MEDEXCOM-TEH SRL
IDNO 1019600008809
Str. Cuza-Vodă 44, of.111, mun. Chisinau,
Republica Moldova

nr. 02-102 din 17.07.2025

Dl Gheorghe GORCEAG

Director Centrul pentru Achiziții Publice Centralizate în Sănătate

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Prin prezenta, compania **MEDEXCOM-TEH SRL**, cu referire la scrisoarea Dvs. nr 02-3173 din 14.07.2025 privind solicitarea clarificărilor pe marginea ofertei depuse la licitaţia deschisă nr. ocds-b3wdp1-MD-1747227021527 „*Achiziționarea dispozitivelor medicale (Aparat digital de radiografie cu fluoroscopie) conform necesităților IMSP SPITALUL DE STAT*”, Vă prezintă informația solicitată după cum urmează:

1

Fluoroscopie continuă: Interval minim: 50 - 125 kV in 1 kV steps	Da, 40-125 kV in 1 kV steps	Vedeți: MAN 1124 Helios USER pag. 16 Fig. 1

X-ray System – Generator and Control Specifications	
High frequency generator	80 kW / 1000 mA
High speed starter	9000/10000 rpm
Interface to Eracle workstation and flat panel	> 10.000 APR
Power Rack dimensions	56,5x50x201
kV in fluoroscopy	40-150 kV (1kV step)
kV in radiography	40-150 kV (1kV step)
Exposure time	0,001s to 6s (36 steps)
mAs range (non-AEC)	0.4-600 mAs (1000 mAs upon request)
Automatic exposure control	AEC up to 3 chambers
AEC settable parameters	6 film screen combinations 3 fields 7 blackening levels Adjustment: -50% +200%

Fig. 1 – MAN 1124 Helios USER

2

Minim 80 linii / cm	Da, 80 l/cm	Vedeți: MAN 1124 Helios USER pag. 17 Fig. 2

Grid Parameters	
Grid ratio	12:1
Lines per cm	80 l/cm
Focal distance	100-180 cm
Grid Width	46cm
f0	140cm
f1	117cm
f2	175cm

Fig.2 - MAN 1124 Helios USER

3

Raport minim: 10:1	Da, R12:1	Vedeți: MAN 1124 Helios USER pag. 17 Fig. 3

Grid Parameters	
Grid ratio	12:1
Lines per cm	80 l/cm
Focal distance	100-180 cm
Grid Width	46cm
f0	140cm
f1	117cm
f2	175cm

Fig.3 - MAN 1124 Helios USER

4

Managementul pacienților	Da, Managementul pacientilor	Vedeți: MAN 1124 Helios USER pag. 14 Fig. 4

Control Console	
Multi-tasking environment capable to manage simultaneously	o System control o Acquisition, images reconstruction and processing o Images Display oPatient management – software for registering and managing patient data and examinations in the X-ray system. o Images Storage and Print
Reduced image display time in radiography	After each single shot in less than 1 second the image is available with all exposure data (kV, mAs) on the monitor

Fig.4 - MAN 1124 Helios USER

5

Posibilitatea de salvare a imaginilor direct pe hard disk	Da, Posibilitatea de salvare a imaginilor direct pe hard disk	Vedeți: MAN 1124 Helios USER pag. 14 Fig. 5

Images processing	Image display: Magnification from 1:1 up to 3:1, inversion H/V, 90° rotation, windowing (CW and CCW adjustment), gamma correction grey scale inversion, spatial filters (sharp/smooth), kernel, harmonization. Image delete: images from mosaic view or entire study. Functionality that allows images to be saved directly onto the system's hard disk for storage and further processing. Image collimation: free collimation with automatic centering. Patient data input, exam and texting

Fig.5 - Extras din: MAN 1124 Helios USER

6

Posibilitatea de a vizualiza cel puțin imaginile în următoarele formate:2x2, 3x3, 4x4	Da, de la 2X2 pina la 11x11 formate Sharp spatial filtering, kernel 2X2 to 11x11; Traducere: Filtrare spațială de claritate (Sharp spatial filtering), kernel de la 3x3 până la 11x11.	Vedeți: MAN 1124 Helios USER pag. 14 Fig. 6

Image display formats	The system allows image display in multiple layouts, including 2x2, 3x3, 4x4, 5x5, 6x6, 7x7, 8x8, 9x9, 10x10, 11x11

Fig.6 - MAN 1124 Helios USER

7

Stația operatorului Interfon pentru comunicare operator-pacient	Da, Stația operatorului Interfon pentru comunicare operator-pacient	Vedeți: MAN 1124 Helios USER pag. 5 Fig. 7

7. CAN-BUS Connection which allows automatic setting of Collimation and S.I.D. (Focal Distance)
8. Adjustable Focal Distance "S.I.D." continuously from 105cm (100 cm optional) to 180cm (200 cm optional) even in case of preset positions based on examination type.
9. Motorized X-Ray-Tube Rotation with automatic and manual adjustments.
10. Interphone device – intercom system for direct communication with the patient.
11. Minimum Patient Table Height (from the floor) less than 50cm. in the HELIOS DRF Version.
12. Room Volumetric Mapping System interfaced with the anti-collision mechanical devices integrated into the system.

Fig.7 - MAN 1124 Helios USER

Cu respect,

Administrator

Digitally signed by Matei Andrei
Date: 2025.07.17 11:54:47 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Andrei MATEI

HELIOS

Remote controlled system: + 90 ° / -90 ° tilting angle suitable for radiographic and fluoroscopic diagnostic examination

DRF

User Manual

MAN1124.pub - Rev. 22 31/03/2023

First emission date 22/10/2010

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1370

ASSING S.p.A.
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SUMMARY

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Revision History

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INTRODUCTION 1

HELIOS system, subject of this manual, is a medical device and has been designed,
manufactured and protected to be used for radiological examinations on human body.
Use of this system is complementary to other essential equipments in order to perform a complete diagnosis.

Operating Functionalities

This device is a radiological accessory designed for traditional imaging diagnostic. It does not manage the start, stop and quality control commands of radiation.
Helios System allows the following Diagnostic/Operating Functionalities

1. Traditional Radiography
2. Traditional fluoroscopy
3. Stitching
4. Tomography
5. Angio-Step Radiography

Use for interventional examinations is excluded.

Contraindications and side effects

There is no contraindication or side effect for the Helios device.
For non-self-sufficient patients, the presence of an assistant at the table, who takes care is required.

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Main features:

Helios System contains the following technical features:

1. Touch-Screen Control Console .
2. Hi-Tech Operating Control Electronics; modular and expandable in order to dialog, trough the most common and widespread communication interfaces , with other devices (like X-Ray Generators, Collimators, Image Acquisition Devices, Remote-Controlled Tele-Diagnosis, etc.) , in order to make a complete Remote Table Diagnostic Room.
3. The "Image-Receptor Carriage" runs under the patient's table and allows 2 possible operating solutions:
   a. Spot.Film-Device for Film cassettes, CR Cassettes o WI-FI panel + Image Intensifier
   b. Flat Panel Dynamic Detector "DR"
4. X-Ray-Tube & Collimator Holder-Column-Stand
5. "Long-Pace" Version for Spot-Film-Device
6. Short-Pace" Version for Flat-Panel-Detector
7. CAN-BUS Connection which allows automatic setting of Collimation and S.I.D. (Focal Distance)
8. Adjustable Focal Distance "S.I.D." continuously from 105cm (100 cm optional) to 180cm (200 cm optional) even in case of preset positions based on examination type.
9. Motorized X-Ray-Tube Rotation with automatic and manual adjustments.
10. Interphone device – intercom system for direct communication with the patient.
11. Minimum Patient Table Height (from the floor) less than 50cm. in the HELIOS DRF Version.
12. Room Volumetric Mapping System interfaced with the anti-collision mechanical devices integrated into the system.
13. Tomography examen is performed without any coupling-mechanical-bar normally to be mounted
14. Optional Abdominal Compressor is separately installable.

The product has a useful life of 10 years. The shelf life depends on how is used, from the level of wear and maintenance.

Manual Addressees :

This manual is intended to allow the correct use of the HELIOS System.
Use of the table, and the manual too, is intended for enabled and qualified personnel only.
Use outside of the instructions for use and/or not in accordance with the instructions for use must be necessarily avoided as any liability arising from such use are charged to the user.
In the event of an accident resulting from the aforementioned use, it must in any case be reported to the manufacturer and to the Competent Authority using the forms prepared by the competent European bodies.

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SAFETY 2

Before any work on the table, read the usage instructions in this manual with maximum attention, drawn up to guarantee correct and safe use of the machine.
Keep this manual in an easily accessible and known place; we advise you to consult it any time doubts, even small doubts, arise.
This manual must accompany the machine for the whole of its lifetime and, in any case, it must be kept for at least 8 (eight) years.

For fast and rational reading, symbols have been used which show situations requiring maximum attention, which give practical advice or which simply give information.
Said symbols can be found at the side of the text (therefore they refer only to the text) or beside a figure (when they refer to the subject illustrated in the figure and the relative text).

ATTENTION! Pay maximum attention to the meaning of the symbols: their function is to avoid repeating technical concepts or safety warnings, therefore they must be considered a real "reminder". Consult this page any time you have doubts on their meanings.

Meanings of the symbols

ATTENTION! Highlight an important description regarding technical actions, dangerous conditions, safety warnings, recommended precautions and/or information of the maximum importance.

DANGER OF FIRE

DANGER OF ELECTROCUTION. During all service operations that require disconnection of the high voltage, pay maximum attention to the risk of electric shocks. Remember that the high voltage wires can maintain an electric charge, or they can be directly connected to parts that maintain an electric charge, even if the machine is switched off.

SWITCH OFF THE MACHINE! Every operation for which this symbol is shown must be carried out strictly with the machine switched off.

RADIATION RISKS AND SAFETY PRECAUTIONS. It is dangerous for any person to use or take avail of this apparatus without first having received appropriate training, also including the methods of using X-rays without causing danger for the patient, the user and anyone else present in the radiology room.

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DANGER OF CRUSHING HANDS Symbol on the arms of the patient's bed. If the level of the said bed is moved, do not rest your hands on the arms of the bed.

DANGER OF EXPLOSION. This apparatus is not classified as anaesthetic proof and can cause flammable anaesthetics to ignite. Flammable agents used for cleaning or disinfecting the skin can also cause a danger of explosion.

SPECIALISED PERSONNEL! Every action indicated by this symbol must be carried out only by a specialised technician of the manufacturing company, or by a technician who has followed a specific training course at the manufacturing company.

EXCLUSIVE DRF OPERATION
Every action, operation and/or description indicated by this symbol regards only the Direct Radiography Fluoroscopy version.

EXCLUSIVE SFD OPERATION
Every action, operation and/or description indicated by this symbol regards only the Spot Film Device.

MANUFACTURER
Symbol on the label; the information near this symbol indicates the manufacturer of the apparatus.

PRODUCTION PERIOD
Symbol on the label; the information near this symbol indicates the month and year of production.

TYPE B PART APPLIED
Part applied with reduced current dispersion

CONSULT THE INSTRUCTION MANUAL
Read the information necessary for the correct use of the device.

THE PRODUCT MUST BE SCRAPPED SEPARATELY
Do n crap by throwing into the non-differentiated waste.
Contact the local dealer for information on scrapping.

EC MARKING
Symbol on the label; the apparatus is EC marked

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⚠ **•The apparatus referred to by this manual is a medical device and it has been designed, constructed and protected for radiological use on the human body; no other use has been considered by the Manufacturer who therefore bears no responsibility whatsoever.**

•If the possibility of measuring anatomic parts is an option, please note that this measuring is approximate with a maximum error of 10%, and therefore it has a purely qualitative value and cannot be used for diagnostic purposes

•The installation, use and maintenance of every calibration action, repair etc., must be carried out exclusively by specialised personnel. The operator is authorised to act only on the console of the X-ray control table.

•If the HELIOS table is used by several operators, each must read the usage instructions carefully.

•The HELIOS must be installed only in a medical radiology room conforming to IEC standards.

•The maintenance of the HELIOS table must be carried out only by qualified and authorised personnel.

•Assing S.p.A. will accept no responsibility whatsoever for damage to persons, property or the apparatus caused by incorrect use of **HELIOS**, non-observance or insufficient observance of the safety criteria given in this manual and in the Provisions regarding the issue of X-rays, from tampering, even slight, and from the use of non-original spare parts which will cause lapse of the guarantee.

For any request or anomaly, always consult **Assing S.p.A.**, always indicating the MODEL and SERIAL NUMBER of the machine and the Assistance Agreement terms.

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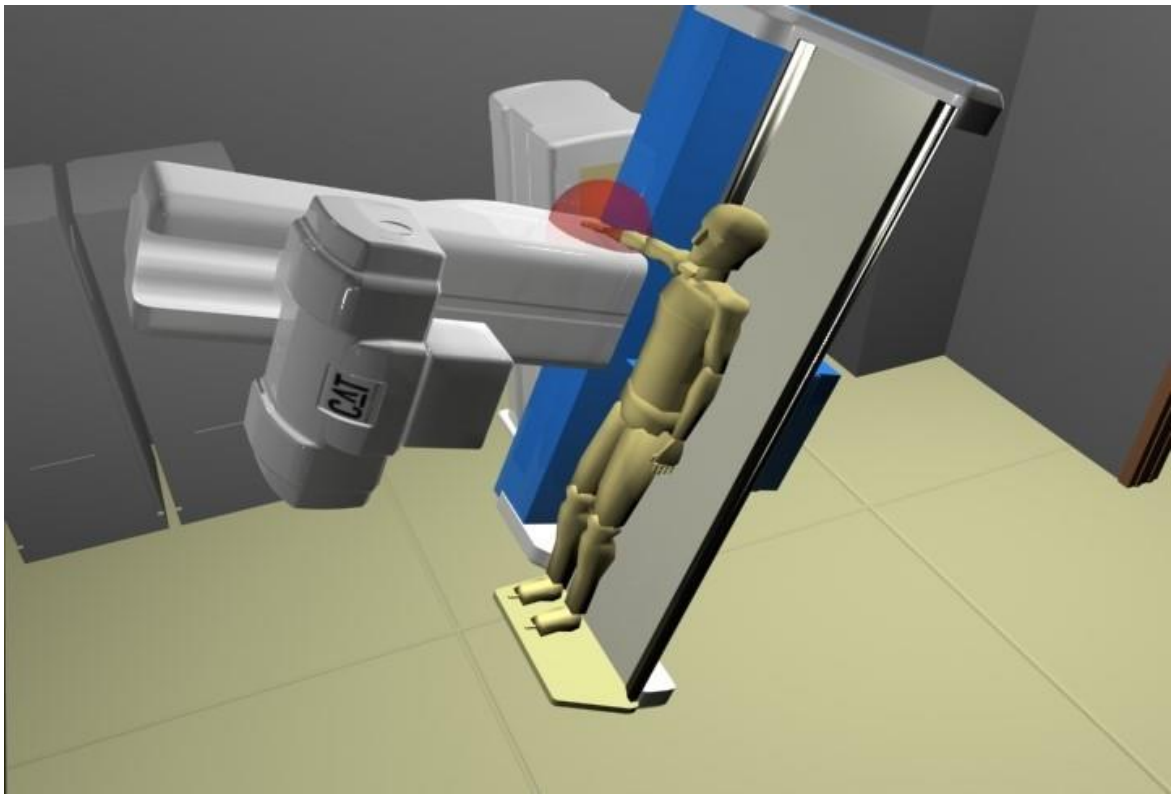
⚠ •Beforeactivatingtheradiologyapparatus,makesure thattheprotective screensareinstalled.
•All personnel not involved in the functioning of the X-ray generator must leave the radiology room or remain behind the protective screens.
•Beforecommandingtheissueoftherays,makesurethatthereisnooneintheradiologyroomexceptttheauthorisedpersonnelandthepatient.
•Useleadaccessoriestoprotectoperators andpatients.
•Always wearthedosimetricplate.
•Operatingpersonnel are forbiddentostandintheareadestinedformovingpartsof theapparatus.
•Attention to potential obstacles that may be on the trajectory of the movement with consequent risk of impact.

Dangers of a Mechanical Nature:

The incorrect position of the patient on the bed and the movement of the patient outside the examination surface could cause risks for his/her safety, due to contact with moving parts of the apparatus.



⚠ **There may be a danger of crushing, the so-called scissor effect, between the vertical upright and the patient's bed if this turns approaching the upright. We recommendthe patient remain within the confines of the surface.**

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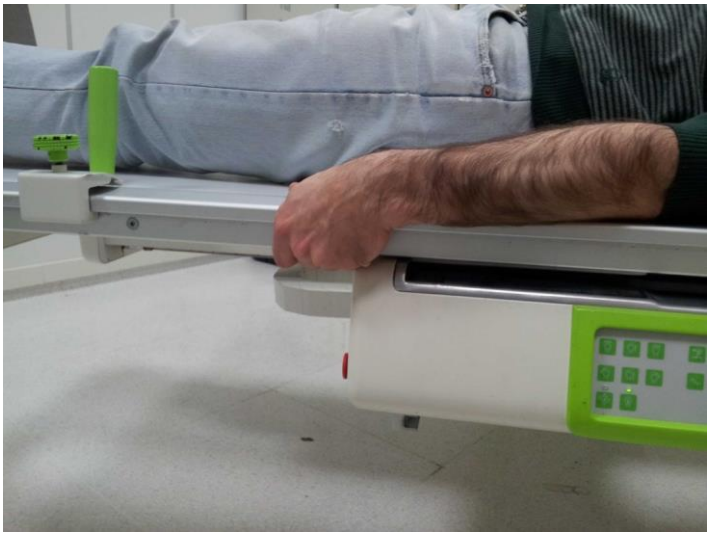
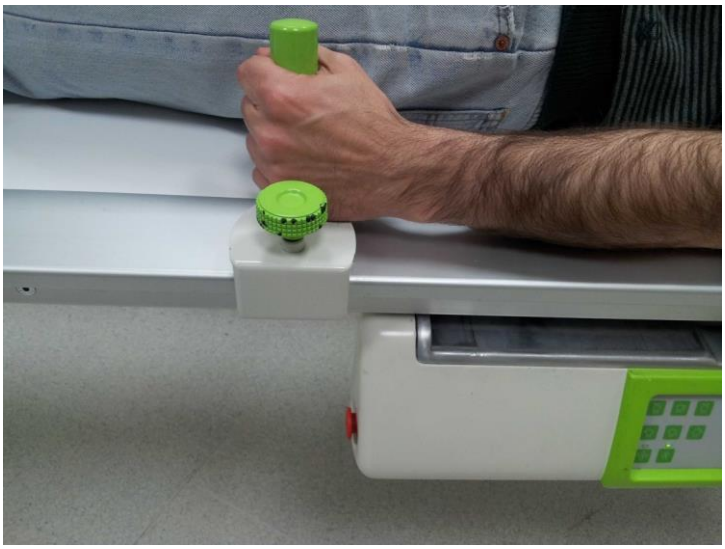
The incorrect position of the patient on the bed and the movement of the patient outside the examination surface or failure to use the safety systems could cause risks for his/her safety, due to contact with moving parts of the apparatus.



Incorrect position of the patient's hand.



Correct position on the handle.

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⚠ •The operator is authorised to act only on the main console, on the keyboard, on the seriograph and on the collimator.

•Before commanding the issue of the rays, make sure that the conditions dictated by the laws on radiation protection are met in the radiology room.

•Before every movement of the patient-bearing surface, make sure that the patient is protected against the risk of falling.

•Use the shoulder support provided for examination in which the patient must be placed in the Trendelemburg position.

•For any request or anomaly always consult**AssingS.p.A.**always indicating the MODEL and SERIAL NUMBER of the machine and the Assistance Agreement terms.

•Any action on the part of unauthorised personnel, modifications and/or tampering, even slight, will relieve**AssingS.p.A.**of all responsibility and will cause lapse of the Guarantee.

