

Perform-X F100–F400 / C100–C400 Radiographic System Operating Instructions

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1 IMPORTANT SAFETY INFORMATION



CAUTION!

This equipment may be used only if the operator is familiar with its operation and safety features. The operating instructions (present document) must be carefully studied before operation.

ELECTRICAL SAFETY

Only trained service personnel are permitted to remove covers & panels from the equipment. The provisions of the local standards and electrical codes shall be observed at all times.

To avoid the risk of fire and electric shock, this equipment shall only be connected to a supply mains with protective earth.

MECHANICAL SAFETY

It is the operator's responsibility to ensure patient safety during positioning and usage.

X-RAY PROTECTION

- This equipment in itself does not have any control, which can trigger radiation. Exposure can be initiated only from a radiation-protected area, from the generator control console. Any person present in the room during radiographic examinations shall comply with applicable local radiation protection regulations. To protect the patient and the operator against unnecessary radiation exposure, additional radiation safety devices shall be installed and used, including personal wearable protection devices.
- **Set safe exposure factors, limit radiation field, keep safe distance and provide radiation protection for the patient.**

DANGER OF INJURY

- Do not reach into the operating device. It may cause injury or the moving part may catch your cloth.
- Positioning the X-ray tube may cause injury to persons in the area of danger.
- Do not reach behind the X-ray tube stand control. The X-ray tube assembly may be hot and could cause injury.

PROTECTION AGAINST EXPLOSION AND FIRE

- Do not use the equipment in the presence of flammable anesthetics – explosion may occur.
- Before disinfecting or cleaning the unit, the power shall be turned off and kept off until the disinfecting or cleaning material has evaporated.

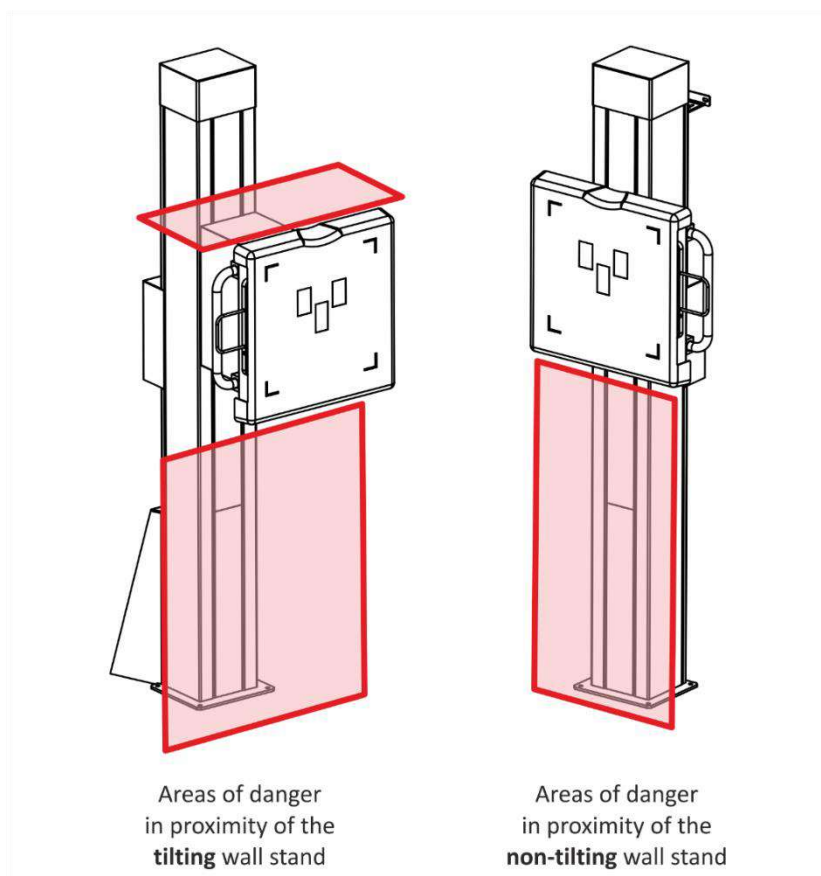


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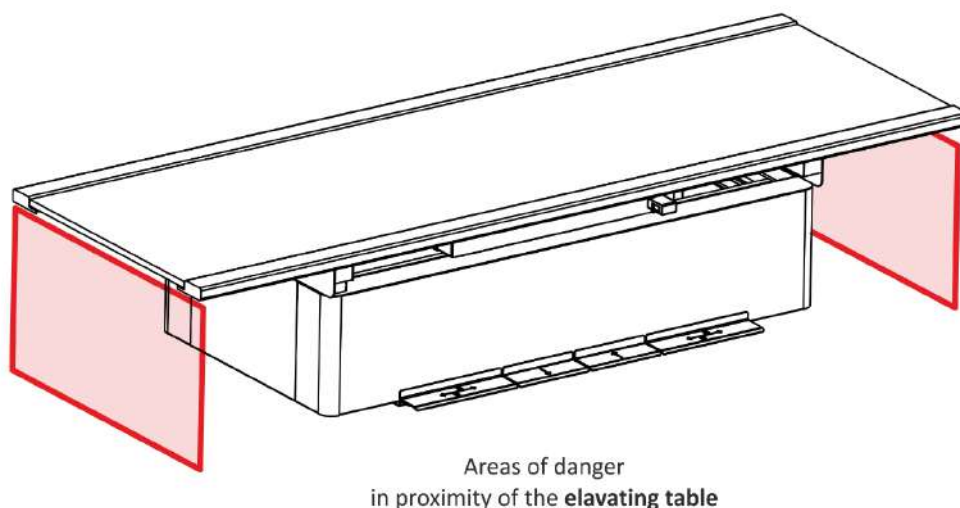
Do not use electronic devices in the x-ray room that emit **high RF energy**, such as radio transmitters and therapeutic equipment operating with electromagnetic radiation.

1.1 AREAS OF DANGER

The following areas of danger are present while operating the Perform-X System:

