting a view during the STANDARD or USER exam procedures (paragraphs 7.1 “STANDARD procedure” and par. 7.2 “USER procedure”).

To fix the fast lock protective screen, insert the rear side of his frame in corresponding rails of x-ray window and push it all the way.

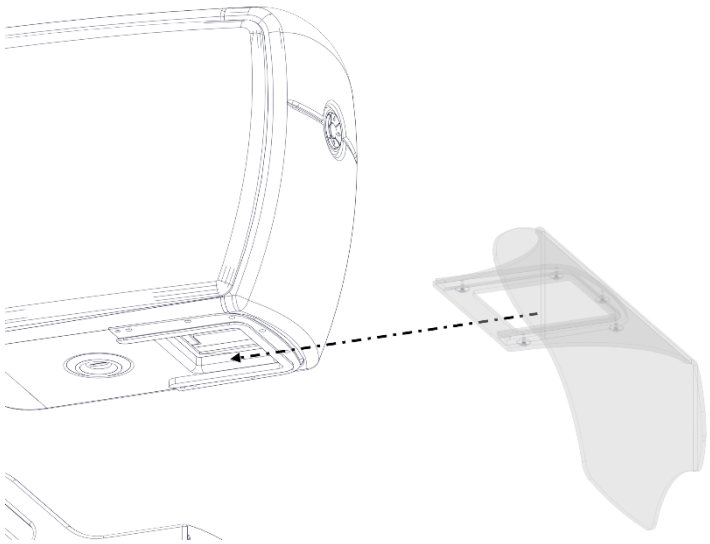
The HELIANTHUS series automatically recognizes the screen inserted. In case of wrong protective screen inserted, an error message will be displayed.

For troubleshooting refer to the paragraph 7.2 “Error Messages”.



To remove the screen is sufficient extract it from the rails.

The same above instructions have to been followed to fix and remove the fast lock protective screen for both bi-dimensional and tomosynthesis exams:



NOTE

The protective screens are not intended for magnification techniques. Do not use it for magnification techniques.

4.16. FOCAL SPOT SELECTION

On HELIANTHUS series the selection of focal spot is automatic; large focus with Potter-Bucky and small focus with device for geometric magnification.

No manual selection allowed.

The selected focal spot is shown on the monitor of mammograph.

4.17. RADIOGRAPHIC EXPOSURE

Radiographic exposure is allowed only when study is open and breast is compressed. Otherwise error messages will appear.

To start the exposure, the X-ray push-button° 18/22 (paragraph “Main Parts”) must be kept pressed until the exposure is over.

Alternatively, as option, the operator can use the X-ray foot-control if provided.

In semi-automatic and fully automatic exposure technique the pre-exposure pulse is announced by a short sound signal.

At the end of exposure, the compression is released only with the function “Auto release” enabled and the paddle rises automatically getting free the patient’s breast.

For further details about the X-Ray exposure phase and the complete operating procedure, see the relative paragraph 6.6 “RADIOGRAPHIC EXPOSURE”.

4.18. DOSE CALCULATOR

The HELIANTHUS series mammography unit automatically provides calculated values of the Average Glandular Dose (AGD).

After each exposure, the dose in mGy or in uSv is displayed on the area n°4 of AWS DSP and recorded.

The Average Glandular Dose is also reported on any acquired image, meantime the overall dose of the study is displayed in real time on the area n°14 of AWS DSP after any exposure.

For proper dose calculator operation, it’s necessary to use the appropriate compression paddle as described “Typical Configurations”.

Shifted paddles have to be used with large focus and straight paddles with small focus because focal spot to skin distance measurement depend on it and dose calculation too.

NOTE

Dose values can be visualized in uSv or in mGy setting a specific item by service.

NOTE

After a CESM sequence, dose displayed is the sum of the low energy and high energy exposures.

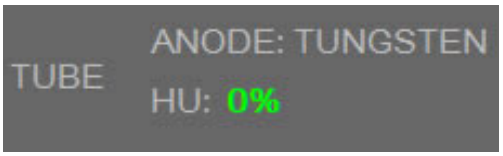
4.19. ERROR MESSAGE RESET COMMAND

All the functions of HELIANTHUS series are controlled by microprocessor with specific safety features. The MAMMO TSD shows textual error messages on user interface.
In the section “Maintenance” of this Manual there’s a list of the error messages, the causes and the actions to remove them.

4.20. HEAT UNIT INTEGRATOR

Depending on X-ray tube temperature % of total HU tube housing capability is displayed as “HUxx%” in the area n° 12 of the MAMMO STD and in the area n°10 of the AWS DSP.

When 90% of the maximum thermal capacity has been reached, an acoustic signal is generated and other exposures are not permitted until the HU drops below the maximum value.



If ambient temperature is higher than 25°C, HU can be greater than zero even if no exposures have been released for a long time.

Section V:
Exposure Techniques

HELIANTHUS series has three different Exposure Techniques:

Table 3

EXPOSURE TECHNIQUE	ADJUSTABLE PARAMETERS
Manual	➢ kV (20÷35) / kV (20÷49 - Optional) ➢ mAs (1÷640) ➢ Filter: Rh Ag Al (only for TOMO exams)
Fully Automatic (ZERO POINT mode)	➢ Mode: PRE (based on breast density) FAST (based on breast thickness) ➢ Filter: AUTO (Rh/Ag/Al) Rh Ag Al (only for TOMO exams)
Semi-Automatic (ONE POINT mode)	➢ Mode: PRE (based on breast density) FAST (based on breast thickness) ➢ kV (20÷35)/ kV (20÷49 - Optional) ➢ Filter: AUTO (Rh/Ag/Al) Rh Ag Al (only for TOMO exams)

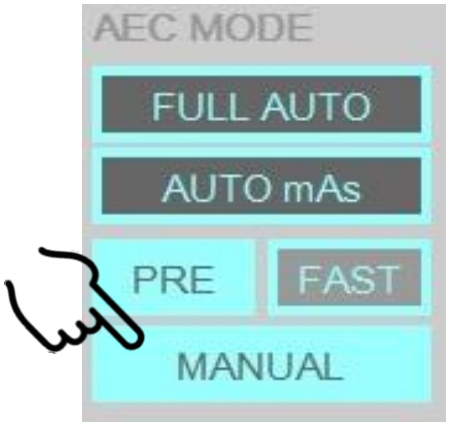
NOTA

The descriptions here below and relative to the exposure techniques, may be displayed on the GUI on different backgrounds (yellow or blue) depending on the type of the study open by the operator. The pictures below in blue are relative to a DICOM study but they are totally equivalent to those ones in yellow which are relative to a LOCAL study. The descriptions are the same for both.

To select the Exposure Technique, click on the corresponding button on the area n°8 of the AWS DSP.

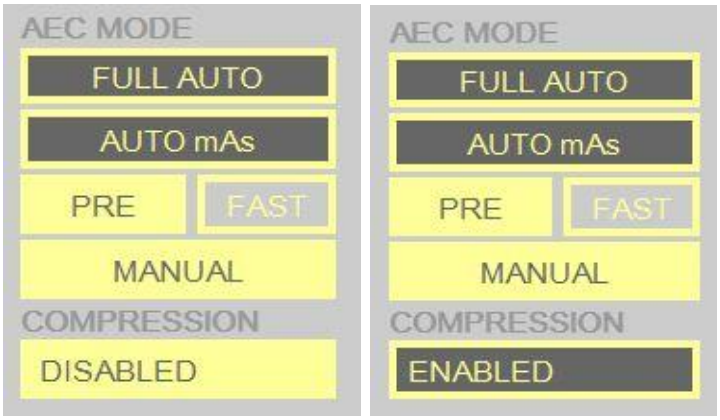
5.1. *MANUAL MODE*

In manual mode the operator can select kV and mAs in the appropriate range allowed. The unit takes care of max tube loading conditions by itself.
The manual mode is signaled by colored button when pressed.



In manual mode the exposure parameters (kV and mAs) can be chosen clicking on corresponding buttons on the areas n°2 and 3 of the AWS DSP.

The kV values change through 0.5 kV steps. The selectable standard range is 20 ÷ 35 kV or 20 ÷ 49 kV optional. The mAs range is 1÷ 640 mAs.
Manual mode allows to acquire an image disabling breast compression.
A specific label “COMPRESSION” indicates a button to manage compression states (enabled/disabled). The compression in manual mode is DISABLED by default



The compression button can be managed according to the operative needs, enabling/disabling compression.

The capability to execute an exam without compression is highly recommended for breast implant for which the compression management is difficult also to avoid any kind of injuries.

In case of compression disabled it is possible manage the compression paddle as follow:

- Place the compression paddle in contact with the breast without applying the minimum compression force;
- Place the compression paddle in any position along the compression travel, according clinical needs (not recommended);

NOTE The compression state can be set also with magnification device inserted.

An exam without compression does not allow the dose evaluation that remains undefined.

NOTE

Compression disabling function can be used only for 2D images.

NOTE

It is highly recommended to perform this type of exam only for specific clinical needs.

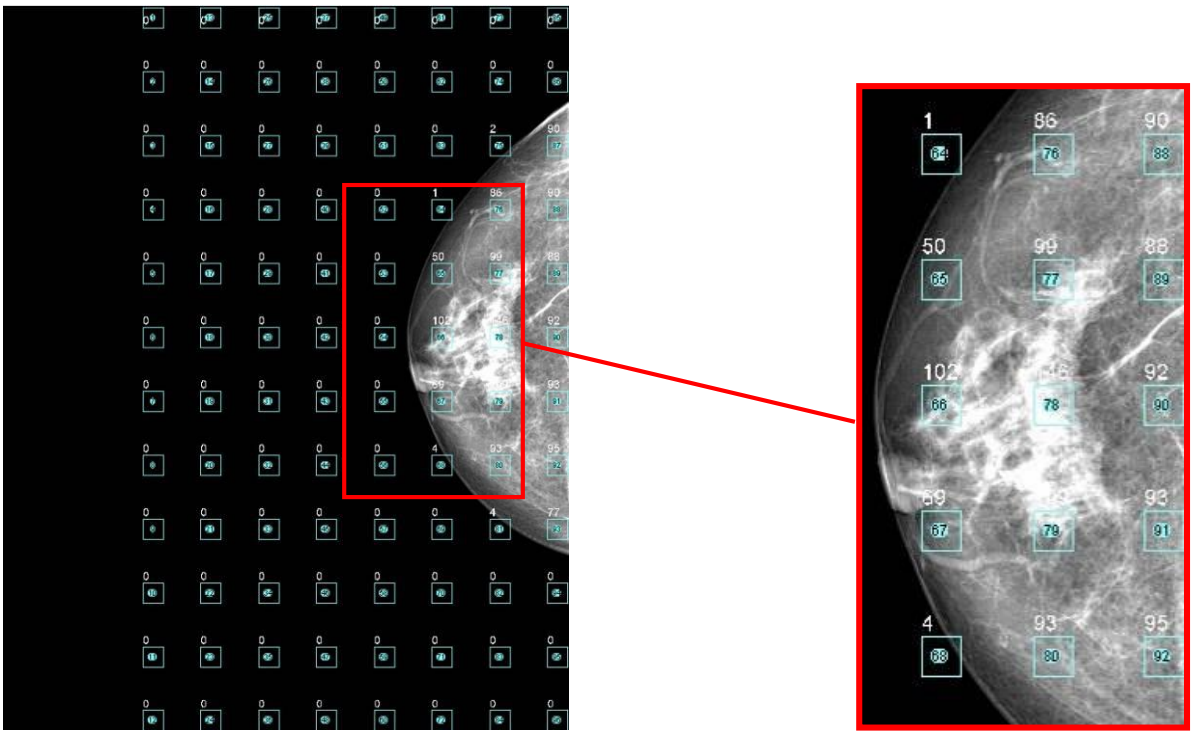
NOTE

Manual mode is not recommended for normal use. Use it only for special application (Breast implant, breast specimen, etc)

5.2. *AUTOMATIC EXPOSURE CONTROL*

The Automatic Exposure Control (AEC) is active in Fully Automatic or Semi-Automatic Exposure Technique. It has dual mode: **PRE** and **FAST**.

PRE-exposure is tissue composition based and exposure parameters are determined by means of a short X-ray exposure proportionally related to the breast size starting from a minimum of 1 mAs. The AEC algorithm considers the entire area covered by the breast in the calculation. There are not empty spaces between the ROIs employed by AEC in automatic and semi-automatic modes.

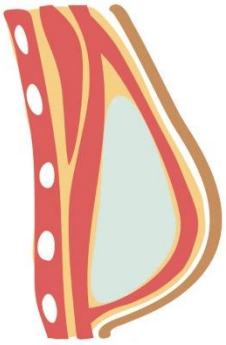


NOTE The image indicates the distribution of the ROIs used in the processing of the AEC and is for reference only.

FAST exposure is based on compressed breast thickness. Exposure sequence is **FAST**er than **PRE**-exposure and gives comparable results in all operating conditions including special cases with breast implants and surgical metal aspects.

Pre and **Fast** techniques are provided to manage specific conditions as follows:

- **Pre** is the standard technique for screening and is also recommended for post surgical intervention examination for which compression force could be painy or dangerous.
- **Fast** is highly recommended for breast implant being kV and mAs thickness related.



WARNING

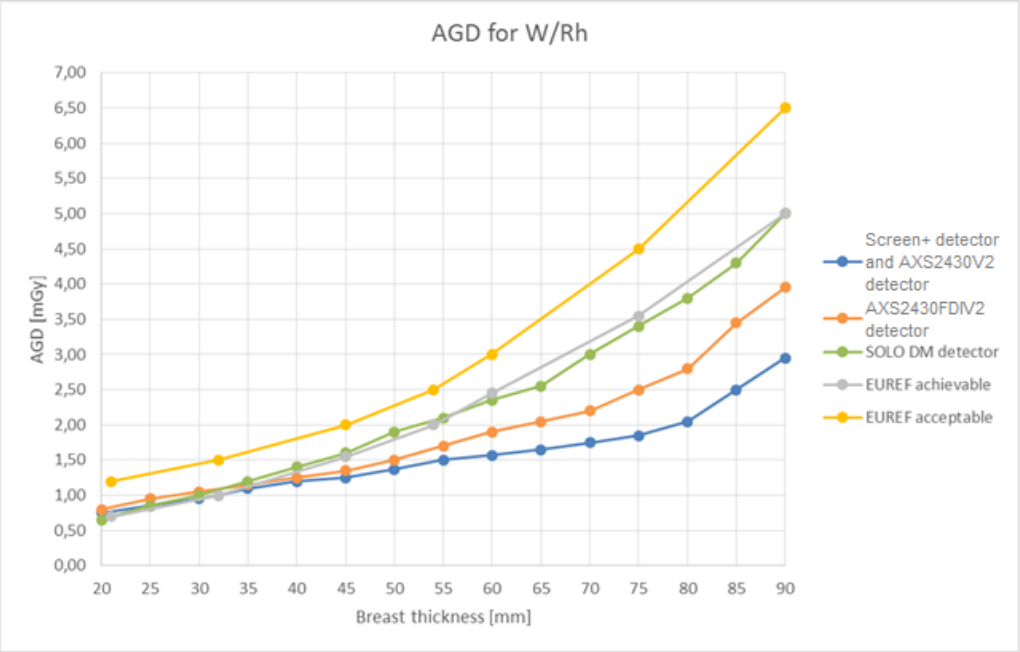
Do not use **Pre** with breast implant.
Do not use **Fast** with light compression force.
In both cases, Dose released will be too high and resulting image most probably unusable.

In FULL AUTO and AUTO mAs modes is not possible execute an exam without compression.
COMPRESSION is set by default as “ENABLED” and it cannot be set as “DISABLED”.
To select the AEC mode click on the corresponding button on the area n°8 of the AWS DSP

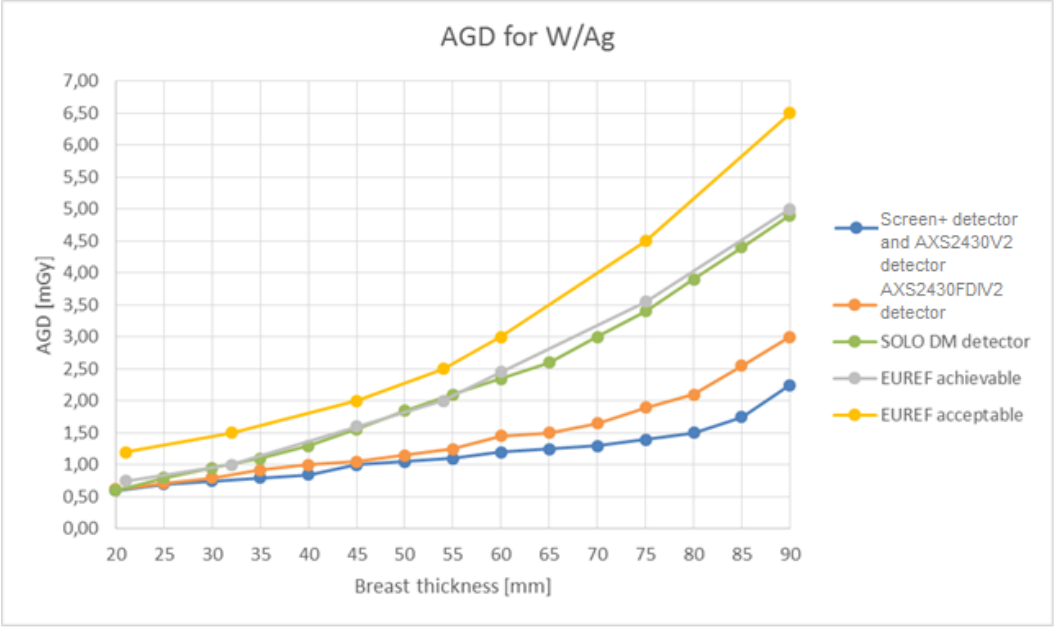
5.3. *EXPOSURE PARAMETERS*

Exposure parameters are set in order to satisfy the EUREF Protocol requirements

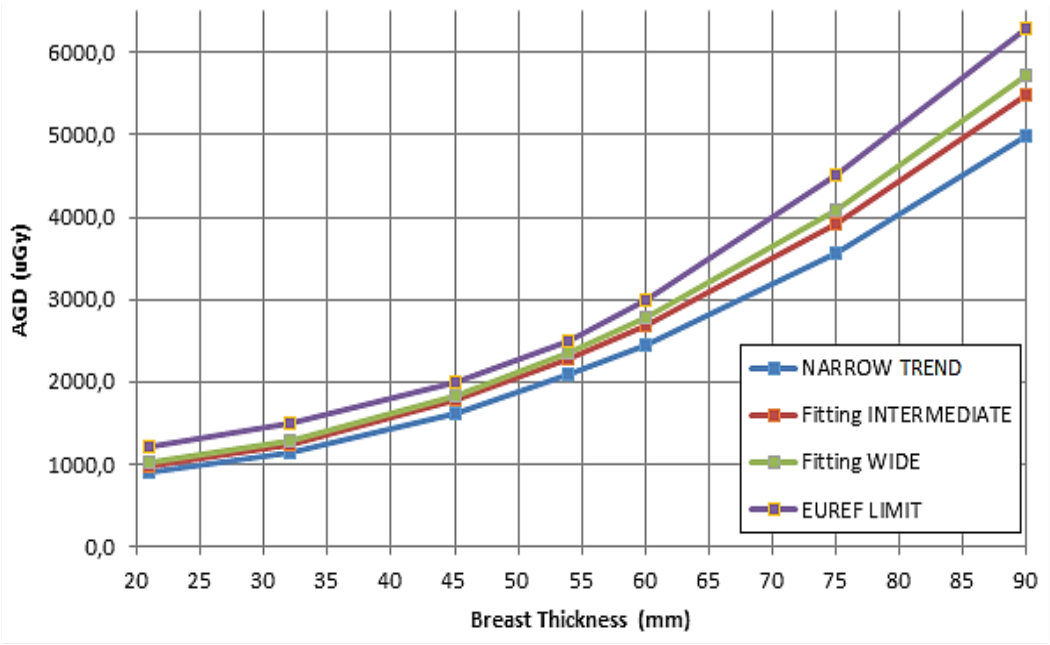
AGD in mGy and W/Rh Anode/filter combination (2D option)



AGD in mGy and W/Ag Anode/filter combination (2D option)



AGD in mGy and W/Al Anode/filter combination (TOMO option)



WARNING

As exposure parameters and dose released are related to breast thickness take care not to shot without appropriate compression applied.

5.4. *ZERO POINT MODE (fully automatic kV and mAs)*

This is the most used operating mode and it is recommended because guarantees the maximum performances of the unit.

The Zero Point mode is signaled on the AWS DSP by colored button. Another button shows the chosen AEC mode.

In automatic mode the mammography unit uses a very powerful algorithm to choose the exposure parameters.

Notwithstanding the images, after the acquisition, are always corrected and enhanced, and only after post-processing are displayed; the exposure parameters remain one of the most important aspects to obtain good quality images, especially in terms of contrast.

Zero Point mode guarantee top quality images in term of AGD and features, moreover, examination time and retake are minimized.

After the exposure the display shows kV, mAs and dose released during the exam.

5.5. *ONE POINT MODE (manual kV and automatic mAs)*

The semiautomatic mode is recommended only when the user needs to select kV manually for special purposes under his control. kV values change in steps of 0,5 kV.

After an exposure in zero-point mode, selecting the one point mode the kV value set on display is the value used for the previous exposure, and of course the operator can change it in the range shown on the display.

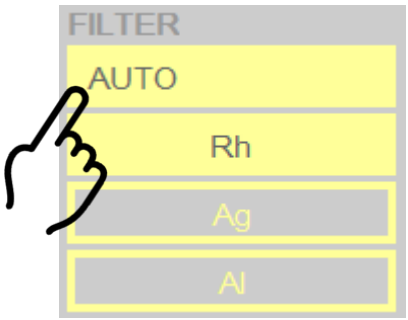
The Zero Point mode is signaled on the AWS DSP by colored button. Another button shows the chosen AEC mode.

5.6. *AUTOMATIC FILTER DEVICE Rh/Ag/Al*

The automatic filter device Rh/Ag/Al is used to have a double combination ANODE/FILTER (W/Rh-W/Ag) for bi-dimensional exams and the W/Al combination for tomosynthesis exams. It optimizes the spectral characteristic of X-rays in function of real density of the breast.
The mixed (Ag) filter is a further improvement for larger and denser breasts and not only gives great imaging performance at lower dose (reduction of about 20%) but also significantly reduces the X-Ray exposure time to eliminate potential patient motion problems.
In PRE mode the breast density is detected with a short PRE-exposure in ZERO POINT and ONE POINT techniques. So that the appropriate TARGET/FILTER, other than the exposure parameters, will be automatically selected.
Trip point after which W/Ag combination is selected, corresponds to about 6 cm of Tissue Equivalent PMMA phantom.

Anode/filter combinations

In automatic or semiautomatic mode, mammo unit can choose automatically the anode/filter combination to use for the exam. To set AUTO mode click on the button n° 11 of the AWS DSP.



In all exposure techniques, the operator can set the anode/filter combination by himself. To set FIX mode and preferred filter, click on the corresponding button n° 11 of the AWS DSP: it changes its feature and shows “FIX” label. Its selection enables and shows AUTO and FIX mode on the button n°11 of the AWS DSP.
When AUTO mode is enabled, filter radio buttons are disabled and not selectable but they will be automatically highlighted when the X-ray sequence starts.

For each acquisition mode, Anode/filter combination is selected automatically in relation to AEC calibration files and/or radio files availability.

If AEC calibration files are absent for a generic filter or if the ANODE/FILTER combination is absent, a specific warning message will be shown (refer to Section VII, paragraph 7.2)

NOTE The Al filter is available only for TOMO option

Section VI :
Operating Instructions

WARNING

The HELIANTHUS series mammography device is a medical equipment and internal calculator not be used as a general purpose calculator. Do not attempt to make any change to system software and do not try to install unauthorized software

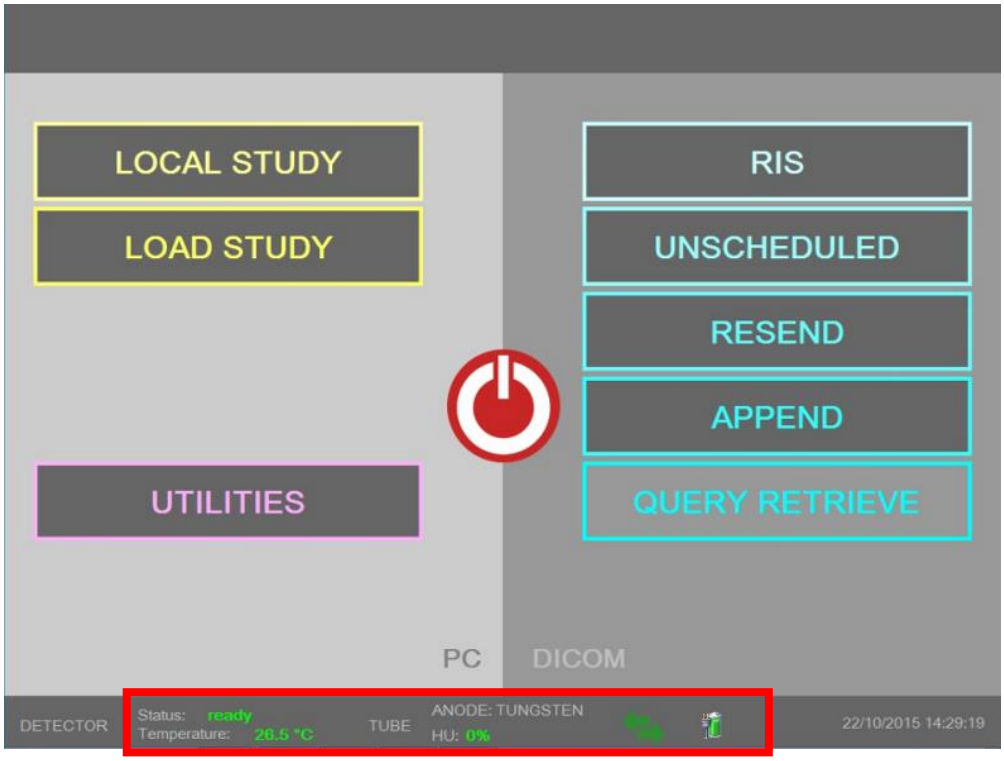
WARNING

The installation of a specific software (under the user responsibility) to protect internal calculator from virus and spywares coming from the servers or external devices connected by USB ports (i.e. portable Hard Disks, flash drives, etc.) is highly recommended (refer to “Safety information”).

6.1. *STARTING THE ACQUISITION WORK STATION*

Switching ON the mammograph (see section IV: General Operations), the software runs automatically, the device is initialized, detector is turned on.

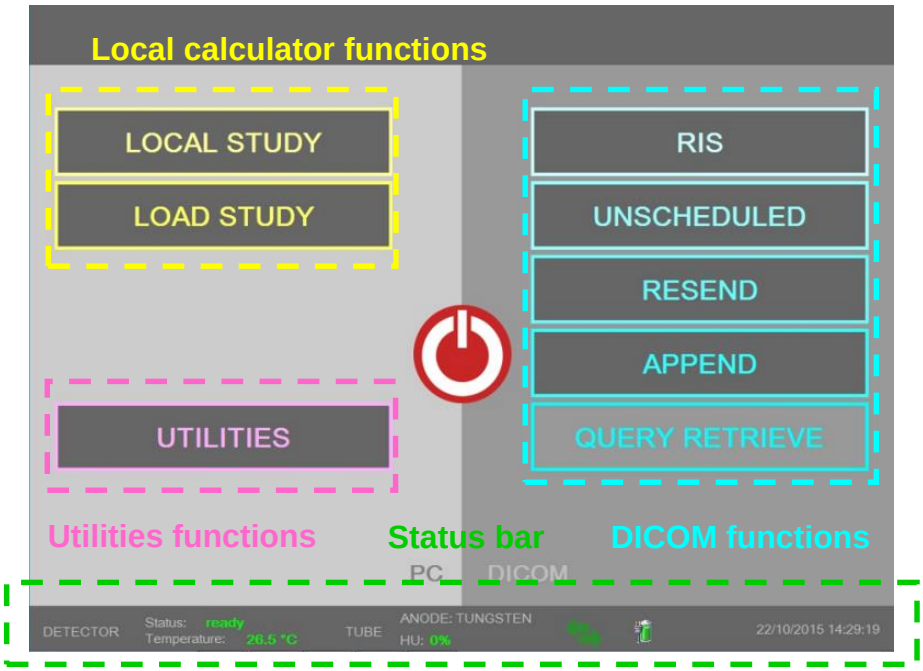
At the end of tuning phase, after about 5 minutes, the User Interface is shown on main monitor of device and a green message on the down bar reveals that the Mammo Unit and calculator correctly communicate and device is now “ready” to use.



6.2. *USER INTERFACE DESCRIPTION*

The User Interface is configured in order to show information regarding the functionality of mammography device and all applicable items.

It is divided in four areas: “Status bar”, “Local calculator functions”, “DICOM functions” and “Biopsy devices and Daily check functions” known as “Utilities function”.

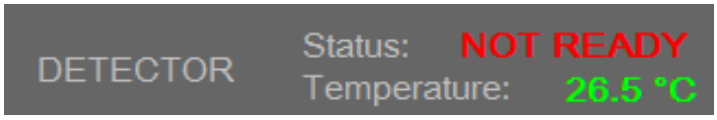


The User interface contains also the button to log off the software.

6.2.1. Status Bar

The Status Bar is divided in two sections and includes a calendar with local time.

The first section indicates the temperature and the “Status” of the detector.

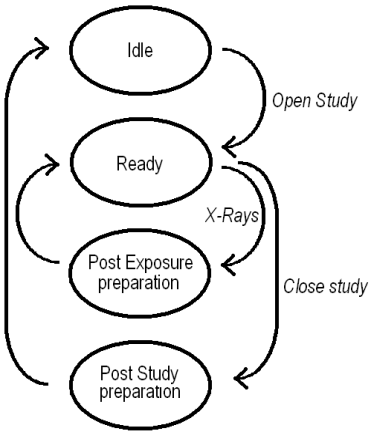


The possible states are:

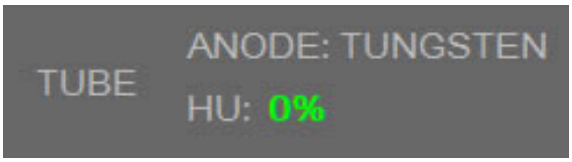
Table 4

Message	Meaning
ready	The detector is ready to receive the X-rays. This is the normal condition when there is an open study (and no elaboration is going on).
NOT READY	The detector is not ready to receive the X-rays. After the detector receives the X-rays and acquires the image, it passes through this state before being ready for a new exposure. **NOTE**: every 15 minutes of inactivity, the detector passes in NOT READY STATE for few seconds (internal update). In this case, it is sufficient waiting for few seconds because it turns automatically in READY STATUS

The following status diagram shows the sequence of states which the detector passes through.



The second section indicates the anode material and the “HU%” of the X-ray tube.



The third section indicates the connection state between calculator and Mammo Unit:

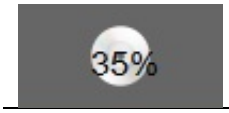
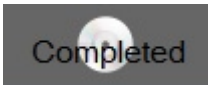
If green: no communication problems between the entities. On the contrary, it appairs red.

The last section indicates the operating state of the device.

If the mammo unit is sending a Study to a DICOM server, the possible states are the following:

Message	Meaning
	First phase of building of the DICOM file.
	Successive and progressive phases of sending to the server.

If the mammo unit is recording a Study on a CD/DVD, the possible states are the following:

Message	Meaning
	The messages of this section define the different and successive phases corresponding to the Study recording on a CD/DVD disk. They automatically follow one other until the end of the process. In this last phase, the indication “Completed” will be displayed on the status bar together with the message “Media can be safely removed”.
	
	
	
 	

6.2.2. Local calculator functions

By means of this menu it is possible make operations on the local calculator, as open new studies and save them locally (i.e. not from the worklist) or reload the local studies (i.e. resident in the internal memory of internal calculator).

The functions are available depending on the status of the device.

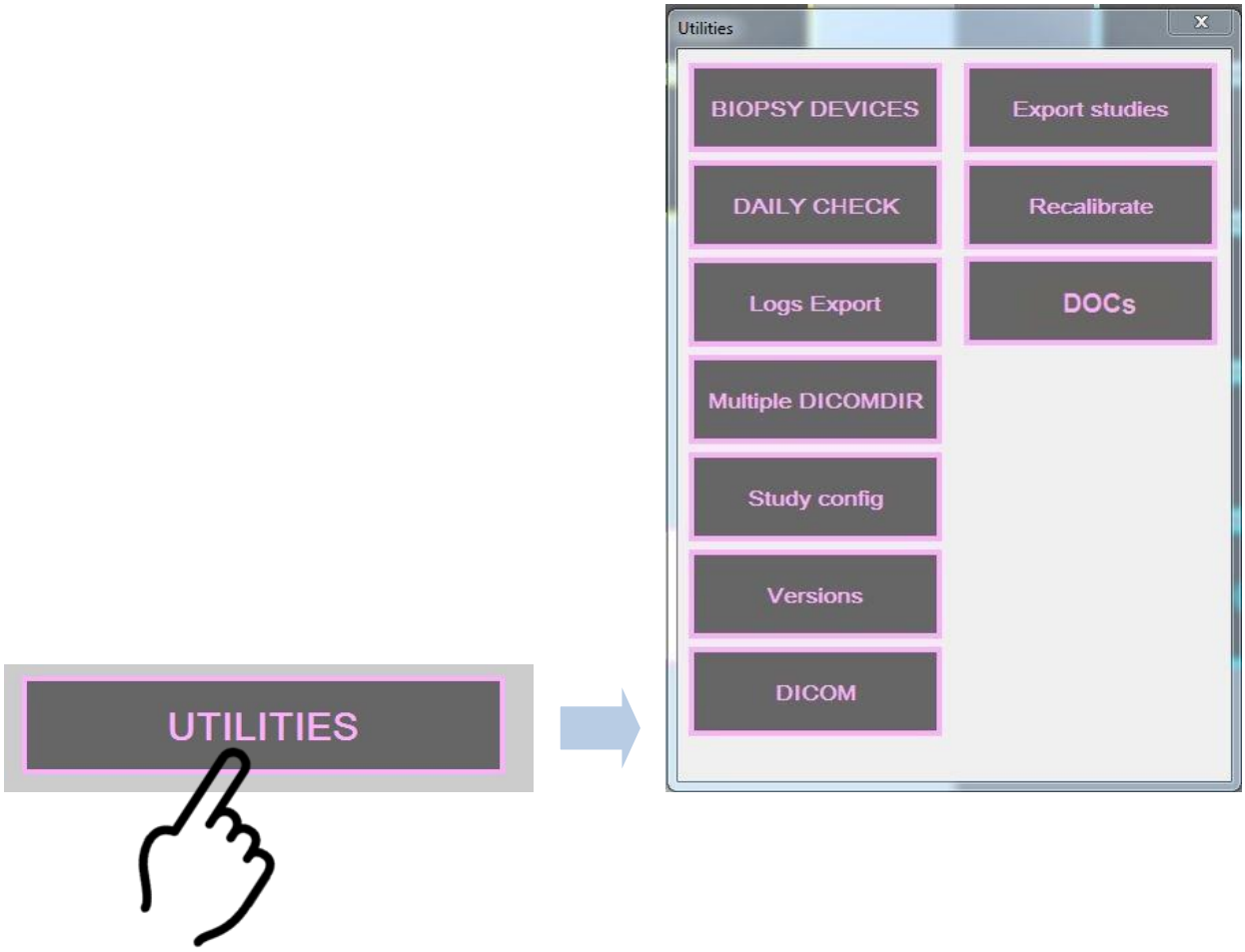
6.2.3. DICOM functions

This menu includes all the commands that involve DICOM functions:

It is used to open and close a study from the Worklist, send studies stored on the local calculator to the appropriate server of the RIS, change the exam typology of the study, integrate a study with other images, print images and make CD of the studies according to the DICOM protocol. The “DICOM menu functions” is available depending on the state of the device.
If the menu is not available, all the buttons are not active. The problem can be due, for example, to the PACS of the medical center that is temporarily not available, or to the connection cable that has been cut. Click on the menu to verify if the connection with the DICOM network has been restored. If after a few seconds the question point disappears, the connection is available and it is possible to open the menu clicking on it. Otherwise the question point persists and the menu is not available. In this case it is not necessary to stop working. Anyway, it is possible to continue acquiring images and store studies locally, on the internal memory of calculator, and when the DICOM connection is restored the studies can be sent to the PACS.

6.2.4. Utilities functions

This menu includes some particular useful functions:

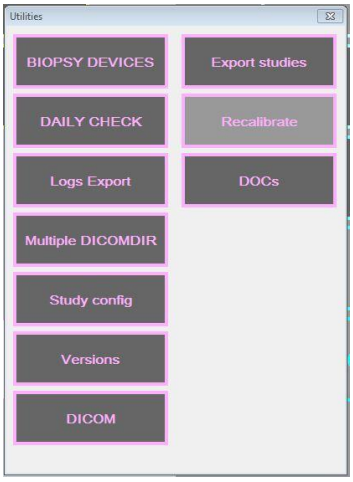


The functions are the following:

1. **BIOPSY DEVICES**: it allows to manage additional biopsy system (needle, gun, etc.) in the available database or to duplicate features of device present;
2. **DAILY CHECK**: it allows to verify the correct functioning of the unit;
3. **LOGS EXPORT**: it allows to export on removable drive all those files which could be useful for Technical Assistance in order to analyze SOFTWARE problems eventually observed and signalled.
4. **MULTPLE DICOMDIR**: it allows to export one or more DICOM studies on CD/DVD or other removable drive.
5. **STUDY CONFIG**: it allows to integrate the DICOM tags with the following information:
    - Operator's name;

- Institution's name.

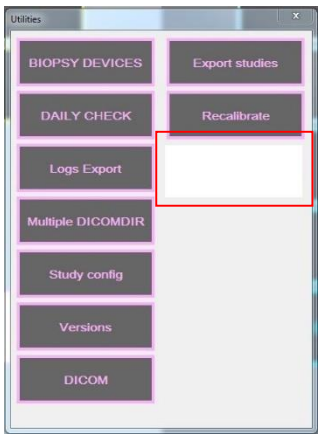
6. **VERSIONS**: it allows to check the current FIRMWARE and SOFTWARE versions installed on the mammograph Unit;
7. **DICOM**: it allows to check if the DICOM servers are properly configured and if Storage commitment (SC) and modality performed procedure step (MPPS) are available.
8. **EXPORT STUDIES:** It allows to export the entire study folder or more studies. This function may be used by service personnel only.
9. **RECALIBRATE:** this function is activated only for a-Si detector installed on board (Not for TOMO option). The operator has to perform this procedure daily and before starting an exam**. If TOMO option is provided the specific function is not enable as show in the following figure**



10. **DOCS:** this function allows the IFU consultation. This section is reserved to the user and may contain other customized documents for device such as Technical manual, IFU

NOTE

If no documents are present, "DOCs" button will not be enabled as shown in the following figure



For further details about those specif functions and their complete procedure of use, see the relative paragraphs into the Section VI “Operating Instructions”.

NOTE

The “BIOPSY DEVICES ” function is available only if the BYM 3D DMD stereotactic device is inserted on HELIANTHUS series mammography unit, otherwise *Biopsy devices* function is not available. Regarding the use of this function, refer to “BYM 3D DMD Operator’s Manual”.

NOTE

The “Daily check” function cannot be used in replacement of calibration tools dedicated to quality control.

6.3. *OPENING STUDY*

To acquire radiological images, it is necessary that a new study is opened either from the Worklist (that is remotely generated), or from the local data storage system.

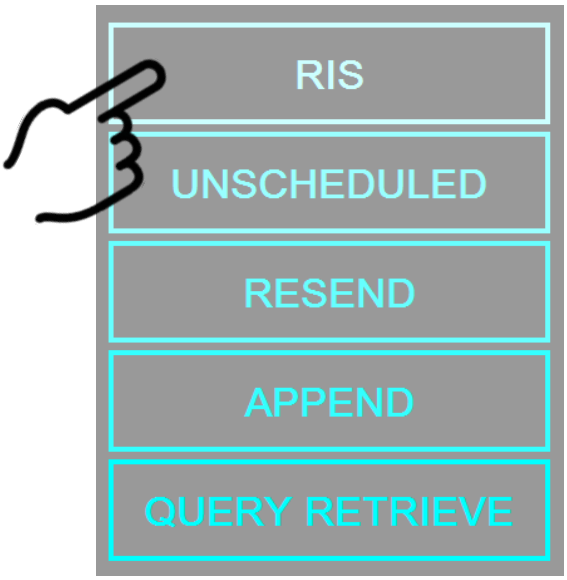
The normal operating mode is opening the study from the Worklist, but if the patient's data are not available from the Worklist (as for example because the DICOM Worklist server is out of service), the unit is able to work: the acquired images and the data of the study are stored in its internal memory.

When the connection with the Worklist server is restored, the data previously memorized in the internal storage are sent to the PACS and synchronized with the Worklist. Then the internal memory gets free.

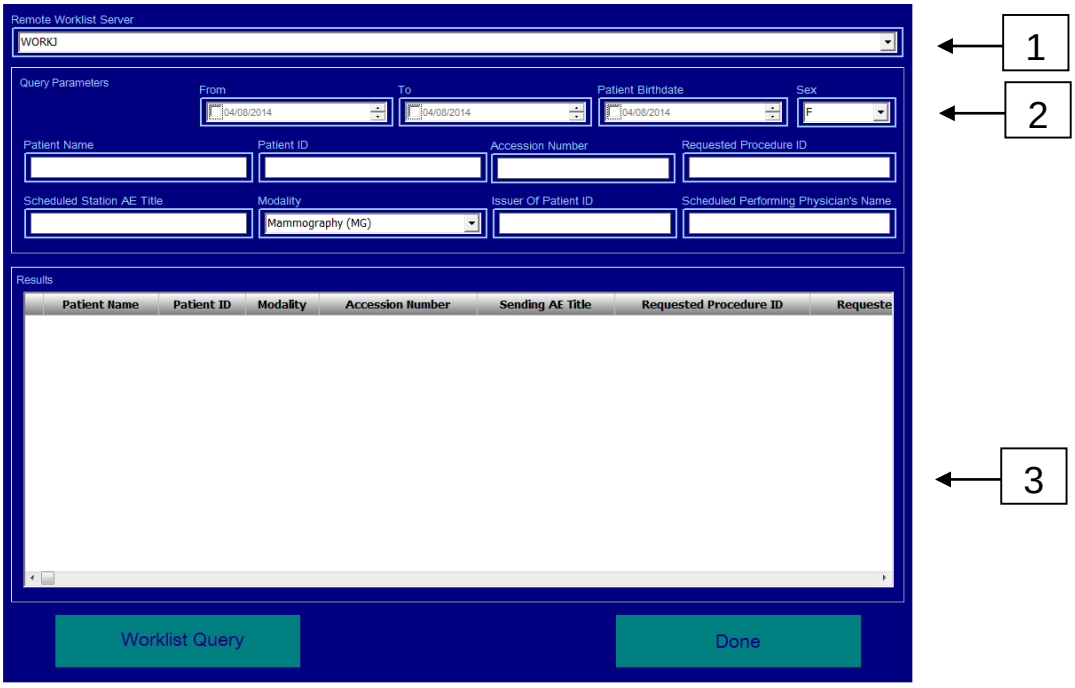
To open a study from the Worklist, it is necessary to know the functions of the "Worklist Query Dialog" window. To open a study from the local database, it is necessary to know the functions of the "Study Data" window.

6.3.1. Opening study from Remote Worklist

To open a study from the Remote Worklist, click on the “RIS” button of “DICOM functions” menu.



A “Worklist Query Dialog” window will appear, the Software automatically will ask the Worklist to the configured server and it will be possible charge data.



The window is subdivided in three different sections:

Section	Title	Function
1	Remote Worklist Server	To choose the worklist server by means of a combo-box.
2	Query Parameters	To filter the data provided by the worklist server.
3	Result	It shows the results of the query. Any row represents a scheduled study and contains its main information.

To open a study from the worklist, first of all it is necessary to query the worklist server to obtain the data. For this scope, it is necessary to set the query parameters using one or more fields present in the “Query Parameters” section.

It is possible choose between:

- From/To: click on the box near the field “From”, “To” or both and change the time references in order to select the acceptance time in which results have to be researched.
- Patient name: pay attention to insert the name exactly as it was inserted in the worklist.
- Patient ID: identification number.
- Issuer of Patient ID: identifier of the Assigning Authority (system, organization, agency, or department) that issued the Patient ID.
- Patient sex: the possible chooses are F (female), M (male), O (other)
- Patient Birthdate
- Scheduled Station AE Title: modality on which the Scheduled Procedure Step is scheduled to perform. This field is empty until an information will be inserted. After every data entry, the information will remain automatically saved and it will be still present in the following Worklist Query.

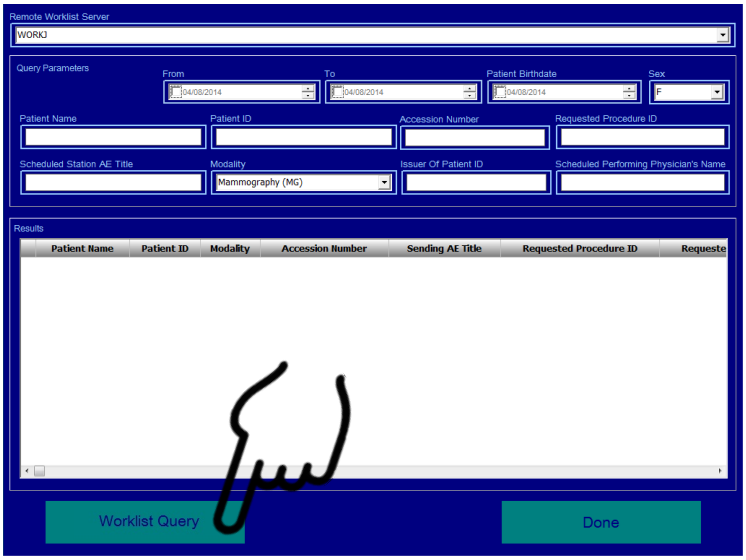
NOTE If you do not want set any parameters for this field it’s necessary, before clicking on the button “Worklist Query”, delete any information just present inside it.

- Modality: the modality for mammography is MG
- Scheduled Performing Physician’s Name: if the acceptance of the medical site schedules the name of the physician who performs the exam, it is possible to filter the worklist by means of this information.
- Requested Procedure ID: when the acceptance creates and inserts a new study in the worklist, this information is automatically created and associated to the study. It is possible to filter the query to the worklist server with this information.

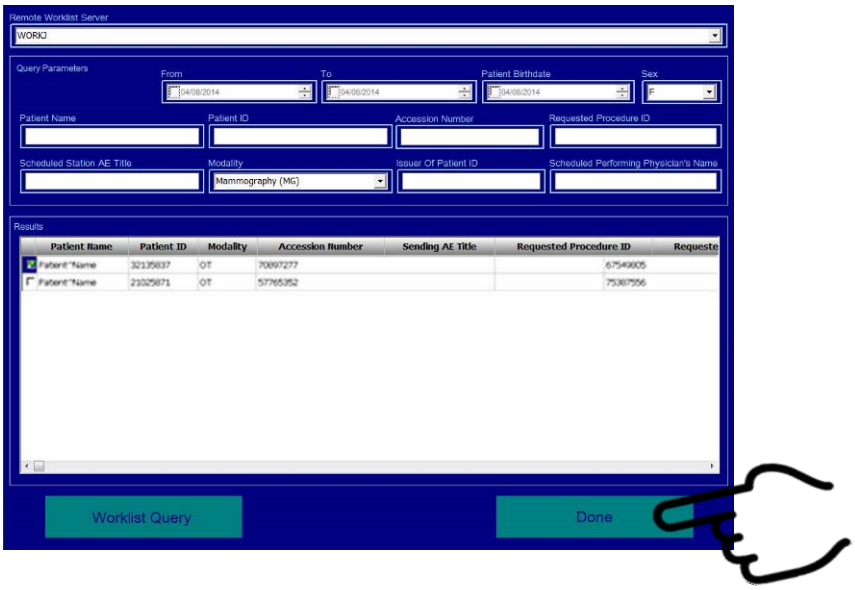
- Requested Procedure Description: this field identifies the type of procedure (for example 4 views ACR CC……)

- Accession Number: when the acceptance creates and inserts a new study in the worklist, this information is automatically created and associated to the study. It is possible to filter the query to the worklist server with this information.

Once set the parameters, push the button “Worklist Query” and all search results will be presented.



To open a study select it and press the button “Done”. If you want to exit without opening any study, do not select any row and click “Done”.

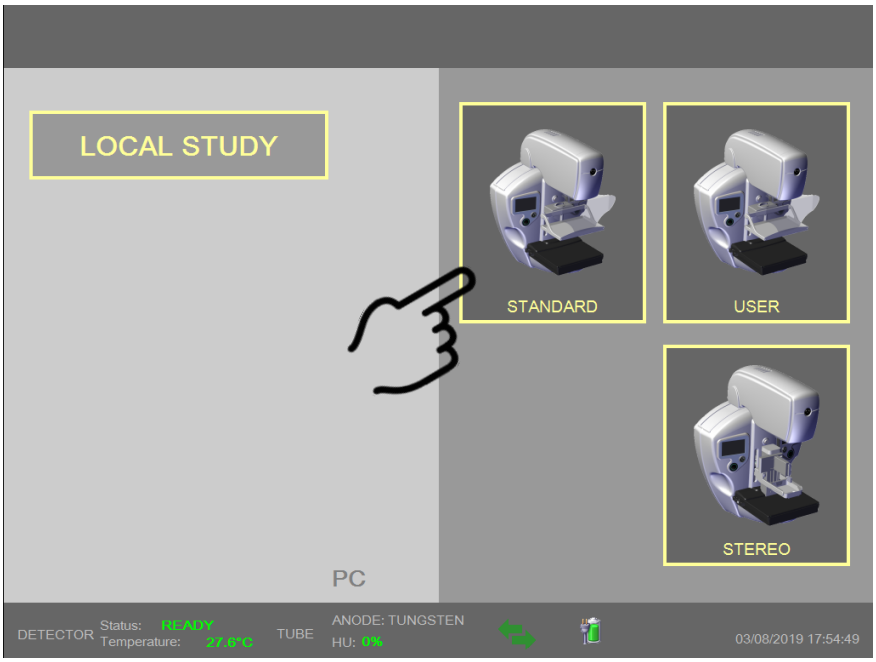


NOTE

If a query to the worklist server does not provide any result, verify that the windows of the query parameters section are correctly filled in.

The device loads the data of the patient and shows the patient name of the currently open study on the MAMMO TSD and the AWS DSP.

At this point, it is possibile to select the exam clicking on the corrisponding icon:



Choose to execute an exam in “STANDARD” procedure, a diagnostic exam customizable (“USER”) or a biopsy procedure (“STEREO”).

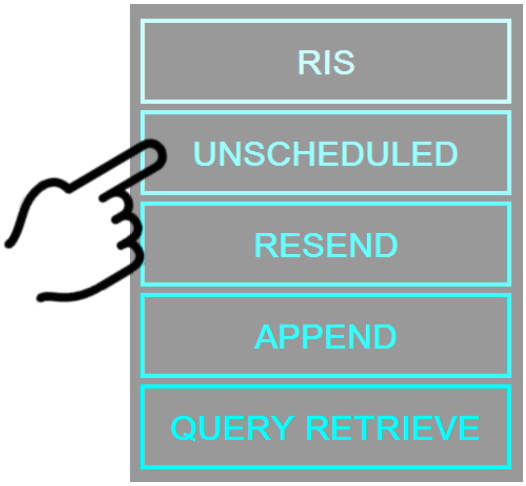
The last procedure results achievable only with the biopsy device BYM 3D DMD inserted on the Mammo Unit.

NOTE

The following descriptions (relative to the STANDARD and USER procedures) are the same independently by the type of study previously open (LOCAL or DICOM).
The background colors of the push buttons are only indicative.
For the description of the STEREO procedure, refer to the Biopsy Device Operator's Manual.

6.3.2. Opening study from Local Worklist

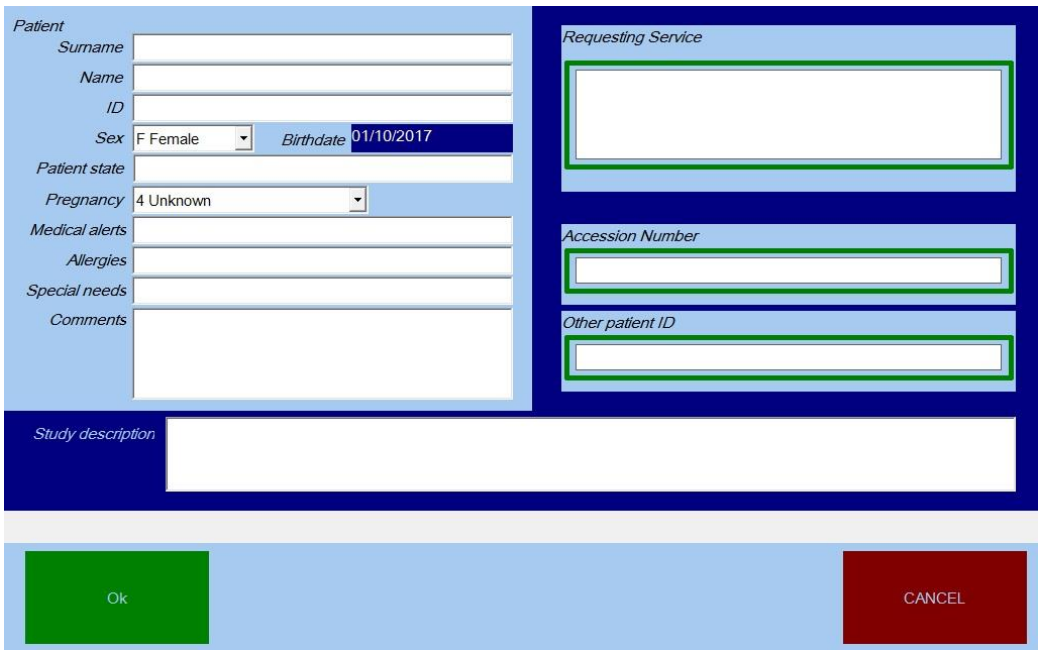
To open a study from the Local Worklist, click on the “UNSCHEDULED” button of “DICOM functions” menu.



NOTE

It is possible to open a Study in this modality also in case of PACS server not available.

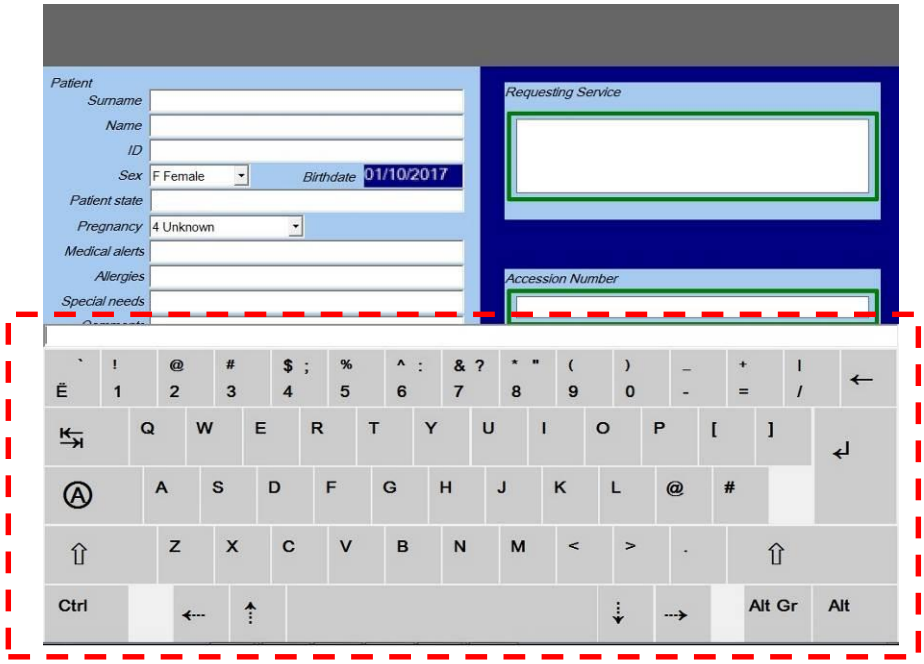
The following window will appear:



It is possible to create a new study without a Worklist item and perform an unscheduled IHE operation later.

To add a new patient, the operator may fill the fields with all the available information.

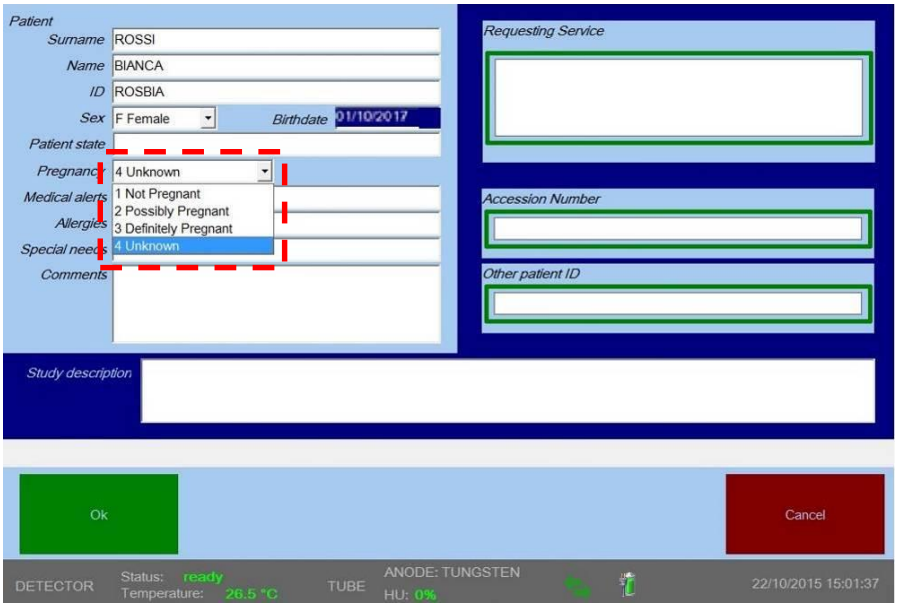
In particular, clicking inside the writeable fields (e.g. name, surname) a virtual keyboard appears:



NOTE

In the writeable fields of “Surname”, “Name” and “ID”, the data inserted can be only alphanumeric. Otherwise, an error messages will be displayed.

Alternatively, and only for some fields (e.g. sex, pregnancy) the following drop-down menu appears:



Only for the Birthdate data, clicking on the corrispondent field, the following windows appears:

in which, for each subfield of Day, Month and Year it is possibile to insert the available information by means of a drop-down menu and then pushing on "√" button.

