CE 0051

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XFM

Digital mobile diagnostic X-ray system

TECHNICAL MANUAL

Cod. **MTE-XFM**
Revision **05**

APPARECCHI RADIOLOGICI ELETTROMEDICALI
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MANUAL INFORMATION		
RELEASE	MTE-XFM Revision 05	VALID FROM SN 10-369-20
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CHECKED	RICCARDO SARTI	(QUALITY ASSURANCE)
APPROVED	A. PASTORELLI	(DESIGN MANAGER)
DATE OF EMISSION		16/11/2020

REVISION INDEX			
Code	**Rev.**	**Date**	**Change**
MTIXFM00	00	02/10/2012	First Emission
MTIXFM01	01	12/02/2013	General revision
MTIXFM02	02	15/07/2013	Introduction new notified body, CE2460
MTE-XFM	03	02/10/2014	Change in the identification number of the notified body CE 0051
MTE-XFM	04	07/08/2019	Modified Par. 4 and 5
MTE-XFM	05	16/11/2020	RDM 570 -RDM 602

This manual in English is the original version.

1 INDEX

2 GENERAL NOTE

2.1 CONVENTION OF THE DOCUMENTS

This manual uses three types of indications to highlight information or potential risks for personnel or equipment: Note, Important and Warning.

WARNING

The WARNING highlights the procedures to be followed scrupulously to avoid damage to yourself, to others, to the system or to any component, loss of data or damage to the files of the software applications. Failure to follow the instructions marked with the word Warning may cause abnormal operation.

IMPORTANT:

The indication "Important" includes essential information that affects how the manual and the product are used.

NOTE:

Notes emphasize additional information, such as suggestions or reminders.

Symbols preceding the information on the identification label:

SYMBOL	***Title***
	Manufacturer
	Device Code
	Serial Number
	Date of Production

Other Symbols Used:

SYMBOL	***Title***
	Attention
	RAEE

	TYPE B APPLIED PART
	Consult the instructions for use
	CE Mark
	Ionizing radiations
	Alternating Current
	Ground Protection
	Dangerous voltage
	Refer to the user manual

2.2 SAFETY INFORMATION

This manual aims at providing the operator of the medical appliance XFM with all the information needed for a correct use of the device.

Read the contents of this manual carefully before using the device.

Italray is relieved of any liability in the main cases:

- improper use of the machine;
- use contrary to specific national regulations;
- incorrect installation;
- power supply defects;
- Serious shortcomings in planned maintenance;
- unauthorized modifications and interventions;

- use of spare parts or materials not specific to the model;

- total or partial non-compliance with the instructions provided;

- exceptional events.

2.2.1 RADIATION PROTECTION

This device emits ionizing radiation for medical purposes: the X-ray source always represents a danger, especially in the event that the operator is not qualified and properly informed. Excessive X-ray exposure causes damage to the body. Consequently, all precautions must be taken to prevent unauthorized and unqualified people from using this equipment, thus creating a danger for themselves and other people. The equipment must not be used for purposes other than those envisaged.
Laws restrict the use of this equipment to physicians or individuals with legal authorization.
The type of radiation exposure that occurs with the use of this device can be divided into two categories:
- professional, for operators
- diagnostic, for patients undergoing examination.
When performing X-ray examinations, there is always a radiation leak; this makes protection from the latter indispensable.

Before performing the examination, the radiologist / doctor must always ascertain the patient's possible state of pregnancy to be examined.

If a person is to be next to the patient, they must wear protective clothing.

Additional radiation protection can be achieved by using the manual button for exposure at least 2 meters away from the X-ray beam. The fully extended spiral cable length of the manual switch is approximately 4 meters. If X-ray equipment is not used properly it can cause injury. Consequently, these instructions must be read and fully understood before putting this equipment into operation. The Manufacturer will be happy to offer the buyer assistance and collaboration to put the equipment into operation. Even if this equipment provides a high level of protection against X-rays, in addition to those of the useful beam, no operative measure can guarantee absolute protection. The operator will be responsible

for taking all the necessary safety measures to avoid risks, both personal and others, deriving from incorrect or excessive exposure to radiation.

2.2.2 ELETTRICAL SAFETY

WARNING

The company declines all responsibility if authorized personnel do not comply with the requirements contained in this manual for the fulfillment of their duties.

WARNING

To avoid the risk of electric shock, this appliance must only be connected to power supply networks with protective earth

WARNING

The device is not protected against the entry of liquids, as in its normal use it does not require the use of liquids. To avoid the risk of electric shock, do not use liquids near the device.

In order to avoid irreparable damage to some components, do not carry out repetitive switching on of the appliance. After each power off of the appliance, wait a few seconds before turning it on again.

If anomalies and malfunctions that cannot be resolved with the indications described in the manual occur, the operator must contact the manufacturer of the appliance to receive the necessary instructions from ITALRAY s.r.l.' s technical office.

Before carrying out any operation, people qualified and authorized to use this equipment must be informed of the protection measures established by the International Commission on Radiological Protection and related national standards.

WARNING

The manufacturing company declines all responsibility for the proper functioning of the machine in the event that its installation or maintenance is carried out by unauthorized persons.

In order not to cause any damage to the functionality of the equipment, do not perform any type of intervention or technical test without explicit authorization from the manufacturer or the authorized technical assistance service. The manufacturer reserves the right to modify the product described in this manual at any time and without notice.

WARNING

The use of accessories, transducers or cables other than those specified, with electro-medical devices or electro-medical systems, can lead to greater emissions or a decrease in the immunity of the electro-medical device or of the electro-medical system.

2.2.3 PRIVACY

It is the responsibility of the manager of sensitive data to regulate the use of the system and access to the data of the same (also through a LAN or wi-fi connection), for the purposes of privacy, data security, protection from any computer viruses which could damage the system. Italray declines all responsibility in this regard.

2.2.4 WARNINGS ON THE BATTERIES IN THE PANEL AND IN THE DEVICE

It is assumed that this product poses no health or safety hazard or hazard when used in the intended manner. If the battery is damaged because it has been opened, cut, crushed, or due to overheating, improper installation, exposure to fire or high temperatures, or charging, its contents may be released. The materials contained in this battery can pose a risk only if the integrity of the battery is compromised or if the battery is physically or electrically damaged. Do not open or disassemble. Do not expose to fire or open flames. Do not mix batteries of various sizes, chemicals or types. Do not puncture, deform, burn or heat.

2.2.5 ENVIRONMENT

The device complies with the WEEE 2012/19 / EC and ROHS 2011/65 / EC (Waste from Electrical and Electronic Equipment Directive and Reduction of Hazardous Substances) Directives on the restriction of harmful substances and on waste electrical and electronic equipment.

Italray s.r.l. is registered in the National Register of Electrical and Electronic Equipment Manufacturers with the number:
IT08020000000971
Registration date: 14/02/2008

Packaging:

- o Wood and bubble film 100% recyclable

- Device materials:

- o 100% recyclable ferrous materials

- o 100% recyclable plastic materials
- o Cables and other electrical material 100% recyclable

For the panel, follow the manufacturer's recommendations. The device cannot be disposed of as normal urban solid waste, it must be delivered to a specific disposal center in compliance with the laws in force.

2.2.6 WARRANTY

ITALRAY guarantees all its medical devices for a period of 1 year from the delivery date. It is possible to extend this term by signing a technical assistance contract in the manner and needs of the customer.

ITALRAY ensures the availability of spare parts and maintenance for a period of 10 years from the date of installation.

2.3 DIRECTIVE AND APPLICABLE STANDARD

This device has been designed and built in compliance with:

Directive	***Description***
93/42/CE e s.m.i	Direttiva dispositivi medici. *Medical device directive*
2006/42/CE	Direttiva macchine. *Machinery Directive*

Regolament	***Description***
UE N° 207/2012	Istruzioni per l'uso elettroniche dei dispositivi medici. *Instructions for electronic use of medical devices*

Technical Standards	***Description***
EN 60601-1:2006/A1:2013	Prescrizioni generali relative alla sicurezza fondamentale e alle prestazioni essenziali. *Medical electrical equipment. General requirements for safety*
EN 60601-1-2:2015	Prescrizioni generali per la sicurezza fondamentale e prestazioni essenziali - Norma collaterale: Compatibilità elettromagnetica. *Medical electrical equipment. General requirements for safety - Collateral standard: Electromagnetic compatibility – requirements and test*
EN 60601-1-3:2008	Protezione dalle radiazioni in apparecchi radiologici diagnostici. *General requirement for radiation protection in diagnostic X-Ray*
EN 60601-1-6:2010/A1:2015	Apparecchi elettromedicali. - Parte 1: Prescrizioni generali relative alla sicurezza fondamentale e alle prestazioni essenziali – Norma collaterale: Usabilità. *Medical electrical equipment. - Part 1: General requirements for basic safety and essential performance - Collateral standard: Usability*
EN 60601-2-54:2009	Apparecchiature elettromedicali. Parte 2. Prescrizioni particolari relative alla sicurezza fondamentale e alle prestazioni essenziali di apparecchi a raggi X per radiografia e radioscopia. *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*
EN 62304:2006/A1:2015	Software per dispositivi medici - Processi relativi al ciclo di vita del software. *Medical Device Software - Software life-cycle processes*
EN 60601-2-28:2010	Apparecchi elettromedicali. - Parte 2: Norme particolari per la sicurezza di complessi radianti a raggi X e complessi tubo-guaina per diagnostica medica. *Medical electrical equipment. - Part 2: Particular rules for the safety of X-ray radiant complexes and tube-sheath complexes for medical diagnostics.*
EN 62366-1:2015	*Medical devices - Application of usability engineering to medical devices.*
EN ISO 15223-1:2016	Dispositivi medici - Simboli da utilizzare nelle etichette del dispositivo medico, nell'etichettatura e nelle informazioni che devono essere fornite - Parte 1: Requisiti generali. *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*
EN ISO 14971: 2012	Dispositivi medici - Applicazione della gestione dei rischi ai dispositivi medici. *Medical devices - Application of risk management to medical devices*
EN ISO 13485:2016	Dispositivi medici - Sistemi di gestione per la qualità - Requisiti per scopi regolamentari. *Medical devices – Quality management systems - Requirements for regulatory purposes*
EN 1041:2008	Informazioni fornite dal fabbricante di dispositivi medici - *Information supplied by the manufacturer of medical devices*

3 ELECTROMAGNETIC COMPATIBILITY

Requirements related to CEI EN 60601-1-2.

XFM requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and put into service in accordance with the electromagnetic compatibility information provided in the accompanying documents.

Portable and mobile radio frequency (RF) devices can disturb electrical medical devices.

MANUFACTURER'S GUIDE AND DECLARATIONS. ELECTROMAGNETIC EMISSIONS		
The XFM system is designed to be operated in the electromagnetic environment described below. The client and/or user of the XFM system must ensure that the working environment corresponds to these indications.		
Emission check	**Conformity**	**Electromagnetic environment - Guide**
RF CISPR 11 - *CEI EN 55011* Emissions	Group 1	XFM uses RF energy only for its internal functions. Therefore, RF emissions are very low and are not likely to interfere with nearby electronic devices.
RF CISPR 11 - CEI *EN 55011* emissions	Class A	The XFM system is suitable for use in all buildings, other than domestic ones, and those directly connected to the low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000 - 3 - 2	Not applicable	
Voltage variation emissions/flicker IEC 61000 - 3 - 3	Not applicable	

MANUFACTURER'S GUIDE AND DECLARATIONS - ELECTROMAGNETIC IMMUNITIES			
The XFM system is designed to be operated in the electromagnetic environment described below. The client and/or user of the XFM system must censure that such an environment is actually in use.			
Immunity check	**Test level IEC 60601**	**Conformity level**	**Electromagnetic environment - Guide**
Electrostatic shock (ESD) IEC 61000 – 4 – 2	± 8 kV in contact ± 15 kV in the air	± 8 kV in contact ± 15 kV in the air	Floors must be wood, concrete or ceramic. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Transient/fast power trains IEC 61000 – 4 – 4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Line voltage quality shall be the one used for a typical commercial or hospital environment.
Overvoltage IEC 61000 – 4 – 5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Line voltage quality shall be the one used for a typical commercial or hospital environment.
Loss of voltage, short voltage interruption or variation on the supply input lines IEC 61000 – 4 – 11	0% UT for 20 Sec 0% UT for 20 Sec 70% UT for 20 Sec	0% UT for 20 Sec 0% UT for 20 Sec 70% UT for 20 Sec	The quality of the mains voltage should be that of a typical commercial or hospital environment. If the user of the XFM system requires continued operation even during the interruption of the mains voltage, it is recommended to power the system with an uninterruptible power supply (UPS).
Magnetic field with mains frequency (50/60 Hz) IEC 61000 – 4 – 8	30 A/m	30 A/m	Magnetic fields with net frequency should have the characteristic levels used for commercial or hospital environments.

Guidance and manufacturer's declaration - electromagnetic immunity

The equipment or EM system is immune to disturbances produced by portable RF equipment not less than 0.3m away.

Test frequency [MHz]	Band[a] [MHz]	Service[a]	Modulation[b]	Maximum Power [W]	Distance [m]	Test level for immunity [V/m]
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM[c] deviation± 5 kHz sinusoidal 1 kHz	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, IDEN820 CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; GSM 1900; DECT; CDMA 1900; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450 LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n,	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE: If it is necessary to reach the TEST LEVEL FOR IMMUNITY, the distance between the transmission antenna and the EM DEVICE or EM SYSTEM can be reduced to 1 m. The test distance of 1 m is permitted by IEC 61000-4-3

[a] For some services, only satellite connection frequencies are included.

[b] The carrier must be modulated using a square wave signal with a 50% cycle.

[c] As an alternative to FM modulation, 50% pulse modulation with a frequency of 18 Hz can be used, as this does not represent actual modulation, but the worst condition.

Interference may occur near devices marked with the following symbol:

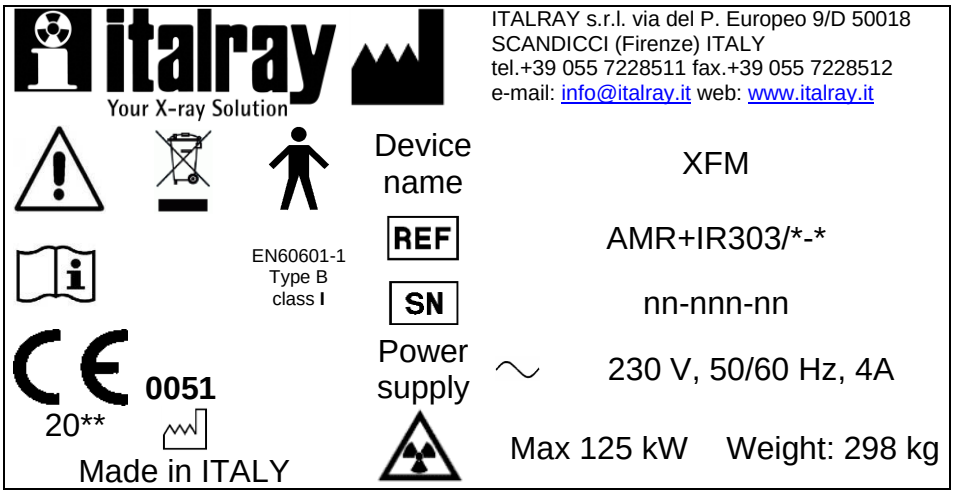
4 TECHNICAL FEATURE

4.1 IDENTIFICATION

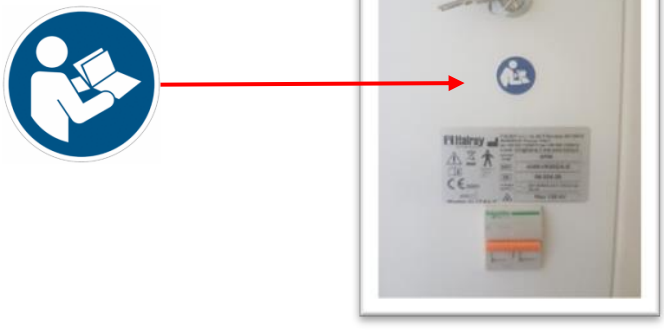
Modelli	
CODE	DESCRIPTION
AMR+IR303/X-X	Mobile digital radiographic device

4.2 LABEL

Always indicate the Code (REF) and Serial Number (SN) of the device for requests for repair or spare parts.



The device also has the following label "Follow instructions for use":



A second label with the characteristics of monobloc and RX tube is placed on the monobloc, these are the points where the labels are applied:

And a label showing the device's on and off-key indication.

Other warning labels are placed inside the device:

Image number	***Description***
1	The electric shock warning is present on the completely closed "capacitor box", located below the device
2	On the "converter" completely closed, there is an electric shock warning.
3	On the rear of the monobloc support column there is a warning sticker for parking the column before moving the device. The sticker is in full view of the operator who moves the device.

4.3 ENVIRONMENTAL CONDITION

XFM	
TRANSPORT AND STORAGE	WORK ENVIRONMENT
Temperature: -25 ÷ +70°C Moisture: 20 ÷ 80% Atmospheric pressure: 500 mbar ÷ 1100 mbar	Temperature: +10 ÷ +40°C Moisture: 20 ÷ 80% Atmospheric pressure: 500 mbar ÷ 1100 mbar

4.4 SPECIFICATIONS

TECHNICAL SPECIFICATION		
Mechanical characteristics	**Length x Width x Height**	1230 x 680 x 1610 mm
	weight	~ 298 kg
	Height (retracted column)	1610 mm
	Maximum distance of fire from the floor:	2050 mm
	Minimum distance of fire from the floor:	700 mm 630 mm parking position
	Tube arm rotation	± 90°
	Tube arm rotation (horizontal axis)	-90° / +180°
	Tube arm rotation (vertical axis)	±90°
	Collimator rotation	0° / +90°
	Maximum front outreach	1030 mm
	Max Side outreach	880 mm
	Braking system	dead man mode
	Drive wheel diameter	435 mm
	Front wheels diameter	100 mm
Power Supply	**Device**	230 Vac 50/60 Hz mono phase
	Standby current	0,5 A
	Maximum instantaneous current	16 A
Radiological parameters	**Power**	40 kW
	Voltage	from 40 kVp to 125 kVp
	Current	from 50 mA to 500 mA

	Exposition time:	1 – 250 ms (battery mode) 1 – 6300ms (power supply)
	mAs values:	0,5 - 400 mAs (27 values)
	Operative mode:	**Two point tecnique** (**kV; mAs** variation) **three point tecnique** (**kV**, **mA and** e **second** variation)
	Anatomical techniques	Over 1000 memories
	RX Tube Safeguard	Control of the overload on the tube by real time thermal units counting
RX Tube	**Model**	I.A.E: RTM 77 H (rotating anode)
	Anode Material	RTM
	Anode Angle	15°
	N° focal spot	2
	focal spot dimensions	0,6 mm / 1,25 mm
	focal spot Power	14 kW / 40 kW
	Filtration	Total: 3,7mm Al (0,7 mm + add. 1mm + 2mm collimator)
	Thermal capacity	224kJ – 300kHU
	Continuous thermal dissipation	Max 750W
Altre Funzionalità	**Enhancement Hierarchical**	YES (EVEREST -X) - Auto
	LUT	Lineare o Logaritmica
	Generator Control	YES
	Anatomical tables	YES - Configurable
	R.O.I.	YES
	Flip/Mirror/ Image rotation	YES
	Pan/Zoom	YES
	exposure Index	YES
	Indice di deviazione	YES
	Livello di grigio min-max	YES
	Visualizzazione multi-immagine	YES
	Salvataggio dati radiologici	YES
	Window/Level	YES
	Window/Level automatic	YES
	note	YES
	Gray scale inversion	YES
	Linear/angular measurements	YES

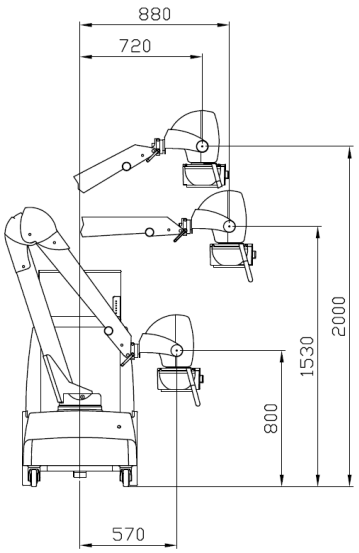
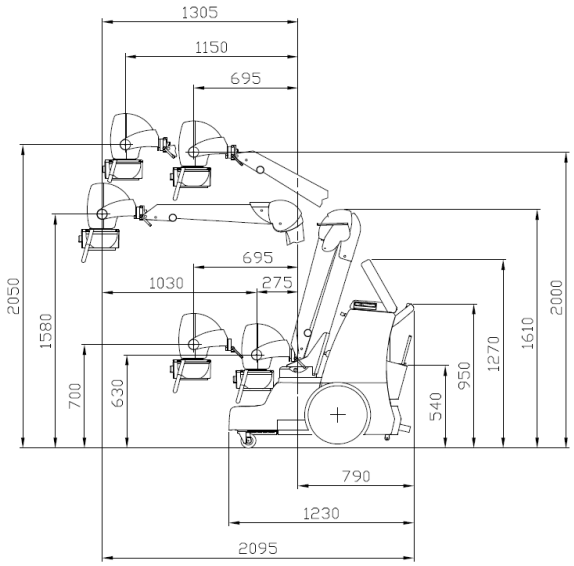
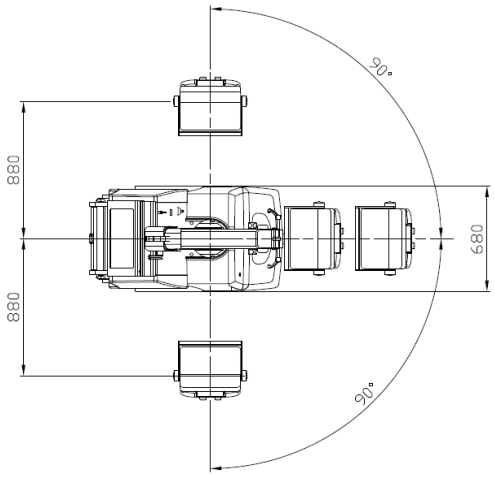
Funzionalità Dicom 3.0	**Storage (SCU e SCP)**	YES. Sending image to PACS
	Modality worklist (SCU)	YES. Interface with HIS / RIS with auto-refresh option
	Media exchange (DICOM DIR)	YES (*). Export of patient images to CD / DVD
	MPPS (SCU)	YES (*). Sending the examination status to the HIS / RIS
	Storage Commitment (SCU)	YES (*). Invio dello stato
	Verification (SCU e SCP)	YES (*).
	Query / Retrieve (SCU)	YES (*) Request and recovery of DX and CR images from PACS
	Grayscale print (SCU)	YES (*). DICOM Printer support
	Structured Dose Report	YES (*) Support for the exchange of structured data produced during image acquisition and / or processing
Personal Computer	**Processore**	Intel
	RAM	4 GB
	Hard disks	32 GB S.O. + 500 GB archivio
	Operative System	Windows 10
Collimator	**Modell**	Ralco R 104, manual
	Lead sheets	6 pair
	Type of light	LED
	Dimension	271x222x140mm
	Field type	Square field, up to 48x48 cm @ 100 cm FFD
	Measuring device and distance display detector (optional)	Optical meter with display on display
	Minimum inherent filtration	2 mm Al eq.
	4 Manual pediatric disc filters	1) 0 mm Al eq 2) 1 mm Al eq + 0,1 Cu 3) 1 mm Al eq + 0,2 Cu 4) 2 mm Al eq
Display TOUCH SCREEN (1)	**Model**	AUO, LCD 19” TOUCH SCREEN Capacitive technology
	Type	5:4
	Contrast	2000:1
	Brightness	600 cd/mq LED

	Resolution	1280x1024
	Viewing angle	178°
Classificazione	**IEC 60601-1**	Classe I Tipo B
	Grado di protezione IP	IP30
Battery Kit		
Type	Li-ion	
Recharge time	Less than 5 hours	
Battery	24 V	
Battery capacity	40 Ah	
Motorization Kit		
Max Speed	5 Km/h (1,38 m/s)	
Maximum slope overcome	12°	
Max. step height	2 cm	
Anti-collision system	Automatic braking system with obstacle recognition (excludable)	
Performance 40 Ah battery		
Number of exposition	Depending on the conditions of use and movement More than 350 exposures with the following parameters: 80 kV, 200 mA 12 mAs	
Exposition power	Up to 40 kW, even with a charge of less than 10%	
Duration in standby	Over 6 hours	
Battery level	The remaining charge percentage is displayed in real time on the lower right monitor	
Battery Capacity	40 Ah	

(*) Opzionale

(1) ITALRAY s.r.l. si riserva il diritto di apportare modifiche al prodotto descritto nel presente manuale in qualsiasi momento senza preavviso

4.5 INGOMBRI

FRONTAL VIEW	
LATERAL VIEW	
VIEW FROM TOP	

5 PRESENTATION OF THE SYSTEM

Intended use of XFM:

Mobile system for the acquisition and processing of digital radiographic images, intended to be used for bedside tests and diagnostic investigations in: orthopedics, first aid, intensive care, pediatrics, sports medicine.