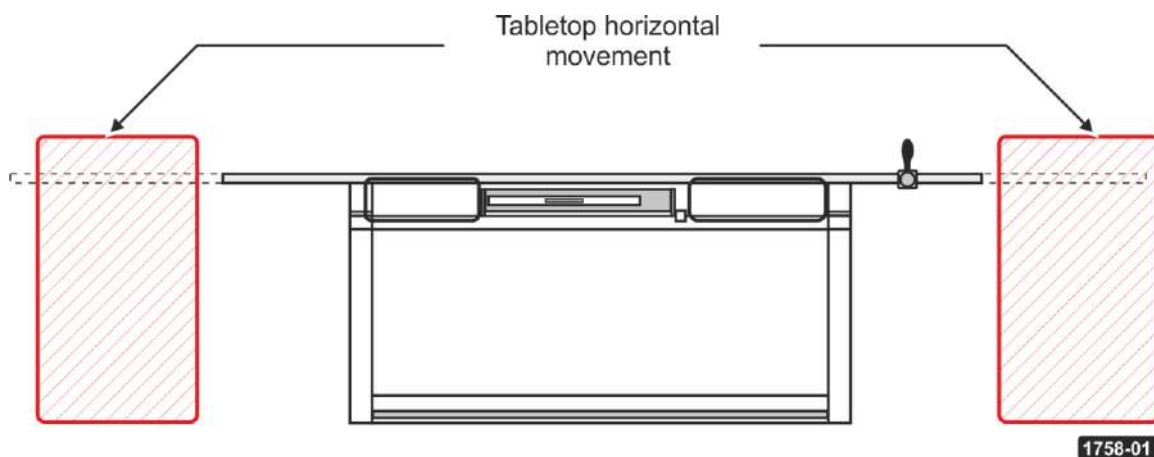


F100 F200 F300 F400 C100 C200 C300 C400



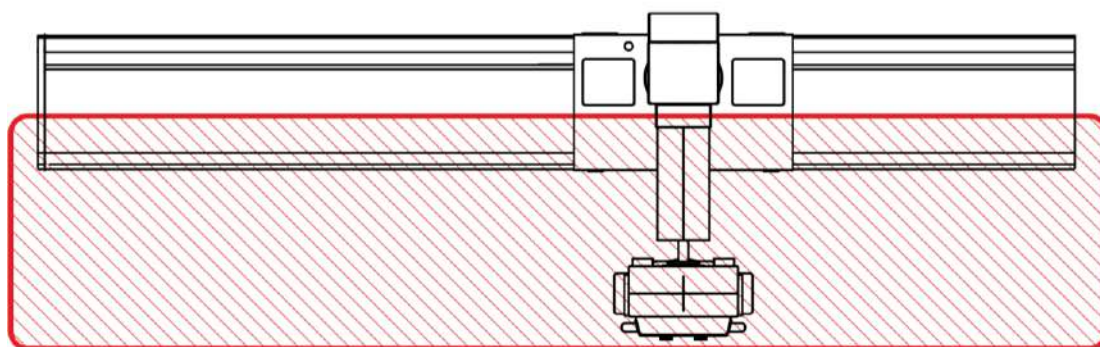
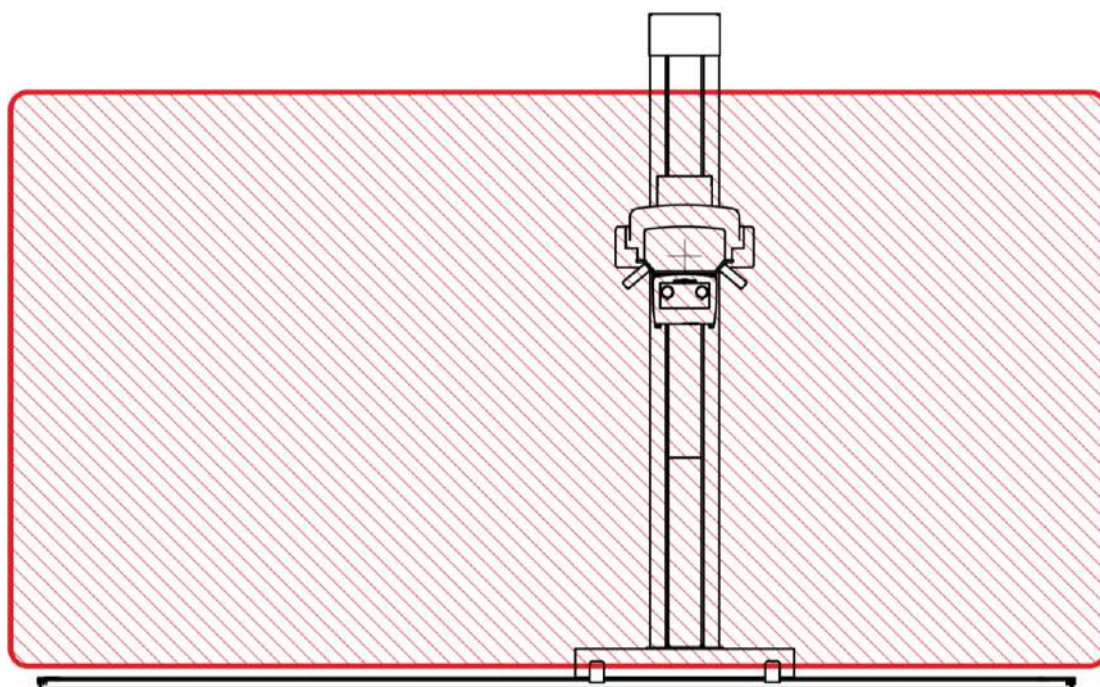
Areas of danger
in proximity of the elevating table

F100 F200 F300 F400 C100 C200 C300 C400



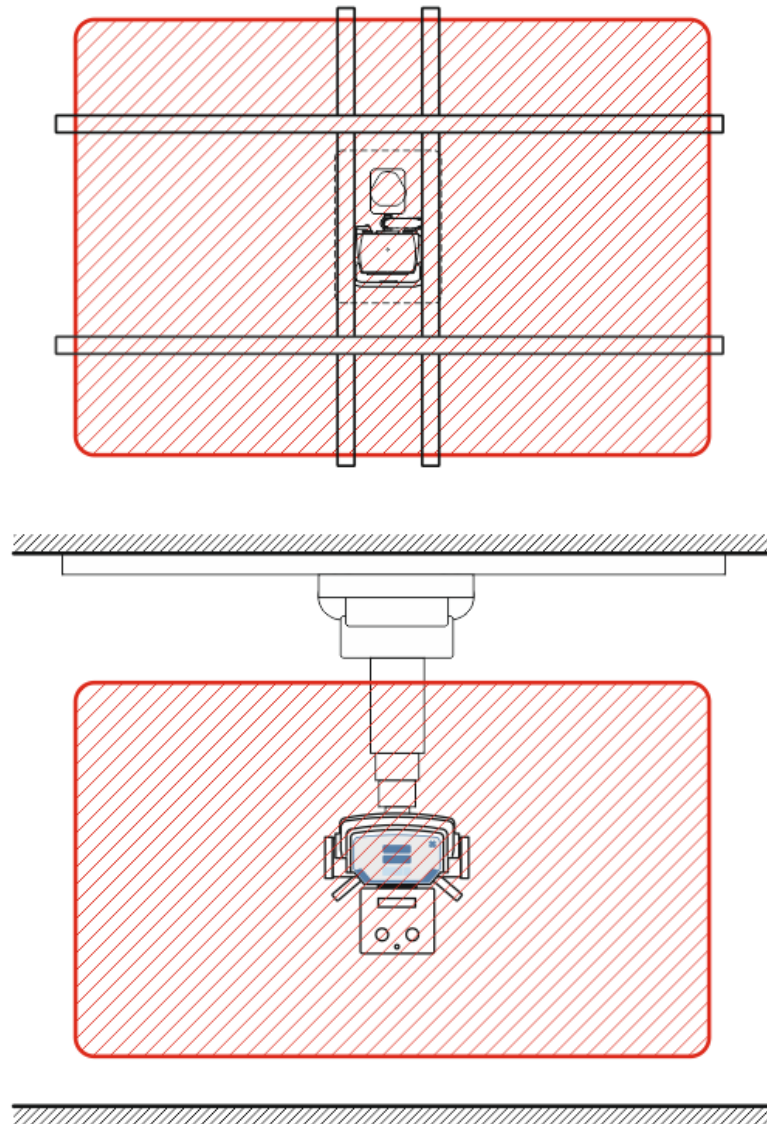
Areas of danger in proximity of the fixed height table

F100 F200 F300 F400 C100 C200 C300 C400



Areas of danger in proximity of the floor mounted tube stand TS99N

F100 F200 F300 F400 C100 C200 C300 C400



Areas of danger in proximity of the ceiling tube stand CTM-200

F100 F200 F300 F400 C100 C200 C300 C400

2 GENERAL INFORMATION

2.1 INTENDED USE, APPLICATION

This document describes the usage of the mechanical components of the **Perform-X F100-F400 and C100-C400 Radiographic System** (hereinafter *Perform-X*). The equipment forms a complete diagnostic system when equipped with other components (e.g. X-ray generator, digital acquisition workstation, flat panel detector, etc.).