Finally, it is also possible identify the local study by means of the Accession Number.
In this case, select the related window and write the number in the box:

Additionally, it is possible to identify the local study also by means of an OtherPatient ID.
In this case, select the related window and write inside it the other's identification number or code used to identify the patient univocally:

WARNING

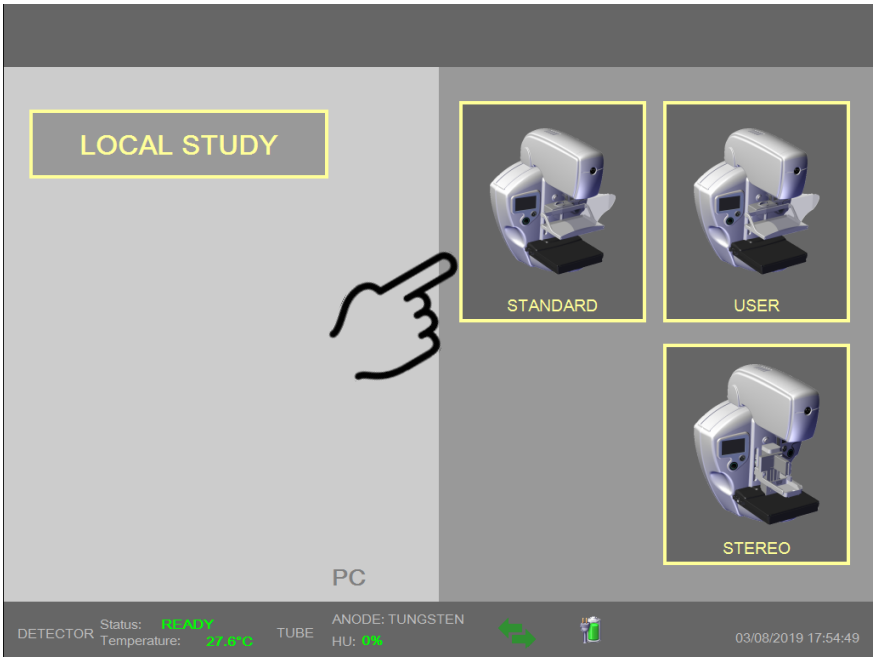
To allow that any study locally generated and stored into the local calculator, later can be matched correctly to the corresponding study of the worklist, take care to identify clearly and univocally each study locally open.
The wrong association between studies of calculator and studies of the worklist can cause wrong diagnosis and loss of clinical information.

After fulfilling the fields with all the available information, push on “OK” button in the bottom-left of the screen to open the study.

NOTE

The ID associated to the study is saved with the study till it is present into local calculator. When the local study will be associated to a Worklist request and transferred to the RIS, the ID will be deleted and the data associated to the mammograms will be the ones supplied by the Worklist.

At this point, it is possibile to select the exam clicking on the corrisponding icon:



Choose to execute an exam in “STANDARD” procedure, a diagnostic exam customizable (“USER”) or a biopsy procedure (“STEREO”). The last procedure results activable only with the biopsy device BYM 3D DMD inserted on the Mammo Unit.

NOTE

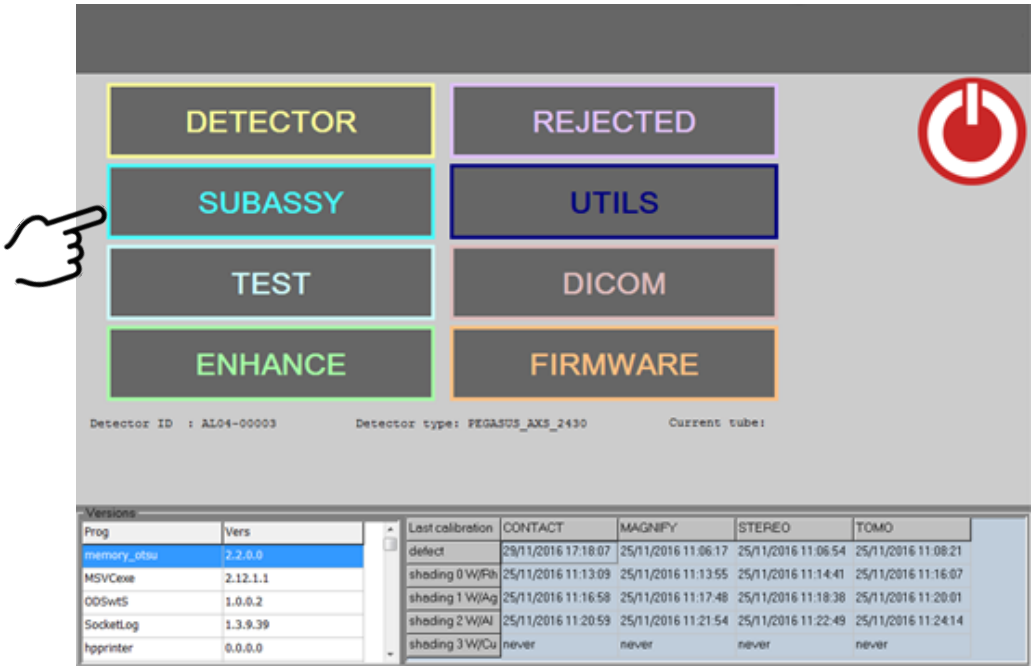
The following descriptions (relative to the STANDARD and USER procedures) are the same independently by the type of study previously open (LOCAL or DICOM).
The background colors of the push buttons are only indicative.
For the description of the STEREO procedure, refer to the Biopsy Device Operator’s Manual.

6.3.3. QR Reader procedure

The QR reader allows the operator to scan the barcode or QR code present on the patient's identity document, in order to automatically insert the fields relating to the personal data after selecting UNSCHEDULED or RIS fields. The calibration procedure of this instrument is as follows and must be preceded by scanning the RESET barcode shown below:

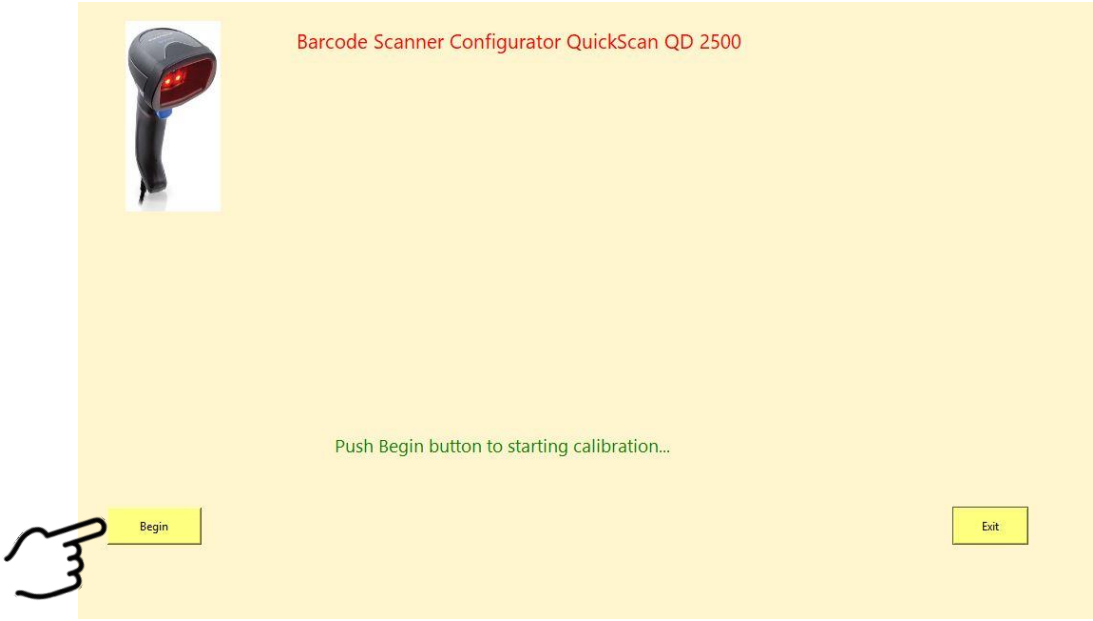
Restore Custom Default
<FNC3>$P,HA00,P<CR>

1. Calibration is done in the Toolkit screen by selecting the SUBASSY menu as indicated in the following figure:

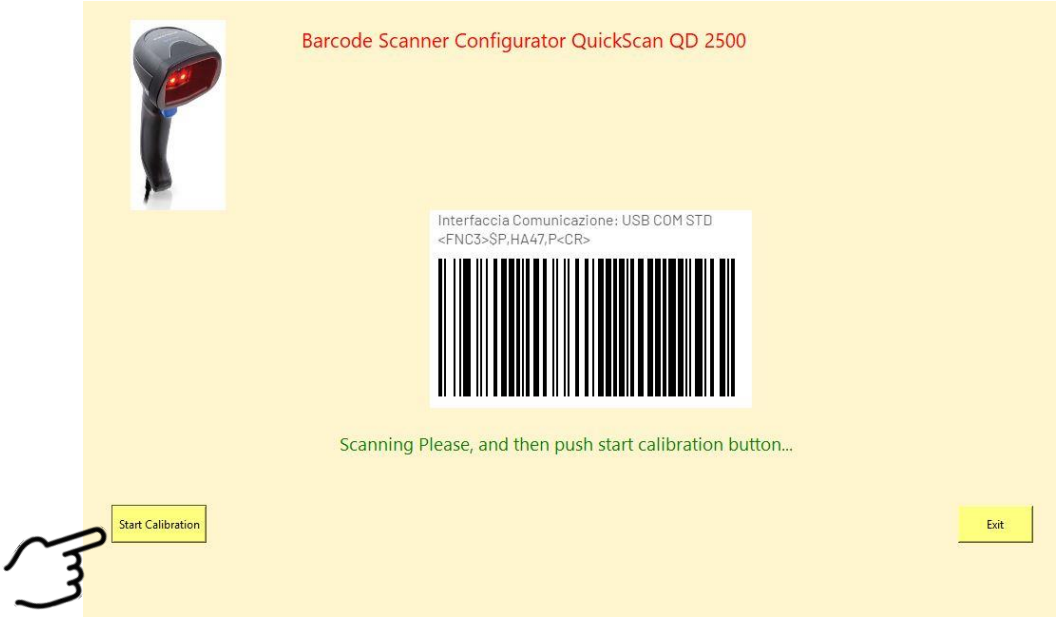


2. Select QRReader option on the displayed window, as indicated below:

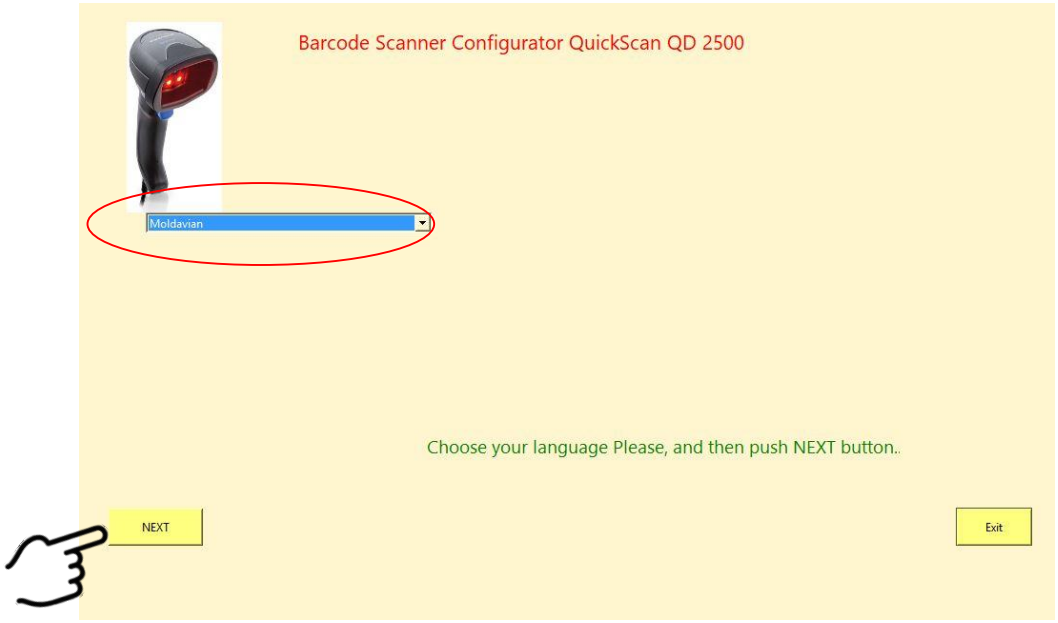
3. The following screen will open. Then click Being button to start with the calibration



4. By scanning the barcode in the center of the screen, RESET option is carried out, then the operator can continue by pressing Start Calibration, as indicated in the next figure:



5. In the next screen, the operator will have the possibility with a drop-down menu to select the language of the country from which to take the identity documents and can continue by selecting NEXT;

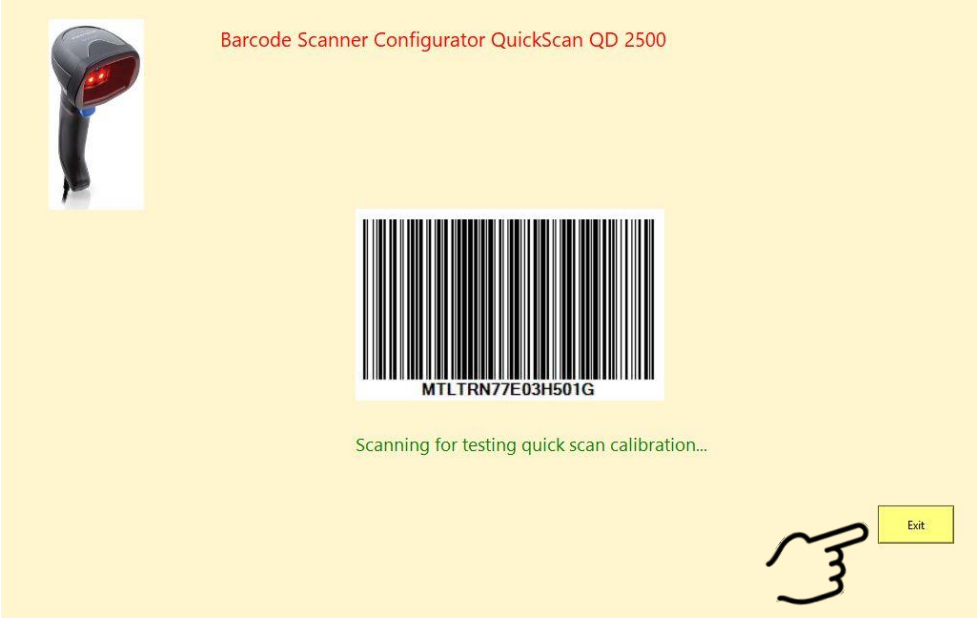


6. In the next screen, the operator can lower the volume of the sounds produced by the QR code reader by pressing the SET VOLUME button;

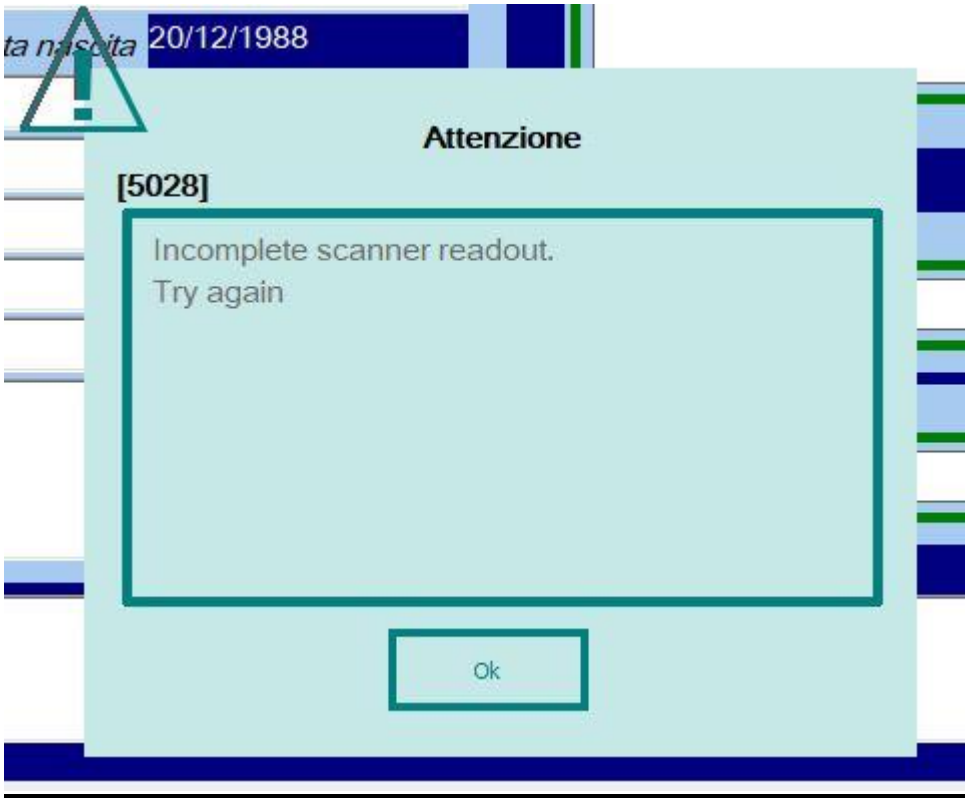
7. Then a screen will appear with a barcode in the center that can be scanned and then the operator will have to press the DET VOL button to continue:

8. The operator must then scan the code that appears on the screen and press TEST CAL as indicated below:

9. Finally, the operator can scan the test barcode before pressing EXIT;

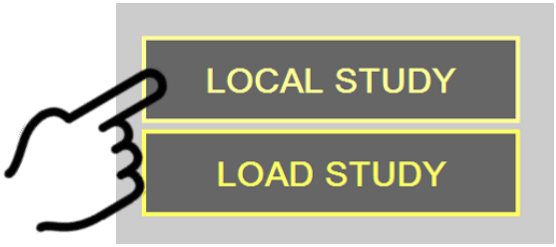


10. If the reading of the QR codes during the registration of a patient is not successful, an error message will appear to indicate this, as indicated in the following figure.
    In this case the whole procedure must be repeated again

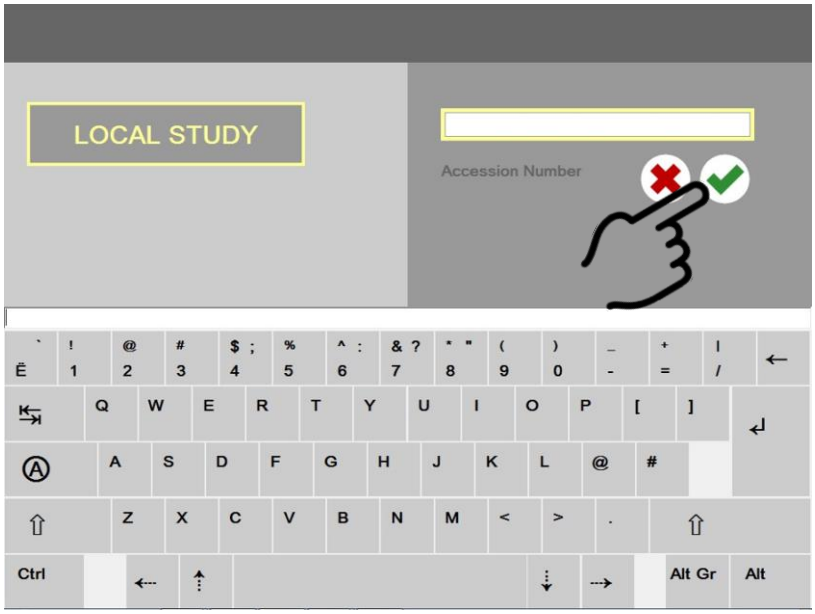


6.4. *OPENING LOCAL STUDY*

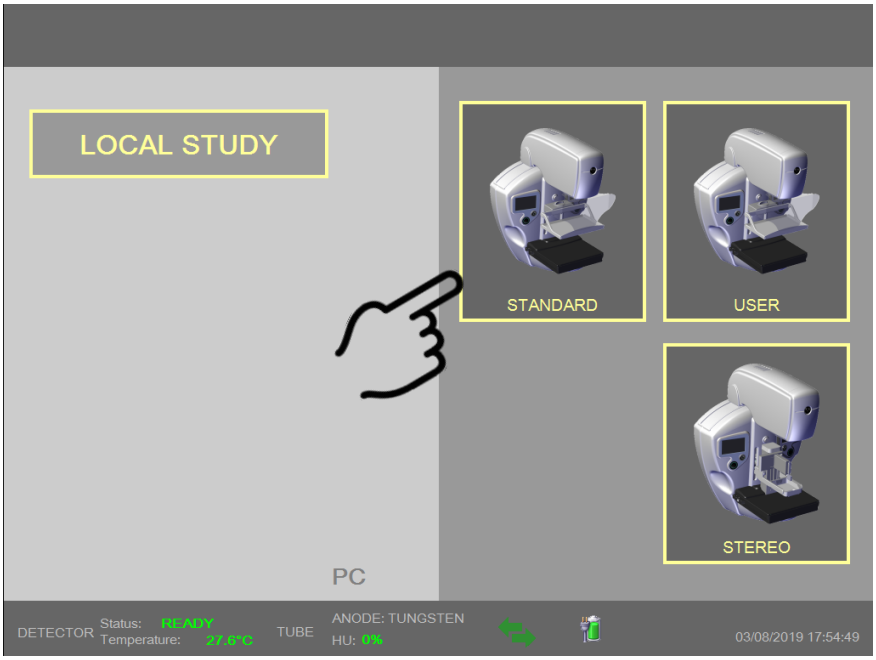
To open a study locally, click on the “LOCAL STUDY” button of “Local calculator functions” menu.



Identify the study associating to it a unique accession number, then push on “√” button.



Select the type of exam clicking on corresponding icon.



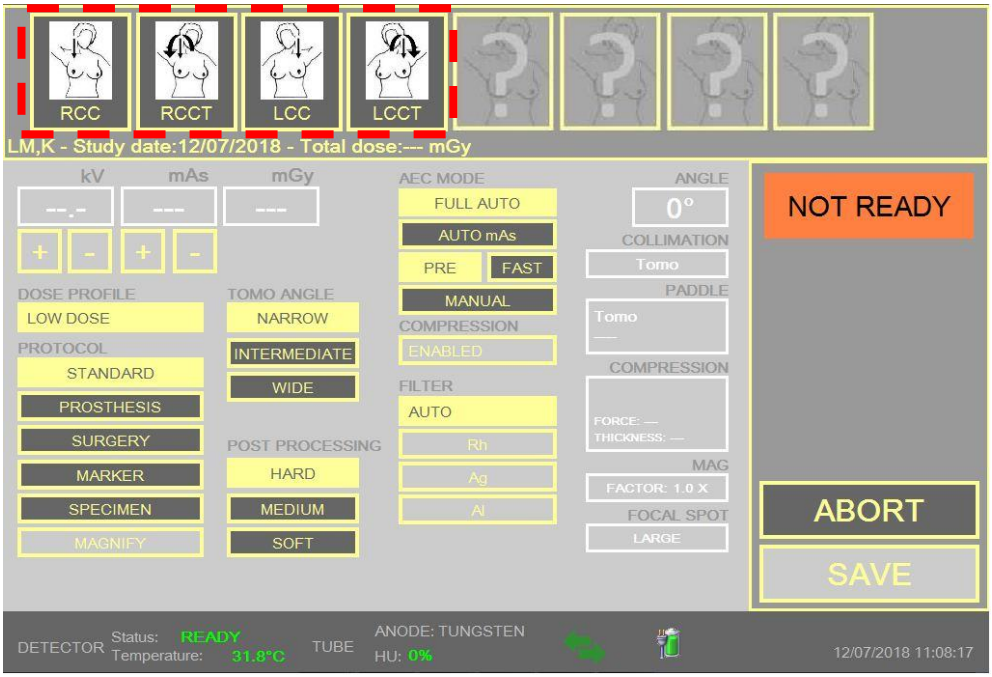
Choose to execute an exam in “STANDARD” procedure, a diagnostic exam customizable (“USER”) or a biopsy procedure (“STEREO”).
The last procedure can be activating only with the biopsy device BYM 3D DMD inserted on the Mammo Unit.

NOTE

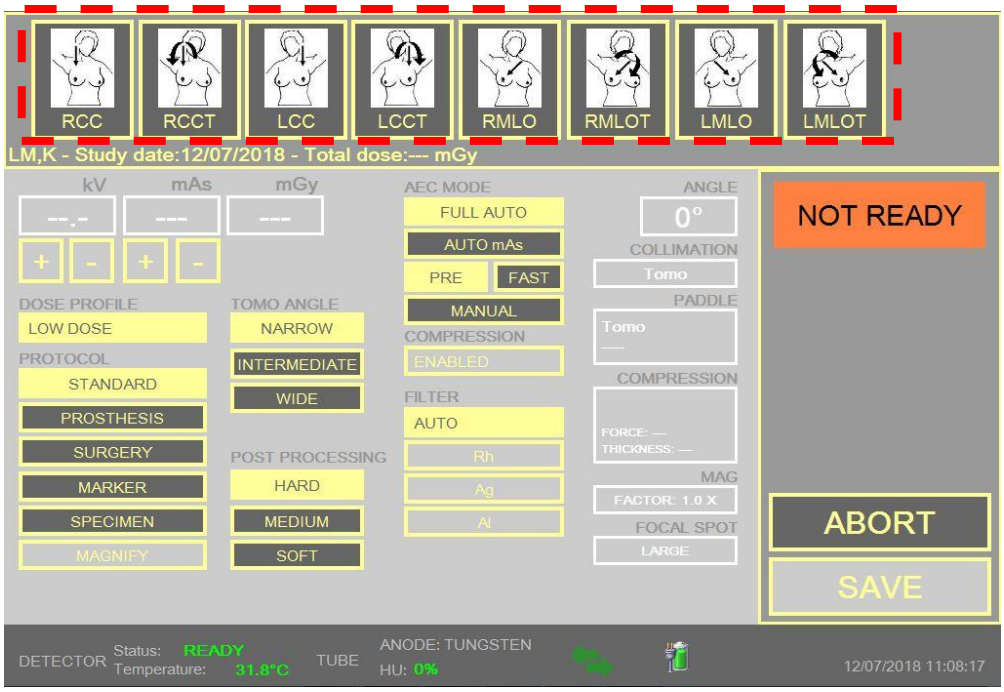
The following descriptions (relative to the STANDARD and USER procedures) are the same independently by the kind of study previously open (LOCAL or DICOM).
The background colors of the push buttons are only indicative.
For the description of the STEREO procedure, refer to the Biopsy Device Operator’s Manual.

7.1. STANDARD procedure

Selecting the standard procedure, the operator is totally guided to execute the exam. He can choose between the pre-selected projections suggested by the SW. Those projections include both 2D and TOMO exposures (if available).
With this procedure, it is therefore possible to combine acquisitions of both modes including them in the same study open.



2D OPTION



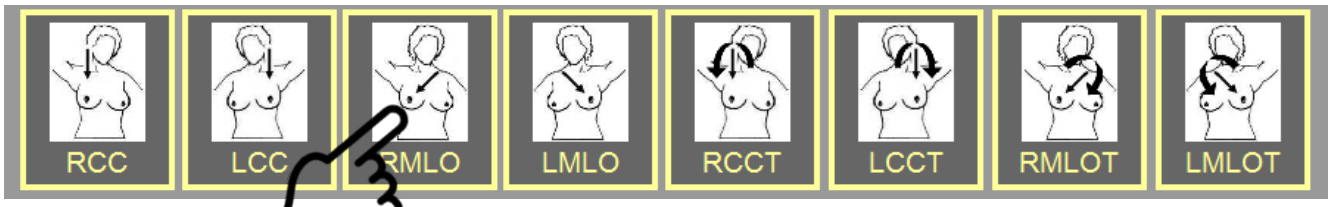
TOMO OPTION

The suggested views for study, depending by the exam selected, are displayed in the upper part of the AWS monitor as shown in the figure above.

NOTE

For a detailed description of 2D views, refer to those ones detailed in the paragraph “SETTING ACR code”
The TOMO views are marked with an ACR code to which follows the addition of a letter "T” (if available).

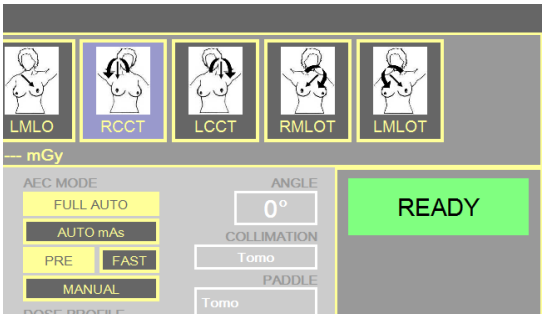
Until the view results as not selected and the C-Arm not rotated in the corresponding position, the indication “NOT READY” still remain visible in the area n°13 of the AWS DSP (see the corresponding paragraph “TOUCH SCREEN COLOUR DISPLAY (AWS TSD)”).
Always in this phase and until the X-ray exposure does not start, it is always possible to abort the study clicking on the push button “ABORT” which is visible in the same area of the AWS DSP.
Pushing on the view icon, the C-arm rotates automatically to corresponding projection angle.



After the projection selection, the icon remains highlighted until the pressure of X-Ray push button or “CANCEL” push button as shown in the following icon (e.g. RCCT)

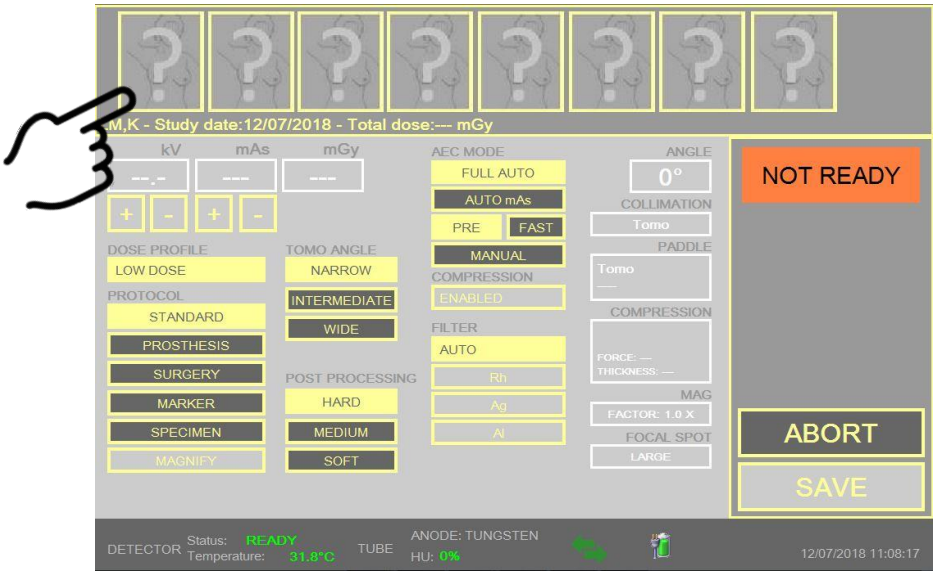
NOTE

“CANCEL” push button appears after exposure parameters setting (kV and mAs) in manual mode or AEC mode.

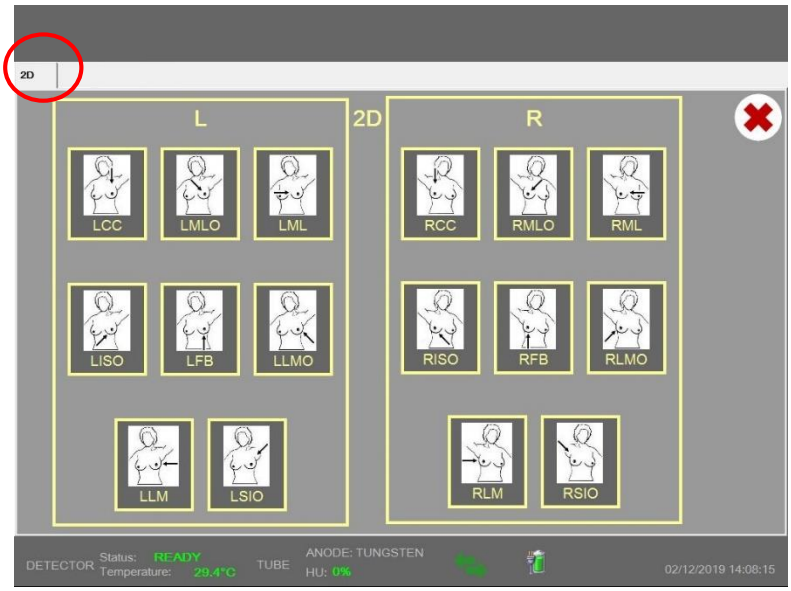


7.2. USER procedure

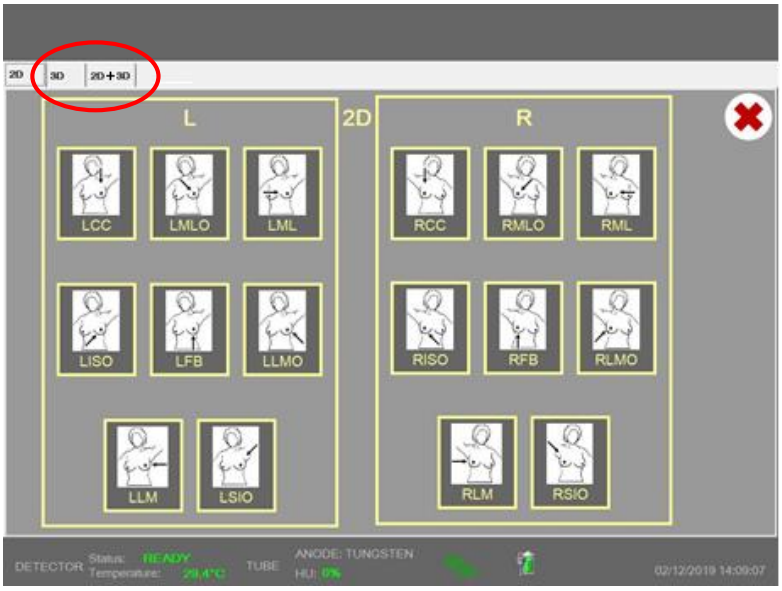
With the customized procedure, the operator can configure the exam selecting until to eight projections.



Pushing on one of the icons with question mark, a new first window appears with 2D views that can be included in the customized procedure.

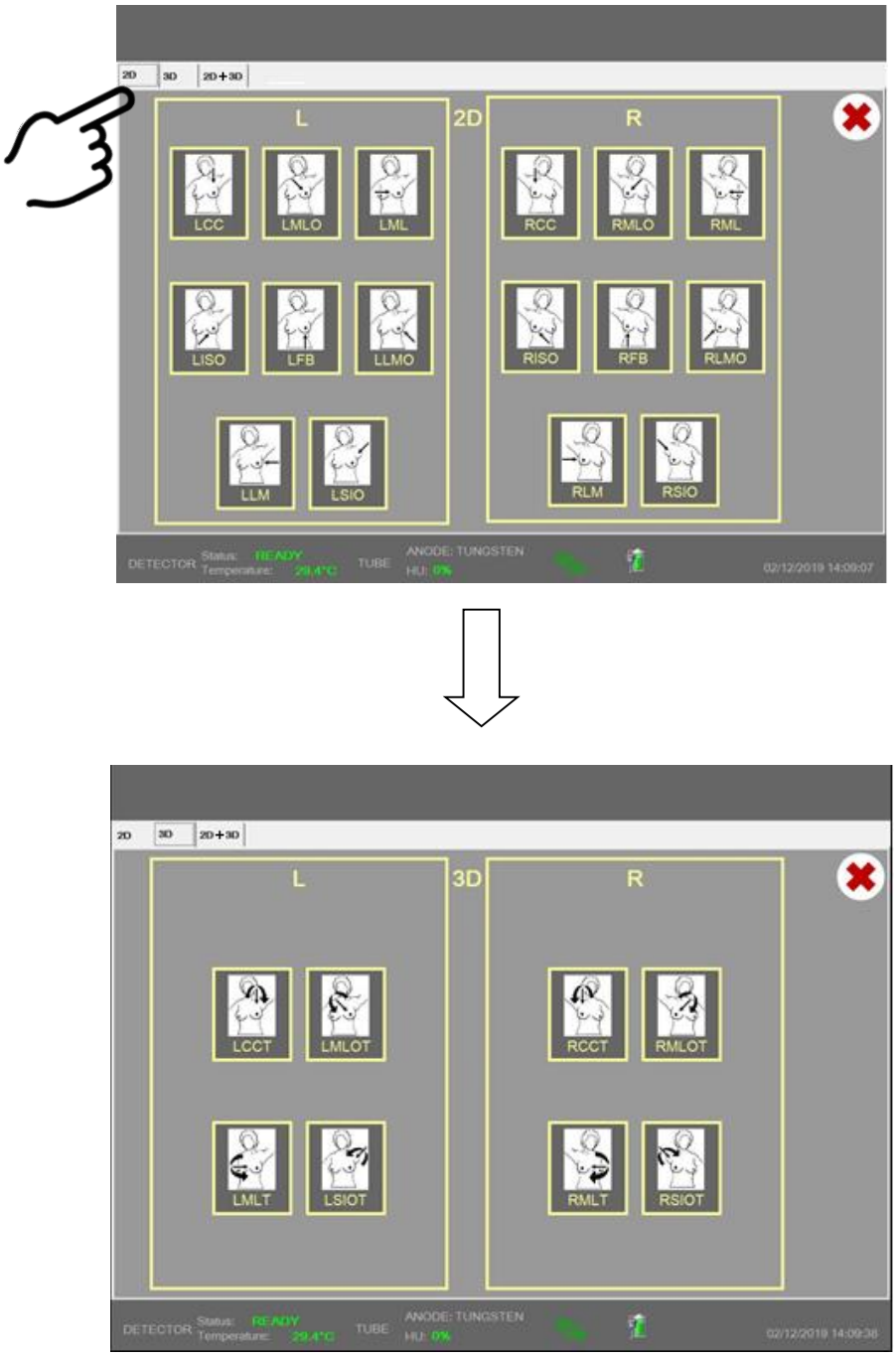


3D and 2D+3D views can be chosen only if TOMO option is activated on device in order to include a 3D views in the study.

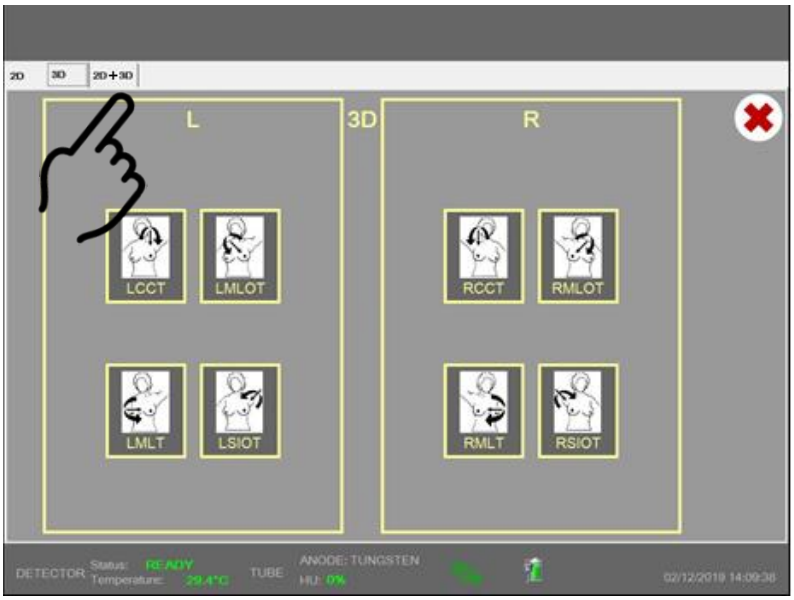


TOMO OPTION

It is possible to make a 3D study instead a 2D or mix views using a dedicated menu accessible clicking on the upper bar shown in the following pictures



To include a mixed view 2D + 3D (Combo or “M-VIEW/VI”) in the study, it is possible to make a new selection using the dedicated menu accessible clicking on the upper bar:


2D
3D
2D+3D
L
3D
R
LCCT
LMLOT
RCCT
RMLOT
LMLT
LSIOT
RMLT
RSIOT
DETECTOR
Status: READY
Temperature: 29.4°C
TUBE
ANODE: TUNGSTEN
HU: 0%
02/12/2019 14:09:38


2D
3D
2D+3D
COMBO
M-VIEW
L
R
LCCB
LMLOB
RCCB
RMLOB
LMLB
LSIOB
RMLB
RSIOB
DETECTOR
Status: READY
Temperature: 29.4°C
TUBE
ANODE: TUNGSTEN
HU: 0%
02/12/2019 14:10:13

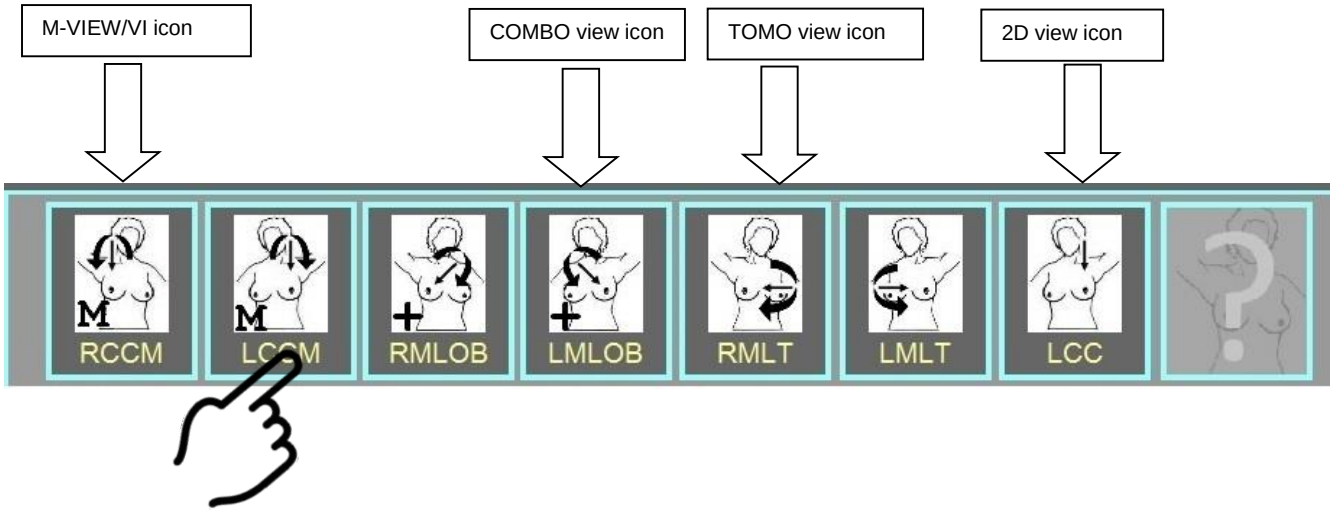
In particular, from the previous menu: the COMBO procedure allows the operator to take a conventional mammography image and TOMO image during a single patient compression.
The available views for this procedure are shown pushing on the COMBO push buttons.

NOTE

During COMBO exam breast remains compressed during switching between 2D TOMO exams. At the end of 2D exposure the breast will be not released by device, it remains compressed until the end of COMBO exam.

The “M-VIEW/VI” push button is a function predisposed to obtain synthetic 2D images automatically reconstructed from TOMO acquisitions with a single exposure. In order to select synthetic view, click on “M-VIEW/VI” button (provided as optional). This process of selection of views (2D, Tomo or Combo or M-VIEW/VI) can be repeated up to complete all 8 possible windows marked with the question mark. The “M-VIEW/VI” function is available only if TOMO function is active.
Until the view results as not selected and the C-Arm not rotated in the corresponding position, the indication “NOT READY” still remain visible in the area n°13 of the AWS DSP (see the corresponding paragraph “TOUCH SCREEN COLOUR DISPLAY (AWS TSD)”).
Always in this phase and until the X-ray exposure does not start, it is always possible to abort the study clicking on the push button “ABORT” which is visible in the same area of the AWS

DSP. Finally, pushing on the view icon, the C-arm rotates automatically to corresponding projection angle and the system is ready for the radiographic exposure.



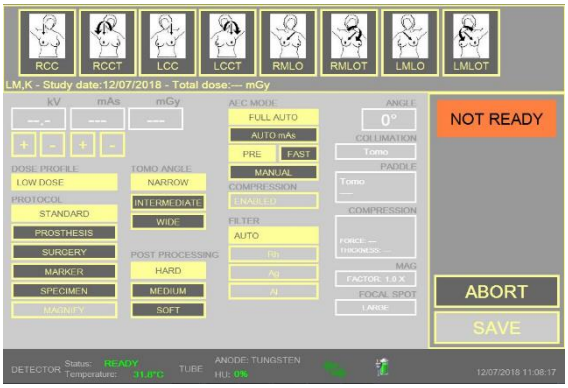
After the projection selection, the icon remains highlighted until the pressure of X-Ray push button or “Cancel” push button as shown in paragraph “STANDARD procedure”.

NOTE

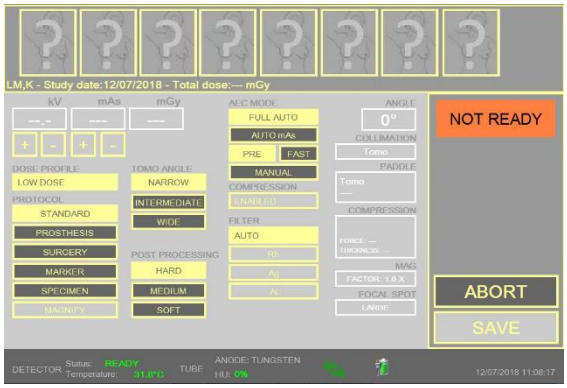
If X-ray pushbutton is released early during the tube movement of TOMO acquisition in COMBO mode, an error happens (See paragraph 7.2: “Error messages”).

NOTE

If license key for image reconstruction is not detected, TOMO projection are not enable to be acquired. If license key is detected, after a system restart, TOMO projection will be available again. The license key for TOMO reconstruction is provided by Metaltronica S.p.A. on request, otherwise it cannot be used.



Tomo study with license key



Tomo study without license key

NOTE

TOMO exam cannot be performed without compression enabled.
If try to operate a TOMO or COMBO exam without compression enabled appear a specific error message. Please refer to the paragraph 7.2: “Error messages”

6.5. *EXAM PROTOCOLS*

According to type of selected study (e.g. Standard, user) it is possible change acquisition settings according to the clinical procedure. There are 6 standard acquisition setting protocols already defined, as shown on grid n°5 of the AWS DSP:

Each protocol guarantees a defined acquisition settings in relationship clinical procedure requested, as shown in Table 5:

Table 5

PROTOCOL	SETTINGS	AUXILIARY COMPONENTS
STANDARD	• **AEC MODE** ◦ Full Auto = (ENABLED | SELECTED)**;** ◦ Pre = (ENABLED | ***SELECTED***); ◦ Fast = (ENABLED | NOT SELECTED); ◦ AutomAs = (ENABLED | NOT SELECTED); ◦ Manual = (ENABLED | NOT SELECTED) • **FILTER** ◦ AUTO = ***SELECTED*** ◦ FIX = NOT SELECTED ▪ FIX RH = DISABLED ▪ FIX AG = DISABLED ▪ FIX AL = DISABLED • **DOSE PROFILE** = ENABLED ◦ LOW DOSE = ***SELECTED*** • **COMPRESSION BUTTON** = DISABLED • **COMPRESSION** = ENABLED • **PARAMETERS** = DISABLED ◦ KV (+|-) = DISABLED ◦ mAs (+|-) = DISABLED • **POST PROCESSING** = HARD	24x30cm Potter bucky with anti-scatter grid

	• **TOMO PROJECTION** = ENABLED • **COMBO PROJECTION** = ENABLED • **"M-VIEW/VI" PROJECTIONS** = NOT ACTIVE • **2D POST PROCESSING** = STANDARD	
MAGNIFY	• **AEC MODE** ◦ Full Auto = (ENABLED | SELECTED); ◦ Pre = (ENABLED | ***SELECTED***); ◦ Fast = (ENABLED | NOT SELECTED); ◦ AutomAs = (ENABLED | NOT SELECTED); ◦ Manual = (ENABLED | NOT SELECTED) • **FILTER** ◦ AUTO = ***SELECTED*** ◦ FIX = NOT SELECTED ▪ FIX RH = DISABLED ▪ FIX AG = DISABLED ▪ FIX AL = DISABLED • **DOSE PROFILE** = ENABLED ◦ LOW DOSE = ***SELECTED*** • **COMPRESSION BUTTON =** DISABLED • **COMPRESSION** = ENABLED • **PARAMETERS** = DISABLED ◦ KV (+|-) = DISABLED ◦ mAs (+|-) = DISABLED • **POST PROCESSING** = HARD • **TOMO PROJECTION** = DISABLED • **COMBO PROJECTION** = DISABLED • **"M-VIEW/VI" PROJECTIONS** = NOT ACTIVE • **2D POST PROCESSING** = MAGNIFY	Device for geometric magnification with variable (1.5x; 1.8x; 2.0x) factor
PROSTHESIS	• **AEC MODE** ◦ Full Auto = (ENABLED | SELECTED); ◦ Pre = (ENABLED | NOT SELECTED); ◦ Fast = (ENABLED | ***SELECTED***); ◦ AutomAs = (ENABLED | NOT SELECTED); ◦ Manual = (ENABLED | NOT SELECTED); • **FILTER** ◦ AUTO = ***SELECTED*** ◦ FIX = NOT SELECTED ▪ FIX RH = DISABLED ▪ FIX AG = DISABLED ▪ FIX AL = DISABLED	24x30cm Potter bucky with anti-scatter grid

	• **DOSE PROFILE** = ENABLED ◦ LOW DOSE **= *SELECTED*** • **COMPRESSION BUTTON** = DISABLED • **COMPRESSION** = ENABLED • **PARAMETERS** = DISABLED ◦ KV (+|-) = DISABLED ◦ mAs (+|-) = DISABLED • **POST PROCESSING** = HARD • **TOMO PROJECTION** = ENABLED • **COMBO PROJECTION** = ENABLED • **"M-VIEW/VI" PROJECTIONS** = NOT ACTIVE • **2D POST PROCESSING** = PROSTHESYS	
SPECIMEN	• **AEC MODE** ◦ Full Auto = (DISABLED | NOT SELECTED); ◦ Pre = (DISABLED | NOT SELECTED); ◦ Fast = (DISABLED | NOT SELECTED); ◦ AutomAs = (ENABLED | NOT SELECTED); ◦ Manual = (ENABLED | ***SELECTED***); • **FILTER** ◦ AUTO = ***SELECTED*** ◦ FIX = NOT SELECTED ▪ FIX RH = DISABLED ▪ FIX AG = DISABLED ▪ FIX AL = DISABLED • **DOSE PROFILE** = ENABLED ◦ **LOW DOSE** = ***SELECTED*** • **COMPRESSION BUTTON** = ENABLED • **COMPRESSION** = DISABLED • **PARAMETERS** = ENABLED ◦ KV (+|-) = ENABLED ◦ mAs (+|-) = ENABLED • **POST PROCESSING** = HARD • **TOMO PROJECTION** = ENABLED • **COMBO PROJECTION** = ENABLED • **"M-VIEW/VI" PROJECTIONS** = NOT ACTIVE • **2D POST PROCESSING** = SPECIMEN	Device for geometric magnification with variable (1.5x; 1.8x; 2.0x) factor
SURGERY	• **AEC MODE** ◦ Full Auto = (ENABLED | NOT SELECTED); ◦ Pre = (ENABLED | SELECTED);	Device for geometric magnification with variable (1.5x; 1.8x; 2.0x) factor

	◦ Fast = (ENABLED | NOT SELECTED); ◦ AutomAs = (ENABLED | NOT SELECTED); ◦ Manual = (ENABLED | ***SELECTED***); • **FILTER** ◦ AUTO = ***SELECTED*** ◦ FIX = NOT SELECTED ▪ FIX RH = DISABLED ▪ FIX AG = DISABLED ▪ FIX AL = DISABLED • **DOSE PROFILE** = ENABLED ◦ **LOW DOSE = *SELECTED*** • **COMPRESSION BUTTON** = ENABLED • **COMPRESSION** = DISABLED • **PARAMETERS** = ENABLED ◦ KV (+|-) = ENABLED ◦ mAs (+|-) = ENABLED • **POST PROCESSING** = HARD • **TOMO PROJECTION** = ENABLED • **COMBO PROJECTION** = ENABLED • **"M-VIEW/VI" PROJECTIONS** = NOT ACTIVE • **2D POST PROCESSING** = SURGERY	
MARKER	• **AEC MODE** ◦ Full Auto = (ENABLED | ***SELECTED***); ◦ Pre = (ENABLED | SELECTED); ◦ Fast = (ENABLED | NOT SELECTED); ◦ AutomAs = (ENABLED | NOT SELECTED); ◦ Manual = (ENABLED | NOT SELECTED) • **FILTER** ◦ AUTO = ***SELECTED*** ◦ FIX = NOT SELECTED ▪ FIX RH = DISABLED ▪ FIX AG = DISABLED ▪ FIX AL = DISABLED • **DOSE PROFILE** = ENABLED ◦ **LOW DOSE** = ***SELECTED*** • **COMPRESSION BUTTON** = DISABLED • **COMPRESSION** = ENABLED • **PARAMETERS** = DISABLED ◦ KV (+|-) = DISABLED ◦ mAs (+|-) = DISABLED • **POST PROCESSING** = HARD	24x30cm Potter bucky with anti-scatter grid

	• **TOMO PROJECTION** = ENABLED • **COMBO PROJECTION** = ENABLED • **"M-VIEW/VI" PROJECTIONS** = NOT ACTIVE • **2D POST PROCESSING** = MARKER	

6.6. *RADIOGRAPHIC EXPOSURE*

Only with an open study (from the Worklist or locally, as explained in the previous paragraph 6.3), it is possible to expose the patient to the X-rays to acquire the diagnostic image.
The operator must position the patient and then set exposure parameters (operating mode, kV and mAs) from the AWS DSP.

At the end of the preparation, the pushbutton “NOT READY” disappears from the area n°13 of the AWS DSP.

and it will be possible to proceed with the X-Ray exposure by means X-rays pushbuttons or foot-control on Acquisition Work Station.
In the first case, the operator must press down the pushbuttons at the same time up to the end of acoustic signal.

NOTE

With the “READY” message (area n°13 of the AWS DSP), will be displayed also the “CANCEL” push button. It allows to modify the selected view and to choose another one before going on with the X-Ray exposure.

In case of image acquisition in magnification technique (for this typical configuration refer to Section IX " Typical Configurations”), the operator has to follow this procedure:

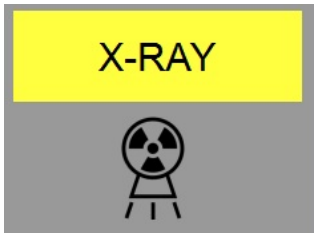
1. Move the C-arm until the desired position using the C-Arm multi-switches placed of both sides of the mammo unit;
2. Remove the protective screen;
3. Remove the compression paddle and insert the Φ 7,5 cm format compression paddle for magnification necessary for this configuration;
4. Remove the Potter-Bucky and insert the geometric magnification device;
5. Position the patient;

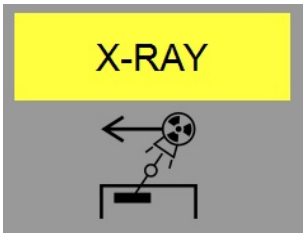
6. Select from AWS DSP, the corresponding ACR view and the exposure parameters;
7. When the READY push button is displayed, proceed the X-Ray exposure by means X-rays pushbuttons or foot-control.

NOTE

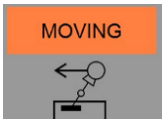
In case of ACR view selection before the insertion of all the component necessary for this configuration with magnification device, click on “CANCEL” push button, select again the ACR view and finally proceed with the X-ray exposure.

The exposure is announced by a long sound signal and by corresponding yellow icon on the AWS DSP (respectively, the first one in case of 2D exposure and the second one in case of TOMO exposure).





NOTE

ONLY in case of TOMO exposure and with the X-ray pushbutton just pressed, the icon 

is shown on the AWS DSP before the X-ray icon, to indicate that the Tube-Arm is moving to the HOME position by which the TOMO sequence will start.

NOTE

In case of X-ray pushbutton early released, the Tube-Arm movement immediately stops and an error message is displayed on the AWS DSP; for its troubleshooting, refer to the paragraph 7.2: “Error messages”.

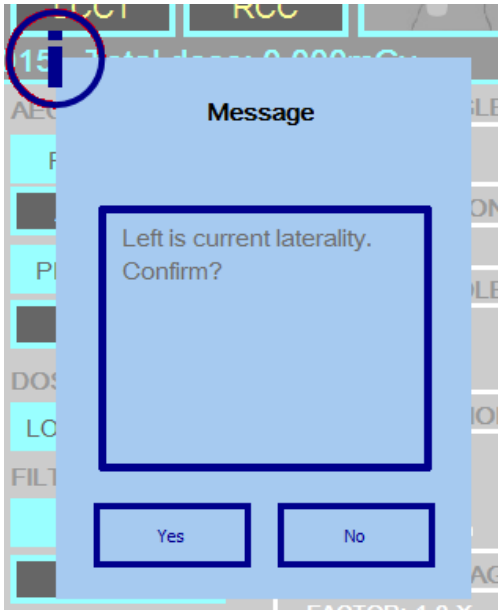
During TOMO acquisition, in order to reduce breast compression time, the tube starts running automatically after the projection selection. The tube will be ready for a TOMO scan at X-ray pushbutton pressure.

After few seconds and only in case of acquisition of one of the following views:

- 2D views (all);

- CC view (Tomo);
- CC view (Combo)

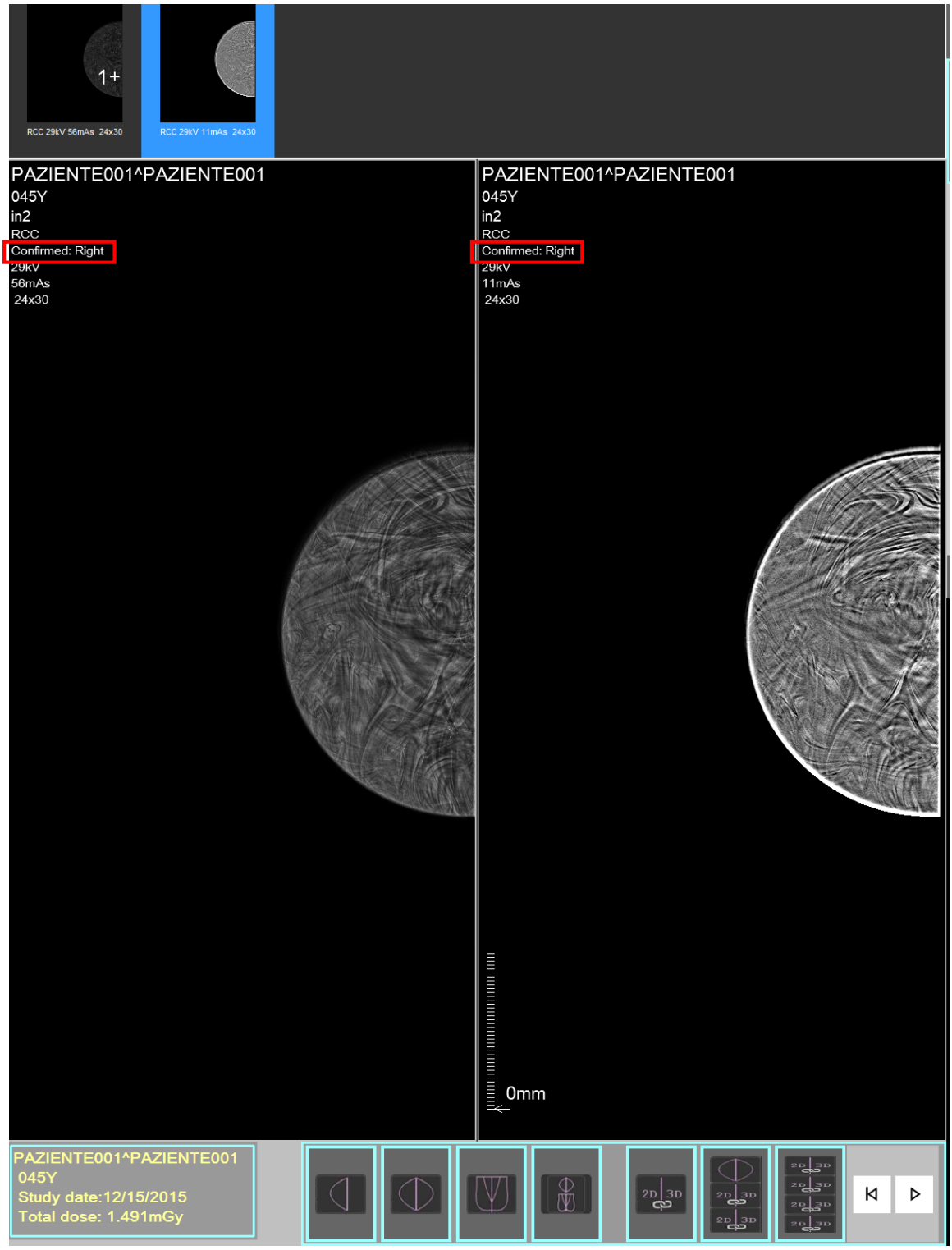
the following message will be shown:



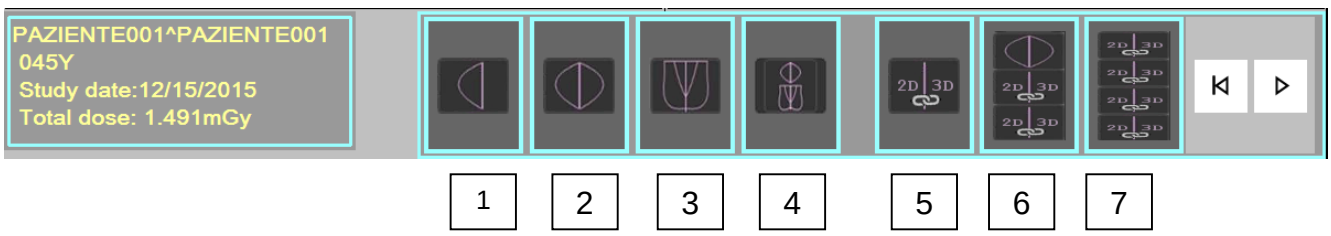
Clicking on “Yes”, the laterality, chosen before the exposure, will be maintained.