•Movements interrupted by anti-collision sensors will remain blocked, in any case, even with the command maintained and the obstacle removed. To obtain restoration of the action, thecommand must be released and the action must be repeated (protection against accidental action or action that, in any case, does not depend on the operator's will).

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Product directives and provisions applied:

•93/42/EEC as successively amended and supplemented, the Medical Device Directive as successively amended and supplemented
•Legislative Decree 46/97 as successively amended and supplemented, Implementation of Directive 93/42/EEC on medical devices
•CEI EN 60601-1:07 + A1, General prescriptions relative to fundamental safety and to essential performances
•CEI EN 60601-1-2:10, General prescriptions relative to fundamental safety and essential performances - Collateral provisions: Electromagnetic compatibility - Prescriptions and tests
•CEI EN 60601-1-3:09, General prescriptions for safety and essential performances - Collateral provisions: General prescriptions for radiation protection in radiology apparatuses for diagnostics
•CEI EN 60601-2-54:11, Special prescriptions relative to the fundamental safety and essential performances of X-ray apparatuses for radiography and radioscopy
•CEI EN 62353:11, Periodic verifications and tests to be carried out after the repair of electro-medical apparatuses
•CEI EN ISO 15223:12, Symbols to be used on the labels of medical devices
•CEI EN 60417-2:01, Graphic signs to be used on the apparatuses
•UNI EN ISO 780:01, Graphic marking for goods handling
•UNI CEI EN 1041:14, Information supplied by the manufacturer of medical devices
•EN ISO 14971:12, Application of risk management to medical devices
•CEI EN 62304:06, Software for medical devices - Processes relative to the life cycle of the software
•EN 62366:08, Application of the engineering of the usage features to medical devices

Environmental and usage conditions:

Conservation and transport:

Temperature: from –25°C to + 70°C
Humidity: maximum 95 R.H. without condensation
Maximum altitude: 5000 m (500 hPa)

Use

Temperature: from +10°C to +35°C
Humidity: from 20 to 80 R.H. without condensation (see limits imposed in Table 2 – Immunity)
Maximum altitude: 2000 m (800 hPa)

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Usage method: continuous functioning
Protection against the dangerous entry of water or dust: IPX0 (the device conforms to the penetration of the test finger for protection against direct contact)

Protection against electric shock: Class I EM apparatus (IEC 60601-1:2005 §6.2)

Features	Grade	Standard
Air pollution scale	2	(IEC 60601-1:2005 §8.9.1.8)
Surge voltage category	III	(IEC 60601-1:2005 §8.9.1.111)
Electrical breakdown (tracking) properties of the surface of the insulating materials	CTI IIIb	(IEC 60601-1:2005 §8.9.1.7)
Noise emission LAeq, for 1 hour of coninuous usage with two guages activated simultaneously	45 dBA max	(IEC 60601-1:2005 §9.6.2.1)

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Technical features:

Control Console	
Multi-tasking environment capable to manage simultaneously	o System control o Acquisition, images reconstruction and processing o Images Display oPatient management – software for registering and managing patient data and examinations in the X-ray system. o Images Storage and Print
Reduced image display time in radiography	After each single shot in less than 1 second the image is available with all exposure data (kV, mAs) on the monitor
Images processing	Image display: Magnification from 1:1 up to 3:1, inversion H/V, 90° rotation, windowing (CW and CCW adjustment), gamma correction grey scale inversion, spatial filters (sharp/smooth), kernel, harmonization. Image delete: images from mosaic view or entire study. Functionality that allows images to be saved directly onto the system's hard disk for storage and further processing. Image collimation: free collimation with automatic centering. Patient data input, exam and texting
Image display formats	The system allows image display in multiple layouts, including 2x2, 3x3, 4x4, 5x5, 6x6, 7x7, 8x8, 9x9, 10x10, 11x11
Graphic tools	**Text -** Adding text to the image. **Angle -** Measuring the angles in the image. **Calibration -** Getting an estimate of the actual size of the "objects" shown in the image **Catheter -** Using a catheter in the image of known diameter for calibration purposes **Grid -** Adding a grid to the image **Ruler -** Measuring the image **Solid rectangle -** Covering parts of the image to hide them **Statistics -** This function is normally used by the Technical Service when checking the system **Frame -** Drawing a frame around the body part of interest

Electrical features	
Standard voltage	3N ~ 400 V
Frequency	50 Hz
Insulation against the mains electricity	Transformer 2 kVA
Protection	8A with Magneto-thermic Differential
Line Impedance	< 1.0 'Ω 400 V ± 10%
Fall of voltage charge	< 2%

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Mechanical features	
Vertical height of table	2580 mm
Vertical height of upright	1960 mm
Width	2545 mm
Maximum necessary height with table in horizontal position at minimum height with SID 180 cm and 200 cm	SID180cm SID200cm Version with Flat Panel: 2370 mm 2570 mm Version with Seriograph or IB 9": 2537 mm 2737 mm Version with Seriograph or IB 12": 2687 mm 2887 mm Version with Seriograph or IB 16": 2687 mm 2887 mm
Minimum and maximum height of examination surface from ground	With detector (DRF): 450 mm – 1450 mm With IB of 9" (SFD): 650 mm – 1450 mm With IB of 12" (SFD): 750 mm – 1450 mm With IB of 16" (SFD): 800 mm – 1450 mm
Depth (Distance between base of upright and bed, all inclusive)	Version SFD: 2460 mm Version DRF: 2040 mm
Access from 4th side (distance of conveyor arm to the bed, all inclusive)	Version SFD: 55 cm Version DRF: 30 cm
Effective stroke for stationary column	2240 mm
Effective stroke of SFD receptor holder	2140 mm
Effective stroke of DRF receptor holder	2250 mm
SFD area of X-ray coverage of patient	430x2020 mm
DRF area of X-ray coverage of patient	430x2100 mm
Surface - Receptor distance and DFF+DPR reduction and enlargement factor	DRF: 70 mm Image enlargement factor at 105 cm = x1.06 Image enlargement factor at 180 cm = x1.03 Area reduction factor at 105 cm = x0.93 Area reduction factor at 180 cm = x0.96 SFD Film: 110 mm Image enlargement factor at 105 cm = x1.104 Image enlargement factor at 180 cm = x1.06 Area reduction factor at 105 cm = x0.90 Area reduction factor at 180 cm = x0.94 SFD IB: 150 mm Image enlargement factor at 105 cm = x1.142 Image enlargement factor at 180 cm = x1.083 Area reduction factor at 105 cm = x0.875 Area reduction factor at 180 cm = x0.923
Maximum height of tube 90° projected on stretcher with column and receptor aligned	2000 mm
Maximum height of tube 90° projected on stretcher with column and receptor at an angle	2100 mm
Electrical cabinet containing all the electrical and electronic command part	600x600x1720 mm
Dimensions of base of vertical upright	600x600 mm with 8 anchorage holes M16
Size of distribution plate	1500x1450 mm 360 kg thickness 20 mm 262 kg thickness 15 mm

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X-ray System – Generator and Control Specifications	
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High speed starter	9000/10000 rpm
Interface to Eracle workstation and flat panel	> 10.000 APR
Power Rack dimensions	56,5x50x201
kV in fluoroscopy	40-150 kV (1kV step)
kV in radiography	40-150 kV (1kV step)
Exposure time	0,001s to 6s (36 steps)
mAs range (non-AEC)	0.4-600 mAs (1000 mAs upon request)
Automatic exposure control	AEC up to 3 chambers
AEC settable parameters	6 film screen combinations 3 fields 7 blackening levels Adjustment: -50% +200%

Accessories	
Standard accessories	Removable platform with supporting surface 400x600 mm approx. with slides for fast attachment to the stretcher profile; Shoulder supports with cushions and built-in plastic shoulder anchorage devices with slides for fast attachment to the stretcher profile; 2 plastic handles with ergonomic grip with slides for fast attachment to the stretcher profile.
Optional accessories	Paper roll holder; Glass holder for LDC; 1 compression band with winder and lock with slides for fast attachment to the stretcher profile; Rotating gynaecological stirrups with slides for fast attachment to the stretcher profile; Side box holder for oblique projections with adjustable box holder arm and slides for fast attachment to the stretcher profile; Head rest; Hand safety band; Additional scopy and graphy pedal in examination room.

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Tomography	
Type	Planigraph with homothetic linear movements with calculation of the electronic fulcrum.
Maximum height of layer	400 mm (Physical limit 450 mm)
Layer increase/decrease	Manual at steps of 1 mm; Automatic (Autostep Function) with programming of the mm per step which can be selected according to the tomographic angle and the chosen starting layer.
Speed	10°-21°/sec. Can be selected.
Hunting angle	Standard Pre-set: 8°-15°-20°-30°-40°. 5 pre-set Can be selected as desired from 5° to 50°.
Tomography times	Up to 5 speed choices are available which represent a percentage of the maximum speed: 35.5 cm/sec. (21°/sec); For every hunting angle, therefore, it is possible to decrease the percentage of the maximum speed in 5 steps of about 10% per step; At maximum speed, a tomography at 40° and DFF 105, will require an exposure time of about 2.2 seconds.
Direction	Bi-directional in any position of the table and of the column/receptor group.
Sequential tomography	Sequential programme with emission during forward and backward movements up to the limit decided by the operator or until reaching the set limit or the limit of the layer, area, etc.
Range of receptor movement	The tomography is allowed in variable receptor positions according to the selected angle, DFF and layer.

Angiography by steps	
Mode	Combined with seriograph with box DR Wi-Fi (SFD) Combined with digital acquisition system (DRF)
Length of step	Manual modifiable during configuration; Automatic with step obtained from the receptor dimensions.
Direction	Can be selected.
Interface	Integrated with Generator, Collimator and digital image acquisition system.

Stitching (Examination of the spinal column and lower limbs) (Optional; only with digital system and FP)	
Mode	Combined with digital acquisition system (DRF); Combined with seriograph with box DR Wi-Fi (SFD).
Image dimensions	43x60 cm (2 images) 43x90 cm (3 images) 43x120 cm (4 images)
Direction	Head – Foot can be reset and automatically linked to the setting of the table side movement commands.
Interface	Integrated with Generator, Collimator and digital image acquisition system

Grid Parameters	
Grid ratio	12:1
Lp/cm	80 l/cm
Focal distance	100-180 cm
Grid Width	46cm
f0	140cm
f1	117cm
f2	175cm

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Abdominal compressor (Optional)	
Mode	Specially designed with attachments for guide rod between receptor carrying carriage and X-ray tube holder column.
Positions	Parking In field Compression
Commands	Designed for touch screen, table edge keyboard and joystick commands
Compression strength	Can be set from 5 kg to 20 kg with steps of 1 kg.
Minimum distance compressor cone - patient-bearing surface	80 mm
Maximum distance compressor cone - patient-bearing surface	420 mm
Stroke of cone in ray field	340 mm
Protections	Compression limiter Compression can be reduced manually
Movement and parking	Motorised
Other features	Remote control mode with automatic parking and possibility of installation separately. Continuous visualisation on the console of the dynamic pressure and of the programmed pressure limit; possibility of leaving the motorised field at the end of the stroke, with longitudinal retraction, for greater safety for patients/ operators.

Physical features SFD (Measuring and weights)		
Group	**Dimensions**	**Weight Kg**
Group	**Dimensions**	**Weight Kg**
Vertical upright	1960 x 900 x 650 mm	580
X-ray tube column	1350 x 340 x 1170 mm	130
Electrical cabinet	800 x 800 x 1760 mm	173
Conveyor	2460 x 310 x 300 mm	235
Patient carrying surface	2500 x 720 x 50 mm	57
Seriography	1300 x 640 x 360 mm	120
Lateral arms	1380 x 120 x 70 mm	56
Console	1080 x 600 x 610 mm	50
Guards		80
Accessories		20
Total weight		
Group	**Dimensions**	**Weight Kg**
Vertical upright	1960 x 900 x 650 mm	580
X-ray tube column	760 x 340 x 1170 mm	115
Electrical cabinet	800 x 800 x 1760 mm	173
Conveyor	2460 x 310 x 300 mm	235
Patient carrying surface	2500 x 720 x 50 mm	57
Receptor carrying carriage	900 x 640 x 280 mm	30
Lateral arms	1110 x 120 x 70 mm	40
Console	1080 x 600 x 610 mm	50
Guards		70
Accessories		20
Total weight		1370

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Automatic seriograph	
Seriographic stroke	168.5 cm
Possibility of continual adjustment of the speed of the seriography movement up to	100 mm/s
Type	With drive belts without box holder.
Acceptable box shapes	Shapes allowed: Film or CR of any shape in both directions; DR Wi-Fi panels.
Divisions in line	Subdivision into bands of 1, 2, 3, 4 and 5; Subdivision of the box in two directions, horizontal and vertical; Special function which allows for optimising the use of the film dividing it into areas of different sizes.
Cross division	No
Operating mode	Standard programme; Fast sequence; DR Wi-Fi programme.
Min. time of scopy-graphy passage	Less than 1 sec
Average fast sequence frequency	2 img/sec
Leaded limiter	Integrated
IB anchorage	Flange for side anchorage designed for any amplifier from 9" to 16" of any brand.
Correction of parallel axis error	Extremely precise inasmuch as electronically controlled with stepper motors in master-slave relationship with oblique projection angle.
Ionising chamber frame	Designed to house several of the most common types and models.

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Commands and controls	
General	Main control console Medical Grade Panel PC Touch Screen;With three key-boards, one on the receptor holder, one on the tube and the other on the colli-mator, near the patient-bearing table, which replicate most of the commands available from the main console.
Function commands	Main control console 19" Medical Grade Panel PC Touch Screen. Connections: Dedicated LAN to dialogue with the power unit control CPU (cabinet side); Standard LAN for normal networking functions; USB for management: Touch screen Joystick controls via I/O interface CAN Bus via NI Interface. 2 port RS232 Front USB for auxiliary use of: USB Memory Stick for configuration data transfer and backup. Mouse for fast set-up operations Minimum features required
Movement commands	Joystick group applied to touch screen console; Membrane keyboard on front of seriograph; Membrane keyboard on collimator; Membrane keyboard on tube cover guard.
User interface	Intuitive GUI customisable according to devices installed and specific needs.
Movement commands features	Dead man device.
Safety of movements	All movements are protected by limit switches which acts in H" on the power supply stop chain.
Other features	Easy and ergonomic to use especially for cleaning and sanitisation operations of all parts; Distance of footrest from floor with table in vertical position: less than 10 cm; Combined and synchronised movements of the X-ray detectors/source sys-tems allowing for examination of head, chest and limbs as for the pelvic and abdominal region; Automatic motorised positioning according to predefined type of examination; Tip-up patient-bearing surface; Possibility of carrying out X-ray investigations with stretchered patients with-out the use of other detectors or suspended devices.

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Collimator
Automatic radiological collimation system with square field and multiple level iris for use on fixed units.Installation surface at 80 mm (3.14") from the X-ray focus. Square field radiological collimator, designed and constructed for installation on fixed anode or rotating anode tube according to paragraph 29.202.3 of EN 60601-1-3 standard. The X-ray field is defined by 6 pairs of blades, four of which are leaded. The six pairs of blades are moved into the X-ray field perpendicularly to each other. Two pairs of blades (in bronze) are placed near the focus, two at the entry window of the X-ray band in the collimator, and the other two (which accurately limit the edges of the X-ray band) are placed on the collimator output window of the X-ray band.Blade movement is motorised with step-by-step motors and their positioning is controlled by the electronic card on the collimator and by two encoders activated by two knobs on the front panel of the collimator. The electronic microprocessor card on the collimator controls the step-by-step motors allowing for both automatic setting of the chosen fields, by means of a serial path with CAN-BUS protocol, and their continuous positioning according the variance of the Distance Focus Film (DFF). The card on the collimator also controls the step-by-step motor which moves the three additional filters in the collimator versions that are fitted with this option. A second electronic card, assembled on the first, powers with direct current the cluster of power LEDs, which simulates the X-ray field, the ventilator and the laser for alignment of the collimator with the image receptor.Square field variable from Min: 4x4 cm. to Max: 48x48 cm. to a DFF of 100 cm. Cluster of power LEDs for the projection of the light field which simulates the X-ray field. Timer which limits the switch-on of the light field from 30 to 60 seconds by means of CAN_BUS. Protection against X-ray dispersion up to 150 kVp 4 mA.Self-centring system for assembling the collimator to the X-ray source tube.Collimator rotation. Linear laser for alignment of the collimator with the image receptor. Minimum internal filtration of 2 mm. In aluminium (1 mm on request). Direct control of the system by CAN BUS protocol. Automatic setting of the X-ray field. LED indicator on the front panel to show functioning mode.Digital display of the functions. Device for monitoring the collimator inclination angle.Key switch to change the system from automatic to manual mode.

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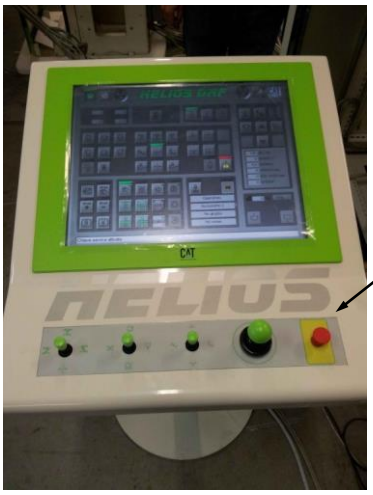
Safety devices

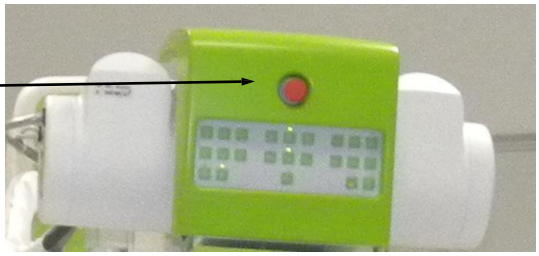
HELIOS has four emergency buttons:



On themainconsole

On both sides of the receptor holder

On top of the X-ray tube keyboard



Pressinganyofthe4emergencybuttonswillinterrupttheelectricitytothe remote control of the table, and only the safety systems will be powered.

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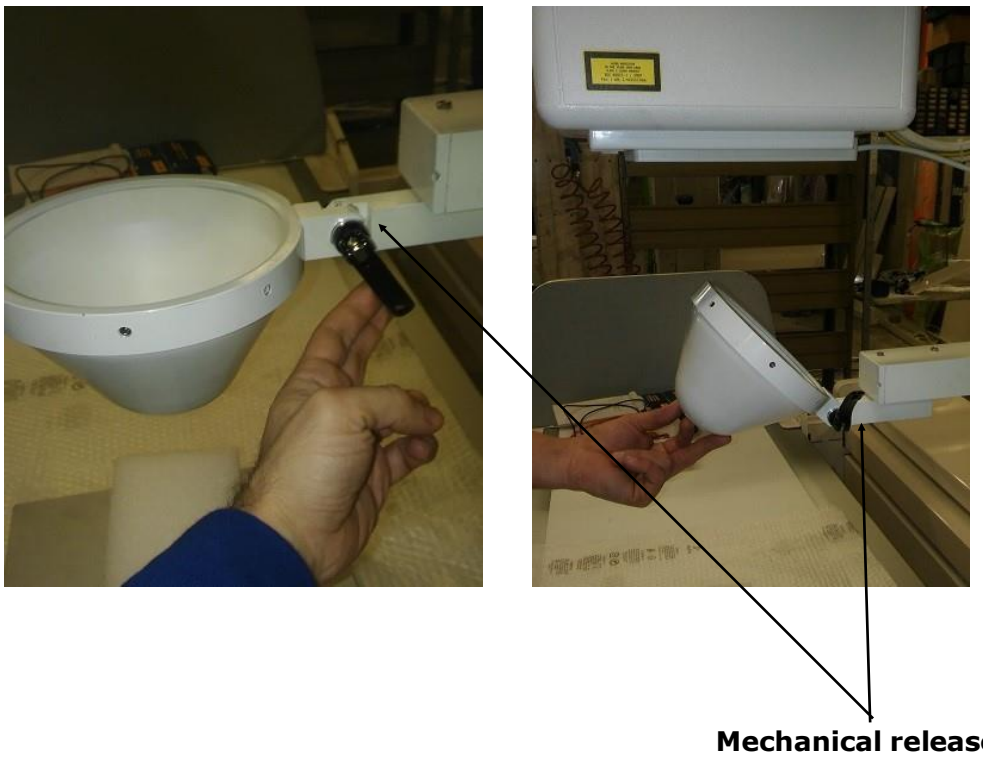
Safety devices

If the system includes a **compressor**, it will have a system for the mechanical release of the cups to free the patient in the case of an emergency.