As part of a complete diagnostic radiographic room, the Perform-X is intended to hold and position the radiation source, the beam limiting device, the X-ray receptor and associated devices and the patient during general radiographic procedures such as

- Chest and spine examinations
- General gastrointestinal radiograms
- Extremities procedures
- Lateral and oblique projections
- Ambulatory / emergency radiograms.

The Perform-X system **cannot be used for fluoroscopic applications**.

There is no need for particular limitation of patients in regards to age, gender or physical condition. General guidelines used in radiography apply:

- Pregnant patients or patients where pregnancy cannot be ruled out must be informed of the potential adverse effects of the ionizing radiation;
- The system can be used for infants and children utilizing proper exposure parameters (but it is not specifically designed for pediatric applications);
- The Phoenix elevating table (optional) may be helpful when examining disabled and/or elderly patients ;
- Optional overhead stretch grips may be used to make patient positioning easier and safer.



ATTENTION!

The Perform-X system may contain a **sensitive flat panel detector** (indirect radiography). To avoid property damage and maintain image quality / performance, observe at all times the handling and maintenance instructions set forth in the flat panel detector's user manual.



ATTENTION!

International standards require the use of an operational **AEC system in indirect radiography systems**. Make sure the generator's acceptance test related to AEC is completed before working with the Perform-X system.



ATTENTION!

If the Perform-X system is used for **pediatric diagnostic procedures**, at least 0.1 mm Cu or 3.5 mm Al **additional filter** is mandatory.

If the system is equipped with a DAP (Dose Area Product) meter, the collimator exit dose is measured and can be recorded in one of two ways:

- automatically if the DAP is compatible with the image acquisition system,

- manually if using a DAP with built-in or remote display.

Refer to the image acquisition user manual for further details.

2.2 COUNTERINDICATIONS

2.2.1 Adverse Effect of X-ray Radiation

There are no short term adverse effects. Generally speaking, the benefit of the X-ray procedure is far more important than the small associated risks. At the dose levels that are utilized in diagnostic radiography there is little or no evidence of health effects.

For standard radiograms made with the Perform-X radiographic system, the radiation dose is no more than the ionizing radiation from normal environmental background over a period of one year.

However, the minimal risk of exposure to any type of medical ionizing radiation needs to be weighed against the potential gain from the diagnostic information provided by the X-ray radiogram.

For further details, please refer to document *D-3633 - Information on the Effects of X-ray Radiation*.

2.2.2 Absolute Counterindications

NONE

2.2.3 Relative Counterindications

- Pregnant patients** or patients where pregnancy cannot be ruled out **must be informed** of the potential adverse effects of the ionizing radiation. The potential **risks of health effects and benefits** of the diagnostic procedure **must be weighed** individually.
- Patients weighing more than the radiographic table weight rating may not be examined on the patient table. The potential risks of equipment damage and benefits of the diagnostic procedure must be weighed individually.

2.3 SYSTEM CONFIGURATIONS

The Perform-X is available in several different configurations.

Config	Example	Tube Stand mount	Manual movements	Auto-tracking	Auto-stitching	Auto-positioning
F100		Floor	YES	NO	NO	NO
F200		Floor	YES	YES	NO	NO
F300		Floor	YES	YES	YES	NO

Config	Example	Tube Stand mount	Manual movements	Auto-tracking	Auto-stitching	Auto-positioning
F400		Floor	YES	YES	OPTION	YES
C100		Ceiling	YES	NO	NO	NO
C200		Ceiling	YES	YES	NO	NO
C300		Ceiling	YES	YES	YES	NO
C400		Ceiling	YES	YES	OPTION	YES

The Perform-X F100 system consist of the following equipment:

Component / option	Description	F100
TS99N	Floor mounted X-ray tube stand	Default
CTM-200	Ceiling mounted X-ray tube stand	Optional
WS99N	Wall bucky stand	Default
Stylix	4-way float top fixed height radiographic table	Default
Phoenix 1	6-way float top elevating radiographic table	Optional
Phoenix 2	6-way float top elevating radiographic table	Optional

2.4 COMPATIBILITY

The Perform-X Radiographic system is compatible with a number of certified diagnostic X-ray accessories. To verify compatibility with a particular device, please contact the service representative and/or the manufacturer. The following is an inexhaustive list of devices compatible with the Perform-X:

Device type	Manufacturer	Model	Comments
X-ray tube	Varex Imaging	RAD-XX / A and G series	Diamond, Leo, Sapphire, B-130 and B-130H housing rotating anode dual focus RAD X-ray tubes
X-ray tube	Toshiba	E72XX series	Rotating anode dual focus RAD X-ray tubes
Collimator	Ralco	R-108 **	Manual collimator (compatible, but no longer offered)
Collimator	Ralco	R-225	Automatic motorized collimator
Collimator	Ralco	R-302F/A	Manual collimator with selectable filters
Collimator	UMI	M38	Manual collimator (compatible, but no longer offered)
Collimator	Varex Imaging	Optica 10 / 20	Manual collimator with optional manual filter
HV cables	Varex Imaging **	Locaflex	Locaflex series HV cables rated 150+ kV
AEC detector	Varex Imaging **	ICX-1153	3-field ion AEC detector
AEC detector	Varex imaging **	SSMC-601	3-field ion AEC detector
Bucky	Innomed Medical	IBC-430	High-speed 115V/230V oscillating grid bucky
Cassette tray	Control-X Medical	CXT-17 CXT-17-DC	ISO 4090 43x43 cm cassette size tray for analogue film cassettes, CR cassettes and wireless flat panels (non-size-sensing)
Cassette tray	Poersch	QKC	ISO 4090 43x43 cm cassette size tray for analogue film cassettes, CR cassettes and wireless flat panels (non-size-sensing)
Cassette tray	Poersch	QJC	Size-sensing ISO 4090 43x43 cm cassette size tray for analogue film cassettes, CR cassettes and wireless flat panels
Flat panel detector	Canon CETD*	FDX(A)-4343R	43x43 cm CsI A-Si fixed flat panel detector
Flat panel detector	Canon CETD*	FDX-3543RP	35x43 cm CsI A-Si tethered portable flat panel detector
Flat panel detector	Canon CETD*	FDX(A)-3543RPW	35x43 cm CsI A-Si wifi portable flat panel detector

Device type	Manufacturer	Model	Comments
Flat panel detector	DRTech	EVS Series	Fixed and portable flat panel detectors (select models)
Flat panel detector	Varian	PaxScan Series	CsI A-Si fixed flat panel detectors
Flat panel detector	Thales	Pixium Series	Pixium series fixed and portable flat panel detectors (select models)
Flat panel detector	Rayence	Xmaru Series	Fixed and portable flat panel detectors (select models)
Flat panel detector	CareRay	1500 & 1800 series	Fixed and portable flat panel detectors (select models)
Flat panel detector	Vieworks	Vivix series	Fixed and portable flat panel detectors (select models)
X-ray generator	Innomed Medical	TOP-X 100LC series	100 kHz 32-50kW three or single phase, single tube RAD generator family
X-ray generator	CPI Inc.	CMP-200 series	200 kHz 32-80kW three phase, single tube RAD generator family
X-ray generator	CPI Inc.	CMP-150 series	150 kHz 32kW single phase, single tube RAD generator family
X-ray generator	CPI Inc.	Indico 100L series	100 kHz 65/80kW three phase, single/dual tube RAD generator family
Anti-scatter grid	UMI	103/178/215 lpi grids	Full size Al spacing focused grids
Anti-scatter grid	JPI	103/178/215 lpi grids	Full size Al spacing focused grids
Dose Area Product Meter	IBA Dosimetry	KermaX Plus	Display and non-display version: compatible with collimators and the DX-R image acquisition software
Image Acquisition Workstation	OR Technology	dicomPACS DX-R	DICOM 3.0 compatible open architecture image acquisition software.