Whereas, clicking on “No”, the SW will rotate the image automatically adapting it to the new one.

The tag relative to the confirmed laterality, will be shown on the corresponding acquired image as below on the AWS HRD:

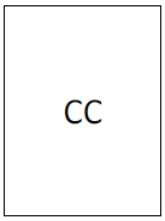
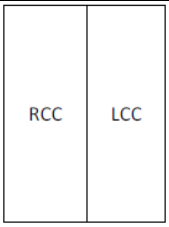
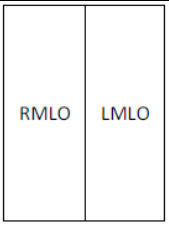
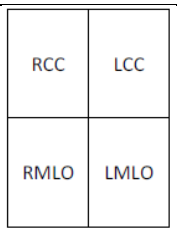
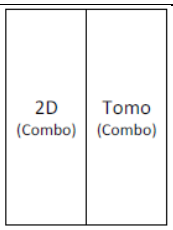


On the lower bar of AWS HRD:



It indicates:

- on the left side, data of study as Patient Name (or accession number), date and Total Dose;
- in the middle, the visualization layout of acquired images. For a detailed description, refer to the following table;
- on the right side, two arrows which appear only in case of selection of a TOMO image.

LAYOUT	ACR code	NOTE
1		Single view in which the first CC 2D (between all the available acquired) will be automatically included. If CC views are not available, the graphic window will be still empty. However, the operator can choose and display inside them every other 2D or Tomo image by means of its thumbnail drag&drop.
2		Double view in which the first RCC 2D and LCC 2D (between all the available acquired) will be automatically and respectively included. If those views are not available, the graphic window will be still empty. However, the operator can choose and display inside them every other 2D or Tomo image by means of its thumbnail drag&drop.
3		Double view in which the first RMLO 2D and LMLO 2D (between all the available acquired) will be automatically and respectively included. If those views are not available, the graphic window will be still empty. However, the operator can choose and display inside them every other 2D or Tomo image by means of its thumbnail drag&drop.
4		Multiple view in which the first RCC, LCC, RMLO and LMLO 2D (between all the available acquired) will be automatically and respectively included. If those views are not available, the graphic window will be still empty. However, the operator can choose and display inside them every other 2D or Tomo image by means of its thumbnail drag&drop.
5		Double view in which the 2D and the related Tomo images of the first COMBO acquired will be automatically and respectively included. If those views are not available, the graphic window will be still empty. However, the operator can choose and display inside them every other 2D or Tomo image by means of its thumbnail drag&drop.

6	RCC 2D / LCC 2D RMLO 2D (Combo) / RMLO Tomo (Combo) LMLO 2D (Combo) / LMLO Tomo (Combo)	Multiple view in which the images defined here on the left will be automatically included. If those views are not available, the graphic window will be still empty. However, the operator can choose and display inside them every other 2D or Tomo image by means of its thumbnail drag&drop.
7	RCC 2D (Combo) / RCC Tomo (Combo) LCC 2D (Combo) / LCC Tomo (Combo) RMLO 2D (Combo) / RMLO Tomo (Combo) LMLO 2D (Combo) / LMLO Tomo (Combo)	Multiple view in which the images defined here on the left will be automatically included. If those views are not available, the graphic window will be still empty. However, the operator can choose and display inside them every other 2D or Tomo image by means of its thumbnail drag&drop.

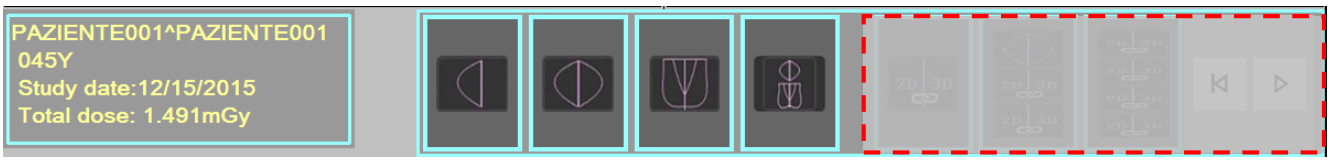
Clicking on one of those icons of lower bar, the operator can choose the preferred visualization layout of acquired images.

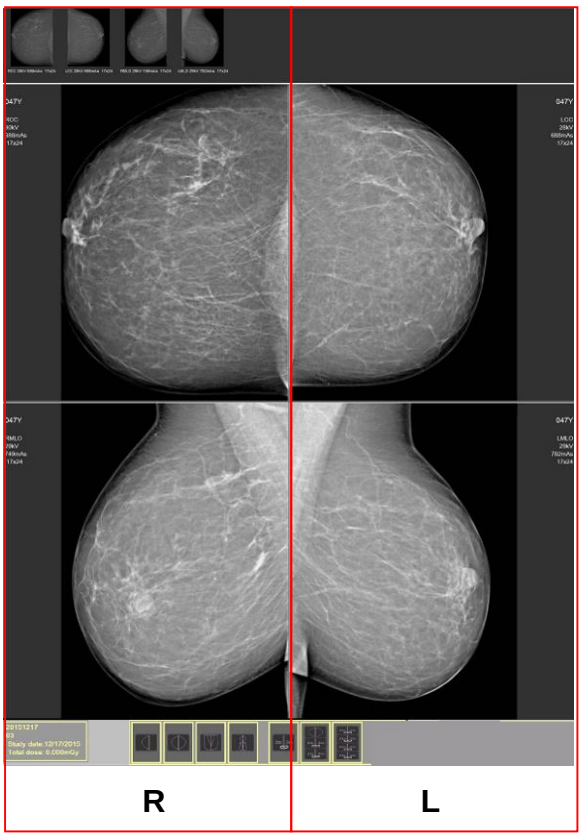
At this point, if the quality of image is good, the operator can proceed with the next exposure positioning newly the patient and setting the parameters, otherwise will be necessary repeat the exposure trying to obtain a better quality.

The new image is displayed on the main part of screen, meantime the overall dose of the study is updated in real time on the AWS HRD and on the AWS DSP.

Thumbnails of acquired images are displayed on upper bar in exposure order.

NOTE TOMO visualization protocols are disabled in 2D study.





The orientation of the image depends on the laterality: if the laterality set in the ACR code is “R” (refer to the following paragraph 4.2), the image is shown with the nipple on the left side; if the laterality is “L”, corresponding to the left breast, the image is shown with the nipple on the right.

Repeat the steps “Position the patient – set the exposure parameters – expose – evaluate the quality”, till the end of the views needed.

NOTE

For any study the operator can acquire a maximum of eight images.

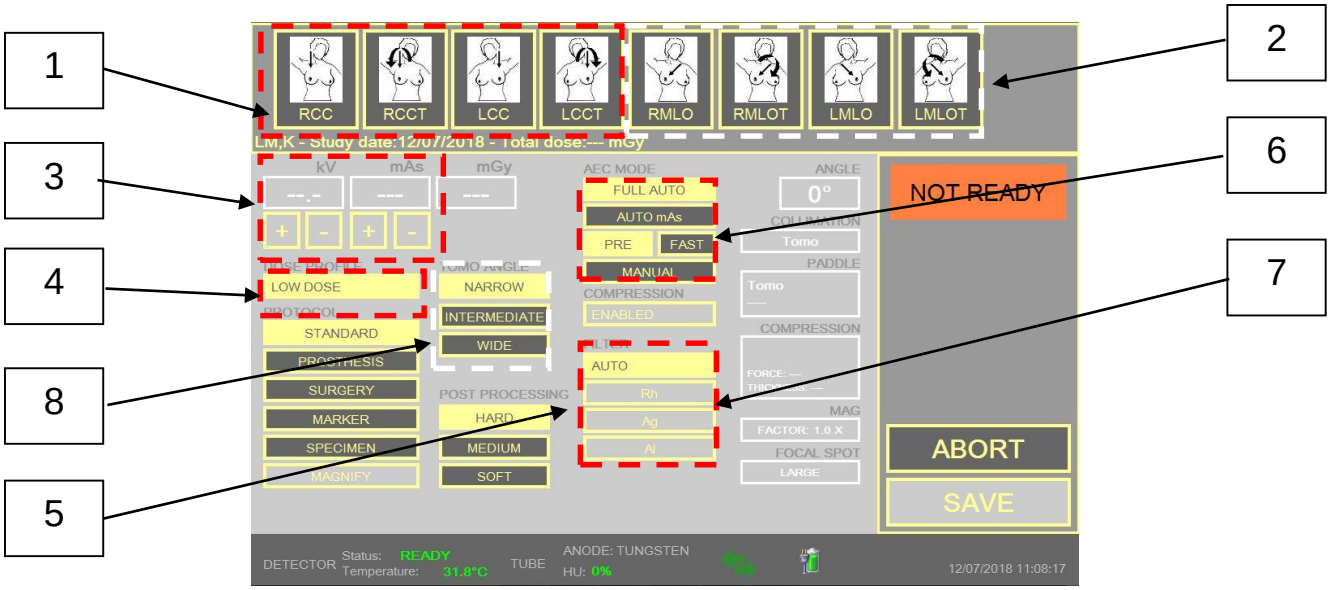
To review a previous exposure is enough select the image clicking on his thumbnail.

6.7. *SETTING EXPOSURE PARAMETERS*

The exposure parameters (operating mode, kV and mAs, and anode/filter combination) can be set on the main GUI.

NOTE

The following screenshot is only indicative, It depends by device configuration chosen.



1. Standard projections
2. TOMO projections (if available)
3. KV/mAs values
4. Dose profile
5. TOMO angle (if available)
6. AEC operating technique
7. Filter selection
8. Post-processing

Choose the preferred dose profile (Low dose or High contrast), the AEC operating technique (full auto mode, auto mAs mode or manual mode) and, in case the kV/mAs values, the filter selection modality. To make this operation refer to the previous paragraph 5.1

The “AUTO” button in filter section is independent and shows alternately “AUTO” and “FIX”. When “FIX” is selected, filter radio buttons are enable and selectable. In “AUTO” mode filter

radio buttons are disable and not selectable, but the filter icon remains highlighted during the X-ray sequence.

Both “Dose profile” modalities allow to obtain dose values less then established by European Guidelines; the “High contrast” modality is preferable to view micro-calcifications, the “Low dose” modality in preferable in screening or diagnostic routine exams in order to reduce X-ray emission to the patient.

NOTE

The button “Low dose/High contrast” is ever active, but is preferable that all projections are performed with the same operating modality to obtain the maximum omogeneity of images.

6.8. *SETTING ACR VIEW*

The ACR code is a standard code created by the American College of Radiology (ACR) to identify the view, the operating technique and other information of the mammographic image.

Any code is composed by three parts: the prefix, the name of the view, and the suffix.

The complete list of codes is:

Table 6

ACR CODE					
PREFIX		**VIEW**		**SUFFIX**	
CODE	**MEANING**	**CODE**	**MEANING**	**CODE**	**MEANING**
R	Right	CC	CranioCaudal	ID	Implant Displaced
L	Left	ML	MedioLateral	S	Spot
M	Magnification	MLO	MedioLateral Oblique	RM	Roll Lateral
		LM	LateroMedial	RL	Roll Medial
		LMO	Lateromedial Oblique	TAN	Tangential
		FB	From Below		
		SIO	Superlateral to Inferomedial Oblique		
		XCC	Exaggerated CranioCaudal		
		CV	Cleavage		
		AT	Axillary tail		

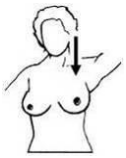
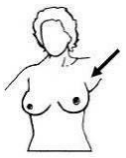
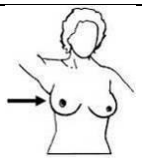
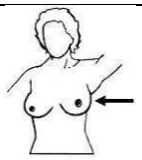
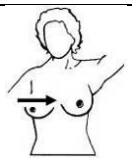
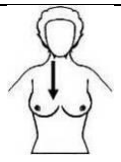
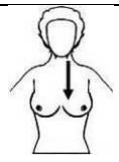
A complete ACR code that identifies an image contains at least the laterality (“R” or “L”) and the view, while the other information are not mandatory. For example, to identify a MedioLateral Oblique projection on the right breast, without other information, the complete ACR code is:

RMLO

Some codes exclude each other, for example, the prefixes of the laterality “R” and “L” cannot be present both in the same string. There are also codes that do not exclude any other code; for example the code for magnification “M” can be present or not in any view. Each code of the view exclude all the others, for example if a view is “LM”, it can’t be also “CC”, “ML”, “MLO”, “LMO” etc.

The name of the projections can be identified by the following table:

Table 7

R CC	Righ breast; Craniocaudal		L CC	Left breast Craniocaudal	
R XCC	Righ breast; Exaggerated Craniocaudal		L XCC	Left breast; Exaggerated Craniocaudal	
R SIO	Righ breast; Superolateral to Inferomedial Oblique		L SIO	Left breast; Superolateral to Inferomedial Oblique	
R LM	Right breast; Lateromedial		L LM	Left breast; Lateromedial	
R LMO	Right breast; Lateromedial Oblique		L LMO	Left breast; Lateromedial Oblique	
R FB	Right breast; From Below		L FB	Left breast; From Below	
R ML	Right breast; Mediolateral		L ML	Left breast; Mediolateral	
R MLO	Right breast; Mediolateral Oblique		L MLO	Left breast; Mediolateral Oblique	
R AT	Right breast; Axillary Tail		L AT	Left breast; Axillary Tail	
R CV	Right breast; Cleavage		L CV	Left breast; Cleavage	

NOTE

The arrow represents the X-ray beam direction (from the tube to the detector).

NOTE

The previous table is only a reference for the radiologist. For the correct positioning and compression of the patient refer to the ACR protocol or other official sources of information.

According to the DICOM standard, a mammographic image must have a header containing many information, including the ACR code. The HELIANTHUS series is able to set some codes automatically, but other codes must be selected by the operator. For example, the insertion of the magnification device automatically sets the code “M” in the prefix (Magnification); and the inclination of the C-arm automatically sets the name of the view (but some of them depend also on the laterality, and others are not unique and can be changed).

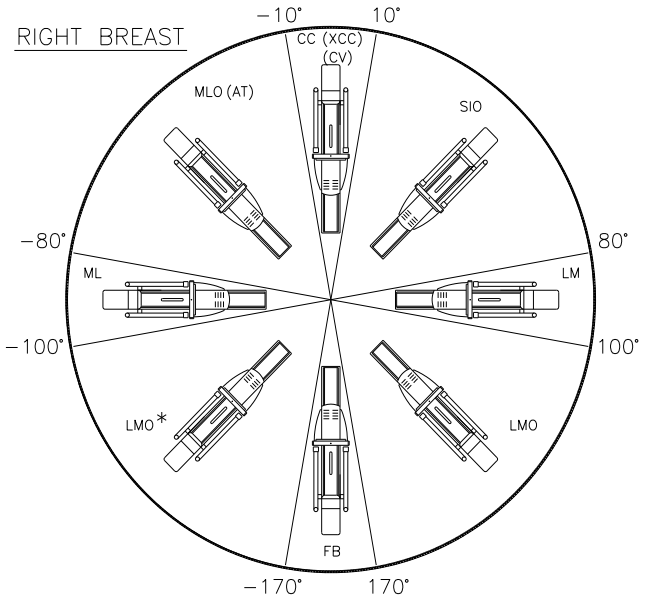
In the following list it is evidenced which codes are automatically selected and which not.

Table 8

	CODE	AUTOMATIC SELECTION	NOTES
PREFIX	L	No	
	R	No	
	M	Yes, when the magnification device is inserted	
VIEW	CC	Yes, depending on inclination of C-arm	
	ML	Yes, depending on laterality and inclination of C-arm	
	MLO	Yes, depending on laterality and inclination of C-arm	
	LM	Yes, depending on laterality and inclination of C-arm	
	LMO	Yes, depending on laterality and inclination of C-arm	
	FB	Yes, depending on inclination of C-arm	
	SIO	Yes, depending on laterality and inclination of C-arm	
	XCC	No	Manually set alternatively to CC
	CV	No	Manually set alternatively to CC
	AT	No	Manually set alternatively to MLO
SUFFIX	ID	No	
	S	Yes, when the magnification device is inserted	
	RM	No	
	RL	No	
	TAN	No	

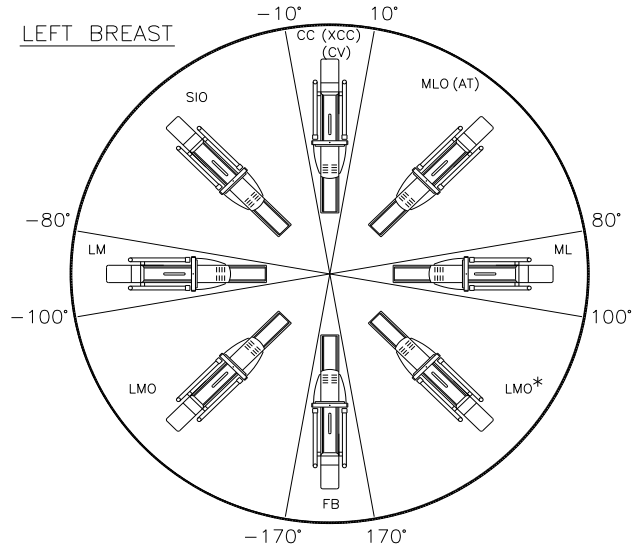
The following circles show the sectors of C-arm rotation in which any ACR Code is selectable:

IF THE LATERALITY IS “R” (RIGHT BREAST)



*: For the right breast the inclination of the C-arm between -100° and -170° should not be used, because it does not correspond to any clinical view according to the ACR protocol. However the LMO code is selected.

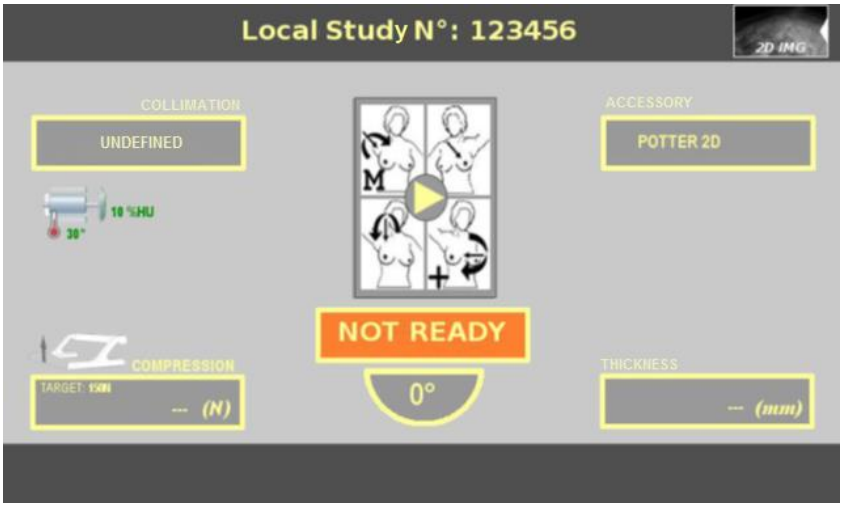
IF THE LATERALITY IS “L” (LEFT BREAST)



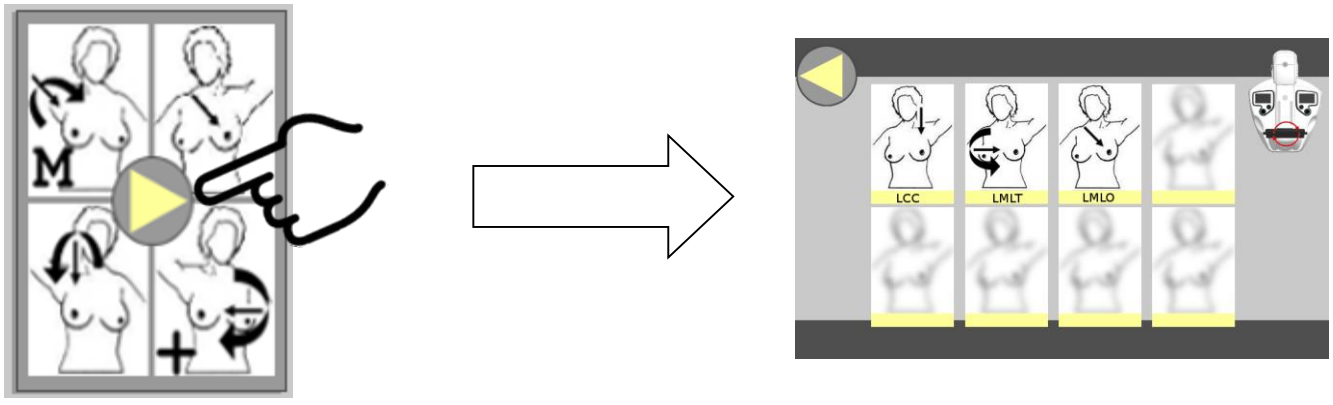
*: For the left breast the inclination of the C-arm between 100° and 170° should not be used, because it does not correspond to any clinical view according to the ACR protocol. However, the LMO code is selected.

After positioning the patient, the C-arm inclination and the related default ACR code are shown both on MAMMO TSD the AWS DSP.

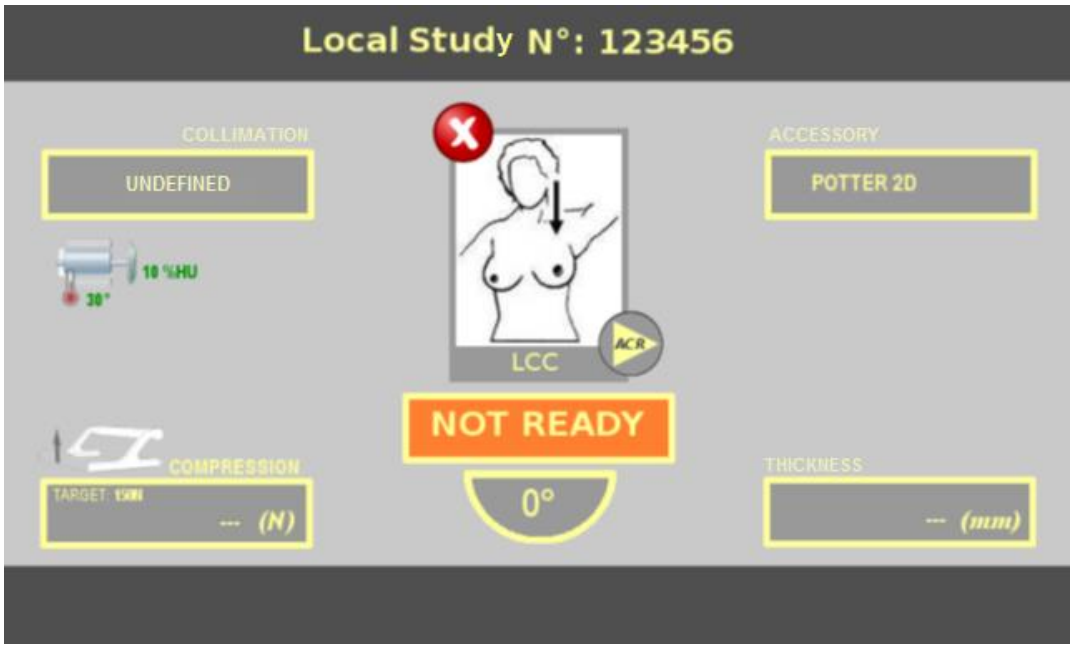
The view and the laterality are automatically selected by Acquisition Work Station, but the operator can change view from MAMMO TSD as show in “TOUCH SCREEN COLOR DISPLAY” paragraph. In case of opened study MAMMO TSD display will show the following:



To set a further ACR code, push on the triangle in the middle of the MAMMO TSD and select it from the list that appears.



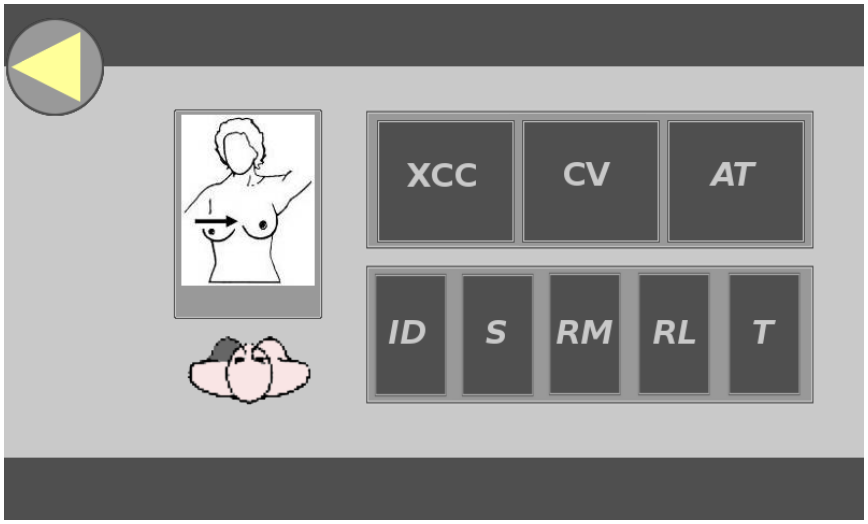
MAMMO TSD allows to select an ACR view available from AWS. A Selection of one view available requires operator agreement because will entail C-arm rotation. After view selection, a specific panel appears, as shown in following figure:



Operator can abort view selected clicking on

Otherwise, operator can change PREFIX / SUFFIX of ACR code clicking on

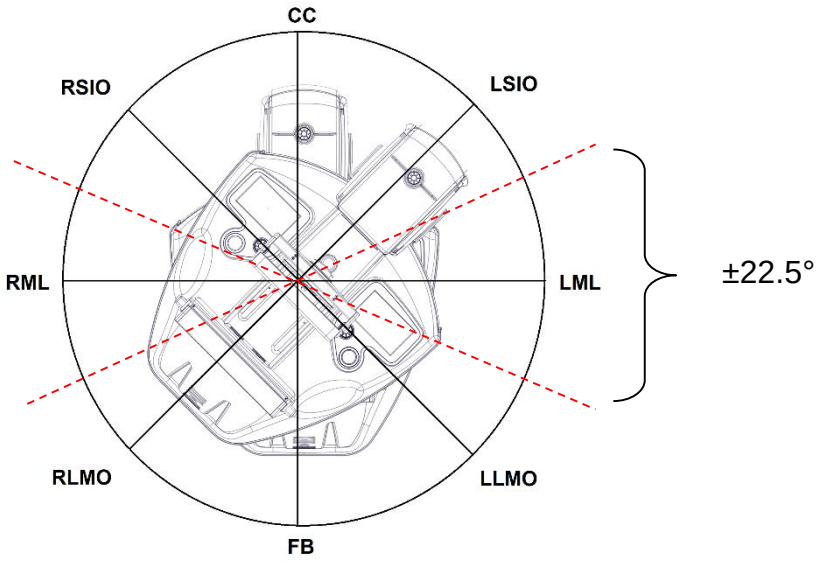
The following window will be opened by the system and the operator con choose the right prefix/suffix for view according to ACR code.



For 2D images, after a projection selection, it is possible to set manually the C-arm angle within a specific range of ±22.5° respect to the current projection angle and set it as new default emission angle. Once the image has been acquired, the following message will appear:

NOTE

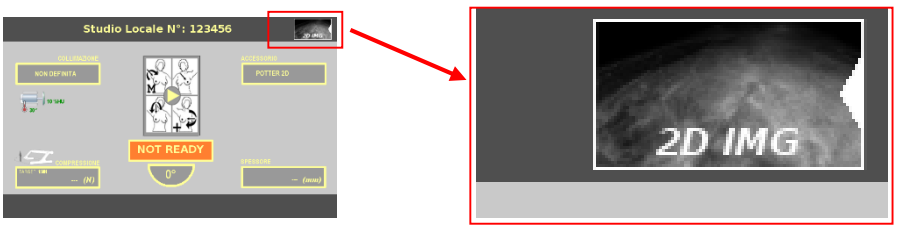
The angle change is permanent until the next variation or default angle restoring.



If the operator rotates the C-arm out of specified range, the image will not be acquired and an error message appears [M: 00935] (see paragraph 7.2: “Error messages”).

2D IMAGE VISUALIZATION from MAMMO TSD:

Mammograph allows the visualization of acquired image directly by MAMMO TSD, layering the image acquired and clicking on the icon shown below:

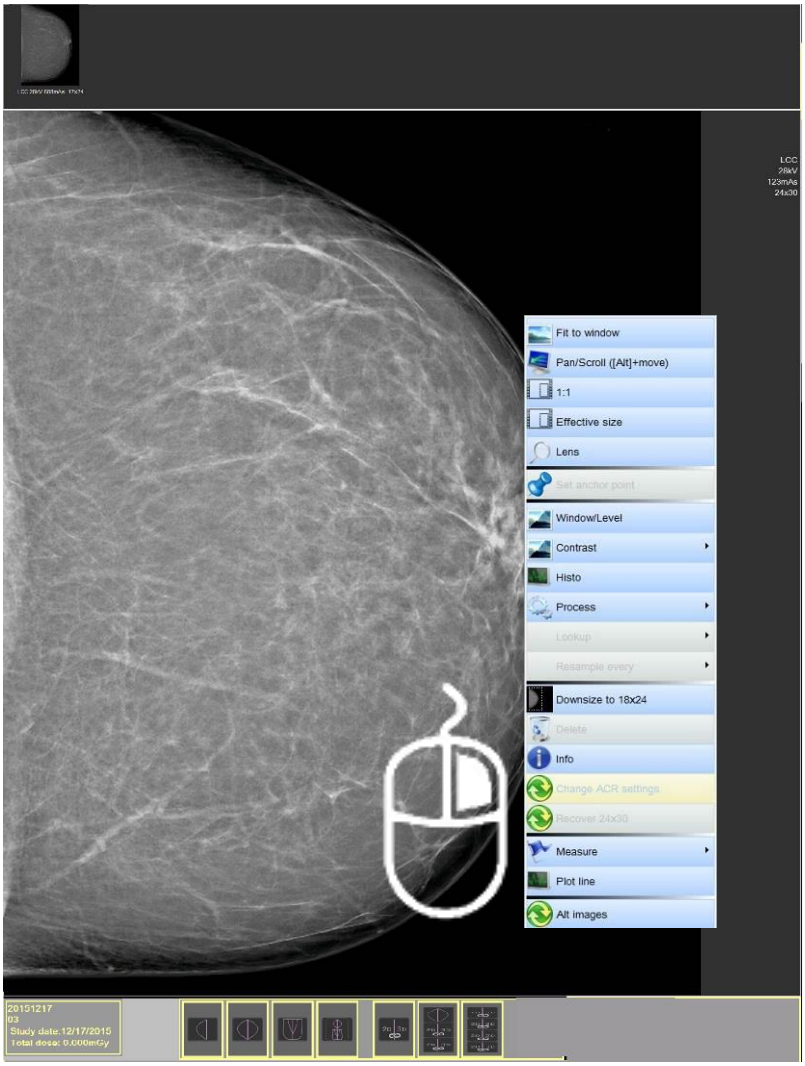


6.9. *IMAGE TOOLS*

When one or several images are displayed, it is possible to manipulate them in terms of visualization as contrast, sharpness, zoom etc. It is also possible to visualize the desired images choosing among the ones of the currently open study, and set up them in the preferred position on the screen.

The modifications are not permanent: it is always possible to return to the initial visualization by means of the “Restore Original” function. The manipulated images are never saved: the copies of the images saved and stored are the same preexisting before the graphic manipulation.

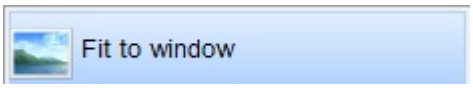
To manipulate the images shown on the AWS HRD, the operator must open a pop-up menu clicking with the mouse right button on the image



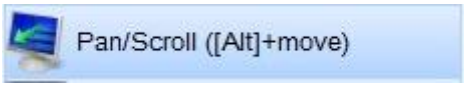
6.9.1. Fit to Window, Pan/Scroll, 1:1, Effective size, Lens

To access these functions right click with the mouse on the desired image. All the functions are active only for the window from which the pop-up menu has been activated.

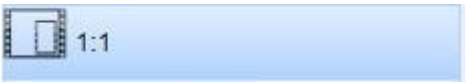
The “Fit to Window” function changes the magnification of the image so that it is adapted to the graphic window in which is contained.



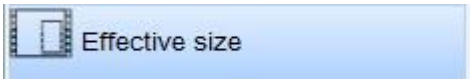
The “Pan/Scroll” function is active only if the image is not fitted to the window. After selecting that tool, move the mouse up and down keeping the left button pressed to scroll (i.e. move the image upward and downward), and right and left to pan (i.e. move the image rightward and leftward). The operator can use this function even during the execution of another function by pushing [Alt] and clicking on image.



The “1:1” function visualizes each pixel of the detector on one pixel of the monitor.



The “Effective size” function makes the image displayed as the same size of breast when exposed.



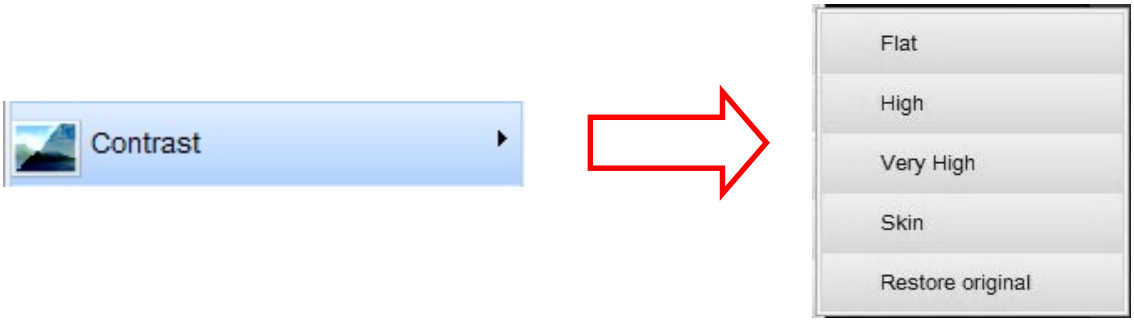
The “Lens” function opens a square window of 300 x 300 dpi where the image is magnified with a ratio of 3x. The window can be positioned on any side of the image according to the mouse position.

6.9.2. Window/Level, Contrast, Histo

To access these functions right click with the mouse on the desired image. All the function are active only for the window from which the pop-up menu has been activated.

The “Window/Level” function allows to modify contrast and brightness of image.
Click on “Window/Level” button and, keeping the left button pressed, move the mouse up and down to increase/decrease contrast, or right and left to increase/decrease brightness.

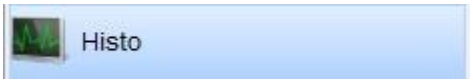
The “Contrast” function allows to modify the contrast of image in a specific side of breast.
Clicking on “Contrast” button, a submenu appears.

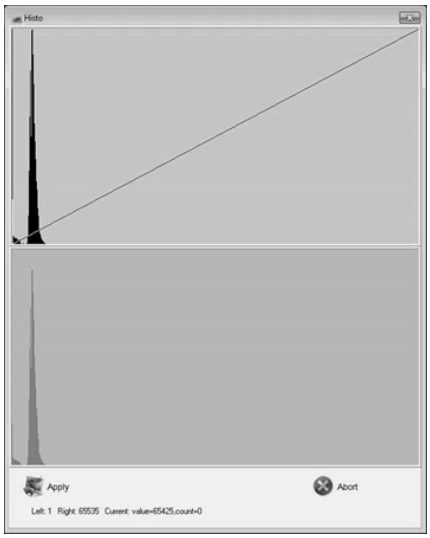


Click on “High” button to set high value of contrast on thorax side; click on “Very High” button to set very high value of contrast on thorax side; click on “Skin” button to set high value of

contrast at skin level; click on “Flat” button to undo all contrast changes; click on “Restore original” button to go back to original image before any manipulation.

The “Histo” function allows to display the histogram of grey level distribution of the whole image and of a selected range of the same.
Click on “Histo” button to open a window with two diagrams.





The upper diagram represents the grey level distribution of the whole image. The lower diagram represents the grey level distribution of selected range in the above diagram.
In order to select the range, click on the left or right edge of the above histogram window to drag the rulers.

Then, click on “Apply” button to save changes or click “Abort” button to exit.

CAUTION

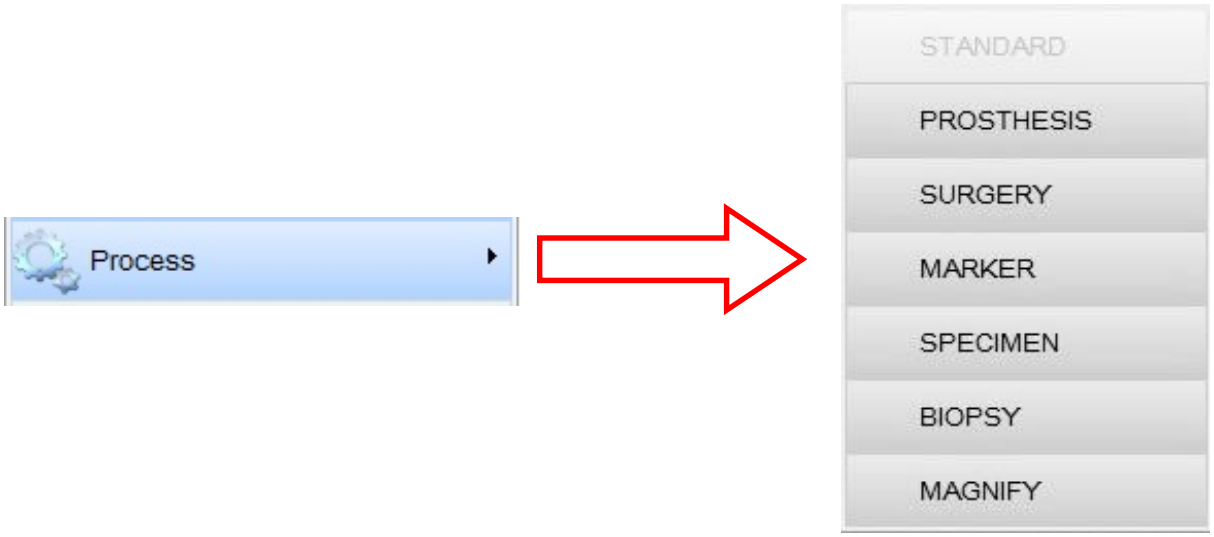
The modifications applied by means of all the functions above described (“Window/Level”, “Contrast” and “Histo”), are permanent and they will change also the images that will be printed.

6.9.3. Process, Lookup, Resample every and Info

To access these functions right click with the mouse on the desired image.

The “Process” function allows to modify some parameters of reconstruction algorithm in order to enhance all structures and reducing noise to show the images on display of Acquisition Work Station with a reading better quality.

Clicking on “Process” button, a submenu appears.



The operator can choose between several optimized algorithms. I.e, for magnification, biopsy, examination of surgical anatomical parts, examination of specimen and in case of metallic clips, surgical makers or numerous clusters of micro calcifications. In case of acquisition in magnification mode with spot compression paddle, it is recommended to select a "STANDARD" option.

CAUTION

For specific request of the reporting physician, at the end of the X-ray exposure and with the image acquired, only the previous button “Process” has to be used to modify the main post processing filter selection. Instead, if you want modify the selection “HARD”, “MEDIUM” or “SOFT”, this option has to be selected using the corresponding push button on the AWS DSP.

The “Lookup” function allows to modify the image contrast.

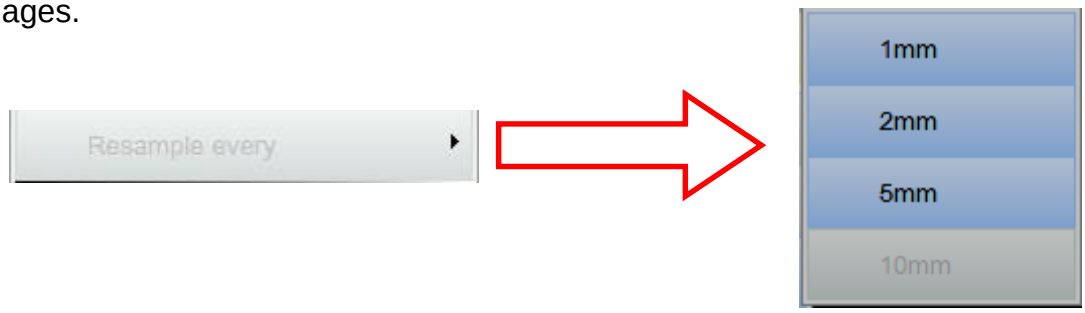
Clicking on “Lookup” button, a submenu appears showing all the available options (“Low Noise”, “High contrast”).

CAUTION

The selected option from this menu, will remain saved and it will be automatically applied also on ALL images acquired by the Mammo Unit.

The “Resample Every” function allows to navigate through Slices within a custom step different to the default one (default value is set to 10 mm). The function is enabled only for TOMO exams.

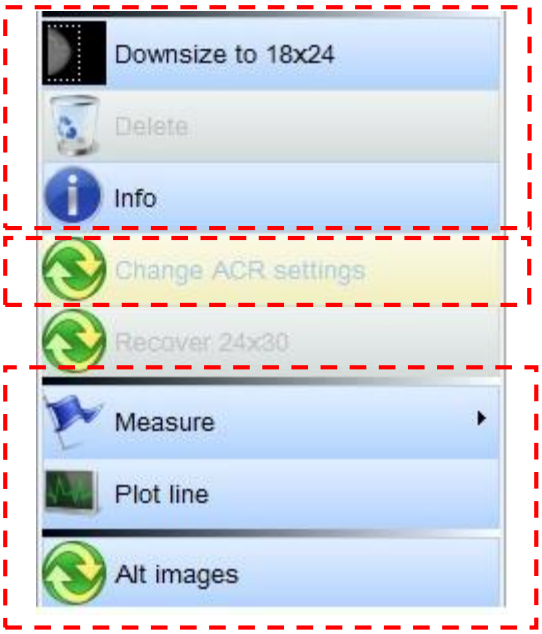
The available values for step are 1 mm, 2 mm, 5 mm, 10 mm. The function is disable for 2D images.



Clicking on “Info” button, a window appears showing all DICOM data and parameters regarding the selected image.

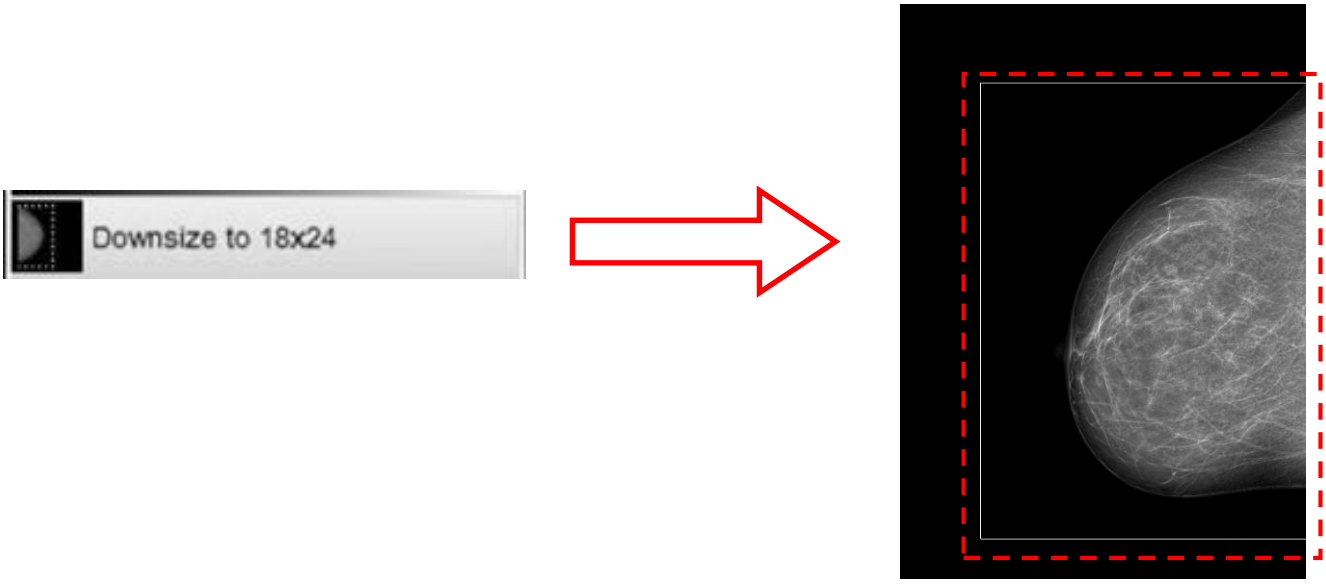
6.9.4. Downsize to 18x24, Delete, Change ACR settings, Measure, Plot Line, Alt Images

To access these functions right click with the mouse on the desired image.



The “Downsize to 18x24” function allows to downsize 24x30 cm acquired image to 18x24 cm format on a specific region selectable by operator.

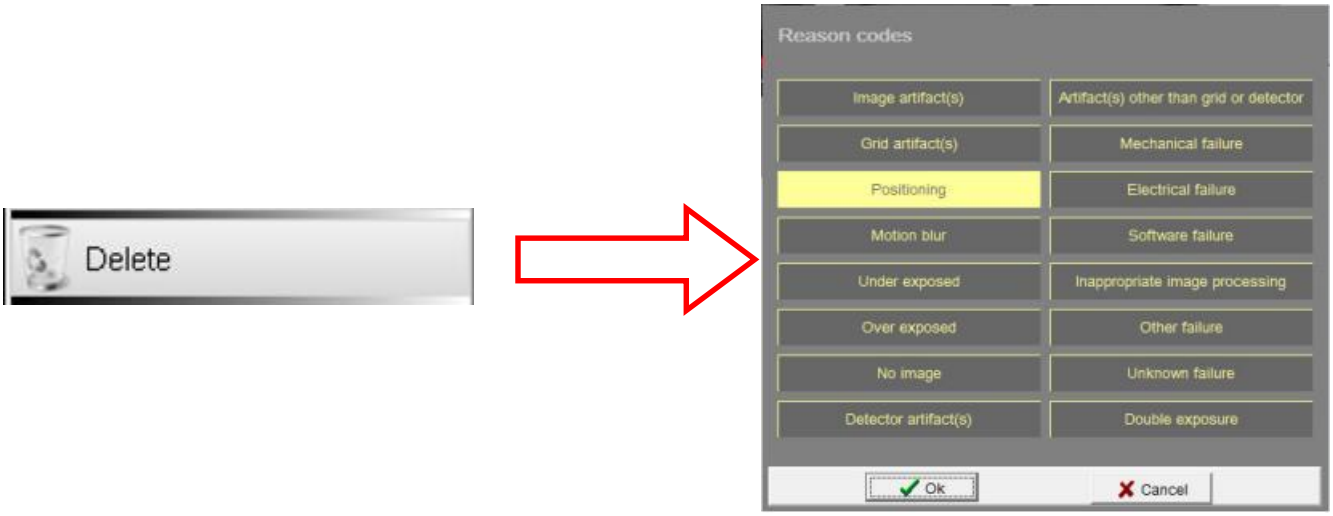
Clicking on “Downsize to 18x24” button a 18x24 cm rectangle appears. The operator must move it with the mouse up to select the region of image that he want crop.



Then clicking newly, a window appears with the message "*Modifications are permanent. Continue?"*.

Confirming the choice, the image is downsized permanently.

The "Delete" function allows to remove the selected image from the study transfer it in a local storage.Clicking on "Delete" button a window with 16 reason codes appears.

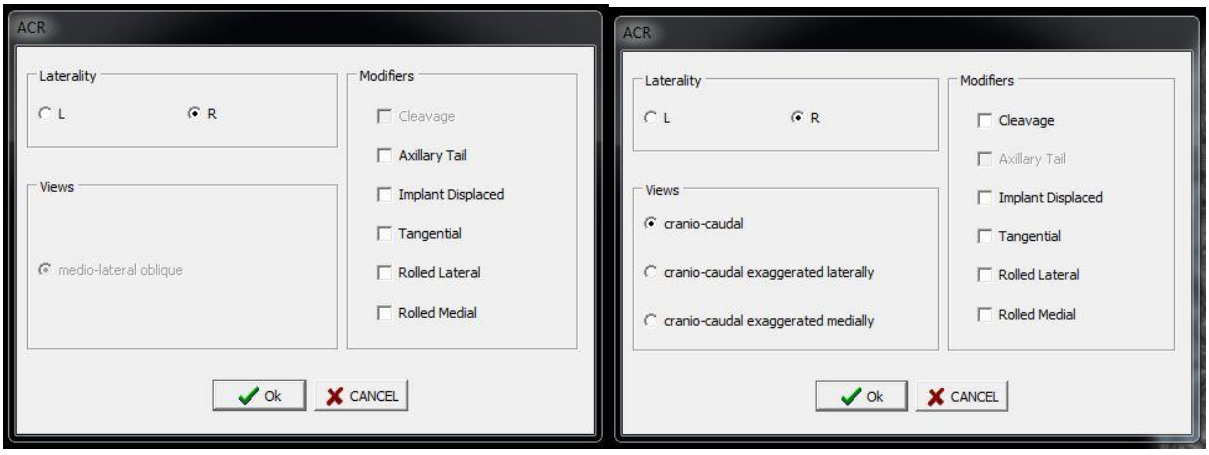


The operator must select the reason of deletion and clicking on "OK" the image will be erased from the study.

The "Change ACR setting" function permits to change ACR setting of a 2D image acquired.

Clicking on "Change ACR setting" a custom menu appears in relation to the projection selected.

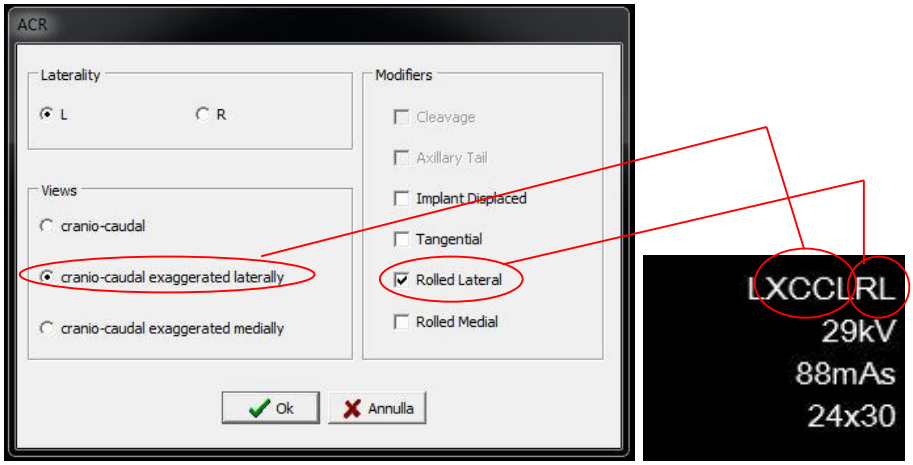
An example of menu is shown in the following figure:



RMLO Projection menu RCC Projection menu

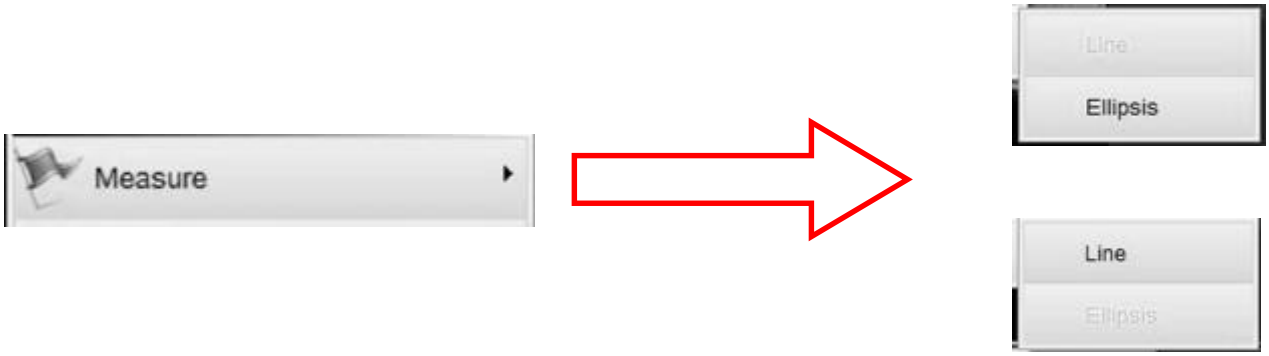
The menu changes its features according to the projection selected before the acquisition, showing only ACR options compatible. Each change applied to the 2D image will be visible directly on the upper corner of the image.

Each change is recorded in a specific DICOM item:



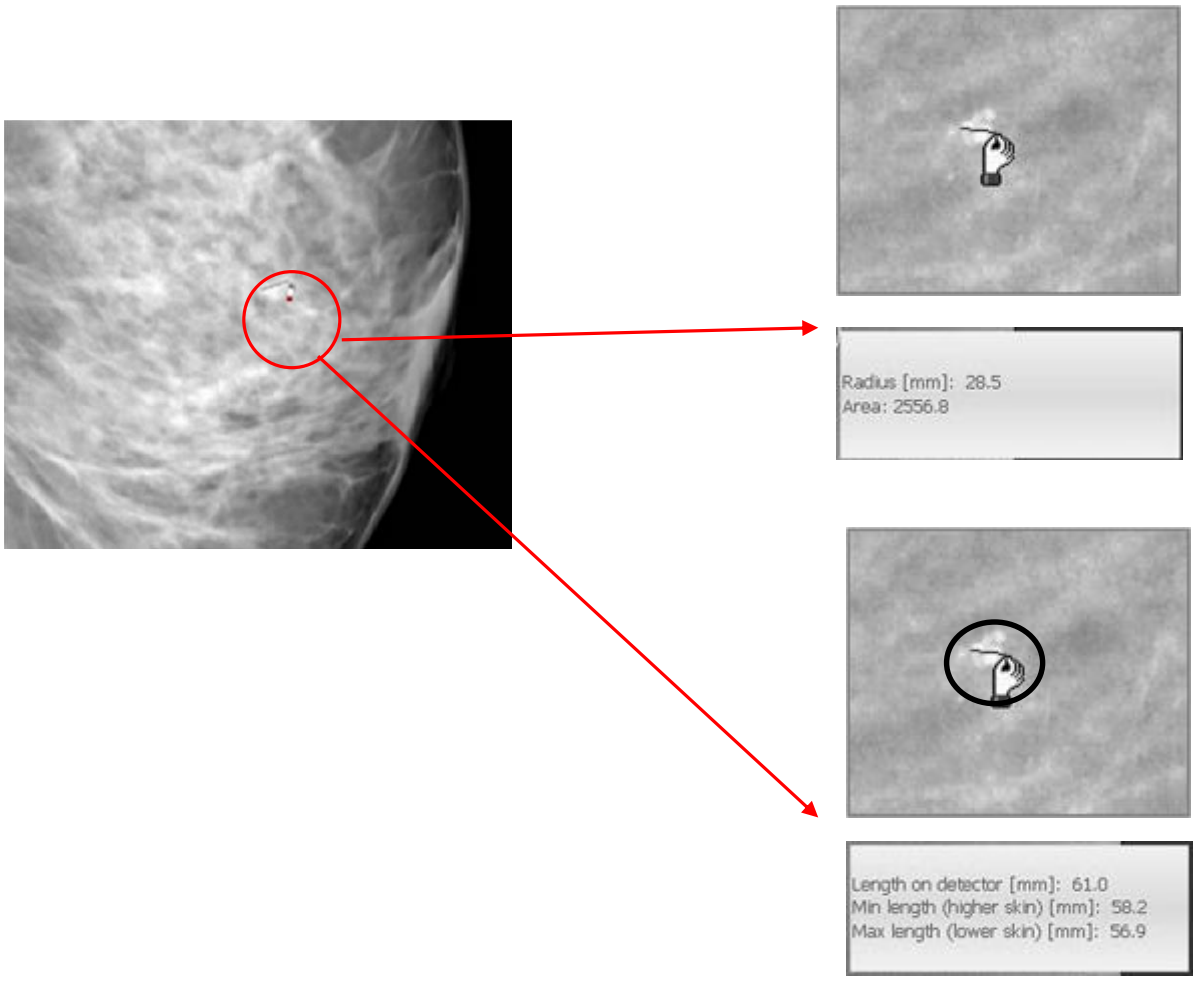
The “Measure” function allows to take some measures on selected image.

Clicking on “Measure” button a Pop-up menu appears to choose between linear or area measure.



Clicking on desired kind of measure, a little hand symbol appears on the image.

Click on one edge of the detail and drag the hand symbol till reaching the other edge of the object to measure. Releasing the button, a window with the measurements results appears.



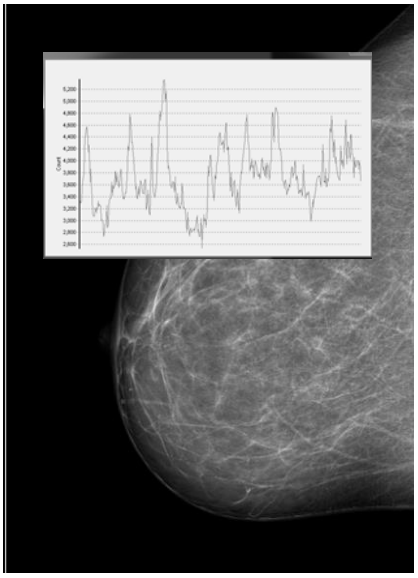
The “Plot line” and “Alt images” functions allow to make preliminary investigations on image quality.

NOTE

The High-resolution display (HRD) is not inteded to be used as review monitor; perform the real image investigation using a dedicated review station.