The typical use consists in moving the device towards the bedridden patient for investigations of the skeletal system. Its use in orthopedics is common for the diagnosis of fractures of the bones especially of the limbs, for dislocations, osteoarthritis, post-operative checks and especially for chest radiography.

5.1 SYSTEM COMPOSITION

1. Monoblock with rotating anode x ray tube;
2. Collimator;
3. Handle for unlocking the parking brake and lever for manual / motorized operation;
4. Monitor touch screen;
5. System ON/OFF;
6. ON/OFF lock key;
7. X-ray push button;
8. Digital detector charging and storage station;
9. Rotating support arm;
10. Arm release handle;
11. DAP (optional);
12. Wireless Digital Detector;
13. Platform for overcoming steps;
14. DVD Writer (right side);
15. Circuit breaker for the exclusion of the power cable;
16. USB and LAN connections

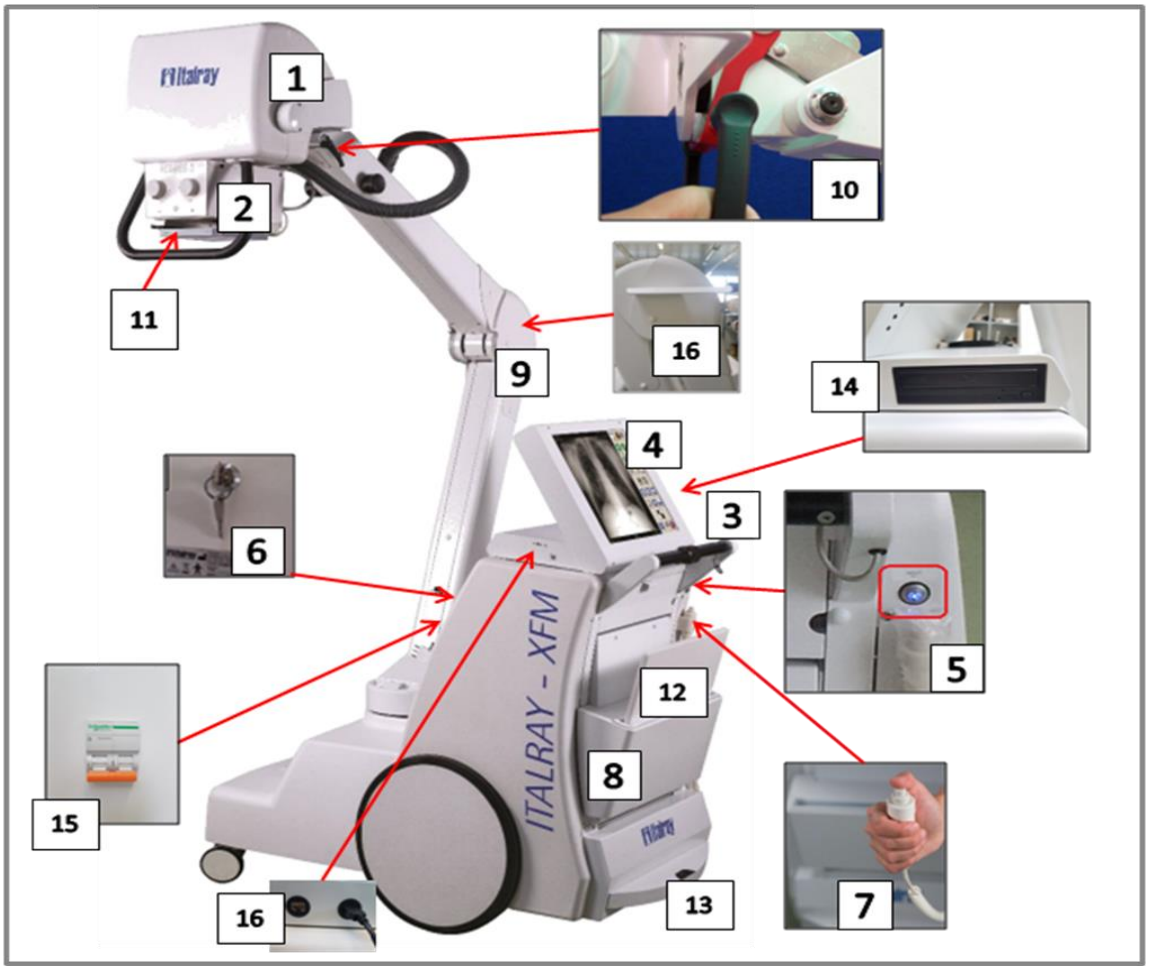


Figura 1 System composition

5.1.1 OPTIONAL ACCESSORIES

- DAP Product Dose Area meter;
- Wireless detector container for carrying out exams under load;
- Grid holder for wireless detector complete with grid;
- Wireless remote control for remote exposure control;
- Connecting the device to the hospital network in Wi-Fi mode;
- Measurement of the DFF with LCD display (present on the tube head).

6 INSTALLATION

6.1 SHIPMENT AND TRANSPORTATION

The equipment is normally shipped in cellophane.

If the equipment is shipped in a box, inside it is wrapped in pluriball sheets and fixed using wood beams to prevent the equipment from moving during transportation. For returns it may necessary to wrap the product as it was originally shipped.

A shockwatch label and the handling and destination instructions are applied on the outside of the box.

6.2 UNPACK THE EQUIPMENT

To unpack the equipment, follow the procedure as indicated in the following photos:

1. Open the box by removing the front panel identified by the label

2. Remove the platform and the beams, removing the screws visible from the outside of the box
3. Position the slide, inside the box and slide out the equipment

6.3 CONNECTING AND STARTING UP THE EQUIPMENT

The equipment does not need any particular installation, component connection, calibration or data entry operation before use.

6.3.1 POWER CABLE

The power cable is positioned frontally, under the key switch (see photo below). To connect the XFM to the mains, grasp the cable and pull. Once the desired length is reached, the cable stops.

IMPORTANT: *The cable has a maximum extension of 8 m, when the cable locks have reached this length,* do not pull the cable further.

To store the power cable, unplug it from the mains, pull it slightly to release it and gently accompany it until the wire is completely retracted.

WARNING Before handling the XFM device, the power cable must be completely rewound, as shown in the photo.

6.3.2 POWER ON

Switching on the device ***with the power cable connected*** (starting condition with the device off, safety key in the OFF position, mains power cable connected):

1) Arm the magnetothermic switch (if not already armed).

2) Turn the key switch to ON;

3) Press the ON / OFF button on the right of the device above the double-click spoke button;

WARNING use the sockets protected by differential switch C = 16A, rated residual current I_n = 30 mA, t = 0 s. The voltage and current power supply must conform to the label requests.

Switching on the device **in battery mode** (starting condition with the device off, safety key in the OFF position, mains power cable disconnected):

1) Turn the key switch to ON;

2) Press the ON / OFF button on the right of the device above the double-click spoke button;

NOTE: *In this case it is not necessary to arm the magnetothermic switch.*

In both cases, the system starts in about 15 seconds after pressing the ON / OFF button. During this period, it is possible to hear an audible signal that will stop when the ignition is complete. The power button lights up in blue.

6.3.3 SHUTDOWN

Once the work session is over, for the **correct shutdown and parking** of the device it is necessary to:

1. Park the XFM device near the wall power supply;
2. Press the ON / OFF button; an audible signal will accompany the system shutdown and will stop when the shutdown is complete;
3. Set the key switch to OFF;
4. Place the device in charge by connecting the power cable.

By performing these operations, the device enters the system's battery charging mode, necessary for motorized movement and for performing exposures without using the power cable.

NOTE: *In case of prolonged non-use, keep the device connected to the mains to use it at its maximum performance (with a charged battery).*

IMPORTANT: *when XFM is turned off and connected to the mains, the magnetothermic switch must be left armed to allow the batteries to recharge. If the switch is lowered, it is NOT possible to recharge the system batteries, because the power cable is excluded.*

IMPORTANT: *When the system is connected to the wall power supply, the motorization controls are disabled for safety reasons.*

it is however possible to make the device perform movements in manual modeF

6.4 PRE-USE CHECKS

WARNING

Before using the device, check whether the exposure cycles indicated here must be performed. Failure to follow the instructions can cause damage to the engine block

Before using the device, if the device has not been used for a number of days longer than indicated below, this exposure cycle must be performed.

If during the operation there are noises of discharges from the x-ray unit or other irregularities, the procedure must be interrupted and resumed after an hour.

IMPORTANT: *During the exposure cycle indicated below, it is advisable to close the collimator, to limit the emission of radiation into the environment.*

If the device has not been used for more than **15 days**, the preheating cycle indicated below must be carried out.

Select the large fire and perform the 6 exposures in the sequence shown below (total duration 2 min):

kVp	mAs	Esp	Intervallo
60	4	1	20 sec
60	10	1	20 sec
80	4	1	20 sec
80	10	1	20 sec
100	4	1	20 sec
100	10	1	20 sec

Monobloc preheating cycle

If the unit hasn't been used for more than **3 months**, run the **formation** cycle indicated below.

Perform the following exposures in the sequence indicated below (total time 1h and 10min):

kVp	mAs	Esp	range
40	6.3	3	20 sec
	pause		120 sec
50	6.3	3	20 sec
	pause		120 sec
60	6.3	3	20 sec
	pause		120 sec
70	6.3	3	20 sec
	pause		120 sec
80	6.3	3	20 sec
	pause		120 sec
90	6.3	3	20 sec
	pause		120 sec
100	6.3	3	20 sec
	pause		120 sec
110	6.3	3	20 sec
	pause		120 sec
120	6.3	3	20 sec
	pause		120 sec

125	6.3	3	20 sec
Pause			**30 min**
40	20	1	180 sec
50	20	1	180 sec
60	20	1	180 sec
70	20	1	180 sec
80	20	1	180 sec

Monoblock formation cycle

If there are no errors the equipment is ready for ordinary operation.

7 MAINTENANCE AND PERIODICAL CONTROLS

WARNING

The installation, the updating and the repairs of the X-ray equipment, must be carried out by personnel authorized by the manufacturer and in any case by technicians aware of the safety regulations on medical electrical equipment

This paragraph explains the list of preventive maintenance controls performed by technical assistance.

7.1 VISUAL CONTROLS

We suggest carrying out the below controls every year.

Part	Control
• Power cable	• Visual control for good condition (no cuts, abrasions, cracks)
• Labels	• Visual control for integrity and clarity
• X-ray monoblock	• Visual control for oil leaks. • Functional control for anode rotation (unusual noise during preparation phase)
• Collimator	• Follow maintenance plan indicated in the manufacturer's manual
• Control desk panel	• Visual control for panel integrity. • Clarity of symbols and characters on display.
• Wheels	• Visual control for integrity
• Fairing	• Visual control for good condition (no cuts, abrasions, cracks, dents, fixing)
• Touch screen	• Visual control for good condition (no cuts, cracks)

Visual controls

7.2 FUNCTIONAL CONTROLS – MECHANICAL ADJUSTAMENTS

We suggest carrying out the below controls every year. The parts of the equipment are in the following table:

Part	Control
1. Collimator	A. Functional control for light operation. B. Functional control for collimator rotation. C. Functional control for fixing of monoblock to flange. D. Functional control for light field-X-ray filed matching
2. X-ray monoblock	A. Functional control for stability of position on the rotation axis and its maximum rotation. B. Functional control for fastening of positioning handle.
3. Arm	A. Functional control for vertical stability and maximum height. B. Functional control for fastening of locking block.
4. Transportation handle	A. Functional control for brake operation (engagement/disengagement)
5. Wheels	A. Proper operation of rotation of front wheels on axis

Functional controls/mechanical regulation

7.2.1 CONTROLS PART 1 (COLLIMATOR)

Control A:

Switch on the machine and light the collimator lamp to verify the operation of the light.
If the light does not work see the manufacturer's manual.

Control B:

The collimator can rotate +/- 90° around the axis of the x-ray beam. The collimator's rotation travel is limited by a mechanical stopper.
If the collimator does not rotate contact the dealer of the machine.

Control C:

Verify that the collimator fixed to the monoblock does not move in other ways than those foreseen. If so, work on the fastening nuts on the collimator (see collimator manual)

Control D:

Verify that the light field matches the X-ray field following the instructions indicated on the collimator manual.

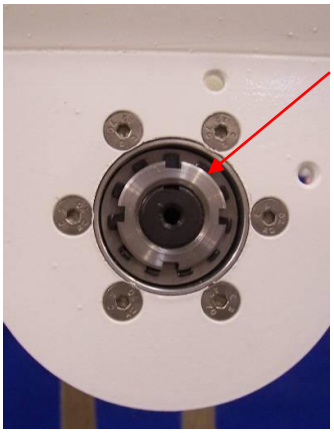
7.2.2 CONTROLS PART 2 (MONOBLOCK)

Control A:

The rotation of the monoblock group on the horizontal axis is ±180°.

Movement on horizontal axis

If the monoblock does not stay in the desired position work on the ring nut (detail indicated by arrow) placed on the fork support to adjust the friction.



Ring nut of horizontal position

The rotation of the monoblock group on the vertical axis is 0° ÷ +90°.

If the monoblock does not stay in the desired position work on the ring nut (detail indicated by arrow) placed on the fork support to adjust the friction.

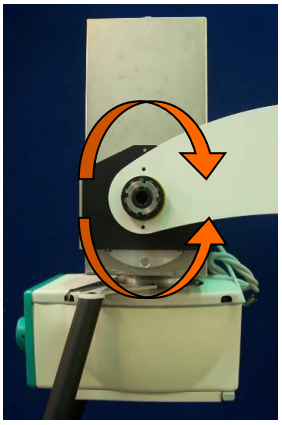


Figure 8 - Movement on vertical axis

Control B:

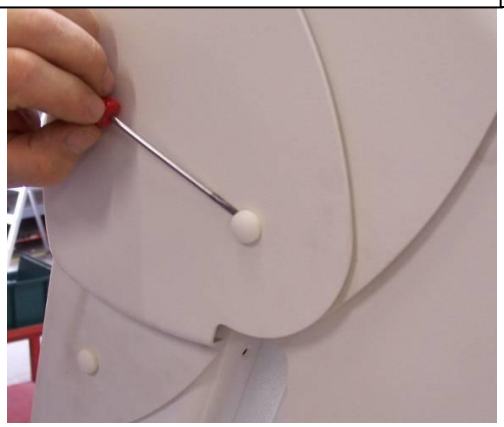
Verify that the handle does not move from its seat.

If it moves tighten the nuts and the fastening screws

7.2.3 CONTROLS PART 3 (ARM)

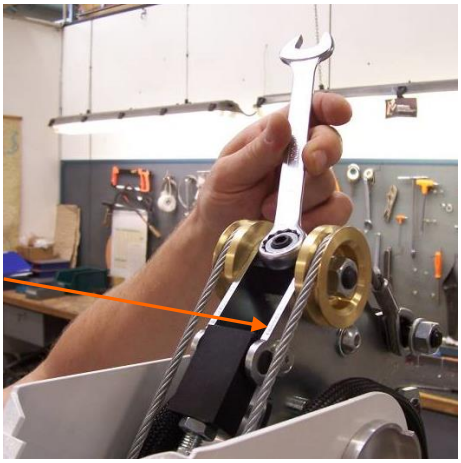
Control A:
Verify that the arms keeps the vertical position for the entire travel up to the maximum height foreseen (2 meters). If the arm does not keep the set vertical position follow the sequent instruction:

- Remove the arm cover and the articulation cover. Follow the sequent steps:

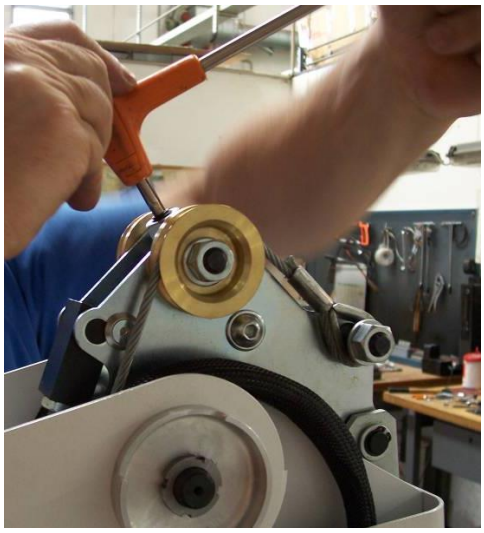
A Take away the plug on the articulation	**B** Take away the plug on the arm	**C** Unscrew the screw on the articulation cover
		
D Unscrew the screw on the articulation	**E** Take apart the second cover	**F** Take apart the third cover
		

Without the cover is possible to start the regulation.

- Loose the nuts to left and right, whit a 19mm key



- Lose the nut but do not remove it



- Tightly the nut whit a 16mm key and make the balance regulation.
- Tight all the nut loosed before
- After this operation restore all the arms covers removed before the balance adjust operation

IMPORTANT: *If after have tight to maximum tension the nut, the arm do not take the right position to balance IS NECESSARY TO REPLACE THE GAS SPRIG KIT.*

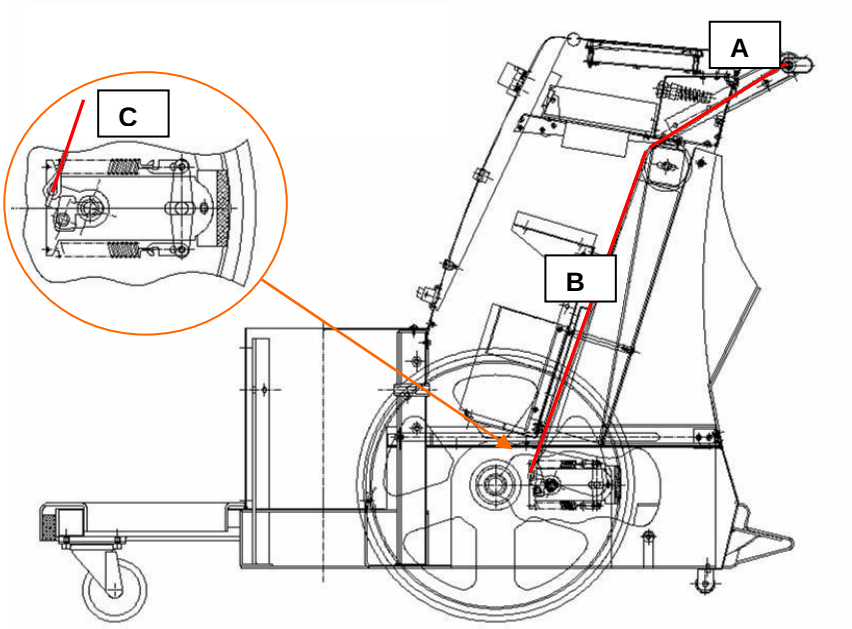
Control B :

Check that the hook of the arm takes the arm in block position to the column the loose hooking is the cause of deterioration of the components, is necessary to replace the hooking system.

7.2.4 CONTROLS PART 4 (TRANSPORTATION HANDLE)

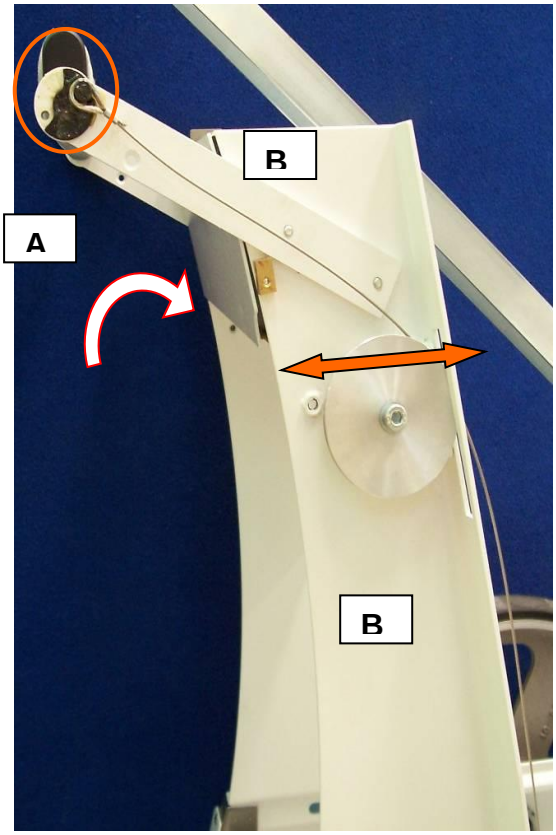
Control A: Check that the unit do not move whit the transport handle (Pos.3) in rest position; for a good functionality can you move the unit only whit a rotation of the handle to the floor.

If the condition of the brake system is no good maybe the iron cord of the brake system is broken.



For replace the brake iron cord is necessary to remove the cover of the unit. After the remove of the cover for change the iron cord of the brake is necessary:

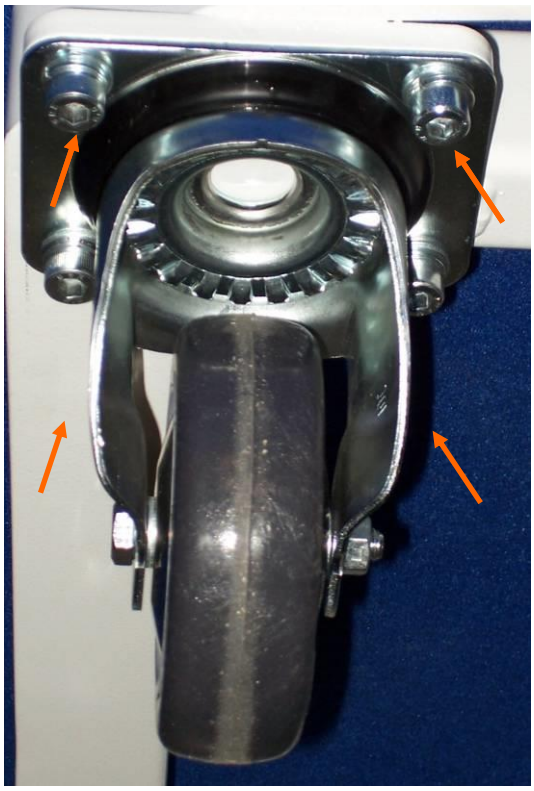
- Loose the broken iron cord to unhook the buttonhole A and C.
- For to adjust the new iron cord lose the nut B for to slide the pulley in back.
- Adjust the new iron cord between the part B and hooking the buttonhole A and C
- Move the part B for take in tension the iron cord. Tight the screw for adjust the pulley in good position.