* Formerly Toshiba TETD

** Formerly Claymount BV

2.5 SYMBOLS AND MARKINGS

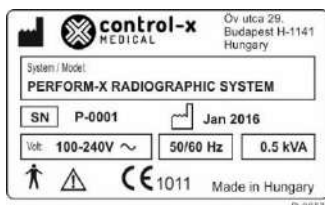
All components of the Perform-X system have a product label with the following information:

- name and address of the manufacturer;
- model number, serial number and manufacturing date of the component / system;
- power supply requirements.

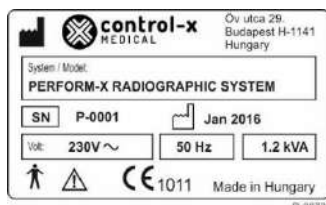
The location of the product labels are as specified below:

- System product label & E-Box (system control box) product label: right side of E-Box;

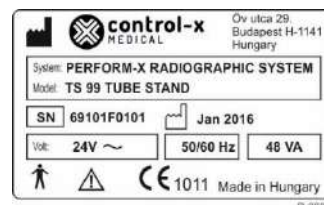
- TS99N tube stand label: right side of column, near the horizontal carriage;
- WS99N wall bucky stand label: right side of the column, near the floor;
- Stylix fixed height and Phoenix elevating table labels: side cover



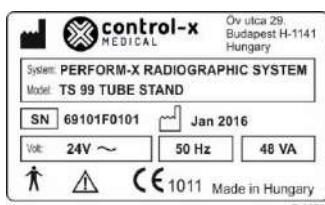
System product label sample
(configurations with Stylix
table)



System product label sample
(configurations with Phoenix
table)



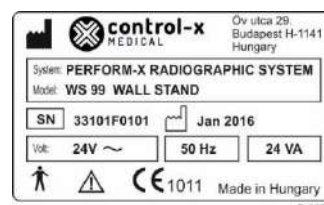
TS 99 product label sample
(configurations with Stylix
table)



TS 99 product label sample
(configurations with Phoenix
table)



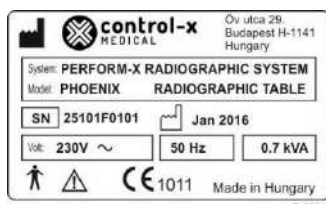
WS 99 product label sample
(configurations with Stylix table)



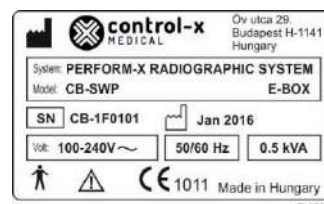
WS 99 product label sample
(configurations with Phoenix
table)



Stylix table product label
sample



Phoenix table product label
sample



Perform-X System Control Box
product label sample

The following is a list of symbols used on the product and the product labels (the symbols conform to standards EN 60601-1 and EN 980):

	Date of manufacture – located on the product labels.
	Name and address of manufacturer – located on the product labels.
	Serial Number of product – located on the product labels.
	Single-phase AC main supply – located on the product labels.
	WARNING! Refer to manual for additional safety information – located on the product labels
	Instruction manual must be read – located on the product.
	Type B equipment – located on the product labels
	Protective earth ground – located inside the equipment at the main grounding terminal
	Taking care to avoid injury to hands when in the vicinity of equipment with closing mechanical parts – located on the product.
	Located on the side of the Phoenix table. (1) The Phoenix elevating table is not designed for continuous vertical movement operation. To prevent damage to the equipment and to reduce risk of fire, the table can only be moved for a maximum of 60 seconds every 5 minutes. (There must be a 4 minute pause after each 60 second movement, giving a 20% duty cycle.). (2) Do not sit or load at tabletop ends! The table may tip over. (3) Warning stating the maximum distributed table load.

2.6 OPERATORS

The Perform-X System is to be operated only by qualified radiology personnel authorized by local authorities to use radiographic diagnostic equipment.

Operators must have clear understanding of the hazard associated with taking X-ray radiograms and of working with patient positioning medical devices.

Operators' training is recommended for each operator before first using the equipment. For operator's training, please contact your local authorized distributor or the manufacturer.


WARNING!

Do not touch patient parts (as described in section 3.6) **and patients simultaneously.**

2.7 SERVICE PERSONNEL, INSTALLATION

The installation instructions (along with all the system documentation, including these operating instructions) are located in the packaging / crate marked with the following label:


ATTENTION!

Only qualified and trained service personnel may perform any installation and/or maintenance on this equipment.

2.8 ENVIRONMENT, FREQUENCY OF USE AND MOBILITY

The Perform-X System is designed and manufactured to be used as a fixed equipment permanently installed in a professional hospital or clinical environment. The **patient environment** is the 1.5m proximity of the patient during the upright, table or special procedures and includes the radiographic stand and tables. The E-Box (system control box) is not part of the patient environment.

2.9 DOSIMETRIC INFORMATION

The Perform-X System is equipped with certified X-ray generators. For detailed and quantitative dosimetric information, please refer to the generator operating instructions.

2.9.1 Repetition of exposures

Pay attention to (local) skin dose levels under intended use but in case of **repetitive** or **prolonged** exposure as it may cause tissue reactions!

2.9.2 Patient entrance reference point

The patient entrance reference point is located 30cm above the patient support for X-Ray equipment with the X-Ray source assembly above the patient support.

2.10 INTERCHANGEABLE OR DETACHABLE PARTS

The Perform-X system does not contain any parts that are interchangeable or detachable by the operator or the service personnel.

3 SPECIFICATIONS

3.1 MECHANICAL DATA, MOTION RANGE

TS99N TUBE STAND MECHANICAL PARAMETER								CONDITIONS	VALUE
F100	F200	F300	F400	C100	C200	C300	C400		
Recommended min floor-to-ceiling distance (room height)								standard (TS99N)	2400 mm
Recommended min floor-to-ceiling distance (room height) with EXTENDED stand height								extended (TS99N-EXT)	2600 mm
Minimum floor space (without generator)									8 m ² (2.5 x 3.2 m)
X-ray tube vertical travel								standard (TS99N)	1545 mm
								extended (TS99N-EXT)	1745 mm
X-ray tube focus-to-floor distance								standard (TS99N)	335 ... 1880 mm
								extended (TS99N-EXT)	335 ... 2080 mm
Tube stand floor rail length								standard rail length (PFX-R247)	2470 mm
								with option PFX-R360	3600 mm
X-ray tube longitudinal movement								with standard FIXED column (P-type or M-type floor carriage)	1770 mm (Option: 2900 mm with extended rail length)
								with ROTATING column option (R-type or X-type floor carriage)	1610 mm (Option: 2740 mm with extended rail length)
X-ray tube column rotation for lateral exposures								with ROTATING column option (R-type or X-type floor carriage)	-180° ... +180° with -90° / 0° / 90° detents
X-ray tube transverse travel								with TRANSVERSE arm option (T-type tube arm)	+/- 102 mm
X-ray tube rotation (around horizontal axis)									330°
CTM-200 TUBE STAND MECHANICAL PARAMETER								CONDITIONS	VALUE
F100	F200	F300	F400	C100	C200	C300	C400		
X-Ray tube vertical travel (CTM)									150 cm (optionally 180 cm or 135 cm)
X-Ray tube vertical movement speed									15 cm/sec
Min. X-Ray tube focus to floor distance								depends on vertical travel and ceiling height	30 cm
Max. X-Ray tube focus to floor distance								depends on vertical travel and ceiling height	180 cm
X-Ray tube longitudinal travel									357 / 343 cm (Option: +140 cm with PX-2116)