⚠ **Whenthemechanicalreleaseleverisopened,thecompressorcupisreleased andthepatientcanbefreed.**

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Resetting normal conditions after an

To reset the emergency button (reset after an emergency), it is only necessary to restore the button that was pressed to its original position by means of a slight pressure in the opposite direction.

To restore the compressor to normal usage conditions (compressor cup in horizontal position), it is sufficient to replace the cup in the original position and mechanically tighten the level of the mechanical release.

Thelockofapparatusmovements,determinedbypressinganemergency button, forces a permanent standby condition.
Afterresettinganemergencycondition,torestorethefunctioningofthe apparatus, the "ON" button on the operator's console must be pressed.

If the functions are not restored, contact the assistance service.

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EMC table

Table 3. Manufacturer's guide and declaration - electromagnetic emissions			
The DM is intended to function in the electromagnetic environment described below. The customer or the DM user must guarantee that it is used in such an environment			
Emission test	**Conformity**	**Electromagnetic environment - guide**	
RF emission CISPR 11	Group 1	The DM uses RF energy only for internal functioning. Consequently its RF emissions are very low and probably cause no interference in nearby electronic apparatuses.	
RF emission CISPR 11	Class [A or B]	Class A	The DM is suitable for use in all environments, including the home and those directly connected to a low voltage public grid which supplies power to buildings for residential use.

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Table 4. Manufacturer's guide and declaration -	electromagnetic immunity		
The DM is intended to function in the electromagnetic environment described below. The customer or the DM user must guarantee that it is used in such an environment.			
IMMUNITY test	**Test level of IEC 60601**	**Conformity level**	**Electromagnetic environment - guide**
Electrostatic discharge (ESD) IEC 61000-4-2	with ± 6 kV contact in the air ± 8 kV	with ± 6 kV contact in the air ± 8 kV	The floors must be in wood, concrete or ceramic tiles. If the floors are coated with synthetic material, the relative humidity must be at least 30%.
Transient/fast electric impulse sequence IEC 61000-4-4	± 2 kV for power lines± 1 kV for entry/exit lines	± 2 kV for power lines± 1 kV for entry/exit lines	The quality of the network voltage should be that of a normal business or hospital environment.
Voltage surges IEC 61000-4-5	± 1 kV between phases±2 kV between phase(s) and the earth	± 1 kV between phases±2 kV between phase(s) and the earth	The quality of the network voltage should be that of a normal business or hospital environment.
Voltage dips, short interruptions and voltage variations on the incoming power lines IEC 61000-4-11	<5 % *UT*(>95 % dip in *UT*) for 0.5 cycles 40 % *UT*(60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*)for 25 cycles <5 % *UT*(>95 % dip in *UT*) for 5 s	<5 % *UT*(>95 % dip in *UT*) for 0.5 cycles 40 % *UT*(60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT*(>95 % dip in *UT*) for 5 s	On interruption, the DM switches off. When voltage returns, it switches on again in the stand by condition.
Magnetic field at network frequency (50/60 Hz) IEC 61000-4-8	3 A/m	NA	The DM bas no elements/circuits that are sensitive to the magnetic field
NOTE	*UT* is the AC voltage before the application of the test level.		

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Table 6. MANUFACTURER'S guide and declaration - electromagnetic IMMUNITY

The DM is intended to function in the electromagnetic environment described below. The customer or user of the .....should guarantee that it is used in such an environment.

IMMUNITY test	Test level of IEC 60601	Conformity level	Electromagnetic environment - guide
RF behaviour IEC 61000-4-6 Irradiated RFIEC 61000-4-3	3 V eff. from 150 kHz to 80 MHz 3 V/m from 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communication devices should not be used nearer to any part of the DM, including the wires, than the recommended safety distance calculated with the equation applicable to the transmitter frequency. **Recommended safety distance** $d = 3.5 \sqrt{P}$ $d = 1.2 \sqrt{P}$ from 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ from 800 MHz to 2.5 GHz where *P* is the maximum nominal output power of the transmitter, in watts (W), according to the transmitter manufacturer, and *d* is the recommended safety distance in metres (m). The field intensity of the fixed RF transmitters, determined by an on-sight electromagnetic investigation [a] should be lower than the conformity level for each frequency interval [b]. Interference can be checked near apparatuses marked with the following symbol: 

NOTE 1 A 80 MHz and 800 MHz is applied to the separation distance for the highest frequency range. NOTE 2 These guidelines may not apply to all situations. The electro-magnetic propagation is influenced by the absorption and by reflections from structures, objects and persons.

[a] The field intensities for fixed transmitters, such as base stations for radio-telephones (mobile/cordless) and terrestrial car radios, apparatuses for radio amateurs, AM and FM radio transmitters and TV transmitters cannot be theoretically foreseen with precision. To asses an electromagnetic environment caused by fixed RF transmitters, an on-sight electromagnetic investigation should be considered. If the field intensity measured on the spot where the DM is used exceeds the above-mentioned applicable conformity level, the functioning of the DM should be kept under observation. If abnormal performance is noticed, additional measures may be necessary, such as a change of the direction or position of the DM. [b]

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Recommended safety distance between portable and mobile radio-communication apparatuses and the DM

The DM is intended to function in an electromagnetic environment where RF irradiated disturbance is under control. The DM customer or user can contribute to preventing electromagnetic interference by ensuring a minimum distance between mobile and portable RF communication apparatuses (transmitters) and the DM, as recommended below, according to the maximum output power of the radiocommunication apparatuses.

Nominal maximum output power of the transmitterW	**Safety distance at the transmitter frequencyM**		
	from 150 kHz to 80 MHz $d = 1.16\sqrt{P}$	**from 80 MHz to 800 MHz** $d = 1.16\sqrt{P}$	**from 800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
0.01	0.11	0.11	0.23
0.1	0.36	0.36	0.73
1	1.16	1.16	2.33
10	3.66	3.66	7.36
100	11.6	11.6	23.3

For specific transmitters for a maximum output power not indicated above, the recommended safety distance *d,*in metres (m.) can be calculated using the equation applicable to the frequency of the transmitter, where *P* is the maximum nominal output power of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 A 80 MHz and 800 MHz is applied to the separation distance for the highest frequency range.

NOTE 2 These guidelines may not apply to all situations. The electro-magnetic propagation is influenced by the absorption and by reflections

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DISPERSED RADIATION Table

13.6A	Table: STRAY RADIATION of X-RAY EQUIPMENT		
Orientation of PATIENT SUPPORT	Region of height (above floor) in SIGNIFICANT ZONE OF OCCUPANCY, cm	Highest permissible AIR KERMA in one hour, mGy	Measured STRAY RADIATION in one hour, mGy
Horizontal tubo sopra, rivelatore sotto	67	1	0,401
	88	1	0,281
	102	1	0,360
	112	1	0,414
	124	1	0,405
	134	1	0,359
	157	1	0,303
	169	1	0,277
Supplementary information: misure effettuate a 70 kV e 10 mAs normalizzate al carico di lavoro 1900 mAs, fuoco piccolo, distanza fuoco-letto 100 cm, centro fantoccio-bordo tavolo 45 cm vedi punto 3 di ALLEGATO 4 RIFERIMENTI, campo 25x25 cm^2, camera di ionizzazione STEP frontale distanza centro campo-punto di misura specificata in Region of height, altezza di misura specificata, altezza terra tavolo 58,5 cm.			

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13.6A	Table: STRAY RADIATION of X-RAY EQUIPMENT		
Orientation of PATIENT SUPPORT	Region of height (above floor) in SIGNIFICANT ZONE OF OCCUPANCY, cm	Highest permissible AIR KERMA in one hour, mGy	Measured STRAY RADIATION in one hour, mGy
Horizontal tubo sopra, rivelatore sotto	67	1,5	1,151
	88	1,5	1,333
	102	1,5	1,384
	112	1,5	1,398
	124	1,5	1,387
	134	1,5	1,235
	157	1,5	1,118
	169	1,5	0,957
Supplementary information: misure effettuate a 150 kV e 50 mAs normalizzate al carico di lavoro 1200mAs, fuoco piccolo, distanza fuoco-letto 100 cm, centro fantoccio-bordo tavolo 45 cm vedi punto 3 di ALLEGATO 4RIFERIMENTI, campo 25x25 cm^2, camera di ionizzazione STEP frontale distanza centro campo-punto di misura specificata in Region of height, altezza di misura specificata, altezza terra tavolo 58,5 cm.			

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CONFIGURATION 3

HELIOS DRF

HELIOS DRF System's main components :

1) Main Elevator Pillar
2) Translation Base
3) X-Ray-Tube stand Column lifter
4) X-Ray-Tube rotation Group
5) X-Ray Tube
6) Collimator Group
7) Patient's Table-Top
8) Image-Receptor Carriage

Compressor group : optional (NOT SHOWN ON THE IMAGE)

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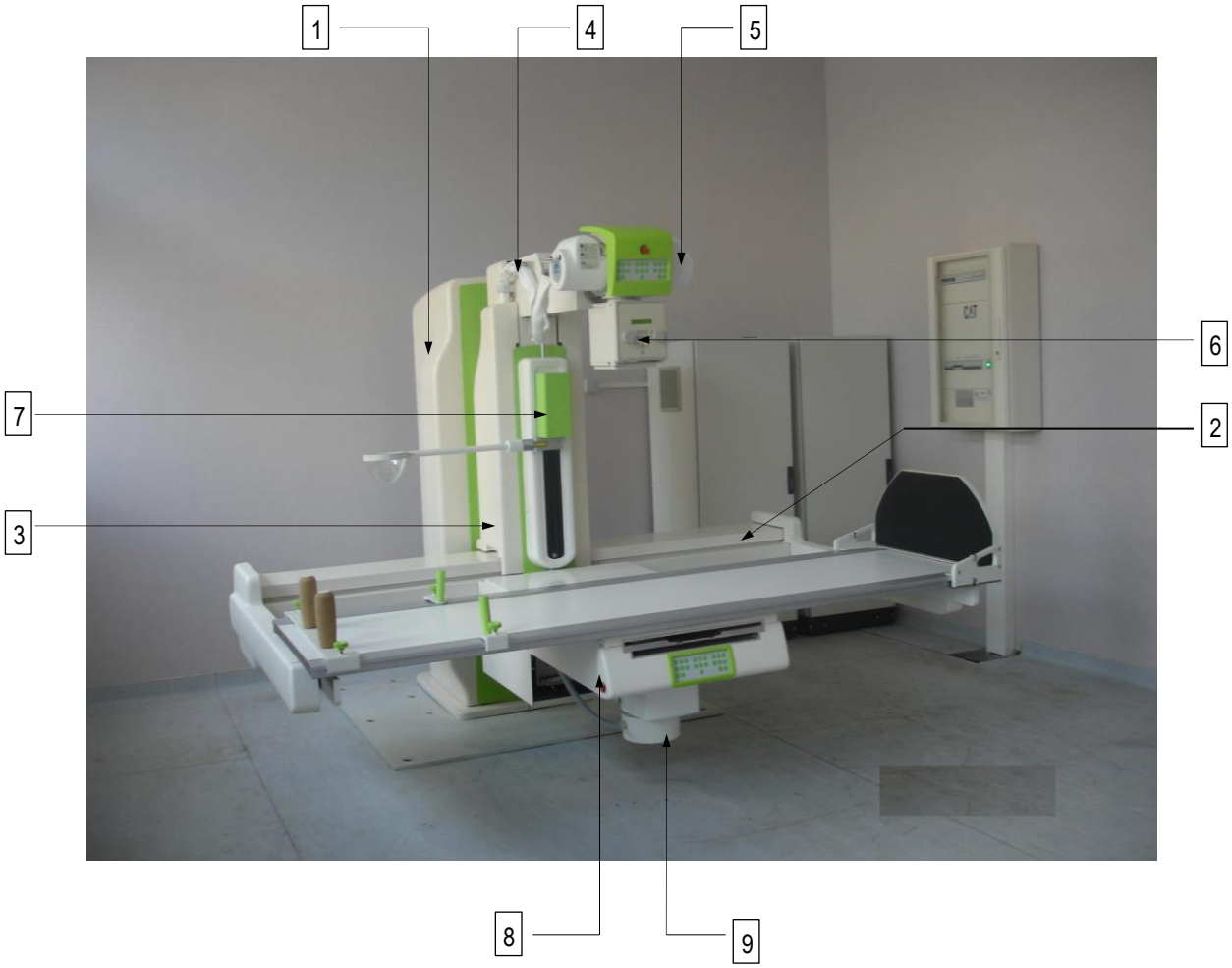
HELIOS SFD



HELIOS SFD System's main components:

1) Main Elevator Pillar
2) Translation Base
3) X-Ray-Tube stand Column lifter
4) X-Ray-Tube rotation Group
5) X-Ray Tube
6) Collimator Group
7) Compressor Group (Optional)
8) Spot-Film-Device
9) Image Intesifier Group
10) Patient's Table-Top

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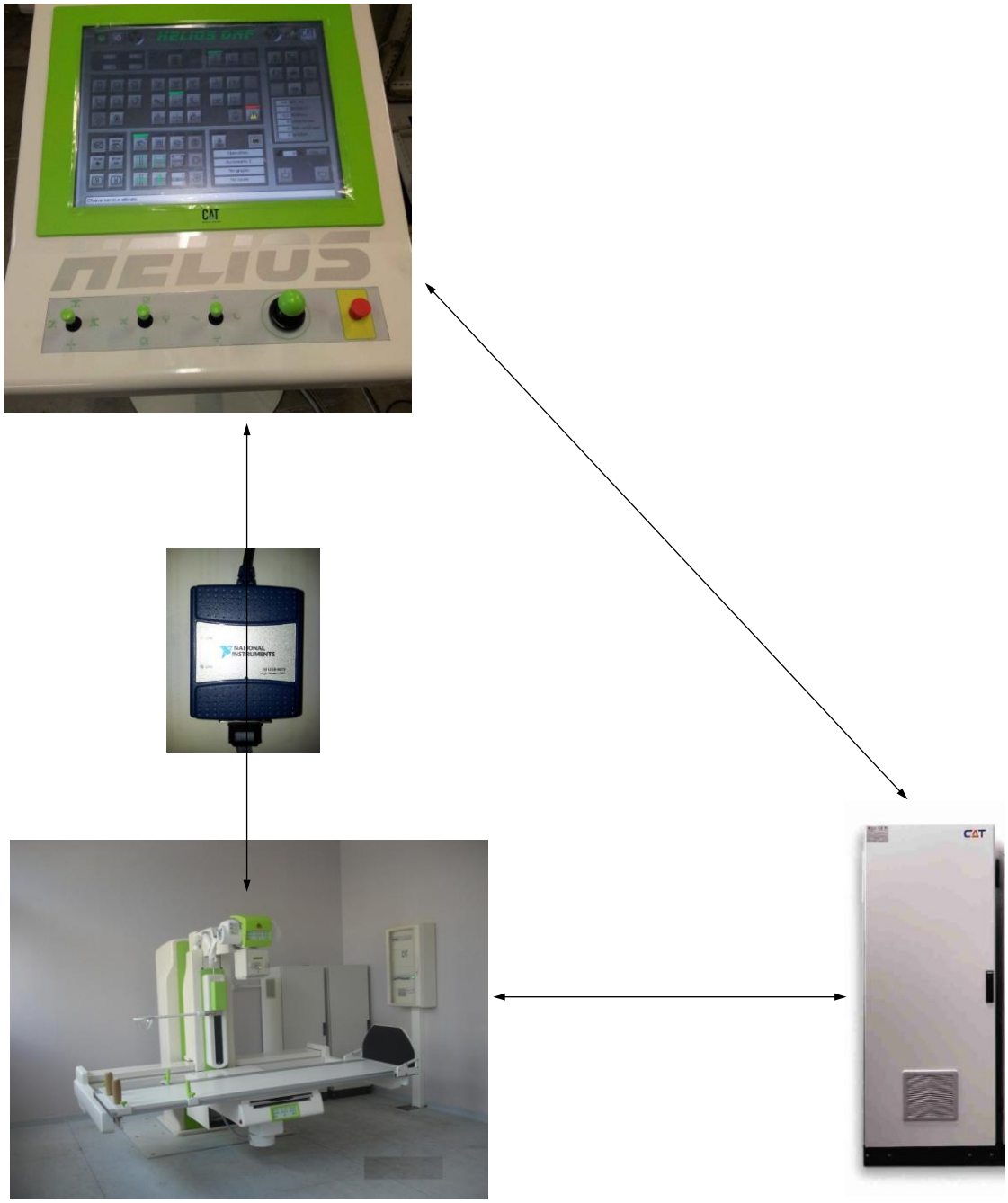
Elements for HELIOS System operations are:

- Panel-pc Touch-Screen Console which represents the main user's interface.
- Control Cabinet where is located the whole system's movements control electronics.
- X-Ray Tube
- Collimator



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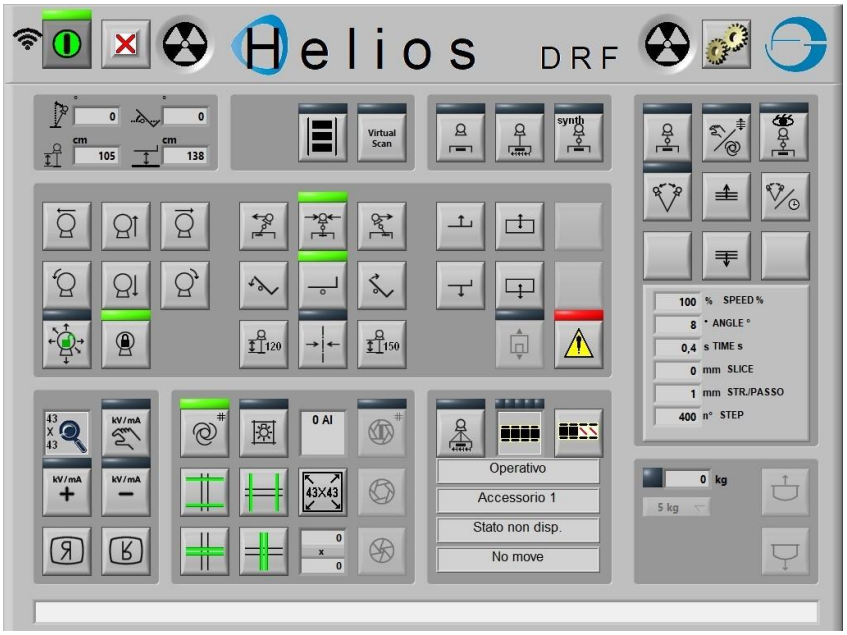
HELIOS System can be operated by means different points of commando as indicated below;

Main Console

It is the main component which allows the total functional system's remote-control; it is provided by a Keyboard and by several alphanumeric displays for visualization of all status information and active operations as well.

Touchscreen



Operator'sdisplayviewing (DRF version).