IMPORTANT: *For have a good functionality of the brake is necessary to have a little tension of the iron cord.*

7.2.5 CONTROLS PART 5 (WHEEL)

Control A:
Check whit all the movements of the front wheels (rotation and rolling condition) and of the rear wheels (rotation), see the pictures paragraph Mechanical parts.



To replace the front wheels, loose the 4 screws indicated whit the arrows.

To replace or remove the rear wheels is necessary remove the wheels cover and loose the iron ring indicated whit red arrow.
For remove or restore the wheel is necessary to unhooking the brake.

FUNCTIONAL ELECTRIC CONTROLS

Part	Control
Power cable	• Earth connection impedance • Leakage current
Control desk panel	• Functional, increase and decrease in the following values: • kVp, mA, sec, mAs, anatomic techniques. • Functional for keys. • Functional for LEDs.
Magnetothermal	• Functional, on and off
mAs	Stability – see next paragraph
kV	Stability – see par. Calibration kV
mA	Stability – see par. Calibration mA
RX time exposure	Stability – see par. Time Calibration

7.2.6 mAs CONTROL

Instrument to use: mAs meter d.c. (es. KEITHLEY 35035).

Remove jumper JP2 from Logic Board S100015, and connect the prods of the instrument.
Set reading on mAs

Perform an x-ray exposure using the parameters in the table

Values	Set values
60 kV	4 mAs
60 kV	10 mAs
60 kV	20 mAs
80 kV	4 mAs
80 kV	10 mAs
80 kV	20 mAs
100 kV	4 mAs
100 kV	10 mAs
100 kV	32 mAs

If the values do not fall within a 10% tolerance range, verify the adjustment of the mA.

NOTE: *At the end of the control, don't forget to reconnect jumper JP2.*

7.2.7 KV CONTROL

Instrument to use: kilovoltmeter (PMX-I/R).

Modality: position the instrument perpendicular to the radioactive source centering it on the collimator's cross at a distance of 100 cm from the focus, measured using the collimators meter.

Perform x-ray exposures using the parameters in the table:

60 kV	10 mAs	80 kV	10 mAs	100 kV	10 mAs

If the values do not fall within a 5% tolerance range, adjust the trimmer P4 of the Logic Board S100015 to bring them back within the range. This adjustment affects the entire kV range. If the values to adjust refer to the high or low values, see the CONFIGURATION instructions (kV I° step range adjust and kV II° step range adjust).

7.2.8 MA CONTROL

Instrument to use: mAs d.c. meter (es. KEITHLEY 35035).

Modality: connect the instrument to the Logic Board S100015, remove jumper JP2 and connect the prods of the instrument.

Power the unit, select modality 3P (KV, mA, s)

Perform x-ray exposures using the parameters in the table.

Verify that at the end of every x-ray exposure the display shows the correct value of the real mAs.

60 kV	50 mA	0,100 s	5 mAs
80 kV	50 mA	0,100 s	5 mAs
100 kV	50 mA	0,100 s	5 mAs
60 kV	100 mA	0,100 s	10 mAs
80 kV	100 mA	0,100 s	10 mAs
100 kV	100 mA	0,100 s	10 mAs
60 kV	200 mA	0,100 s	20 mAs
70 kV	200 mA	0,100 s	20 mAs
60 kV	320 mA	0,100 s	32 mAs
80 kV	320 mA	0,100 s	32 mAs
60 kV	400 mA	0,100 s	40 mAs
70 kV	400 mA	0,100 s	40 mAs

If the values do not fall within a 10% tolerance range, verify the adjustment of the mA to perform this operation (see paragraph ***mA adjustment***).

NOTE: *At the end of the control, don't forget to reconnect jumper JP2.*

7.2.9 X-RAY TIMES CONTROL

Instrument to use: Oscilloscope.

Modality: on Logic Board S100015

- Connect the probe to the test point TP20
- Take mass from test point TP12
- Suggested configuration of oscilloscope:
    - TP20, times base 1 msec/div, amplitude 1V/div, for exposures up to 0,006 s
    - TP20, times base 2 msec/div, amplitude 1V/div, for exposures at 0,012 s
    - TP20, times base 5 msec/div, amplitude 1V/div, for exposures at 0,040 s

Power the unit, select modality 3P (KV, mA, s). Perform x-ray exposures using the parameters in the table:

60 kV	200 mA	0,003 s	0,6 mAs
80 kV	200 mA	0,003 s	0,6 mAs
60 kV	200 mA	0,006 s	1,2 mAs
75 kV	200 mA	0,006 s	1,2 mAs
60 kV	200 mA	0,012 s	2,4 mAs
75 kV	200 mA	0,012 s	2,4 mAs
60 kV	200 mA	0,040 s	8 mAs
75 kV	200 mA	0,040 s	8 mAs

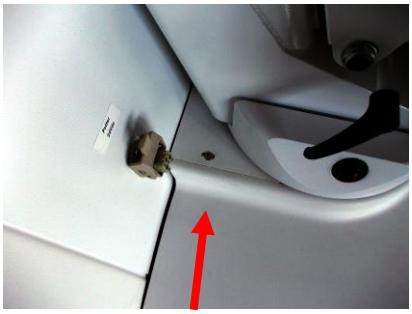
Verify the times on the oscilloscope, counting the beginning of the beams starting from 75% of the amplitude value read on the TP20. If the values do not fall within a 5% tolerance range, replace the CPU board.

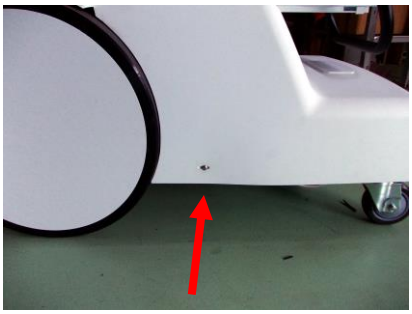
NOTE: *At the end of the control, don't forget to reconnect jumper JP2.*

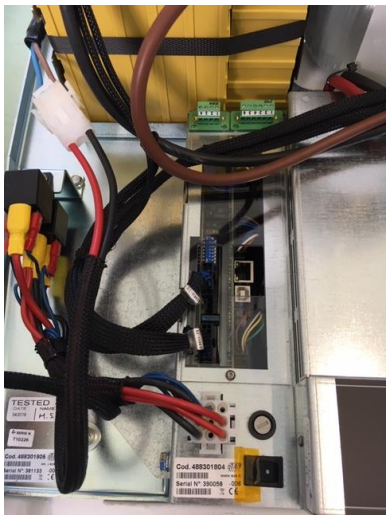
7.2.10 POWER SYSTEM BATTERY REPLACEMENT

Before proceeding with the batteries replaciment, make sure that the device is power off. If the device is power, shut down it proceeding in this manner:

Using a tool, remove the cover carter located over the battery compartment by removing the four screws that are located behind the arm stand and on the left and on the right side of cover carter.





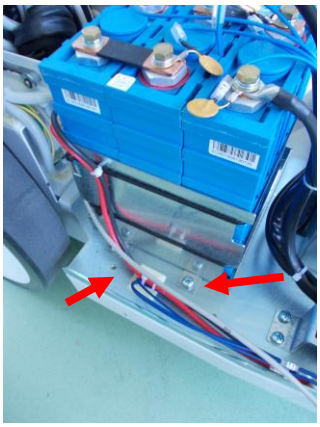


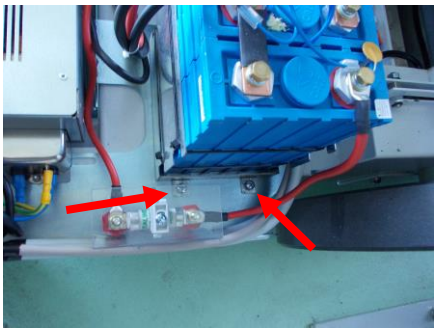
Disconnect the two connectors on one side of the UPS holder (see the figure below).

Take care during this operation: press the locking tabs located at the bottom of the connector body.

Insulate the connection between the batteries and the UPS by removing the gray connector on the back of the holder.

At this point, the electrical connections between the batteries and the rest of the system are completely removed and it is possible disassemble the batteries.
Each battery pack has two screws that lock it to the housing; remove the screws using a tool. Once the two packs are mechanically free, it is possible remove them.





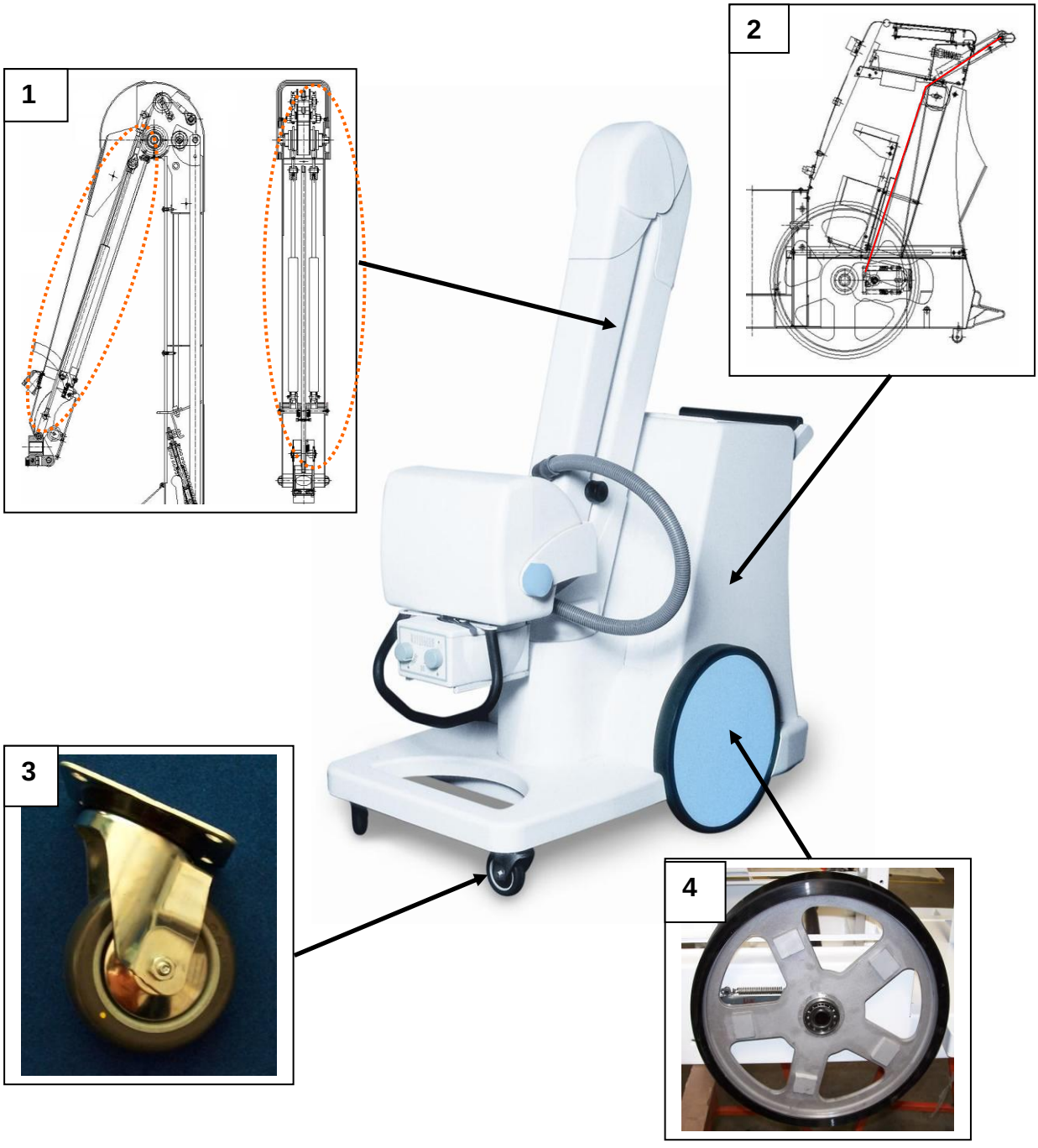
Follow the reverse procedure to install the new batteries. Due to the two battery packs are not equal in size, respect the positions.

When the two connectors should be reinserted, once completed the operation, check every single wire and make sure that everyone is properly inserted into the housing.

Perform this control is important, in order to prevent possible malfunctions.

8 SPARE PARTS AND REPLACING

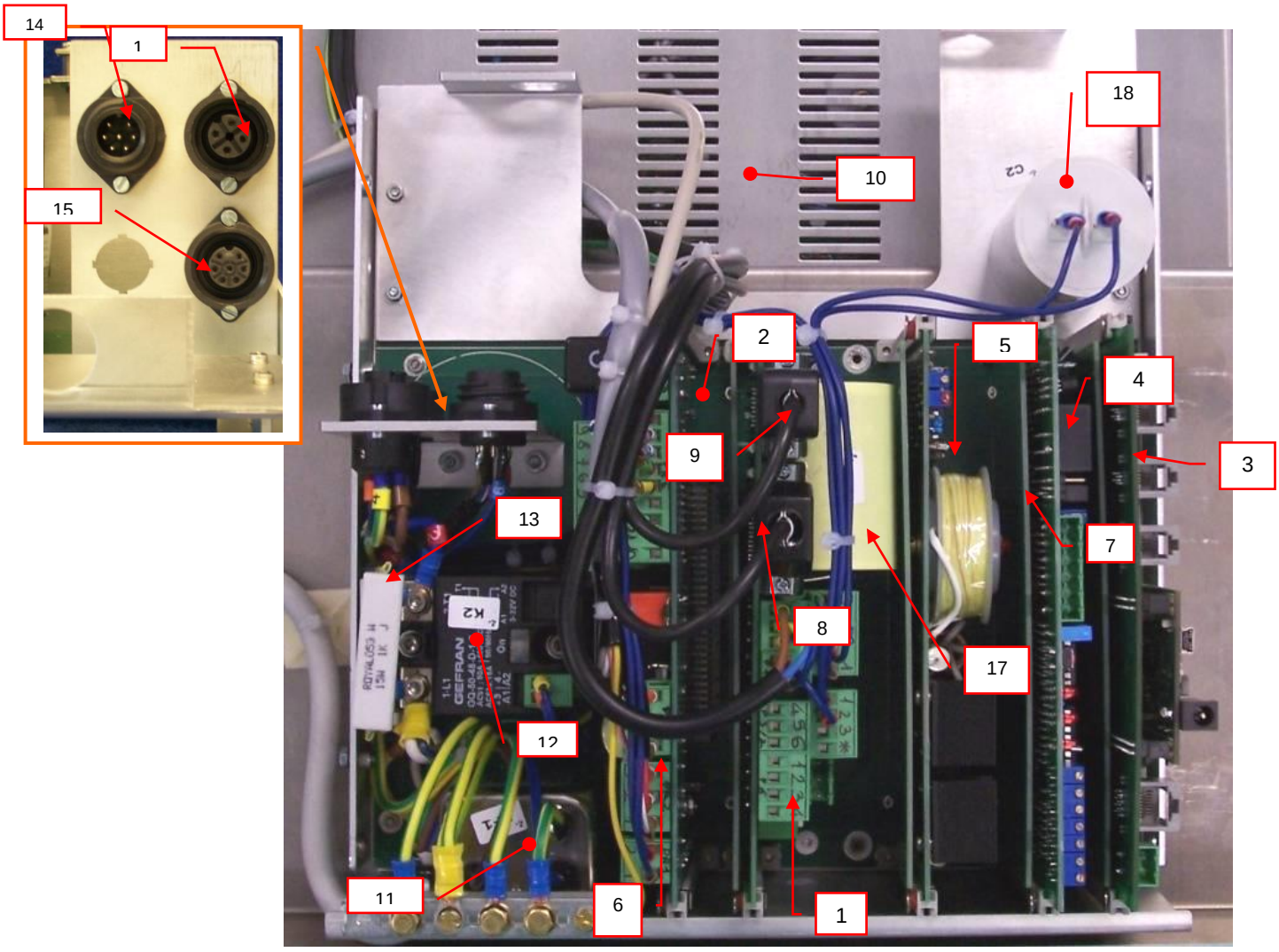
8.1 MECHANICAL PARTS



Position	Code	DESCRIPTION
1	SCOOK9	KIT GAS SPRING
2	73AO71	BRAKE ROPE
3	M20C24	FRONT WHEEL
4	73A008	BACK WHEEL

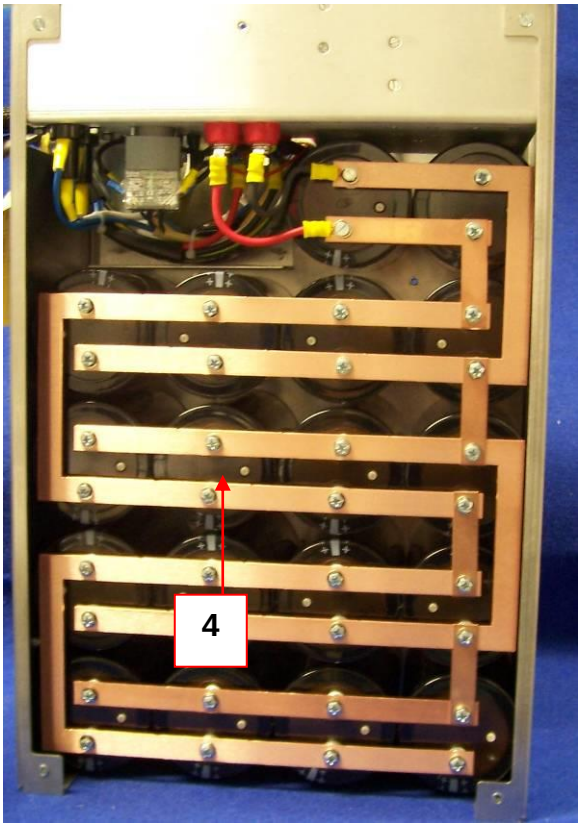
8.2 ELECTRONIC PARTS

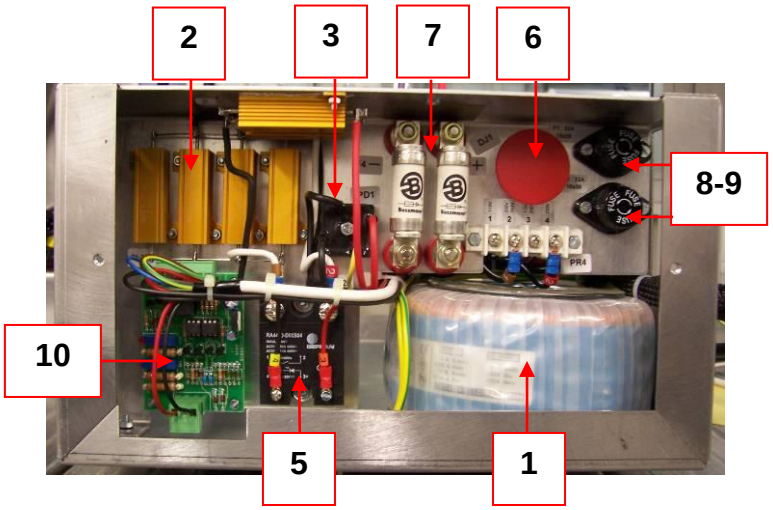
ELETTRONIC RACK F07S11

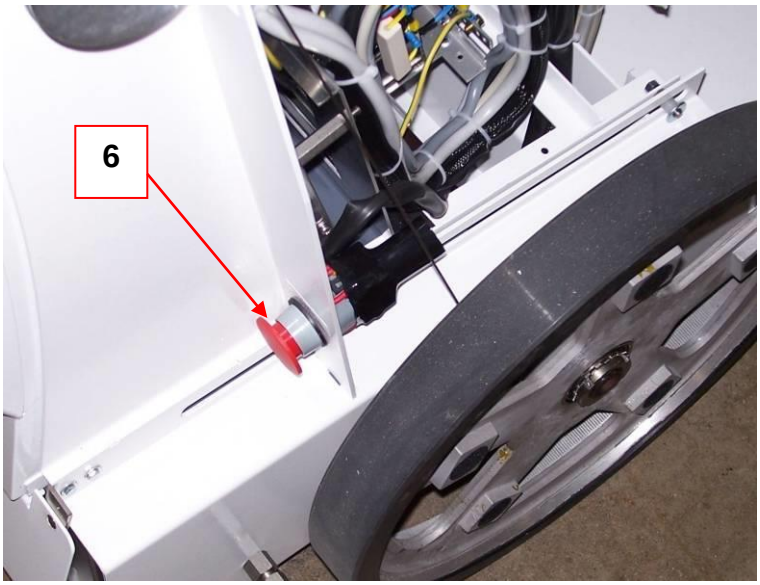


Pos.	Code	Description
1	E68S96	C.S. Conv. & Starter Interf.
2	E68S30	C.S. Back Plane
3	E68S45	C.S. Modulo Vulcano UC3C
4	E68SC7	C.S. Logic Board
5	E68S33	C.S. Filament Board
6	E68S41	C.S. PSU 8.5kW
7	E68S37	C.S. Schermo RF S1000H8
8	E50A50	Cable conn. conv. FB-I
9	E50A51	Cable conn. conv. PWM
10	F04S11	Converter
11	E55A30	Line Filter FN660B-16/06
12	E58A03	STATIC RELAY
13	E54A16	Resistor 1K
14	E62A34	Conn. Pann. M7P
15	E62A38	Conn. Pann. F7P
16	E62A35	Conn. Pann. F4P
17	E55A47	Cap. 250V 33uF
18	E55A29	Cap. 400V 40uF (40x94)

8.2.1 BOX CAPACITORS

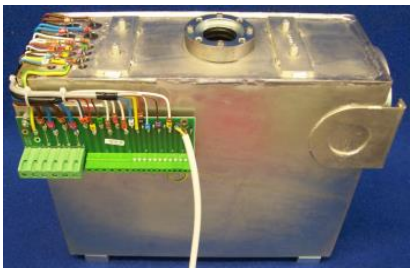






Position	Code	Description
1	E53A16	TOROIDAL TRANSFORMER SEC.0/285/305V
2	E54A14	RESIST. RB50 560R
3	E55A10	RECT. BRIDGE 36MB80
4	E55A41	CAPACITOR 1.76 6800uF 450V
5	E58A03	STATIC RELAY RA4450-D08-S04
6	E60A09	PULS. 704.070.2.704.9103
7	E61A01	FUSE BUSSMAN 50PE
8	E61A04	FUSE HOLDER 10x38 P1891
9	E61A16	RAPID FUSE 32A 10x38
10	E68S81	C.S. RELE COND. S100072

8.2.2 MONOBLOCK

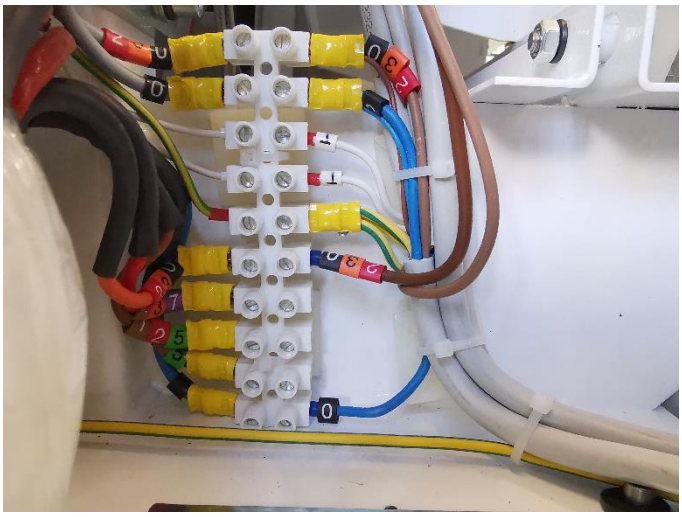


CODE	DESCRIPTION
F01S26	MONO 125/500HF (version 40kW)
F01S27	MONO 125/300HF (version 30kW)
E68SEB	Mono connection S003

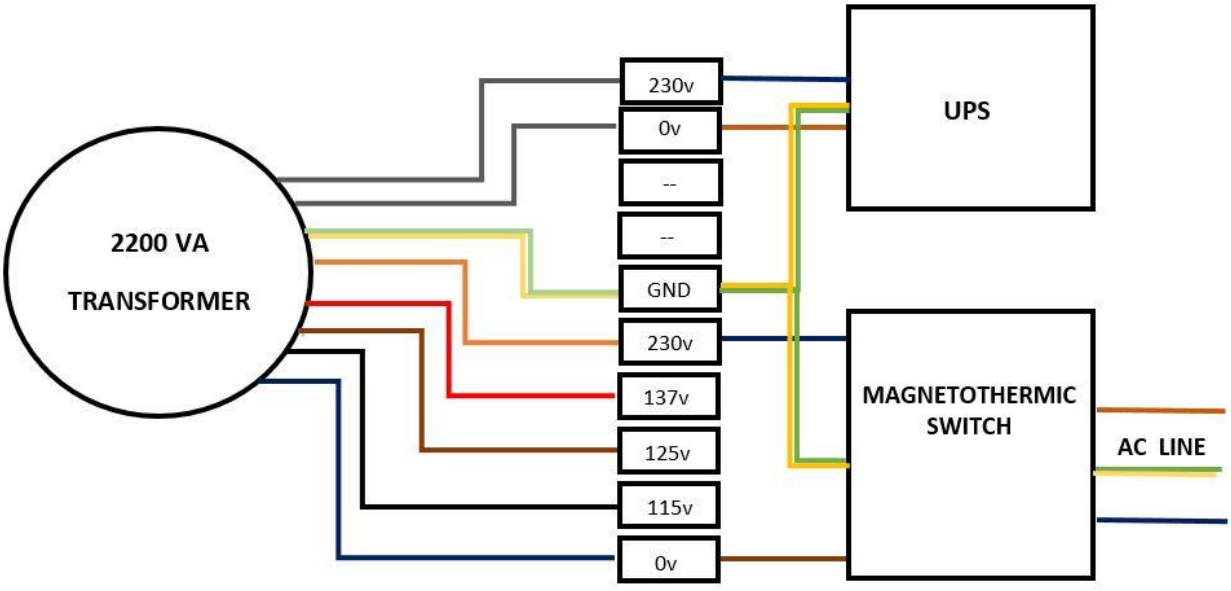
8.2.3 ISOLATION TRANSFORMER

General scheme of the wiring of the isolation transformer for 220/230V or 110/115V devices.