X-Ray tube longitudinal rail length		440 cm (Option: +140 cm with PX-2116)
X-Ray tube longitudinal movement speed		25 cm/sec
X-ray tube transversal travel		207 / 203 cm (Option: 287 / 283 cm with PX-2117)
X-Ray tube transversal rail length		300 cm (Option: 380 cm with PX-2117)
X-Ray tube transversal movement speed		13 cm/sec
X-ray tube rotation (around horizontal axis)	total rotation: 334°	120° / -214°
X-ray tube rotation (around vertical axis)	total rotation: 338°	138° / -200°
WALL STAND MECHANICAL PARAMETER F100 F200 F300 F400 C100 C200 C300 C400		
Mounting	CONDITIONS	VALUE
	standard	Floor to wall
	with option PFX-2035	Floor only
Detector STANDARD vertical travel	with bucky CXB-17 (TS99N)	1450 mm
	with grid cabinet SGC (TS99N)	1530 mm
Detector EXTENDED vertical travel	with bucky CXB-17 (TS99N-EXT)	1650 mm
	with grid cabinet SGC (TS99N-EXT)	1730 mm
STANDARD detector center-to-floor distance	with bucky CXB-17 (TS99N)	380 ... 1830 mm
	with grid cabinet SGC (TS99N)	300 ... 1830 mm
EXTENDED detector center-to-floor distance	with bucky CXB-17 (TS99N-EXT)	380 ... 2030 mm
	with grid cabinet SGC (TS99N-EXT)	300 ... 2030 mm
Detector tilt range	(T or M type tilting device)	-25 ... +90°

PATIENT TABLE MECHANICAL PARAMETER								CONDITIONS	VALUE
F100	F200	F300	F400	C100	C200	C300	C400		
Tabletop surface									810 x 2200 mm or 810 x 2000 mm (optional)
Tabletop transverse movement									+ / - 120 mm
Tabletop longitudinal movement								left / right direction	500 mm / 600 mm
Tabletop height								Stylix fixed height table	fixed at 750 mm
								Phoenix 1 elevating table	550 ... 850 mm
								Phoenix 2 elevating table	450 ... 900 mm
Tabletop vertical movement								Stylix fixed height table	N/A
								Phoenix 1 elevating table	300 mm
								Phoenix 2 elevating table	450 mm
Table top vertical movement speed:								Stylix fixed height table	N/A
								Phoenix 1 & 2 table	approx. 22 mm / sec
Vertical exposure position (distance from floor)								Stylix fixed height table	750 mm, fixed
								Phoenix 1 & 2 only	750 mm (adjustable during installation)
Elevating table safety functions								Phoenix 1 / 2 table	Double-kick (optional) Crash-guard Audible warning
								Phoenix 2 table ONLY	Crash-guard with automatic upward movement upon touching an obstruction
Table detector horizontal movement								with bucky CXB-17	550 mm
								with grid cabinet SGC	610 mm
Tabletop maximum distributed load								equivalent to maximum patient weight – no additional accessories for table procedures	250 kg
Max tabletop to image receptor distance									70 mm

3.2 X-RAY PARAMETERS

Wall bucky and tabletop Al equivalency		typ. 03 mm Al max 0.8 mm Al (99.9% purity or higher)
Cassette size	(CR / film / portable FP)	According to ISO 4090
Bucky grid type	with CXB-17	Fixed mounted oscillating grid
Grid cabinet grid type	with SGC-100/200	Removable stationary grid
AEC detector	optional	3-field ion chamber or solid state detector with preamp
Shortest irradiation time	with AEC (recommended)	10 ms
	without AEC	1 ms
Longest possible exposure	limited by the flat panel	Typically 2.5 sec
	limited by X-ray generator	Maximum 6 sec

For detailed X-ray parameter ranges and accuracy, please refer to the X-ray generator accompanying documents.

For the following specifications please refer to the X-ray tube datasheet:

- maximum symmetrical radiation field size
- focal spot size
- target angle.

3.3 POWER SUPPLY

WS99N wall bucky stand and	24VDC, 50VA (powered from E-Box)
TS99N X-ray tube stand (including collimator light field)	24VDC, 150VA (powered from E-Box)
CTM-200 X-ray tube stand (including collimator light field)	230VAC, 560VA (powered from E-Box)
Stylis fixed height radiographic table	24VDC, 48VA
Phoenix elevating radiographic table	~230V 50 Hz, 690VA
Supply mains internal impedance	Refer to the generator and flat panel display documentation (0.2 Ohms if otherwise not specified by the generator or flat panel)

3.4 ENVIRONMENTAL DATA

Storage and transport temperature	-20°C – 55°C
Operating temperature	10°C – 40°C
Max. relative humidity (operation)	80%
Max. relative humidity (storage)	90%
Environmental protection	IP20

3.5 USAGE CONDITIONS

Exposure cycle time without positioning	Typically 10 sec (depends on the flat panel / DR component)
Exposure cycle time including positioning	Approx. 1 min. depending on positions and image of receptor
Useful expected life time	10 years (with proper maintenance and average case load of 30 positioning cycles per day)

3.6 APPLIED PARTS

The Perform-X Radiographic System contains the following applied parts that may come into contact with the patient:

1. Wall detector / cassette holder cover
2. Wall detector overhead patient grip
3. Tabletop (if applicable).



WARNING!

Do not touch the unused (unplugged) electrical sockets / connections on the equipment, e.g. the RJ45 (Ethernet) socket on the back of the WS99N.



WARNING!

No additional MULTIPLE SOCKET+OUTLET or extension cord shall not be connected to the Perform-X System.



WARNING!

Connect only the items that have been specified as part of the Perform-X System or that have been specified as being compatible with the Perform-X System

3.7 CLASSIFICATION

Protection against electric shock		Type B equipment
Safety classification as a medical device / radiographic system (classification is based on MDD annex IX rule 10)		Class II/b medical equipment

3.8 ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions		
The Perform-X Radiographic System is intended for use in the electromagnetic environment specified below. The owner or operator of the Perform-X Radiographic System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Perform-X Radiographic System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with? nearby electronic equipment.
RF emissions CISPR 11	Class A+20dB	The Perform-X Radiographic System is suitable for use in all establishments other than domestic. It may however be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: - This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Perform-X Radiographic System or shielding the location; - The Perform-X Radiographic System must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that exits the shielded location, a minimum RF filter attenuation of 20dB for radio signals between 30MHz ... 1000MHz.
Harmonic emissions IEC 61000-3-2	not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Perform-X Radiographic System is intended for use in electromagnetic environment specified below. The owner or operator of the Perform-X Radiographic System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/ bursts 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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ (>95% dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycle $70\% U_T$ (30% dip in U_T) for 25 cycle $< 5\% U_T$ (>95% dip in U_T) for 5 sec	$< 5\% U_T$ (>95% dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycle $70\% U_T$ (30% dip in U_T) for 25 cycle $< 5\% U_T$ (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the Perform-X Radiographic System requires continued operation during power mains interruptions, it is recommended that the Perform-X Radiographic System be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Perform-X System is suitable for use in the electromagnetic environment specified below. The owner or the operator of the Perform-X System should assure that it is used in such an electromagnetic environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands ^a 10 Vrms 150 kHz to 80 MHz in ISM bands ^a		The Perform-X System must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location, a minimum RF filter attenuation of 20 dB. See D-3541 - Perform-X Radiographic System Installation Instructions (ID 3541) , Section 4.2. Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 V/m. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz		
Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Note 2: It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.			