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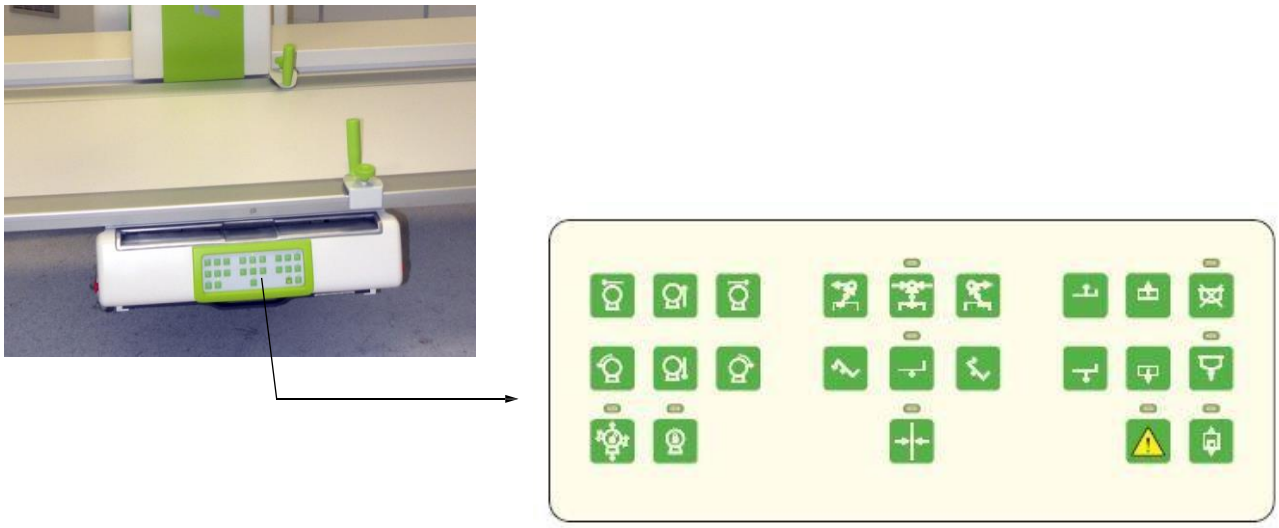
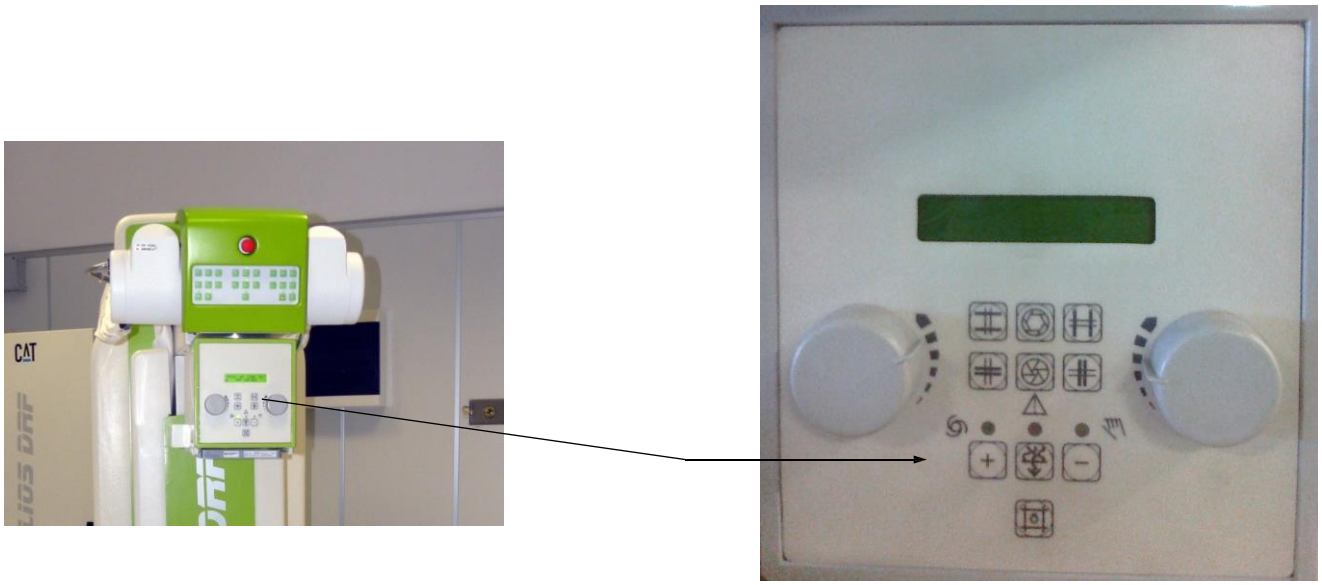
Image Receptor (SFD/DRF) Carriage's Keyboard

The Keyboard is located just under Grid aperture in FPD version or under Cassette load aperture in the SFD version.
This Keyboard allows to activate all system's main movements when the operator stands beside the table .



Collimator Keyboard

This Keyboard is located on Collimator's front panel; it allows to control locally collimator's functions:longitudinal & lateral blades and iris, only if this latter is enabled by the chosen conditions.



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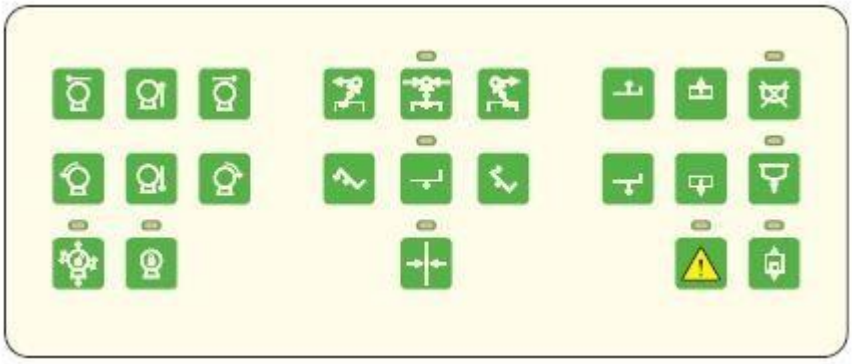
X-Ray Tube Keyboard

This Keyboard is located on the X-Ray Tube front-panel-cover. It allows (on both FPD and SFD versions) to activate all system's main movements when the operator stands in front of the X-Ray



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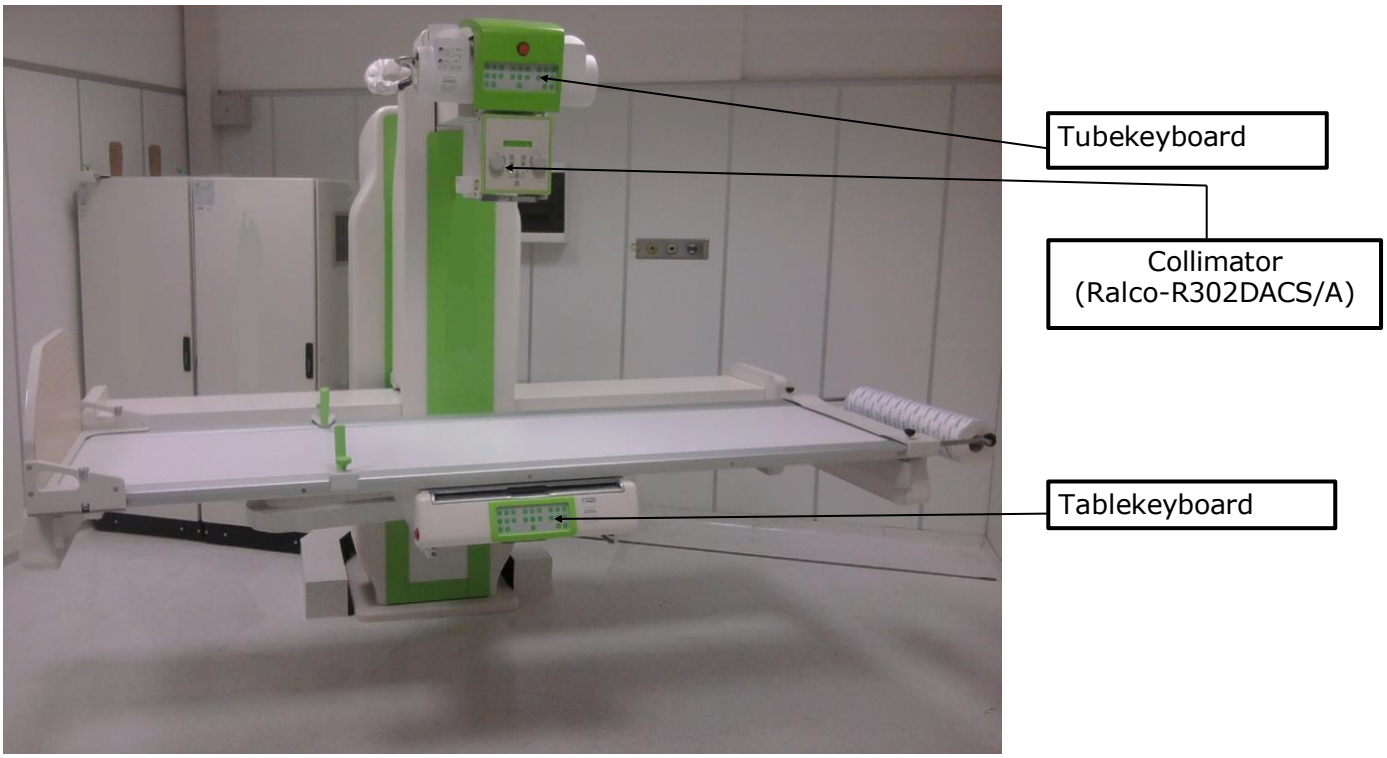
OPERATING DESCRIPTION 4

Table management mode

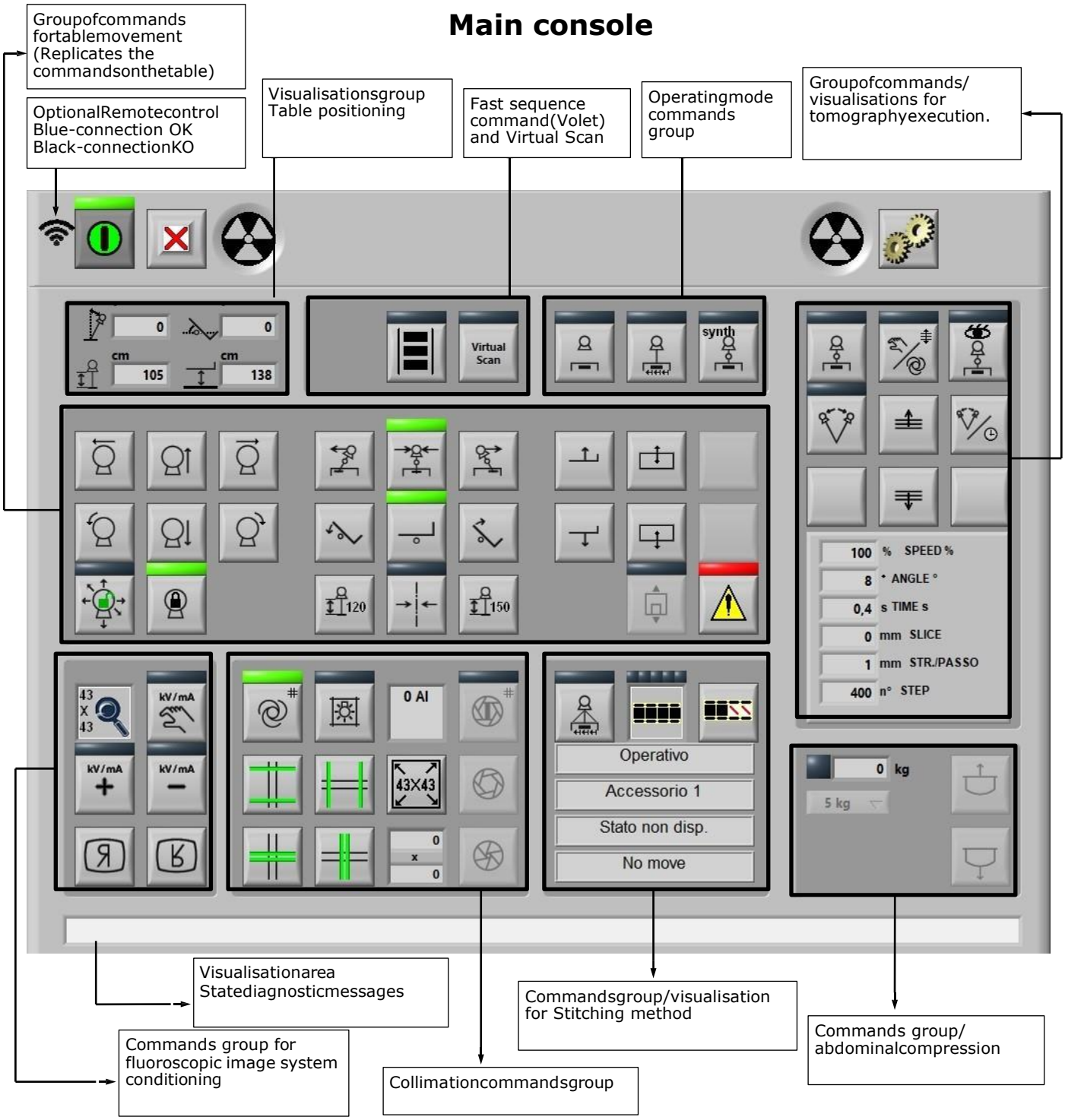


The methods of using HELIOS contemplate various control tools, mostly equivalent to each other.
The definitions of this paragraph allow for their unequivocal identification.
Table keyboard - This is on the front mask of the receptor holder carriage.
Tube keyboard - This is on the front mask of the tube.
The G.U.I. - Graphic User Interface - of the console is the software control application used on a pc touch-screen panel, and is an integral part of the operators main control console. This method allows for single movements of the table, unlike the table and tube keyboards which allow for several commands to be accepted simultaneously.
Joystick module - Optional control module which complements and expands the G.U.I. action command possibilities.
The joystick panel allows for managing multiple commands also from the console.
Collimator (Ralco - R302DACS/A) - The commands relative to this component are described in the manual supplied by the manufacturer. In any case, they determine a series of functions that can be controlled from the G.U.I. of the console, with a single excepted, namely the type of filter. This function will be explained in a specific paragraph.

DESCRIPTION OF THE OPERATIONS CARRIED OUT BY THE BUTTONS ON THE CONSOLE

A complete functional description of **HELIOS SFD and DRF** follows, starting with the buttons on the main console, following a functional grouping logic.

Main console



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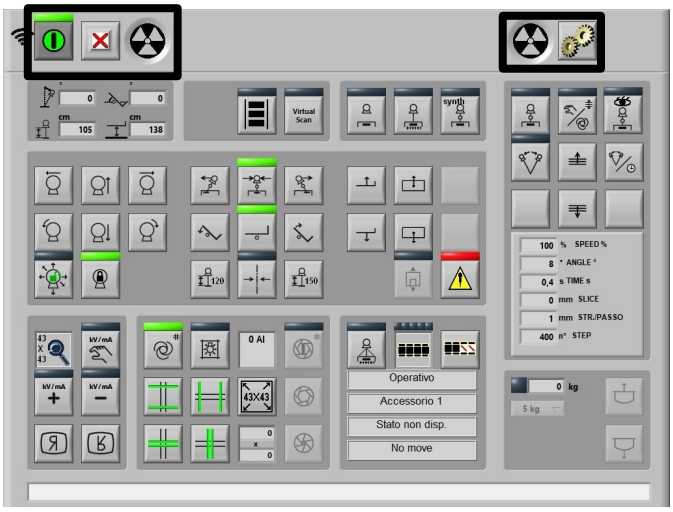
General commands:



	**STAND-BY:** This is the state assumed w hen pow er is sw itched on to **HELIOS** I n this state all the other keys of the main console (except POWER ON, SERVICE), as well as all the keys of the two keyboards on board the table near the receptor and tube holders, are not active. If a command is given starting from a previous 'POWER ON' state, Stand-by is ordered, in which state the power for movement is cut off: all the keys of the main console are deactivated and the LED indicator relative to this key, starts flashing.
	**POWER ON:** This is the command w hich requests activation of the apparatus. I f this state is validated, all the keys of the main console are activated and the led indicator relative to the STAND-BY key switches off. The display will show an initial series of information on the state of the machine; if the state has not been validated, there may be a block of conditions (emergency buttons pressed down); in this case, please refer to the specific section of this manual.
	**SERVICE:** This is the command for requesting access to the section for parameter management, configuration and calibration. Once selected, a **password** will be requested, without which access will not be possible. This section may be used only by authorised personnel.
	**RAYS LEDs:** I ndicator lights, active only w hen, after having issued the request for the issue of rays, the specific signal from the generator is intercepted. The effective emission of the rays is indicated by a yellow indicator light.
	**APPLICATION OUTPUT:** W hen this button is pressed, the application exit procedure is activated, with forced current to the Stand-by state.

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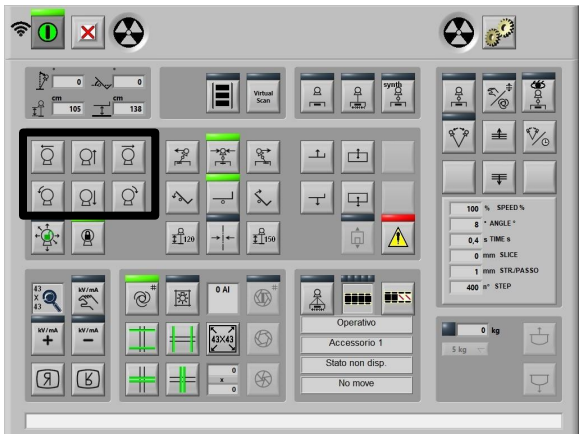
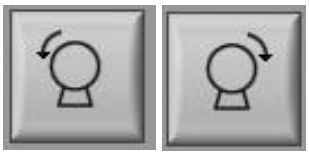
Table movement commands group



	**INCREASE OF X-RAY TUBE FOCUS DISTANCE**: the X-ray tube rises to the maximum focus-receptor distance. When this maximum position is reached, the movement is blocked.
	**DECREASE OF X-RAY TUBE FOCUS DISTANCE:** the X-ray tube descends to a minimum focus-receptor distance at a height of between 105 and 108 cm according to the set-up adjustment.
	**SIDE MOVEMENT TO THE LEFT OF THE COLUMN-RECEPTOR HOLDER GROUP:** The group moves to the left of the patient-bearing table. The table moves with a progressive speed which differs according to the keyboard used to give the command, and precisely:at gradual steps (2) and successive constant speed if the table keyboard, that on the tube or the G.U.I. of the console is used; with a progressive speed if the command is given by the joystick, in the version with that accessory installed.
	**SIDE MOVEMENT TO THE RIGHT OF THE COLUMN-RECEPTOR HOLDER GROUP:** The group moves to the right of the patient-bearing table. The movement modes are the same as those for the movement to the left.
	**CLOCKWISE AND ANTI-CLOCKWISE MOVEMENT OF THE X-RAY TUBE:** This allows the X-ray tube to rotate on its axis. These commands, which naturally change the ray-receptor alignment, force the table to work in a mode better known as "out of potter", indicated by the specific message on the state communications bar, where it is specified that the ray commands will be disables and only the generator can be controlled. Choosing the button with the left pointing arrow, the tube will rotate in an anti-clockwise direction, while the right pointing arrow will cause the instrument to rotate clockwise.These functions involve an automatic stop every 90° to facilitate the operator in obtaining different positions and projections.