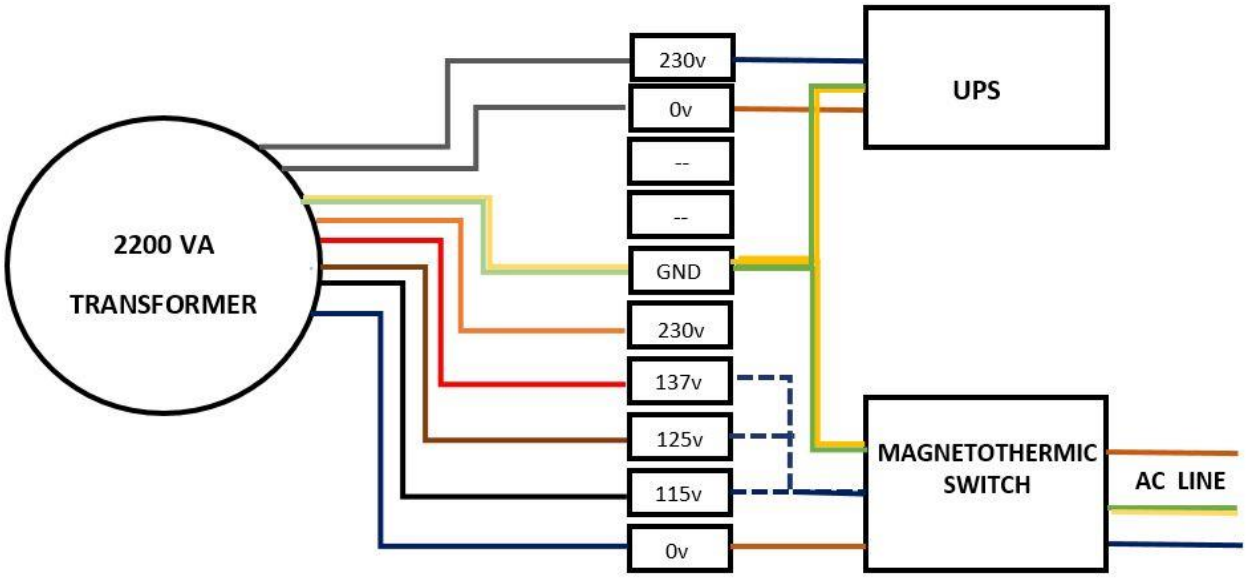
Fixing clamps in the isolation transformer wiring, for 230vac devices.



Insulation transformer wiring

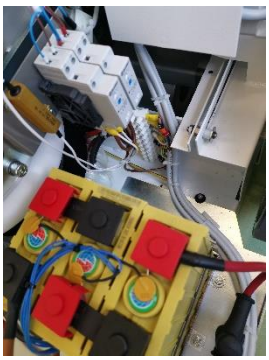


General scheme of the wiring of the isolation transformer for 110/115V devices.



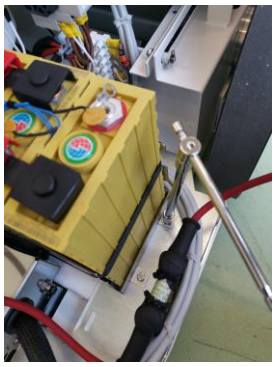
The wiring of the isolation transformer for the 115 AC line is very similar to the other;
The only difference is the connection of the input wires to the transformer.
Since the rated voltage of the power supply line is 115Vac, the standard connection is made by connecting the wires coming from the magnetothermic switch to terminals 0 V and 115 V.

Sometimes the power supply line could have a higher level;
If the situation is detected, it is possible to solve, by moving the input blue wire on the terminals, to connect one of the other voltage values (125V – 137V).

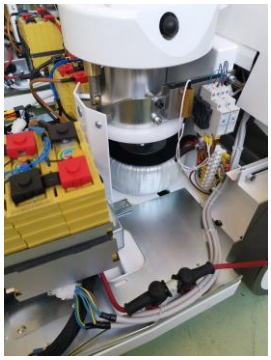


When this operation is necessary, since the terminals are positioned behind one of the two battery packs, the operator must remove it to have the possibility of working better.

First operation, remove the positive conductor from the last cell, it will be easier to move the battery pack.



Then, remove the two fixing screws that secure the battery pack to the metal floor



Last operation, carefully position the battery pack on the top cover of the UPS.

When the modification of the cabling on terminal clamps is done, place again the battery pack, then reconnect the positive conductor.

8.2.4 POWER CORD REPLACEMENT

Carry out at least one meter of cable:

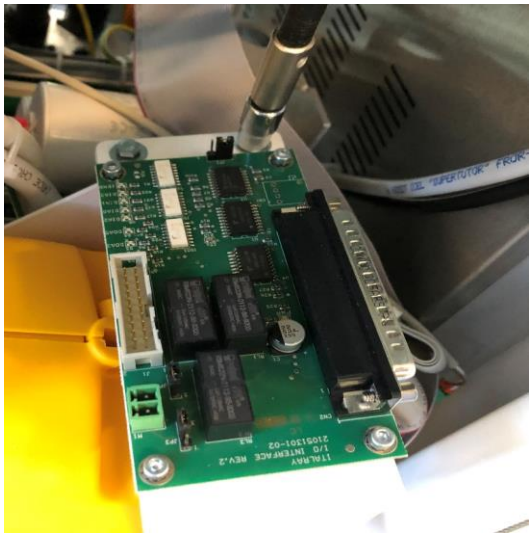
Disconnect the cable from the plug, then cut the clamp that holds the cable stop ball.

Remove the cable stop ball.

Remove the side cover by unscrewing the four M4x12 screws that fix it to the machine.

Disconnect the I / O board wiring.

Remove the cover on which the I / O board is attached to gain access to the cable reel, unscrewing the three M4x12 bolts using a 7 mm key



Remove the cable reel locking bracket by unscrewing the M4x12 connector

Remove the cable reel from its seat, cut the cable ties that block the cable out of the wiring

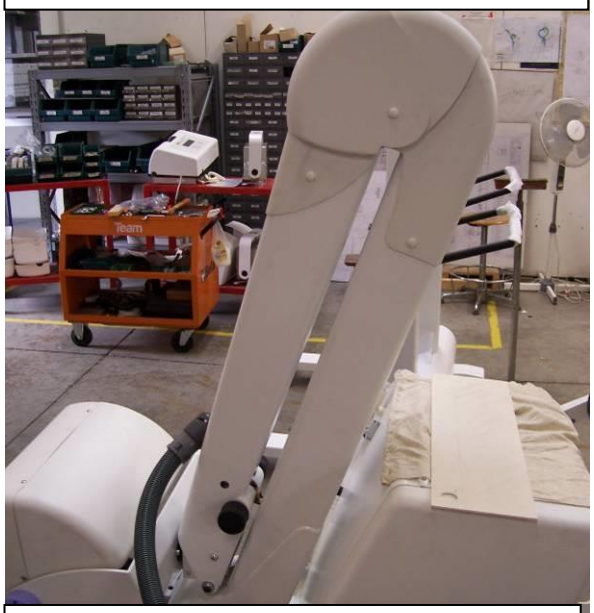
Remove the magneto-thermal switch from its seat, connect the wiring coming from the cable reel.

Once the cable reel disconnection is complete, replace the part and use the reverse procedure to install the new replacement part.

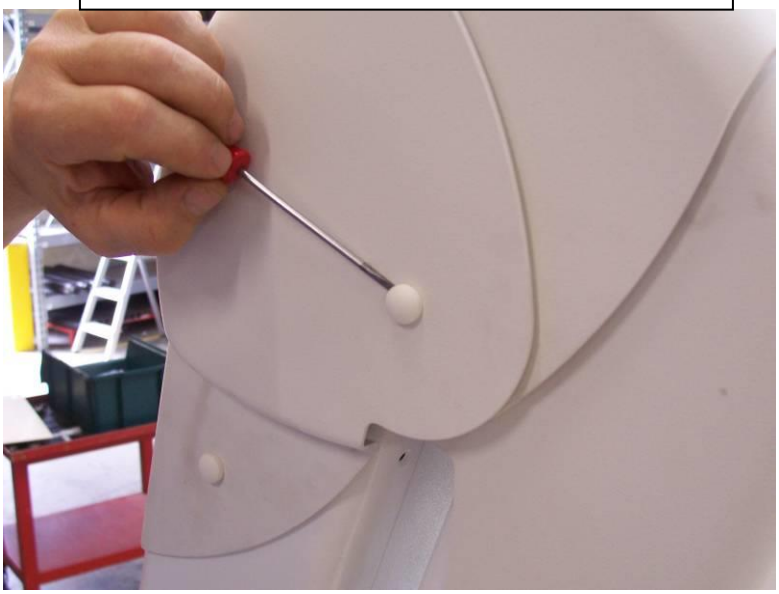
Check the operation of the new cable reel before closing the device.

8.2.5 GAS SPRING SUBSTITUTION PROCEDURE

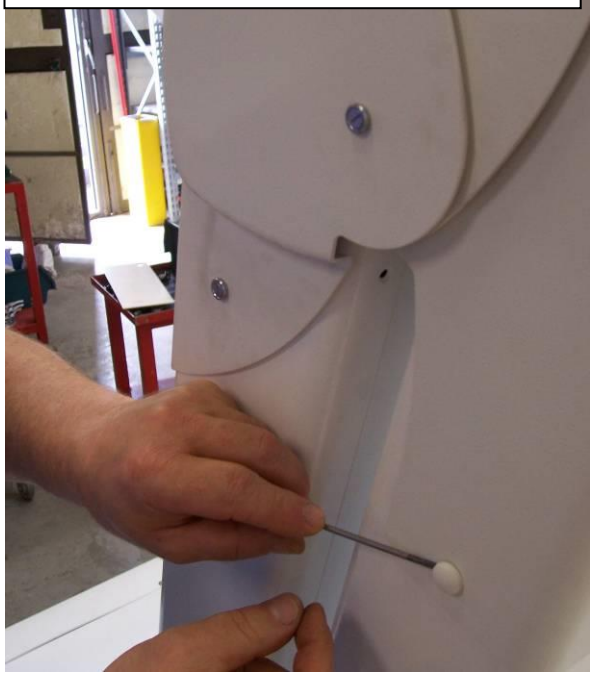
PHASE 1
PUT THE PHANTOGRAPH ARM IN CLOSE REST POSITION



PHASE 2
REMOVE THE PLASTIC CAP LIKE PHOTO



PHASE 3
REMOVE THE PLASTIC CAP LIKE PHOTO IN ALL POSITION OF THE COVERS



PHASE 4
WITH A PLANE SCREW DRIVER REMOVE THE SCREWS OF THE COVER SECTION 1

PHASE 5
OPEN THE COVER FACE *WITH A LITTLE FORCE AND REMOVE THE COVER SECTION 1*

PHASE 6
REMOVE THE N°2 WHITE PLASTIC RING

PHASE 7
WITH A LITTLE FORCE
OPEN THE COVER FACE AND REMOVE THE SECTION COVER 2

PHASE 8
WITH A PLANE SCREW DRIVER REMOVE THE SCREW OF THE COVER SECTION 3

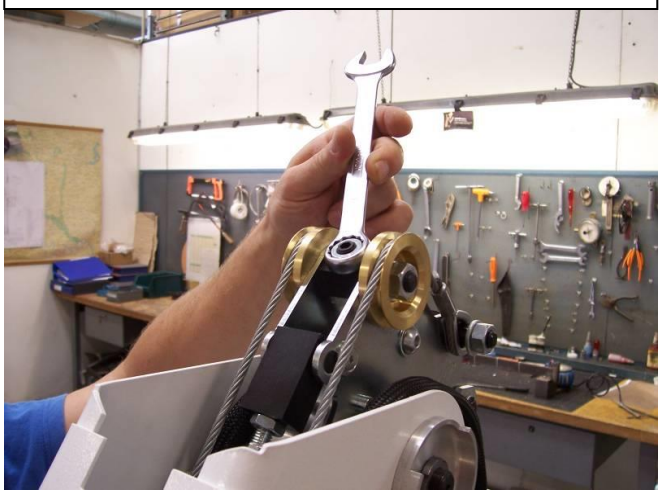
PHASE 9
REMOVE THE OTHER N°2 PLASTIC *WHITE RING*

PHASE 10
WITH A PLANE SCREW DRIVER REMOVE THE N°2 SCREW OF BACK METAL COVER OF THE ARM

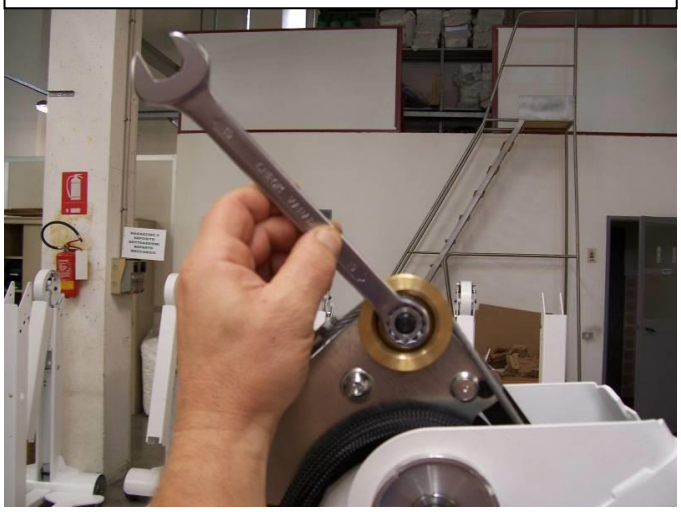
PHASE 11
REMOVE THE METAL COVER

PHASE 12
PUT THE “U” BARS IN THE GAS SPRING BAR, FOR MAKE IN REST SAFETY POSITIONS THE SPRINGS

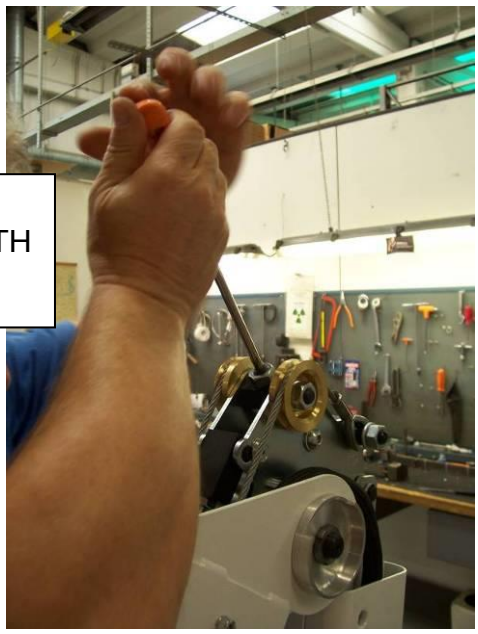
PHASE 13
LOOSE THE NUT WITH A 19 mm KEY

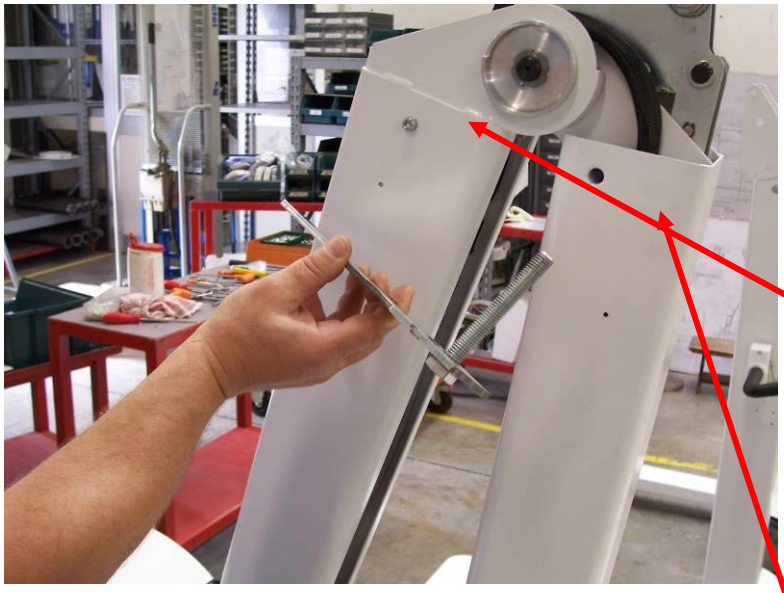


PHASE 14
LOOSE THE N°2 NUT



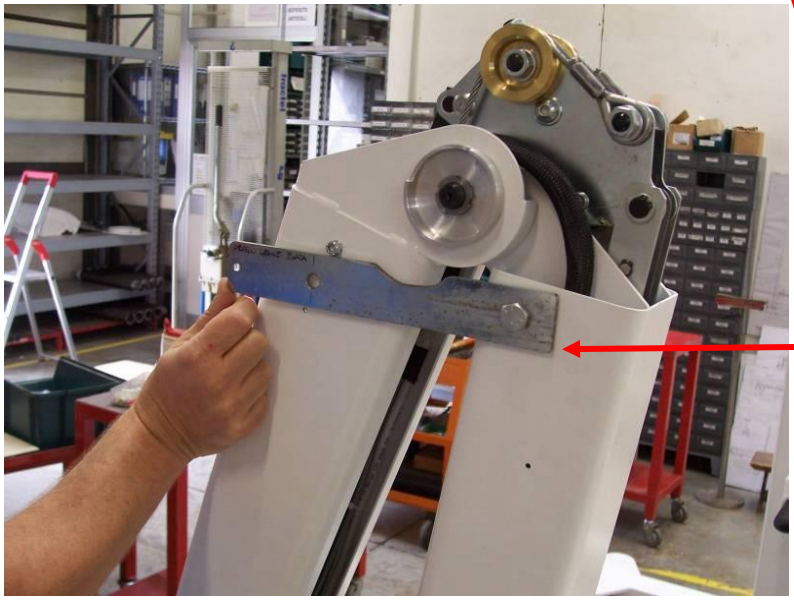
PHASE 15
LOOSE THE NUT INSIDE IN THE NUT WITH A 6 mm EXEGONAL SCREW DRIVER





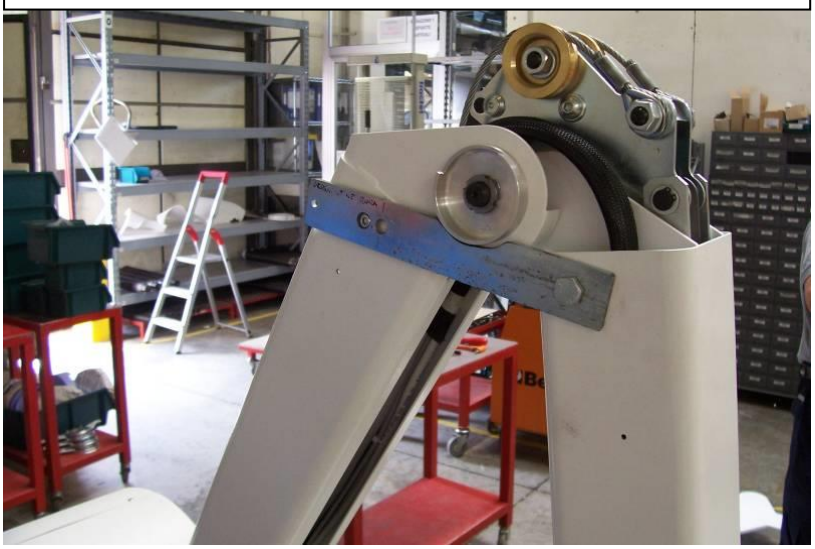
PHASE 16
PUT THE TOOL FOR MAKE THE ARM IN CHANGE GAS SPRING POSITION

(FOR MAKE THE HOLE FOR THE SCREW SEE THE DESIGN IN ANNEXE N°72A001) PUT ONE SCREW 6X25mm

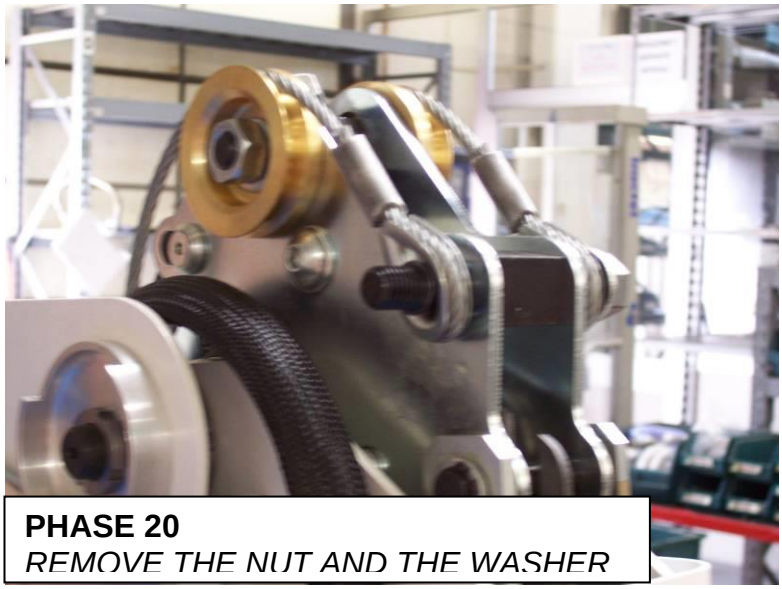


PHASE 17
ADJUST THE TOOL IN THE HOLE OF THE ARM
COD. 73A087

PHASE 18
ADJUST THE TOOL INTHE SCREW FIXED IN PREVIOUS SECTION.