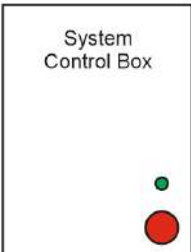
^a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

^b Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the Perform-X System is used exceeds 3 V/m, observe the Perform-X System to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the Perform-X System or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

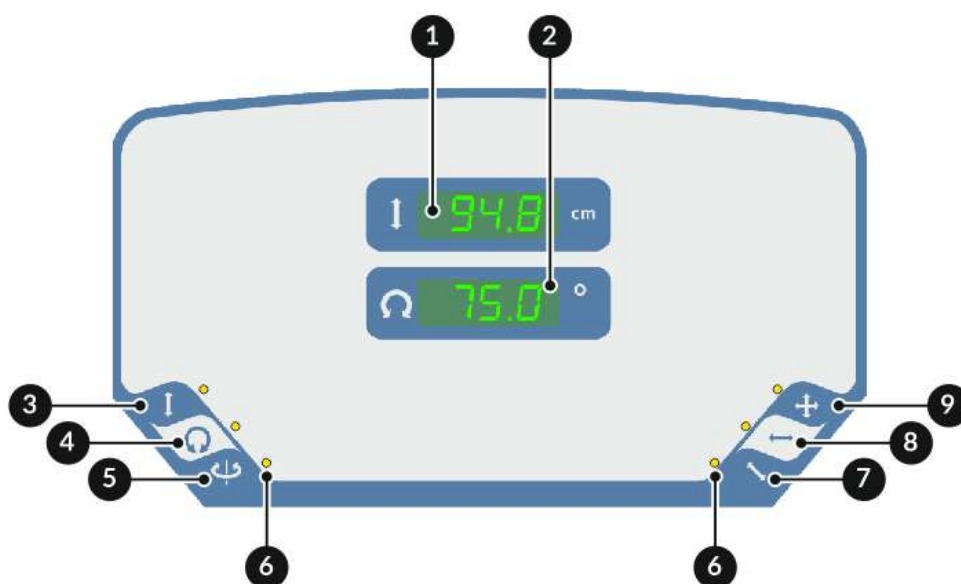
Guidance and manufacturer’s declaration – electromagnetic immunity			
The Perform-X System is suitable for use in the electromagnetic environment specified below. The customer or the user of the Perform-X System should assure that it is used in such an electromagnetic environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz		The Perform-X System must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location, a minimum RF filter attenuation of 20 dB. See <u>D-3541 - Perform-X Radiographic System Installation Instructions (ID 3541), Section 4.2</u> . Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 V/m. ^a Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz		
Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Note 2: It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the Perform-X System is used exceeds 3 V/m, the Perform-X System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the Perform-X System or using a shielded location with a higher RF shielding effectiveness and filter attenuation.			

4 OPERATOR CONTROLS

4.1 SYSTEM CONTROL BOX

Symbol / Control		Operation
		SYSTEM POWER indicator. When lit green, the system is powered up.
		EMERGENCY STOP Switch Push it to fully power off the system. Turn the knob to the right to switch the system back on again.

4.2 TUBE STAND MANUAL MEMBRANE CONSOLE

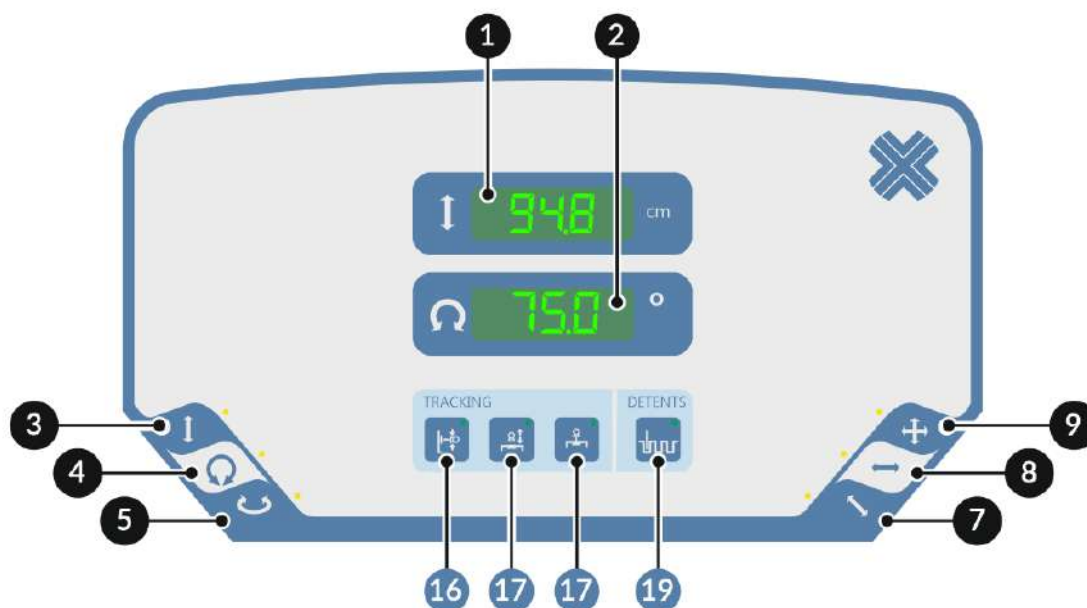


TS 99 / CTM-200 membrane console

- 1 SID (source image distance) display
- 2 X-ray TUBE INCLINE display
- 3 Brake release for VERTICAL movement
- 4 Brake release for X-ray TUBE ROTATION (incline)
- 5 Brake release for COLUMN or TELESCOPE ROTATION (pivot)
- 6 BRAKE ON indicator lights (lit when brake is engaged)
- 7 Brake release for transversal manual movement
- 8 Brake release for LONGITUDINAL movement
- 9 Brake release for VERTICAL and LONGITUDINAL movement