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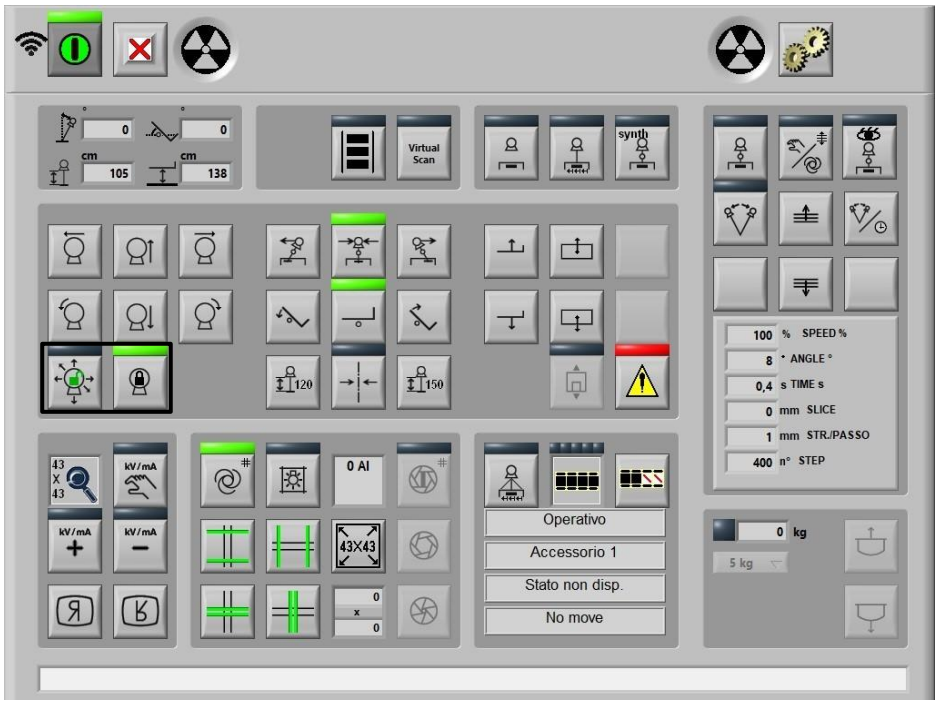

	**RECEPTOR TUBE PROJECTION ALIGNMENT COMMAND:** The tube movements are restricted to those of the column and of the receptor holder in order to always keep the X-ray band on the latter.
	**COMMAND FOR THE RELEASE OF COMBINED ROTATION-LIFTING MOVEMENTS:** This disables the synchronisation of the table movements. It allows for an operating mode suitable for single, minimum lifting and rotating movements, independent of each other, in order to optimise the final position.These adjustments are allowed within the safety margins imposed by the anti-collision volumetric control which is always active.

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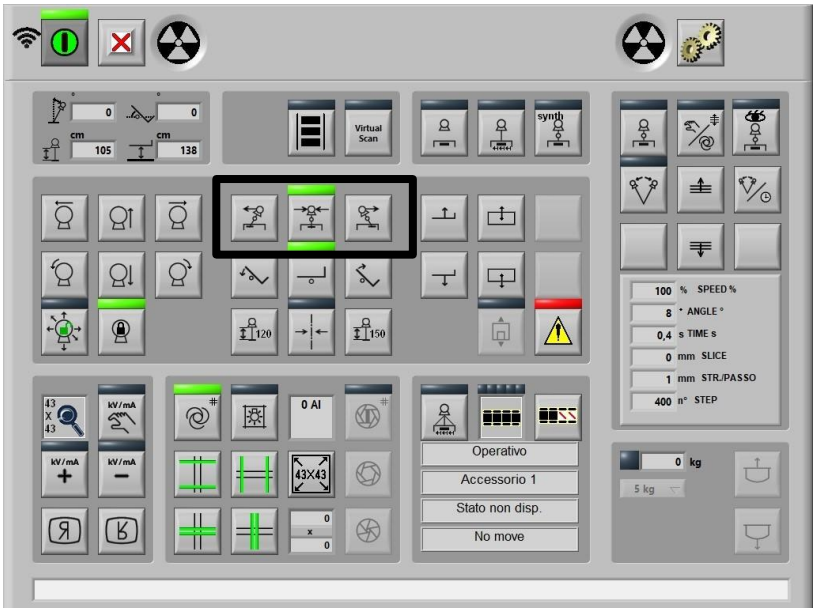

	**OBLIQUE LEFT PROJECTION.** The column moves to the left, and the receptor holder carriage in the opposite direction because of the set layer, until the pre-set inclination limit is reached.
	**OBLIQUE CENTRED PROJECTION.** The column and the receptor holder move sidew ays until completely aligned vertically (at an angle of 0°); on completion of the movement, the relative indicator light will come on.
	**OBLIQUE RIGHT PROJECTION.** The column moves to the right, and the receptor holder carriage in the opposite direction because of the set layer, until the pre-set inclination limit is reached.

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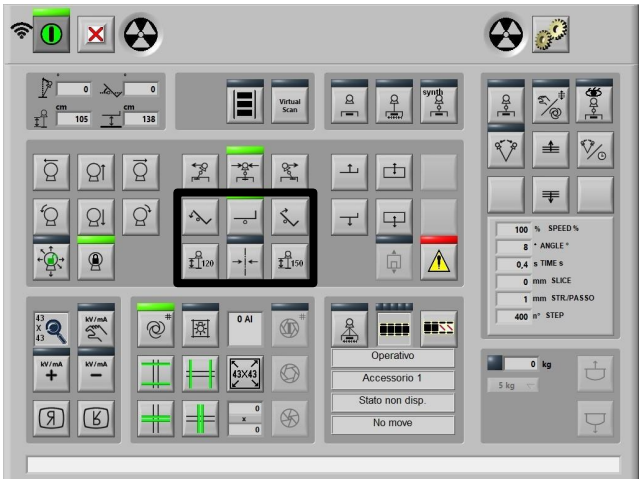

	**ANTICLOCKWISE ROTATION OF THE PATIENT-BEARING SURFACE:** The patient-bearing surface tips in an anticlockwise direction as far as the -90° position and ascends proportionately if this position does not allow for the desired inclination (combined movement).
	**LEVELLING OF THE PATIENT-BEARING SURFACE:** The patient-bearing surface moves to a horizontal position (the LED indicator comes on at 0° inclination). If the indicator light is on, the condition has been reached.
	**ANTICLOCKWISE ROTATION OF THE PATIENT-BEARING SURFACE:** The patient-bearing surface tips in an anticlockwise direction as far as the 90° position and ascends proportionately if this position does not allow for the desired inclination (combined movement).
	**GLOBAL RE-POSITIONING (HOME):** A global position is commanded to annul all the previous setting conditions and to return to an initial reference position. If the relative LED indicator is on, the condition has been reached.
	**PRE-SETTING OF X-RAY TUBE FOCUS DISTANCE**: the X-ray tube moves to a focus distance, indicated by the icon, of 120 cm.
	**PRE-SETTING OF X-RAY TUBE FOCUS DISTANCE**: the X-ray tube moves to a focus distance, indicated by the icon, of 150 cm.

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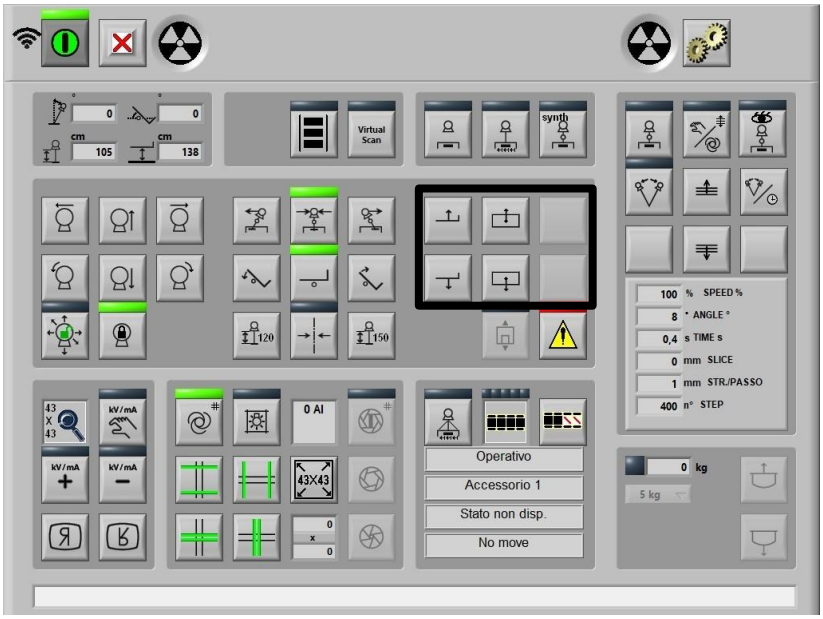

	**RAISING THE PATIENT-BEARING SURFACE**
	**LOWERING THE PATIENT-BEARING SURFACE** The patient-bearing surface descends in combination with the possible rotation in the case of combined movements; otherwise, it moves as far as its limits determined by the volume of the space occupied.
	**SIDE MOVEMENT OF THE PATIENT-BEARING SURFACE** The patient-bearing surface approaches the base of the movement as far as the minimum position, regardless of the angle of the surface.
	**SIDE MOVEMENT OF THE PATIENT-BEARING SURFACE** The patient-bearing surface moves away from the base of the movement as far as the minimum position, regardless of the angle of the surface.

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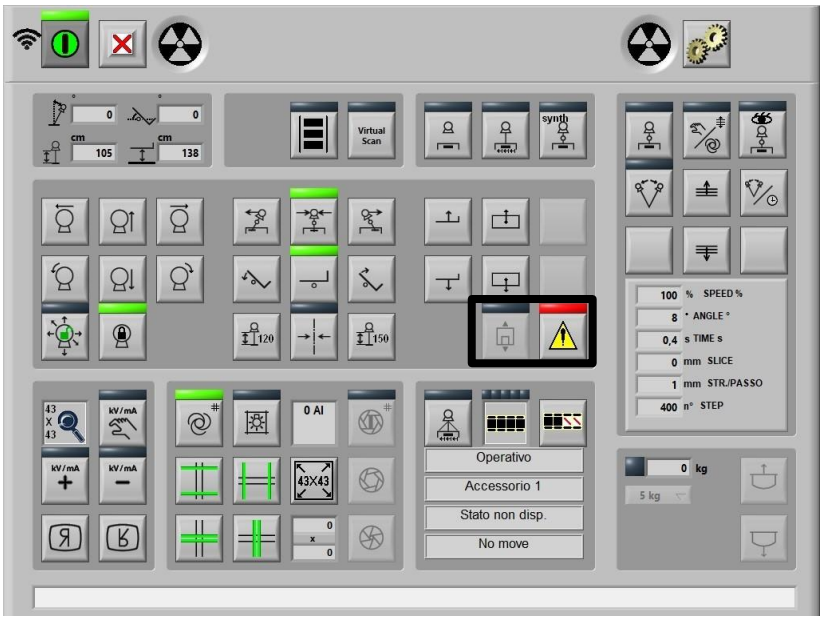

	In the DRF version this key is disabled since the function is not active.
	**ALARM RE-SETTING**

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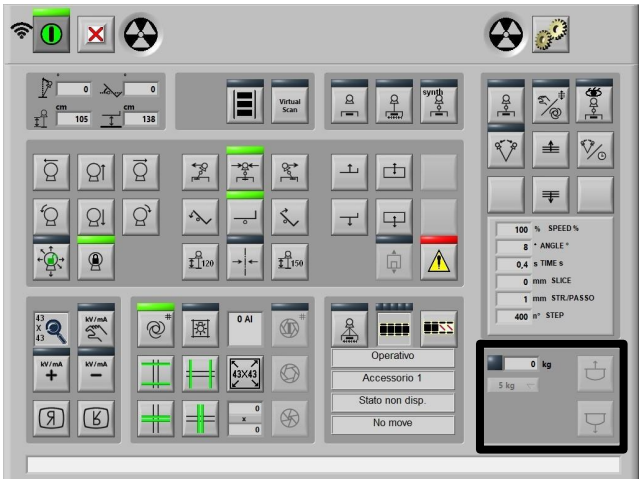
Abdominal compression

Optional.



RAISING THE COMPRESSOR The compressor piston is commanded to rise to the parking position.

LOWERING THE COMPRESSOR The compressor piston is commanded to descend from the parking position to that of the anatomic area to be compressed.

SELECTION OF SETTING AND VISUALISATION OF COMPRESSION FORCE EXPRESSED IN KG.

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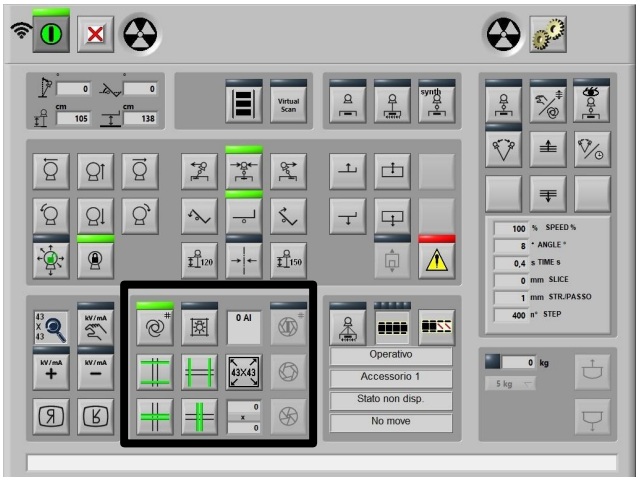
Collimation commands:



	**LIGHT** This allow s for the sw itching on and off of the light by direct command. The relative indicator light replicates the state. The state is limited in time, in any case, to about 30 seconds. The button also has an LED. If the collimator has a laser centring device, it will be simultaneously activated by this command.
	**AUTOMATIC/MANUAL** Toggle the collimator state AUTOMATIC The command of the blades and of the iris is adjusted automatically. MANUAL The opening of the blades and of the iris is adjusted manually, according to the limits imposed by the action in progress: 1. FLAT PANEL ACTIVE: the opening movements are limited by the physical dimensions of the panel. 2. DIRECT EXPOSURE: the opening movements are limited by the physical extent of the strokes of the X and Y blades and of the iris. 3. ROTATED TUBE: the opening movements are limited by the physical extent of the strokes of the X and Y blades. The state is shown by a flashing indicator light.
	In the DRF version this key is disabled since the function is not active.
	In the DRF version this key is disabled since the function is not active.
	Select collimator filter

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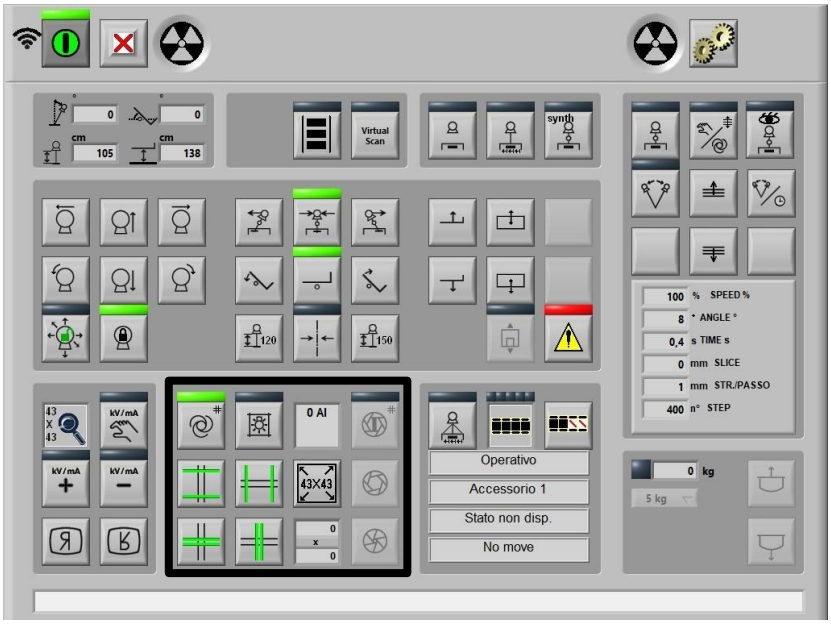

	In the DRF version this key is disabled since the function is not active.
	**PRE-SETTING OF OPENING TO MAXIMUM RECEPTOR FORMAT** Regardless of whether the collimator is in manual or automatic mode, the command is issued to open the receptor to maximum format.
	**VISUALISATION AREA OF TRANSVERSAL AND LONGITUDINAL BLADES** Visualisation in real time of the opening format of the light-rays band collimation.

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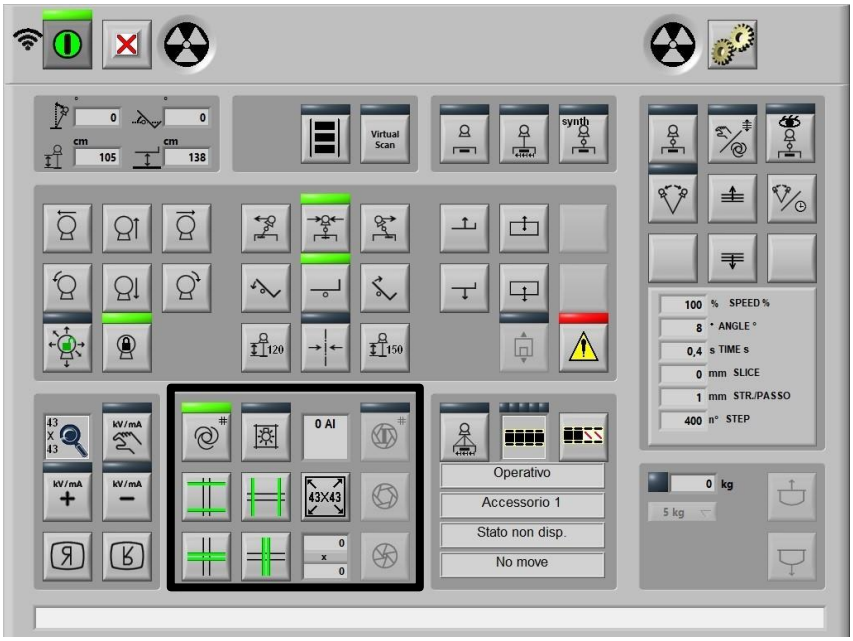

	**TRANSVERSAL OPENING** This allows for the transversal opening of the blades (left side/right side of the patient).
	**TRANSVERSAL CLOSURE** This allows for the transversal closure of the blades (left side/right side of the patient).
	**LONGITUDINAL OPENING** This allows for the longitudinal opening of the blades (head/feet of the patient).
	**LONGITUDINAL CLOSURE** This allows for the longitudinal closure of the blades (head/feet of the patient).

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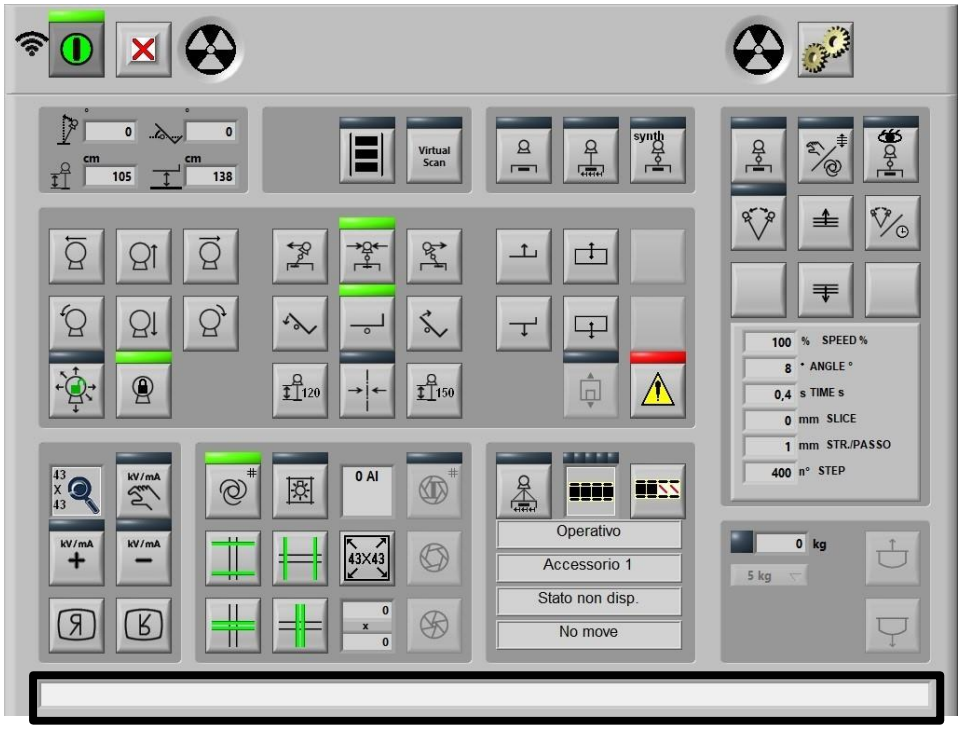
Visualisation area of state commands:



In this area, diagnostic state messages, alarms and operating suggestions intended for the operator are visualised.