Clicking on “Plot line” button, a little hand symbol appears on the image.

Click on one edge and drag the hand symbol till draw a line. Releasing the button, a window with a profile of the gray levels on the drawn line appears.



Clicking on “Alt images” button, the unprocessed image (RAW format before the application of enhancement algorithm) is displayed.

6.9.5. Geometric transformations, measurements, annotations and markers

Geometric transformations and measurements allow you to perform non-permanent image changes (i.e. they will not be applied permanently on the image, their action is limited to the current analysis). Annotations and Markers, on the other hand, are real DICOM objects and are sent to the network nodes together with the reference images.
These tools can be used through the image menu.

6.9.5.1 Geometric transformations

- Invert: the grayscale of the current image is inverted;
- Mirror: this tool is in "Edit-Geometric Transformation", by clicking on it, the image is mirrored horizontally;
- Flip: this tool is in "Edit-Geometric Transformation", by clicking on it, the image is mirrored vertically;
- 90° CW rotation: this tool is in "Edit-Geometric Transformation"; by clicking on it, the image is rotated clockwise by 90 degrees;
- 90° CCW rotation: this tool is in "Edit-Geometric Transformation"; by clicking on it, the image is rotated counter-clockwise by 90 degrees;
- Reset: this tool is in "Edit", this tool reset the original image.

6.9.5.2 Measurement

- Ruler: this tool is in "Edit-Measures", once the function is activated, clicking on the image in one point places the first point of the line, clicking in a second point draws a line joining the two points with a label indicating the length of the same in mm;
- Oval: this tool is in "Edit-Measures", once the function is activated, by clicking on the image in a point and holding down the left mouse button, an oval figure will be drawn with a label that will indicate the length of the axis and the underlying area in mm. By holding down the Shift key on the keyboard while drawing the figure, it will automatically be scaled in a circle. Once the left mouse button is released, the figure will remain visible to the operator until another action is performed;
- Freehand: this tool is in "Edit-Measures", once the function is activated, clicking on a series of points on the image will build a closed broken line. To finish the creation of the polygon, click twice with the left mouse button.The figure will remain visible to the operator until another action is performed;

- Angle: this tool is in "Edit-Measures", once the function is activated, by clicking on a point in the image, a first point will be set. By clicking on a second point, the straight line passing between the first and the second point will be the first angular side considered. By clicking on a third point, the straight line passing between the second and the third point will become the second angular side. The angular measurement (in deg) will take place concurrently with the positioning of the third point. The figure will remain visible to the operator until another action is performed;

6.9.5.3 Annotations

As mentioned, the annotations (as well as the subsequent Markers) are DICOM objects, and are sent to the network nodes together with the relative images.

- Free text: this tool is in "Edit-Annotations", Free Text is free text that can be inserted on the image. Activating the function, a window will appear in the center of the acquisition form where the operator can enter the text he intends to add in the dedicated input bar. By pressing OK, the insertion is confirmed, pressing "Cancel" cancels the operation. By clicking OK, the text is hooked to the mouse cursor and the operator can place it within the image by clicking the left mouse button. At this point, the operator can decide to change the properties of the text just placed. Note that in the “Edit” menu the Annotations submenu is colored orange. Clicking on it a window will appear with all the Free Text and Text Bubble inserted in the current image. By clicking on the colored button of the specific annotation it will be possible to change its color. By clicking on the annotation text, it will be possible to modify its content. By clicking on the "Edit font" button it will be possible to change its Font and character. By clicking on the button with the trash can, the specific annotation can be deleted.
- Text bubble: this tool is in "Edit-Annotations", the Text Bubble is a box containing free text from which an arrow starts pointing to a specific region of the image. By activating the function, a window will appear in the center of the acquisition form in which the operator can enter the text he intends to add in the dedicated input bar. By pressing OK, the insertion is confirmed, pressing "Cancel" cancels the operation. By clicking OK, the text is hooked to the mouse cursor and the operator can place it within the image by clicking the left mouse button. A second click will hook the arrowhead; properties of Text bubble can be changed as for Free Text;
- Delete All: this tool is in "Edit-Annotations", by clicking on it all the annotations inserted in the current image will be deleted.

6.9.5.4 Markers

The markers are added to the annotation list, as mentioned in the previous paragraph, where it is possible to modify their characteristics (color and delete).

- Arrow: this tool is in "Edit-Marker", once the function is activated, clicking on the image in one point places the first point of the line, clicking in a second point draws a line joining the two points with the arrow pointing towards the second point;
- Oval: this tool is in "Edit-Marker", once the function is activated, by clicking on the image at a point and holding down the left mouse button, an oval figure will be drawn. By holding down the Shift key on the keyboard while tracing the figure, it will automatically be scaled in a circle;
- Freehand: this tool is in "Edit-Marker", once the function is activated, clicking on a series of points on the image will build a closed broken line. To finish the creation of the polygon, click twice with the left mouse button.
- Delete all: this tool is in "Edit", by clicking on it, all the markers inserted in the current image will be deleted;
- Save all: this tool is in "Edit", the Save All button saves all the annotations and all markers present in the current image, or all the changes made starting from a previous annotation and marker configuration. if the operator does not press save all, the annotations and markers not previously saved will be lost if the study is closed. save all must also be pressed after pressing delete all, to save the deletion of the inserted tools. in a nutshell, save all saves the current configuration of the current image.

6.9.5.5 Markers for 3D images

As for the 3D images, the operator can insert markers and annotations on the current slice (which is therefore considered individually with respect to the stack), but it is necessary to specify the operation of the Delete All and Save All buttons. The entire tomosynthesis image is instead considered as a whole as “current image”, therefore Delete All will delete markers or annotations on the whole stack and not only on the current slice. Similarly, the Save All button will save the current configuration across the stack.

In the menu that allows the editing of annotations and markers will be present all the annotations of the stack.

Slices in which at least one annotation or marker is present are highlighted.

6.9.5.6 Annotations for biopsy images

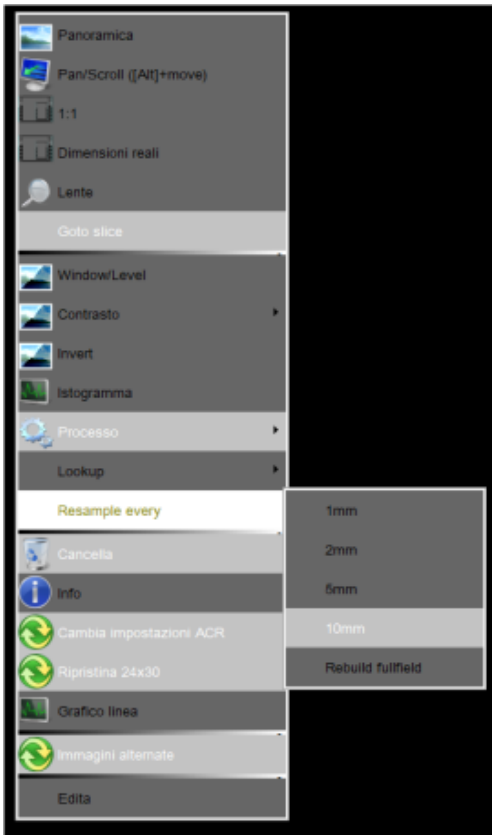
The annotations can be inserted in a similar way to what was seen also during a biopsy study. The EDIT button will be disabled only when you are inside the procedure (START PROCEDURE) and will be re-enabled once the procedure is finished (END PROCEDURE). This means that no annotations can be made in control images. Or rather, it can be done later by reloading the study via LOAD STUDY.

6.9.6. MAPPING

This function correlates the 3D image with any corresponding VI and it can be applied for LOCAL STUDY, LOAD STUDY, RIS and UNSCHEDULED.
When a VI image is open on HRD, opening the menu you can see that the “Goto slice” buttoni s activated. Clicking on i twill activate the function that starts the 3D-VI visualization. Clicking on any point of the VI image, the related 3D image will show the slice from which that point was generated.

6.9.7. REBUILD FULLFIELD (available only for TOMO option)

The 3D and M-VIEW/VI images acquired in tomosynthesis mode undergo the cropping action during the processing phase. In the case of M-VIEW/VI images, cropping acts in the same way on the 3D image and on the derived synthetic 2D image.
The operator can decide to rebuild the entire original 24x30 image by selecting the "Rebuild fullfield" function under the "Resample every" menu, therefore the image reconstruction is performed again without cropped frames. By selecting the "Rebuild fullfield" function, the image cannot be subjected to cropping again, as this action is performed only when the image is acquired.



6.10. *CLOSING STUDY*

For any study it is possible acquire a maximum of eight images.

When the images acquisition is complete the operator must close and save the study.

If the study has been open by means of the “LOCAL STUDY” window, it is saved locally. The study can be saved also on DICOM server in a second time by “RESEND” command.

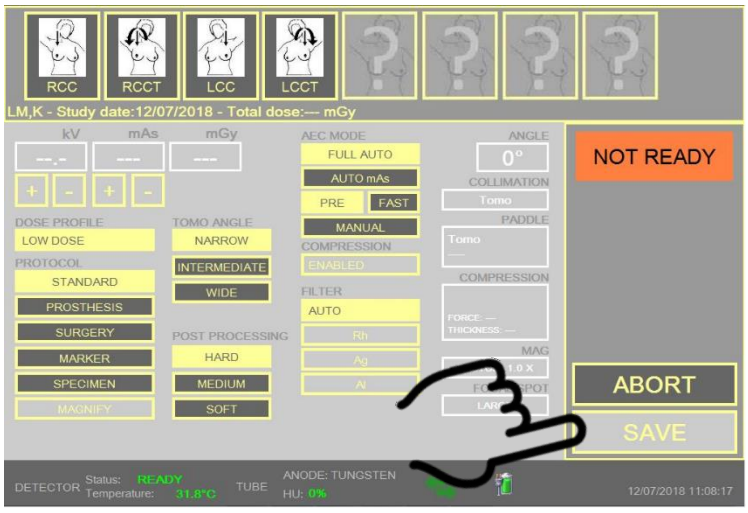
If the study has been open from the Worklist by means of the “RIS” “window, it is saved on DICOM server. A copy of the study is also saved locally for a time configurable in installation phase.

NOTE

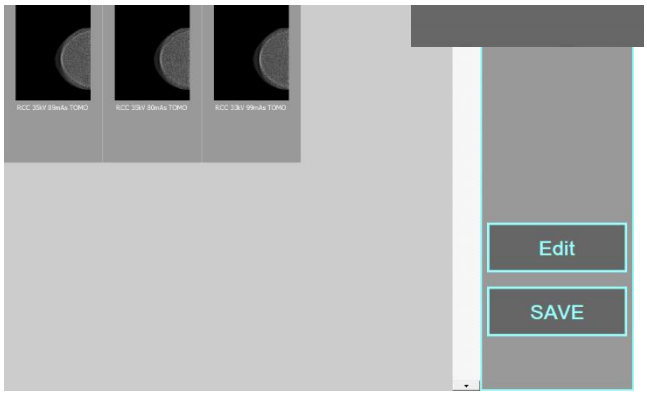
At the end of time of local storage, all studies are erased from the Hard Disk of the Acquisition Work Station.

6.11. *CLOSE AND SAVE STUDY (OPEN FROM WORKLIST)*

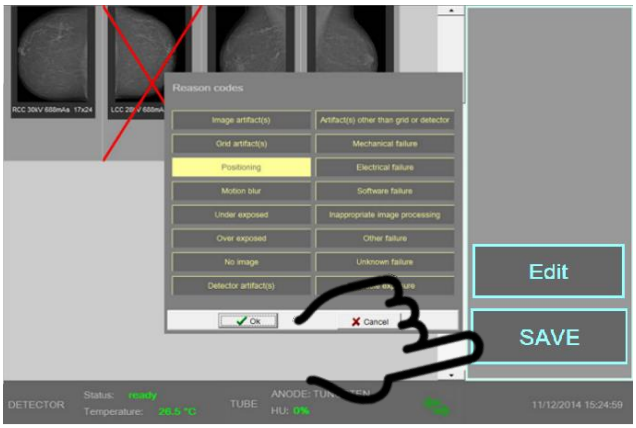
At the end of exam, the operator can send and save study with data and images into store server.
However, if the connection is not available or the net is busy, data are stored locally and sent to the server when connection is newly available.



Pushing on the “SAVE” button a window appears with the thumbnails of acquired images.



The operator can erase some image, justifying the choice with a reason code.

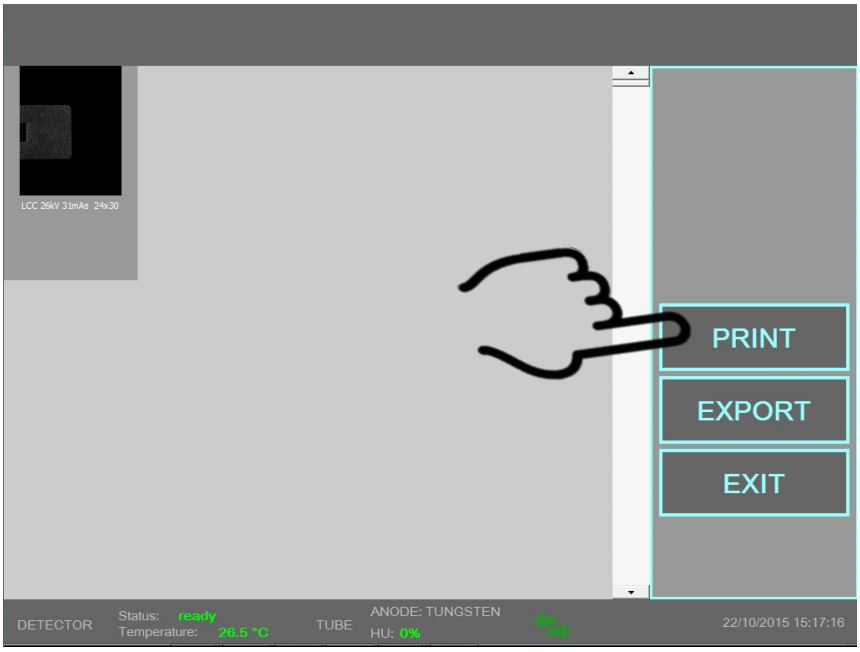


Clicking on EDIT the operator can possibly modify the patient's personal data.

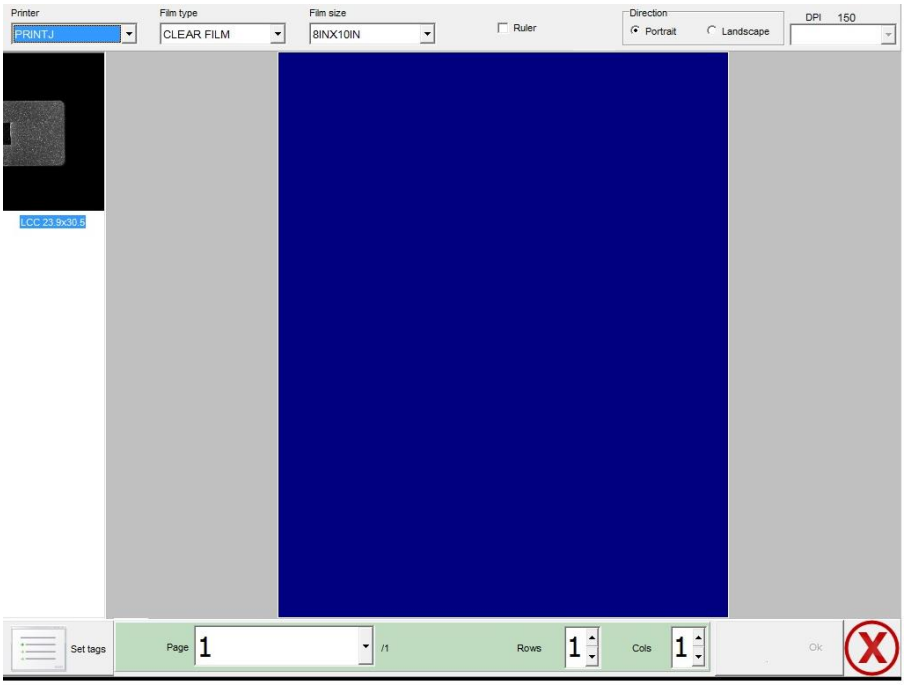
Then, pushing newly the “SAVE” button, the study is sent to the server and new buttons appear to allow to print the selected images or to store the study in a CD/DVD.

6.12. *PRINT STUDY*

The “PRINT” function allows to send to a DICOM printer the images of an open study.



Pushing on the “PRINT” button the following window appears:

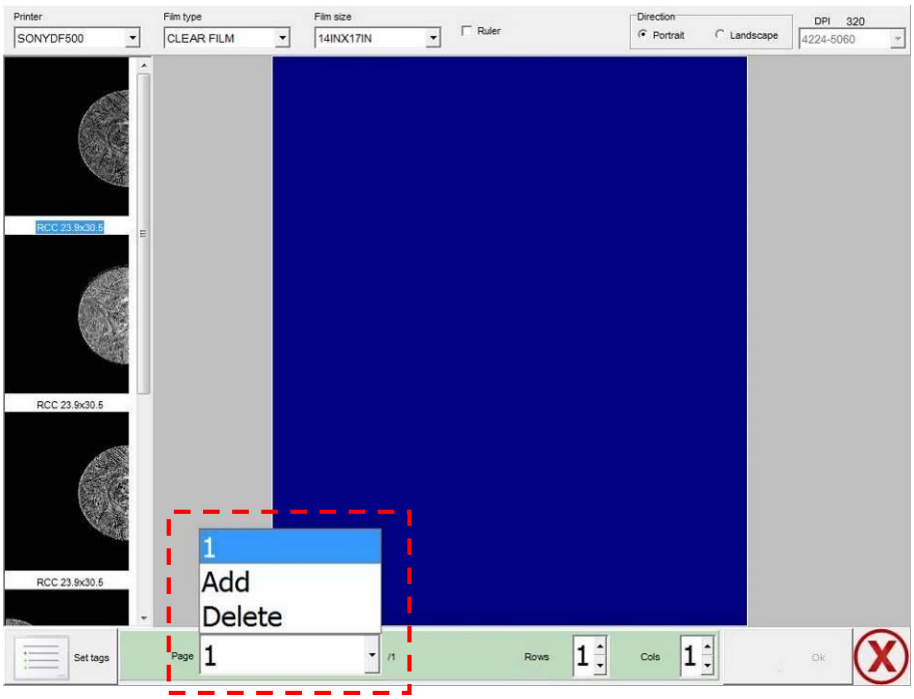


The thumbnail of the images, acquired in the current study, are displayed on its left side, the printer parameters on the upper side while the layout configuration parameters on the lower side.

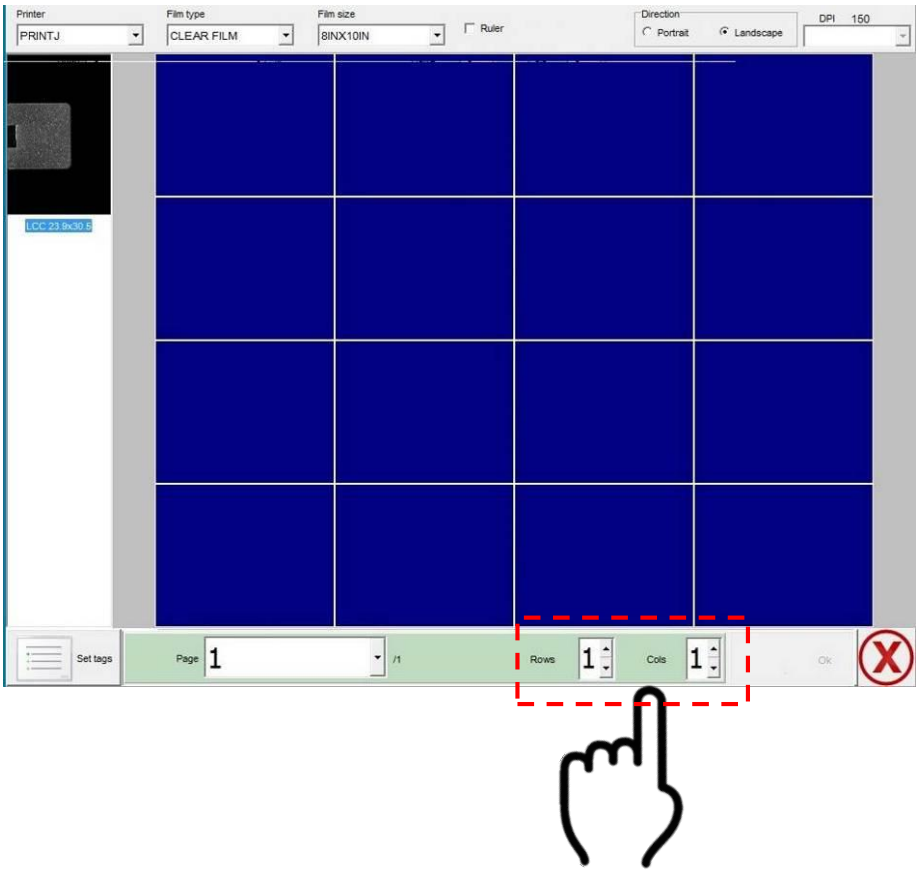
From the upper bar, the printer parameters adjustable by the operator are the following:

- Printer model
- Film type and size
- Direction (landscape or portrait)
- Resolution (DPI)

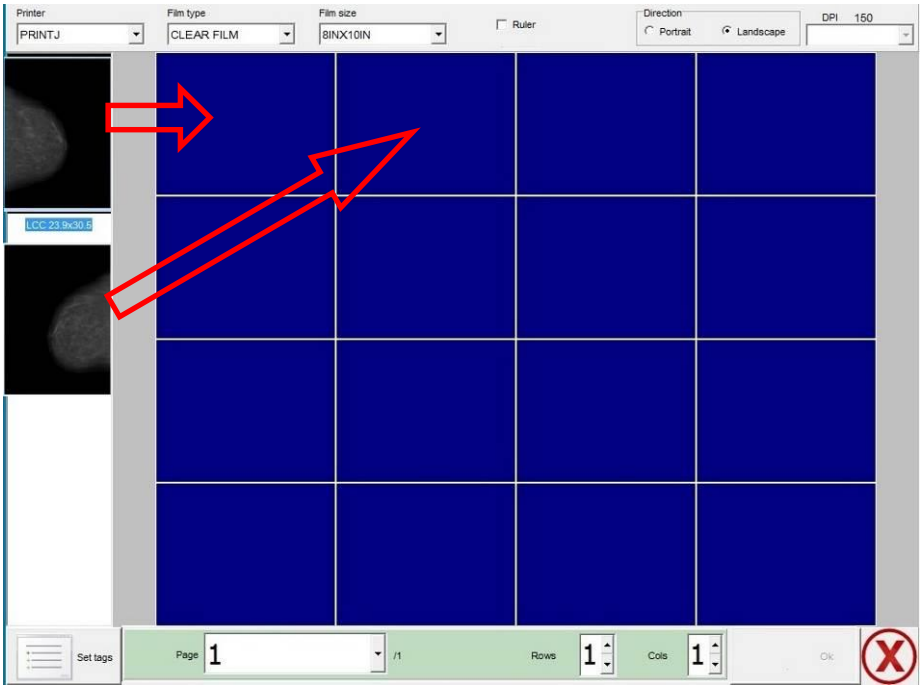
From the lower bar, the operator can choose and modify the number of pages to print. For example, clicking on the icon "▼" of the "Page" field, he can add or delete several pages:



For each page, the operator can modify the specific printing layout increasing, for example, the number of rows and columns in which the same area will be separated:

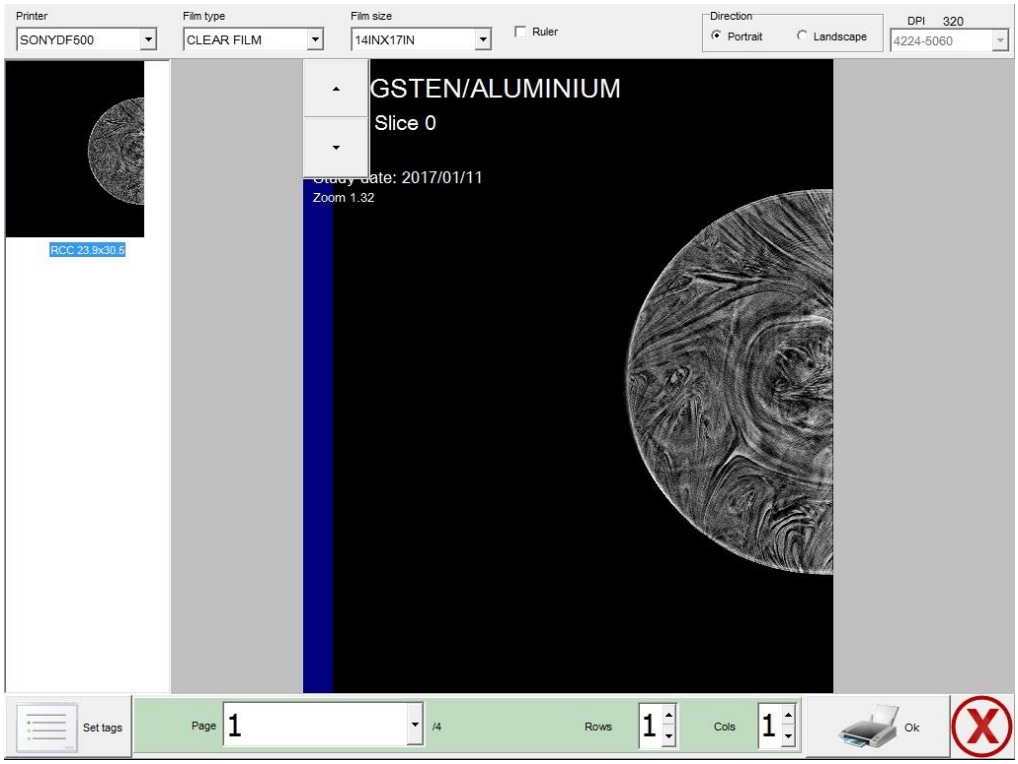


and assemble the images to print in a customized layout, choosing the views and drawing their corresponding thumbnail:

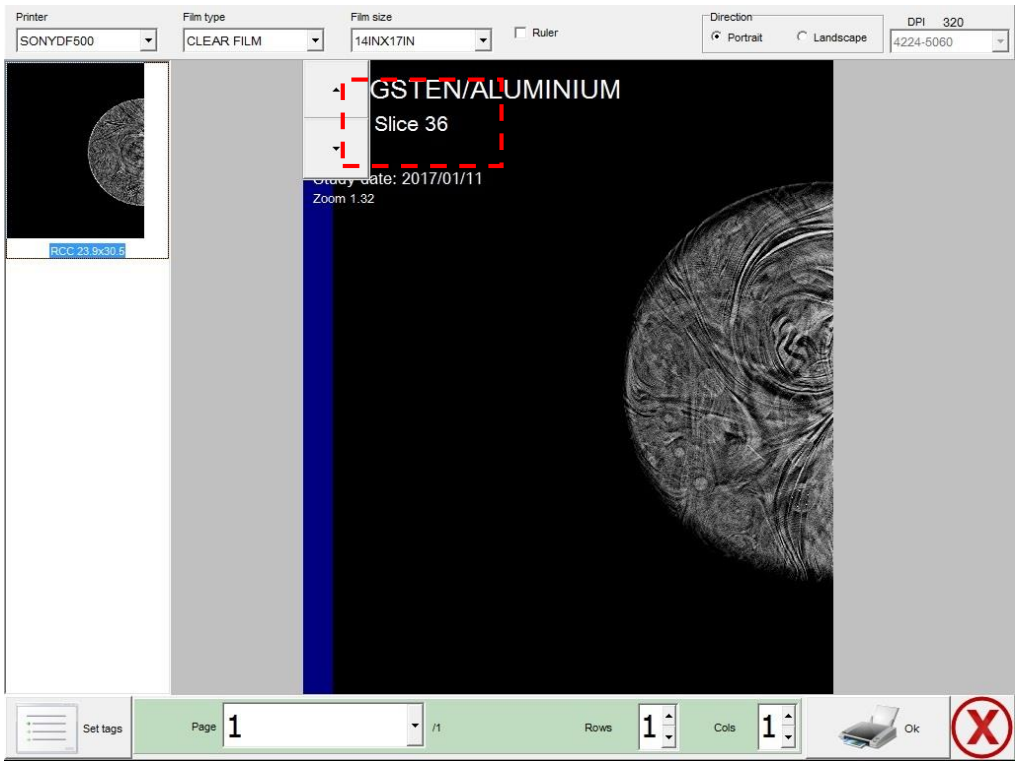


Only for TOMO images acquired, the operator can also select slices to print.

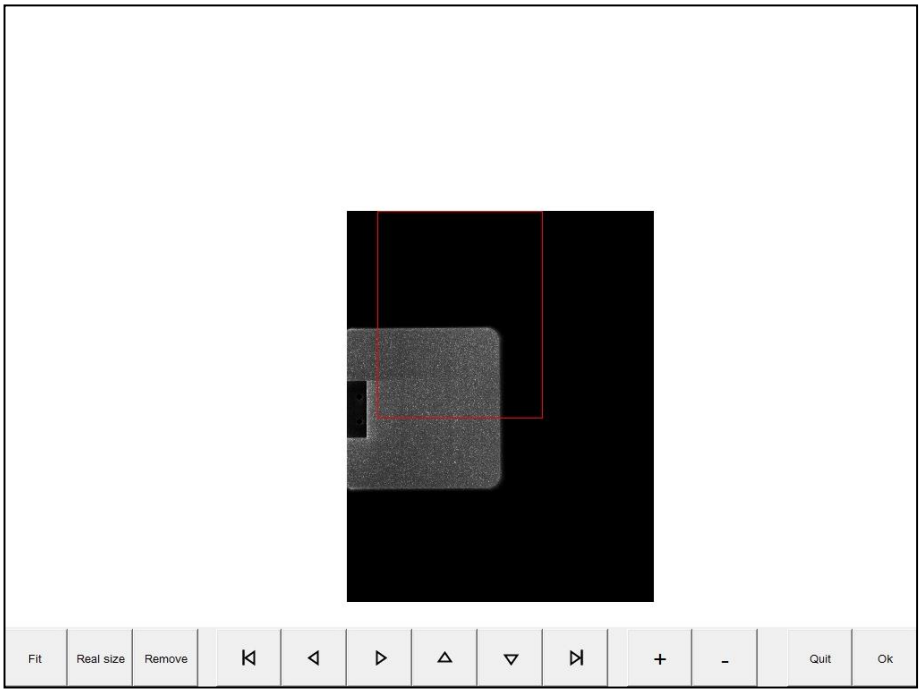
Automatically, the software sets the Slice 0 (zero) but this setting can be modified clicking on the specific view in the main window:



In this way and how above shown, the tool  will be displayed. Clicking on the pushbuttons "▲" or "▼",the slice will be modified and its corresponding number shown on the image:



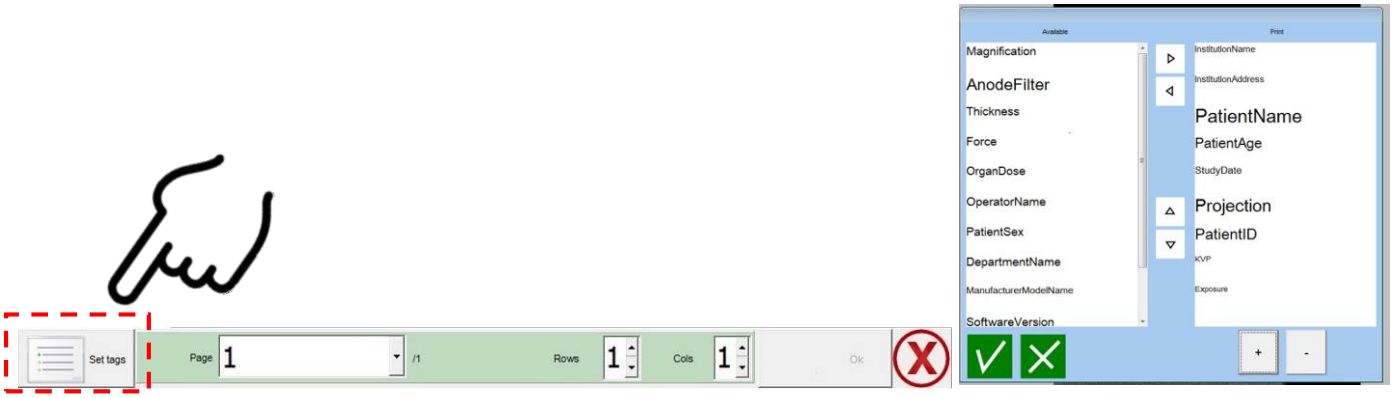
Choosing an image from the customized print layout and clicking on the corresponding icon, the following window will be displayed:



in which it will be possible to modify the image view features by means of the commands bar at the bottom. Clicking on “OK” it will be possible to exit and save.

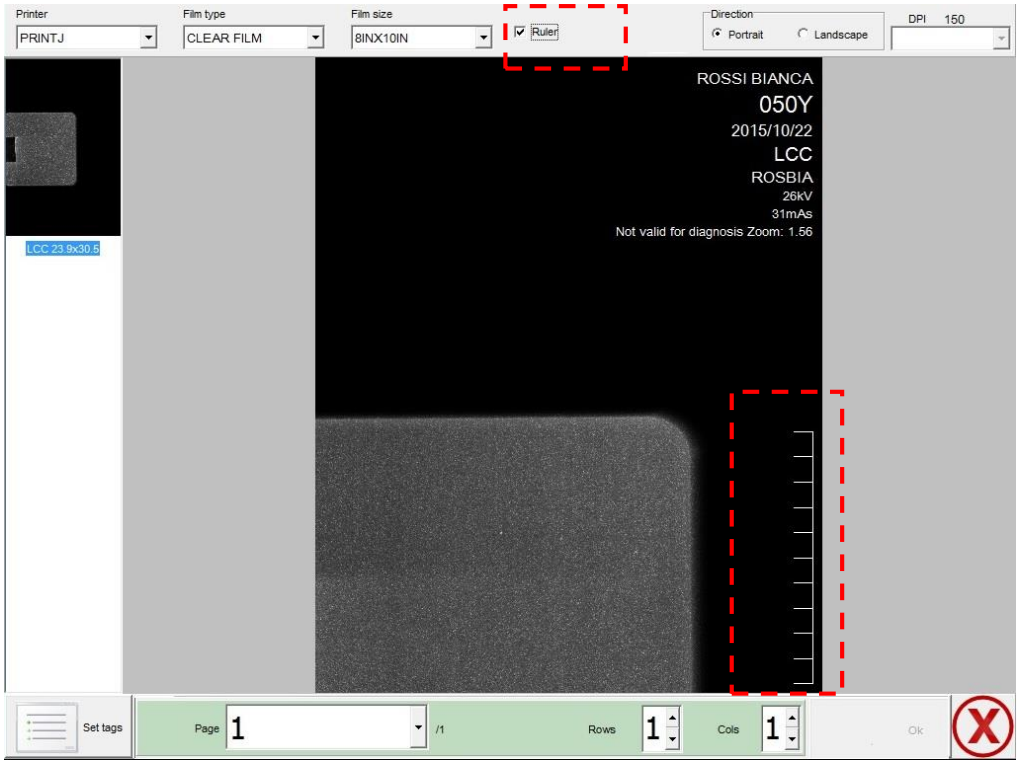
The images can be printed integrating them with many exposure parameters.

Clicking on “Set tags” button on the bottom-left, a window appears with a list of printable parameters:



In particular, it is possible to choose, between the available tags (left column “Available”), those ones which have to be included moving them to the right column “Print” using the pushbuttons “◄” or “►”. Once selected, their order of presentation can be modified using the pushbuttons “▲” or “▼” and their dimensions clicking on “**+**” or “**-**“.

It is also possible to insert a ruler of 10 cm on the image to print:



NOTE

The ruler dimensions, as displayed on the print preview, do not follow the image dimensions if a magnification factor has been applied on it.

The ruler inserted will be right dimensioned only and directly on the printed images.

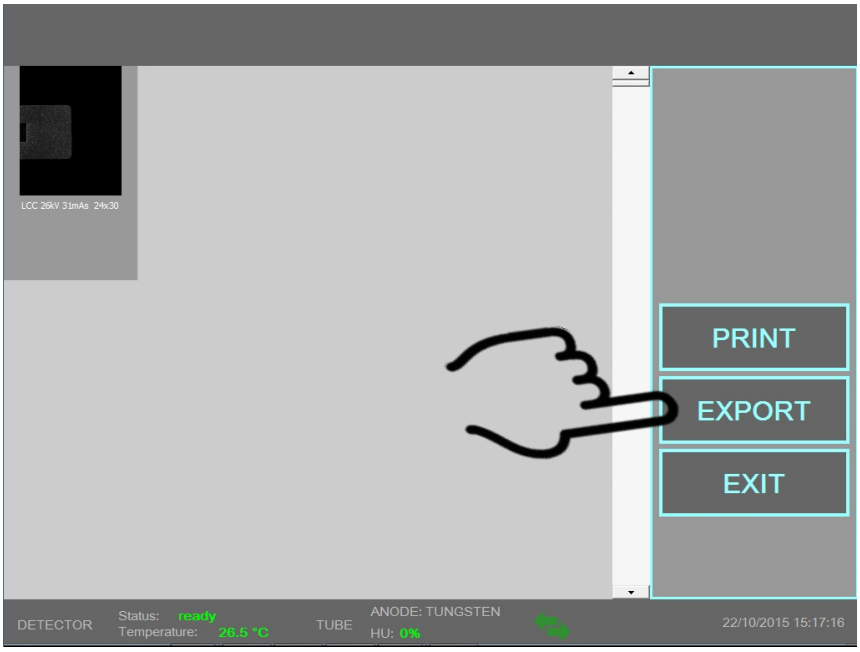
Finally, clicking on “PRINT” button, all the images in the customized layout are sent to the printer

WARNING

For diagnosis, use only images with scale factor of 1:1, printed on film for mammography and with printers specific for mammography.

6.13. *EXPORT*

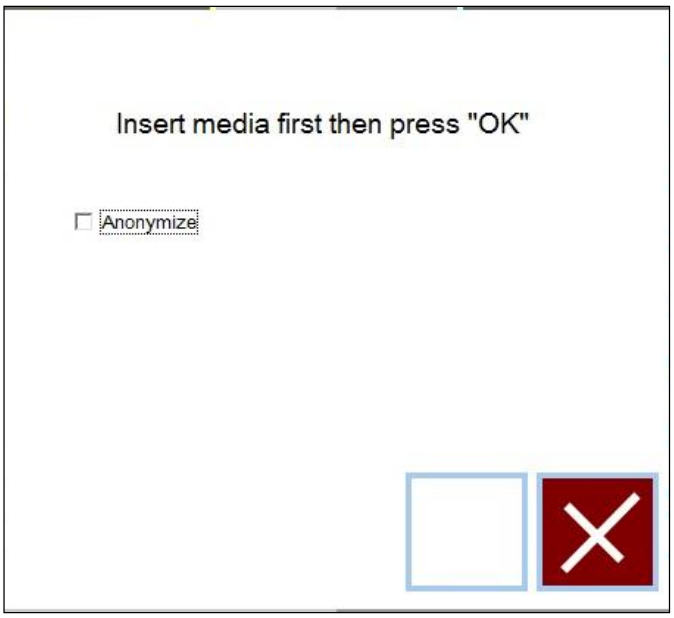
An open study can be saved on a CD/DVD or on a removable drives as DICOMDIR; in both cases an essential viewer is also included.



WARNING

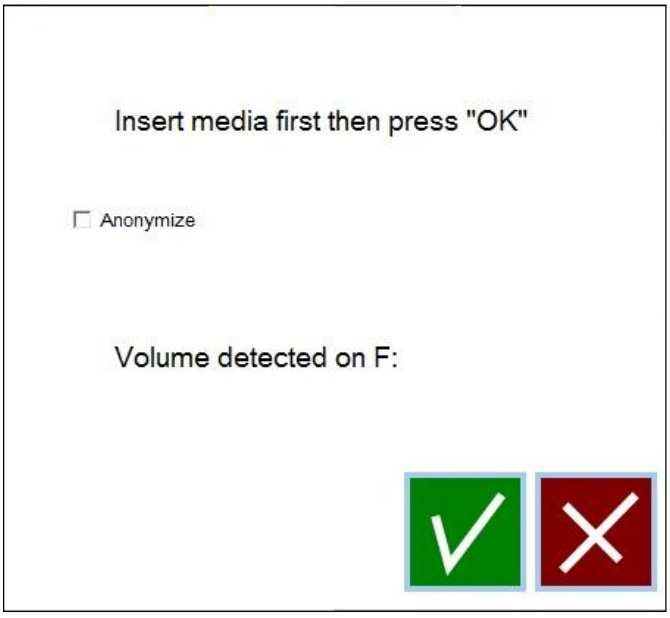
The included viewer has no approval as medical device. It is therefore not to be used for clinical purposes and in any way to effect patient management.

Clicking on the “EXPORT” pushbutton, the following message appears:



Insert a CD/DVD or a removable drive.

The system automatically shows the following message after finding the drive inserted:



For an anonymous recording of the study select “Anonymize”.

NOTE

The anonymization procedure allows the substitution of the patient name with date and hour of the study export.

Clicking on “√”, the process starts and may take several minutes.

Only when recording succeed, the following message appears and the media can be removed.

In case of CD/DVD inserted, it will be automatically ejected.

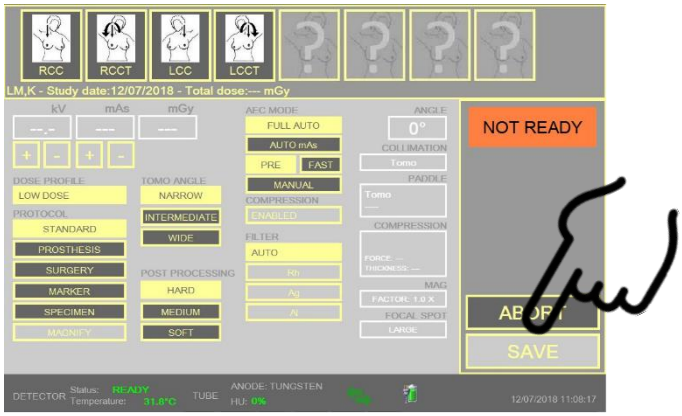
NOTE

The internal CD/DVD recorder is not intended for an intensive use. To write many optical disks is recommended to employ external devices specifically designed.

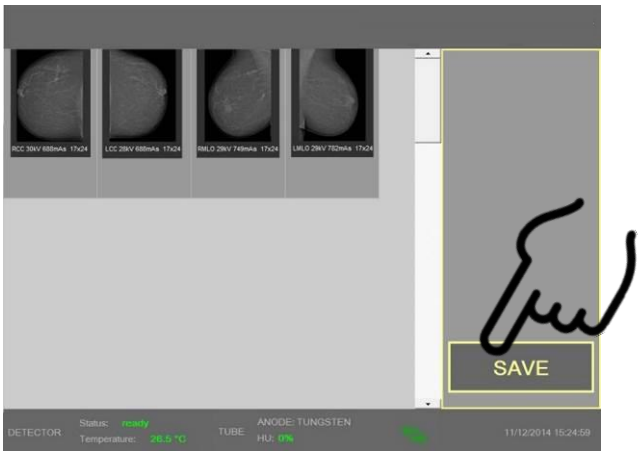
6.14. *CLOSE AND SAVE STUDY (OPEN LOCALLY FROM ACQUISITION WORK STATION)*

A study open locally can be saved on the internal memory of device.

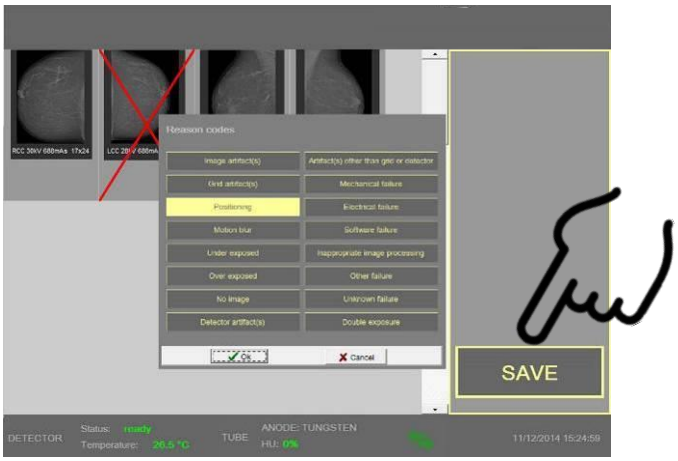
NOTE All the colors in the pictures below are indicative.



Pushing on the “SAVE” button a window appears with the thumbnails of acquired images.



The operator can erase some image, justifying the choice with a reason code.

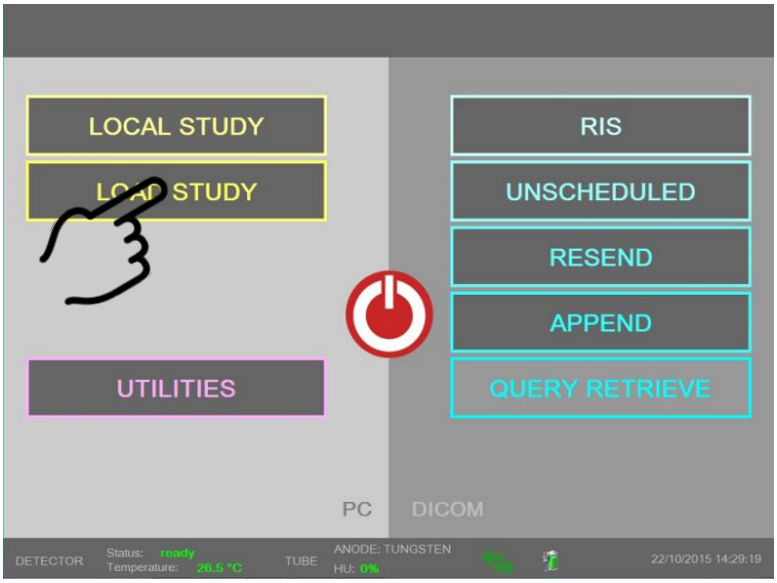


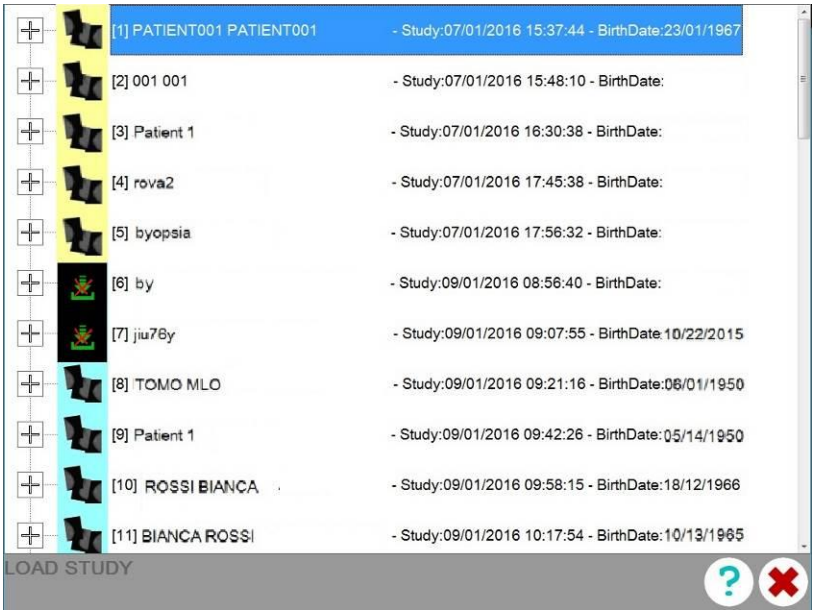
Then, pushing newly the “SAVE” button, the study is stored into local memory.

6.15. *LOADING STUDY FROM INTERNAL CALCULATOR*

It's possible to load the studies saved into internal memory only for reading.

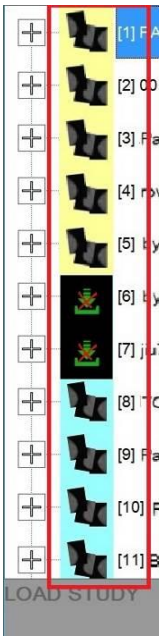
Pushing the "LOAD STUDY" button on the AWS DSP a window appears with the list of all studies.





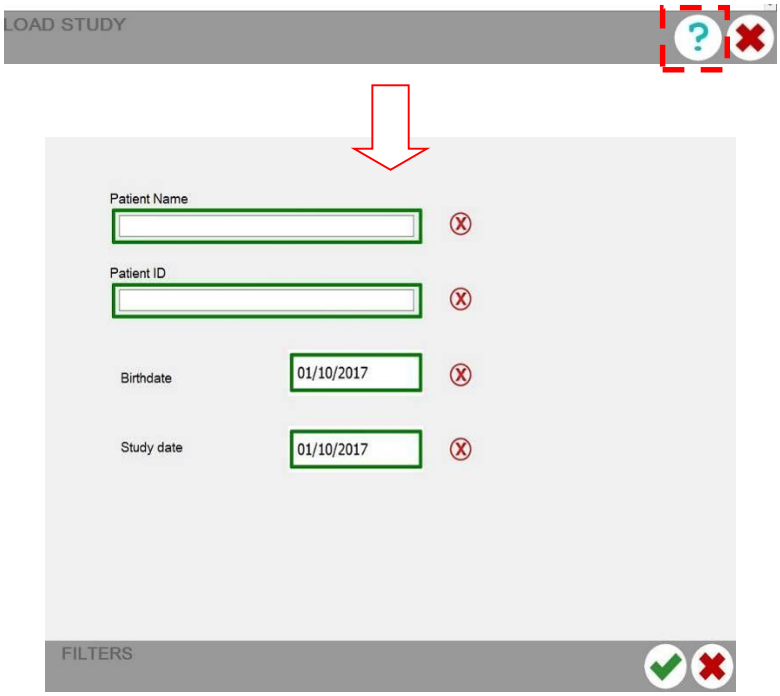
The icons corresponding to those Study open locally are displayed on light yellow background; the icons corresponding to those Study open from Worklist, are displayed on light blue background. Finally, the DICOM Study not yet sent are identified by the icon on black background.

Each study of this list, is identified by a numerical index (i.e. [1], [2], etc) in order to simplify the research activities.



Clicking on the question mark icon on the lower bar, the operator can start a specific research setting one or more of the following parameters:

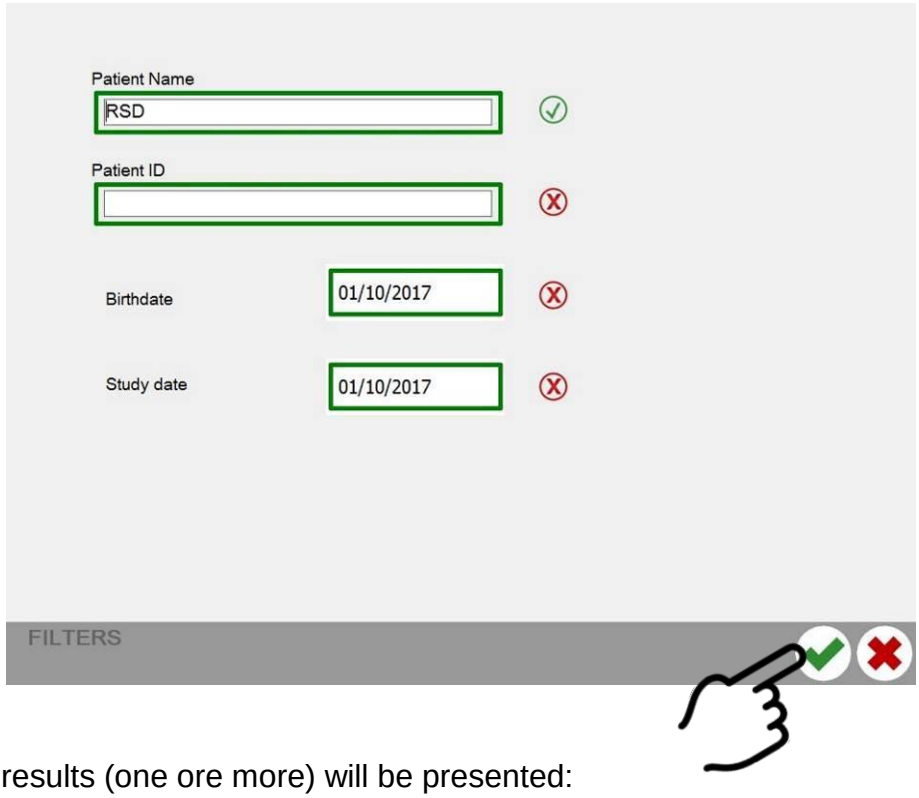
- Patient Name;
- Patient ID;
- Birthdate;
- Study Date



Before to go on with the research filling the chosen fields, the operator has to enable the corresponding parameters pushing on the symbol “X” on their same lines.

Here below an example:

Once set the data, the operator can start the research clicking on the “√” symbol:

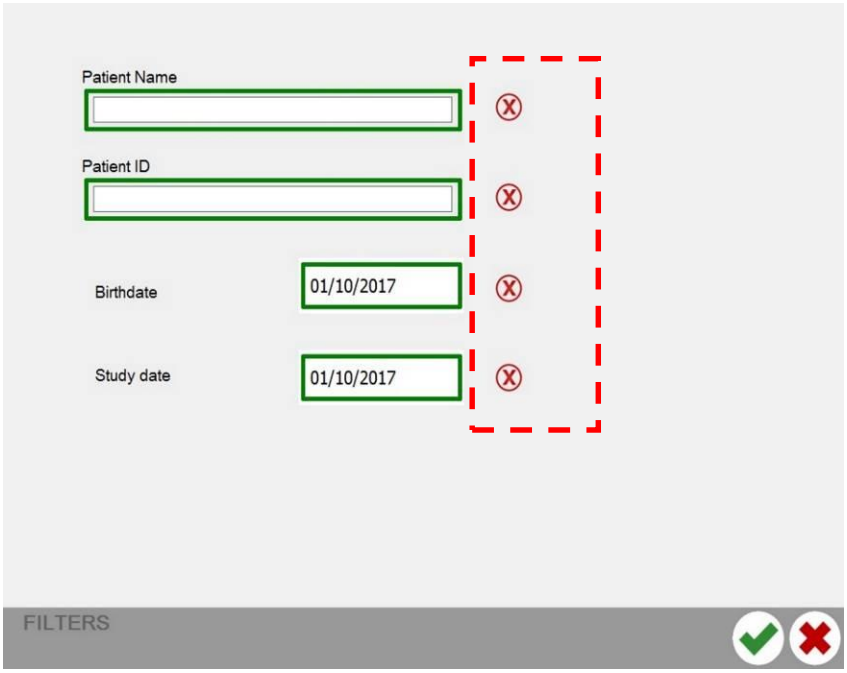


All the search results (one ore more) will be presented:

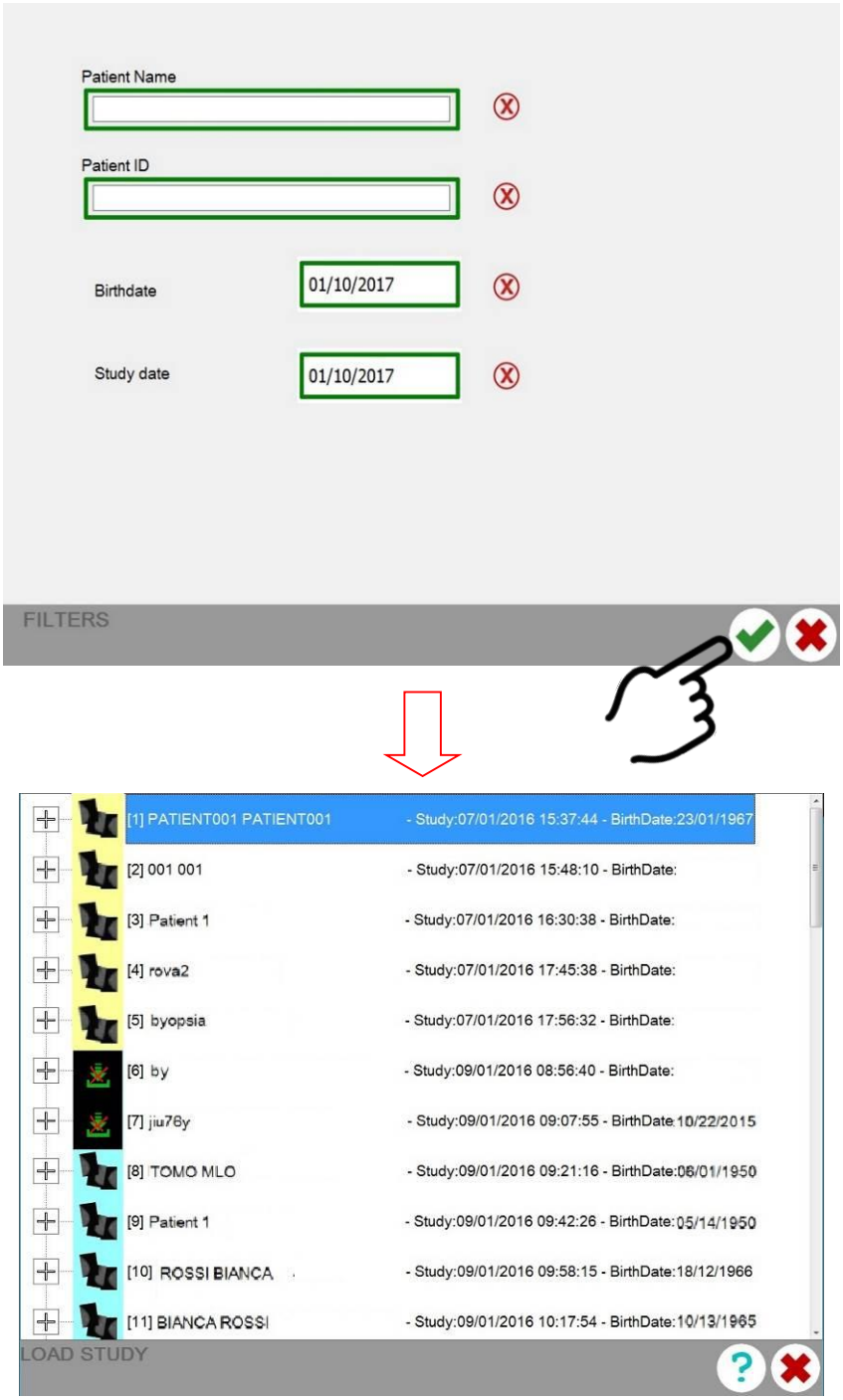
To load a Study, double click on desired study to select it.