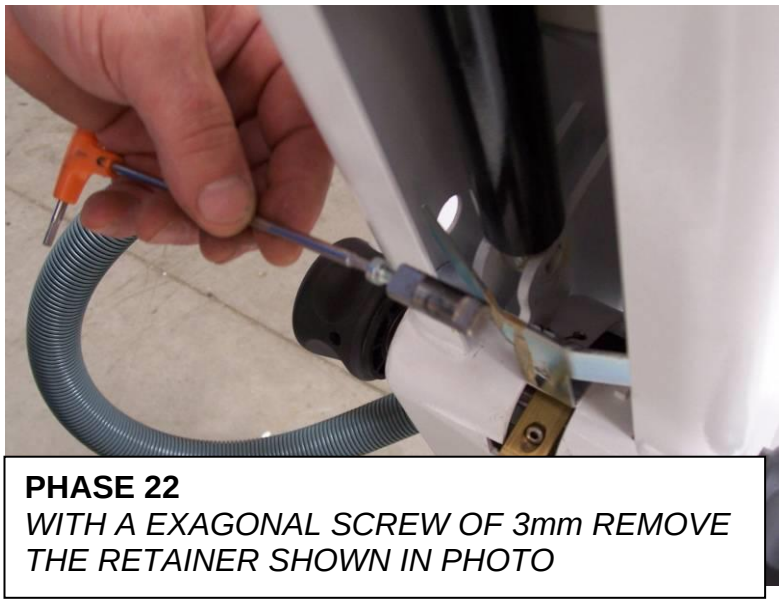


PHASE 19
LOOSE THE COMPONET IN FIGURE WITH A 19mm AND 20mm KEY

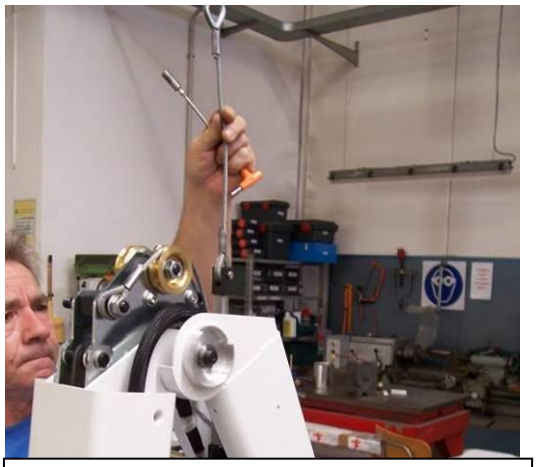


PHASE 20
REMOVE THE NUT AND THE WASHER

PHASE 21
MAKE IN FREE POSITION THE METAL CORD OF THE GAS SPRNIG ASSY



PHASE 22
WITH A EXAGONAL SCREW OF 3mm REMOVE THE RETAINER SHOWN IN PHOTO

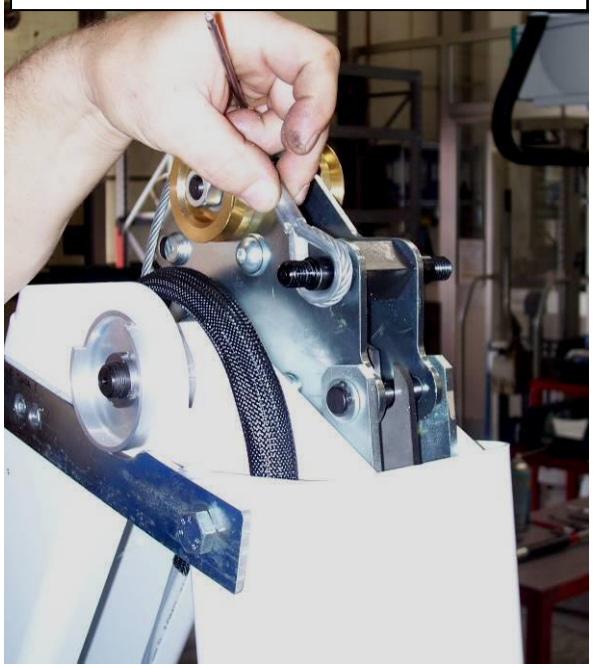


PHASE 23
TAKE OFF THE GAS SPRING ASSY TO REPLACE

PHASE 24
REINSERT THE NEW GAS SPRING KIT IN CORRECT *POSITION AS SHOWN IN PHOTO*

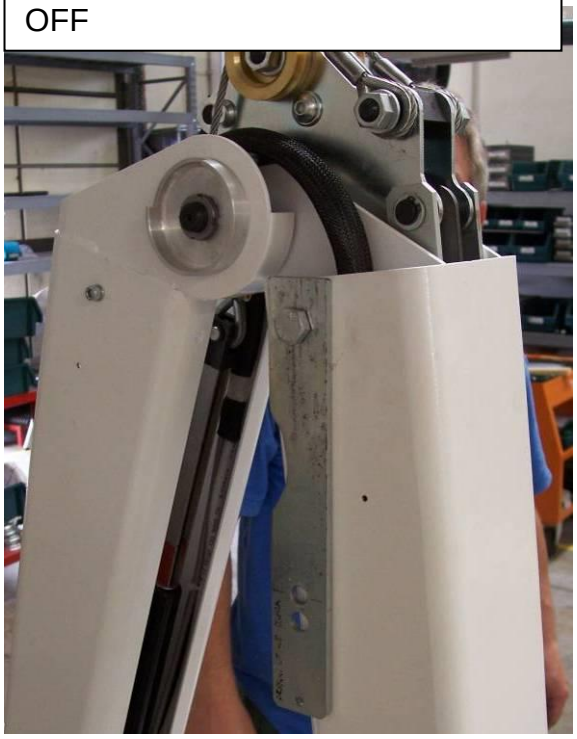
PHASE 25
PUT THE PARTICOULAR REMOVED IN PHASE 22 AND WITH a 3mm EXAGONAL SCREW DRIVER TO LOCK THE SCREW

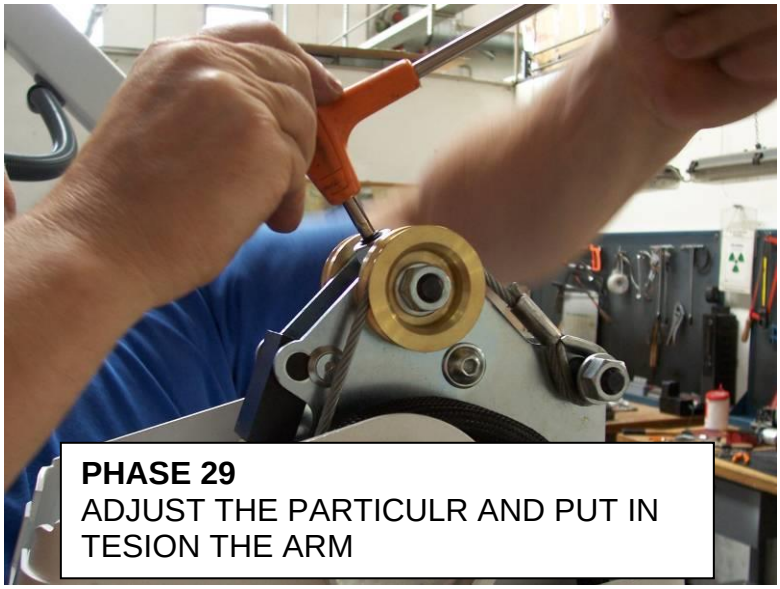
PHASE 26
TO HOOK THE GAS SPRING CORD OF THE NEW GAS SPRING KIT



PHASE 27
LOCK THE WASHER AND THE NUT FOR CORD RETAINER

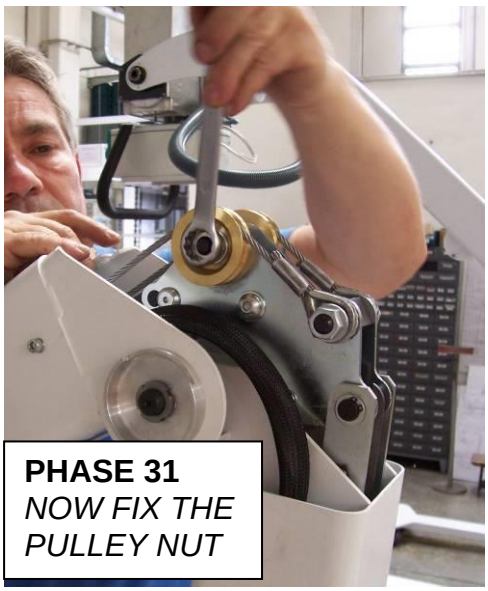
PHASE 28
REMOVE THE TOOLAND TAKE IT OFF





PHASE 29
ADJUST THE PARTICULR AND PUT IN TESION THE ARM

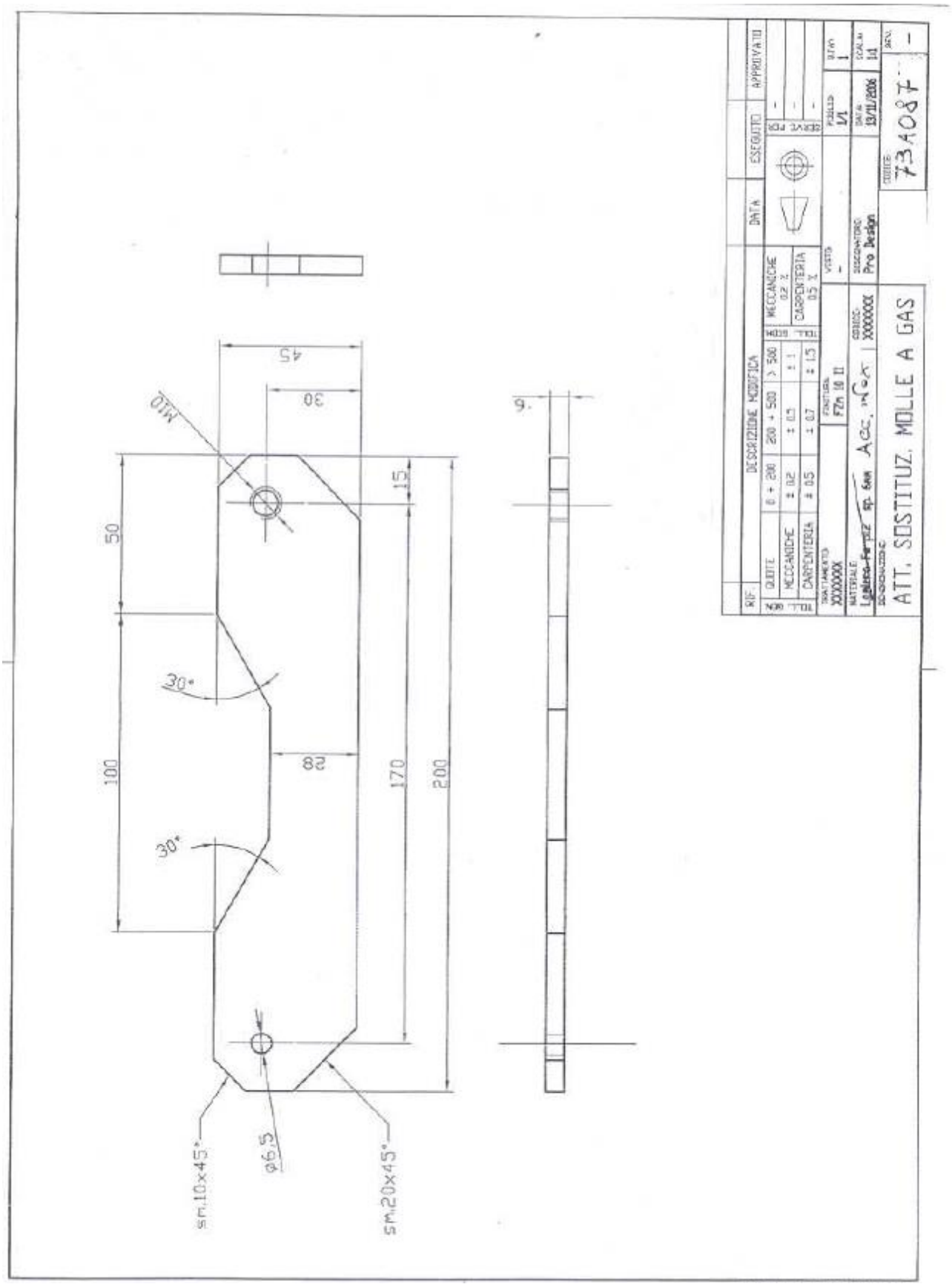
PHASE 30
TAKE OFF THE "U" BAR RETAINER



PHASE 31
NOW FIX THE PULLEY NUT

PHASE 32
FIX THE NUT FOR LOCK THE SYSTEM

AFTER THIS OPERATIONS RESTORE ALL THE PLASTIC ELEMENTS AND THE PLASTIC COVERS .


45
30
M10
15
50
100
30°
30°
28
170
200
9
sm.10x45°
ø6,5
sm.20x45°
ATT. SOSTITUZ. MOLLE A GAS
Pro Design
13/11/2006
73408F

9 ACQUISITION AND IMAGES ELABORATION SYSTEM

9.1 STARTING THE SYSTEM

Portable XFM has an internal system designed for the acquisition and processing of high resolution digital images for static radiology and it is based on the use of a digital detector and a computer-based acquisition system. The user interface of the device appears as a Personal Computer, so the proper use of the device requires a basic level of computer literacy.

The Examination management window opens as soon as the initialisation is complete and allows the operator to access an examination in three different modes:

- Opening the examination via the **Local Database** containing all the examination stored in the system
- Opening from the **Dicom Worklist** acquired from the **RIS**
- Opening of a **Insert New Examination**

The following image shows the initial work tab (**Local Database**):

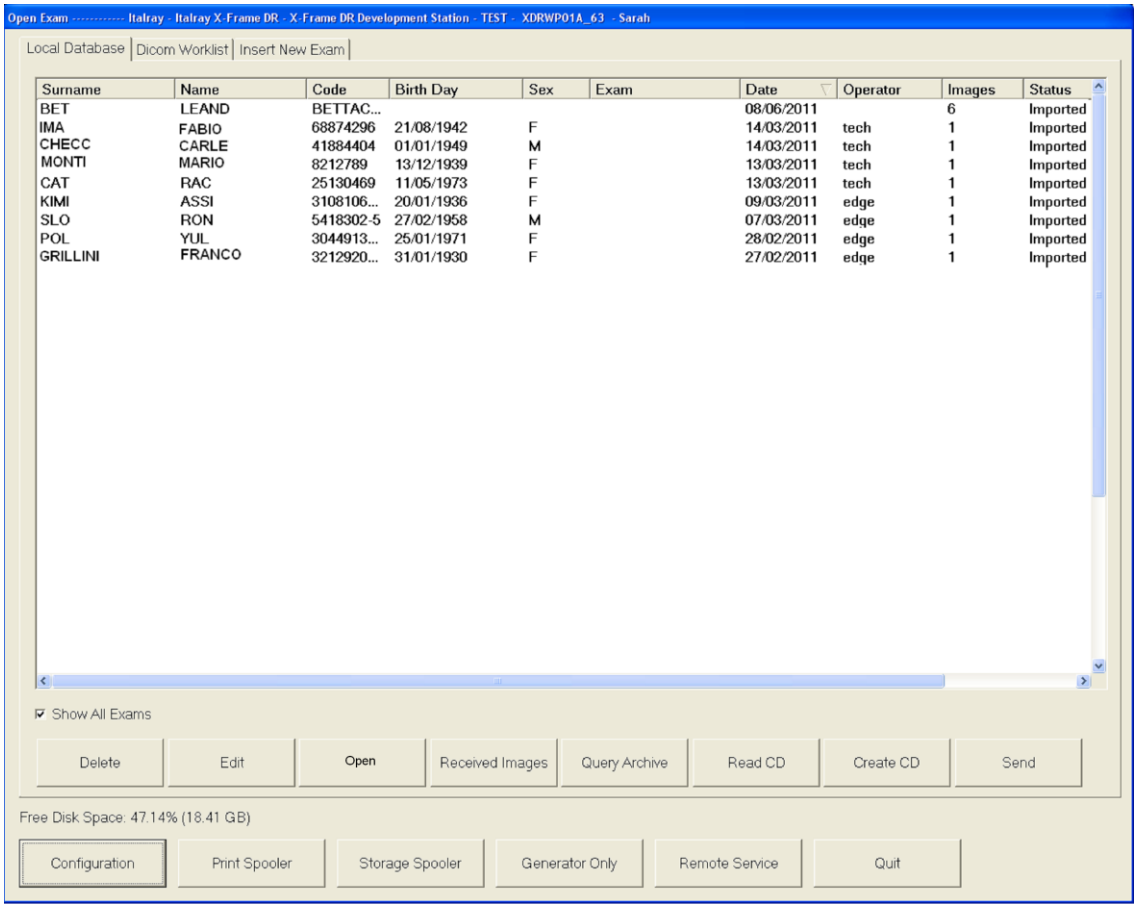


Figure 10: the figure shows the list of examinations on the first window that it is opened at the start of X-Frame DR software.

Besides the three worksheets, the **EXAMINATION MANAGEMENT** window also includes the following buttons:

- **Configuration** - generates a confirmation dialogue with access password
- **Print Spooler** - shows all printing jobs queuing for processing.
- **Storage Spooler** - shows the queue of all data to be sent to the **SERVER**
- **Generator Only** to enter the direct examination mode, opens a window for setting the radiological parameters and allows x-rays in order to carry out the examinations with the CR cassette.
- **Remote Service** allows the request remote assistance by entering a password.
- **Quit** - turns off the system (generates a confirmation dialogue with password)

And the following function keys:

- **Delete:** for deleting of one or more selected examinations. Attention: before carrying out this operation ensure that the examination was sent to the PACS and/or is saved on a digital support.
- **Edit:** to modify the examination parameters: anatomic region, type of test, user name, Accession Number, surname and name of patient, code, gender, date of birth.
- **Open:** in order to open the selected examination.
- **Images Received:** only available in case images can be received
- **Query Archive:** opens the dialogue window to import the examinations list in the queue at the RIS (see in figure 2)
- **Read CD:** starts the examination import procedure from the CD/DVD
- **Create CD:** initiates the procedure of creating the CD/DVD after selecting at least one test from the Examination Manager window. To select more than one test, hold down the SHIFT key (for tests that are listed in sequence) or the CTRL key (for tests not in sequence).
- **Send:** to send one or more examinations to the archive, after selecting the archive from the control box (see Operator Manual).

The switching off of the system takes place through the **Quit** button, that enables the shutting down of all the system (see figure 10).

It is recommended to power the system when the computer is off, in order to avoid dangers to the detector, created by humidity.

The software is working yet. The configuration and the settings of the system are set by the factory. The radiological parameters concerning specific examinations can be configured in agreement with customer requirements.

The device, during the first start in the customer DR room, has to complete the starting procedure with an X-ray CALIBRATION and with a performance test in agreement with the indication of MAINTENANCE section.

9.1.1 CONFIGURATION MENU

The **Setup** button (configuration) allows access to the system configuration (it generates a confirmation dialog with password access reserved for maintenance technicians).
Select the Configuration button on the bottom-left of Local Database tab and enter in configuration mode. The window that will appear has got 9 tabs:

- **Operators**: to insert the name of operators and their restrictions;
- **Exams**: to insert the body part and the RIS code for every exam;
- **Projection**: to configure the parameters for every projection of an exam of a body part (type of detector, image elaboration, radiological parameters, etc..);
- **Detector**: to perform the calibration of the detectors and to control the status of the detector;
- **Acquisition**: to configure the collimator, grids, type of acquisition board and overlays on image for its orientation;
- **X-Ray Generator**: to configure the type of generator, to calibrate it and to manage the device connected (AEC, DAP, collimator);
- **Station**: to enable some optional tools. This tab shows the software release;
- **Display**: to change the overlay appearance;
- **Dicom**: to configure the whole Dicom communication.

Following the tabs will be shown.

NOTE: the software is designed to manage different types of DR rooms. Some tabs of configuration menu are not applicable to the XFM system because they involve others systems. Only the parts that can be managed will be shown in this manual.

9.1.2 CONFIGURATION MENU - OPERATORS

Pressing the button “Configuration” the first time, the system asks to you to insert the password. There are three different passwords that allow to enable the configuration menu. Depending on the level of security of the password used, the tabs enabled are different. Contact the Technical Office for more details about passwords and level of security.

The first tab in the configuration window is “OPERATORS” and it allows to manage the list of operators. Write the name of operator in the circled box and click the button Add to add the new operator. Select the name of operator in the bigger white box and press the button Delete to delete the operator’s name (see figure 11).

From the tab *Operators* it is possible to enable these tools: use windows user name; ask password to delete images and logout on quit.

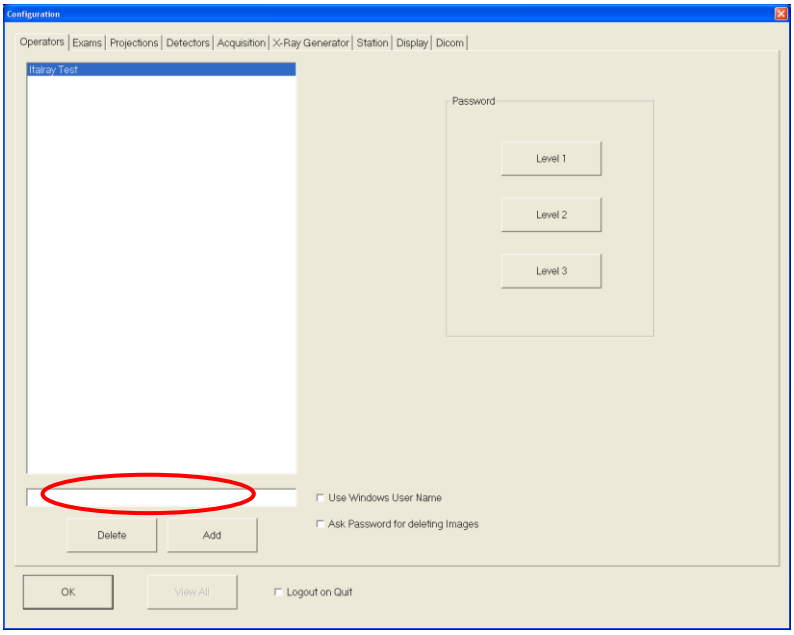


Figure 11:configuration menu (tab operators). Write the name of operator in the circled box and select the button **Add** to add the new operator. Select the name of operator in the bigger white box and press the button **Delete** to delete the operator’s name.

It is possible also change the password. The system will ask to insert the old password if the level of security request to make changes is higher. The system will ask the new password twice.

9.1.3

9.1.4 CONFIGURATION MENU - EXAMS

The tab *Exams* of the Configuration Menu allows to manage the list of all body parts, the examination for a single body part and their associated DICOM codes.

If a Database is just compiled, from this tab is possible import it. Select the button “import Database” and insert the patch to the file. If there is not a Database compiled, with the tab *Exams* it is possible to create a new database (that is custom configurable). The figure 12 shows the tab *Exams* of configuration menu and the operations that need to create a new database.