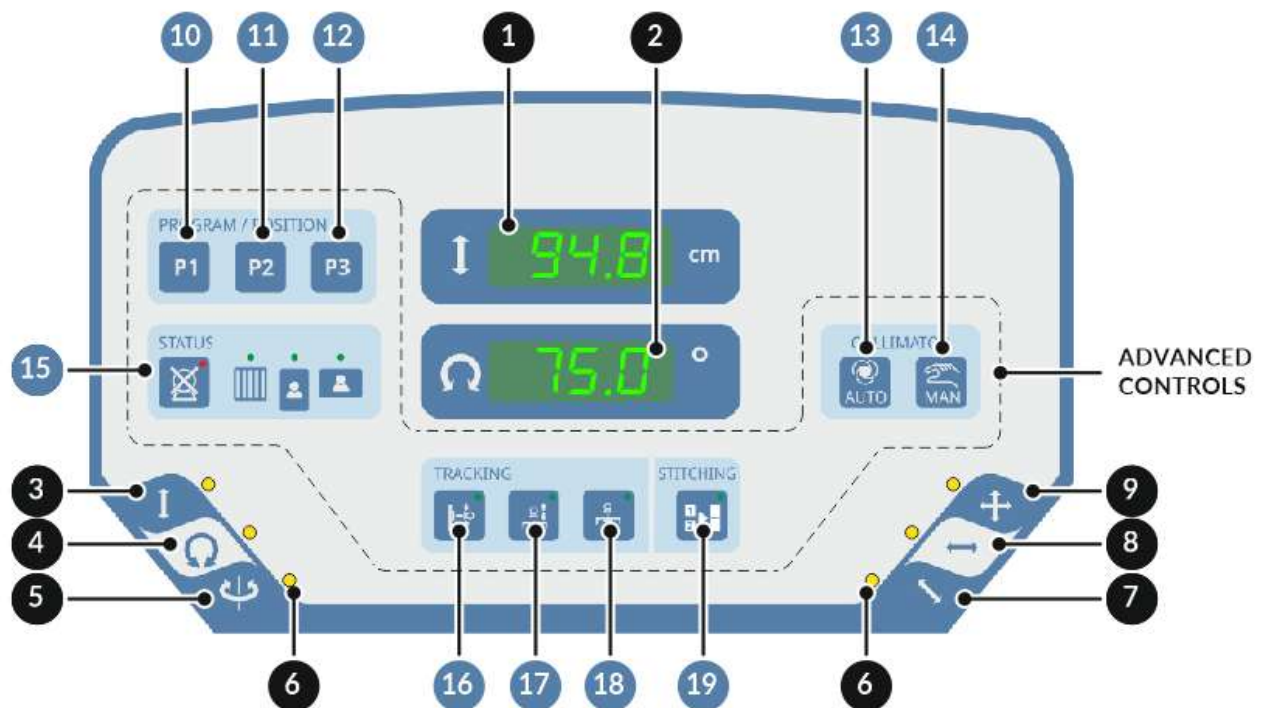
4.3 TUBE STAND BASIC MEMBRANE CONSOLE

F100 F200 F300 F400 C100 C200 C300 C400



- 1 SID (source image distance) display
- 2 X-ray TUBE INCLINE display
- 3 Brake release for VERTICAL movement
- 4 Brake release for X-ray TUBE ROTATION (incline)
- 5 Brake release for COLUMN or TELESCOPE ROTATION (pivot)
- 6 BRAKE ON indicator lights (lit when brake is engaged)
- 7 Brake release for transversal manual movement
- 8 Brake release for LONGITUDINAL movement
- 9 Brake release for VERTICAL and LONGITUDINAL movement
- 16 Wall receptor vertical tracking ON / OFF
- 17 Table receptor vertical tracking (constant SID) ON / OFF
- 18 Table receptor auto-centering ON / OFF
- 19 Stitching mode ON / OFF

4.4 TUBE STAND ADVANCED MEMBRANE CONSOLE



- 1 SID (source image distance) display
- 2 X-ray TUBE INCLINE display
- 3 Brake release for VERTICAL movement
- 4 Brake release for X-ray TUBE ROTATION (incline)
- 5 Brake release for COLUMN or TELESCOPE ROTATION (pivot)
- 6 BRAKE ON indicator lights (lit when brake is engaged)
- 7 Brake release for transversal manual movement
- 8 Brake release for LONGITUDINAL movement
- 9 Brake release for VERTICAL and LONGITUDINAL movement
- 10-12 Move to preprogrammed positions P1-P3. In Stitching Mode, they select stitching Frame 1-3.
- 13 Turns collimator AUTOMATIC mode ON (light field is set/maintained when changing SID)
- 14 Turns collimator MANUAL mode ON (light field is set manually with the face knobs)
- 15 Status controls (interlock, grid IN, landscape / portrait receptor orientation)
- 16 Wall receptor vertical tracking ON / OFF
- 17 Table receptor vertical tracking (constant SID) ON / OFF
- 18 Table receptor auto-centering ON / OFF
- 19 Stitching mode ON / OFF

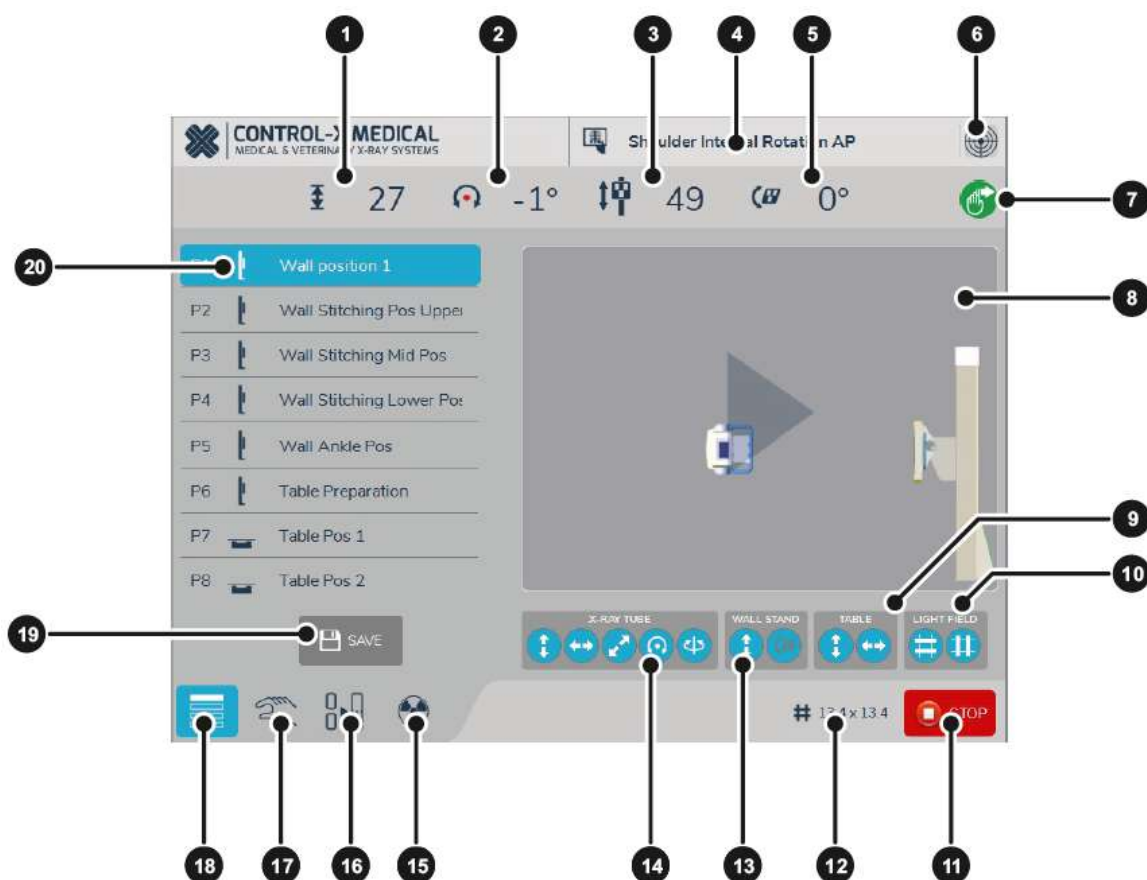
4.5 TUBE STAND LCD TOUCHSCREEN CONSOLE

F100 F200 F300 F400 C100 C200 C300 C400



ATTENTION! In order to ensure proper functioning of the touchscreen and avoid false input or unintended parameter changes, always make sure that your **hands are dry** and there are **no waterdrops, dirt or other residue** on the surface of the screen.