On the contrary, to undo the research and return to the complete list of Studies, the operator has to push on the question mark symbol “?” at the bottom:

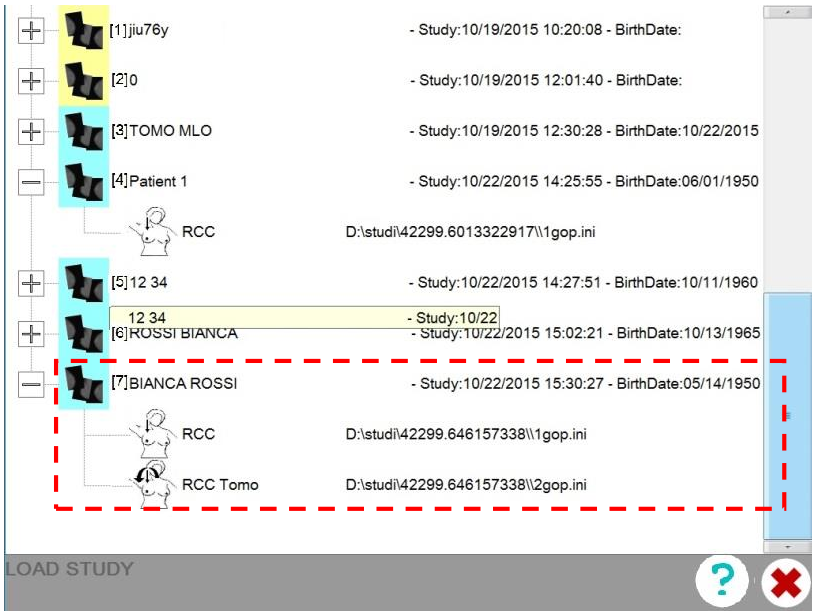
then disable all the parameters previously selected:



and finally push again on the √″ symbol:



In all the cases of Study selection, it is possible to see the list of all the projections clicking on the symbol "**+**":



Double touch on desired study to select it.

As the study is read only, no permanent actions can be released on it.

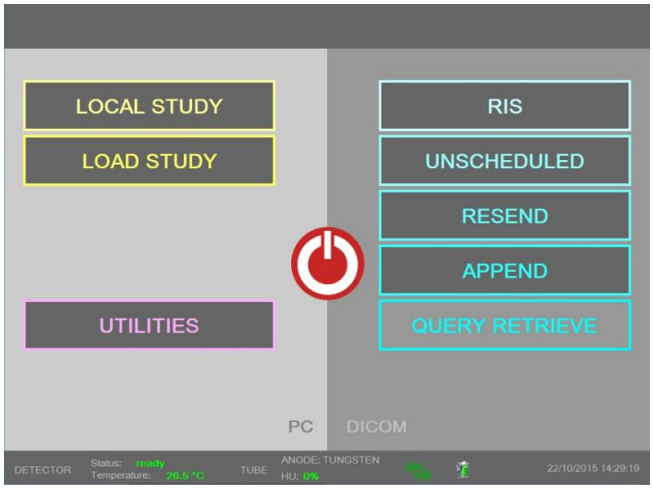
To exit from the study, simply make the next operation (load or open another study, etc.).

NOTE

The position of the study selected and loaded is saved and its numerical index will be the starting point for the following research.

6.16. *DICOM FUNCTIONS*

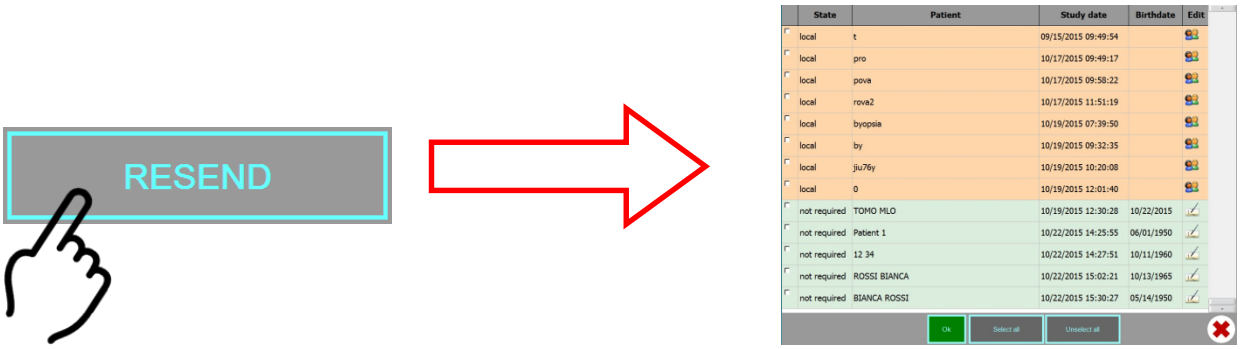
By “DICOM functions” menu, various operations (RESEND, APPEND, QUERY RETRIEVE) can be applied on the studies.



6.17. *RESEND*

The “RESEND” function allows to send a local stored study to the DICOM server.

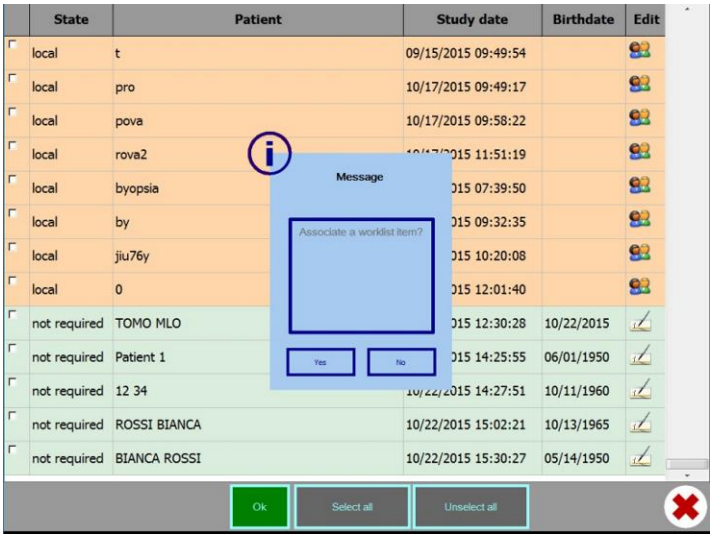
Pushing on “RESEND” button, a window appears with the list of studies saved locally.



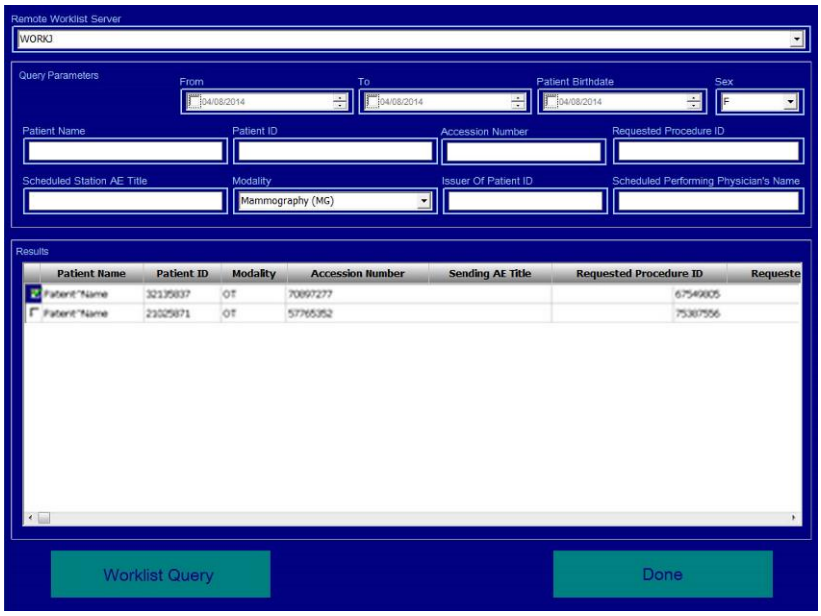
Studies open from the Worklist are displayed on light green background; the studies open locally are displayed on orange background.

Select the study that has to be resend to the PACS flagging the corresponding box on the left and then click on “OK”.

Selecting a study open locally, the following message appears: the operator can associate the study at a worklist item



Then clicking on “OK” Selecting a study open locally, the “Worklist Query Dialog” window appears; the operator can associate the study to a patient and send the images to the server.



Selecting a study open from the Worklist, it is sent directly to the server.

6.18. *APPEND*

The “APPEND” function allows to recall a study earlier open from Worklist in order to integrate it with other images. In any case, the information associated to the study are not modifiable. Pushing on “APPEND” button, a window appears with the list of studies.

The images relative to the recalled study, are shown on the AWS HRD system and the mammography device is ready to take X-rays exposures.

Once the study has been integrated, close it according to the foreseen modalities.

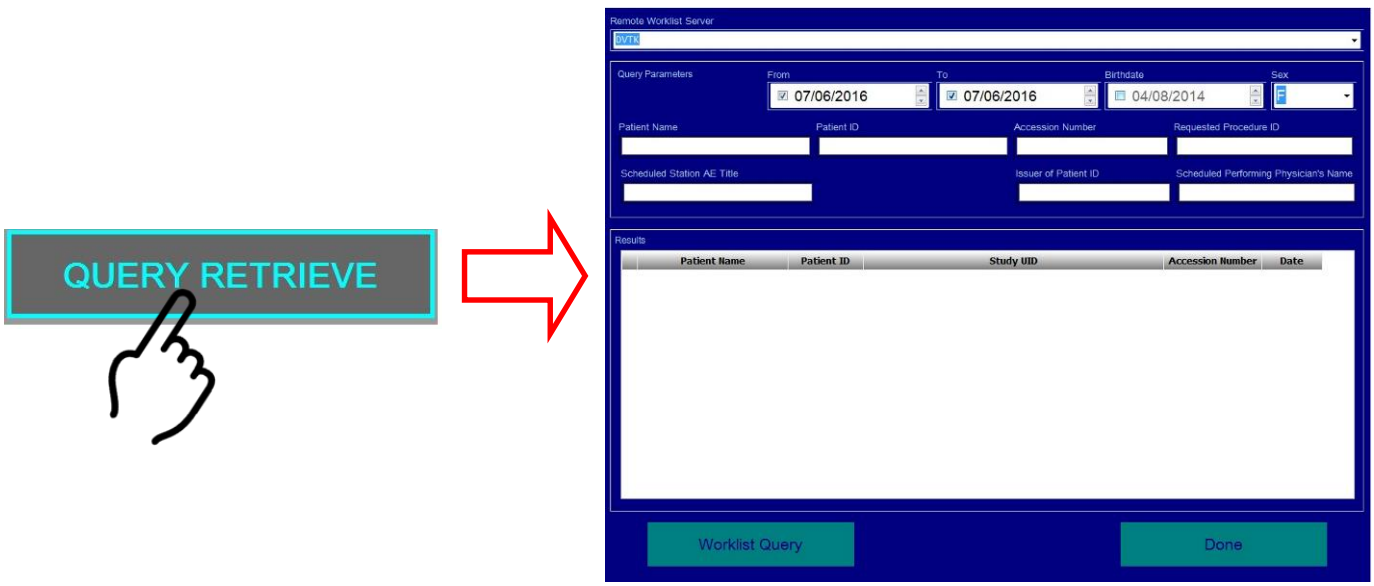
NOTE

The “APPEND” function can be used to restore study in case of mammo unit restart.

6.19. *QUERY RETRIEVE*

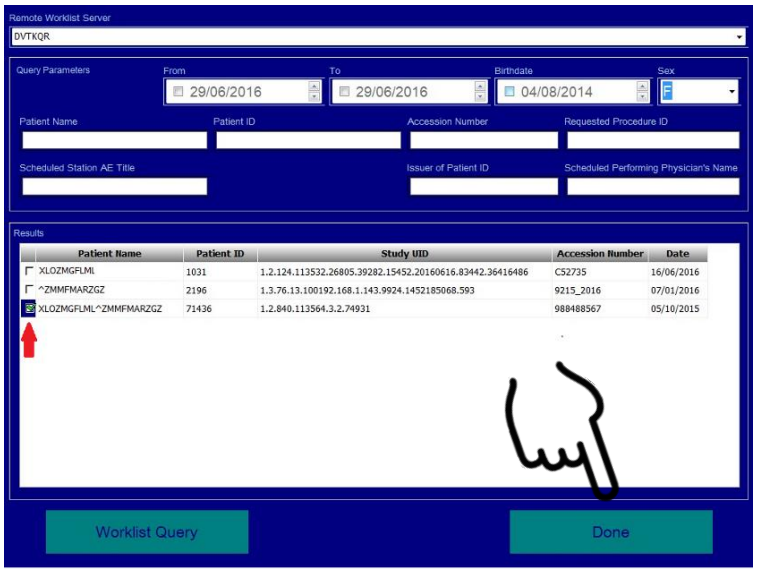
The “QUERY RETRIEVE” function allows to retrieve images from remote DICOM servers.

Pushing on “QUERY RETRIVE”, the following window appears:



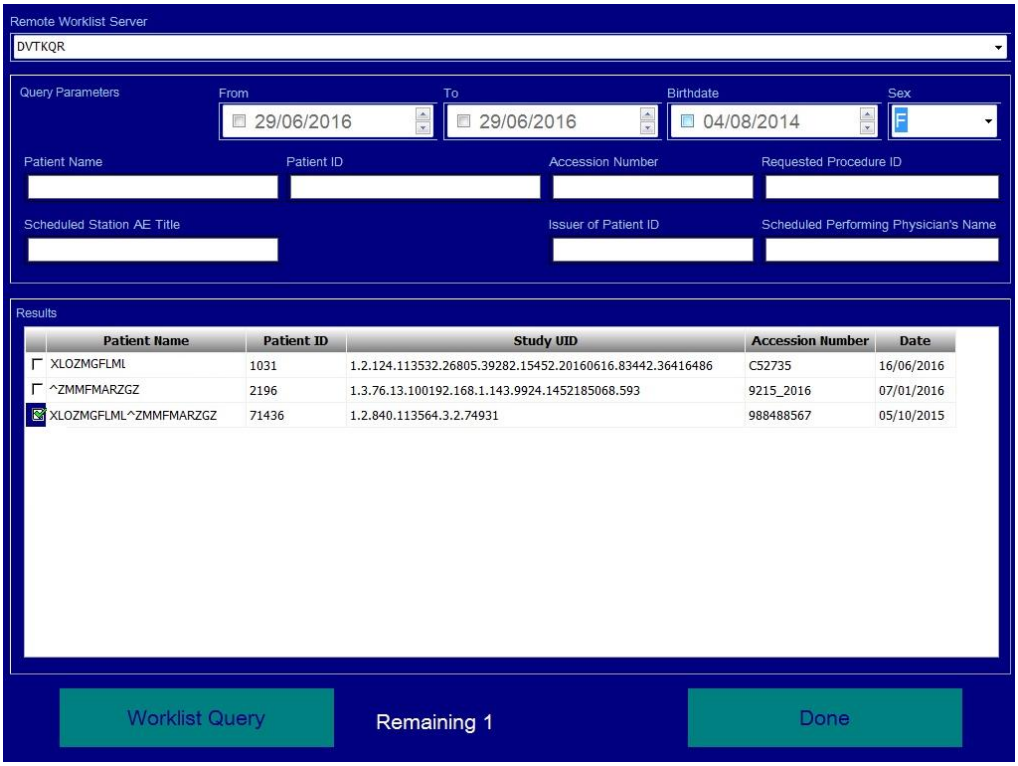
Then:

- Choose the DICOM server between the ones available in the field “Remote Worklist Server”;
- Set the query parameters using one or more fields present in the “Query Parameters” section;
- Push on “Worklist Query” button. All search results will be displayed;
- Select the Study of interest and open it pressing the button “Done”:



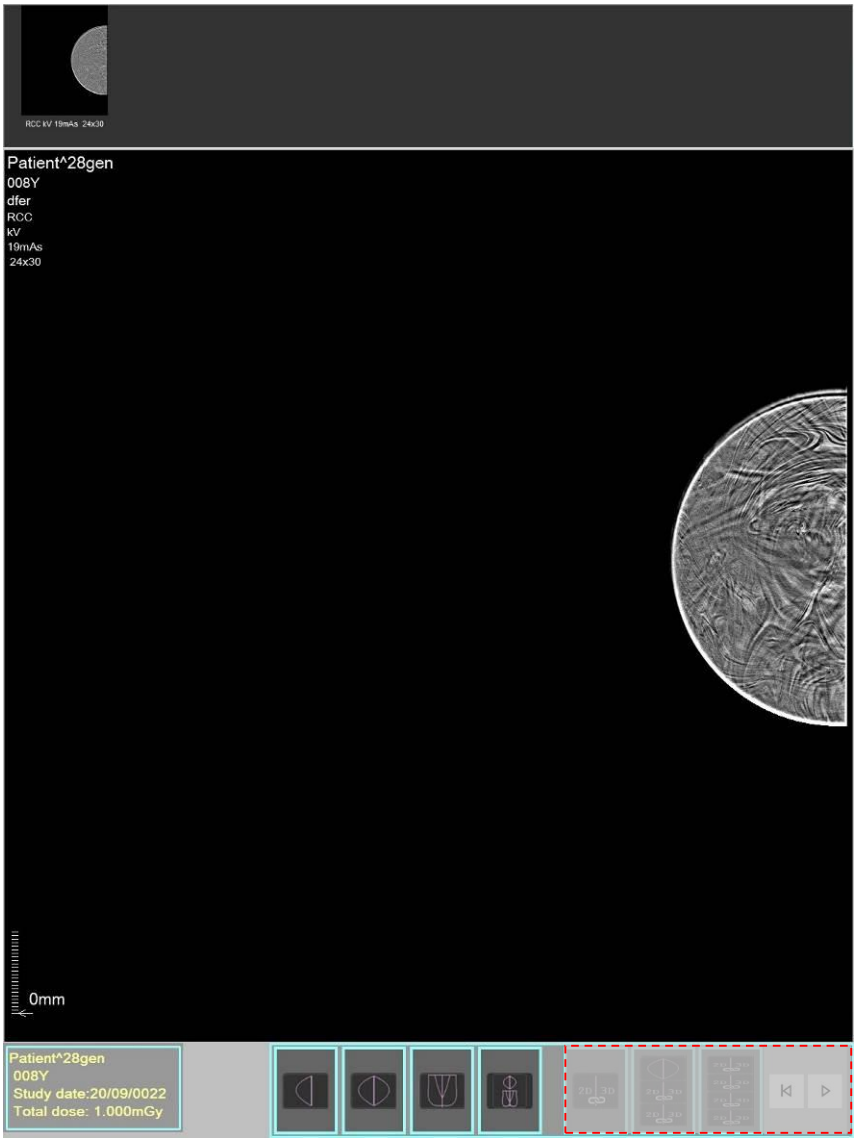
Otherwise, if you want to exit without opening any study, do not select any row and click on “Done” to turn back on the main window of the AWS DSP.

- In case of Study selected, the following window appears on the AWS DSP:



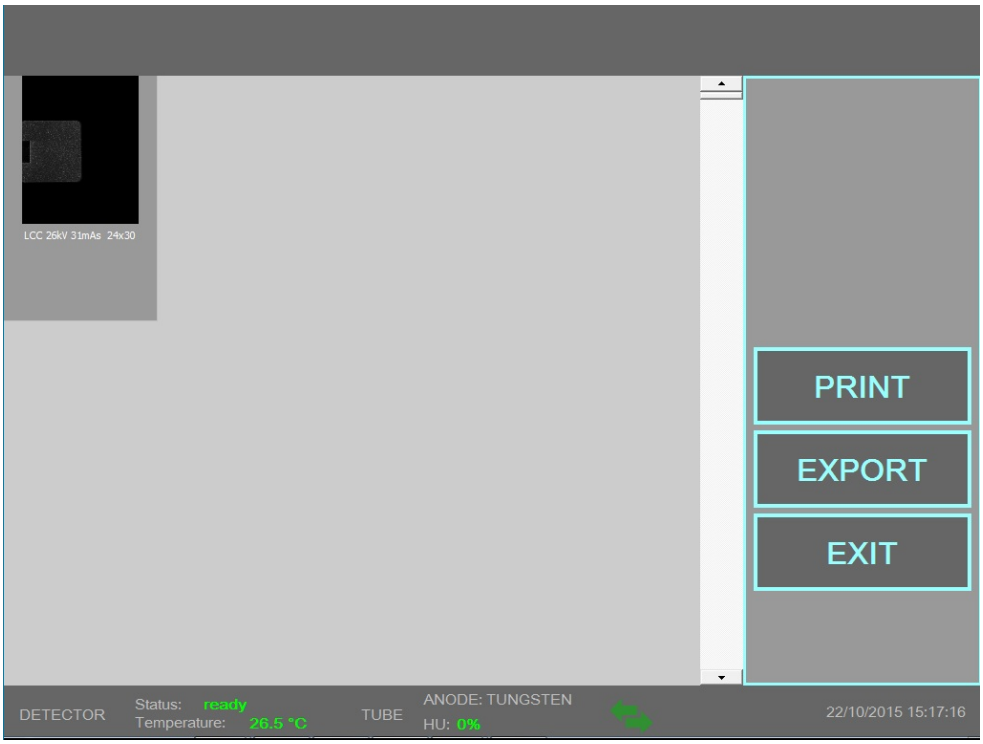
- Wait that the indication “Remaining 1” decreases and finally disappears from the lower section of the AWS DSP. This operation may take several minutes.
- At the end of the import phase, the Study will be opened:

and all images displayed on the AWS HRD:



Only for TOMO options

- On the AWS DSP clicking on “HOME” it is possible to select if “PRINT”, “EXPORT” the Study or close it.



For more details about the options of “PRINT” and “EXPORT”, see the related paragraphs of this manual.

ONLY in case of Study with TOMO images and before the images visualization on the AWS HRD, the following window appears on the AW TSD:

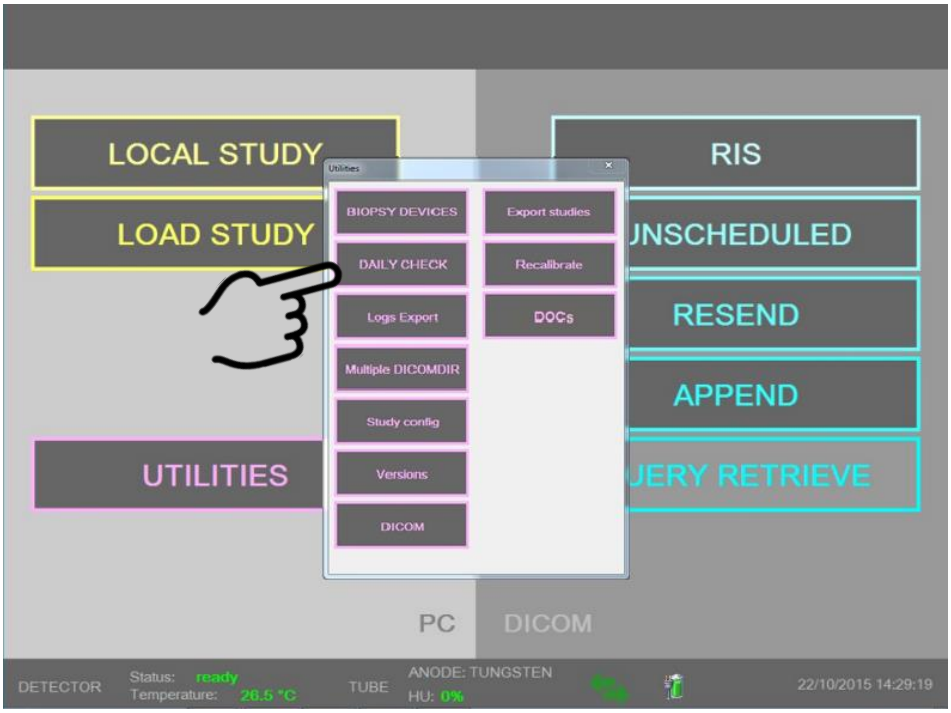
in order to indicate that the system is importing all the image slices.

NOTE

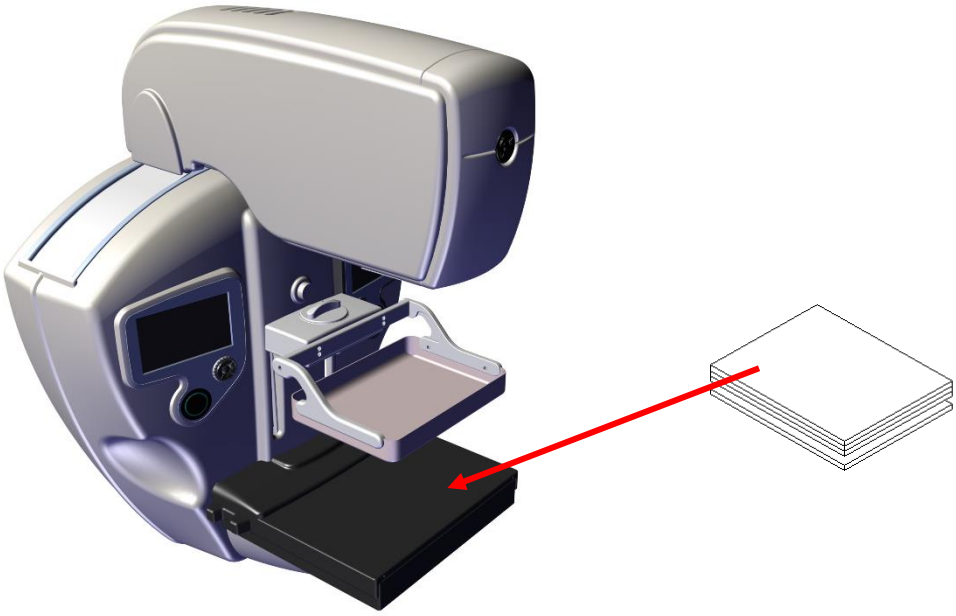
6.20. *DAILY CHECK*

Daily, prior to start to perform the exams, the operator can verify the right operating of mammography unit, through a specific tool achievable from GUI.

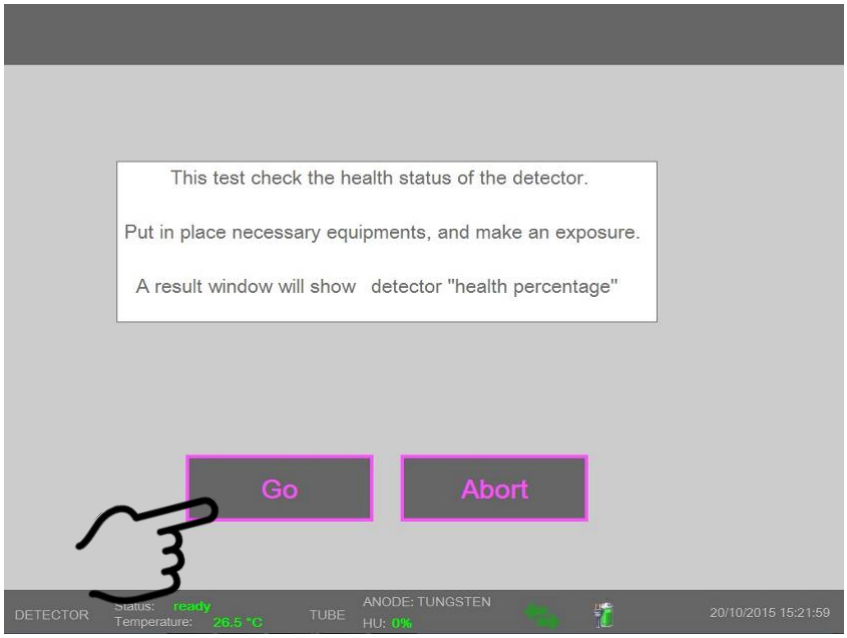
By means of the “Utilities” menu, it is possible to enable this function clicking on the push button “DAILY CHECK”:



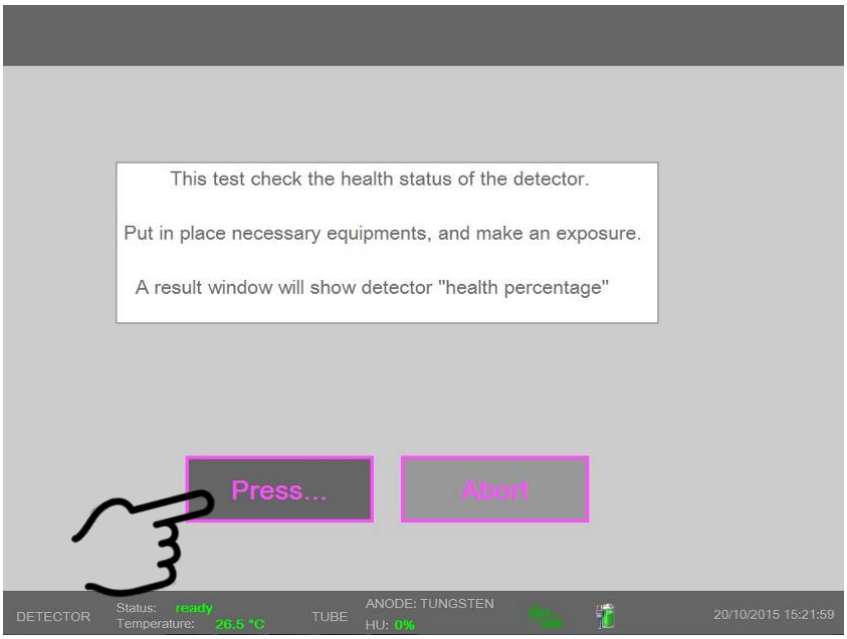
To perform the check procedure is necessary to use an phantom (see List of tools) to place on Potter-Bucky.



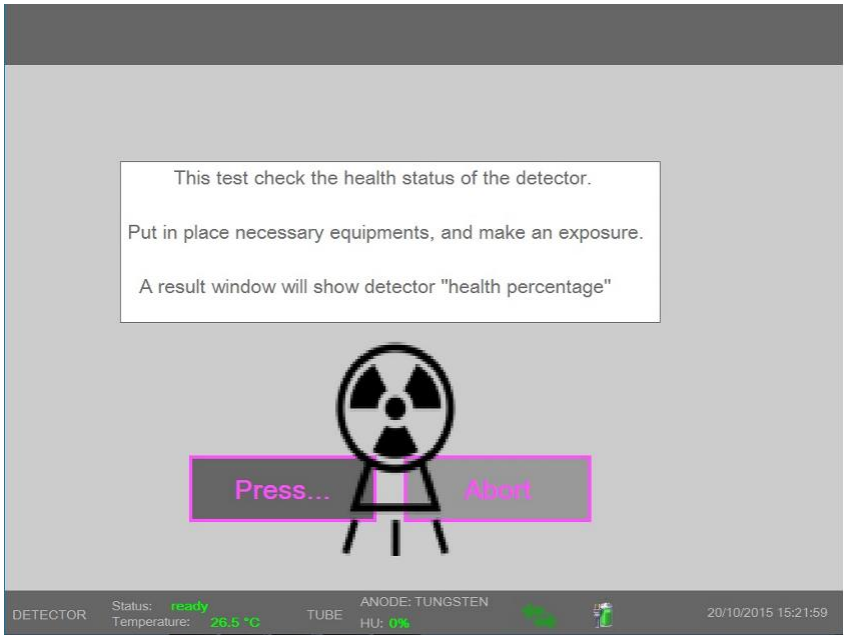
At this point, a window appears with a brief description of the test. Place the 50mm PMMA phantom over the carbon fiber of the Potter-Bucky, make a compression on it until make in contact its surface with that one of the compression paddle and click on “GO”.



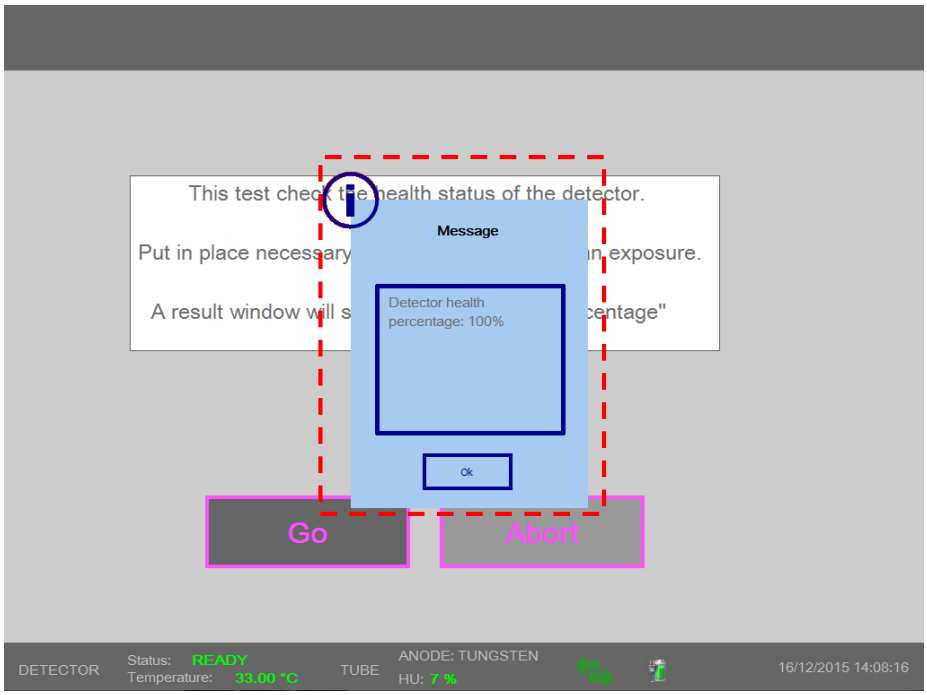
When the system is ready to start the test, the following window appears:



Clicking on “PRESS”, the check procedure starts and the X-ray icon will be displayed to indicate the radiation emission.



At the end, a window with the measurement results appears.



This tool has been developed according with Euref Protocol point 2b.2.2.3.1 “Image Receptor Homogeneity”.

Detector health percentage is related to the number of ROI passing the test, if the value is lower than 100% call Service for periodic Detector Calibration.

NOTE

This tool has been developed for daily check and cannot be used in replacement of calibration tools dedicated to quality control.

6.21. *LOGS EXPORT*

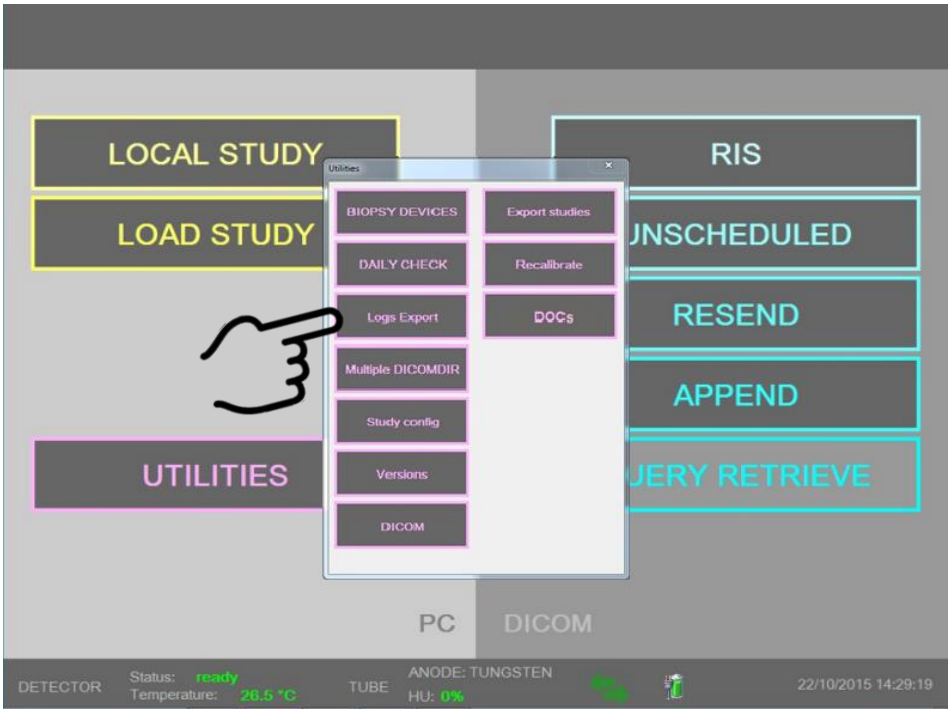
In case of occurrence of SW problems, the Technical Assistance may ask the operator to send some files which may be useful for their analysis and troubleshooting.

Using the available function “LOGS EXPORT”, the operator can export the requested files on a removable drive.

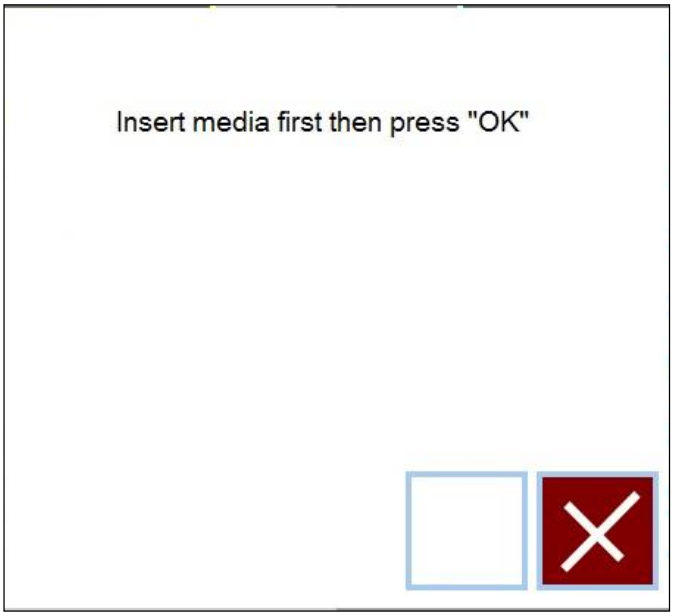
NOTE

Before starting this export, it is advisable to make sure that the removable drive does not contain other files.

By means of the “Utilities” menu, it is possible to enable this function clicking on the push button “Logs export”:

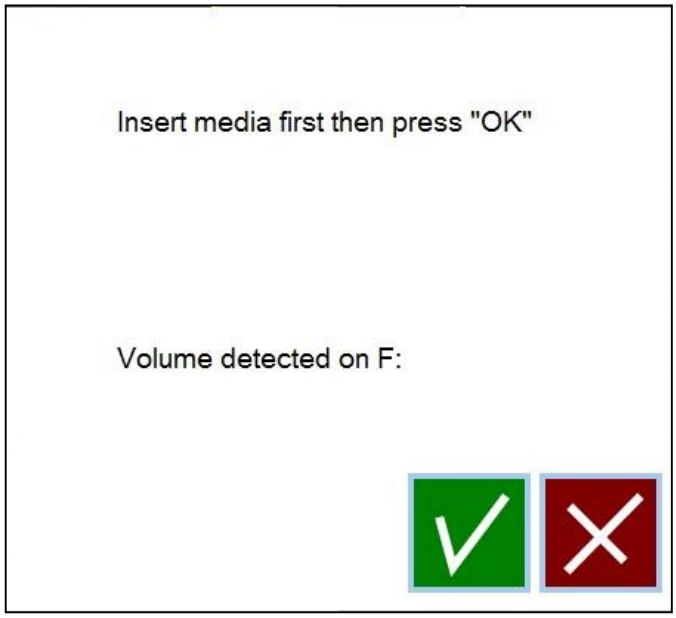


When the following window appears:



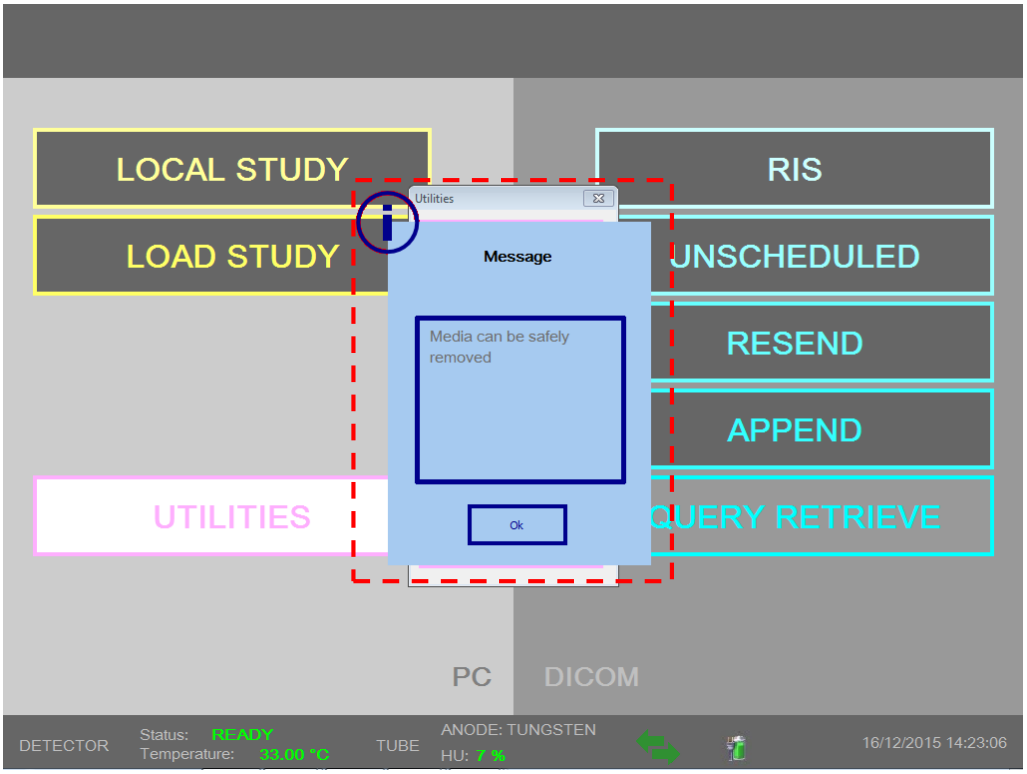
I nsert a removable drive.

The system automatically shows the following message after finding the drive inserted:



Clicking on "√", the process starts and may take several minutes.

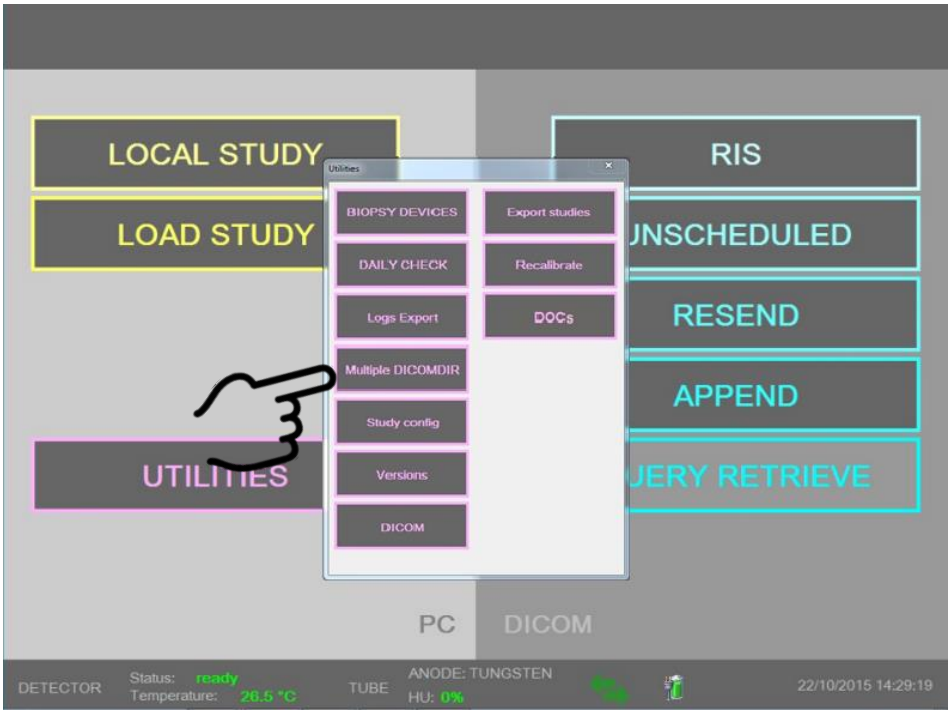
Only when recording succeed, the following message appears and the media can be removed.



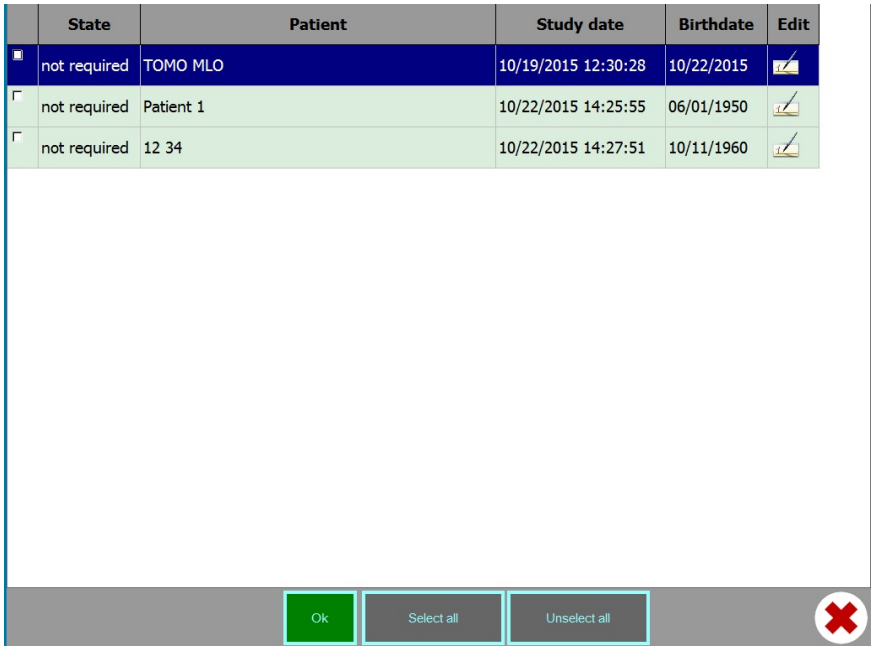
6.22. *MULTIPLE DICOMDIR*

This function allows to export the DICOM studies on CD/DVD or removable drives.

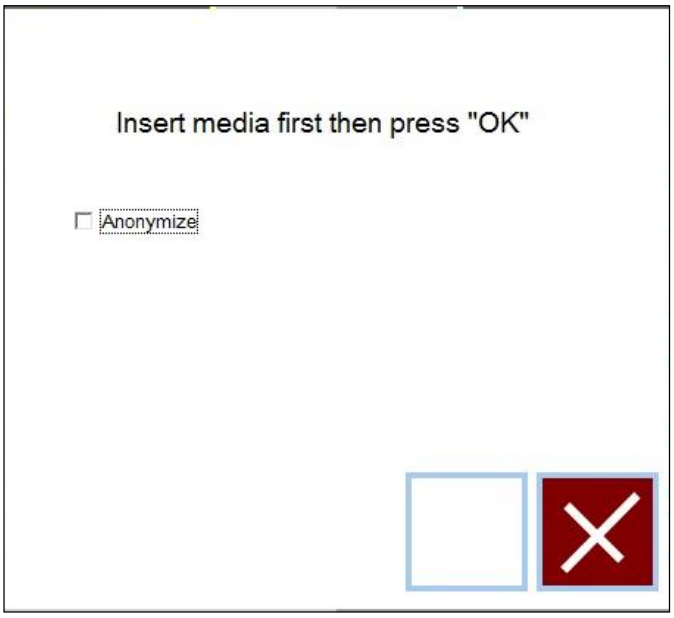
By means of the “Utilities” menu, it is possible to enable this function clicking on the push button “Multiple DICOMDIR”:



In this way, a window appears with the list of studies saved locally. Select the study to send to the media checking the corresponding box on the left and then click on “OK”:

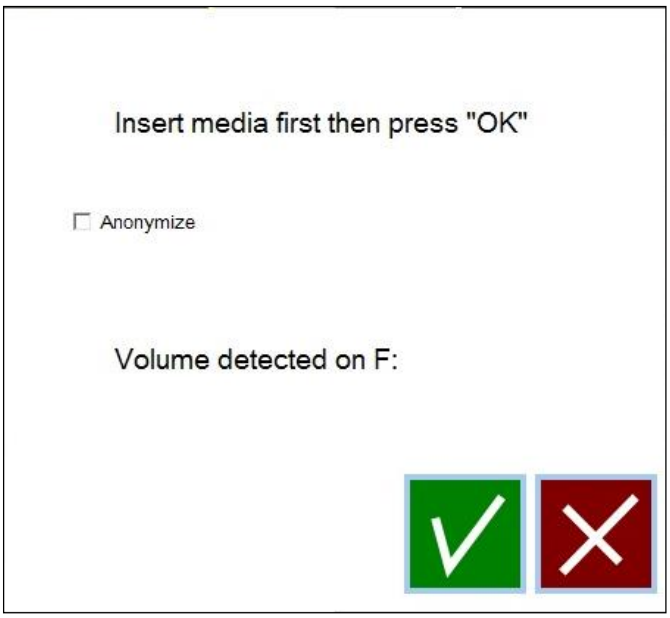


The following message appears:



Insert a removable drive.

The system automatically shows the following message after finding the drive inserted:



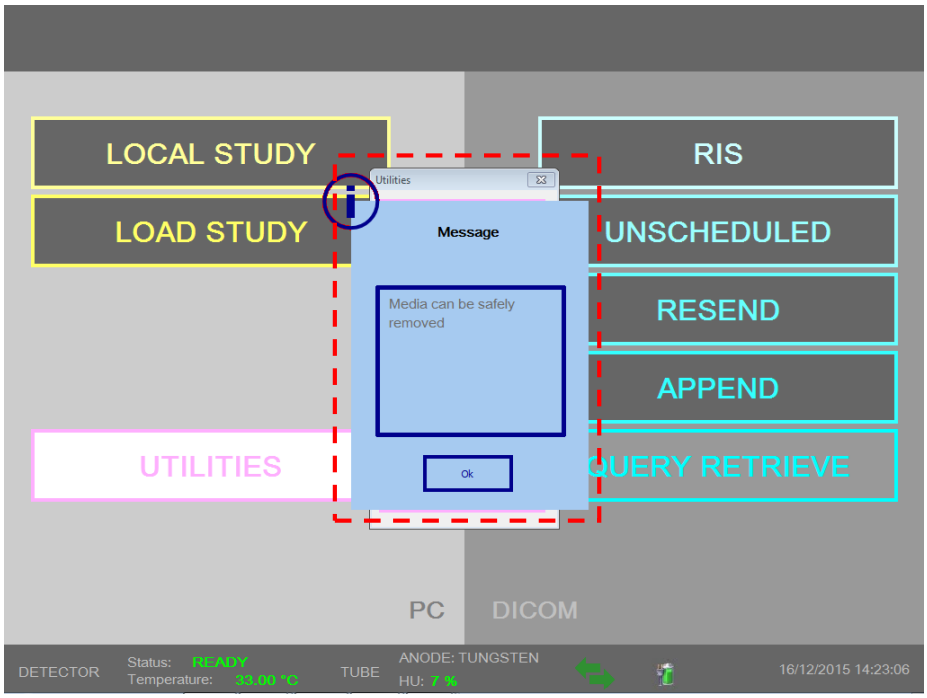
For an anonymous recording of the study select “Anonymize”.

NOTE

The anonymization procedure allows the substitution of the patient name with date and hour of the study export.

Clicking on “√”, the process starts and may take several minutes.

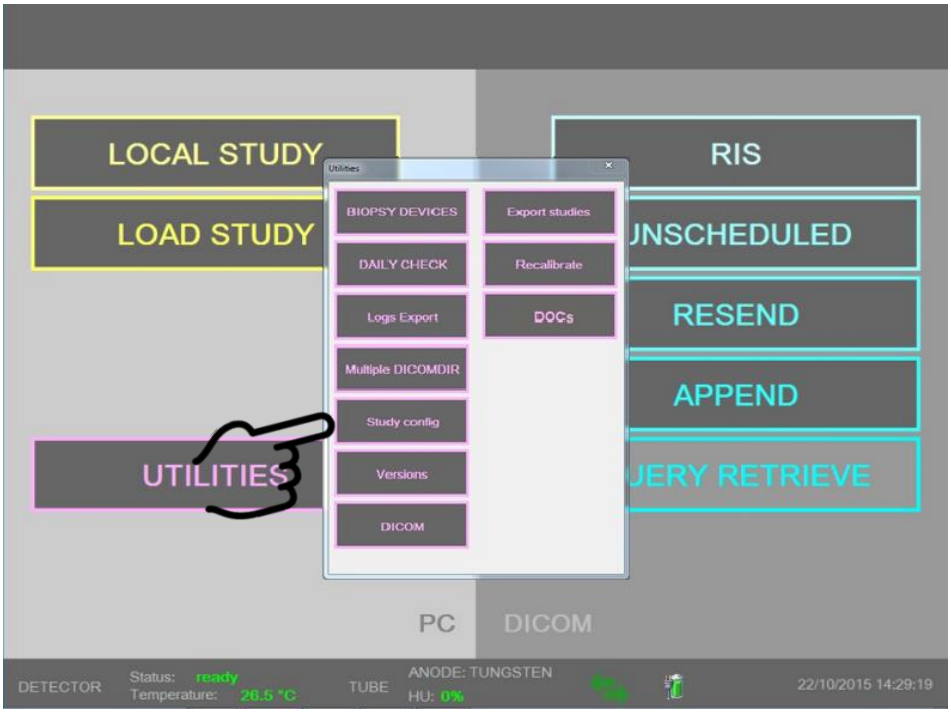
Only when recording succeed, the following message appears and the media can be removed.



In case of CD/DVD inserted will be automatically ejected.

6.23. *STUDY CONFIG*

By means of the “Utilities” menu, clicking on the push button “STUDY CONFIG”:



It is possible to integrate the DICOM tags with the following data:

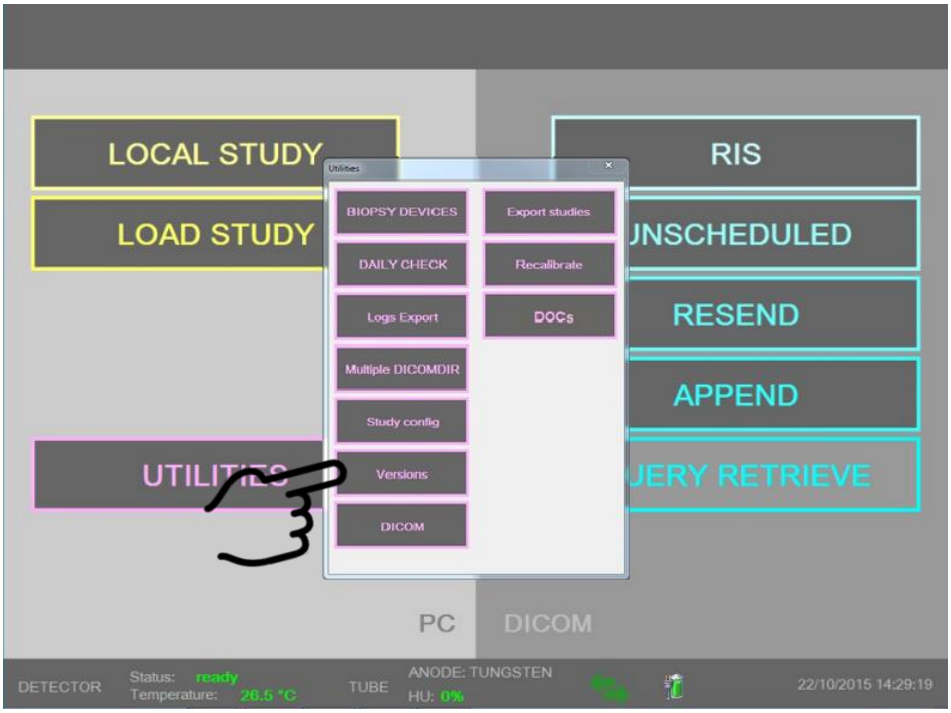
Operator’s name

Institution’s name

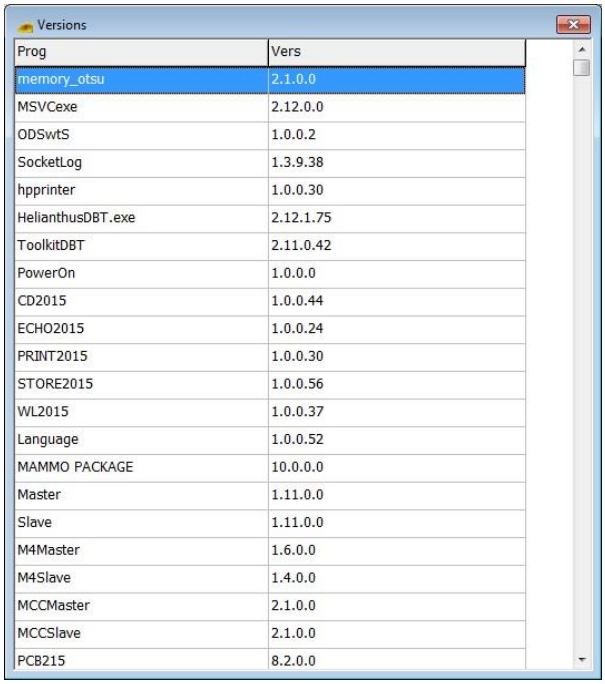
For both, after filling fields with the available information, click on “OK” to save them.