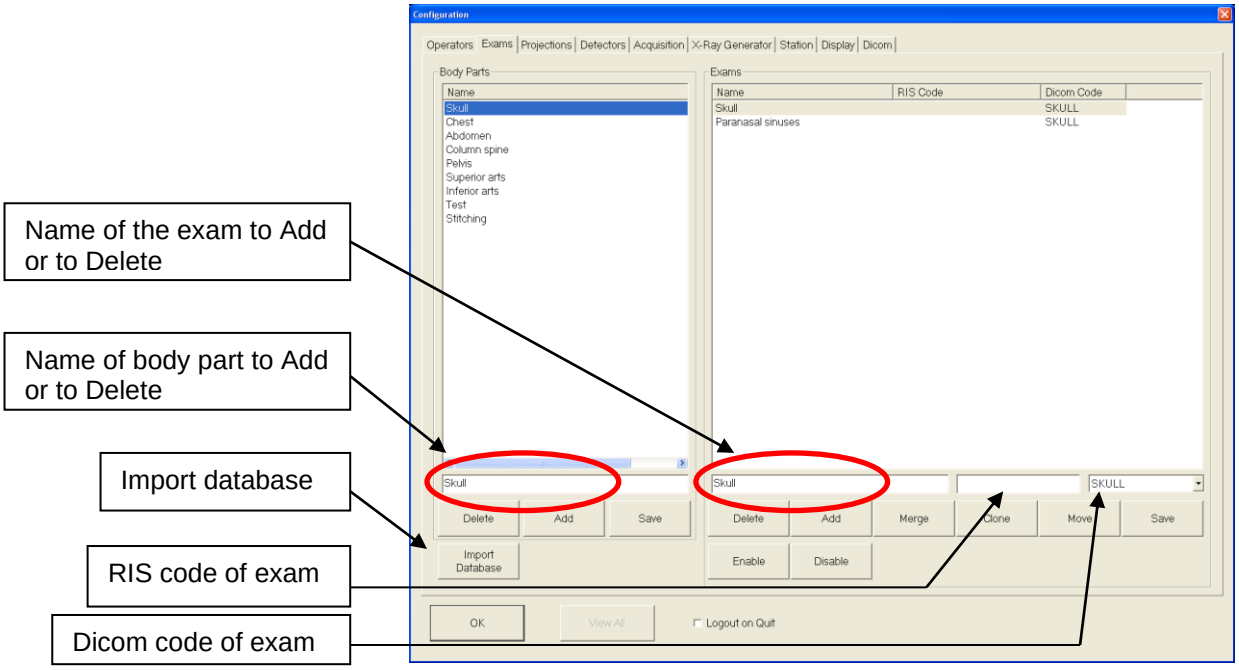


Figure 12: configuration menu (tab exams). Insert the name of body part in the box circled under the window body parts and select **Add** to add the body part. Select the body part and press **Delete** to delete the body part. Select the body part and insert the name of exam in box under the window exams. Insert the RIS code, the Dicom Code and select **Add** to add the exam. Click save at the end of insertion and/or deletion.

The tab is divided in two big windows: in the left is visible a white window where the body parts are reported and in the right is visible a white window with the exams. For every body part it is possible to configure various exams, or different parts of body to investigate (for example in the body part Skull it is possible to investigate the skull but also the paranasal sinuses, so the exams for the body part Skull are Skull and Paranasal Sinuses as shown in figure 3). These body parts and the corresponding exams will be reported in the tab projection, where the radiological parameters will be configurable.

9.1.5 CONFIGURATION MENU - PROJECTIONS

In the tab *Projections* of Configuration Menu, it is possible to configure the projections of exams. In the top on the left of the tab, all the exam previously inserted in the tab *Exam* are reported. To add a new projection it is necessary: select the body part trough the drop-down menu; select the exam in the same way; write the name of projection on the white window in the bottom on the right; press “Add” and then “Save”.

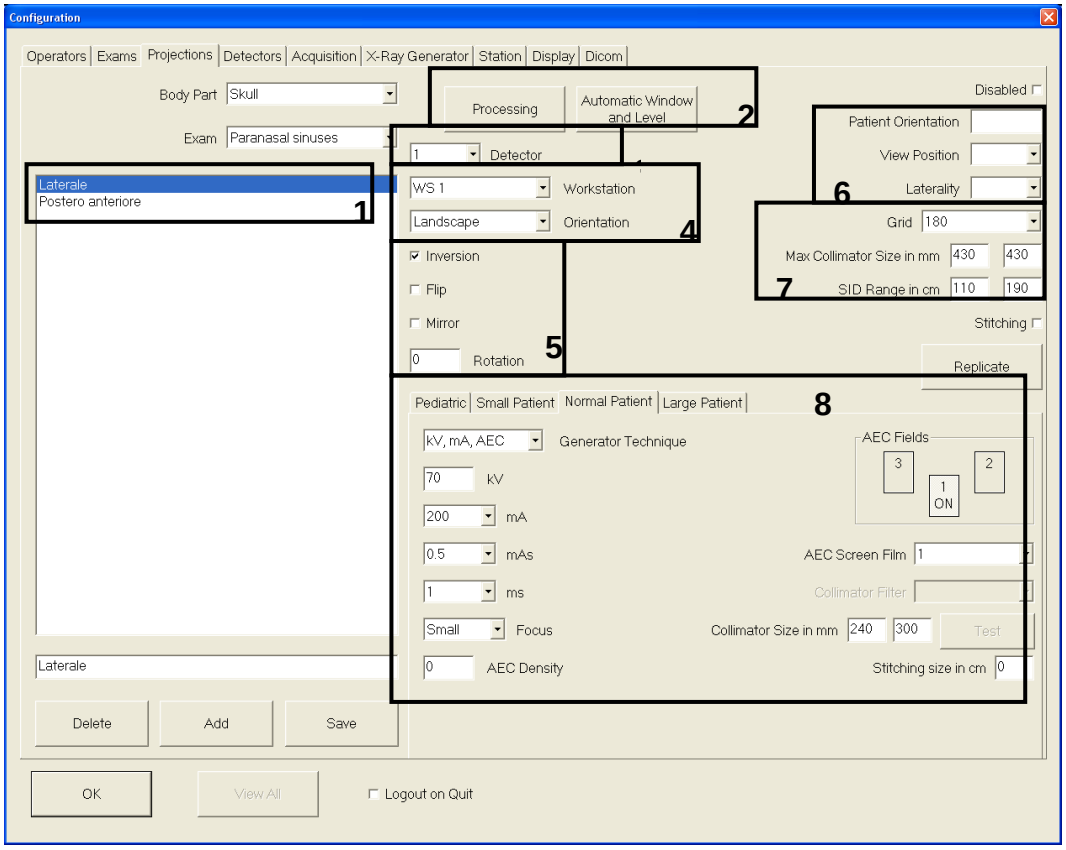


Figure 13: tab Projection of Configuration Menu.

Selecting the projection in the central white window (box number 1 in figure 4), it will be possible to delete it or to configure it through the tools that are in the right (boxes from n°2 to n°8 in figure 13). The tolls allow to configure:

- the software elaboration on the image (Processing) and the area for the automatic window and level (Automatic Window and Level) on the image (box number 2 in figure 13). They are applied after the acquisition of the image and the operator can not modify or delete them;

- the detector, if there are more than one detector (box number 3 in figure 13) not applicable;
- the workstation and the type of orientation (box number 4 in figure 13), not applicable;
- other software elaboration like Inversion of Grays, Flip, Mirror and Rotation (box number 5 in figure 13). They are applied after the acquisition of the image and they are not removable. They depend from the orientation of patient and detector and it is necessary to make some tests with a oriented phantom to configure them;
- patient orientation (box number 6 in figure 13) PA, AP, LAT, OBL;
- grid, max collimator size, SID range, Stitching and Tomo exam (box number 7 in figure 13) not applicable;
- radiological parameters for every patient size (from pediatric to large patient) that will be visualized by the operator as default parameters (box number 8 in figure 13). The operator can change these parameters when he perform an exam.

9.1.6 CONFIGURATION MENU - DETECTORS

The tab Detectors in configuration menu allows to manage the detectors. The following figure shows the tab:

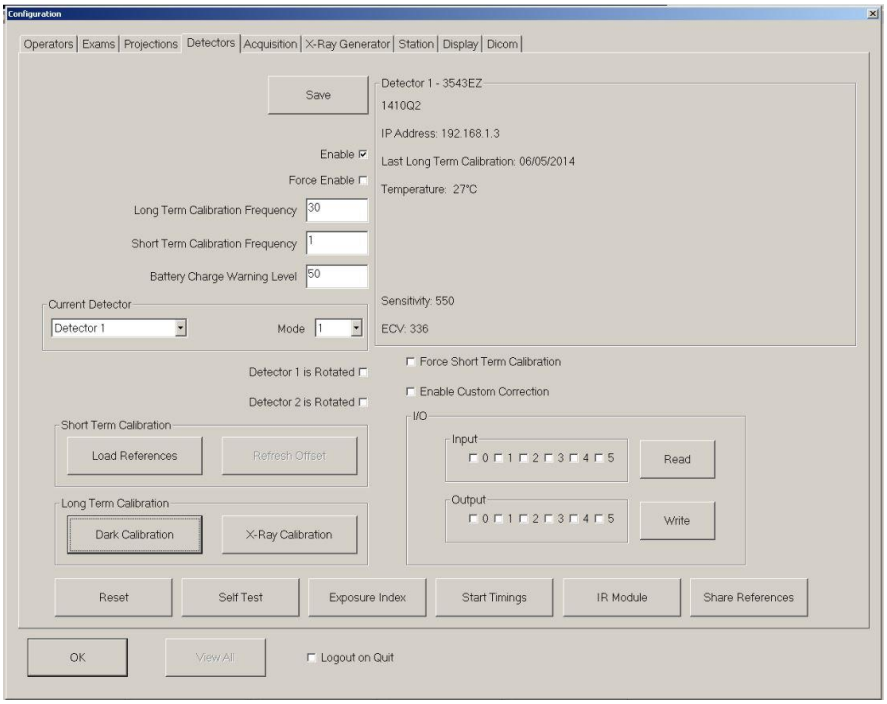


Figure 14: tab *Detectors* of Configuration menu.

In the top, on the right, are reported the data of detector. For example, over the label Detector 1 – 3543EZ (see figure 14) are reported: the IP address of detector, the date of last x-ray calibration, the temperature, the sensitivity and the Effective Cluster Value (ECV).

In the top, on the left, are reported the command *enable* and *force enable* that turn on the communication with the panels if they are disabled; the long term calibration frequency that provides a message to the operator that reminds to perform the x-ray calibration and the short term calibration frequency that automatically starts a dark calibration when the operator turns on the system. Long term calibration frequency shall not exceed 90 days. Short term calibration frequency must be 1 day. Press **Save** when all the changes are completed.

Using the portable detector, it is possible to set a warning message that inform the operator that the level of battery is low. By default the message pops up when the battery

is 50% low, but it is possible change the value at the level preferred changing it near the label “Battery Charge Warning Level”.

In the center of the tab there are two labels: “Detector 1 is rotated” and “Detector 2 is rotated”. They are not available.

In the centre, there is “Enable Custom Corrections”, that enable the software correction on the row image (like offset or gain correction, clipping dose, ecc..). This tool is useful for understand if there is a ghost on the image or if there is a defect of calibrabration fault.

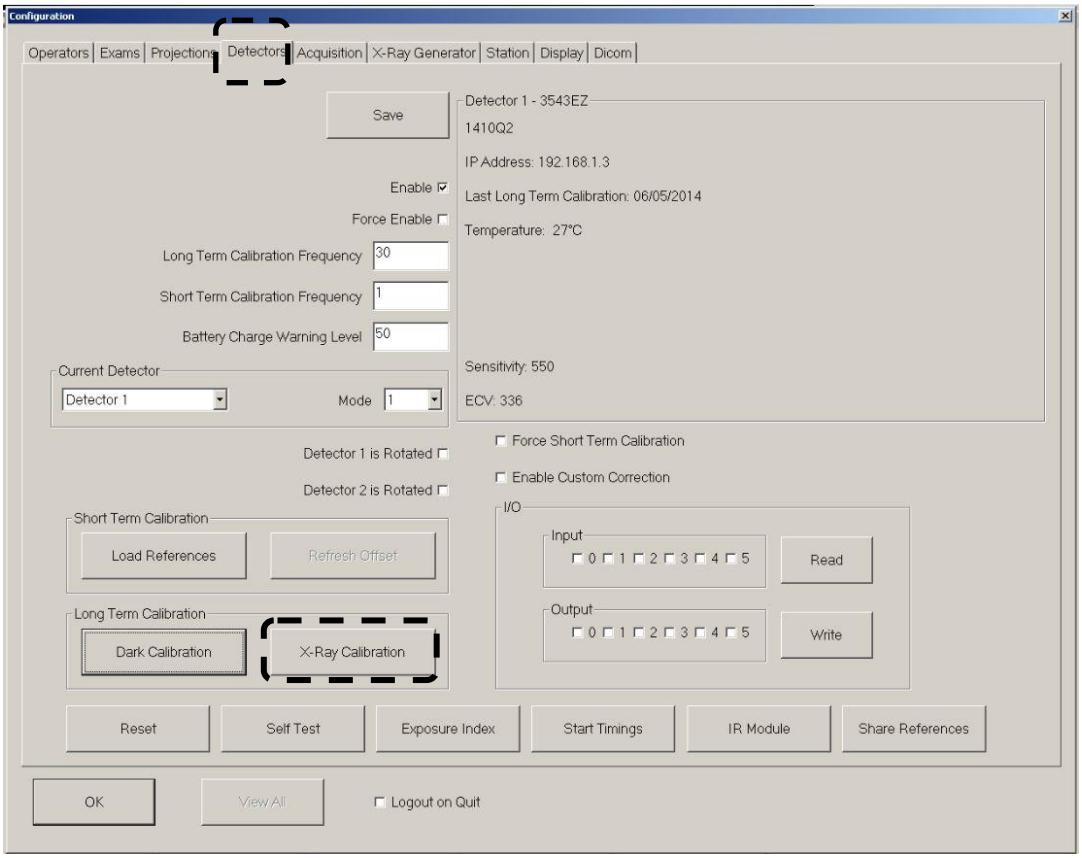
NOTE: *if the detector does not work, tray to enable it. If it does not work jet, use the Pixrad Software to find the problem (see the manual attached).*

9.1.6.1CALIBRATION

From the tab Detectors, in configuration menu, it is possible to calibrate the detectors with dark and x-ray calibration. The DARK CALIBRATION and the X-RAY CALIBRATION (long term calibration) shall be performed in sequence and following the simple indications given by the software. Run *Dark Calibration* in Configuration menu – Detectors.

To perform the x-ray calibration:

- remove the DAP and all the objects between x-ray source and detector;
- Align the x-ray beam with the detector at a distance of 120 cm, it is necessary that the vertical axis of the x-ray beam and the plane of the detector are perpendicular;
- open diaphragms of the collimator (check that the x-ray beam covers the whole detector);
- use 21mm Al or 1mmCu placed under the collimator in DAP position;
- connect the detector to docking station with back-up cable and remove the detector from the docking station;
- Click on the button “X-Ray Calibration” and follow the instructions on the monitor;



- The message “x-ray Dose” will pop up. Try to use always 70kVp (change the mAs but not the kVp if it is possible, if not change ±1kV);
- launch the calibration pressing x-ray calibration button and follow the procedure from the start to the end without stops of the procedure. Suspension of procedure involves its abort.
- For each sequence of exposures you will view 2 messages at the bottom of the progress bar:
    - Start Preparation
    - Start X-Ray

X-Ray button has to be pressed immediately as soon as the calibration procedure starts, and **must be keep pressed till the message “x-ray Dose” will pop up again**.

- Repeat the procedure till the end of calibration at 4 different doses.

Control the temperature of detector during the calibration, because a big difference between the temperature in calibration and the temperature during the work (more than 5°C) can cause ghosts or artifacts.

Control if the sensibility is correct and the ECV value reported on test report of the detector. If the sensibility has a wrong value, change it on the file “XrayDoses**.ini” in the patch “C:\X-FrameDR\pixium”. If the ECV is higher than the reported one, the calibration was not performed in the correct mode. Repeat the calibration if the ECV value is higher than the maximum ECV value reported on the test report.**

9.1.6.2 EXPOSURE INDEX

The exposure index (E.I.) is a parameter that helps the operator to understand if an examination was performed with the correct dose. It is useful because is the automatic exposure (AEC) is not applied in this system and the E.I. is the only way for the operator to understand if the detector was correctly exposed, or if it has received low dose or high dose. When the exposure is fished, bottom left on the image will appear in overlay the E.I. abbreviation and a number followed by a mark that means:

- (+) high dose;
- (OK) right dose;
- (-) low dose.

The exposure index is configurable from the tab Detector on Configuration Menù. For detectors with 550LSB/uGy of sensitivity, set 600 min and 2500 max.

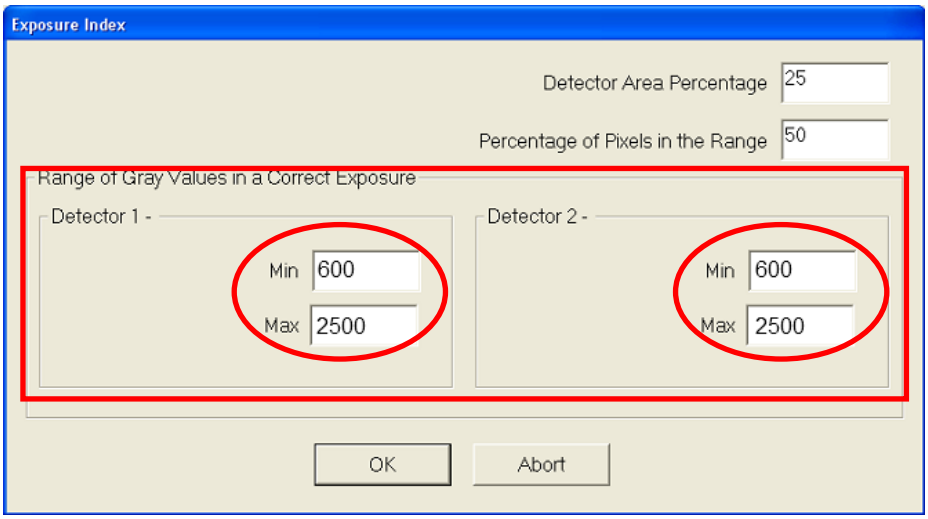


Figure 15: configuration of exposure index.

Check if the *Range of Gray Values in a Correct Exposure* is correct.
Near the label Detector Area Percentage it is reported the percentage of image that is investigate. For example 25 means that the area investigated is ¼ of the whole image and it is positioned on the center of image. The Percentage of Pixel in the Range is the number of pixel within the area investigated that should have a level of gray within the range of Gray Values in a correct exposure. The I.E. is the same for every projection.

9.1.7 CONFIGURATION MENU - ACQUISITION
9.1.8

In the tab Acquisition of Configuration Menu (see figure 16), some useful tools are present.

There are also some tools for the manage of exams:

- confirm acquisition in non Today Exams;
- Load for Acquisition in not Today exams;
- Save Compressed Images (lossless JPEG);
- Enable/disable the orientation of image and set the Display names (Top, Bottom, R, L).

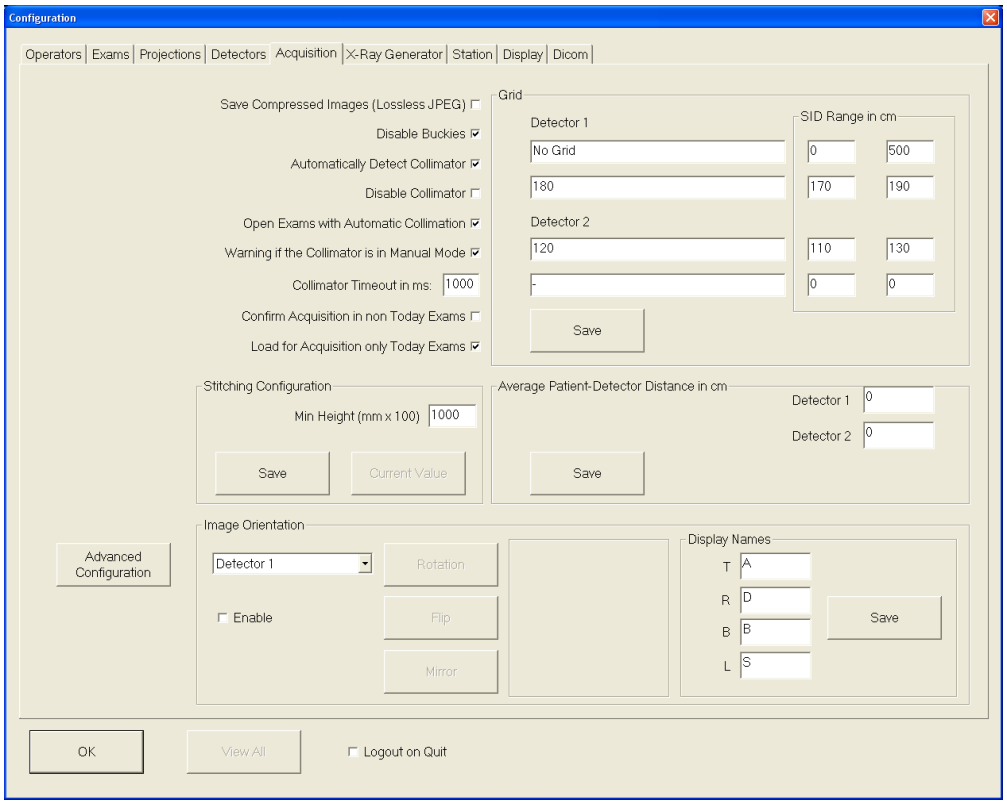


Figure 16: tab Acquisition of Configuration Menu

9.1.9 CONFIGURATION MENU – X-RAY GENERATOR

The tab X-Ray Generator of Configuration Menu manages the generator: the settings are by default and they cannot be changed.

Figure 17 shows a possible configuration.

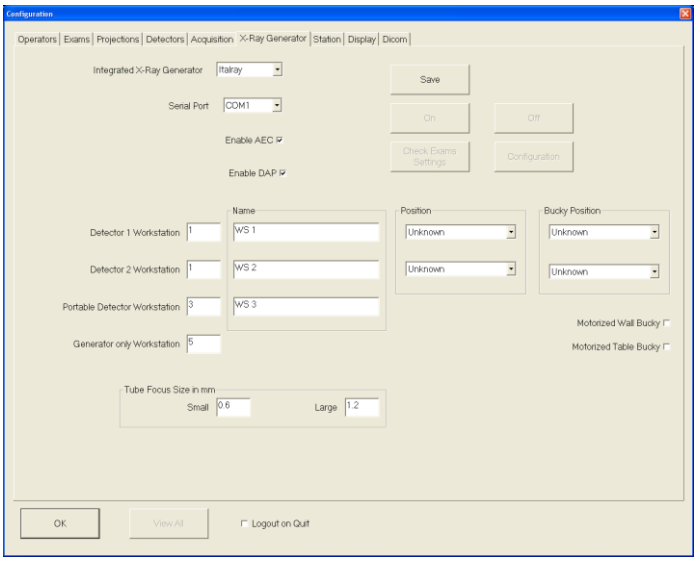


Figure 17: tab *X-Ray Generator* of Configuration Menu.

9.1.10 CONFIGURATION MENU - STATION

From the tab *Station* of Configuration Menu, some useful information are reported:

- Station Name, Institution Name, Remote Service Server address (click Save after every change of it);
- Manufacture, Model Name, Device Serial Number and **Software Version**;
- Software Libraries.