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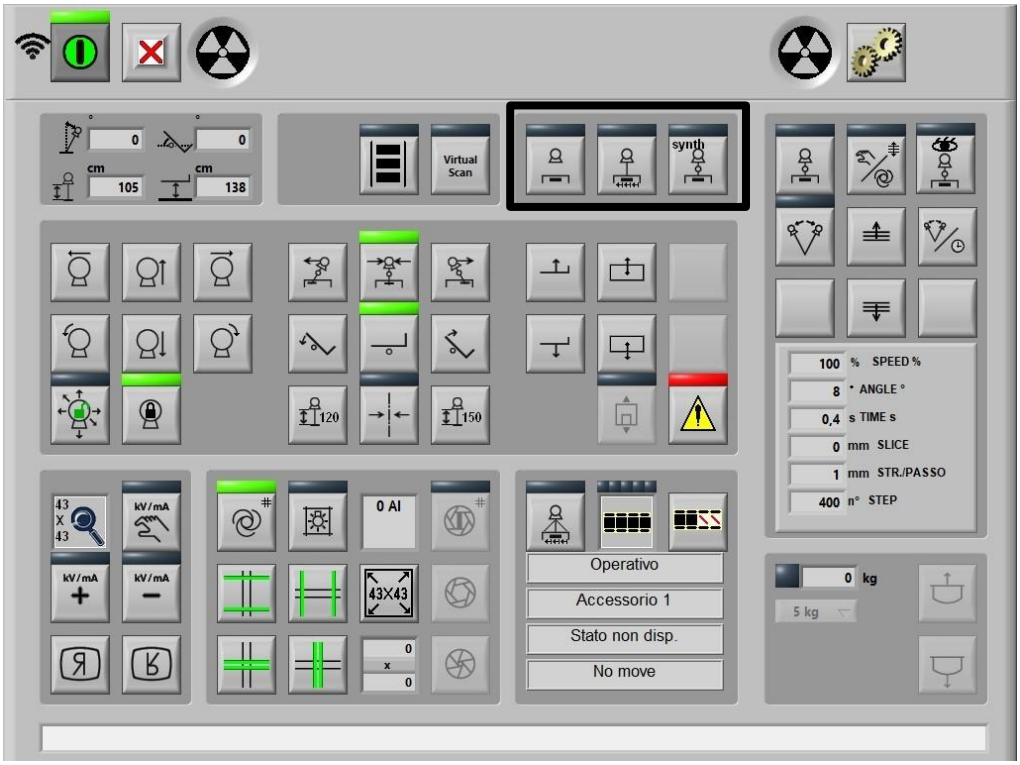
Operating mode commands:



	**X-RAY MODE SELECTION** This selection causes the deactivation of all the other functioning modes contemplated: TOMOGRAPHIC, ANGIO-STEP, STITCHING, TOMOSYNTHESIS, etc. The activation is not indicated by indicator lights, but it is indicated by the deactivation of all the other modes that may have been active.
	**ANGIO-STEP FUNCTION:** This enables the angio -step: the sequential acquisition of X-ray images at fixed steps with a horizontal movement of the X-ray tube and of the receptor holder.
	**TOMOSYNTHESIS MODE SELECTION** The TOMOSYNTHESI S functioning mode is enabled in combination with the system for the acquisition of functionally integrated images. The function is activated once the acceptability conditions are reached, dictated by the anatomic configurations of the workstation and by the table state condition.

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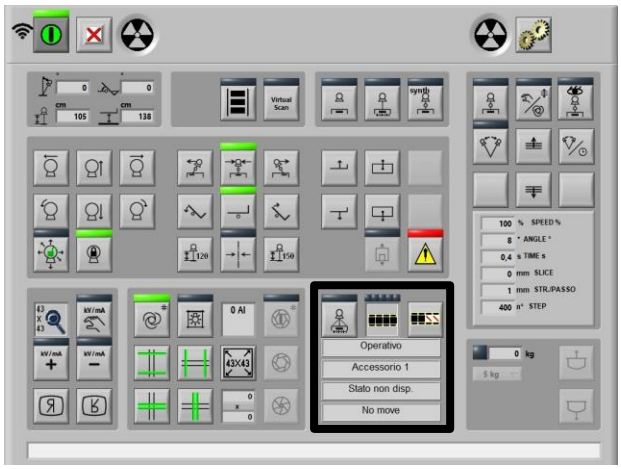
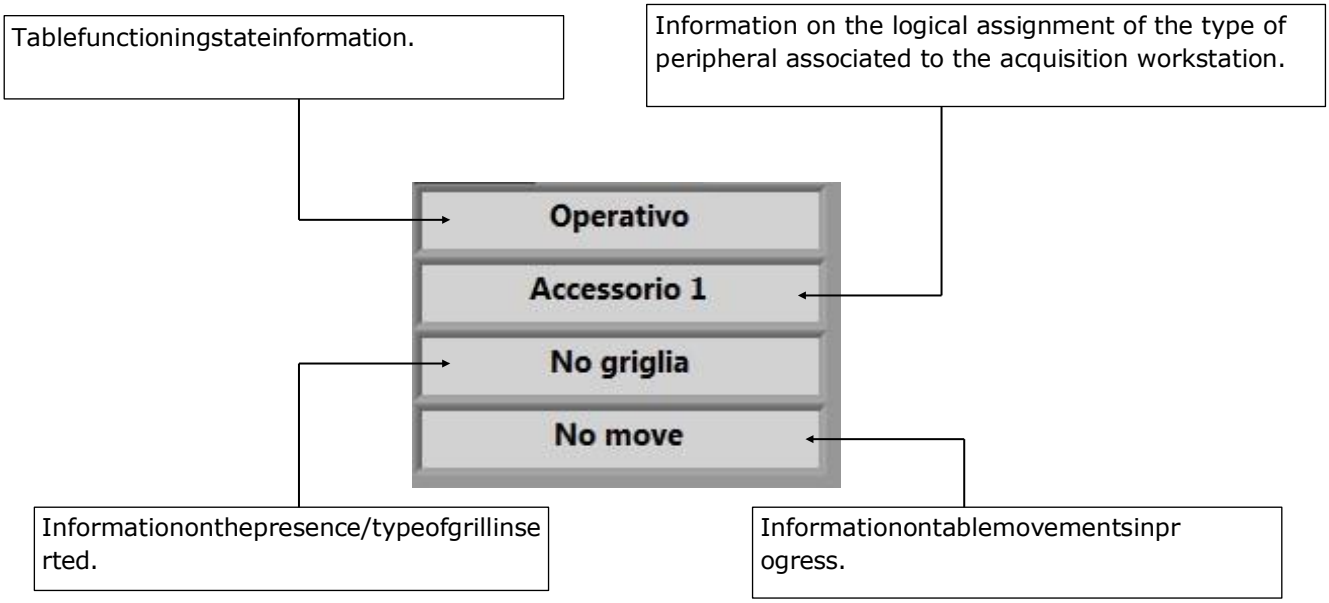
Visualisation for stitching method :



	**STITCHING MODE SELECTION** This command is inactive in the absence of an image acquisition system (workstation), which is specifically referred to in the Service Manual. The flashing yellow light will indicate the pre-STITCHING condition, i.e. that a request for this action is requested by the image acquisition system. By pressing the key, the light will turn green and become fixed; this means that the necessary conditions for the execution of the examination have been reached.
	**STITCHING FRAMES VISUALISER/SELECTOR** Pressing this allows for choosing the number of frames you wish to use for the stitching examination.



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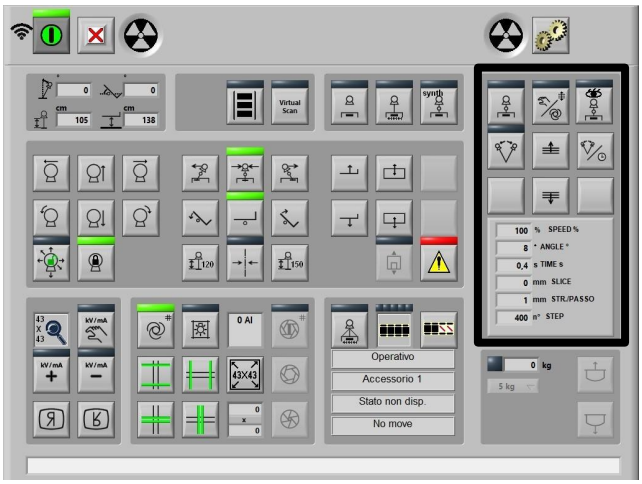
Visualisation for tomography:



	**TOMOGRAPHIC MODE SELECTION** The TOMOGRAPHIC functioning mode is enabled with implicit acceptance of the DEFAULT angle (or that previously selected). The indicator light comes on when the acceptance conditions are reached (receptor holder column centred or, at any rate, sufficiently far from the edges of the bed, and with the compressor outside the working area).
	**Selection of automatic increase of thetomography layer: AUTOSTEP**
	**TOMOSCOPY** The same type of tomographic use, but with low fluoroscopy emissions. Optional method. 
	**SELECTION OF TOMOGRAPHY ANGLE.** By pressing cyclically, all the tomography angles that can be selected (8°, 15°, 20°, 30°, 40° for standard settings or as is preseted in the range 5°±50°). The selected state that is active is underlined by a flashing indicator light. After deciding the angle, the tomographic mode must be selected for acceptance. If the operation is successful, the indicator light stops flashing and remains on. Actionable only before acceptance (**topograhic mode selection**). 

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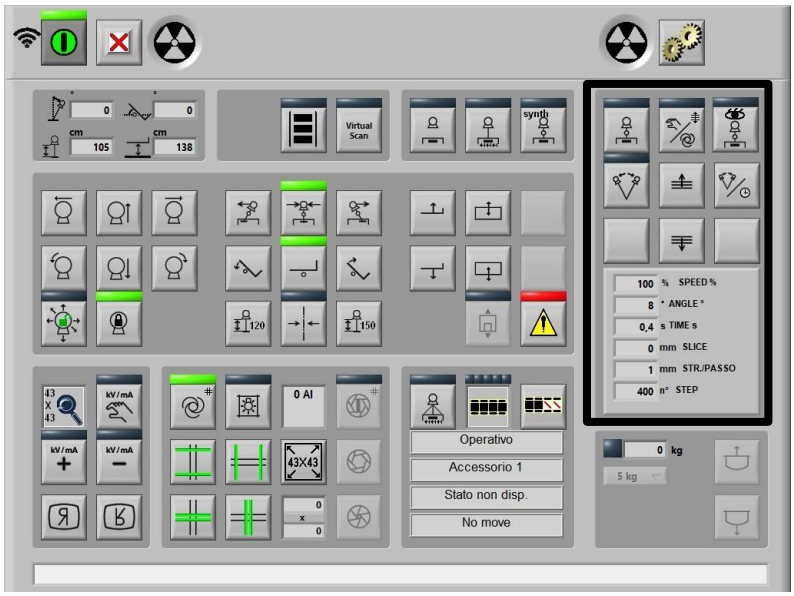

	**INCREASE OF TOMOGRAPHY LAYER/LAYER STEPS:** *Autostep deactivated*: the layer is increased (and visualised) up to a maximum of 300 mm or the maximum set during configuration. The estimated time of tomography is continuously updated in the specific visualisation area. *Autostep active*: the setting of the increase value is commanded and the level reached will be automatically updated after every tomography.
	**DECREASE OF TOMOGRAPHY LAYER/LAYER STEPS.** The layer is decreased (and visualised) down to the minimum. The estimated time of tomography is continuously updated in the specific visualisation area. If the AUTOSTEP function is active, the setting of the decrease value is commanded and the level reached will be automatically updated after every tomography.
	**SELECTION OF ACTION SPEED CHANGE IN TOMOGRAPHY.** **Preliminary condition: Apparatus in "Tomographic" mode.** Once the tomographic mode is activated, this button will allow for selecting various percentages of the deceleration of the hunting speed, from the pre-set maximum (100%). The estimate of the time is visualised in the specific area of the tomography visualisation.

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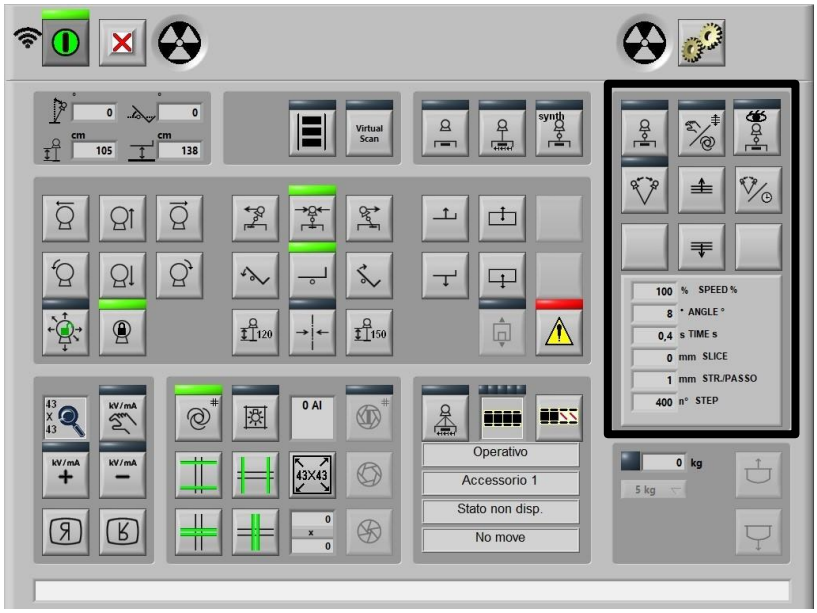
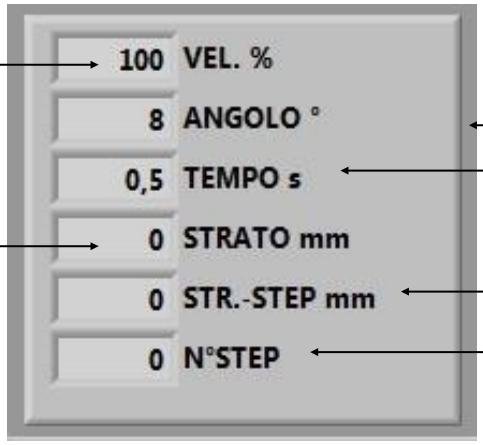


SPEED

HUNTER'SANGLE



ESTIMATEDTIMEOFEXPOSURE TORAYSINSIDETHEHUNTER'SA NGLE

LAYER/STEPINCREASEDECREASE

CHOICEOFSTARTINGLAYER

NUMBER OF STEPS POSSIBLE ACCORDING TO LAYER/STEP WITHINTHE SETLIMITS

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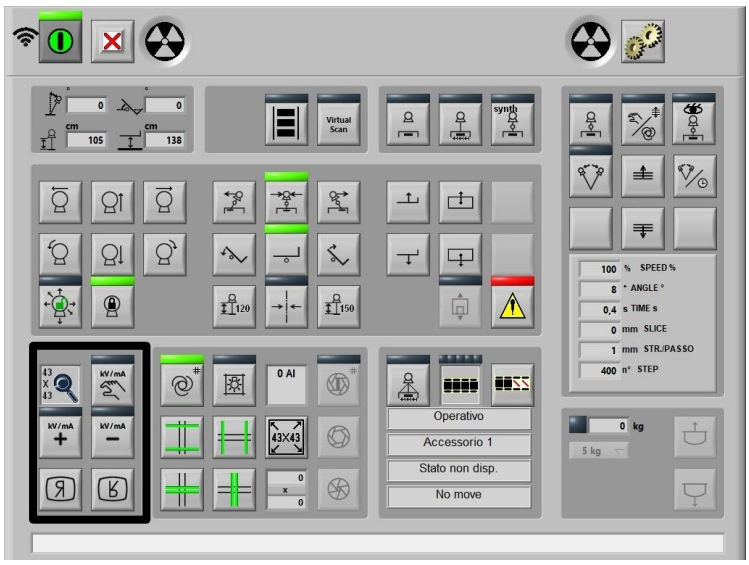
Commands which condition the fluoroscopic image system:



	**ENLARGEMENT SELECTOR** This allows for access to a sub-menu from which to select one of 5 zoom factors available and active during functioning and depending on the system installed.
	**FLUOROSCOPE MANUAL CONTROL COMMAND**
	**INCREASE OF THE kV/mA**
	**DECREASE OF THE kV/mA**
	**LEFT/RIGHT INVERSION OF VIDEO IMAGE**
	**HEAD/FEET INVERSION OF VIDEO IMAGE**

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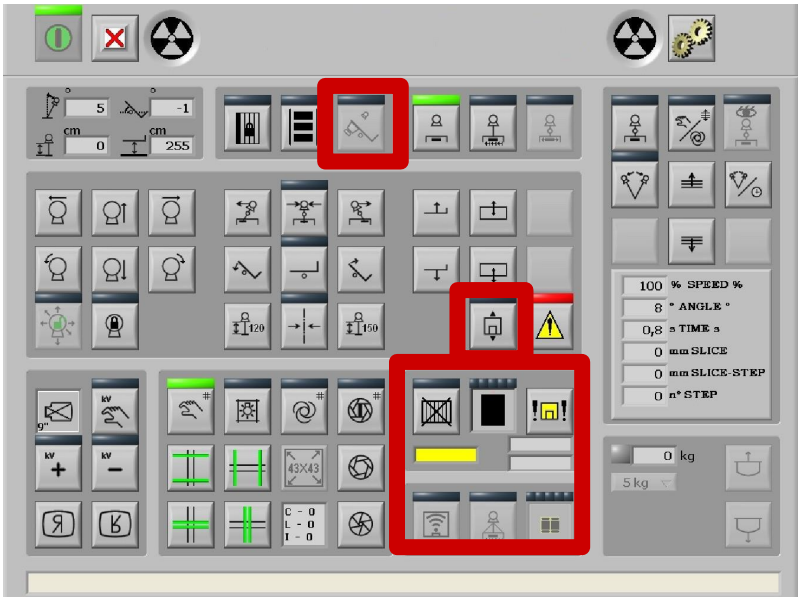
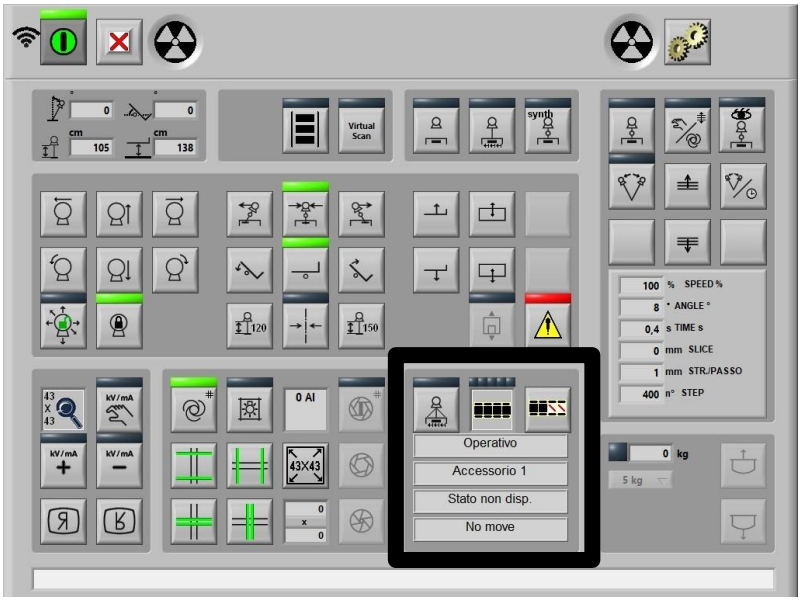
Commands exclusive to the HELIOS SFD version:

The **SFD** version differs from the **DRF** version for the different type of receptor installed, which also determines a considerable difference in the functions, in the outfitting and in size.
This chapter describes only the commands that differ in the **SFD** from the **DRF** version. **All the commands not specifically described in this chapter are identical to those already described in the previous pages, and which are therefore common to both versions.**

The images on this page are only to show the different icons on one or the other console, to facilitate reading the manual.