6.24. *VERSIONS*

By means of the “Utilities” menu, clicking on the push button “VERSIONS”:

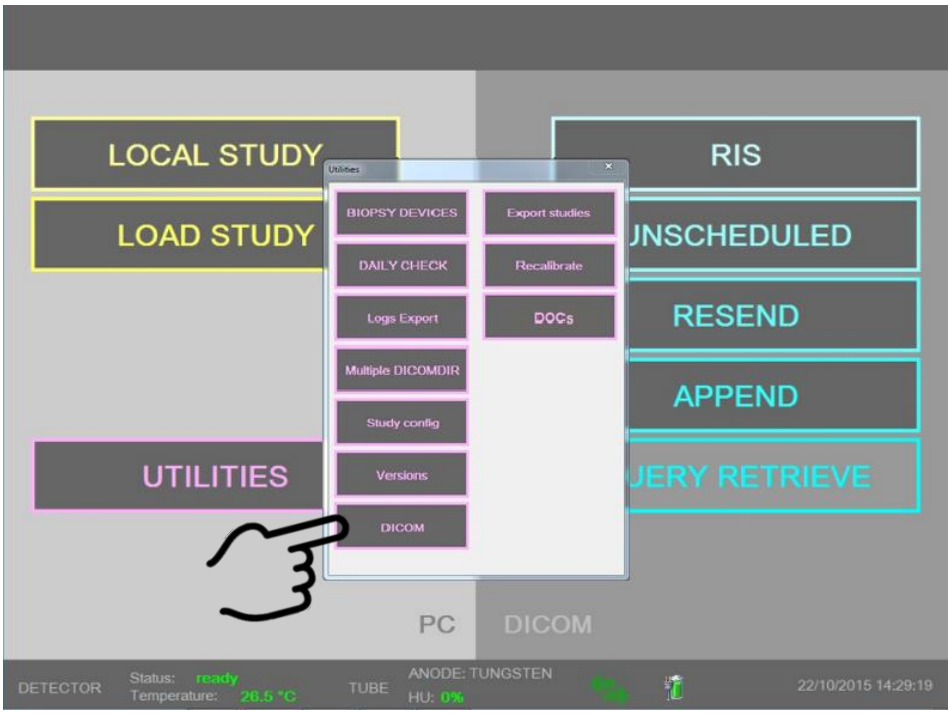


It is possible to check the FIRMWARE and SOFTWARE versions installed on the Mammo Unit:



6.25. *DICOM*

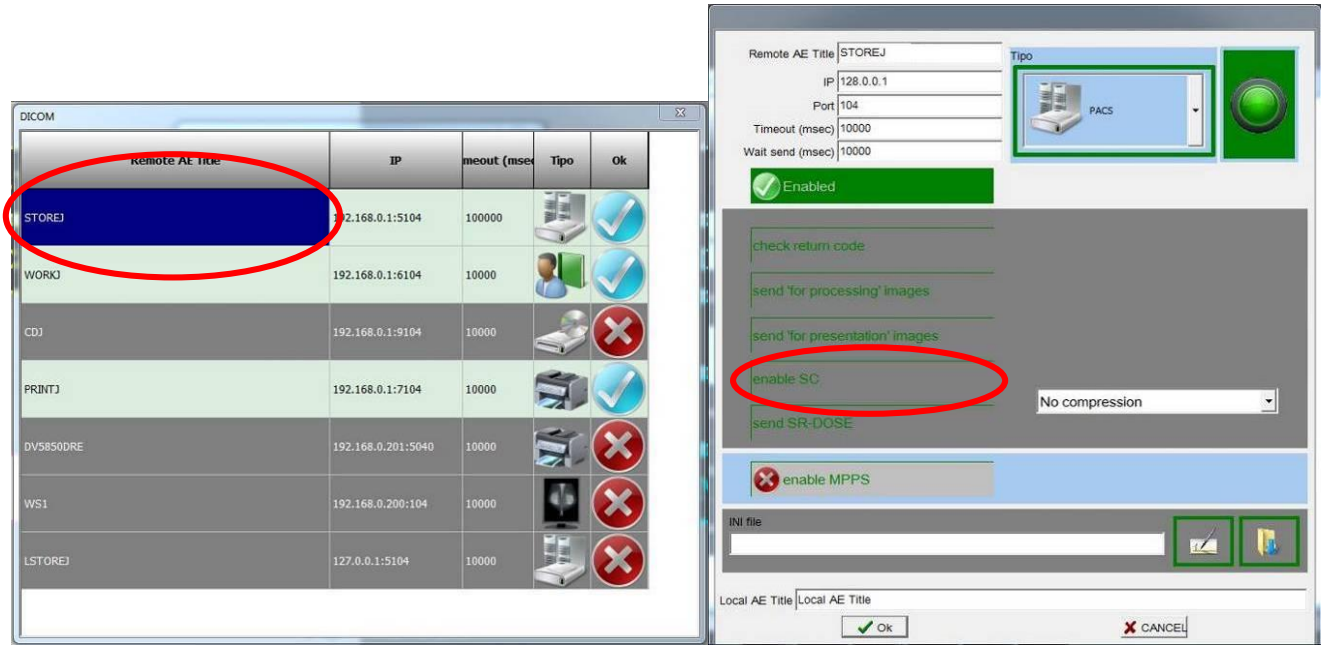
By means of the “Utilities” menu, clicking on the push button “DICOM”:



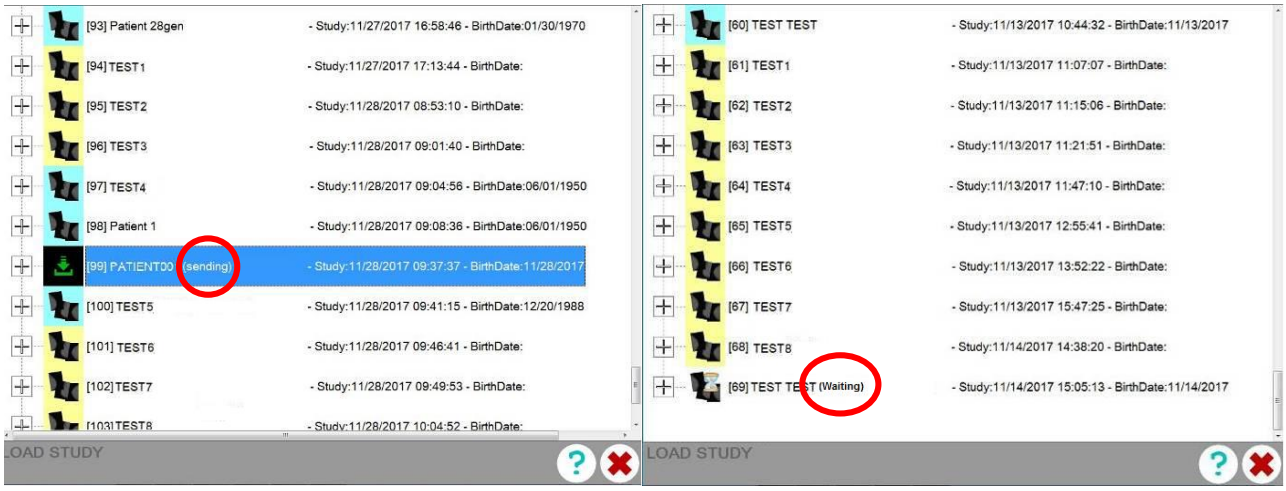
It is possible to check DICOM servers and their state of configuration:

Dicom Storage Commitment (SC)

In order to enable Storage Commitment (SC) click twice on the current AE (PACS) and select “Enable SC” as show in following figures:



In order to check the right working of DICOM service, it is possible to display the commitment status from “LOAD STUDY” menu. The study will be labeled as “(SENDING)” if SC works correctly. If no information are received, the load study will be marked as “(WAITING)” as shown in the following figures.

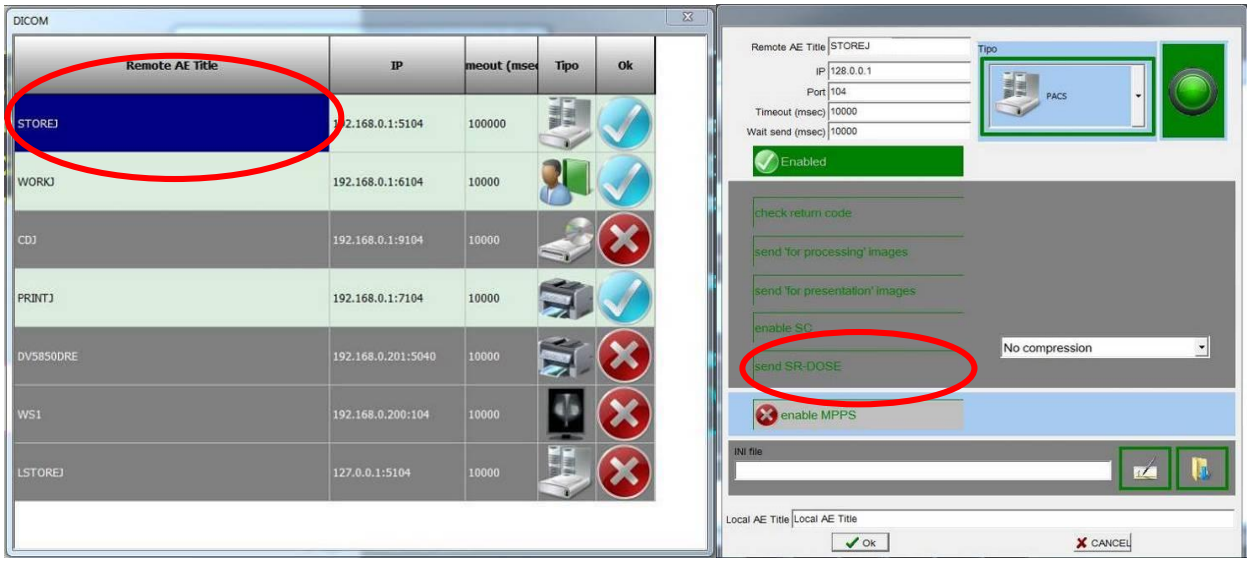


SR-DOSE sending service

In order to enable SR-DOSE sending service click twice on the highlighted current AE (PACS) and enable “send SR-DOSE”

NOTE

Enabled button “send SR-DOSE” in dicom mode configuration form related to REVIEW stations.



NOTE

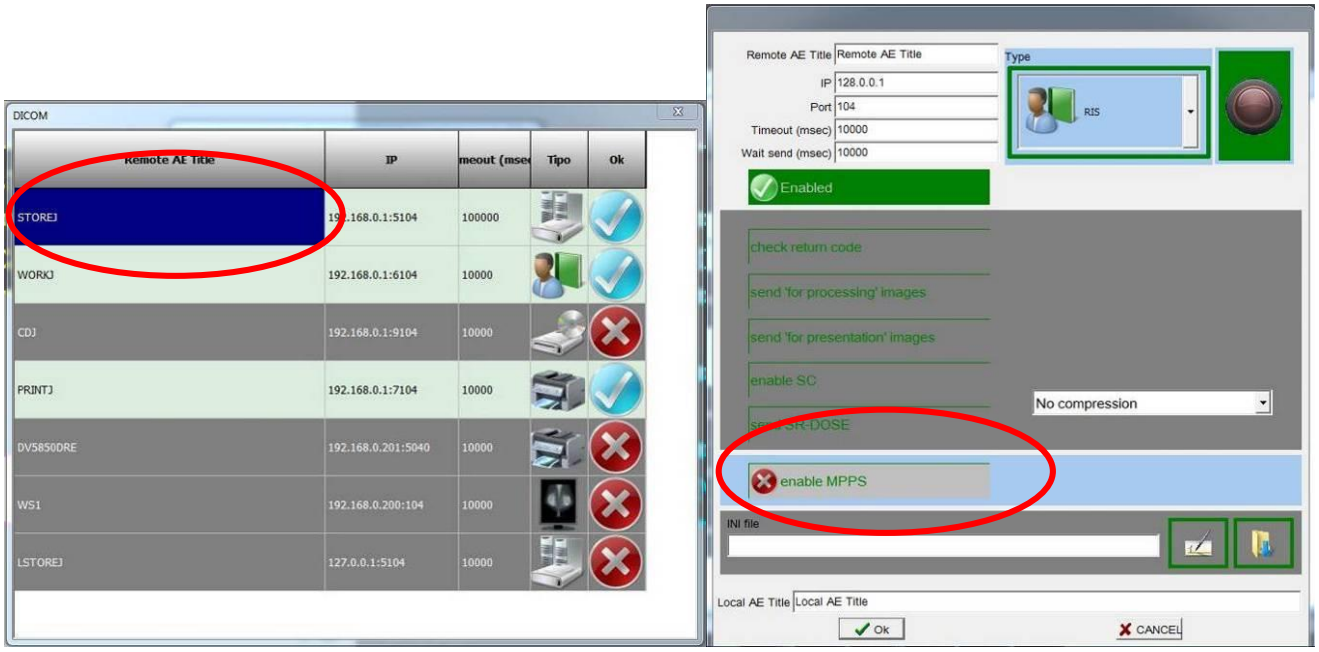
The PACS has to be able to receive SR-DOSE for a correct service availability

NOTE

SR-DOSE is always included in the EXPORT folder and in Multiple DICOMDIR modality.

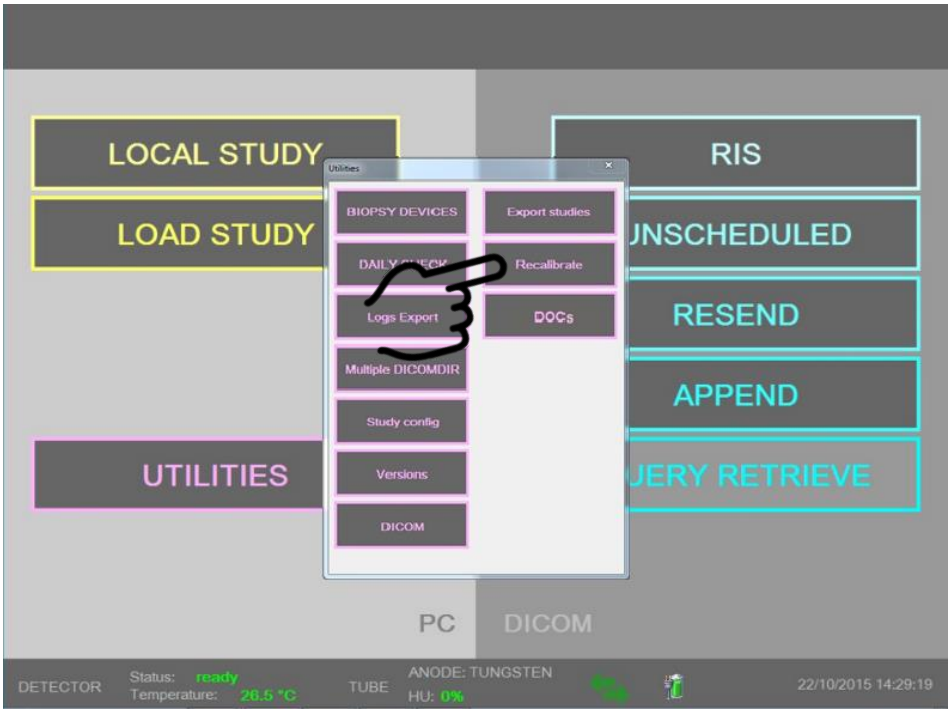
Dicom Modality Performed Procedure Step (MPPS)

In order to enable MPPS click twice on the current AE (RIS) and enable MPPS button as shown in the following figures



6.26. *RECALIBRATE*

By means of the “Utilities” menu, clicking on the push button “RECALIBRATE”:



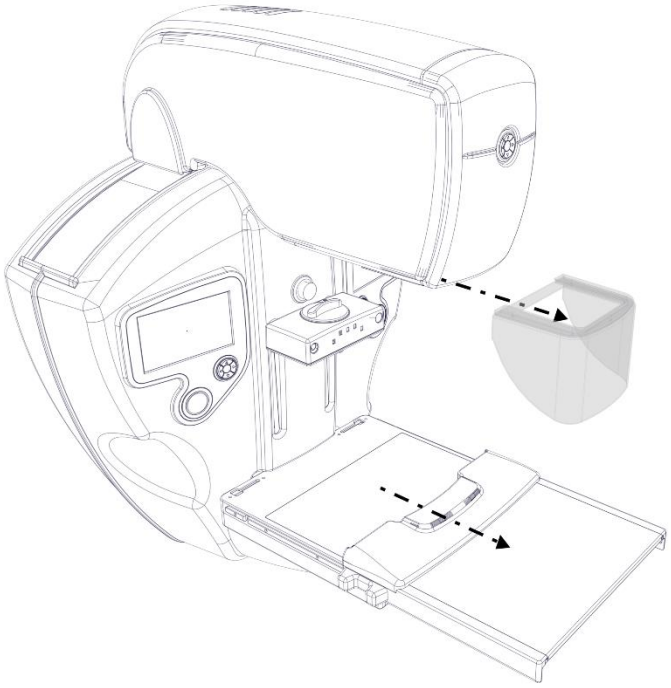
The calibration procedure (shading calibration) is mandatory before starting an exams for a-Si detector. To perform this procedure is necessary to use the phantom for periodical system calibration without compression in place of Potter-Bucky and protective screen. Moreover, itis necessary select the anode filter/combination (W/Rh or W/Ag) and perform the calibrate procedure only with large Focus.

NOTE

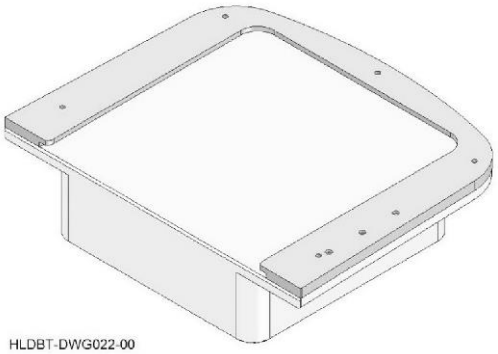
Before to perform the procedure the operator must clean the surface of detector.

For Shading Calibration:

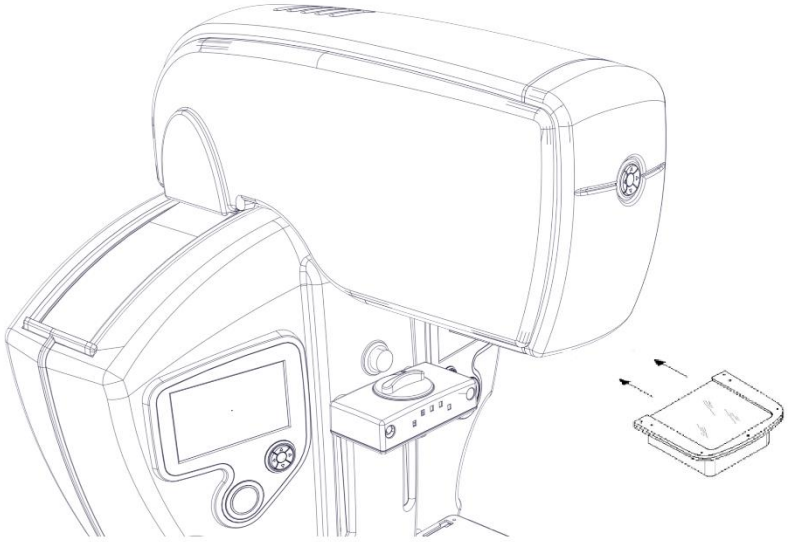
1. Remove Potter Bucky and Lexan protection screen



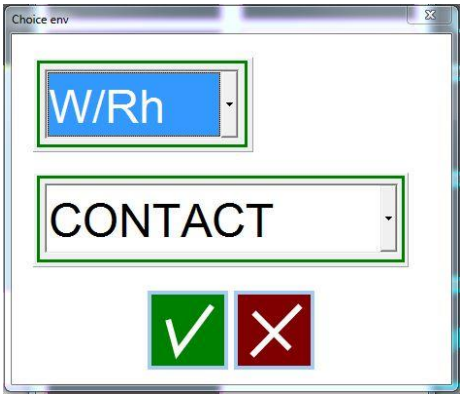
2. Plug in the calibration phantom



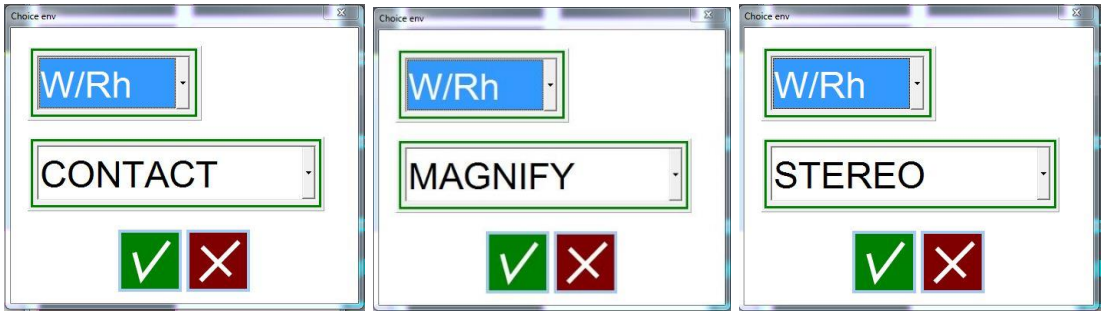
3. Place it as shown in the following picture

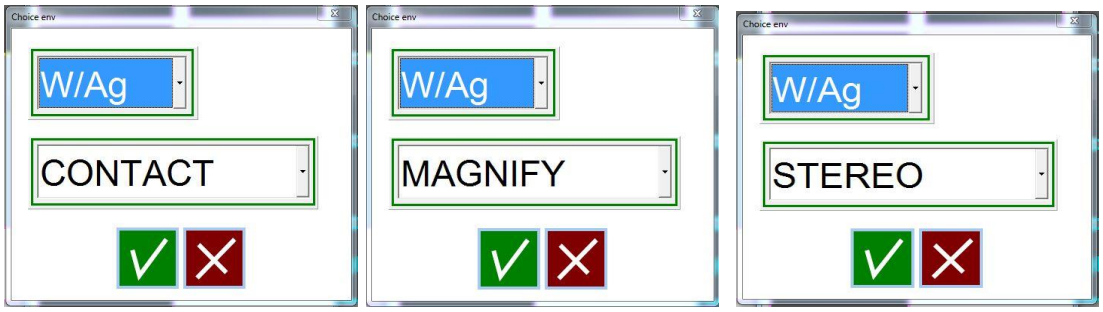


The following menu appears:



Select Anode-filter and context to be calibrated:

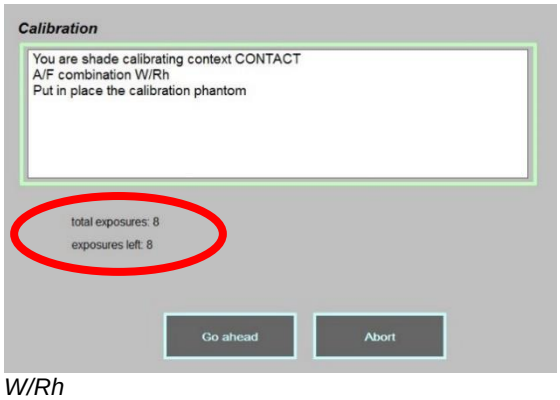




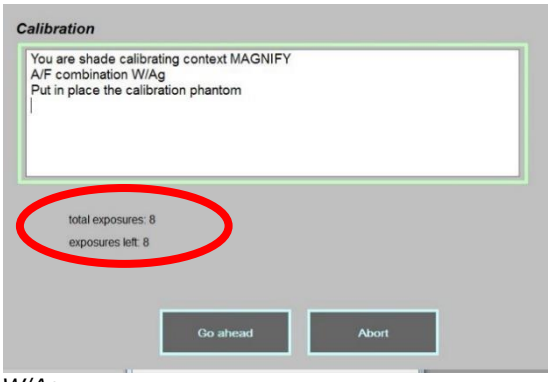
Once selected the parameters, pressing on

The following window appears:

1. Select “Go Ahead for each context and Press exposure button when required”



W/Rh



W/Ag

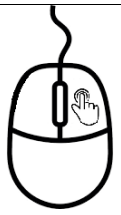
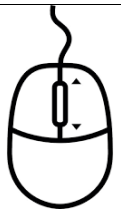
2. Press X-ray pushbutton when required.
3. Repeat step 2 for other 7 times, after 8th exposure the calibration is performed.

6.27. *DOCs*

By means of the “Utilities” menu, clicking on the push button “DOCs”:

Select document and click “ok” for visualization. It is possible select only one document at time. It is possible to interact with documents (e.g IFU, technical manual, etc) using a common mouse or trackball in **Navigation command table** above (Table 9).

Table 9

Navigation Command	***Mouse***
Go to the next page	
Zoom IN/Zoom OUT	
Close the document (“ESC” button with keyboard)	
Scroll up/down	

Section VII : Maintenance

7.1. GENERAL CONCEPTS

The expected service life of mammography unit is defined and based on Service and Maintenance Instructions contained in the Technical Manual and on applicable official QC protocols for image quality.

Maintenance procedures and checklist are included in Technical Manual and can be carried out only by qualified personnel.

General maintenance procedures are suggested every 6 months or recommended every 1 year as better described in Technical Manual.

Image quality inspection will be established according to locally applicable standards and QA protocols but periodicity must be less than six months.

User should be daily (or before every switching on of Mammo unit) check:

- External damages to covers or unit
- Check of mains and earth connections, cables and corrugated tube

7.2. ERROR MESSAGES

HELIANTHUS series is provided with a High internal diagnostic System.

For each malfunction a message appears to inform user on each unusual event.

In the following two tables all error messages are listed on the base of their univocal codes.

TABLE A

- **Column 1**: Error code
- **Column 2**: Error message displayed
- **Column 3**= What to do. If no suggested action is possible to solve the problem, please contact the Technical Assistance.

The following messages are displayed **ONLY** on the AWS DSP:

CODE	MESSAGE (EN)	USER CORRECTIVE ACTION
1221	"Media can be safely removed"	Informative.
1222	"Invalid media"	Insert valid Media
1226	"Daily check failed Performances may be degraded. Contact technical support: "	Contact technical support.
4002	"Ini file not found"	Export log files and contact technical assistance
4003	"PEGASUS interface not found"	Export log files and contact technical assistance
4004	"Unable to create PEGASUS pipe"	Export log files and contact technical assistance
4006	"Config file not found"	Export log files and contact technical assistance
5000	"Detector not responding\nMaybe off..."	Check if the detector is turned on and check the correct functionality and connection of the appropriate ethernet cable. Export log files and contact techinical assistance
5001	"Detector not initialized"	Check if the detector is turned on and check the correct functionality and connection of the appropriate ethernet cable. Export log files and contact techinical assistance
5002	"Mammo not responding\nMaybe off..."	Check if the mammography unit is turned on and check the correct functionality and connection of the appropriate ethernet cable.
5003	"Dose lower than expected"	Informative.
5004	"Select a marker to execute the procedure"	Select a marker and proceed or quit the procedure.
5005	"No study selected"	Informative.
5006	"Cannot select more than one study"	Select a single patient or abort the sending procedure.
5007	"Error in AE Title field"	contact technical assistance
5008	"Error in IP field"	Contact technical assistance
5009	"Error in Port field"	Contact technical assistance
5010	"Error in Timeout field"	Contact technical assistance
5011	"Wrong Accession number"	Insert a correst AccessionNumber or quit the procedure
5012	"Tube-Arm will move..."	Informative.
5015	"No printers found"	Quit the program, check the power and the correct functionality of the DICOM printers, check the correct configuration of the printer in the application. Acquire DICOM printers.
5016	"already running"	Wait for the end of the current export. Export log files and contact technical assistance.
5019	"Wait study sending..."	Wait for the sending to be finished
5020	"No device selected"	Insert a valid parameter
5021	"Not enough projections to compute slices. Image empty"	Early release button. Informative

CODE	MESSAGE (EN)	USER CORRECTIVE ACTION
5022	“Hard disk almost full”	Contact technical assistance
5023	"Tomo dose configuration files are missing. Degraded performance. Contact technical customer support."	Contact technical assistance
5024	"Tomo AEC configuration files are missing. Degraded performance Contact technical customer support."	Contact technical assistance
5025	AEC configuration files are missing. Degraded performance Contanct technical customer support."	Contact technical assistance
5026	"Air Kerma default configuration files used. Degraded performance Contact technical customer support"	Contact technical assistance
5027	"AEC data seems to have anomalous behaviour.Check image"	Follow indication
6000	“Depth not acceptable.\nMarker not usable”	Change projection. It’s impossible to perform a biopsy in the selected point.
6001	“Depth greater than breast thickness.\nMarker not usable”	Change projection. It’s impossible to perform a biopsy in the selected point.
6005	“Unable to identify Mammo”	Check if the mammography unit is turned on and check the correct functionality and connection of the appropriate 248thernet cable.
6007	“Wrong potter”	remove the biopsy device and insert the right potter (or vice-versa)
6008	“Cannot open study”	Export log files and contact technical assistance
6009	“Error changing wgl”	Export log files and contact technical assistance
6010	“Unable to perform enhancement”	Save the study, export log files and contact the technical assistance
6011	“Unable to compute percentage”	Check the positioning of the needed phantoms. Save the study, export log files and contact technical assistance.
6015	“Breast too thick”	If possible, apply an higher compression. Export the log files and contact the technical assistance.
6016	“No Breast detected”	Try to perform a new compression. Export the log files and contact the technical assistance.
6017	“Error computing synthetic image”	Close the study. Try reload it. If all ok try append the same study and go ahead with the protocol. Otherwise open an other study and terminate the protocol. – Restart system
6018	“CD Error: Pipe not present”	Fatal error. Avoid using CD or restart system
6019	“CD Error: Parser not present”	Fatal error. Avoid using CD or restart system
6020	“CD Error: Error creating files”	Fatal error. Avoid using CD or restart system
6021	“CD Error: Error defining recorders”	Fatal error. Avoid using CD or restart system
6022	“CD Error: Error initializing recorders”	Fatal error. Avoid using CD or restart system
6023	“CD Error: Not exclusive owner”	Fatal error. Avoid using CD or restart system
6024	“CD Error: Error crating image”	Fatal error. Avoid using CD or restart system
6025	“CD Error: Image too large for media type”	Media capacity insufficient for the operation. Change media or store less data
6026	“CD Error: Error creating file system”	Fatal error. Avoid using CD or restart system
6027	“CD Error: No CD/DvD inserted”	No disc inserted – Damaged disc inserted. Change disc
6028	“CD Error: Media not blank”	Non empty disc – Damaged disc inserted. Insert a disc or change it
6029	“Incorrect length”	Insert a valid parameter
6030	“Incorrect tip”	Insert a valid parameter
6031	“Incorrect tip length”	Insert a valid parameter
6034	“Unable to complete request to Mammo”	Export log files and contact technical assistance
6035	“Unable to save emission data”	Export log files and contact technical assistance
6036	“Error Copying files”	Media capacity insufficient for the operation. Change media or store less data
6037	“Invalid date”	Insert a valid date
6038	"Hard Disk FULL. New study disabile Urgently contact technical customer support"	Call Technical assistance
6039	“No Anode/filter combination available”	Contact technical assistance
6040	“Adapter in short circuit”	Contact technical assistance

CODE	MESSAGE (EN)	USER CORRECTIVE ACTION
6041	“Wrong adapter”	Install proper adapter. If proper adapter is already installed and problem persists, contact technical assistance
6042	“Error calibrating EO”	Contact technical assistance
6043	“Unable to create folder”	Check in UTILITIES→STUDY CONFIG that institution name doesn’t contains special characters. Or, check USB storage device integrity. If problem persists, contact technical assistance
6044	“Procedure not executable without compression”	Enable compression
6045	"Preference already exist"	A favourite biopsy device is already present: is not possible to add, as favourite device, two biopsy device with the same features
6046	Marker not valid for downward approach	Action not allowed
6047	You could not insert specimen collimator now	Remove collimator
6048	Unable to complete procedure. Remove collimator	Remove collimator
6900	"Unable to launch OTSU(n)"	Export log files and contact technical assistance
6901	"Unable to launch STORE2015"	contact technical assistance
6902	"Unable to launch ECHO2015"	contact technical assistance
6903	"Unable to launch WL2015"	contact technical assistance
6904	"Unable to launch QR2015"	Export log files and contact technical assistance
6905	"Unable to launch PRINT2015"	contact technical assistance
6906	"Unable to launch CD2015"	Restart the program. Export log files an contact technical assistance.
6907	"Unable to launch PEGASUS"	Export log files and contact technical assistance
6908	“Send SR-DOSE”	Export log files and contact technical assistance
6909	“Unable to launch MkDCM2015”	Export log files and contact technical assistance
8001	"Detector replaced"	contact technical assistance
8002	"Detector password expired"	Export log files and contact technical assistance
8003	"field not filled"	Insert the required fields/types or abort the study
8004	"Power-on error.\nPlease check if any emergency pushbutton\nis activated, unlock it and select Continue"	Follow the directions in the message. In case the problem is still not solved, contact technical assistance.
8005	"WARNING: The entire system will be now turned on.\nAre you sure you want to continue?"	Check if the system (MAMMO+AWS)turn on is effectively required and no service operations are on components which are going to be powered
F000	"The entire system is now going to shut down.\nClick OK to continue"	Check if the system (MAMMO+AWS) shut down is effectively required and no other activity is on going
F001	"Error in power-down sequence.\nPlease call for service"	contact technical assistance
F002	"Error in power-on sequence.\nPlease call for service"	contact technical assistance
F003	"Error in power-on sequence.\nPlease call for service"	contact technical assistance
F004	"Error in power-on sequence.\nPlease call for service"	contact technical assistance
F005	"Error in power-on sequence.\nPlease call for service"	contact technical assistance
F006	"Error in power-on sequence.\nPlease call for service"	contact technical assistance
F007	"Error in power-on sequence.\nPlease call for service"	contact technical assistance
F008	"Error in power-on sequence.\nPlease call for service"	contact technical assistance
F009	"Error in power-on sequence.\nPlease call for service"	contact technical assistance
F010	"Error in power-on sequence.\nPlease call for service"	contact technical assistance
F011	"Error in power-on sequence.\nPlease call for service"	contact technical assistance

CODE	MESSAGE (EN)	USER CORRECTIVE ACTION
F012	"Error in power-on sequence.\nPlease call for service"	contact technical assistance
0	"Unable to launch"	Export log files and contact technical assistance

MESSAGE (EN)	USER CORRECTIVE ACTION
“Pegasus interface has stopped working”	Switch off the calculator by means of the dedicated pushbutton and contact technical assistance

TABLE B

- **Column 1**: Error code
- **Column 2**: Error message title displayed
- **Column 3**: Error message description displayed
- **Column 4**= What to do. If no suggested action is possible to solve the problem, please contact the Technical Assistance.

The following messages are displayed **BOTH** on the AWS DSP and on the MAMMO TSD:

CODE	TITLE	DESCRIPTION	USER CORRECTIVE ACTION
[M:00001]	BIOPSY ERROR!	The X shaft activation failed to reach the requested target position	Repeat the command or reset the Biopsy device.
[M:00002]	BIOPSY ERROR!	The Y shaft activation failed to reach the requested target position.	Repeat the command or reset the Biopsy device.
[M:00003]	BIOPSY ERROR!	The Z shaft activation failed to reach the requested target position	Repeat the command or reset the Biopsy device.
[M:00101]	C-ARM ROTATION NOT ALLOWED!	One of the safety conditions prevent the C-ARM activation	Checks the rotation motor cover protection switch, the compression status, the integrity of the power supply.
[M:00102]	C-ARM ZERO SETTING ERROR!	A not allowed C-ARM zero setting has been requested.	Check the Startup completion or safety conditions..
[M:00103]	C-ARM ZERO SETTING ERROR!	A not allowed C-ARM zero setting has been requested.	Check the Startup completion or safety conditions..
[M:00104]	C-ARM ZERO SETTING ERROR!	Timeout during C-ARM zero setting process.	Check the cable connections.
M:00105]	C-ARM POSITIONING ERROR!	A not allowed C-ARM positioning has been requested.	Repeat the command;
M:00106]	C-ARM POSITIONING ERROR!	A not allowed C-ARM positioning has been requested.	Repeat the command;
M:00107]	C-ARM POSITIONING ERROR!	Timeout during C-ARM positioning process	Check the cable connections.
M:00108]	C-ARM POSITIONING ERROR!	Obstacle detected during positioning process	Check the cable connections.
[M:00109]	C-ARM DRIVER ERROR!	The C-ARM driver detected an internal error. See the C-ARM driver service panel	See the service panel for more information.
M:00110]	C-ARM INVALID ACTIVATION ERROR!	The C-ARM activation is currently disabled.	Check the safety conditions.
M:00111]	C-ARM WRONG RANGE ERROR!!	Out of allowed position range has been requested.	Repeat the command and check the command data.
M:00112]	C-ARM BUSY ERROR!	The C-ARM or the TUBE-ARM is currently running.	Repeat the command

CODE	TITLE	DESCRIPTION	USER CORRECTIVE ACTION
M:00113]	C-ARM SAFETY ERROR!	The C-ARM Engine cover is out of place.	Close the cover or check the cable integrity
M:00114]	C-ARM DRIVER COMMUNICATION ERROR	The System is unable to communicate to the C-ARM driver. See the C-ARM driver service panel and check the CAN BUS integrity and cabling	See the C-ARM driver service panel and check the CAN BUS integrity and cabling
M:00115]	C-ARM OBSTACLE SYSTEM FAILURE	The Obstacle detection system input is blocked.	Check the obstacle device integrity.
M:00116]	C-ARM POSITIONING ERROR	An excess resistance force has been detected during rotation.	Check the integrity of device and eventual obstacles in the movements
[M:00301]	COLLIMATION PROCEDURE FAILED!	Unlock then lock the compression paddle to force a new collimation attempt. If unsuccess restart the system.	Repeat the collimation sequence: unlock the compressor support and lock it again. This sequence will force e new collimation.
[M:00302]	FILTER SELECTION FAILED!	Repeat filter selection or restart the system	Repeat the filter selection
[M:00303]	MIRROR ACTIVATION FAILED!	Repeat the Mirror activation or reboot the system.	If the mirror has not been activated, repeat the command turning on the collimation light.
[M:00304]	UNABLE TO ACTIVATE THE COLLIMATION LAMP!	Repeat the collimation lamp activation action.	Turn on manually the collimation light.
[M:00401]	TUBE-ARM ACTIVATION NOT ALLOWED!	The Tube-Arm couldn't be configured or busy	Repeat the command or reboot the system.
[M:00402]	TUBE-ARM ZERO SETTING NOT ALLOWED!	The Tube-Arm couldn't be configured or busy	Repeat the command or reboot the system.
[M:00403]	TUBE-ARM ZERO SETTING NOT ALLOWED!	The Tube-Arm couldn't be configured or busy	Repeat the command or reboot the system.
[M:00404]	TUBE-ARM ERROR!	Timeout during zero setting process	Check the connection cables, the power supply.
[M:00405]	TUBE-ARM ACTIVATION NOT ALLOWED!	The Tube-Arm couldn't be configured or busy	Repeat the command or reboot the system.
[M:00406]	TUBE-ARM ACTIVATION NOT ALLOWED	The Tube-Arm couldn't be configured or busy	Repeat the command or reboot the system.
[M:00407]	TUBE-ARM ERROR!	Timeout during positioning process	Check the connection cables, the power supply.
[M:00408]	TUBE-ARM ERROR!	Obstacle detected during positioning process.	Check the connection cables, the power supply and the obstacle device integrity.
[M:00409]	TUBE ARM DRIVER ERROR	The TUBE-ARM driver detected an internal error. See the TUBE-ARM driver service panel	See the TUBE-ARM driver service panel
[M:00410]	TUBE-ARM ACTIVATION NOT ALLOWED	The Tube-Arm couldn't be configured or busy	Repeat the command or reboot the system.
[M:00411]	TUBE-ARM WRONG RANGE ERROR	The system requested a wrong Tube-Arm target angle.	Verify the current system configuration file related to the TubeArm targets.
[M:00412]	TUBE-ARM BUSY ERROR	The C-ARM or the TUBE-ARM is currently running.	Repeat the command

CODE	TITLE	DESCRIPTION	USER CORRECTIVE ACTION
[M:00413]	TUBE-ARM SAFETY ERROR	The external safety device has been activated. Switch off the system then check the TUBE-ARM integrity	Check the safety conditions and repeat the command
[M:00414]	TUBE-ARM DRIVER COMMUNICATION ERROR	The System is unable to communicate to the TUBE-ARM driver. See the TUBE-ARM driver service panel and check the CAN BUS integrity and cabling.	See the TUBE-ARM driver service panel and check the CAN BUS integrity and cabling.
[M:00415]	TUBE ARM OBSTACLE SYSTEM FAILURE	The Obstacle detection system input is blocked	See the TUBE-ARM driver service panel and check the CAN BUS integrity and cabling.
[M:00416]	TUBE ARM POSITIONING ERROR	An excess resistance force has been detected during rotation	Check the engine integrity.
[M:00501]	TUBE TEMPERATURE TOO HIGH!	The System cannot proceed with the X-RAY sequence until the Tube temperature decreases to a safer level.	Wait for the tube to cool down.
[M:00502]	FOCUS SETTING FAILED!	Repeat the operation or reboot the system.	Abort the exposure on the current view and repeat the current view selection, forcing the focal spot selection. Restart the unit
[M:00503]	ANODIC CURRENT ERROR!	The system detected a malfunction in the Anodic Current monitoring. Reboot the system.	Abort the exposure then contact technical assistance.
[M:00504]	GROUND CONNECTION ERROR!	The system detected a missing ground connection in the inverter device. Check the Ground connection	Abort the exposure then contact technical assistance.
[M:00505]	SYSTEM CALIBRATION ERROR	The Main power calibration is missing. See the HV calibration service panel	Abort the exposure then contact technical assistance.
[M:00506]	POWER VOLTAGE ERROR!	The system measured a wrong power voltage level. Check the main power or the power level calibration.	Abort the exposure then contact technical assistance.
[M:00507]	MAS METER MONITORING ERROR!	The system detected an anomaly in the mAsmeter device.	Abort the exposure then contact technical assistance.
[M:00508]	STAND-BY FILAMENT CURRENT ERROR!	The system detected a wrong stand-by filament current.	Abort the exposure then contact technical assistance.
[M:00509]	FILAMENT AMPLIFIER TEMPERATURE ERROR!	The system detected a too high Filament Amplifier temperature.	Abort the exposure then contact technical assistance.
[M:00510]	LOW SPEED STARTER ERROR!	Wrong MAIN-OFF current detected	Check the starter connection, the starter calibration, and the anode rotating wires and integrity.
[M:00511]	LOW SPEED STARTER ERROR!	Wrong SHIFT-OFF current detected	Check the starter connection, the starter calibration, and the anode rotating wires and integrity.
[M:00512]	LOW SPEED STARTER ERROR!	Wrong MAIN-RUN-MAX current detected	Check the starter connection, the starter calibration, and the anode rotating wires and integrity.
[M:00513]	LOW SPEED STARTER ERROR!	Wrong MAIN-RUN-MIN current detected	Check the starter connection, the starter calibration, and the anode rotating wires and integrity.
[M:00514]	LOW SPEED STARTER ERROR!	Wrong MAIN-KEEP-MAX current detected	Check the starter connection, the starter calibration, and the anode rotating wires and integrity.
[M:00515]	LOW SPEED STARTER ERROR!	Wrong MAIN-KEEP-MIN current detected.	Check the starter connection, the starter calibration, and the anode rotating wires and integrity.
[M:00516]	LOW SPEED STARTER ERROR!	Wrong SHIFT-RUN-MAX current detected	Check the starter connection, the starter calibration, and the anode rotating wires and integrity.

CODE	TITLE	DESCRIPTION	USER CORRECTIVE ACTION
[M:00517]	LOW SPEED STARTER ERROR!	Wrong SHIFT-RUN-MIN current detected	Check the starter connection, the starter calibration, and the anode rotating wires and integrity.
[M:00518]	LOW SPEED STARTER ERROR!	Wrong SHIFT-KEEP-MAX current detected	Check the starter connection, the starter calibration, and the anode rotating wires and integrity.
[M:00519]	LOW SPEED STARTER ERROR!	Wrong SHIFT-KEEP-MIN current detected.	Check the starter connection, the starter calibration, and the anode rotating wires and integrity.
[M:00520]	LOW SPEED STARTER ERROR!	Low Speed starter not calibrated.	Check the starter connection, the starter calibration, and the anode rotating wires and integrity.
[M:00521]	ANODE HU TOO HIGH!	The Tube Anode is too hot for further exposures	Wait until the Tube temperature drops to a valid level.
[M:00522]	X-RAY TUBE TEMPERATURE ERROR!	The X-RAY Tube temperature sensor seems to be damaged. Replace the sensor.	Abort the exposure then contact technical assistance.
[M:00601]	SYSTEM ERROR!	Restart the system.	repeat operation or restart the system
[M:00602]	SYSTEM ERROR!	The System detected non compatible device firmware revisions.	Restart the system
[M:00603]	WARNING!	The System is switching off in few seconds.	Wait for system switching off
[M:00701]	COMPRESSION PADDLE NOT CORRECTLY LOCKED!	Insert properly the compression paddle then lock it with the upper knob.	Insert the compression paddle correctly and lock it until the green light is on
[M:00702]	COMPRESSION PADDLE HOLDER NOT CORRECTLY LOCKED!	Insert properly the compression paddle holder then lock it with the lower knob.	Insert the compression paddle correctly and lock it until the green light is on
[M:00703]	UNDETECTED COMPRESSION PADDLE!	The system detected a wrong compression paddle code.	insert the compression paddle
[M:00704]	COMPRESSION BREAST WITH CLOSED STUDY!	It is strongly suggested to compress a breast only when in OPEN STUDY. In case of test session, ignore this message.	This is just a notice. It can be ignored. In case the message appears with a study opened or without an actual compression, call technical assistance
[M:00705]	UNDETECTED COMPONENT!	The system didn't detect a validComponent.	Insert the appropriate Component. Check the correct insertion of the Component, clicking at the end-run.
[M:00801]	MAGNIFICATION DEVICE ERROR!	Invalid magnification factor.	Call technical assistance
[M:00802]	MAGNIFICATION DEVICE ERROR!	Magnification device not configured.	Call technical assistance
[M:00901]	XRAY SEQUENCE DISABLED!	The current contest requires the use of lead protection.	Insert the calibration shield.
[M:00902]	XRAY SEQUENCE DISABLED!	The current contest requires the use of test phantom	Insert the test phantom
[M:00903]	XRAY SEQUENCE DISABLED!	The current contest requires the use of 2D protective screen.	Insert the protective screen for 2D exams.
[M:00904]	XRAY SEQUENCE DISABLED!	The Door of the room results open.	Close the door.
[M:00905]	XRAY SEQUENCE DISABLED!	Exposure data error. Repeat the sequence or restart the system.	Ripeat the exposure. Restart the system.
[M:00906]	XRAY SEQUENCE DISABLED!	IO system error. Repeat the sequence or restart the system.	Repeat the sequence or restart the system.
[M:00907]	XRAY SEQUENCE DISABLED!	Timeout High Speed Starter. Repeat the sequence or restart the system.	Repeat the exposure. Contact technical assistance.
[M:00908]	X-RAY SEQUENCE ABORTED!	X-ray push button early released.	Keep the button pushed during the exposure until the end of the beeping sound. Possibly, use both the x-ray buttons together.
[M:00909]	X-RAY SEQUENCE ABORTED!	X-ray push button early released.	Keep the button pushed during the exposure until the end of the beeping sound. Possibly, use both the x-ray buttons together.
[M:00910]	X-RAY SEQUENCE ABORTED!	X-ray push button early released.	Keep the button pushed during the exposure until the end of the beeping sound. Possibly, use both the x-ray buttons together.

CODE	TITLE	DESCRIPTION	USER CORRECTIVE ACTION
[M:00912]	X-RAY SEQUENCE ABORTED!	The Detector doesn't activate the EXP-WIN signal.	Repeat the exposure. Restart the system.
[M:00913]	X-RAY SEQUENCE ABORTED!	The system detected a too high kV output level.	contact technical assistance
[M:00914]	X-RAY SEQUENCE ABORTED!	The system detected a too low kV output level.	contact technical assistance
[M:00915]	X-RAY SEQUENCE ABORTED!	The system detected a too high anodic current output level.	contact technical assistance
[M:00916]	X-RAY SEQUENCE ABORTED!	The system detected a too low anodic current output level.	contact technical assistance
[M:00917]	X-RAY SEQUENCE ABORTED!	The system detected a too higher filament current output level.	Repeat the sequence. In case of new interruption, contact technical assistance.
[M:00918]	X-RAY SEQUENCE ABORTED!	The system detected a too higher filament voltage output level.	Repeat the sequence.
[M:00919]	X-RAY SEQUENCE ABORTED!	The system detected a too lower power supply voltage level.	Repeat the sequence.
[M:00920]	X-RAY SEQUENCE ABORTED!	X-ray sequence time out.	restart the system
[M:00921]	X-RAY SEQUENCE ABORTED!	Invalid kV selection. Check the X-ray tube configuration file.	Insert kV in the allowed range. Restart the system.
[M:00922]	X-RAY SEQUENCE ABORTED!	Invalid mAs selection. Check the X-ray tube configuration file.	Insert mAs in the allowed range. Restart the system.
[M:00923]	X-RAY SEQUENCE ABORTED!	Check the X-ray tube configuration file.	contact technical assistance
[M:00924]	X-RAY SEQUENCE ABORTED!	The selected kV level has not been calibrated. Proceed the calibration.	contact technical assistance
[M:00925]	X-RAY SEQUENCE ABORTED!	The selected mA of filament current has not been calibrated. Proceed the calibration.	Contact technical assistance.
[M:00926]	X-RAY SEQUENCE ABORTED!	Check the X-ray tube configuration file.	Contact technical assistance
[M:00927]	X-RAY SEQUENCE ABORTED!	The system requested the selection of a non configured focus.	Abort the current sequenceand select a new one.
[M:00928]	X-RAY SEQUENCE ABORTED!	The system requested a selection of a non configured filter.	Contact technical assistance.
[M:00929]	X-RAY SEQUENCE ABORTED!	The system requested a selection of a non configured collimation.	Contact technical assistance.
[M:00932]	X-RAY SEQUENCE ABORTED!	Invalid compression paddle in this context.	Insert the requested compression paddle.
[M:00933]	X-RAY SEQUENCE ABORTED!	Invalid compression paddle classification.	Remove and then insert again the current compression paddle.
[M:00934]	X-RAY SEQUENCE ABORTED!	Component not detected.	Insert the appropriate Component for the current exam.
[M:00935]	X-RAY SEQUENCE ABORTED!	C-arm position differs from the expected position.	Set the C-ARM in the target position requested by the acquisition work station.
[M:00936]	X-RAY SEQUENCE ABORTED!	Apply compression first.	Apply a compression.
[M:00937]	SYSTEM ERROR!	Internal error prevents the current sequence completion. Restart the system.	Restart the system.
[M:00938]	SYSTEM ERROR!	Internal error prevents the current sequence completion. Restart the system.	Restart the system.
[M:00939]	SYSTEM ERROR!	Internal error prevents the current sequence completion. Restart the system.	Restart the system.
[M:00940]	SYSTEM ERROR!	Internal error prevents the current sequence completion. Restart the system.	Restart the system.
[M:00941]	SYSTEM ERROR!	Internal error prevents the current sequence completion. Restart the system.	Restart the system.
[M:00942]	SYSTEM ERROR!	Internal error prevents the current sequence completion. Restart the system.	Restart the system.
[M:00943]	SYSTEM ERROR!	Internal error prevents the current sequence completion. Restart the system.	Restart the system.
[M:00944]	SYSTEM ERROR!	Internal error prevents the current sequence completion. Restart the system.	Restart the system.

CODE	TITLE	DESCRIPTION	USER CORRECTIVE ACTION
[M:00945]	X-RAY SEQUENCE ABORTED!	The system didn't receive the AEC data for the next exposure.	Repeat the sequence.
[M:00946]	X-RAY SEQUENCE ABORTED!	The system didn't receive the AEC data for the next exposure.	Repeat the sequence.
[M:00947]	X-RAY SEQUENCE ABORTED!	The system is unable to activate the dynamic collimation for the Tomo sequence. Repeat exposure or restart the system.	Repeat the sequence.
[M:00948]	X-RAY SEQUENCE ABORTED!	Error in HOME Tomo Tube-Arm positioning. Repeat exposure or restart the system.	Repeat the sequence.
[M:00949]	X-RAY SEQUENCE ABORTED!	Error in HOME Tomo Tube-Arm positioning. Repeat exposure or restart the system.	Repeat the sequence.
[M:00950]	X-RAY SEQUENCE ABORTED!	Error in Tube-Arm activation for the incoming Tomo sequence. Repeat exposure or restart the system.	Repeat the sequence.
[M:00951]	X-RAY SEQUENCE ABORTED!	Error in Tube-Arm activation for the incoming Tomo sequence. Repeat exposure or restart the system.	Repeat the sequence.
[M:00952]	X-RAY SEQUENCE ABORTED!	Error in CC Tomo Tube-Arm positioning.	Continue with a new sequence. This error doesn't compromise the last and completed sequence result.
[M:00953]	SYSTEM ERROR!	Internal error prevents the current sequence completion. Restart the system.	Restart the system.
[M:00954]	X-RAY SEQUENCE ABORTED!	The system has detected an invalid (or not configured) mag. factor.	Remove and then insert again the Component.
[M:00955]	X-RAY SEQUENCE ABORTED!	The system detected an invalid use of the Large Focus with the magnification device.	select the right focus for the Component in use (see configurations in the operator's manual)
[M:00956]	X-RAY SEQUENCE ABORTED!	The use of the small focus is allowed only with the magnification device in this contest.	select the right focus for the Component in use (see configurations in the operator's manual)
[M:00957]	X-RAY SEQUENCE ABORTED!	A detected obstacle prevents the Tomo sequence completion.	Remove the obstacle that prevents the Tube-Arm Movement.
[M:00958]	X-RAY SEQUENCE ABORTED!	Error in mirror positioning out of the field	Repeat the X-RAY sequence.
[M:00959]	X-RAY SEQUENCE ABORTED!	Error in HOME Tomo Tube-Arm positioning. Repeat exposure or restart the system.	Repeat the sequence.
[M:00960]	X-RAY SEQUENCE ABORTED!	Error in Tube-Arm activation for the incoming Tomo sequence. Repeat exposure or restart the system.	Repeat the sequence.
[M:00961]	XRAY SEQUENCE DISABLED!	The current contest requires the use of 3D protective screen.	Insert the protective screen for 3D exams.
[M:00962]	X-RAY SEQUENCE ABORTED!	Low speed starter error code: %1	Restart the system and repeat the exposure. If the error persist / exposure not allowed please contact technical assistance.
[M:00963]	X-RAY SEQUENCE ABORTED!	The Tube Anode is too hot for further exposures.	The tube Anode is to hot to be used, please stop exposure for few minutes.
[M:00964]	X-RAY SEQUENCE ABORTED!	The System cannot proceed with the X-RAY sequence until the Tube temperature decreases to a safer level.	The tube is to hot to be used, please stop exposure for few minutes.
[M:00965]	X-RAY SEQUENCE ABORTED!	The Tube temperature sensor can be damaged or not properly connected.	The temperature sensor for tube is damages or not connected, please contanct technical service.
[M:00966]	X-RAY SEQUENCE ABORTED!	The Tomo sequence cannot be executed because the Tube-Arm cannot be activated with the C-ARM in this position.	Change position to C-arm

CODE	TITLE	DESCRIPTION	USER CORRECTIVE ACTION
[M:01003]	COMPRESSOR DEVICE ERROR!	The Compresor device detected an excees compression. Power off the system and check the device integrity	Restart the system. In case of the problem should happens again, contact technical assistence.
[M:01101]	POWER MONITORING ERROR!	Power Down detected. Save the study then power off the system.	Follow Indications
[M:01102]	POWER MONITORING ERROR!	The Emergency Push Button has been activated. Reset the button to proceed.	Follow Indications
[M:01103]	POWER MONITORING ERROR!	The system is completing the power startup. Wait the power startup completion before to activate the C-ARM or to expose.	Follow Indications
[M:01201]	POWER MONITORING ERROR! DRIVER LENZE ERROR!	The position sensor cable appears disconnected .	Check the position sensor cable
[M:01202]	DRIVER LENZE ERROR!	Wrong position sensor connection detected	Check the position sensor cable
[M:01203]	DRIVER LENZE ERROR!	The Driver detected an internal error. Check the Lenze Driver service panel.	Check the Lenze Driver service panel
[M:01204]	DROP C-ARM SIGNAL DETECTED!	The C-arm control system could be damaged. Switch off the system and contact service.	contact service.
[M:01301]	X-RAY PUSH BUTTON ERROR!	The system detected the X-RAY push button blocked.	Check the xray push button integrity
[M:01401]	COMPRESSION PEDAL ERROR!	The compression pedal blocked. Release the pedals or check the pedal integrity	Check the compression pedal integrity
[M:01501]	LENZE ERROR!	The pedals result blocked. Release the pedals or check the pedal integrity	Check the lenze pedal integrity
[M:01601]	C-ARM MANUAL PUSH BUTTON ERROR!	The C-ARM manual activation push buttons result blocked!	Check the C-ARM manual buttons integrity
[M:01701]	SYSTEM NOT READY FOR EXPOSURE!	The system didn't start correctly	Check System and Call Technical assistance
[M:01702]	SYSTEM NOT READY FOR EXPOSURE!	The Main power calibration is missing	Call Technical assistance
[M:01703]	SYSTEM NOT READY FOR EXPOSURE!	Low Speed starter not calibrated	Call Technical assistance
[M:01704]	SYSTEM NOT READY FOR EXPOSURE!	The Door of the room results open	Please, close the Door
[M:01705]	SYSTEM NOT READY FOR EXPOSURE!	The system detected a wrong compression paddle code.	Please, select correct compression paddle
[M:01706]	SYSTEM NOT READY FOR EXPOSURE!	Apply compression first	Follow indication
[M:01707]	SYSTEM NOT READY FOR EXPOSURE!	Invalid Component.	Please, select correct Component
[M:01708]	SYSTEM NOT READY FOR EXPOSURE!	Missing patient protection	Please, use patient protection
[M:01709]	ACTION NOT ALLOWED!	The operating page is disabled when the toolkit is connected	Informative
[M:01801]	SYSTEM ERROR!	The generator's configuration file is corrupted.	contact techincal assistance

CODE	TITLE	DESCRIPTION	USER CORRECTIVE ACTION
[M:01802]	CONFIGURATION ERROR!	The generator's configuration file is corrupted.	contact techincal assistance
[M:01803]	CONFIGURATION ERROR!	The Dose calculator is not configured for the installed filters.	contact techincal assistance
[M:01804]	SYSTEM ERROR!	The system detected an invalid power up sequence completion. Try to restart the system	contact techincal assistance
[M:01805]	CONFIGURATION ERROR!	Missing collimator configuration file.	contact techincal assistance
[M:01806]	CONFIGURATION ERROR!	Missing compressor configuration file.	contact techincal assistance
[M:01807]	CONFIGURATION ERROR!	Missing system configuration file.	contact techincal assistance
[M:01808]	CONFIGURATION ERROR!	Missing system configuration file	contact techincal assistance
[M:01809]	CONFIGURATION ERROR!	Missing system configuration file	contact techincal assistance
[M:01810]	CONFIGURATION ERROR!	Missing Serial Number.	contact techincal assistance
[M:01811]	CONFIGURATION ERROR!	Missing system configuration file.	contact techincal assistance
[M:01901]	ERROR C-ARM PARKING!	Error during the Tube Arm repositioning.	Call technical assistance
[M:01902]	ERROR C-ARM PARKING!	Up/Down motor busy.	Call technical assistance
[M:01903]	ERROR C-ARM PARKING!	Up/Down motor activation Timeout.	Call technical assistance
[M:01904]	ERROR C-ARM PARKING!	Up/Down positioning failed.	Call technical assistance
[M:01905]	ERROR C-ARM PARKING!	C-ARM rotation Timeout.	Call technical assistance
[M:01906]	ERROR C-ARM PARKING!	C-ARM shall be rotated to 180° to proceed.	Follow indications
[M:01907]	C-ARM PARKING ACTIVATION!	Be careful, C-ARM is moving.	Follow indications
[M:01908]	C-ARM UNPARKING ACTIVATED!	Be careful, C-ARM is moving.	Follow indications
[M:01909]	C-ARM PARKING ACTIVATION ERROR!	The Parking position isn't calibrated.	Call technical assistance

7.3. CLEANING AND DISINFECTION

MAMMOGRAPHY UNIT

Regular cleaning of the compression paddle and Potter-Bucky (or magnification device) is necessary prior to proceed with examination.

Use only a soft cloth and distilled water to avoid damage to protective plate of compression paddle getting it hard with risks of cracks. For other surfaces use cleaning agents that do not damage plastics, aluminum and carbon fiber.

CAUTION

Do not use abrasive detergents or harsh cleaners.
Do not use excess of liquid and be careful washing liquid does not drip inside detector or mammography unit.
Do not use steam or high temperature liquid on equipment parts.
Do not use cleaning sprays directly to avoid to damage electronic components.

Wipe any parts that contact the patient using a clean lint-free or pad.

WARNING

To cleaning and disinfecting parts that has come in contact with blood or other potentially infectious materials follows a protocol assigned by your Infection Control representative.

To avoid electrostatic dust collection over the plastic covers, use anti-static dashboard wet-wipes.

ACQUISITION WORK STATION

LCD SCREEN AND TOUCH SCREEN DISPLAYS

To clean the LCD screen, use a microfiber cloth to remove any obvious dust and gently brush off any dirt particulars.
Although use a 50/50 solution of distilled water/isopropyl alcohol, using a clean soft, lint-free cloth. Very, very gently wipe the screen in a circular motion. Do not press hard on the cloth. Let the cleaning solution do its job.
It is recommended acquire a proper cleaning kit (with an alcohol and ammonia-free solution) to clean and keep LCD screen in a crisp clear pristine condition.

CAUTION

Never spray any cleaning solutions directly onto the screen, spray it into the cleaning cloth.
Do not press hard or touch the screen with to avoid leave oily prints and smears.

TRANSPARENT ANTI-X PROTECTIVE BARRIER

To clean the transparent anti-X protective barrier, use any specific glass cleaner and a clean soft, lint-free cloth. Then wipe carefully the surface with another dry cloth.

CAUTION

Never spray any cleaning solutions directly onto the anti-X protective barrier, spray it into the cleaning cloth.
Be careful detergent liquid does not drip on desk.

7.4. DETECTOR FANS FILTERS CHECK AND REPLACEMENT

The air flow for Detector cooling is protected from dust by washable and reusable Polyurethane Foam filters (1/4" Thick, 45 Pores/Inch).