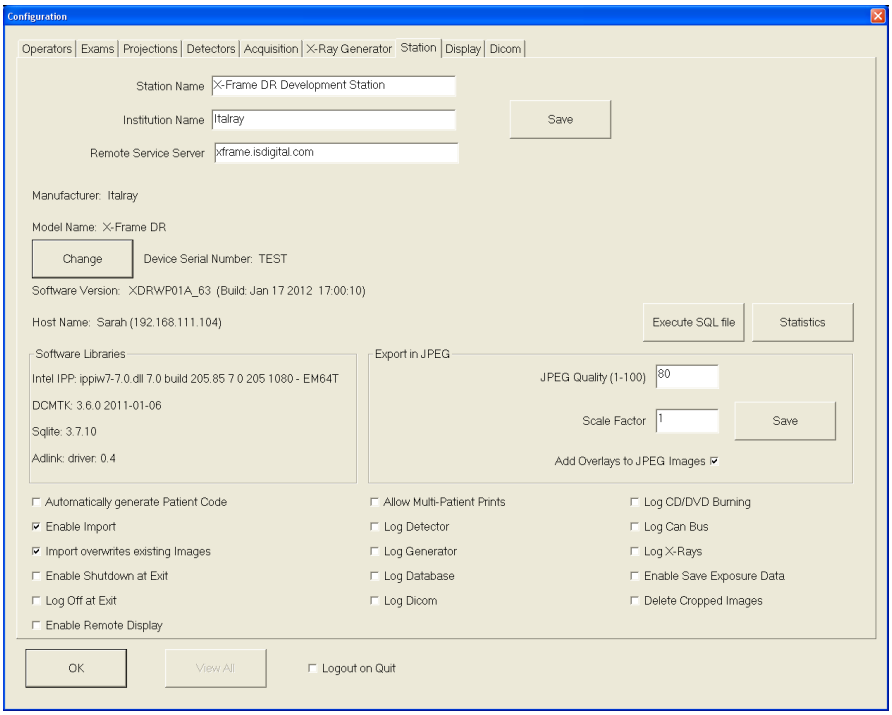


Figure 18: Station tab of Configuration menu.

On the bottom of the

tab there are some useful tools: enable/disable functions like automatic generation of patient code, prints of multi patients, import examinations, shutdown, log off, remote display. From this section is possible enable the logs of various devices (generator, detector, database,…) that are saved on the local Hard Disk (for example C:\X-FrameDR\Log).

9.1.11 CONFIGURATION MENU – DISPLAY

The tab *Display* of Configuration Menu is used to manage parameters referring to the visualization of data and images and to the format of overlay.

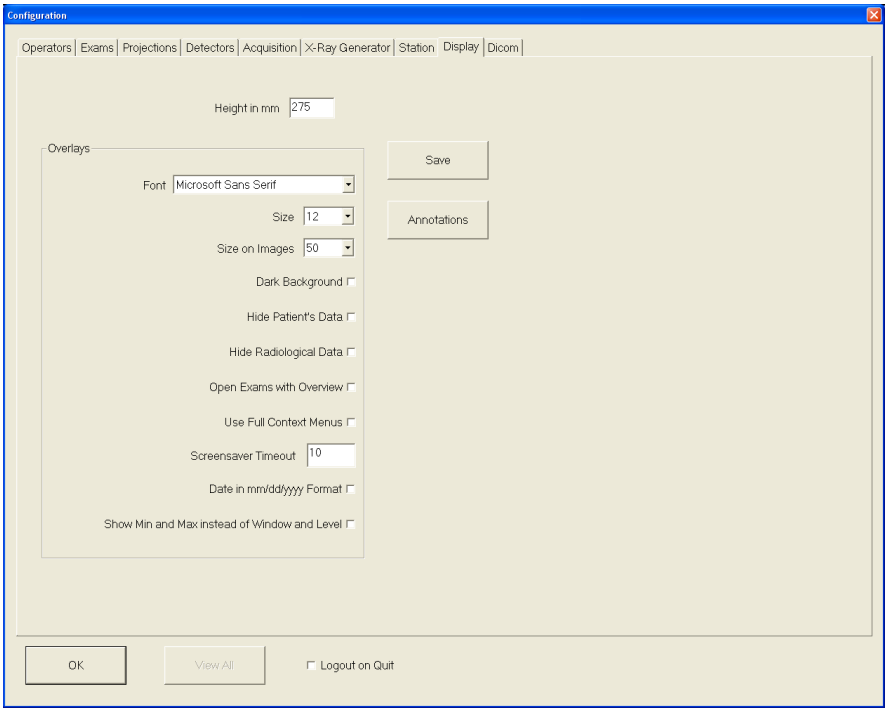


Figure 19: Display tab of Configuration Menu.

In particular, from this tab it is possible to choose the format of date in mm/dd/yyyy instead dd/mm/yyyy, to visualize the min and max values of level of gray instead the window and level.

9.1.12 CONFIGURATION MENU - DICOM

DICOM consists of many different services, most of which involve transmission of data over a network. The tab *DICOM* of Configuration Menu has got many functions configurable by X-Frame DR that now will be shown.

9.1.13 WORKLIST

With the function Worklist of DICOM tab it is possible to configure the parameters to connect to the server of RIS to obtain details of patients and scheduled examinations electronically, avoiding the need to type such information multiple times (and the mistakes caused by retyping). To configure the Worklist it is necessary to use the same address of RIS Server. Insert the Name of Server (here is not important that it is the real name of Server), the AE Name (here is important that it is the real name of application), host (IP Address), Port, the Local AE Name (configurable with *Local Server* function) and the max PDU (by default). Add and test it, clicking on “Add” and than “Test” buttons.

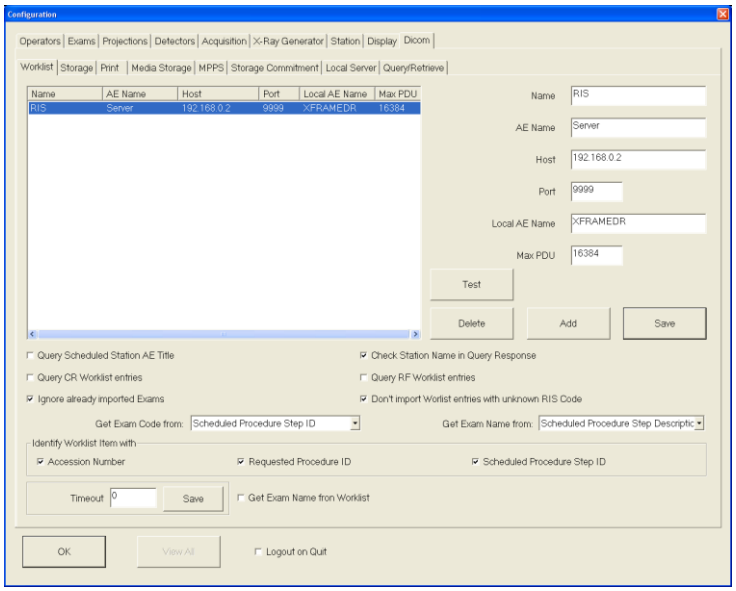


Figure 20: function Worklist of *Dicom* tab of Configuration menu.

9.1.14 STORAGE

The DICOM Store service is used to send images to a PACS or workstation. Insert the Name of Server MPPS (here is not important that it is the real name), the AE Name (here is important that it is the real name of application), host (IP Address), Port, the Local AE Name (configurable with *Local Server* function) and the max PDU (by default). Add and test it, clicking on “Add” and than “Test” buttons. There are also some tools that enable the drawing of the overlays on the sent images, the warnings if the Accession Number is not found and the automatic send.

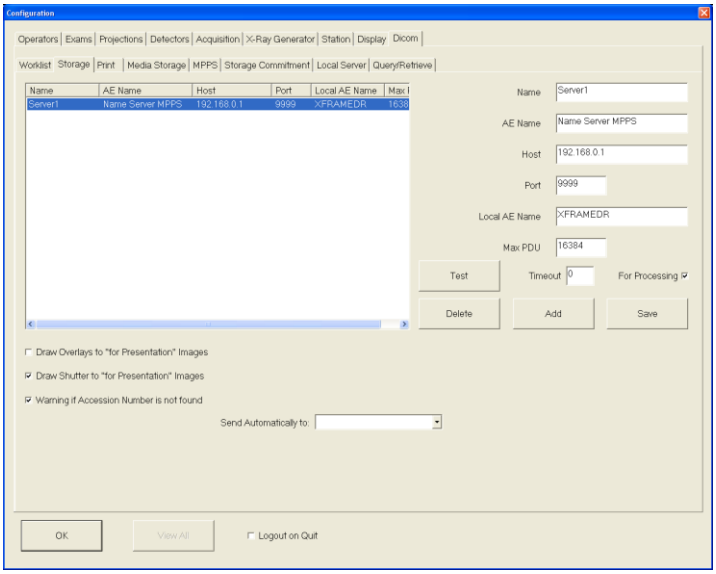


Figure 21: function Storage of *Dicom* tab of Configuration menu.

9.1.15 PRINT

The DICOM Printing service is used to send images to a DICOM Printer. In the tab Print one or more network printers are configurable.

Insert the Name of Printer (here is not important that it is the real name), the AE Name (here is important that it is the real name of application), host (IP Address), Port, the Local AE Name (configurable with *Local Server* function) and the max PDU (by default). Add and test it, clicking on “Add” and than “Test” buttons.

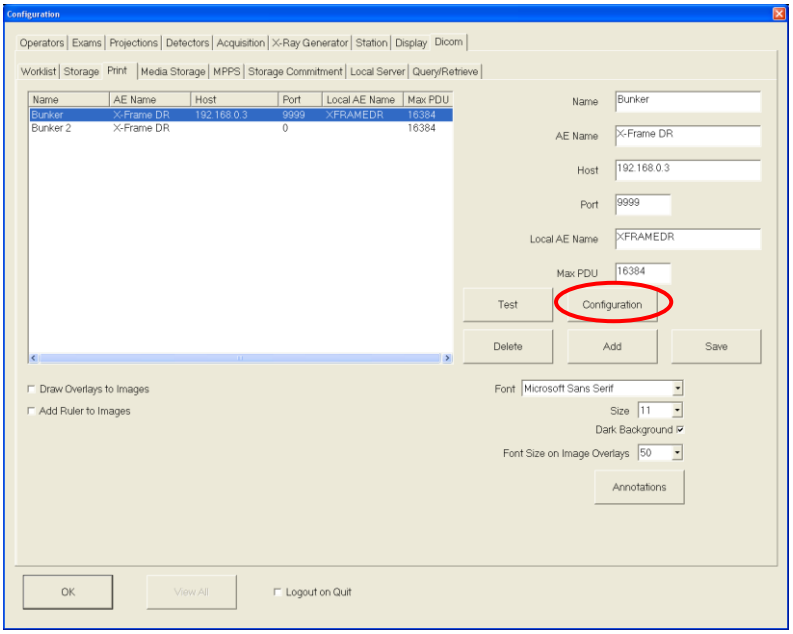


Figure 22: function Print of *Dicom* tab of Configuration menu. In the circled box, the button “configuration” enables the configuration of print layout.

Press “configuration” to configure the print layouts (see figure 22). It

will appear a new window with some tools to configure (Magnification type, Resolution, Film Destination, Medium type,…). On the right in the top various print layouts are configurable:

- The number of columns and the rows where the images will be collocate;
- The film size (8in x 10in; 8.5in x 10in; 10in x 12in; 10in x 14in; 11in x 14in; 11in x 17in; 14in x 14in; 14in x 17in; 24cm x 24cm; 24cm x 30cm; A4; A3);
- Film Orientation (Landscape, Portrait or None);
- Image width in mm.

After selecting these parameters, click “Add” and the layout will be configured. It is possible to configure various layouts and, during the printing operation, the operator will choose the preferred one.

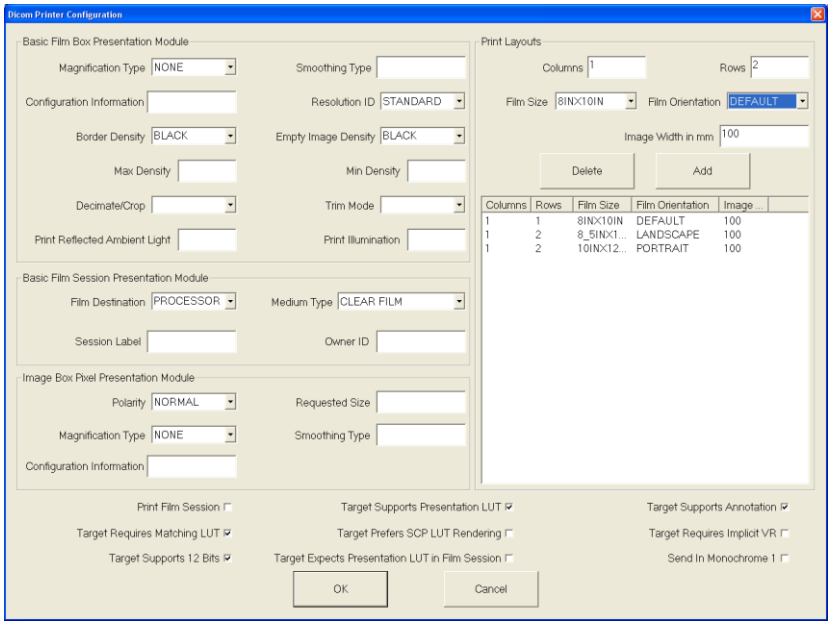


Figure 23: Print Configuration of *Dicom* tab of Configuration menu.

Media Storage

In the tab Media Storage there are some tools for the configuration of image's storage. The dimensions and the patch of media for the storage are configurable.

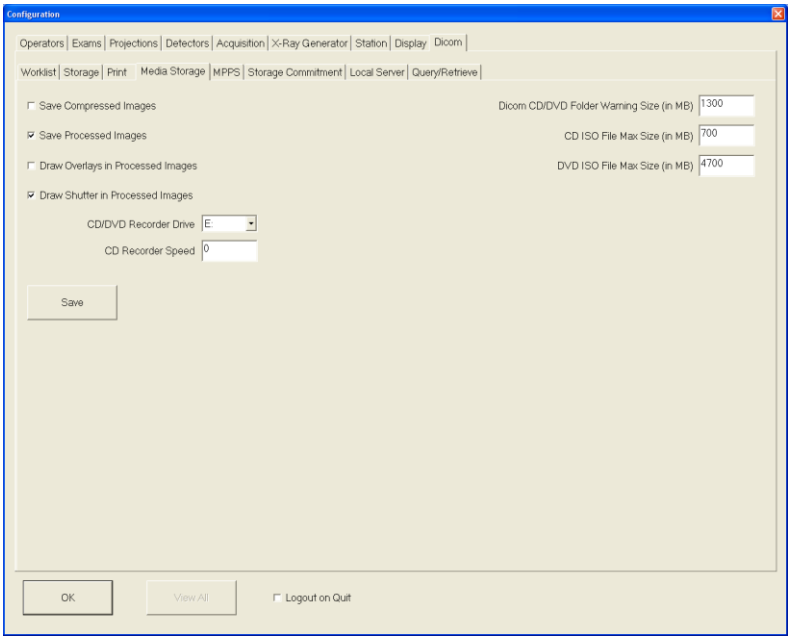


Figure 24: function Media Storage of *Dicom* tab of Configuration menu.

9.1.15.1 MPPS (MODALITY PERFORMED PROCEDURE STEP)

This is a complementary service to Modality Worklist. MPPS sends a report about a performed examination including data about the images acquired, beginning time, end time, and duration of a study, dose delivered, etc. To configure the MPPS it is necessary to use the same address of Store Server.

Insert the Name of Server

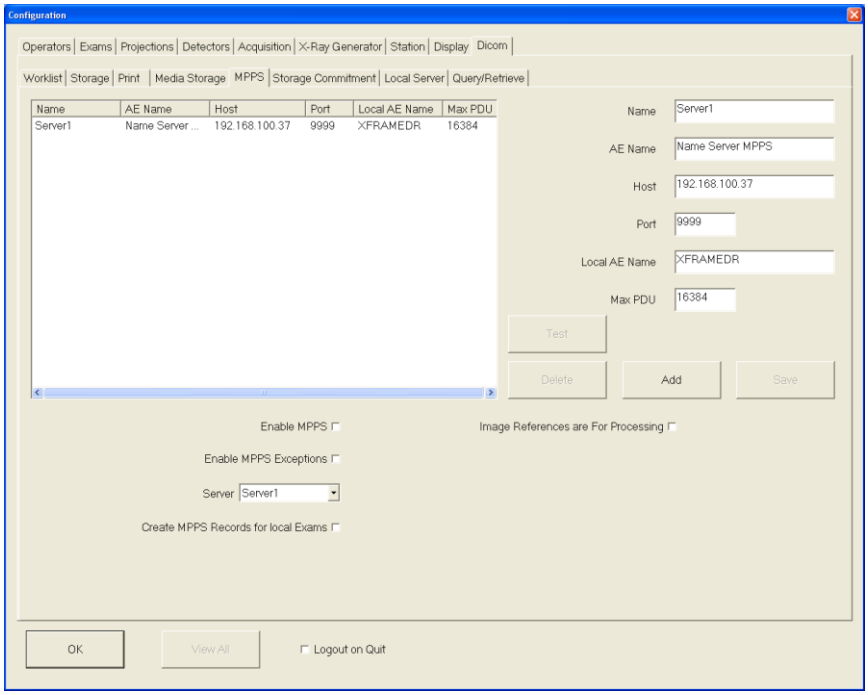


Figure 25: function MPPS of *Dicom* tab of Configuration menu

MPPS (here is not important that it is the real name), the AE Name (here is important that it is the real name of application), host (IP Address), Port, the Local AE Name (configurable with *Local Server* function) and the max PDU (by default). Add and test it, clicking on “Add” and than “Test” buttons. Select “Enable MPPS” to enable it.

9.1.15.2 STORAGE COMMITMENT

The DICOM storage commitment service is used to confirm that an image has been permanently stored by a device (either on redundant disks or on backup media, e.g. burnt to a CD). To configure the Storage Commitment it is necessary to use the same address of Store Server. Insert the Name of Server MPPS (here is not important that it is the real name), the AE Name (here is important that it is the real name of application), host (IP Address), Port, the Local AE Name (configurable with *Local Server* function) and the max PDU (by default). Add and test it, clicking on “Add” and than “Test” buttons. Select “Enable Storage Commitment” to enable it.

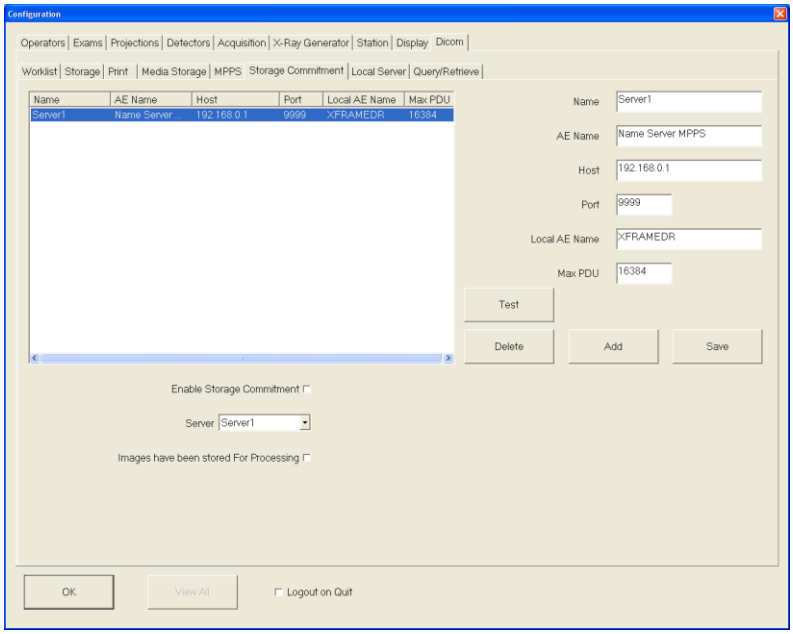


Figure 22: function Storage Commitment of *Dicom* tab of Configuration menu.

9.1.15.3 LOCAL SERVER

The Local Server function allows to change the AE Name, the Port and the max PDU. It allows to enable the storage and the storage commitment.

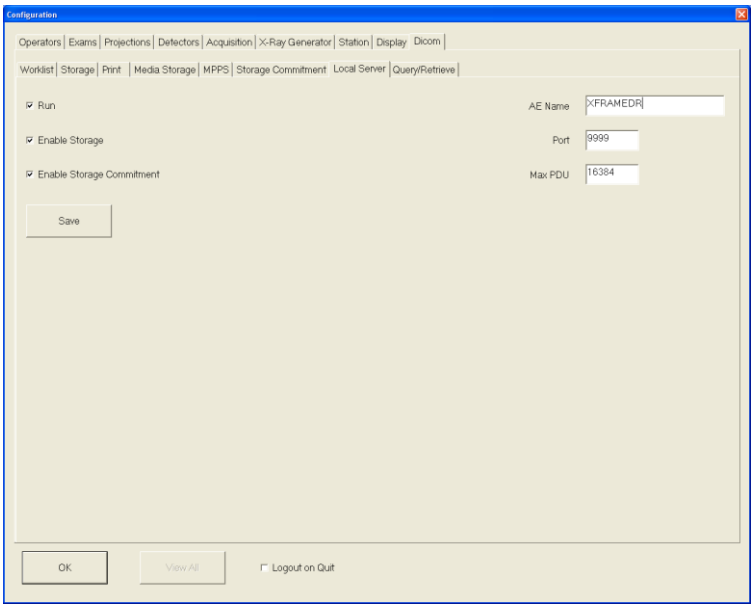


Figure 26: function *Local Server* of *Dicom* tab of Configuration menu.

9.1.15.4 QUERY/RETRIEVE

The tab Query/Retrieve enables a workstation to find lists of images or other such objects and then retrieve them from a PACS. To configure the Query/Retrieve it is necessary to use the same address of Store Server.

Insert the Name of Server MPPS (here is not important that it is the real name), the AE Name (here is important that it is the real name of application), host (IP Address), Port, the Local AE Name (configurable with *Local Server* function) and the max PDU (by default). Add and test it, clicking on “Add” and than “Test” buttons.

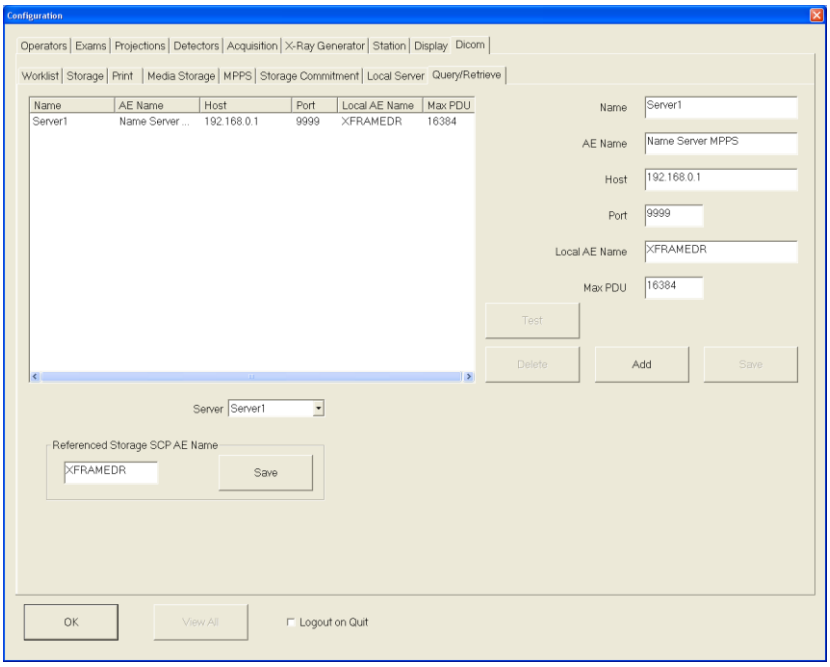


Figure 27: function Query/Retrieve of *Dicom* tab of Configuration menu.