View of the SFD console.



View of the DRF console.

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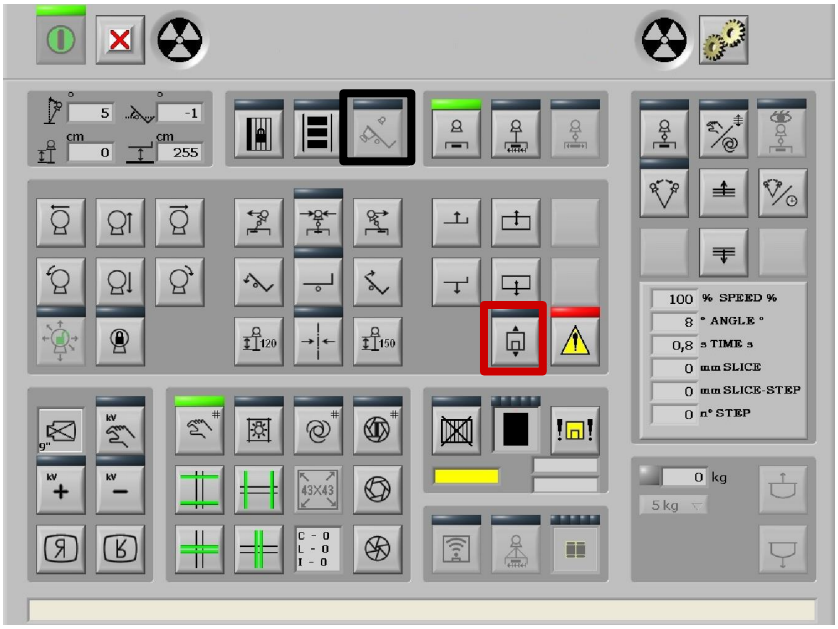

SERIOGRAPH EXCLUSION COMMAND
The activation of this command forces the table to operate in X-ray and fluoroscopy mode using only the brilliance intensifier.

SERIOGRAPH BOX COMMAND
This allows for extracting the image capture support, whether it is an X-ray box with film, CR, or Wi-Fi panel.

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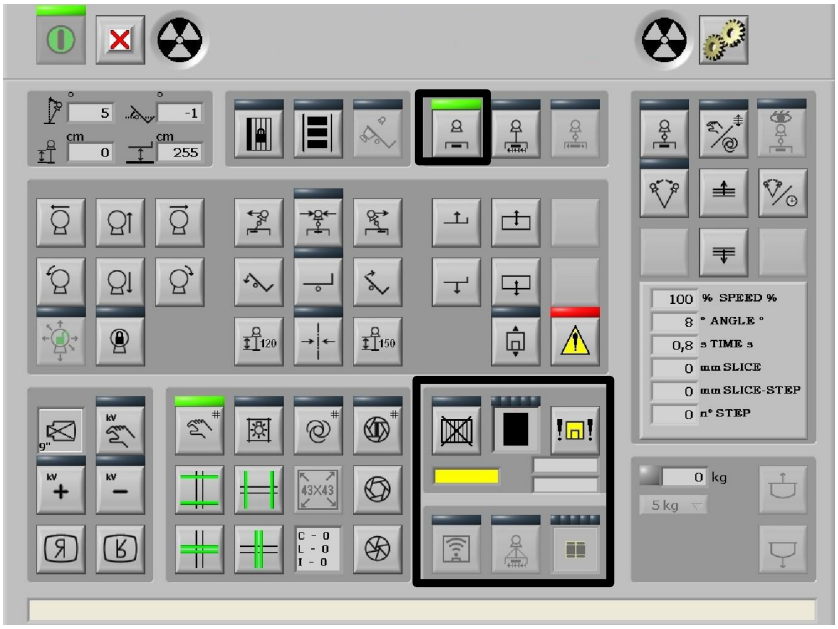

	**GRILL MOVEMENT COMMAND** This allows for use of the non-oscillating frill during X-ray exposure.
	**BOX DIVISION SELECTION COMMAND** This allows for access to a sub-menu from which to select the number of divisions possible according to the recognised format of the box.
	**COMMAND FOR RE-SETTING THE OPERATIONAL CONDITIONS OF THE SERIOGRAPH SCROLLING SYSTEM** This allows for access to a sub-menu designed for function re-setting after operations have been blocked.

VISUALISATION AREA REGARDING THE RECOGNISED AND ACTIVE BOX FORMAT AND THE GRILL STATE
Definition

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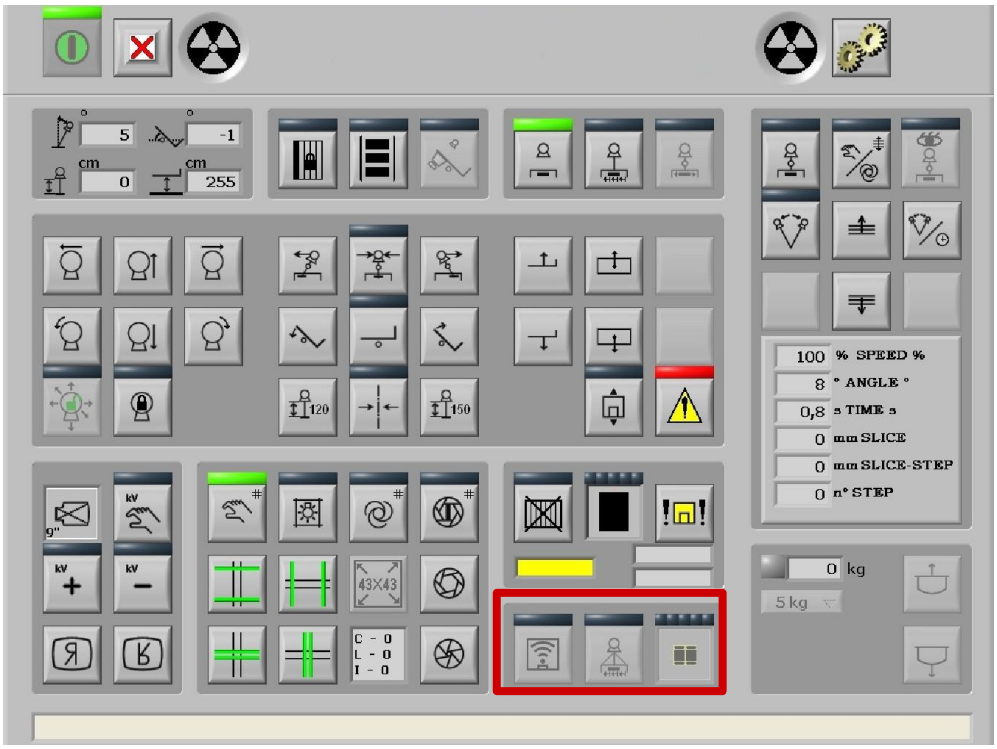

The commands of the group, given on this page, allow for the execution of the STITCHING method providing the image collection system is fitted with the specific processing function.

	**SUPPORT MANAGEMENT COMMAND** This allows for a different management of the film box or CR support instead of Wi-Fi which must never be used after exposures, but only at the operator's discretion.
	**STITCHING MODE SELECTION** This command is inactive in the absence of an image acquisition system (workstation), specifically referred to in the Service Manual.
	**STITCHING FRAMES VISUALISER/SELECTOR** Pressing this allows for choosing the number of frames you wish to use for the stitching examination.

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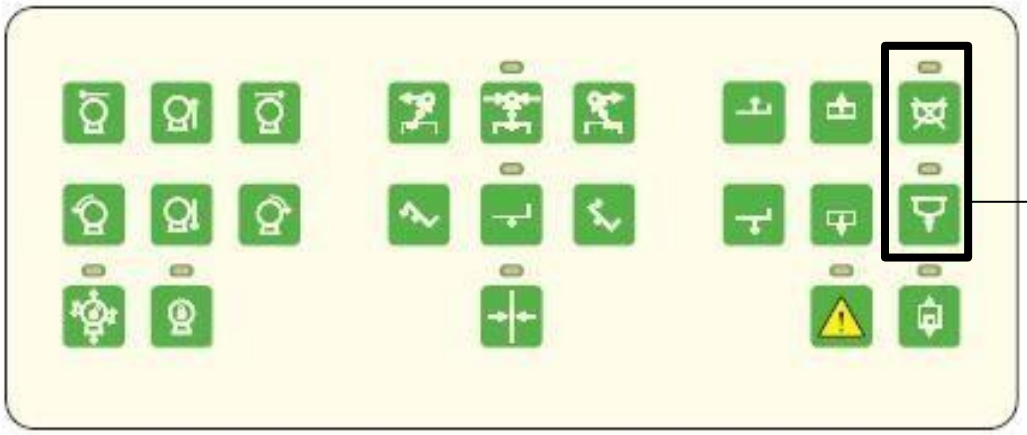
Table keyboard - Tube keyboard

This page presents the table keyboard and the tube keyboard.
Both the icons and the functions associated to the commands are the same as those already described in the G.U.I. of the console.

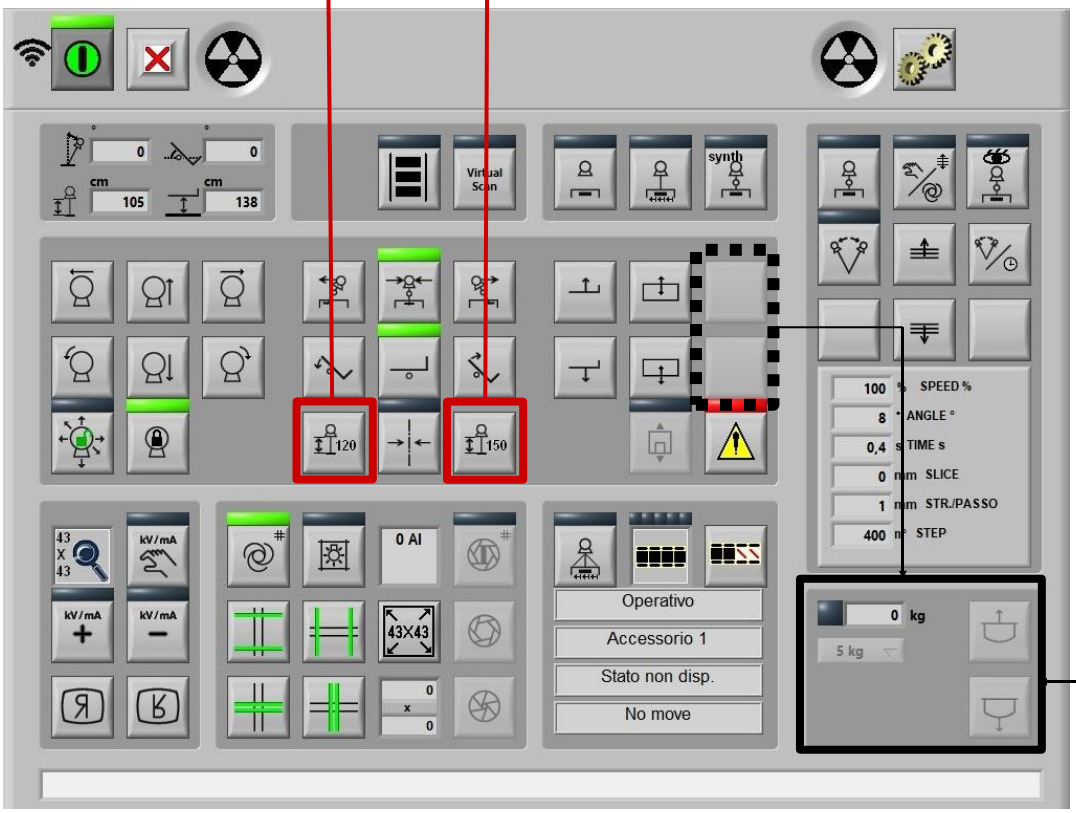
Table keyboard - Tube keyboard

Modification of the position of the



G.U.I. Consolle

Elements present exclusively on the G.U.I.



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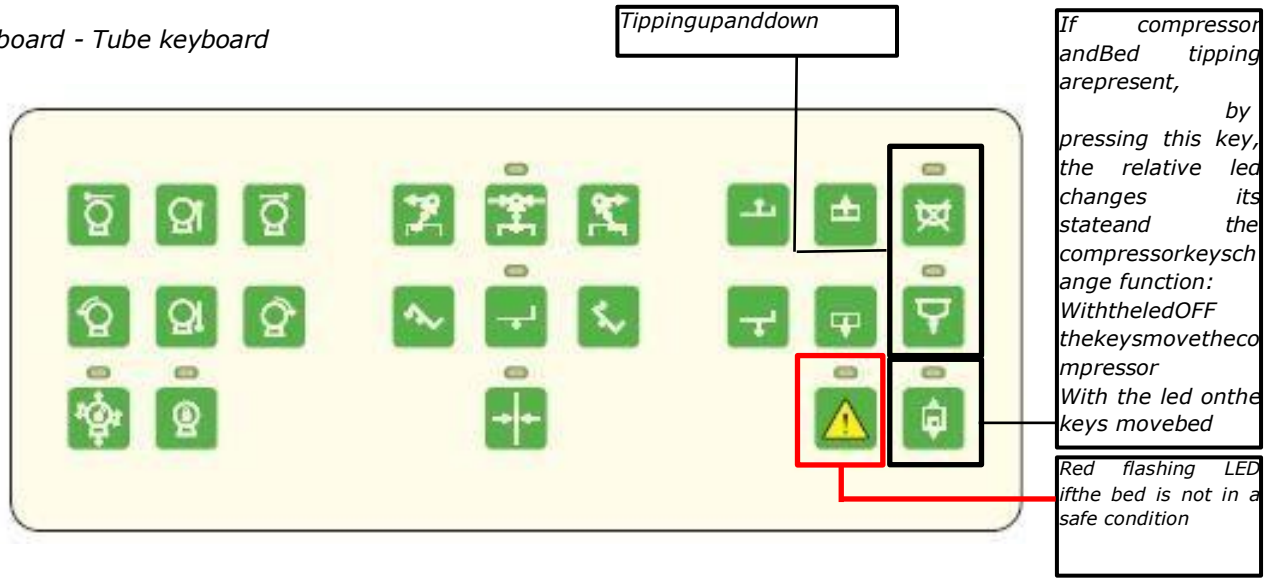
Tipping of the bed outside the working

If the presence of an automatic system for tipping up the bed outside the working area has been set, the keys dedicated to the compressor are used for managing the movement.
The two keys tip the table up and down; the movement stops at the end of the stroke.

Table keyboard - Tube keyboard



The position in which it rests on the arms of the bed is considered the **standard position**.
When the bed is tipped up, this is known as the **outside working area position**. The outside working area position is that shown in the figure. To tip the bed to the outside working position, all the accessories must be removed (foot rest, handles and shoulder supports).

Outside working area position

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By pressing the "tip up" button, the table automatically moves to a starting position and is then tipped up. The tipping movement proceeds automatically until the final position is reached, with the click (audible) of the safety devices.
In the case of need, the automatic tipping can be interrupted by pressing either the tip-up or tip-down keys.
The tipping can be resumed later by pressing the "tip up" key again. By pressing the "tip down" key, the table can be brought to normal position. For safety reasons, to bring down the table, it is always necessary to keep the "tip down" key pressed. The key must be pressed until the click of the safety devices is heard. Only when the safety devices are inserted can the tipping down movement be completed and therefore the bed is in the **standard position** (resting n the arms of the bed).
If the bed is not in the standard position, warning message no. 20 is visualised: "Bed safety not inserted".
In the case of the warning, the bed cannot be raised, tipped up or moved in or out.

The maximum length of the insertable stretcher when the bed is in the outside working area position is 2 m.

If the red LED is flashing on the keyboard, the patient can not be inserted in the exam position.

The label in the following figure indicates a danger of crushing the operator's hands: avoid placing hands on the arms of the bed carriage while the bed is moving.
There are two labels, one on each arm of the bed carriage.

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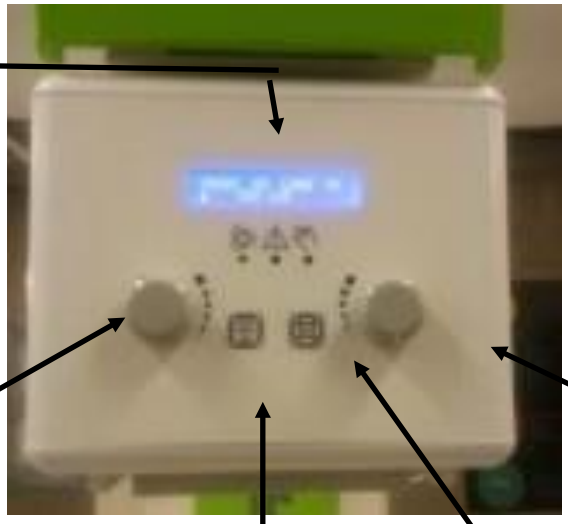
Collimator: (ex:Ralco - R3025DACS/A)

Detailed indications regarding the collimator use mode are given in the specific collimator manual. However, the functions of the commands on the collimator are the same as those used in remote mode via the console, already described.
Theonlyexceptionisthefilteringtypecommand,describedbelow.
This command can be used only by the collimator or automatically set in the re-set examinations (anatomic APR) of the image acquisition system, functionally associated.
Similarly, the display gives the same information that can be obtained in remote mode on the console, with the additional and exclusive indication of the type of X-ray filtering selected.



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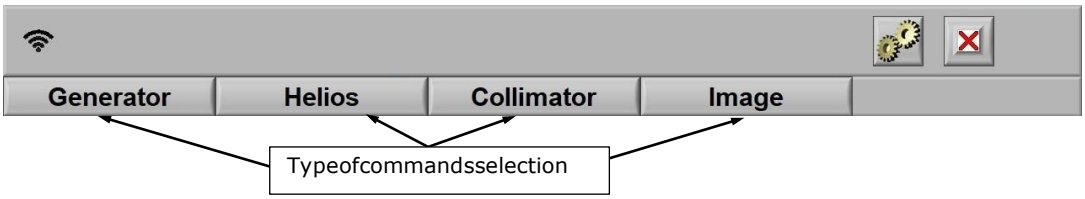
Auxiliary Control (Optional)

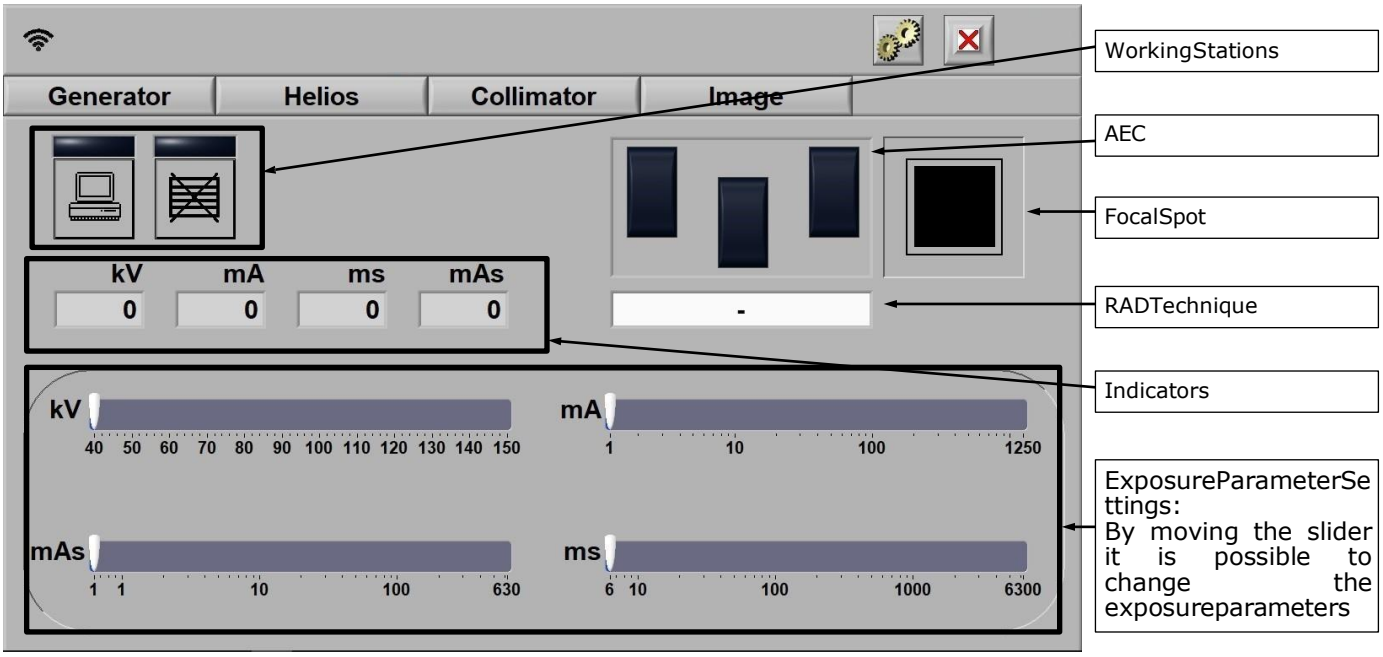
The remote-controlled table can be equipped with an optional auxiliary control system where, depending on the configuration of the room components, it is possible to replicate some commands of the generator, the collimator, the image system and the remote-controlled table. All replicable commands are described below, divided by type.