Dust affects reliability because a thick layer of dust can exhibit a certain amount of electrical capacitance and conductivity. Just as seriously, it will reduce the working life of fans and increase the risk of overheating.
The Foam density has designed to be high enough to catch dust, but low enough not to reduce airflow.

In particularly dusty places, every month, it's advisable to verify filters cleaning to avoid a dust accretion. If filters are dirty must be replaced quickly with new others.
In any case, the filters must be changed periodically with a frequency depending by the installation environment.
The dirty filters can be washed (only with water) and reused totally dry in the next replacement.
The filters replacement procedure is described on Technical Manual and must be carried out only by Qualified Personnel.

If periodic inspection is not carried out and filters gaps are obstructed the cooling fans can periodically oscillate with a rate of about 2/3 s generating a typical audible noise that can recall the operator attention.
Filters obstruction cause a Detector overheating. In this case the temperature can go out of calibration range and a red message is visible on Status Bar (see also the Section V and Paragraph 6.2.1 of this Manual).

CAUTION Detector fans filters must be changed only with original kit.

7.5. MOVING THE UNIT TO ANOTHER PLACE

Refer to Technical Manual and use only qualified personnel.

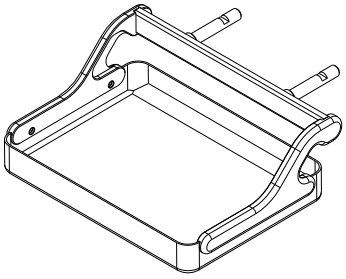
Section VIII: Auxiliary Components & Optional Parts

8.1. LIST OF AUXILIARY COMPONENTS

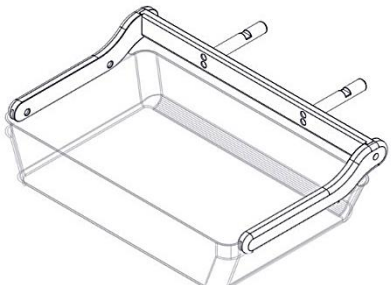
AUXILIARY COMPONENTS	DESCRIPTION	CODE NUMBER	PART NUMBER
COMPRESSION PADDLES	24x30 cm FORMAT COMPRESSION PADDLE	$C-VAR$-CMT24X30	K-CMT24X30
	24x30 cm FORMAT COMPRESSION PADDLE (TOMO exam)	$C-VAR$-CMT3D_A	K-CMT3D_A
	18x24 cm FORMAT COMPRESSION PADDLE WITH LATERAL SHIFTING	$C-VAR$-CMT18/24/30	K-CMT18/24/30
	10x24 cm FORMAT COMPRESSION PADDLE	$C-VAR$-CMT10X24	K-CMT10X24
	9x21 cm FORMAT COMPRESSION PADDLE FOR MAGNIFICATION	$C-VAR$-CMT9X21	K-CMT9X21
	18x24 cm FORMAT SPOT D75 COMPRESSION PADDLE	$C-VAR$-CMT18X24SP	K-CMT18X24SP
	18x24 cm FORMAT COMPRESSION PADDLE FOR 2D BIOPSY	$C-VAR$-CMTB18X24	K-CMTB18X24
	Φ 7.5 cm FORMAT SPOT COMPRESSION PADDLE FOR MAGNIFICATION	$C-VAR$-CMTS75M	K-CMTS75M
	9X9 cm FORMAT SPOT COMPRESSION PADDLE FOR MAGNIFICATION	$C-VAR$-CMTS90M	K-CMTS90M
	10x24 cm FORMAT COMPRESSION PADDLE FOR PROSTHESES	$C-VAR$-CMTP10X24	K-CMTP10X24
	18x24 cm FORMAT SQUARE SPOT COMPRESSION PADDLE	$C-VAR$-CMT18X24/9X9	K-CMT18X24/9X9
POTTER-BUCKY	24X30 CM POTTER-BUCKY WITH 2D GRID	$C-VAR$-PMD2-DBT/2D	$C-VAR$-PMD2-DBT/2D
	24X30 CM POTTER-BUCKY WITH 3D GRID	$C-VAR$-PMD2-DBT/3D	$C-VAR$-PMD2-DBT/3D
MAGNIFER	DEVICE FOR GEOMETRIC MAGNIFICATION WITH VARIABLE (1,5x,2x) FACTOR	$C-VAR$-7INFL/DBT	ING DMD
STEREOTACTIC BIOPSY DEVICE (STD CONFIG)	**BIOPSY DEVICE**	**$C-VAR$SBD/T2**	
	NPU	$D-BYM3D/SBD$-CRP-TRT	$D-BYM3D/SBD$-CRP-TRT
	NEEDLE SIMULATOR	AEM0250	AEM0250
	14x17 cm FORMAT COMPRESSION PADDLE	$C-VAR$-CMTB14X17	K-CMTB14X17

AUXILIARY COMPONENTS	*DESCRIPTION*	*CODE NUMBER*	*PART NUMBER*
STEREOTACTIC BIOPSY DEVICE (FULL CONFIG)	**BIOPSY DEVICE**	**$C-VAR$SBD/T2-LA**	**AI-DG-BIOPSY-FULL**
	NPU	AEM0227	AEM0227
	14x17 cm FORMAT COMPRESSION PADDLE (TWO INTERCHANGEABLE PLANS)	AEM0261	AEM0261
	REMOTE CONTROL	AEM0222	AEM0222
	NEEDLE SUPPORT	AEM0224	AEM0224
	NEEDLE SIMULATOR	AEM0250	AEM0250
	BIOPSY SPACER	MQ12183	MQ12183
BIOPSY SPECIMEN	BIOPSY SPECIMEN COLLIMATION PLATE	AME0111	AME0111
ANTI-X BARRIER	STANDALONE ANTI-X BARRIER FOR OPERATOR PROTECTION (0,34EQ.PB)	$C-3MT$-ANTI-X	$C-3MT$-ANTI-X
	STANDALONE ANTI-X BARRIER FOR OPERATOR PROTECTION (0,5 EQ.PB)	$C-HF$-ANTI-X	$C-HF$-ANTI-X
PROTECTIVE SCREEN	STANDARD EXAMINATION	$C-DBT$-SCH-PAZ/PMA	$C-DBT$-SCH-PAZ/PMA
	EXTENDED PROTECTIVE SCREEN TO KEEP PATIENT'S FACE OUT OF X-RAY BEAM DURING TOMO EXAMS	$D-HDT$-SCH-PAZ-LG/3D	$D-HDT$-SCH-PAZ-LG/3D

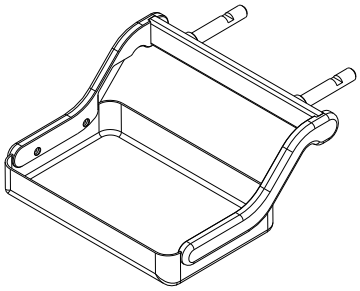
COMPRESSION PADDLES



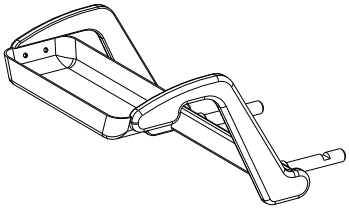
24x30 cm FORMAT COMPRESSION PADDLE



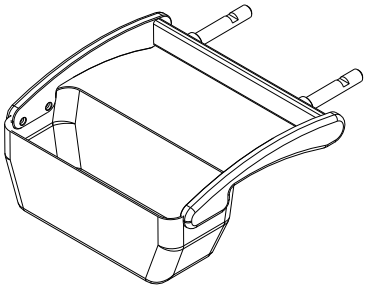
24x30 cm FORMAT COMPRESSION PADDLE (TOMO exam)



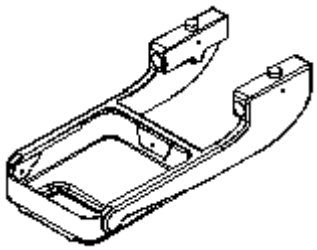
18x24 cm FORMAT COMPRESSION PADDLE WITH LATERAL SHIFTING



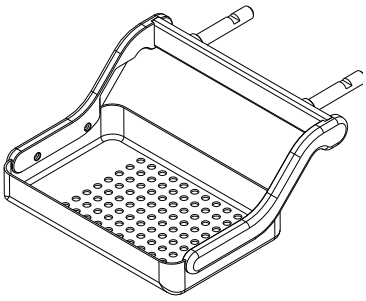
9x21 cm FORMAT COMPRESSION PADDLE FOR MAGNIFICATION



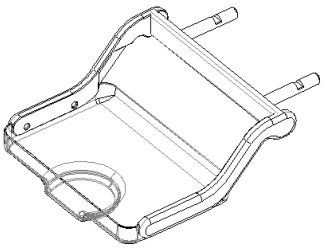
10x24 cm FORMAT COMPRESSION



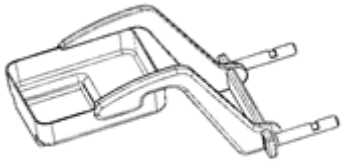
14x17 cm FORMAT COMPRESSION PADDLE FOR BIOPSY



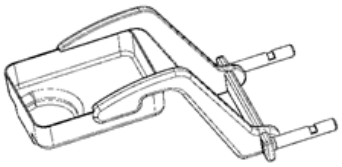
9x9 cm FORMAT SPOT COMPRESSION PADDLE FOR MAGNIFICATION



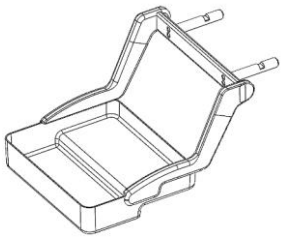
18x24 cm FORMAT SPOT D75 COMPRESSION PADDLE



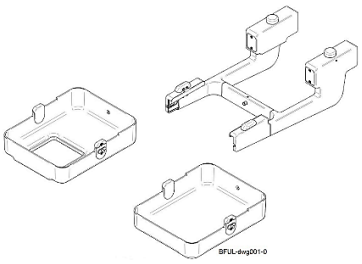
18x24 cm FORMAT COMPRESSION PADDLE FOR 2D BIOPSY



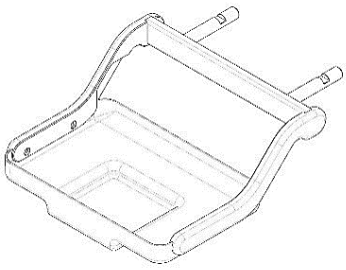
Φ 7.5 cm FORMAT SPOT COMPRESSION PADDLE FOR MAGNIFICATION



10x24 cm FORMAT COMPRESSION PADDLE FOR PROSTHESIS

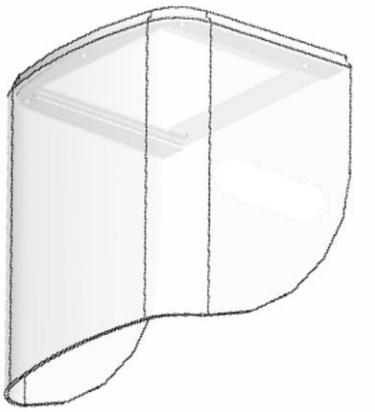


14x17 cm FORMAT COMPRESSION PADDLE FOR FULL CONFIGURATION BIOPSY (TWO INTERCHANGEABLE PLANS)

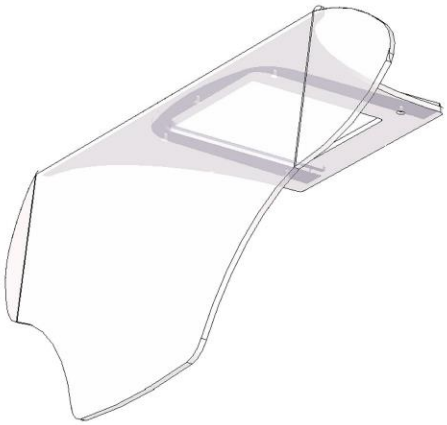


18x24 cm FORMAT SQUARE SPOT COMPRESSION PADDLE

PROTECTIVE SCREENS

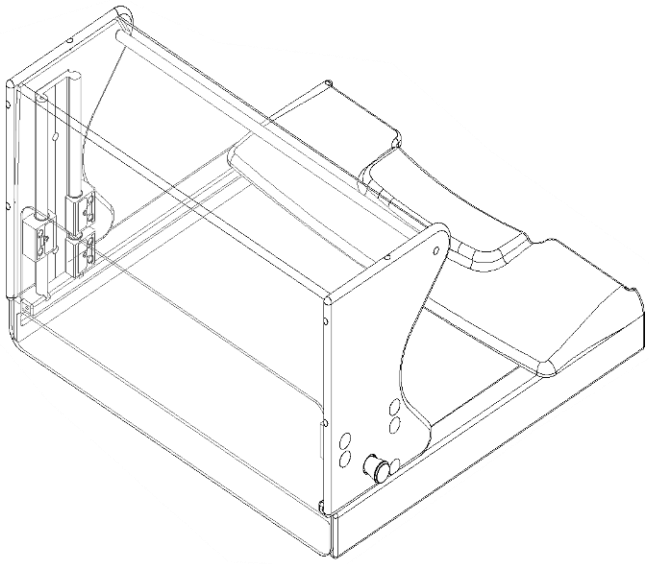


FOR BI-DIMENSIONAL EXAM

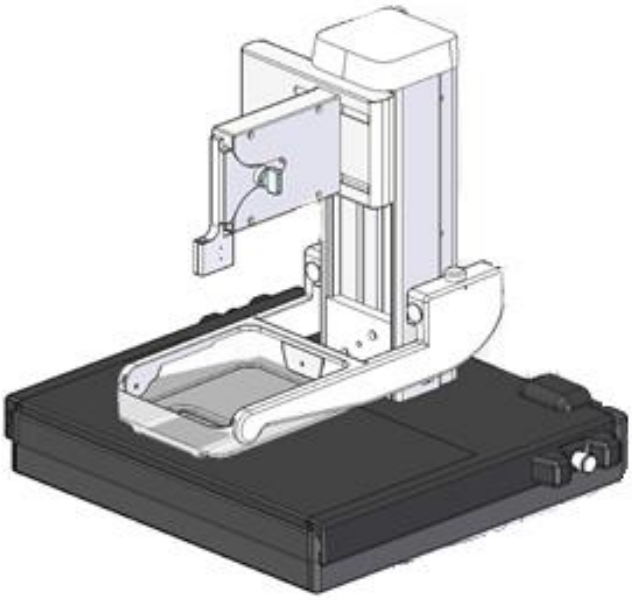


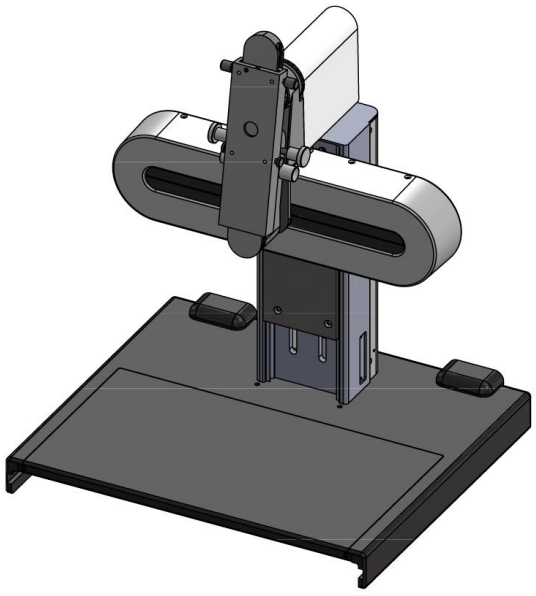
FOR BI-DIMENSIONAL AND TOMOSYNTHESIS EXAM

DEVICE FOR GEOMETRIC MAGNIFICATION WITH VARIABLE (1,5x/1,8x,2x) FACTOR

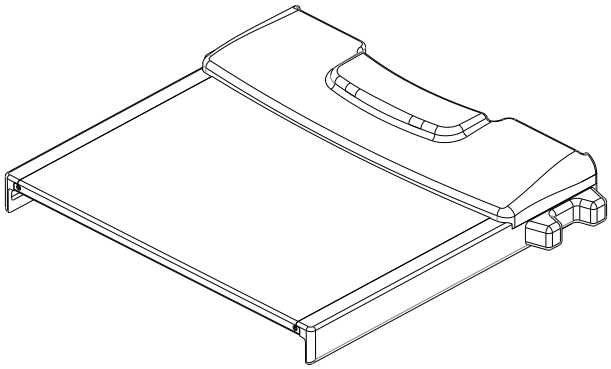


STEREOTACTIC BIOPSY DEVICE and LATERAL APPROACH option

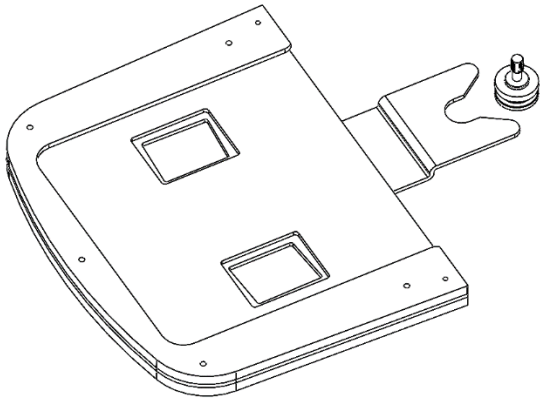




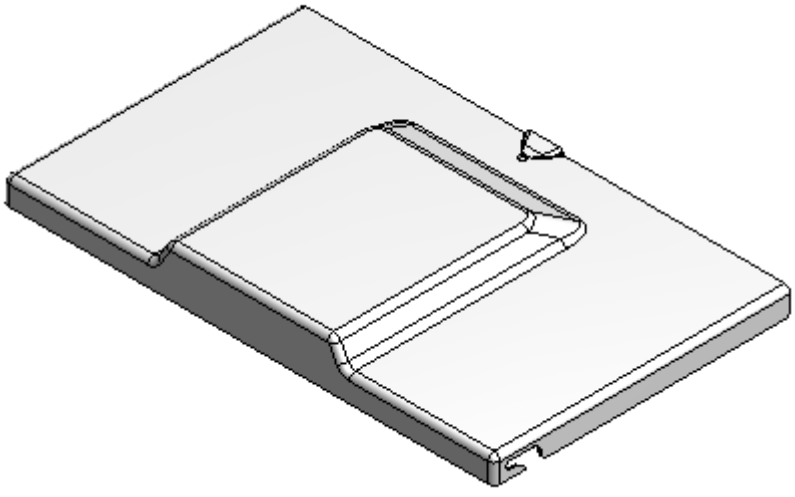
POTTER-BUCKY



BIOPSY SPECIMEN COLLIMATION PLATE



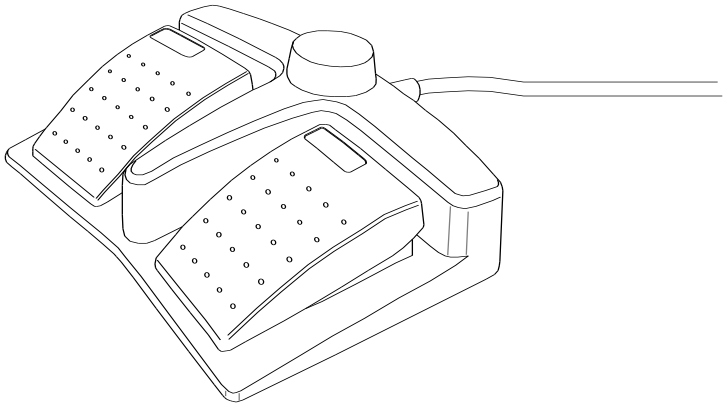
BIOPSY SPACER



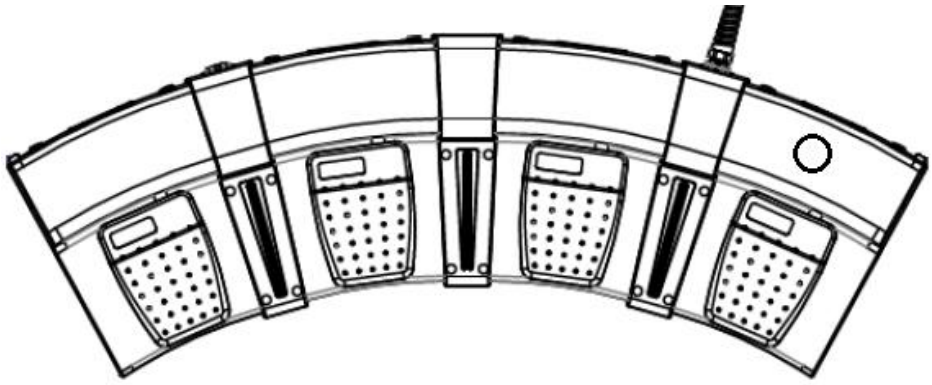
8.2. LIST OF OPTIONS

COMPONENT	DESCRIPTION	PART NUMBER
FOOT CONTROLS	STANDARD	PE/HG-S60LT3
	MULTIFUNCTION	PE/S439LT5
	XRAY FOOT CONTROL	KTSVA0405
ANTI-X BARRIER	Standalone anti-X barrier for operator protection (0,34Eq.Pb)	$C-3MT$-ANTI-X
	Standalone anti-X barrier for operator protection (0,5 Eq.Pb)	$C-HF$-ANTI-X

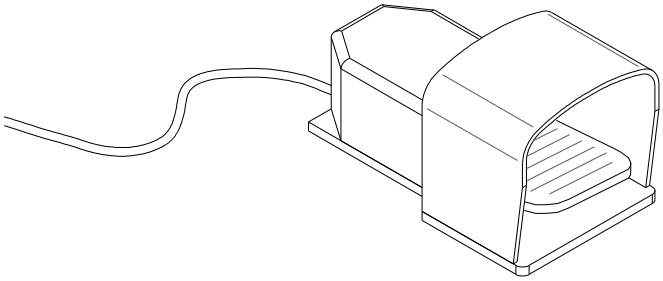
FOOT-CONTROL



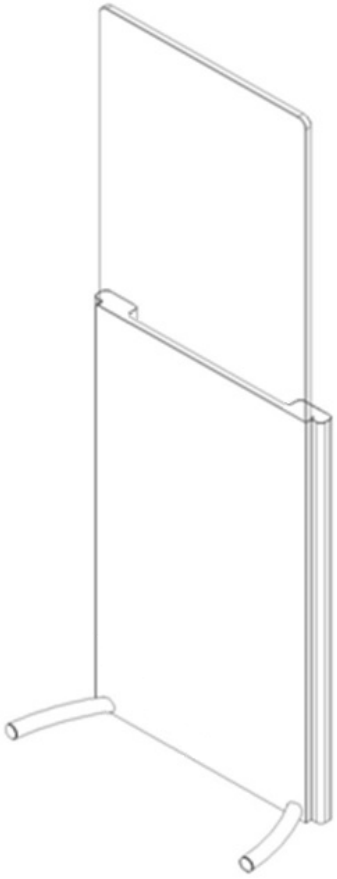
MULTIFUNCTION FOOT-CONTROLS



XRAY FOOT-CONTROL (Option on AWS)



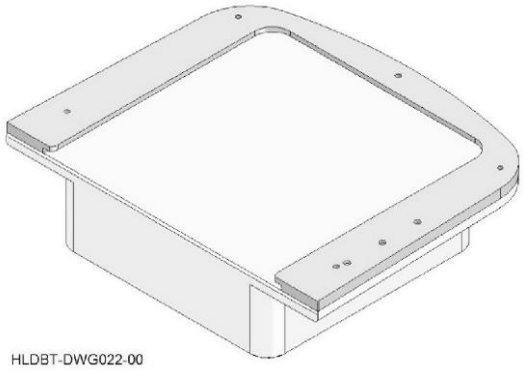
ANTI-X PROTECTIVE BARRIER



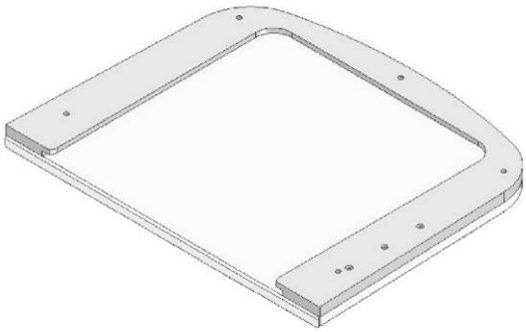
8.3. LIST OF TOOLS

COMPONENT	DESCRIPTION	PART NUMBER
TOOLS	PHANTOM PERIODICAL CALIBRATION	$C-VAR$PH/DBTC
	CALIBRATION SHIELD	$C-VAR$PB/DBT
	PHANTOM FOR AEC CHECK	$C-VAR$PH/DL-CH

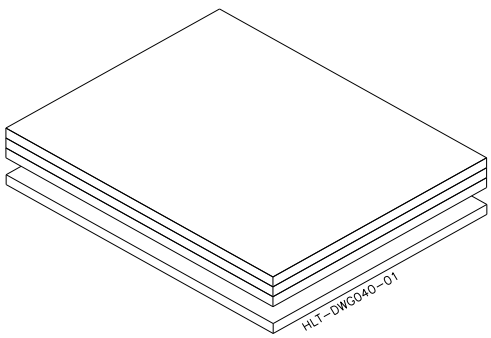
PHANTOM FOR PERIODICAL SYSTEM CALIBRATION WITHOUT COMPRESSION

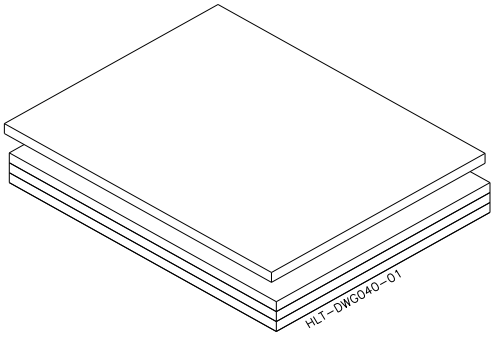


CALIBRATION SHIELD



PHANTOM FOR AEC / DAILY CHECK WITH COMPRESSION





Section IX:
Typical Configurations

Three different exposure techniques are possible with mammography unit HELIANTHUS series.

Each technique has a unique combination of Potter-Bucky, collimation device, compression paddle, focal spot, magnification device etc.,that generates a ***Typical Configuration*** of the mammography unit.

Use of different configurations can result in bad images with unwanted artifacts due to compression paddle arms in the picture, wrong x-ray field coverage, wrong dose measurement and others. Proper collimation selection is also essential to guarantee correct X-ray field and patient protection according to applicable IEC standards.

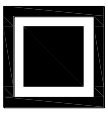
In this chapter we give a description of permitted ***Typical Configurations***.

To avoid operating mistakes, wrong dose measurement and other problems, it is recommended to operate the unit only in the ***Typical Configurations*** described in this chapter.

NOTE

Use of different configurations other than the ones described in this chapter can cause bad images with unwanted artifacts, wrong dose measurement, excessive X-ray field and other problems.

CONFIGURATION FOR STANDARD EXAMINATION (LARGE BREAST)



0,3 mm

LARGE FOCUS

PROTECTIVE SCREEN

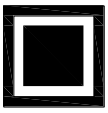
24x30 cm FORMAT SHIFTED COMPRESSION PADDLE

24x30 cm FORMAT
POTTER-BUCKY

NOTE

Use of shifted compression paddle makes pulling of the breast easy.

CONFIGURATION FOR STANDARD EXAMINATION (NORMAL BREAST)

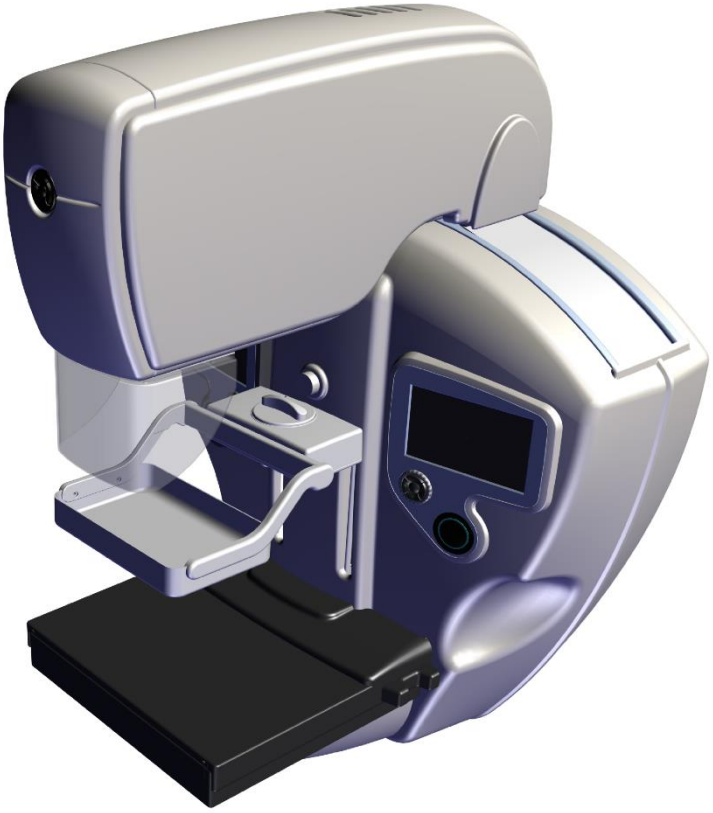


0,3 mm

LARGE FOCUS

PROTECTIVE SCREEN

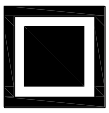
18x24 cm FORMAT SHIFTABLE
COMPRESSION PADDLE



24X30 cm FORMAT
POTTER-BUCKY

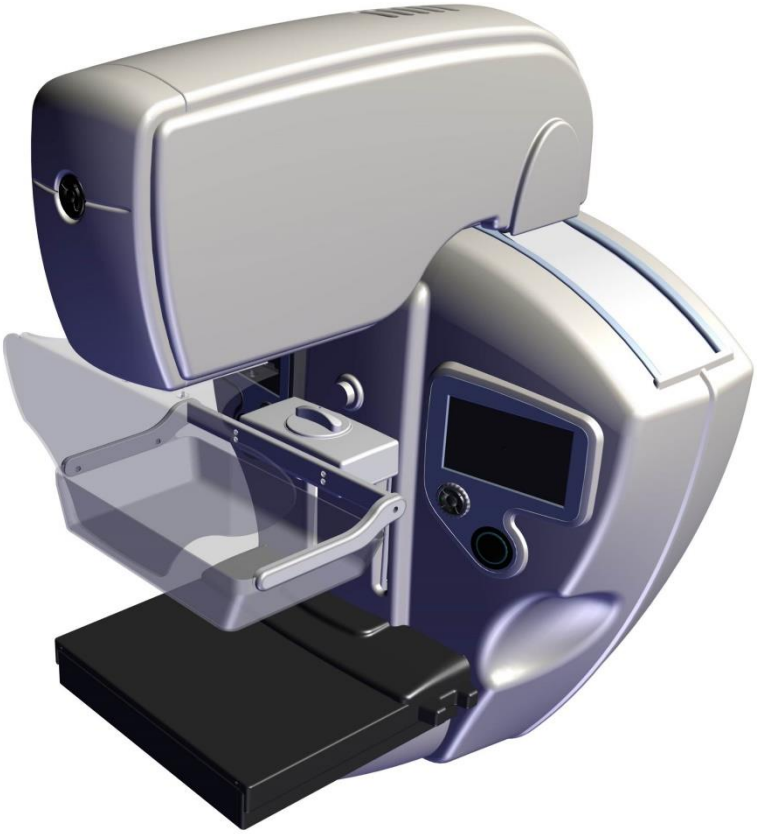
NOTE Use of shifted compression paddle makes pulling of the breast easy.

CONFIGURATION FOR TOMOSYNTHESIS EXAMINATION
(with fast lock protective screen)



0,3 mm

LARGE FOCUS



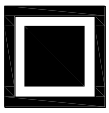
FAST LOCK PROTECTIVE SCREEN FOR TOMOSYNTHESIS

24x30 cm FORMAT SHIFTED COMPRESSION PADDLE

24X30 cm FORMAT POTTER-BUCKY

NOTE Use of shifted compression paddle makes pulling of the breast easy.

CONFIGURATION FOR SPOT CONTACT EXAMINATION

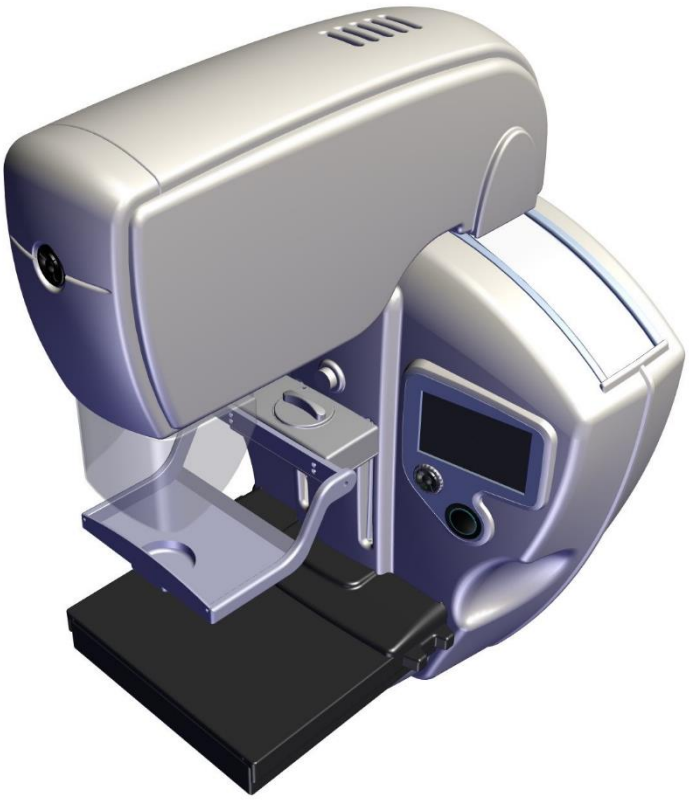


0,3 mm

LARGE FOCUS

PROTECTIVE SCREEN

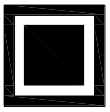
18x24 cm with Φ7.5 cm
FORMAT SPOT
COMPRESSION PADDLE



24X30 cm FORMAT
POTTER-BUCKY

NOTE Use of shifted compression paddle makes pulling of the breast easy.

CONFIGURATION FOR AXILLARY EXAMINATION



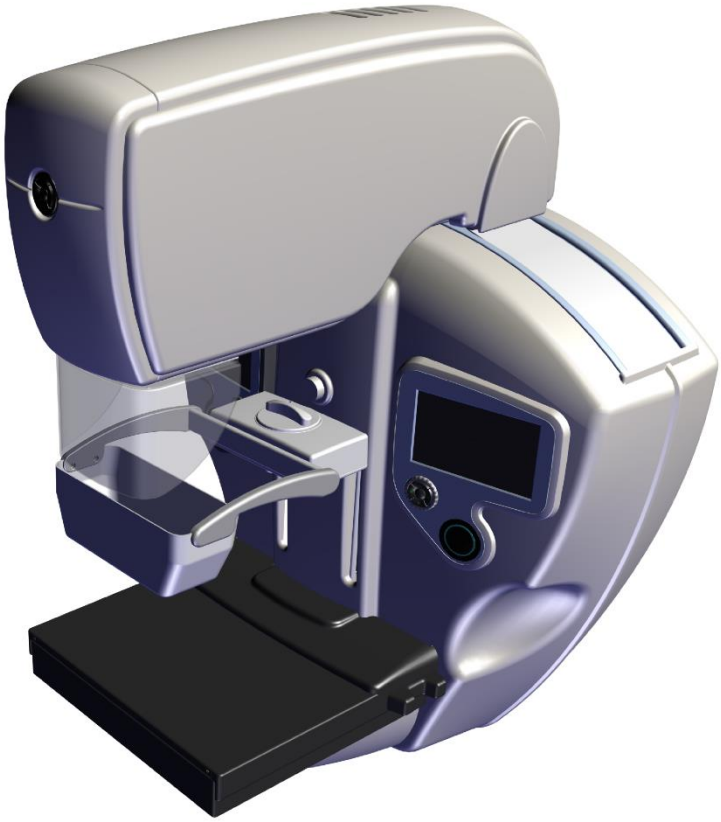
0,3 mm

LARGE FOCUS

PROTECTIVE SCREEN

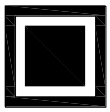
10x24 cm FORMAT COMPRESSION PADDLE

24X30 cm FORMAT POTTER-BUCKY



NOTE Use of shifted compression paddle makes pulling of the breast easy.

CONFIGURATION FOR PROSTHESIS EXAMINATION



0,3 mm

LARGE FOCUS

PROTECTIVE SCREEN

10x24 cm FORMAT COMPRESSION PADDLE FOR PROSTHESIS

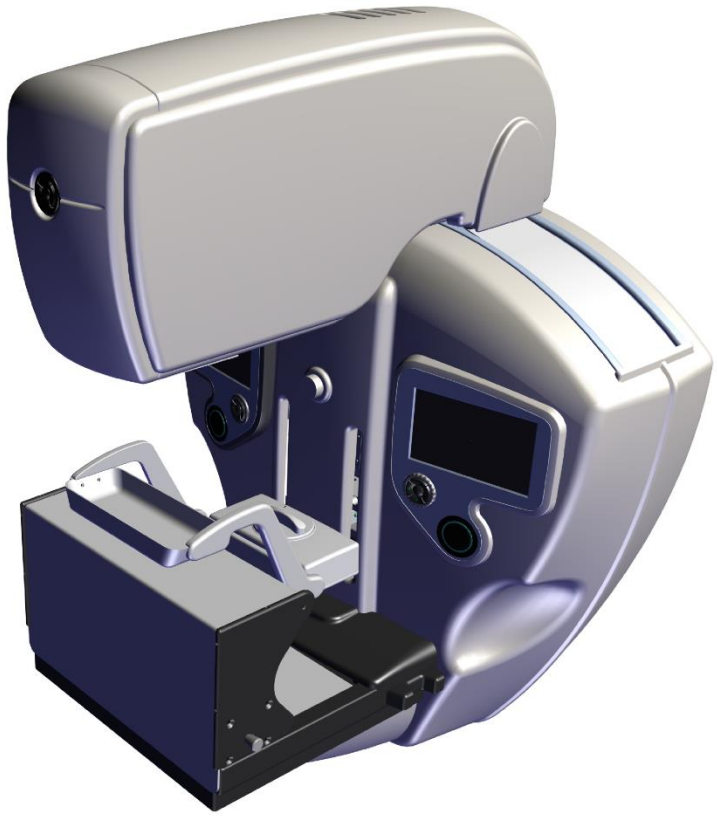
24X30 cm FORMAT POTTER-BUCKY

CONFIGURATION FOR GEOMETRIC MAGNIFICATION
(WITH 9X21CM COMPRESSION PADDLE)

SMALL FOCUS

9X21 cm FORMAT STRAIGHT COMPRESSION PADDLE

24x30 cm GEOMETRIC MAGNIFICATION DEVICE

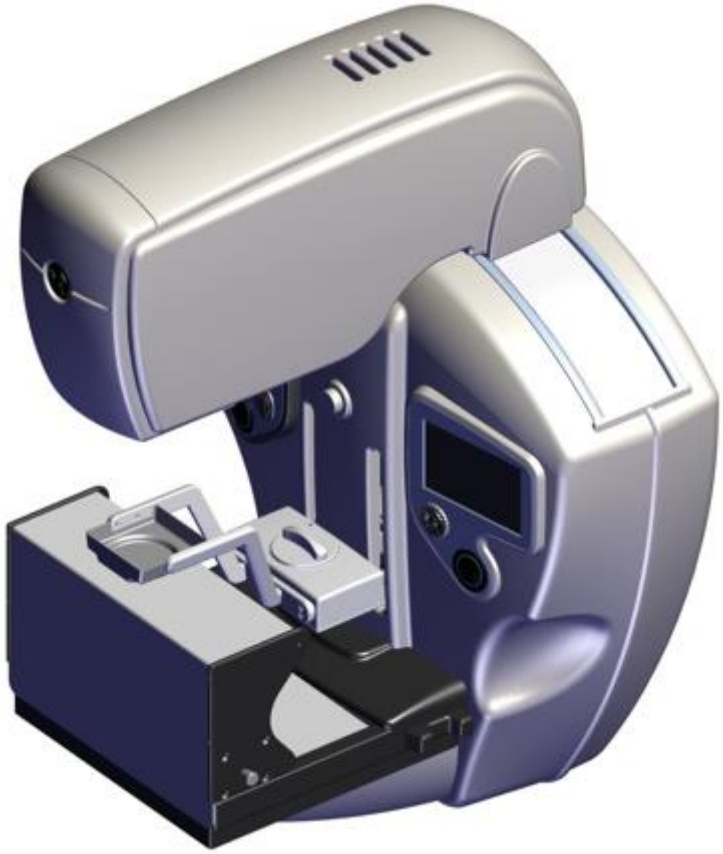


NOTE

Protective screen can’t be used with magnification techniques not having room enough to be fitted.

CONFIGURATION FOR GEOMETRIC MAGNIFICATION (WITH Φ 7,5 CM COMPRESSION PADDLE)

SMALL FOCUS



Φ 7,5 cm FORMAT
COMPRESSION PADDLE
FOR MAGNIFICATION

24x30 cm GEOMETRI
MAGNIFICATION DEVICE

NOTE

Protective screen can't be used with magnification techniques not having room enough to be fitted.

NOTE

After inserting the device for geometric magnification and selecting this mode, the system automatically selects and controls the correct association of focus and collimation field which correspond to the chosen configuration

CONFIGURATION FOR GEOMETRIC MAGNIFICATION (WITH 9X9 CM COMPRESSION PADDLE)

SMALL FOCUS

9x9 cm FORMAT
COMPRESSION PADDLE
FOR MAGNIFICATION

24x30 cm GEOMETRIC
MAGNIFICATION DEVICE

NOTE

Protective screen can't be used with magnification techniques not having room enough to be fitted.

NOTE

After inserting the device for geometric magnification and selecting this mode, the system automatically selects and controls the correct association of focus and collimation field which correspond to the chosen configuration

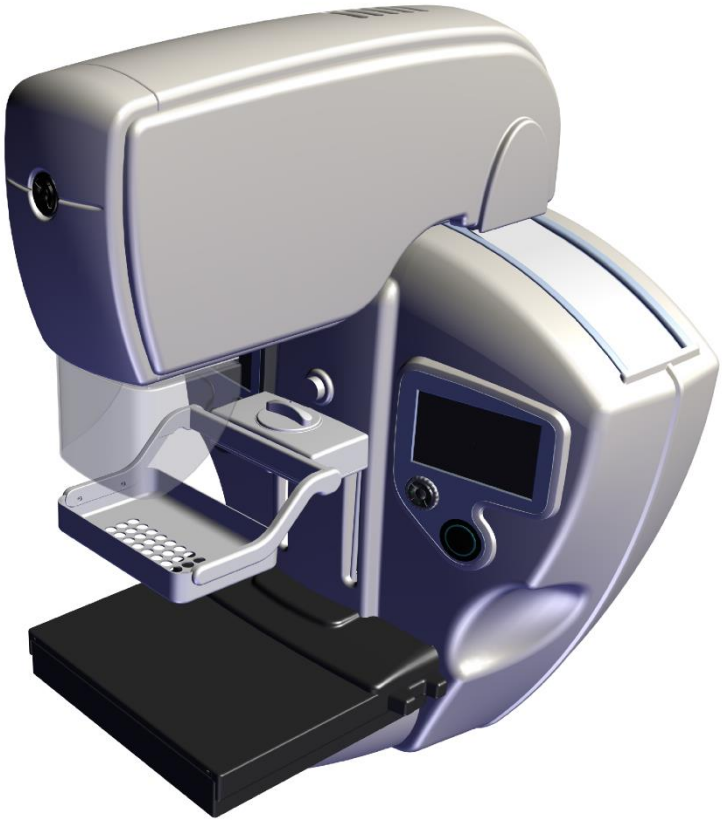
CONFIGURATION FOR BIDIMENSIONAL BIOPSY

0,3 mm

LARGE FOCUS

PROTECTIVE SCREEN

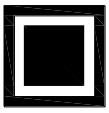
18x24 cm FORMAT SHIFTED COMPRESSION PADDLE FOR 2D BIOPSY



24X30 cm FORMAT
POTTER-BUCKY

NOTE Use of shifted compression paddle makes pulling of the breast easy.

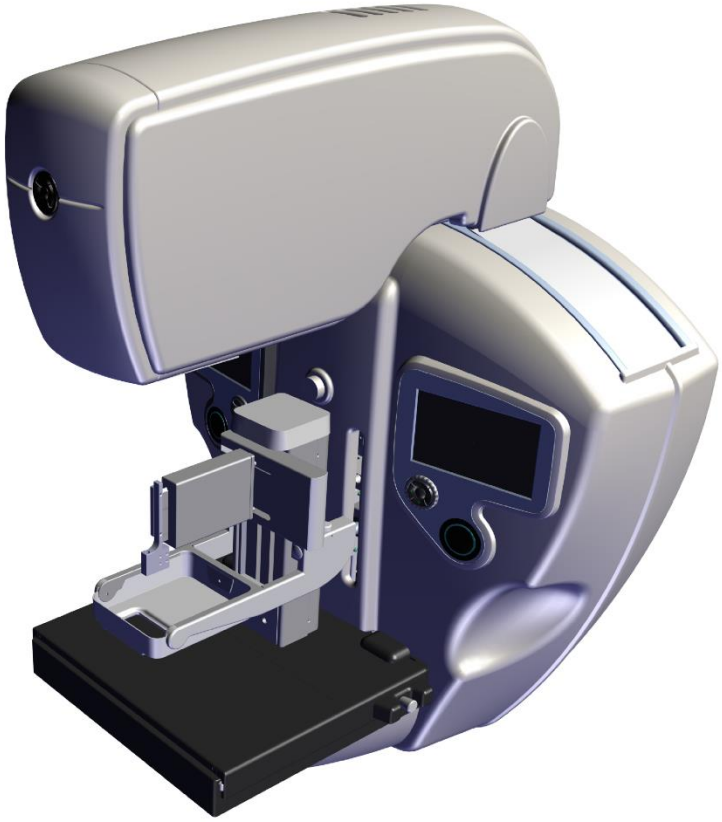
CONFIGURATION FOR STEREOTACTIC BIOPSY



0,3 mm

LARGE FOCUS

STEREOTACTIC
BIOPSY DEVICE
SBD DMD



Section X: Special Hints - ImageRecovery Strategy-Troubleshooting

The Acquisition Work Station software provides the customer with different strategies for images recovery which for various reasons were acquired improperly, avoiding to expose again the patient.

10.1. PATIENT POSITIONING

An adequate patient positioning permits to:

- Simplify the image reading process
- Use the specular systematic viewing techniques in an optimal way (binocular magnification, Tabar's masks, etc.)
- Guarantee the best performances of the image presentation algorithms

From the poor care in positioning result:

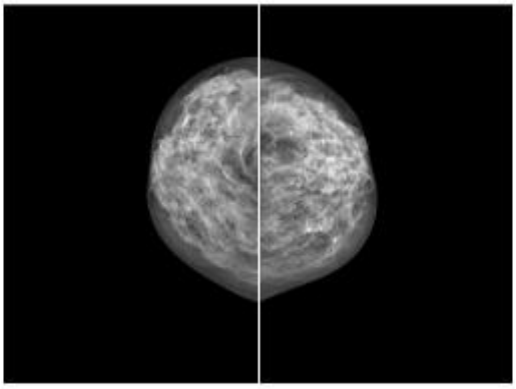
- Asymmetric images
- Skinfolds
- Presence of extraneous parts in the image field (shoulder, hairs, earrings, etc.)

Often, to worsen the situation:

- Inadequate breast compression

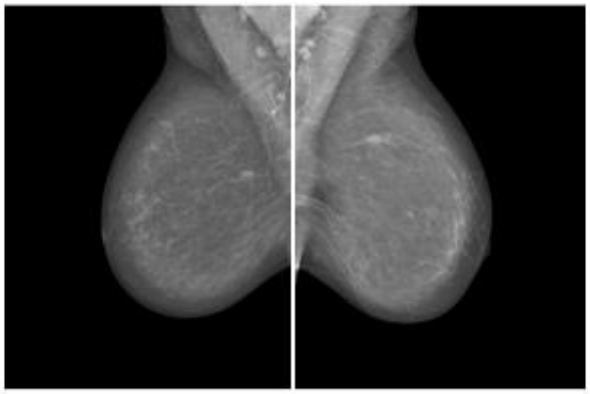
Symmetry

- Example of correctly aligned images (CC):



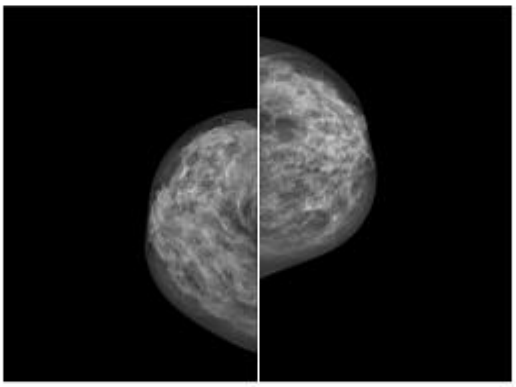
Symmetry

- Example of correctly aligned images (MLO):



Symmetry

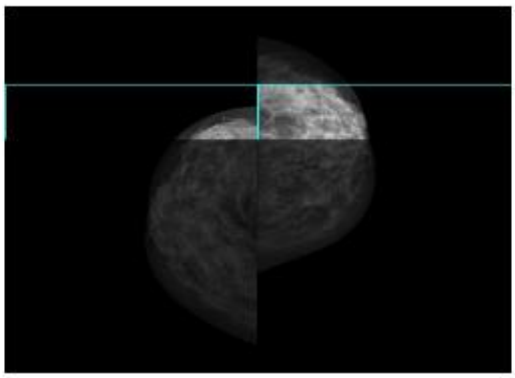
- In case of bad alignment:



Symmetry

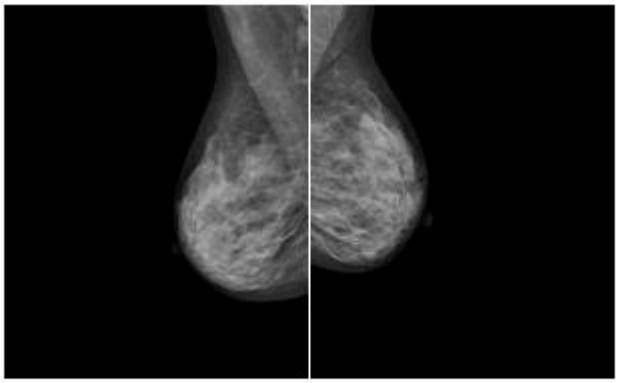
- In case of bad alignment:

specular tools (dual magnify glasses, Tabar's masks, etc.) points to different areas

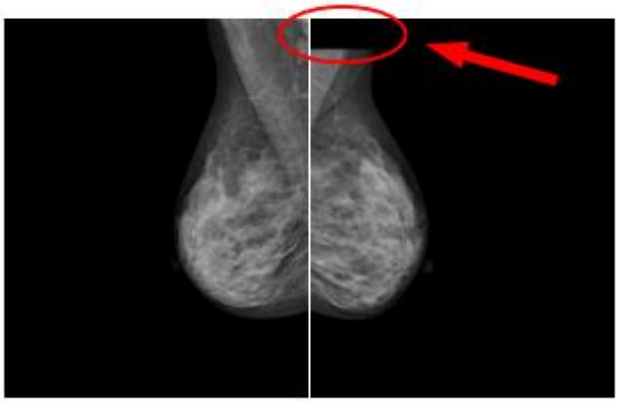


Symmetry

- The following image presents several problems due to bad positioning

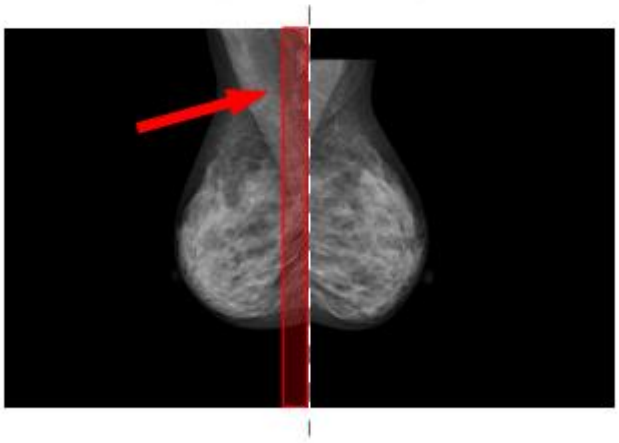


Symmetry



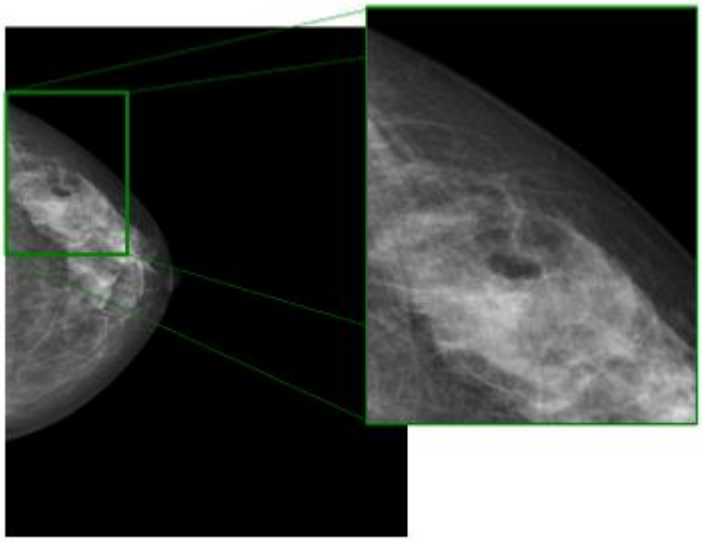
Evident reduction of the diagnosable area in the image on the right compared to the left

Symmetry

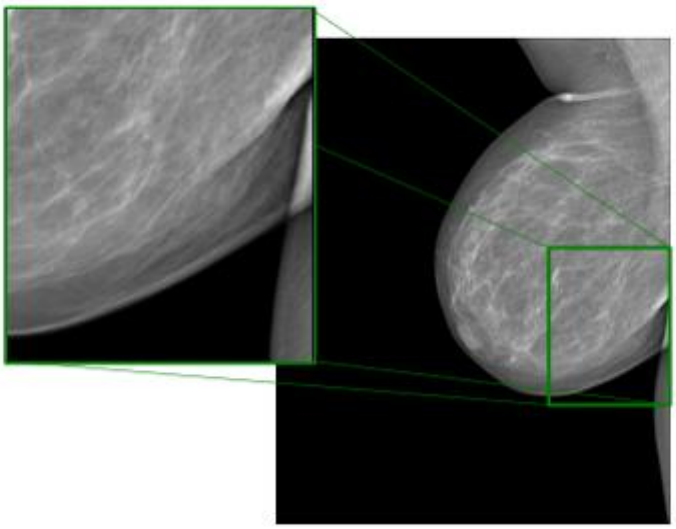


Missing part on the other view, with significant reduction of the diagnostic possibilities (i.e.: sentinel lymph nodes)

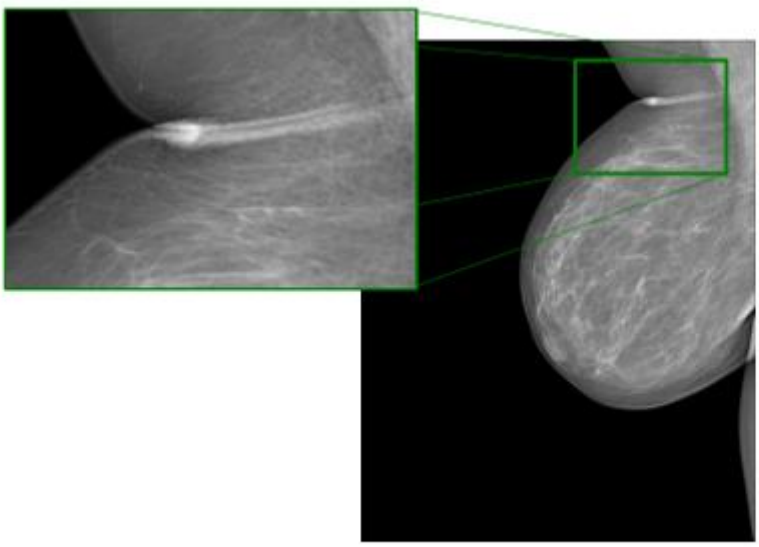
Skinfolds



Skinfolds



Skinfolds

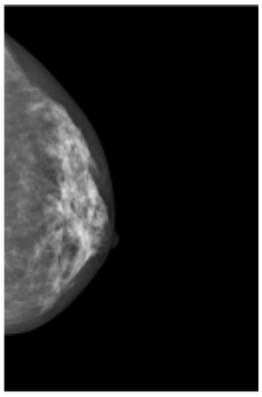


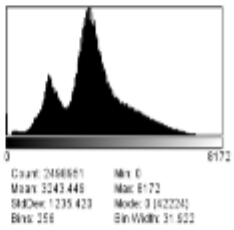
Extraneous parts in the image field

- Unlike analog images, digital images tolerate less the presence of extraneous parts in the image field
- The presence of extraneous parts in the image field negatively affects the functioning of presentation algorithm, with impact on:
  - Breast border recognition
  - Worse contrast and dynamic range because of "heavier" histogram

Extraneous parts in the image field: Dynamic Range

- Correctly enhanced image

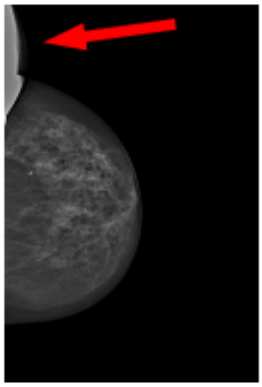


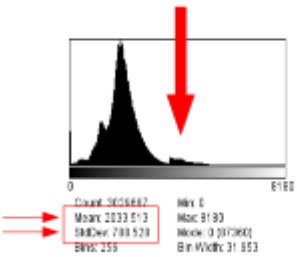


Optimal dynamic range histogram

Extraneous parts in the image field: Dynamic Range

- Wrong image: a shoulder in the field



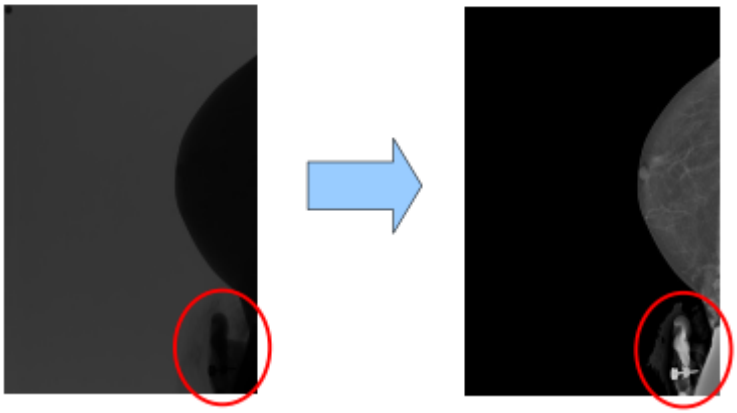


Histogram with reduced dynamic range

The algorithm recognizes the mistake and tries to correct it by darkening the area, but it can't cancel it out completely

Extraneous parts in the image field: Border recognition

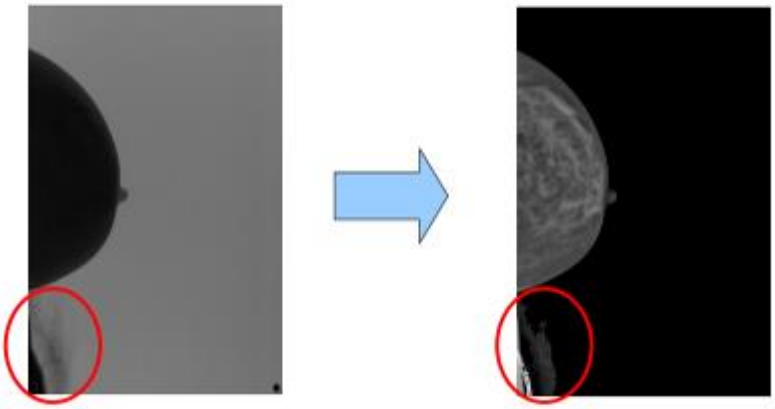
- Hairs and earring in the field



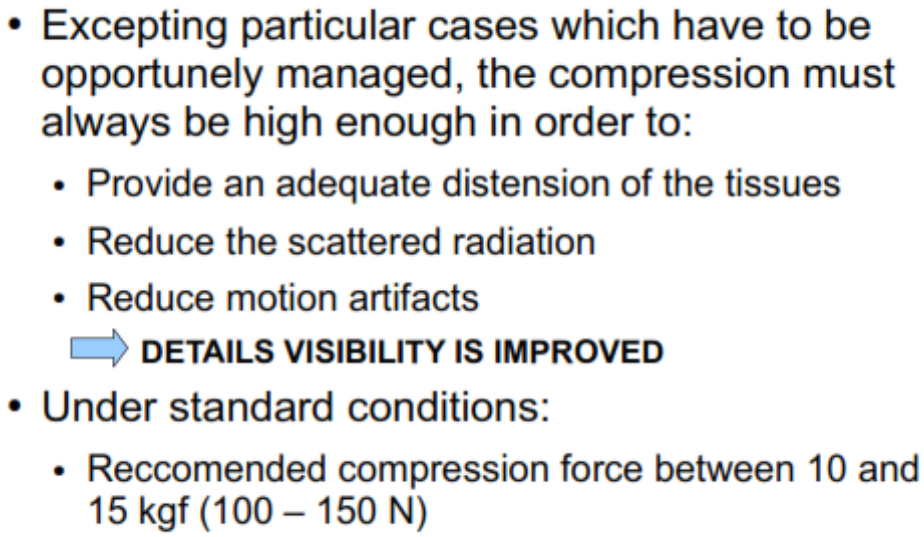
The RAW image (on the left) does not contain artifacts, which are instead added by the algorithm for the image on the right

Extraneous parts in the image field: Border recognition

- Another example: hairs and a finger!