WARNING: finished the configuration of the X-Frame DR, copy all files in an external media. In this way, if the system has a fault and should be re-installed the software, or if the system needs to support, the process will be faster. Please copy all the files that are in the folders C: \ X-FrameDR; C:\WINDOWS\system32.

9.2 CONTEXT MENU

Using the context menu, some features are available both for the operator and for the service. To activate the context menu it needs the mouse. Pressing the right button of mouse and the normal context menu will appear. The normal context menu contains some functions, available for the operator, that are described on the Operator Manual (control keys). The extended configuration menu contains more functions that are useful for the service. To open the extended menu from a radiological image, press the key “m” on the keyboard and insert the password. Click the right button of mouse and the context menu extended will appear.

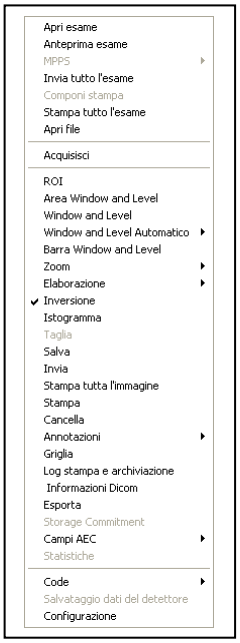


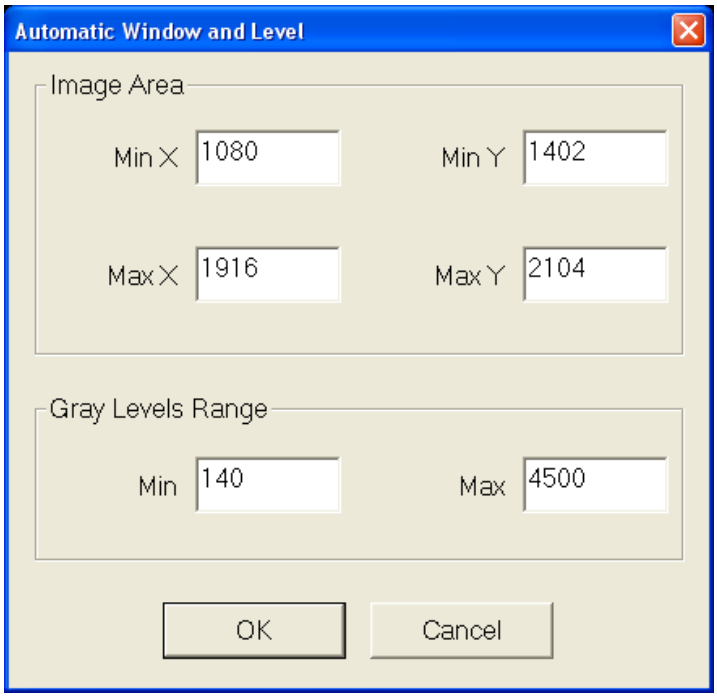
Figure 28: contest menu extended.

The function “**Automatic Window and Level**” is an important tool that allows to set the correct level of gray on the image for each projection. It needs to take a radiological image for every projection (chest, abdomen, arts, ecc..). The procedure to set it is the follow:

- in configuration menu, tab *Display*, select the item “Show min and max instead window and level”;
- open a radiological image. Select “Window and Level Area” (third button on the forth line) and take an area on the image in order to obtain the desired level of gray for the projection.
- on the extended contest menu, select “Processing” and then **“undo default processing”**. On the bottom left of the image will appear two numbers after the letters **m** and **M** (minimum an maximum). Store these values.
- exit from the exam and open again it;
- select “Window and level area” and take an area similar to the first one;

- select “Automatic Window And Level” on the extended context menu and than select “set”.

- Now take the values m and M and set the Automatic Window and Level using this values on the box Grey level Range:



- Repeat the procedure for every projection (or for the projection more used).

From the context menu it is possible import images (row or dicom) or export the images in jpeg format list.

To import an exam: select from configuration menu extended the function “open”. The system will open row images (if the number of columns, rows and bits of image are known) or dicom images.

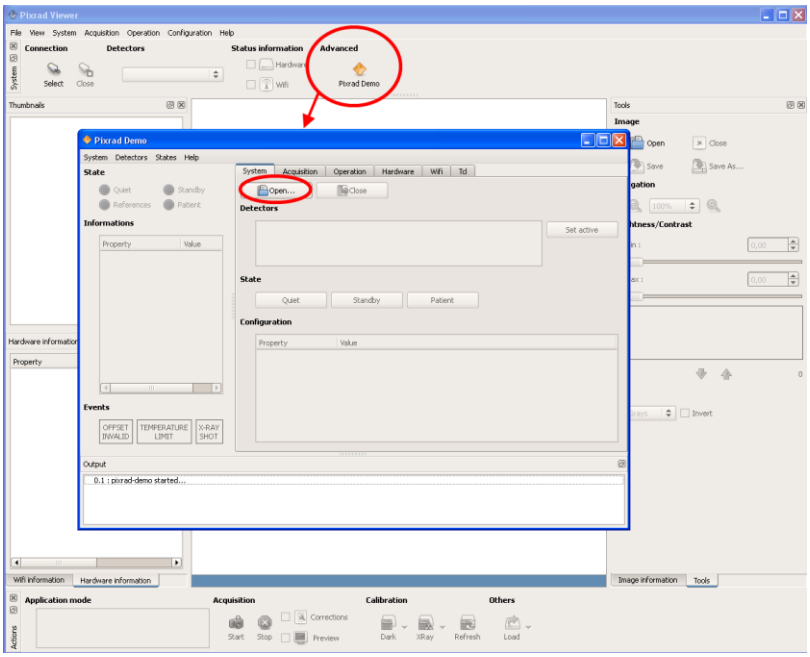
To export an exam in jpg format: select the image to export, click the right button of mouse and select export.

9.3 UTILITY IN WINDOWS ENVIRONMENT

Closing X-Frame DR software and login windows as Administrator, there are some tools that can be used.

To check if the detector works correctly without the X-Frame DR software, launch the *PixRad 3.2.2 software*, Trixell brand. Click on Start, PixRad 3.2.2 software, PixRad Viewer. Click on the button *Pixrad Demo* (Advanced) and then open the folder *C:\X-FrameDR\pixium*. If the detector works, the software will give a message of detector ready, if it doesn't work the software will give an error message with an indication about the error found.

.

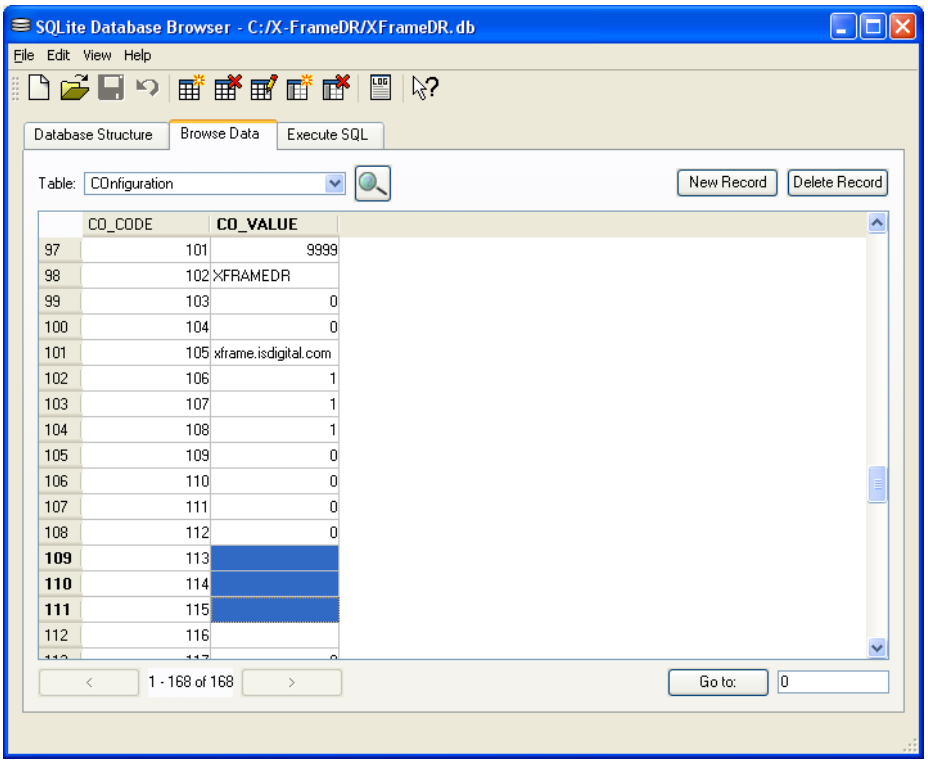


9.3.1 WARNING ERRORS SENDING BY E-MAIL

This option (automatic sending of e-mail with warning messages of system fault) is always disabled, both during the production and the installation in radiological room. It is possible to enable it only when a internet connection is established.

To enable this option it needs change the values on the x-frame.db database file. On the folder *C:\X-FrameDR*, launch the *SQLite Database Browser.exe* file. Open the database *XFrameDR.db* that is positioned in the same folder. Select the tab *Browse Data* and than the Table *Configuration*. Take the CO_CODE 113, 114 and 115. On the corresponding CO_VALUE write the e-mail of destination and the e-mail of the sender (it can be the same, e.g. xframe@italray.it) and the name and the IP address of mailserver

(mail.regiter.it or, if it is possible the mailserver of hospital network). To disable this option it needs to delete the three CO_VALUE values.



9.3.2 FOLDER C:\X-FRAMEDR\PIXIUM

On the folder *C:\X-FrameDR\Pixium* there are some files that are useful for the detector. For example file *Pixrad.ini* defines the general setting of the library:

- Log File Path

logfile.path = c:/X-FrameDR/Pixium/log

- ini file for the first detector

configfile.detector.0 = c:/X-FrameDR/Pixium/ Detector3543.ini

- XRay Doses ini file path

;configfile.include = c:/X-FrameDR/Pixium/ XrayDoses_3543.ini

- Reference Path

references.path = c:/X-FrameDR/Pixium/references

  - Last Image Data Path

lastimage.data.path = c:/X-FrameDR/Pixium/last_data

- Acceptance test path

acceptance.test.path = c:/X-FrameDR/Pixium/acceptance_test

- Detector Image Format Output

image.output.format = 16

- offset in float image before conversion (yes: per aumentare l'offset)

image.output.offset.talon = no

image.output.offset.talon.value = 0

For more explanation see the Pixrad Manual "*Pixrad_SIS_62408726.pdf*".

The files Detector****_*.ini define the hardware of detector and the configuration's options. The files XrayDoses****.ini define the settings of the x-ray doses for the calibration with x-rays. In these files it is important **check the level of sensitivity**. Verify if the value of *level.sensitivity* is the same of that reported on the Test Report of Detector.

10 DIAGNOSTIC AND DATA RESETTING

10.1 ERROR MESSAGES

If there is an error the equipment warns the operator by showing the error message on the display.

Below is an explanation of:

- The error messages
- Description of the possible cause that generated the error.
- Actions needed to restore the operating conditions of the equipment

MESSAGE	CAUSE and SOLUTION
AEC NOT READY	**Cause**: Ready signal of automatic exposure meter not available **Action**: Verify the connections to the module and the AEC chamber. Verify the voltages +12Vdc, -12Vdc, +5Vdc on the AEC module.
ADJUSTMENT NOT COMPLETED	**Cause**: Loss of configuration data **Action**: Switch the unit off. Repeat the reconfiguration procedure (see pag.**Errore. Il segnalibro non è definito.**). Enter the data on the form FRP11/L drawn up by the Manufacturer. If the configuration values are lost repeatedly, the cause might be electrical due to high voltage discharges coming from the X-ray tube or high disturbances coming from the power cable. In the first case follow the monoblock formation procedure (see pag.**Errore. Il segnalibro non è definito.**). In the second case verify that there are no other units nearby that may disturb the mains.
LOADING IN PROGRESS	Loading of capacitors in progress. If after 90 sec the loading has not been completed, contact technical assistance for help.
MAXIMUM LOAD	kVp, mA parameters or times too long; reduce load values to tube.

MESSAGE	CAUSE and SOLUTION
MAXIMUM CURRENT	**Cause:** mA higher than 50% of set value **Action:** verify whether led L1 of the Logic Board lights up during the x-ray exposure. If the led is on: • L1 overcurrent: it indicates an over-current in the primary of the monoblock; Possible causes: o mA too high, verify the adjustment of the mA (see pag. 37) o The led lights up even with low mA for high voltage discharges inside the monoblock or in the X-ray tube. Perform the monoblock formation procedure (seepag.**Errore. Il segnalibro non è definito.**). If outcome is negative contact manufacturer.
MINIMUM CURRENT	**Cause**: mA lower than 50% of set value **Action:** verify the adjustment of the mA (see page 37), and verify that leds L1 – L2 of the Logic Board light up during the X-ray exposure. If the leds are on: • L1 overcurrent: indicates an overcurrent in the primary of the monoblock; Possible causes: o mA too high verify the adjustments of the mA (see page 37) o The led lights up even with low mA for high voltage discharges inside the monoblock or in the X-ray tube. Perform the monoblock formation procedure (seepage **Errore. Il segnalibro non è definito.**). If outcome is negative contact manufacturer. • L2 overload: indicates an excess current load on the exposure time. Possible causes: o Wrong adjustment of mA (see page 37) o Voltage on heads of capacitor box below the minimum value (190Vcc). Verify the value of the line resistance that could be too high (> 0,4 Ohm).
O.K. STARTER NOT PRESENT	**Cause**: The output signal O.K. Starter of the board Starter S001 is not present. **Action**: Verify the correct rotation of the anode of the x-ray tube. Verify fuse F1 of the Converter Starter Interface board. Verify the connection of connector PR2 Starter (See Layout diagram) Verify the connections between PR2 and the x-ray group.

MESSAGE	CAUSE and SOLUTION
OVC	**Cause**: Over-current in the monoblock primary Verify whether led L1 of the Logic Board switches on during the X-ray exposure. If the led is on: Possible causes: o mA too high, verify the adjustment of the , mA (see page 37) o The led lights up even with low mA for high voltage discharges inside the monoblock or in the X-ray tube. Perform the monoblock formation procedure (see page **Errore. Il segnalibro non è definito.**). If outcome is negative contact manufacturer.
OVL	**Cause**: Over-current in the monoblock. **Action**: Verify the fuses F1, F2 (8-9 par.Box Capacitors F 6S01), F3, F4 (7 par. Box Capacitors F 6S01)of the box capacitor. Verify that led L2 of the Logic Board switches on during the x-ray exposure. Possible causes: o mA too high, verify the adjustment of the , mA (see page 37) o voltage on the ends of the capacitor box is below the minimum value (190Vcc).Verify the value of the line resistor which could be too high a (> 0,4 Ohm).

MESSAGE	CAUSE and SOLUTION
OVERCURRENT PROTECTION ACTIVE	**Cause:** the x-ray signal was interrupted before the end of the set x-ray time **Action** Verify that the LEDs **L1** – **L2** – **L3** are off before and during the x-ray exposure. If the leds are on: • **L1 overcurrent**: indicates an overcurrent in the primary of the monoblock; Possible causes: ○ mA too high, verify the adjustment of the , mA (*see page 37*) ○ The led lights up even with low mA for high voltage discharges inside the monoblock or in the X-ray tube. Perform the monoblock formation procedure (*see page* ***Errore. Il segnalibro non è definito.***). If outcome is negative contact manufacturer. • **L2 overload**: indicates an excess current load on the exposure time. Possible causes: ○ mA too high, verify the adjustment of the , mA (*see page 37*) ○ the power voltage of the Power Block board has dropped below the minimum value (190Vcc). Verify the value of the line resistance that could be too high (> 0,4 Ohm). • **L3 kV unbalance**: indicates that the positive and negative kV are unbalanced, or that one of the signals is missing. Possible causes: ○ interruption of a connection cable (see Layout diagram) ○ interruption inside the monoblock In the second case it is necessary to contact the manufacturer.
RELEASE 1ST STEP	Released 1st step before performing the 2nd X-ray step. Repeat the exposure
RELEASE 2ND STEP	Released 2nd step before the X-ray time. Repeat the exposure

MESSAGE	CAUSE and SOLUTION
X-RAY BLOCKED	**Cause:** The output x-ray signal of the CPU is blocked **Action:** Verify the fuses F1, F2 (8-9 par. Box Capacitors F 6S01), F3, F4 (7 par. Box Capacitors F 6S01) of the box capacitor. Verify that the leds **L1** – **L2** – **L3** of the Logic Board are on before the x-ray exposure. If the leds are on: • **L1 overcurrent**: indicates an overcurrent in the primary of the monoblock; Possible causes: o mA too high, verify the adjustment of the , mA (*see page 37*) o The led lights up even with low mA for high voltage discharges inside the monoblock or in the X-ray tube. Perform the monoblock formation procedure (*see page* ***Errore. Il segnalibro non è definito.***). If outcome is negative contact manufacturer. • **L2 overload**: indicates an excess current load on the exposure time. Possible causes: o mA too high, verify the adjustment of the , mA (*see page 37*) o the power voltage of the Power Block board has dropped below the minimum value (190Vcc). Verify the value of the line resistance that could be too high (> 0,4 Ohm). • **L3 kV unbalance**: indicates that the positive and negative kV are unbalanced, or that one of the signals is missing. Possible causes: o interruption of a connection cable (see Layout diagram) o interruption inside the monoblock In the second case it is necessary to contact the manufacturer.
SIGNAL 85% NOT AVAILABLE	**Cause**: the converter or the active safety micros are not powered **Action**: Verify the fuses F1, F2 (8-9 par.12.2.3), F3, F4 (7 par.12.2.3) of the box capacitor. Verify that the leds L1 – L2 – L3 of the Logic Board are on before the x-ray exposure. If the LEDs are on: • **L1 overcurrent**: indicates an overcurrent in the primary of the monoblock; Possible causes: o mA too high, verify the adjustment of the , mA (*see page 37*) o The led lights up even with low mA for high voltage discharges inside the monoblock or in the X-ray tube. Perform the monoblock formation procedure (*see pag.****Errore. Il segnalibro non è definito.***). If outcome is negative contact manufacturer. • **L2 overload**: indicates an excess current load on the exposure time. Possible causes: o mA too high, verify the adjustment of the , mA

MESSAGE	CAUSE and SOLUTION
	(*see page 37*) o the power voltage of the Power Block board has dropped below the minimum value (190Vcc). Verify the value of the line resistance that could be too high (> 0,4 Ohm). • **L3 kV unbalance**: indicates that the positive and negative kV are unbalanced, or that one of the signals is missing. Possible causes: o interruption of a connection cable (see Layout diagram) o interruption inside the monoblock **In the second case contact the manufacturer**
SYSTEM NOT CONFIGURED	**Cause:** due to strong interferences on the mains power or to high voltage discharges inside the monoblock, the system could have lost the configuration data **Action:** re-configure the unit (*see page* ***Errore. Il segnalibro non è definito.***) Perform the monoblock formation procedure (*see page* ***Errore. Il segnalibro non è definito.***). If outcome is negative contact manufacturer.
STOP X-RAY AEC NOT PRESENT	**Cause:** Stop signal of automatic x-ray exposure meter not available **Action:** Verify the connections between the AEC module and AEC chamber.

Table 1 – Error Messages

11 MAINTENANCE WARNINGS

Maintenance shall be performed only by the manufacturer or by personnel authorized by ITALRAY s.r.l. The company cannot be held liable for any consequences arising from actions performed by unauthorised personnel.

Programmed maintenance of this equipment shall be performed according to the following schedule:

- DARK and X-RAY CALIBRATION with TEST_AT every 3 months whenever there is evidence of an artifact can not be removed by repeated exposure to high uniform dose to the panel,
- replacement of the Hard Disk: whenever defects appear (eg excessive slowness of the system in daily operations.

The system automatically sends a warning when quarterly maintenance is needed.

12 CLEANING WARNINGS

For all the system: proper cleaning procedures are essential for the good preservation of the equipment, at least once a month clean the outside surfaces.
Products used to clean the external surfaces of the machine should have low alcohol content and contain no corrosive or abrasive detergent, no solvents (gasoline, alcohol, acetone, etc). Do not use aggressive chemical products (solvents, disinfectants, detergents) that could damage the surfaces (ex. Cidex). Cleaning external surfaces shall therefore be performed only with a wet cloth and neutral detergent and the surface shall be dried with a soft dry cloth.

To perform cleaning operations always respect the following indications:

- Turn off the appliance.
- Check that no liquid can penetrate into the device so as to avoid short-circuit and corrosion of the components. If a liquid product is accidentally poured onto the equipment, dry and clean immediately.

The material used to clean, sterilise, and disinfect a PIXIUM FE 3543 pR / Pixium 3543EZ, such as towelettes and dust clothes, must be processed using dedicated waste recycling procedures. The detector remains functional under limited exposure to the liquids defined in the table here below.

Active substance class	Cleaning agent	Concentration	Functional DS, FE, GF, BUC	Clean DS, FE, GF, BUC
	Water		DS, FE, GF, BUC	+ + + +
Aldehyde	Lysofomin 3000	3 vol%	DS, FE, GF, BUC	+ + + +
Quaternary compounds	Biguanid Fläche	4 vol%	DS, FE, GF; BUC	+ + + +
Guanidine derivates	Bacillocid spezial	6 vol%	DS, FE, GF, BUC	+ + + +
Peroxide compounds	Dismozon pur	4 weight%	DS, FE, GF, BUC	+ + + +
Pyridine derivates	Spray active	undiluted	DS, FE, GF, BUC	0 0 0 +
Chlorine derivates	Clorina	1 weight%	DS, FE, GF, BUC	+ + + +
Alcohol	Ethyl alcohol	undiluted	DS, FE, GF, BUC	0 0 0 +
Benzine	benzine	undiluted	DS, FE, GF, BUC	0 0 0 +
Household dishwashing liquid, washing active substances	Grün und Mild	10 vol%	DS, FE, GF, BUC	+ + + +
	Isopropanol	100%	DS, FE, GF, BUC	0 0 (0 +)
	Ethanol	70%	DS, FE, GF, BUC	0 0 (0 +)
	Chlorehexidine 0,5% in 70% Ethanol	0,5%	DS, FE, GF, BUC	0 0 (0 +)
	Haemosol in 1 l water	1%	DS, FE, GF, BUC	+ + (+ +)
	Chlorine : 250ppm in 1 litre DI water	250 ppm	DS, FE, GF, BUC	+ + (+ +)
	Artificial sweat (5% KCL, pH=3)	5%	DS, FE, GF, BUC	+ + (+ +)
	Natriumchloride 0,9% (NaCL)	0,9%	DS, FE, GF, BUC	+ + (+ +)
	Iodine 1% in 70% ethanol	1%	DS, FE, GF, BUC	no, no, no, no
	Hexabrix 320		DS, FE, GF, BUC	+ + (+ +)

The column “clean” means that neither discoloration nor aesthetic (nor functional) damage occurs due to a limited exposure of the corresponding part to the corresponding liquid.
For each part indicated in the first line, a quote “+” means a perfect cleanness even after several hours exposure, a “0” means that slight discoloration might occur especially for several minutes to hours exposure, a “no“ means that the surface might be seriously affected and thus is not guaranteed by specification. Values into brackets are to be confirmed.

13 Storage and Handling Instructions

Pixium Portable 3543pR/3543EZ detectors:

- Refer to the Unpacking Instruction Label attached to the outer cardboard box for the storage and handling conditions of the incoming shipment (stacking limitations, environmental temperature and humidity, pressure, etc...).

- The detector must be stored and handled within its original larger outer cardboard box. Do not open this outer box if there is no need.

- While not used nor powered, the detector should be stored within the inner protective bag resealed or closed with adhesive tape, and using desiccant material inside the bag to avoid any humidity on the detector

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