Main Control Area:



	**CONNECTION:** Indicates the connection status with the main system, the blue color indicates the correct connection.
	**SERVICE:** This is the request command to enter the parameter, configuration and calibration management section. Once selected, a password will be requested without which access will not be possible. This section is for use by authorized personnel only.
	**EXIT:** Pressing this button activates the exit procedure from the application .

Generator:



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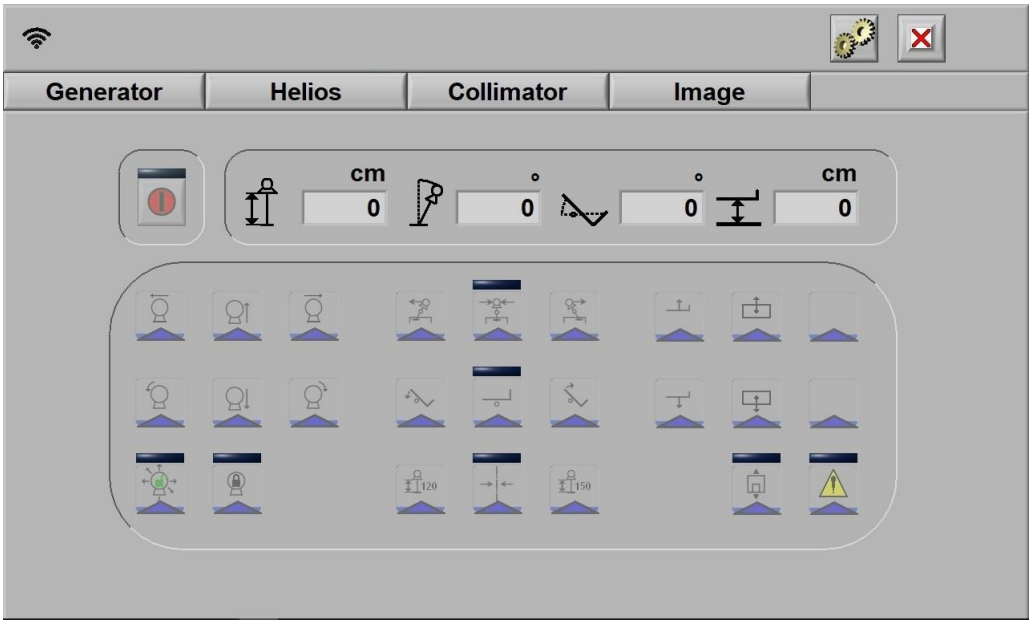
Helios:

All the movement controls and indicators of the remote-controlled table are replicated; this section is to be used by authorized personnel only. To activate the commands, slide the corresponding blue arrows upwards.



Collimator:

All collimator controls and indicators present in the Helios GUI are replicated. To activate the movement commands of the shutters it is necessary to slide the corresponding blue arrows upwards.

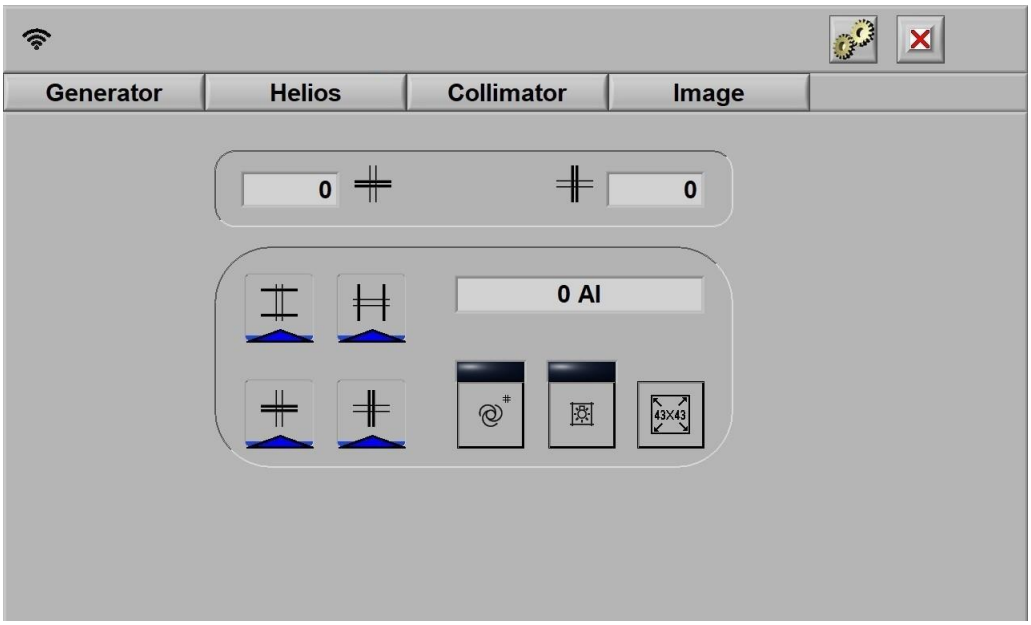


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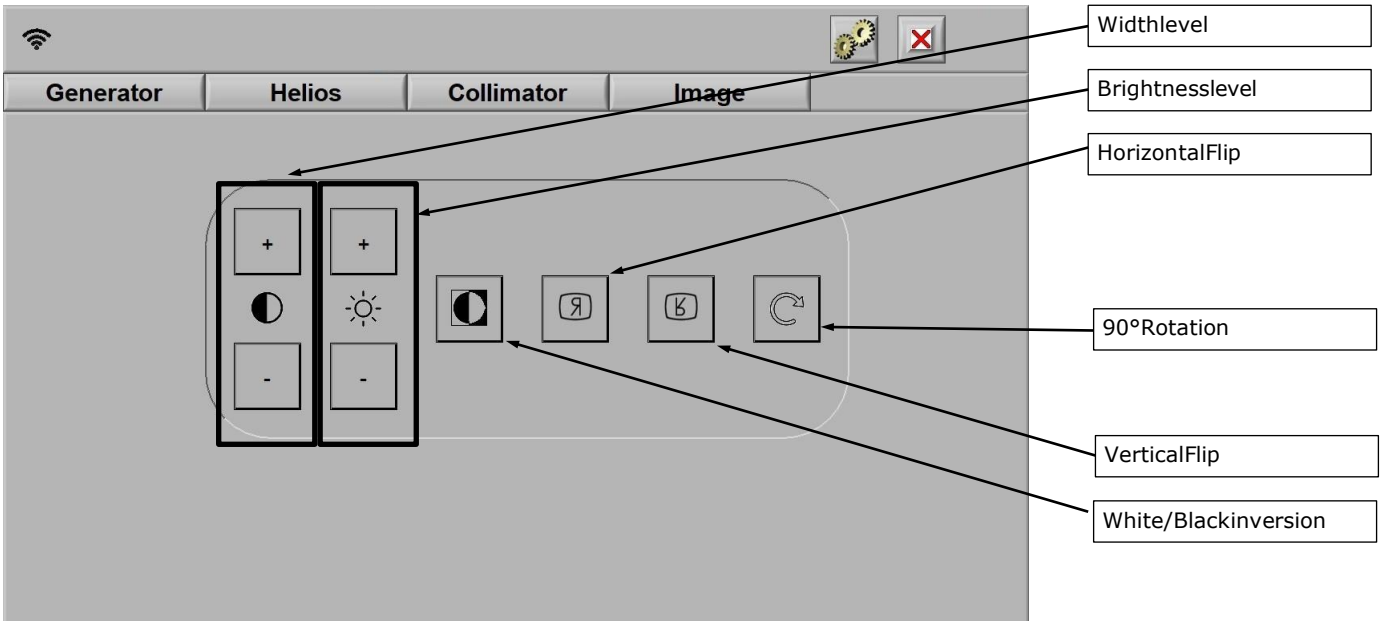
Image System:

There are some controls to adjust the image on the acquisition system. Depending on the type of image system present, some commands may not be active.



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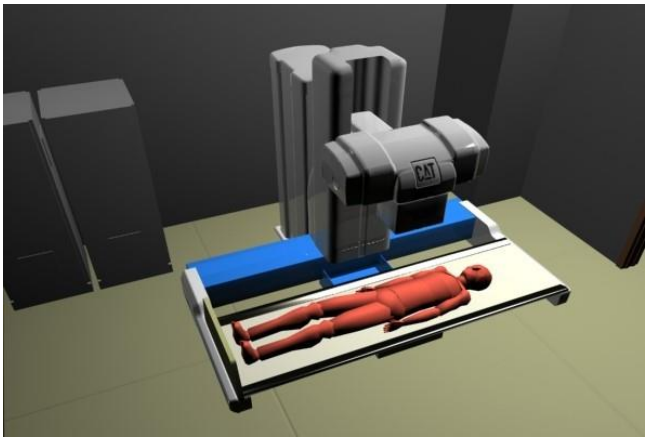
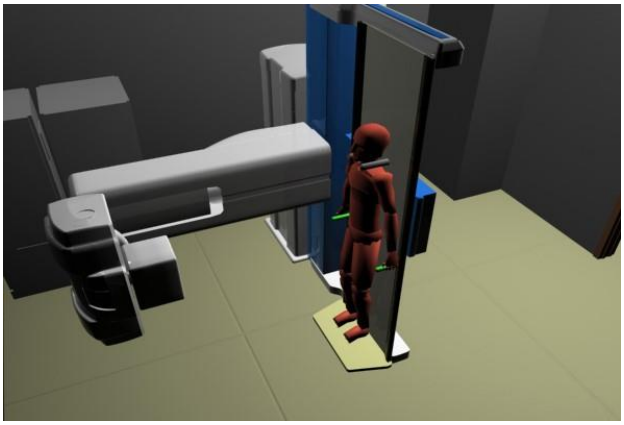
USEFUL INFORMATION 5

Positioning of the patient





The images below, for exemplification purposes, show two of the most common positions of the patient for the execution of the most appropriate type of examination.

In the case of a large self-sufficient patient (more than the declared maximum weight, see Chap. 2 Safety - "EXAMINATION TABLE") examined in a horizontal positionlyingfaceuporfacedown,itisadvisabletopositionthetablevertically, requesting the patient to stand on the footrest, and to rotate the table. This will avoid mechanical stresses that could damage the apparatus.

Pressinganyofthetwoemergencybuttonswillinterrupttheelectricitytothe remote control of the table, and only the safety systems will be powered.

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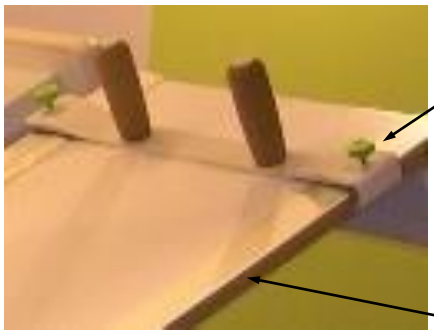
Itisabsolutelyforbiddentopositionstools,chairsorsimilarobjectsnearthe patient-bearing surface to avoid squashing parts of the surface.

Accessories

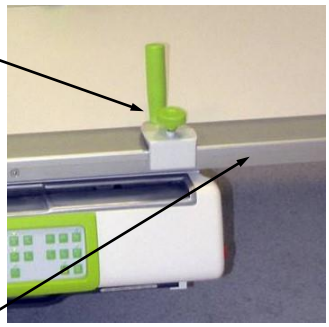
Adjustable shoulder support

It is positioned along the guides, and loosed and blocked by the knobs.



KNOBSusedtoloosenor block the sliding shoulder support.

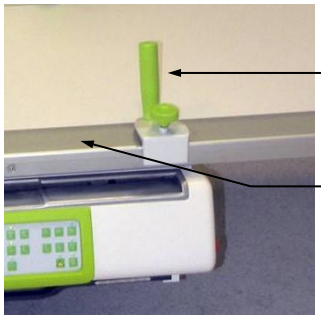
GUIDES*usedforpositioningthesliding shoulder support, handle and footrest platform*.



Attention: Makesurethattheaccessoriesarecorrectlypositionedandfirmlyfixedto the table before allowing the patient access

Sliding handle

This is positioned by sliding it along the guides, after having loosened it by turning it anti-clockwise. Once the position has been found, it must be blocked by turning it clockwise.



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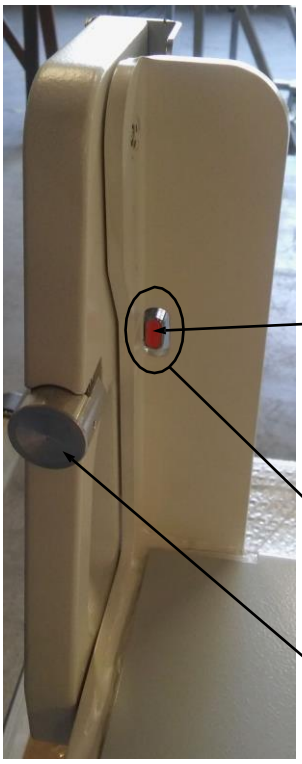
Sliding footrest platform



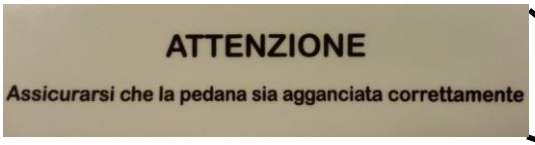
Position the platform along the guides by means of the release of the specific buttons. Slide the platform until it is near the block position, release the buttons and continue to slide the platform to the fixed position; when the position has been reached, both buttons will click, which confirms the position and guarantees correct fixing of the platform.
The footrest platform is fixed correctly when the red part of the locking pin is clearly visible and at the same level as the pinholes.
The platform has 7 fixed positions.

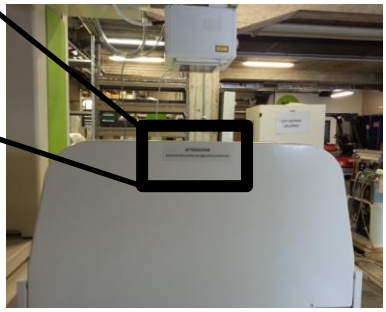
Locking pinwith redpositioningindicator, it crosses the holes of the aluminumprofilesofthebedtoblock the

Platform pinholeindicatesthecorrectlevel oftheredpartofthe locking pin

Buttonusedtoreleaseorblockfootrest platform on the guides

Attention: Thereis aspeciallabelontheplatform(seefigure)statingthatit is necessary to ensure that the platform has been correctly positioned and hooked into one of the 7 fixed positions.





N.B. Topositiontheplatform,bringthepatient-bearing bed to a horizontal position, and make sure that the red part of the locking pin is clearly visible and at the same level as the platform pinholes before lifting the patient.

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Introduction of frame containing grill (SFD version)

• Insert the frame with the grill into the special opening.
The seriograph has a device with guides which allows for the correct insertion of the grill holding frame
•Push the frame as far as possible.
•Press the handle A of the frame to action the lock switches.
These switches serve to recognise the type of grill and consequently the correct DFF to be used.

To extract the grill frame, press the handle inwards until the switches click.
•Grip the hand and pull the frame out of its housing.

N.B. Thedevicecanalsofunctionwithoutthegrill,dependingonthetypeofdiagnosisto be carried out.

Insertingtheframeincorrectly,withtheupperfacedownwardsortheuseofvery deformed frames can damages the receptor holder carriage.

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Introduction of frame containing grill (DRF version)

· Insert the frame with the grill into the special opening.
The receptor holder carriage has a device with guides which allows for the correct insertion of the grill holding frame
•Push the frame as far as possible.
•Press the handle A of the frame to action the lock switches.
These switches serve to recognise the type of grill and consequently the correct DFF to be used.

To extract the grill frame, press the handle inwards until the switches click.
•Grip the hand and pull the frame out of its housing.
•Replace the extracted frame in the special guides below the receptor holder carriage.

N.B. Thedevicecanalsofunctionwithoutthegrill,dependingonthetypeof diagnosis to be carried out.

⚠ Insertingtheframeincorrectly,withtheupperfacedownwardsortheuseofvery deformed frames can damages the receptor holder carriage.

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Sanitisation

Machine cleaning

WARNING!!!!

DONOTPOURLIQUIDSDIRECTLY ON ANY PART OF THE MACHINE

Before cleaning the machine, cut off the electricity.
Open and move the main switch.

Clean the parts of the machine that come into contact with the patient, such as:

- the patient-bearing surface
- the handles
- the receptor holder carriage
- the guards
- the surface coating

Cleaning: *use cloths dampened with NON aggressive detergent (e.g. alcohol, disinfectant...).*
Do not use acids or solvents.

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Disposal

Scrapping of the apparatus

Useful information on scrapping can also be found in the Technical Manual provided together with the apparatus. Contact the manufacturer/dealer of the apparatus for further information on decommissioning and disposal of the materials and parts used in the construction of the unit. You can also contact public or state entities for assistance in the correct disposal and elimination of the materials.

Help us to keep the environment clean. Do not discard potentially dangerous material in the environment.

N.B.*Thisindicatesthat theapparatusissubjecttotheEuropeanDirectiveWEEE 2002/96/96 and the successive directive 2003/108/EC relative to procedures for the decommissioning and disposal of the parts of the apparatus. Contact the manufacturer for assistance relative to recyclable or hazardous material.*

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REVISION HISTORY

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Revisioni:		
Rev.	Date	Note
13	18/07/2017	Handles with compressor instrucions, Revision Hstory added Filled by: Alessandro Biasini Checked: Rosaria Sottile Approved: Giselda De Silva
14	22/06/2018	new platform coupling Filled by: Alessandro Biasini Checked: Rosaria Sottile Approved: Giselda De Silva
15	06/07/2018	technical features adaptation to modifications RDM 9 and RDM10 Filled by: Alessandro Biasini Checked: Rosaria Sottile Approved: Giselda De Silva
18	18/12/2019	Selectable TOMO angles Filled by: Alessandro Biasini Checked: Rosaria Sottile Approved: Giselda De Silva
19	09/01/2021	Image Revision to modifications RDM22 Filled by: Alessandro Biasini Checked: Rosaria Sottile Approved: Giselda De Silva
20	17/09/2021	New Company Logo Filled by: Alessandro Biasini Checked: Rosaria Sottile Approved: Giselda De Silva
21	31/03/2022	Console image update Filled by: Alessandro Biasini Checked: Rosaria Sottile Approved: Giselda De Silva
22	31/03/2023	technical features updates Filled by: Alessandro Biasini Checked: Rosaria Sottile Approved: Giselda De Silva

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