Compression

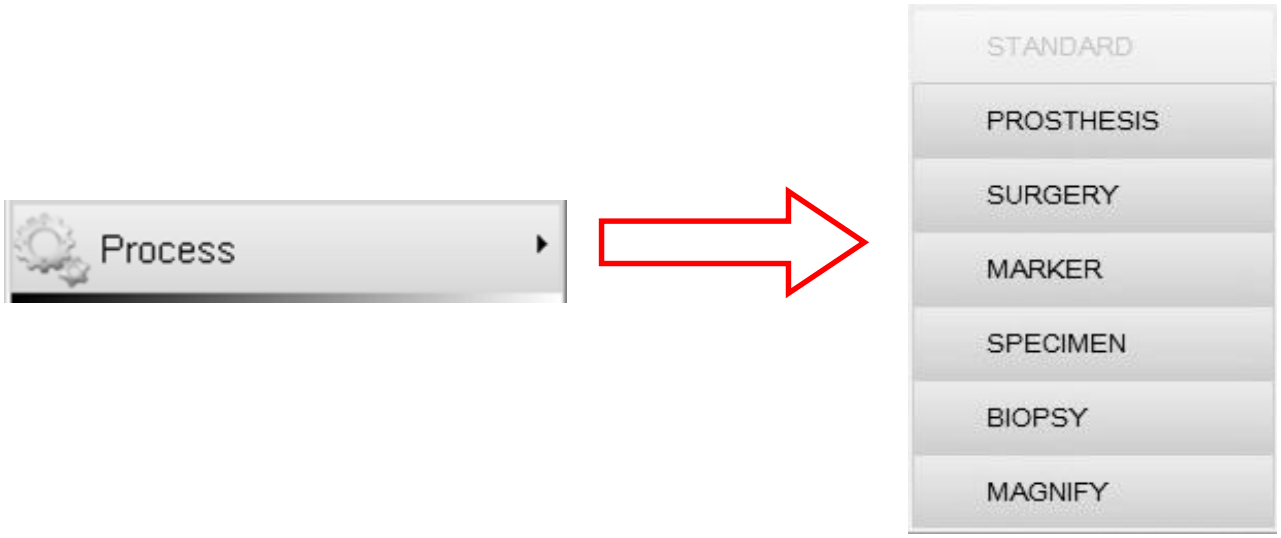


- Clinical assessment of positioning in digital mammography matches that required for screenfilm and evaluates the retromammary aspects of the breast between the craniocaudal (CC) and mediolateral oblique (MLO) views. On the CC view, the posterior nipple line of the breast (the distance between the nipple and the posterior edge of the image) should be no more than 1 cm less (approximately) than that on the MLO view (the distance between the nipple and the anterior edge of pectoral muscle). The anterior edge of the pectoral muscle on the MLO view should be convex, and it is desirable for the muscle to extend to the level of the nipple. The posterior nipple line should be drawn at an angle, perpendicular to the muscle, usually at about 45 degrees on the MLO image.
- Large breasts may require imaging of the breast in sections. The resulting multiple images in the same projection must be viewed together to form the complete mammogram. An increase in radiation dose occurs to regions of the breast that are exposed to X-rays in more than one image in the same view projection. Standard tiling methods that double expose the least possible amount of breast tissue should be used.

10.2. IMAGE RECOVERY STRATEGY – TROUBLESHOOTING

10.2.1 Images with metallic clips, surgical marker and cluster of micro calcification

In case of image with metallic clips, surgical marker and numerous cluster of micro calcification, in which image contrast could be not adequate for radiologist physician, you have to right click on image and select Process → Marker, as shown in following image.



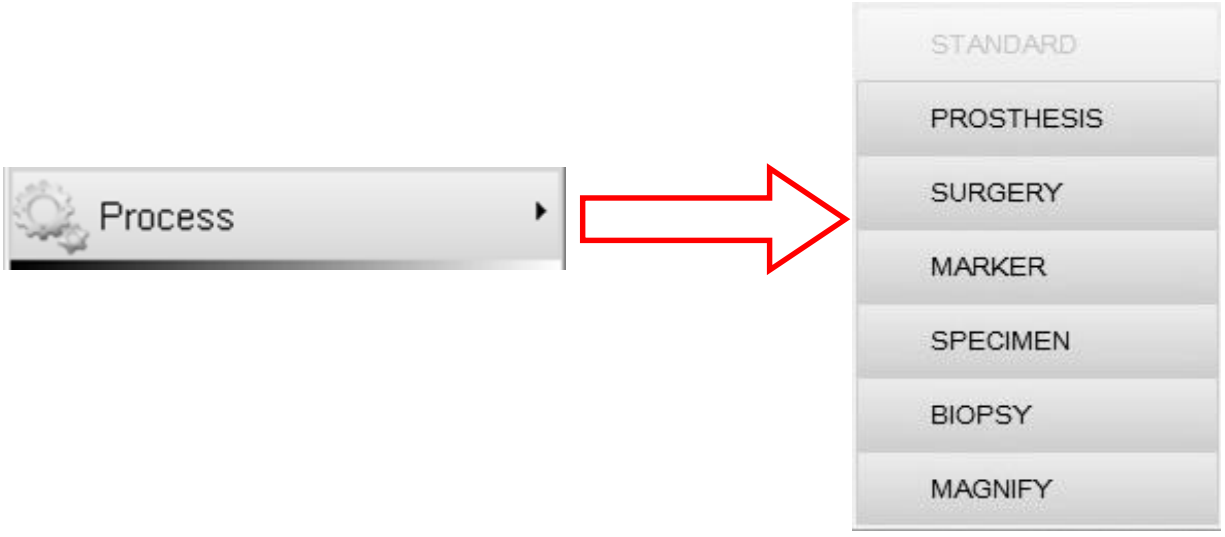
To recover the original image contrast, you have to right click on image and select Process → Marker

NOTE

The “marker” filter can be used also in that case in which the patient is not properly positioned and earrings or other object are in the image plane.

10.2.2 Images with surgical anatomical parts

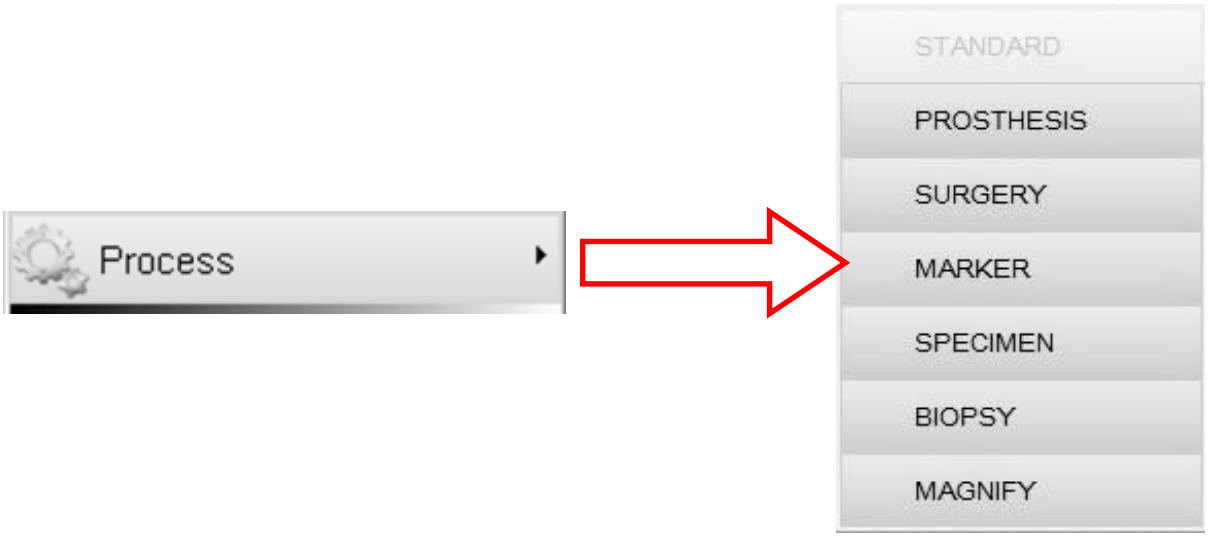
In case of image with surgical anatomical parts, in which image contrast could be not adequate for radiologist physician, you have to right click on image and select Process → Surgery, as shown in following image



To recover the original image contrast, you have to right click on image and select Process → Surgery

10.2.3 Images with breast specimen

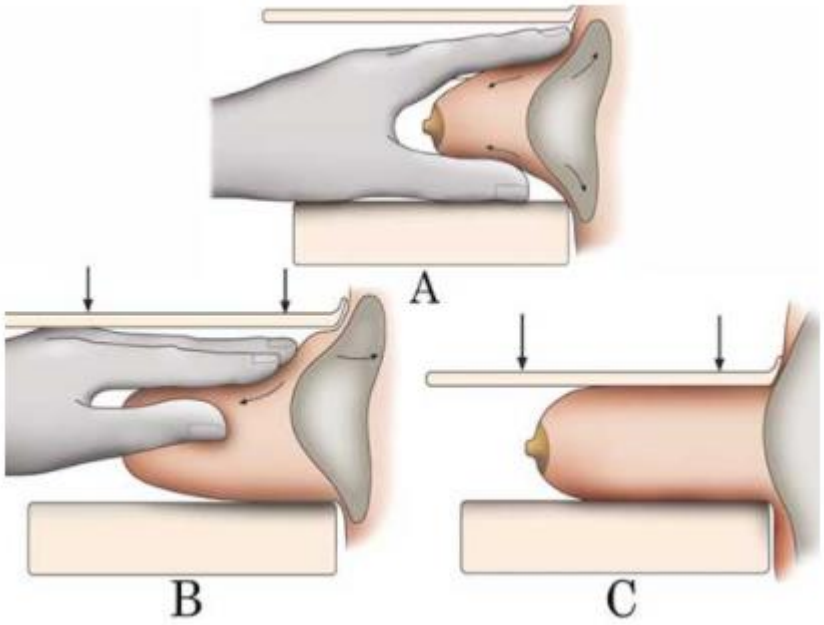
In case of image with breast specimen (i.e. vacuum assisted biopsy, trucut biopsy) , in which image contrast could be not adequate for radiologist physician, you have to right click on image and select Process → Specimen, as shown in following image



To recover the original image contrast, you have to right click on image and select Process→ Specimen

10.3. MANIPULATION TECHNIQUE FOR BREAST WITH PROSTHESIS

The Eklund maneuver is indicated for performing mammography examinations on patients with breasts with subglandular prostheses. This maneuver performed by the operator allows the glandular tissue to be viewed optimally by manually applying a compression force to dislocate the breast prosthesis so as to bring it towards the patient's chest wall.



Section XI:
Technical Specifications

NOTE

Metaltronica S.p.A. reserves the right to make further improvements while keeping main features unchanged.

GENERAL SPECIFICATIONS

CLASSIFICATION (IEC 60601-1/A1)	
Protection against electric shock	Class I, with type B applied parts
Applied parts	• Potter-Bucky/Biopsy Device carbon fiber • Compression Paddles • Magnification Device
Protection degree according to IEC 60529 and 60601-1 (Third edition)	IP X0 (Mammo Unit) where "X" means that the protection against foreign objects is not required to be specified and "0" means Not-protected against ingress of water; IP X2 (Foot Controls) where "X" means that the protection against foreign objects is not required to be specified and "2" means protected against vertically falling water drops when ENCLOSURE tilted up to 15°
Degree of safety in the presence of flammable anesthetics mixture with. air or with oxygen or with nitrous oxide	Not suitable for use in the presence of Flammable Anesthetics Mixture with air or with oxygen or with nitrous oxide
Mode of operation	Continuous operation with intermittent loading

POWER SUPPLY	
Line voltage	115/220/230/240 Vac ±10% 50/60 Hz
Power	**115/220/230/240 Vac:** Momentary: 85/45/43/41 A Long-time: 2.5/1.3/1.2/1.2 A
Number of phases	1 or 2 configurable
Connection	Permanently installed (IEC 60601-1)
Wall connection	20 A Thermal-magnetic circuit breaker (40 A Thermal-magnetic circuit breaker in 115 Vac option) **NOTE**: for more details about this specification, please refer to the planning guide
Mains resistance	<0.50 Ω R=0,48 Ω (@220-230-240V) R=0,13 Ω (@115V)

ENVIRONMENTAL CONDITIONS	
Mammography Unit Transit/Delivery and Storage Conditions	Temperature: -20°C÷+70°C Relative humidity: 10%÷90% Barometric pressure: 700 hPa÷1060 hPa
Detector Conditions during: • Transfer to Transport Terminal • Destination Terminal Custom Clearance Period • Door Delivery • Storage conditions • Mammo unit switched off	**a-Si Detector** Temperature: -15°C÷+65°C Relative humidity: 10%÷85% Barometric pressure: 700 hPa÷1060 hPa **a-Se Detector** Temperature: +5°C÷+40°C Relative humidity: 10%÷90% Barometric pressure: 700 hPa÷1060 hPa **SOLO DM Detector** Temperature: -5°C÷+55°C Relative humidity: 10%÷65% Barometric pressure: 700 hPa÷1060 hPa
Detector Conditions during: • International Air Transport Note: Detector packed in the original crate	**a-Si Detector** Temperature: -18°C÷+70°C (under 36h) Relative humidity: 10%÷85% Barometric pressure: 700 hPa÷1060 hPa **a-Se Detector** Temperature: -20°C÷+60°C (24h) Relative humidity: 10%÷90% Barometric pressure: 700 hPa÷1060 hPa **SOLO DM Detector** Temperature: -5°C÷+55°C Relative humidity: 10%÷85% Barometric pressure: 700 hPa÷1060 hPa
Operating Conditions • Mammo Unit switched on	**a-Si Detector** Temperature: +5°C÷+40°C Relative humidity: 30% to 85% Barometric pressure: 700 hPa÷1060 hPa **a-Se Detector** Temperature: +20°C÷+25°C Relative humidity: 30%÷75% Barometric pressure: 700 hPa÷1060 hPa **SOLO DM Detector** Temperature: +10°C÷+40°C Relative humidity: 10%÷65% (operating) 35%÷70% (installation/testing) Barometric pressure: 700 hPa÷1060 hPa
Detector Maximum rate of temperature change	**10 °C in 20 min**
Heat dissipated in max load condition of 35 kV 500 mAs (1 shot every 5 minutes)	316 kCal/h

ENVIRONMENT PROTECTION AND WASTE DISPOSAL	
System contains in some of its parts and subassemblies, solid and liquid substances that must be disposed only by designated companies according to local laws.	
Tube assembly	Beryllium, glass, dielectric oil (PCB free), other metals and plastic.
H.V. transformer	Dielectric oil (PCB free), plastic, copper other metals
Other subassemblies	Plastic, other metals, electronic components glass-epoxy printed circuits, amorphous selenium

MAMMOGRAPHY UNIT

X-RAY HIGH VOLTAGE GENERATOR	
Line voltage compensation	AUTOMATIC High voltage generator with kV closed loop and line Feed forward compensation
Inverter Technology	Current fed, Mosfet bridge with output current limit capability and short circuit protection
Inverter Frequency	50 kHz
Ripple Frequency/Amplitude	100 kHz < 2%
Generator Rating	7,4 kW
kV range	20÷49 kV
kV resolution (Manual & Auto mode)	0.5 kV
kV precision	±1%
kV repeatability	± 0.1%
kV risetime	≤1.5 ms from 0 to 100%
kV display	XX,X kV (3 digits)
Lowest Current Time Product IEC 60601-2-45:201.7.9.2.1.f)	1 mAs
mAs maximum value	640 mAs (allowed)
mAs resolution (Automatic)	0,1 mAs
mAs values	in accordance with R'20 series (Note: values rounded down on the base of standards tolerance and series limited to 640 mAs)
mAs display	XXX.X mAs (4 digits)
Exposure Time range	0.02/4.7 s (640 mAs@135 mA) Automatically selected in function of selected mAs
Safety timer	10 s

X-RAY TUBE	I.A.E. XM1016 T
Anode rotation speed	3000 rpm (optionally 10000 rpm)
Target material	Tungsten Focal track: RT (Tungsten+Rhenium) Bulk: TZM (Molibdenum+Titanium+Zirconium)
Anode Heat Storage Capacity	300 kHU (225 kJ)
Maximum Anode Heat Dissipation Rate	60 kHU/min (750 W)
X-Ray Tube Assembly Heat Storage Capacity	500 kHU (375 kJ)
X-Ray Tube Assembly Heat Dissipation Rate	108 HU/s (80 W)
Cooling method	Free air convection
Anode Disc Target Angle	10° (Small focus)/16° (Large focus)
Anode Disc Diameter	80 mm
Focal spots	2
Focal spot size according to IEC 336, EN60336	0,1x0,1 mm (Small)/0,3x0,3 mm (Large)
Power (Nominal Anode Input Power)	2400 W (Small)/9600 W (Large) (10000 rpm)
Nominal X-Ray Tube Voltage and Highest X-Ray Tube Current available at that voltage (IEC 60601-2-45: 201.7.9.2.1.a)	**2D mode:** Large Focus: 49kV; 80mA Small Focus: 49kV; 42mA **Tomosynthesis mode:** Large focus: 49kV; 140mA
Highest X-Ray Tube Current and Highest X-Ray Tube Voltage available at that current (IEC 60601-2-45: 201.7.9.2.1.b)	**2D mode:** Large Focus: 35kV; 135mA Small Focus: 35Kv;65mA **Tomosynthesis mode:** Large Focus: 35kV; 200mA
Corresponding combination of X-Ray Tube Voltage and X-Ray Tube Current which results in Highest Electric Output Power (IEC 60601-2-45:201.7.9.2.1.c)	**2D mode:** Large Focus: 35kV*135mA= 4725W Small Focus: 42kV*55mA= 2310W **Tomosynthesis mode:** Large Focus: 35kV*200mA= 7000W
Nominal electric power given as the highest constant electric output power in kilowatts which the X-Ray Generator can deliver at an X-Ray Tube Voltage of 30 kV, for a Loading Time of 1 s, a Cycle Time of 1,0 minute and for an indefinite number of cycles, or if these values are not selectable, at an X-Ray Tube Voltage nearest to 30 kV, for a Loading Time nearest to but not less than 1 s and a Cycle Time of 1,0 minute and for an indefinite number of cycles (IEC 60601-2-45: 201.7.9.2.1.d)	**2D mode:** Large Focus: 30kV*135mA= 4050W Small Focus: 30kV*50mA= 1500W **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100W
Nominal electric power shall be given together with the combination of X-Ray Tube Voltage and X-Ray Tube Current and Loading Time (IEC 60601-2-45: 201.7.9.2.1.e)	**2D mode:** Large Focus: 30kV*135mA= 4050W Loading time: 4.74” Small focus 30kV*50mA= 1500W Loading time: 4.40” **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100

Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f)	1mAs for both operation mode
For Mammographic X-Ray Equipment provided with automatic Exposure Control controlling Loading Time, shortest Loading Time and/or the lowest resulting Current Time Product (IEC 60601-2-45: 201.7.9.2.1.h)	8mAs (using 20mm PMMA phantom)
Range of X-Ray Tube Voltage when X-Ray Tube Voltage is controlled by AEC (IEC 60601-2-45: 201.7.9.2.1.i)	20-49 kV
X-Ray Window	0,5 mm Beryllium
Housing X-Ray protection	>=0,5 mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 522:1999-02
HVL measured at 28 kV	>0,5 mm Al equiv.
Total filtration	>0.5 mm Al

TUBE ASSEMBLY THERMAL OVERLOAD PROTECTION	
With active temperature sensor under main CPU control	Upper limit temperature 65° outside tube assembly. HU and °C display available in technical menu.

FILTER PROPERTIES	
50 μm Silver (Ag)	0.54 mm Al eq. @ 28 kV, measured with W target
50 μm Rhodium (Rh)	0.51 mm Al eq @ 28 kV, measured with W target
500 μm Aluminium (Al)	0.4 mm Al eq @ 28 kV, measured with W target
700 μm Aluminium (Al) (optional)	0.51 mm Al eq @ 28 kV, measured with W target
300 μm Copper (Cu) (optional, predisposition for future Dual Energy implementation)	3.85 mm Al eq @ 49 kV, measured with W target

STANDARD X-RAY TUBE	I.A.E. XK1016 T
Anode rotation speed	3000 rpm (optionally 10000 rpm)
Target material	Tungsten Focal track: RT (Tungsten+Rhenium) Bulk: TZM (Molibdenum+Titanium+Zirconium)
Anode Heat Storage Capacity	300 kHU (225 kJ)
Maximum Anode Heat Dissipation Rate	60 kHU/min (750 W)
X-Ray Tube Assembly Heat Storage Capacity	500 kHU (375 kJ)
X-Ray Tube Assembly Heat Dissipation Rate	108 HU/s (80 W)
Cooling method	FORCED air convection
Anode Disc Target Angle	10° (Small focus)/16° (Large focus)
Anode Disc Diameter	80 mm
Focal spots	2
Focal spot size according to IEC 336, EN60336	0,1x0,1 mm (Small)/0,3x0,3 mm (Large)
Power (Nominal Anode Input Power)	2400 W (Small)/9600 W (Large) (10000 rpm)
Nominal X-Ray Tube Voltage and Highest X-Ray Tube Current available at that voltage (IEC 60601-2-45: 201.7.9.2.1.a)	**2D mode:** Large Focus: 49kV; 80mA Small Focus: 49kV; 42mA **Tomosynthesis mode:** Large focus: 49kV; 140mA
Highest X-Ray Tube Current and Highest X-Ray Tube Voltage available at that current (IEC 60601-2-45: 201.7.9.2.1.b)	**2D mode:** Large Focus: 35kV; 135mA Small Focus: 35Kv;65mA **Tomosynthesis mode:** Large Focus: 35kV; 200mA
Corresponding combination of X-Ray Tube Voltage and X-Ray Tube Current which results in Highest Electric Output Power (IEC 60601-2-45:201.7.9.2.1.c)	**2D mode:** Large Focus: 35kV*135mA= 4725W Small Focus: 42kV*55mA= 2310W **Tomosynthesis mode:** Large Focus: 35kV*200mA= 7000W
Nominal electric power given as the highest constant electric output power in kilowatts which the X-Ray Generator can deliver at an X-Ray Tube Voltage of 30 kV, for a Loading Time of 1 s, a Cycle Time of 1,0 minute and for an indefinite number of cycles, or if these values are not selectable, at an X-Ray Tube Voltage nearest to 30 kV, for a Loading Time nearest to but not less than 1 s and a Cycle Time of 1,0 minute and for an indefinite number of cycles (IEC 60601-2-45: 201.7.9.2.1.d)	**2D mode:** Large Focus: 30kV*135mA= 4050W Small Focus: 30kV*50mA= 1500W **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100W
Nominal electric power shall be given together with the combination of X-Ray Tube Voltage and X-Ray Tube Current and Loading Time (IEC 60601-2-45: 201.7.9.2.1.e)	**2D mode:** Large Focus: 30kV*135mA= 4050W Loading time: 4.74” Small focus 30kV*50mA= 1500W Loading time: 4.40” **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100

Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f)	1mAs for both operation mode
For Mammographic X-Ray Equipment provided with automatic Exposure Control controlling Loading Time, shortest Loading Time and/or the lowest resulting Current Time Product (IEC 60601-2-45: 201.7.9.2.1.h)	8mAs (using 20mm PMMA phantom)
Range of X-Ray Tube Voltage when X-Ray Tube Voltage is controlled by AEC (IEC 60601-2-45: 201.7.9.2.1.i)	20-49 kV
X-Ray Window	0,5 mm Beryllium
Housing X-Ray protection	>=0,5 mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 522:1999-02
HVL measured at 28 kV	>0,5 mm Al equiv.
Total filtration	>0.5 mm Al

TUBE ASSEMBLY THERMAL OVERLOAD PROTECTION	
With active temperature sensor under main CPU control	Upper limit temperature 65° outside tube assembly. HU and °C display available in technical menu.

FILTER PROPERTIES	
50 μm Silver (Ag)	0.54 mm Al eq. @ 28 kV, measured with W target
50 μm Rhodium (Rh)	0.51 mm Al eq @ 28 kV, measured with W target
500 μm Aluminium (Al)	0.4 mm Al eq @ 28 kV, measured with W target
700 μm Aluminium (Al)	0.51 mm Al eq @ 28 kV, measured with W target
300 μm Copper (Cu) (optional, predisposition for future Dual Energy implementation)	3,85 mm Al eq @ 49 kV, measured with W target

OPTIONAL X-RAY TUBE (ONLY FOR 2D models)	**VAREX M113T**
Anode rotation speed	3000 rpm 50 Hz
Target material	Tungsten Focal track: W-Re-Mo
Anode Heat Storage Capacity	300 kHU (225 kJ)
Maximum Anode Heat Dissipation Rate	60 kHU/min (750 W)
X-Ray Tube Assembly Heat Storage Capacity	500 kHU (376 kJ)
X-Ray Tube Assembly Heat Dissipation Rate	135 HU/s (100 W)
Cooling method	Free air convection
Anode Disc Target Angle	10° (Small focus)/16° (Large focus)
Anode Disc Diameter	77 mm
Focal spots	2
Focal spot size according to IEC 336, EN60336	0,1x0,1 mm (Small)/0,3x0,3 mm (Large)
Power (Nominal Anode Input Power)	1400 W (Small)/5900 W (Large) (3000 rpm)
Nominal X-Ray Tube Voltage and Highest X-Ray Tube Current available at that voltage (IEC 60601-2-45: 201.7.9.2.1.a)	**2D mode:** Large Focus: 49kV; 80mA Small Focus: 49kV; 42mA
Highest X-Ray Tube Current and Highest X-Ray Tube Voltage available at that current (IEC 60601-2-45: 201.7.9.2.1.b)	**2D mode:** Large Focus: 35kV; 135mA Small Focus: 35Kv;65mA
Corresponding combination of X-Ray Tube Voltage and X-Ray Tube Current which results in Highest Electric Output Power (IEC 60601-2-45:201.7.9.2.1.c)	**2D mode:** Large Focus: 35kV*135mA= 4725W Small Focus: 42kV*55mA= 2310W
Nominal electric power given as the highest constant electric output power in kilowatts which the X-Ray Generator can deliver at an X-Ray Tube Voltage of 30 kV, for a Loading Time of 1 s, a Cycle Time of 1,0 minute and for an indefinite number of cycles, or if these values are not selectable, at an X-Ray Tube Voltage nearest to 30 kV, for a Loading Time nearest to but not less than 1 s and a Cycle Time of 1,0 minute and for an indefinite number of cycles (IEC 60601-2-45: 201.7.9.2.1.d)	**2D mode:** Large Focus: 30kV*135mA= 4050W Small Focus: 30kV*50mA= 1500W
Nominal electric power shall be given together with the combination of X-Ray Tube Voltage and X-Ray Tube Current and Loading Time (IEC 60601-2-45: 201.7.9.2.1.e)	**2D mode:** Large Focus: 30kV*135mA= 4050W Loading time: 4.74” Small focus 30kV*50mA= 1500W Loading time: 4.40”
Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f)	1mAs for both operation mode

For Mammographic X-Ray Equipment provided with automatic Exposure Control controlling Loading Time, shortest Loading Time and/or the lowest resulting Current Time Product (IEC 60601-2-45: 201.7.9.2.1.h)	8mAs (using 20mm PMMA phantom)
Range of X-Ray Tube Voltage when X-Ray Tube Voltage is controlled by AEC (IEC 60601-2-45: 201.7.9.2.1.i)	20-49 kV
X-Ray Window	0,63 mm Beryllium
Housing X-Ray protection	>=0,5 mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 522:1999-02
HVL measured at 28 kV	>0,5 mm Al equiv.
Total filtration	>0.5 mm Al

TUBE ASSEMBLY THERMAL OVERLOAD PROTECTION	
With active temperature sensor under main CPU control	Upper limit temperature 65° outside tube assembly. HU and °C display available in technical menu.

FILTER PROPERTIES	
50 μm Silver (Ag)	0.54 mm Al eq. @ 28 kV, measured with W target
50 μm Rhodium(Rh)	0.51 mm Al eq @ 28 kV, measured with W target

C-ARM	
F.F.D. (Focus Detector Distance)/S.I.D. (Source to image receptor Distance)	66 cm
Motorized Movements	Vertical translation (motorized) Rotation (manual or optionally motorized) ±15° Rotation (only with BYM 3D DMD)
Tomosynthesis scan angles	±7.5° (15°) ±12° (24°) ±25° (50°)
C-arm vertical movement (Floor-Table)	From 54 to 145 cm (travel of 91cm)*
Vertical movement Speed	5 cm/s
C-arm rotation Range	±180° (CW, CCW continuous to any position)
Projection preset positions	N° 7 Programmable projections
Rotation speed	20°/s (automatic rotation); 10°/s (manual rotation) with acceleration and deceleration ramp for smooth operation
Protection of examination field	Removable polycarbonate screen

*tolerance ±0.5cm

CONTROL SWITCHES	
Number and type	Three multiswitches (five push-buttons) Two on both sides of C-Arm, one on tip of X-RAY tube cover
Control actions	Vertical movement of C-Arm Continous rotation of C-Arm Switch-on of collimation light

AUTOMATIC COLLIMATION DEVICE	
Type	Automatic recognition of compression paddle format and position
Light Source	LED (Risk Group 2 at 20 cm- according to IEC EN CEI 62471) (Risk Group 1 at 50 cm - Low Risk - according to IEC EN CEI 62471)
Light beam	Switch ON by push-button or automatic when operating compression (selectable by service) Electronic timer
Light intensity	≥ 150 lux
Light beam collimation accuracy	according to IEC 60601-2-45:203.8.5.4
Mirror	with automatic out of field function
Image Formats*	Trapezoidal dynamic for TOMO tomosynthesis 24x30 cm 18x24 cm 14x30 cm 12x30 cm 11x30 cm 10x24 cm 11x14 cm 9x13 cm 8x11 cm

	7x7 cm 8x5 cm/7x5 cm (Biopsy)
Protection of examination field	Protective screen to keep patient's face out of X-ray beam during bidimensional exams Extended protective screen to keep patient's face out of X-ray beam during tomosynthesis exams
*depending on typical configuration used	

EMERGENCY STOPS	
Number and Type	Two red push-buttons on both sides of mammography unit One red push-button on Acquisition Work Station (if in option)
Function	To Switch totally off the power of mammograph except calculator and logic interfaces (Safety to close/save studies and switch off the unit)

DIGITAL FLAT PANEL DETECTOR **AXS2430, AXS2430V2, AXS2430FDI, AXS2430FDIV2 DETECTORS**	
Detector Technology	(a-Si) TFT Array + Pin photodiode Amorphous Silicon Amorphous Selenium (a-Se)
Selenium thickness	200 μm
Case dimensions	35,9x34,6 cm (24x30 cm format)
Top Cover	Carbon fiber 0.1 mm Al equivalent
Chest Gap	3,9 mm
Cooling Method	Air + Fan (integrated) NOTE: The detector blowers will typically create a difference of around 4-5 degrees with respect to the ambient temperature.
Digitalization type	Logarithmic
Pixel dimension	85x85 μm
Pixel dimension in tomosynthesis reconstruced slices	85x85 μm (with any scan angle)
Pixel dimension in synthetic 2D images	85x85 μm
Active Area	23.9x30.5 cm (24x30 cm format)
Image Matrix	2816x3584 (24x30 cm format)
Image Depth	16 bit
Fill factor	88 % geometric (for a-Se Detector) 80% geometric (for a-Si Detector)
MTF (Modulation Transfer Function)	**For a-Se Detector:** >90% @ 1 lp/mm >40% @ 5,8 lp/mm **For a-Se Detector v2:** >95% @ 1 lp/mm >50% @ 5,8 lp/mm **For a-Si Detector:** >75% @ 1 lp/mm (typical 85%) >10% @ 5 lp/mm for a-Si Detector (typical 20%) **For a-Si Detector v2:** >85% @ 1 lp/mm (Minimum>75%) >20% @ 5 lp/mm (Minimu>10%)
DQE (Detector Quantum Efficiency) (for exposure of 28kV)	**For a-Se Detector:** >50% @ 1 lp/mm >20% @ 5,8 lp/mm) **For a-Se Detector v2:** >70% @ 1 lp/mm >20% @ 5,8 lp/mm **For a-Si Detector:** >45% @ 1 lp/mm (typical 50%) >10% @ 5 lp/mm (typical 20%) **For a-Si Detector v2:** >50% @ 1 lp/mm (Minimum>45%) >20% @ 5 lp/mm (Minimum>10%)
Resolution	5,9 lp/mm (Nyquist)
Signal to Noise Ratio (SNR)	15,19 (28,5 kV-10 mAs)

(with 45 mm PMMA Phantom)	
Ghost Image factor (Point n°2b.2.4.5 of "European Guidelines")	EUREF 0,05
Reconstruction time from last exposure (Model 020 BR3D CIRS phantom, 50 mm thick)	< 15 s (in 2D mode) **Tomosynthesis mode (all slices)**: 9 s (scan angle of 15°) 10 s (scan angle of 24°) 11 s (scan angle of 50°)
Time to display the image on the acquisition workstation from last exposure (Model 020 BR3D CIRS phantom, 50 mm thick)	< 15 s (in 2D mode) **Tomosynthesis mode (slab of 10 mm)**: 19 s (scan angle of 15°) 20 s (scan angle of 24°) 30 s (scan angle of 50°)
Tomosynthesis acquisition time	**Option a-Si Standard:** 5 s (with scan angles of 15°) 6 s (with scan angles of 24°) 11.5 s (with scan angles of 50°) **Option a-Se Standard:** 10 s (with scan angles of 15°) 12 s (with scan angles of 24°) 30 s (with scan angles of 50°) **Option a-Se Fast:** 2.5 s (with scan angles of 15°) 4 s (with scan angles of 24°) 7.7 s (with scan angles of 50°)

SOLO DM DETECTOR	
Detector Technology	Crystalline Silicon
Conversion Screen	CsI Direct Deposited on FOP / Hi-Res GadOx
Case dimensions	354 × 265.7 × 31.5 (mm)
Active area	228 x 291 (mm)
Top Cover /sensor protection material	Carbon Fiber (2.0 mm thick)
Chest wall distance	1,6mm
Housing material	Aluminum Alloy
Weight Limit (kg)	Applied to a single spot with diameter of 10 cm: 20 kg Distributed evenly over the detector area: 200 kg
Cooling Method	There are two cooling modes available: Active cooling (three stage, programmable) and Passive cooling (the fans are powered down). The cooling mode depends on the heat transfer conditions between the detector and environment and is determined by the user/integrator of the detector for the actual operating conditions of the detector. The evaluative criterion for increasing the fans power is temperature above 35 °C in the CMOS sensor area. This temperature can be checked using specific feature "TileTemperature".

Ingress protection	IP21
Pixel Size	49.5 × 49.5 μm
Pixel resolution limit (cyc/mm)	10.1
Usable Pixel Area (pixels)	4608 × 5888
Fill Factor	79%
Energy Range (kVp) Standard Option Rad-Hard Option	 20 – 40 20 – 160
Scan Method	Progressive, Rolling Shutter
A/D Conversion (bits) Standard Extended	Linear 14 16
Dynamic Range (dB) Standard Extended	 72 82
Sensitivity (DN / μGy)	~105
MTF (Modulation ransferFunction)(%) 2 cyc/mm 4 cyc/mm 6 cyc/mm 8 cyc/mm	W/Rh Beam 70 43 25 15
DQE (Detector Quantum Efficiency) 1 cyc/mm 4 cyc/mm 6 cyc/mm 8 cyc/mm	W/Rh Beam 100 μGy 65 45 30 20
Signal to Noise Ratio (SNR) (with 45 mm PMMA Phantom)	10-14 (28,5 Kv-10 mAs)
Ghost Image factor (Point n°2b.2.4.5 of "European Guidelines")	<0,2
Image processing time after exposure	< 2 s (in 2D mode)
Minimal Time Between Two Consecutive Images Acquisition	< 5 s (in 2D mode)
Tomosynthesis acquisition time	**Option Standard:** 10 s (with scan angles of 15°) 12 s (with scan angles of 24°) 25 s (with scan angles of 50°) **Option Fast:** 5 s (with scan angles of 15°) 6 s (with scan angles of 24°) 12,5 s (with scan angles of 50°)

GRID	
Type	Linear, Vibrating
Interspace Material	Carbon Based Polymer (2D); Graphite (3D)
Ratio	6:1 (2D); 5:1 (3D)
Lines/cm	36(2D); 102 (3D)
Contrast factor	1,54 (2D); 1,30 (3D)

DEVICE FOR GEOMETRIC MAGNIFICATION (OPTIONAL)	
Type	Gridless, Interchangeable with Potter-Bucky
Magnification ratio	1,5x /1,8x/2x
Small focus selection	Automatic once fitted

IMAGE QUALITY	
Spatial resolution	Conformity with: "European Guidelines for quality assurance in mammography screening", Fourth edition, and with "Recommended specifications" for Quality assurance in mammography of American College of Radiology

"SensROI" AUTOMATIC EXPOSURE CONTROL	
Controlled parameters	Auto kV / Auto mAs (Zero Point Mode) Manual kV / Auto mAs (One Point Mode)
Auto parameters selection criteria	Dual mode: PRE and FAST PRE: tissue composition based (parameters evaluated by short X-Ray exposure) FAST: compressed breast thickness based
Sensitive area (only for PRE mode)	Automatically selected in function of employed compression paddle

"POEt" POST-PROCESSING ALGORITHM	
Type	Specific for mammography to optimize the quality of acquired images
Description	Processing of acquired RAW images and display in "For Presentation" format to enhance breast tissue structures and reduce the noise
Dedicated Filters	For geometric magnification and in case of prosthesis, metallic clips, surgical markers, clusters of microcalcifications, breast specimens and surgical anatomical parts
Images compression format	JPEG LOSSLESS (JL) JPEG 2000 LOSSLESS (J2L)
Images saving/export format	DICOM FOR PROCESSING FFDM DICOM FOR PROCESSING (TOMO projection)

TOMOSYNTHESIS	
Number of X-Ray exposures (projections)	11 (with scan angle of 15°) 13 (with scan angle of 24°) 24 (with scan angle of 50°) Angular span remains constant during TOMO views
Reconstruction method	Back-projection technique (FBP) with incorporated iterative technique to improve image quality and remove artifacts
COMBO procedure	Function that allows a 2D+tomosynthesis acquisition with a single breast compression
Distance between reconstructed slices	1 mm
Tomo acquisition control	Push-button with spiral cable Push-buttons on AWS (with AWS upgrade kit) Foot-control (optional)

RECONSTRUCTION SW OF SYNTHETIC VIEW FROM TOMO EXAM (OPTIONAL)	
Name	"M-VIEW/VI"

DOSE CALCULATOR	
Method of Calculation	Average Glandular Dose (AGD) according to: "D.R. Dance et al."
Data visualization (mGy)	On Acquisition Work Station
Method of recording	Image Header (DICOM)
AGD with a 4 cm PMMA phantom*	1,4 mGy (a-Se detector) 1,5 mGy(a-Si detector)
AGD with a 4 cm PMMA phantom for TOMO (Measured 43 mm PMMA)	1,6 mGy (Narrow) 2,2 mGy (Intermediate) 2,3 mGy (Wide)
Dose limits	According to European Protocol for Dosimetry and EUREF protocol
*Only for 2D acquisition	

"SMART µPRESS" COMPRESSION SYSTEM

Compression Paddle movement	Motor driven or manual with fine adjustment by double rotating controller
Standard compression Paddles	24x30 cm shifted for normal breasts 24x30 cm specific for TOMO breasts 18x24 cm with lateral shifting for small breasts
Compression Paddles	9x21 cm straight for magnification 18x24 cm with spot Φ7,5 cm for contact examination Φ7,5 cm spot for magnification examination 9x9 cm for magnification examination 18x24 cm with holes for bidimensional biopsy 10x24 cm for axillary examination 10x24 cm for prosthesis examination
Compression Paddle Holder	Fast mechanical unlock with rotating knob Right lock warning LED
Maximum free space available between Compression Paddle and top cover of Potter-Bucky/ top table of magnification device	182 mm with shifted Compression Paddles *In Magnification Mode* *(straight compression paddle)* 183 mm @ MAG. 1.5X 123 mm @ MAG. 1.8X 83 mm @ MAG. 2X
Compression Force (range)	Adjustable from 70 to 200 N
Minimum detectable value of compression force	30 N
Compression Force (visualization)	Effective applied force with 1 N resolution
Compression thickness accuracy	±1 mm
Compression Paddle Descent Speed	4 cm/s at the start Proportionally decreasing compressing the breast
Maximum Compression Force Safety Device	Triple: electronic, electro-mechanical, mechanical
Soft Compression paddle release after exposure	Selectable from control panel
Compression paddle aluminum equivalence	< 0.2 mm Al (0.135 mm Al≈30 kV)

ROTATING CONTROLLERS FOR MANUAL COMPRESSION	
Number and type	Two rotating wheels with central push-button on both sides of C-Arm

TOUCH SCREEN COLOUR DISPLAYS (MAMMO TSD)	
Number and type	Two TFT LED backlight resistive touch screens on both sides of C-Arm
Screen Size (aspect ratio)	7” (4:3)
Display resolution	640x480
Information	Compression force, compressed breast thickness, patient name, projection angle, breast laterality, ACR code, collimation format, magnification factor

FOOT-CONTROLS	
Number and type	One with two pedals and one push-button for motor driven compression unlock Two with two pedals and one push-button
Control Actions	Vertical movement of compression Paddle Motor driven compression unlock

MULTIFUNCTIONS FOOT-CONTROLS	
Number and type	One or two with four pedals and one push-button for motor driven compression unlock
Control Actions	Vertical movement of C-Arm Vertical movement of compression Paddle Motor driven compression unlock

INTEGRATED ACQUISITION WORK STATION (AWS)

CALCULATOR (INTEGRATED IN MAMMO UNIT)	
Operating Systems	Windows 10 IoT Enterprise
CPU	Intel Core i5-6500 (Quad Core) 3.2 GHz
RAM	8 or 16 GB
HDD	128 GB SSD for Operating System, DMD Acquisition Software and DMD Toolkit Software (256 GB SSD optional) 1 TB SATA for images storage (~ 25.000 images) (2 TB SATA optional)
Pointing and selection device	Keyboard with integrated touchpad
CD/DVD recorder	24x
USB port	1 (3.1)
Power pack	250 W

2 MP (standard), 3 or 5 MP (optional) COLOR MONITOR	
Technology	TFT Color LCD
Screen Size (diagonal)	24'' (2MP), 21,3''(3MP), 21,3''(5MP)
Display Resolution (pixels)	1.920X1.200 (2MP), 2.048X1.536 (3MP), 2.800X2.100 (5MP)
Viewing Angle	178° horizontal and vertical
Response Time	7ms (2MP), 20ms (3MP), 12.5ms (5MP)
Brightness	600 cd/m² max-350 cd/m² DICOM calibrated (2MP) 900 cd/m² max-500 cd/m² DICOM calibrated (3MP) 1000 cd/m² max-500 cd/m² DICOM calibrated (5MP)
Contrast ratio	1000:1 typical (2MP), 1400:1 typical (3 and 5 MP)

ANTI-X PROTECTIVE BARRIER (OPTIONAL)	
Type	Half transparent screen (metallic lower part and transparent upper part)
Pb equivalence and thickness	> 0.34 mm @35 kV (IEC 60601-2-45) = 0.26 mm @49 kV (thickness 20 mm) >0.5mm up to 150kV (optional) (thickness 11mm)
Dimensions	773x2100x505 mm

SEPARATED ACQUISITION WORK STATION (AWS)

CALCULATOR (INTEGRATED IN MAMMO UNIT)	
Operating Systems	Windows 10 IoT Enterprise
CPU	Intel Core i5-6500 (Quad Core) 3.2 GHz
RAM	8 or 16 GB
HDD	128 GB SSD for Operating System, DMD Acquisition Software and DMD Toolkit Software (256 GB SSD optional) 1 TB SATA for images storage (~ 25.000 images) (2 TB SATA optional)
Power pack	250 W

CONSOLLE WITH TRANSPARENT ANTI-X PROTECTION BARRIER	
Pb equivalence	> 0.34 mm @35 kV (IEC 60601-2-45) = 0.26 mm @49 kV (thickness 20 mm) >0.5mm up to 150kV (optional) (thickness 11mm)
Pointing and selection device	Touchscreen on 15” or 17’’ color display
CD/DVD Recorder	24x
USB port	1 (3.1)
Dimensions	857x2003x640 mm
Weight	90 kg (0,34 mm Pb eq) 56 kg (0,50 mm Pb eq)

TOUCH SCREEN COLOUR DISPLAY (with optional AWS)	
Technology	Resistive LCD screen (Active matrix TFT LCD for optional touch screen display)
Screen Size (aspect ratio)	15” or 17’’ (4:3)
Display Resolution (pixels)	1024x768
Viewing Angle	160° horizontal/150° vertical (160° horizontal/150° vertical for optional touch screen display)
Brightness	350 nits (300 nits for optional touch screen display)
Contrast ratio	500:1 (800:1 for optional touch screen display)

2 MP (standard), 3 or 5 MP (optional) COLOR MONITOR	
Technology	TFT Color LCD
Screen Size (diagonal)	24’’ (2MP), 21,3’’(3MP), 21,3’’(5MP)
Display Resolution (pixels)	1.920X1.200 (2MP), 2.048X1.536 (3MP), 2.800X2.100 (5MP)
Viewing Angle	178° horizontal and vertical
Response Time	7ms (2MP), 20ms (3MP), 12.5ms (5MP)
Brightness	600 cd/m² max-350 cd/m² DICOM calibrated (2MP) 900 cd/m² max-500 cd/m² DICOM calibrated (3MP) 1000 cd/m² max-500 cd/m² DICOM calibrated (5MP)
Contrast ratio	1000:1 typical (2MP), 1400:1 typical (3 and 5 MP)

11.1. ELECTROMAGNETIC INFORMATIONS ACCORDING TO IEC 60601-1-2

Basic Safety and Essential performance of medical equipment

Medical electrical equipment is safe according to IEC 60601-1. It is protected against:

- electrical hazards;
- environmental hazards;
- radiation hazards;
- thermal hazards;
- mechanical hazards;
- biological and biocompatibility hazards;
- use errors and functionality hazards;
- general hazardous outputs.

Essential performance:

- Correct functioning
- Unintended X-ray radiation

See also “Compliance statement”.

Basic Safety notes for EMC

Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided in the accompanying documents. Portable and mobile RF communications equipment can affect medical electrical equipment.

Fixed equipment or system cabling, which cannot be removed by the user, is not listed. This cabling is part of the system and was present at all EMC-measurements. Without this cabling there is no complete functionality of the system.

Medical Electrical equipment must be installed and used in an environment where radiofrequency is controlled i.e. Professional Healthcare facility environment (CISPR 11 Class A).

WARNING

The use of components, transducers and cables other than those specified, with the exception of transducers and cables sold by Metaltronica S.p.A. of the equipment or system as replacement parts for internal components, may result in increased emission or decreased immunity of the equipment or system.

WARNING

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

CAUTION

Do not use the HELIANTHUS series in electromagnetic environment in which radiated RF disturbances are not controlled.

CAUTION

It is strictly recommended to keep no closer than 0.3 m (12 inch) to any part of medical equipment (including cables) portable RF communication equipment such as antennas, mobile phones or other emitting EMC waves in order to prevent EMC interferences. If a mobile RF source emits 450 MHz or 930 MHz, keep it no closer than 0.7 m and 0.38 m, respectively.

CAUTION

This system may cause radio interference or may disrupt the operation of nearby equipment. It may necessary to take mitigation measures such as re-orienting / relocating the equipment or shielding the location.

CAUTION

If RF/EMC interferences causes essential performances lost such as incorrect functioning, incorrect display visualization or unintentional changes in operating mode, please stop immediately the exam, switch-off the unit and remove cause of interference.

EMC reference tables

Guidance and manufacturer's declaration – Electromagnetic emissions		
The HELIANTHUS series is suitable for use in the specified electromagnetic environment. The purchaser or user of the HELIANTHUS series should assure that it is used in an electromagnetic environment as described below:		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The HELIANTHUS series uses RF energy only for its internal function. Therefore, its RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The emission characteristics of HELIANTHUS series is 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 measured, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	N.A.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant	

Guidance and manufacturer's declaration – Electromagnetic immunity

The HELIANTHUS series is suitable for use in the specified electromagnetic environment. The purchaser or user of the HELIANTHUS series should assure that it is used in an electromagnetic environment as described below:

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	DIRECT DISCHARGE Air discharge voltage (kV): 15, 8, 4, 2 Contact discharge voltage (kV): 8 INDIRECT DISCHARGE Contact discharge voltage (kV): 8	IEC 60601-1-2 test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 % and maximum 60% during the test.
Radiated electromagnetic field IEC 61000-4-3	3 V/m (80 MHz to 2.7 GHz)	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of the EUT. including cables. Minimum distance 30 cm
Electrical fast transient/burst IEC 61000-4-4	±2 kV for input a.c. and d.c. power ports ±1 kV for signal input/output ports whose maximum cable length is more than 3m	IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	INPUT POWER PORTS 0.5 and 1.0 kV (differential mode) 0.5, 1.0 and 2.0 kV (common mode) SIGNAL INPUT/OUTPUT 2.0 kV	IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3V RMS (Outside ISM band) 6V RMS (Inside ISM band) Frequency range: 150 kHz to 80MHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of the EUT. including cables. Minimum distance 30 cm
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	IEC 60601-1-2 test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	VOLTAGE DIPS 0% U_T for 0.5 cycle (at 0°,45°,90°,135°,180°,225°,270°, and 315°) 0% U_T for 1 cycle (at 0°) 70% U_T for 25 cycle (@ 50 Hz) and for 30 cycles (@ 60 Hz) (at 0°) VOLTAGE INTERRUPTIONS 0% U_T for 250 cycle (@ 50 Hz) and for 300 cycles (@ 60 Hz) (at any Sync Angle degree)	IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HELIANTHUS series requires continued operation during power mains interruptions, it is recommended that the HELIANTHUS series be powered from an uninterruptible power supply or battery.

Frequency Range and Level: proximity fields from RF wireless communication equipment		
Test Frequency (MHz)	**Modulation**	**Immunity Level (V/m)**
385	Pulse Modulation: 18Hz	27
450	Pulse Modulation: 18Hz	28
710 745 780	Pulse Modulation: 217Hz	9
810 870 930	Pulse Modulation: 18Hz	28
1720 1845 1970	Pulse Modulation: 217Hz	28
2450	Pulse Modulation: 217Hz	28
5240 5500 5785	Pulse Modulation: 217Hz	9

WEEE INFORMATIONS ACCORDING TO DIRECTIVES 2012/19/EU and 2002/96/EC (Waste Electrical and Electronic Equipment)

The following crossed-out wheeled bin symbol,

that is present on the device, means that within the European Union the product must be taken to separate collection at the product end-of life. Therefore, at the end of the life-cycle of the device, the user should deliver the device to the proper collection facilities of the Electric and Electronic Equipments. Alternatively, the user can return the device to the seller, on a one-to-one basis, as long as he is buying a new one of equivalent type and that fulfills the same functions as the old one.

Disposing of the device separately avoids possible negative consequences for the environment and health deriving from inappropriate disposal and enables the constituent materials to be recovered to obtain significant savings in energy and resources.

Who disposes any Electric and Electronic Equipment, reporting the above symbol, as unsorted municipal waste, instead of collecting it separately, incurs the administrative sanctions in accordance with law.

Section XII: Warranty Conditions

WARRANTY CONDITIONS

Metaltronica S.p.A. is committed to replacing, free of charge, any part of the machine that proves to be faulty, for a period of twelve months from the date of installation.
THIS WARRANTY DOES NOT PROVIDE FOR DEFECTS DUE TO:

- damage caused during transportation
- damage for storage/operation outside temperature and humidity limits
- damage caused by the incorrect installation of the unit, if not carried out by personnel trained by Metaltronica S.p.A.
- damage caused by inappropriate connection to other units
- damage caused by improper use, negligence, carelessness or inability to use unit.
- use of not original spare parts or components

GLASS PARTS are excluded by any kind of warranty.

THE WARRANTY DOES NOT APPLY TO MATERIAL SUBJECT TO WEAR AND TEAR .
X-Ray tube is covered by pro rata temporis warranty

THE WARRANTY EXPIRES AUTOMATICALLY IN THE EVENT OF TAMPERING AND/OR INTERVENTION BY PERSONNEL THAT IS NOT EXPRESSLY AUTHORIZED BY METALTRONICA S.P.A..

The aforesaid terms are to be considered valid except as otherwise set forth in the contract.

METALTRONICA S.P.A. RESERVES THE RIGHT TO MAKE FURTHER IMPROVEMENTS WHILE KEEPING MAIN FEATURES UNCHANGED.

To: METALTRONICA S.p.A.
Service Department
Via delle Monachelle, 66
00071 Pomezia (Rome) – ITALY
Tel. +39/0666160206
Fax. +39/0666160357

FAILURE REPORT

IMPORTANT NOTICE:

This report shall be submitted whenever a failure occurs. Information given through this form will expedite manufacturer's technical assistance.

In case of warranty claim this report is mandatory: warranty will not be processed without receiving this form properly filled in.

DISTRIBUTOR: NAME _____

ADDRESS _____

USER: NAME _____

ADDRESS _____

X-RAY EQUIPMENT: TYPE _____

SERIAL NUMBER _____

DATE OF PURCHASE _____

DATE OF INSTALLATION _____

SOFTWARE RELEASE _____

NUMBER OF EXPOSURES _____

FAILURE: DESCRIPTION _____

_____

_____

_____

_____

_____

_____

FAILURE:

EXPOSURE TECHNIQUE AT THE MOMENT OF THE FAILURE OCCURRENCE:

MANUAL ☐ ZERO POINT ☐ ONE POINT ☐

kV _____ mAs _____ mm _____ _____

EVENTUAL PREVIOUS FAILURES SIMILAR TO THE PRESENT ONE:

_____

_____

DETAILED DESCRIPTION OF X-RAY EQUIPMENT OPERATING CONDITIONS AT THE MOMENT OF THE FAILURE OCCURRENCE:

_____

_____

EVENTUAL REPAIRS TEMPORARILY CARRIED OUT:

_____

_____

DEFECTIVE AND/OR DAMAGED COMPONENTS:
(Please specify Metaltronica S.p.A. code and description)

MECHANICAL _____

ELECTRICAL _____

ELECTRONIC _____

DATE OF FAILURE ____/____/____

DATE ____/____/____ REPORT FILLER SIGNATURE _____

SEAL OF THE COMPANY AND SIGNATURE OF AUTHORIZED PERSON

SAFETY FEEDBACK

A/*To*: **METALTRONICA S.p.A.**
Servizio Assistenza Tecnica Medicali
Technical Assistance
Via delle Monachelle, 66
00040 Pomezia (Rome) – ITALY
Tel. +39/0666160206
Fax. +39/0666160357
e-mail: satme@metaltronica.com

Al fine di migliorare continuamente la qualità e la sicurezza dei prodotti offerti, vi chiediamo di segnalarci tempestivamente, compilando il presente modulo, qualsiasi potenziale causa di rischio legata ai nostri dispositivi medici.
In order to continuously improve quality and safety of our medical products, we kindly ask you to quickly signal us, filling in this form, any potential cause of risk bound to our medical devices.

DISTRIBUTORE *DISTRIBUTOR*	**NOME** *NAME*	
	INDIRIZZO *ADDRESS*	

OPERATORE *USER*	**NOME** *NAME*	
	INDIRIZZO *ADDRESS*	

APPARECCHIATURA *EQUIPMENT*	
TIPO *TYPE*	
NUMERO DI SERIE *SERIAL NUMBER*	
DATA DI ACQUISTO *PURCHASE DATE*	
DATA DI INSTALLAZIONE *INSTALLATION DATE*	
REVISIONE SOFTWARE *SOFTWARE REVISION*	
NUMERO DI ESPOSIZIONI *NUMBER OF EXPOSURES*	

DESCRIVERE DETTAGLIATAMENTE IL RISCHIO RILEVATO (REALE O POTENZIALE) CIRCOSTANZIANDO LE CONDIZIONI OPERATIVE IN CUI SI E' RISCONTRATO. SUGGERIRE ANCHE EVENTUALI SOLUZIONI. *PROVIDE US WITH A DETAILED DESCRIPTION OF THE REVEALED RISK (REAL OR POTENTIAL) HIGHLIGHTING THE RELATED OPERATING CONDITIONS. EVENTUAL SUGGESTION ARE WELL ACCEPTED.*

DATA *DATE*		**FIRMA** *SIGNATURE*	

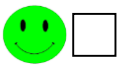
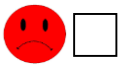
Ref;PD8.2-d Mod. 8.2-d A5_FDS Rev. xx

Do you have any annotations on this Manual?

Your opinion matters for us!

We would like to make effort to improve our product manuals. Do you have a moment? Please, give us your direct feedback, note or suggestion about this manual, it help us to do better!

Overall Operator comprehension

Notes	Reference page
Manual reference:	

Optional information

Hospital		City/Country	
Date	____/____/____	E-mail/Phone	
Name		Signature	

Send it to our customer care service team:
metaltronica@metaltronica.com