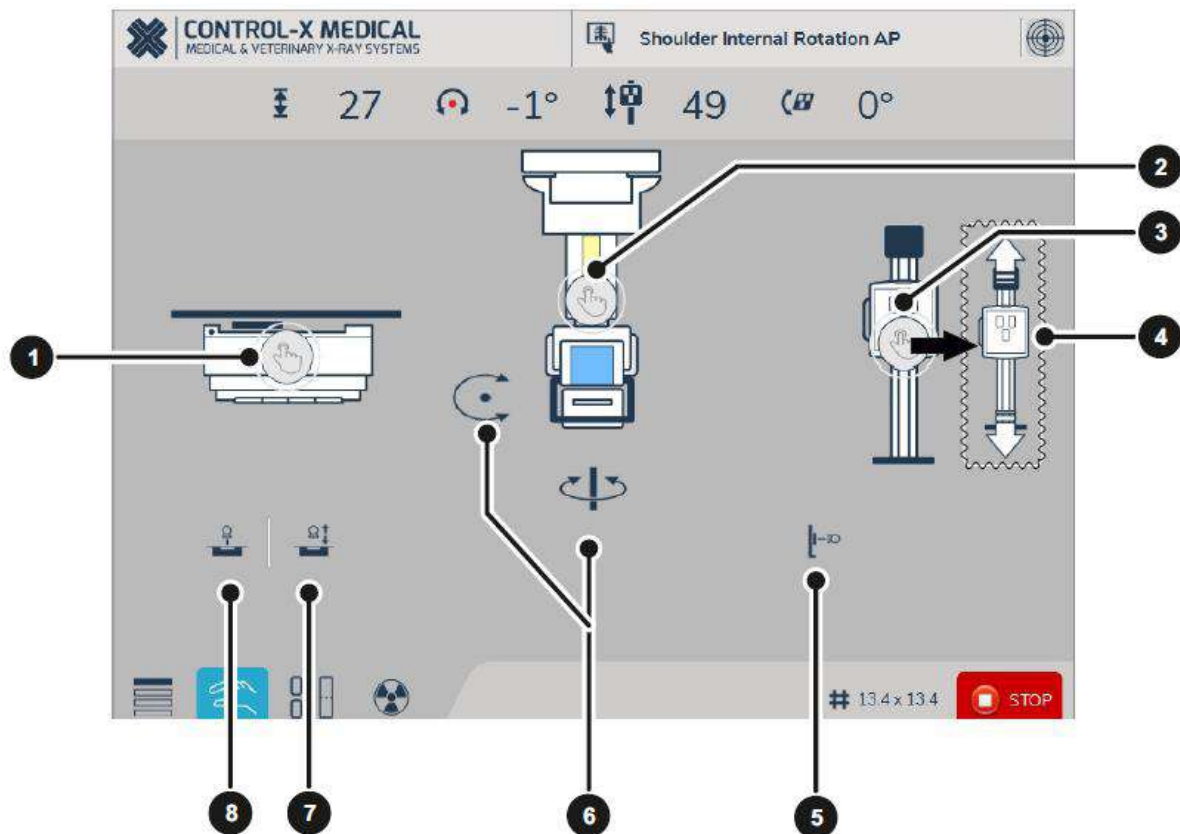
4.5.1 Preprogrammed position screen



- 1 Source-image distance
- 2 X-ray tube incline
- 3 Wall detector center height
- 4 Name of selected APR
- 5 Wall detector tilt
- 6 The system has reached the target position (after an automatic positioning)
- 7 Movement indicator (appears in case of any equipment movement)
 -  : Motorized movement (e.g. system positions itself to a preprogrammed position)
 -  : Manual movement (e.g. one of the manual brakes is released)

- 8 Equipment location displayed for the selected position, with “Go to position” button in the middle
- 9 Enabled motorized table (bucky) movements (vertical/horizontal)
- 10 Enabled motorized collimator shutter movements (cross/longitudinal)
- 11 Stop equipment movement

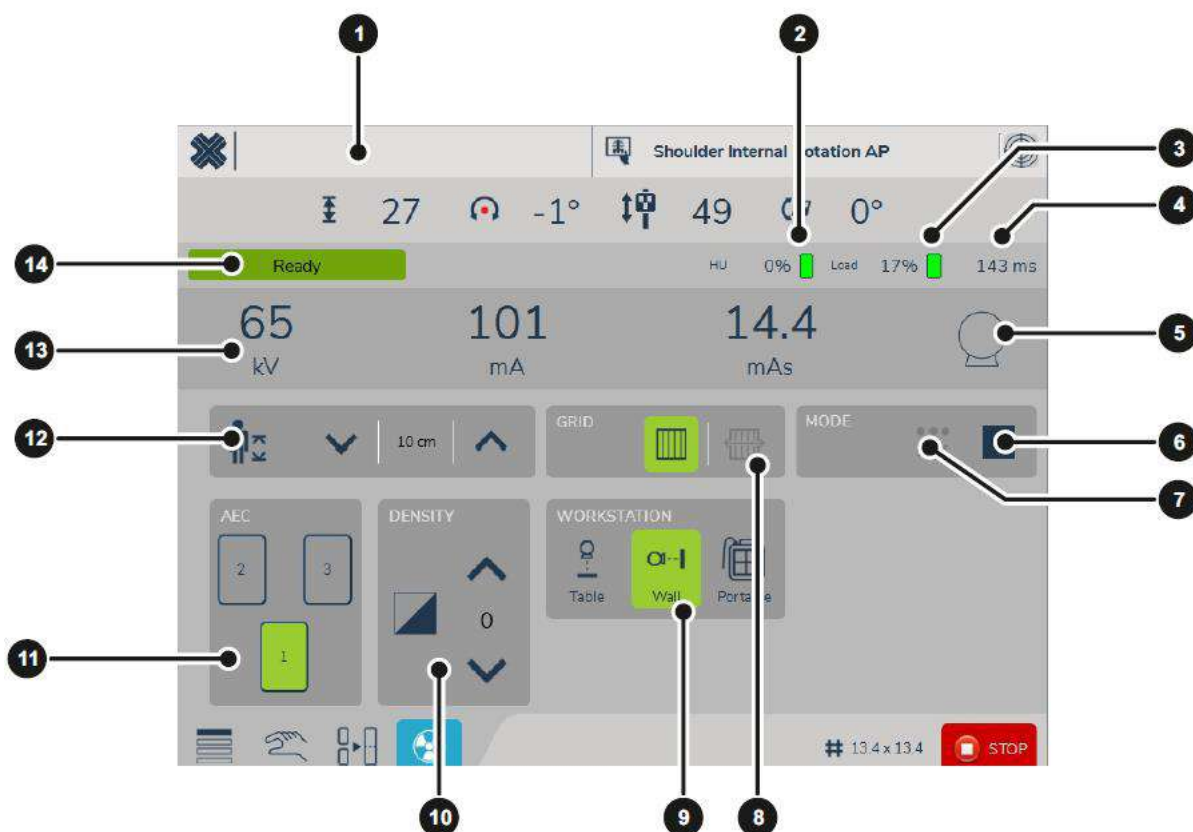
4.5.2 Manual positioning screen



- 1 Table detector motorized movement button
- 2 X-ray tube motorized movement button
- 3 Wall detector motorized vertical movement button
- 4 Movement arrows for manual positioning (appear after movement button is pressed and held)
- 5 Wall detector vertical tracking enabled/disabled
- 6 X-ray tube motorized rotation / pivot buttons
- 7 Constant vertical SID over the table enabled/disabled
- 8 Table detector auto centering enabled/disabled

4.5.3 Stitching Mode Screen

4.5.4 Generator Control screen



- 1 Patient name (if patient ID transfer feature is enabled)
- 2 Anode Heat Unit percentage
- 3 Generator load percentage
- 4 In mAs mode: calculated exposure time (in 3 point mode: calculated mAs value is indicated)
- 5 Exposure indicator - symbol appears during exposure
- 6 Small/ large focus selected
- 7 3 point mode enabled/disabled
- 8 Grid inserted / grid oscillation enabled/disabled
- 9 Configured workstations
- 10 AEC density settings
- 11 AEC filed selection
- 12 Tissue thickness
- 13 Exposure parameters
- 14 Generator status



When the X-ray tube is rotated (e.g. while preparing for exposure using wall stand detector) the **screen rotates automatically**. In this case the icons on the screens may be arranged differently, but all icons keep their functions.

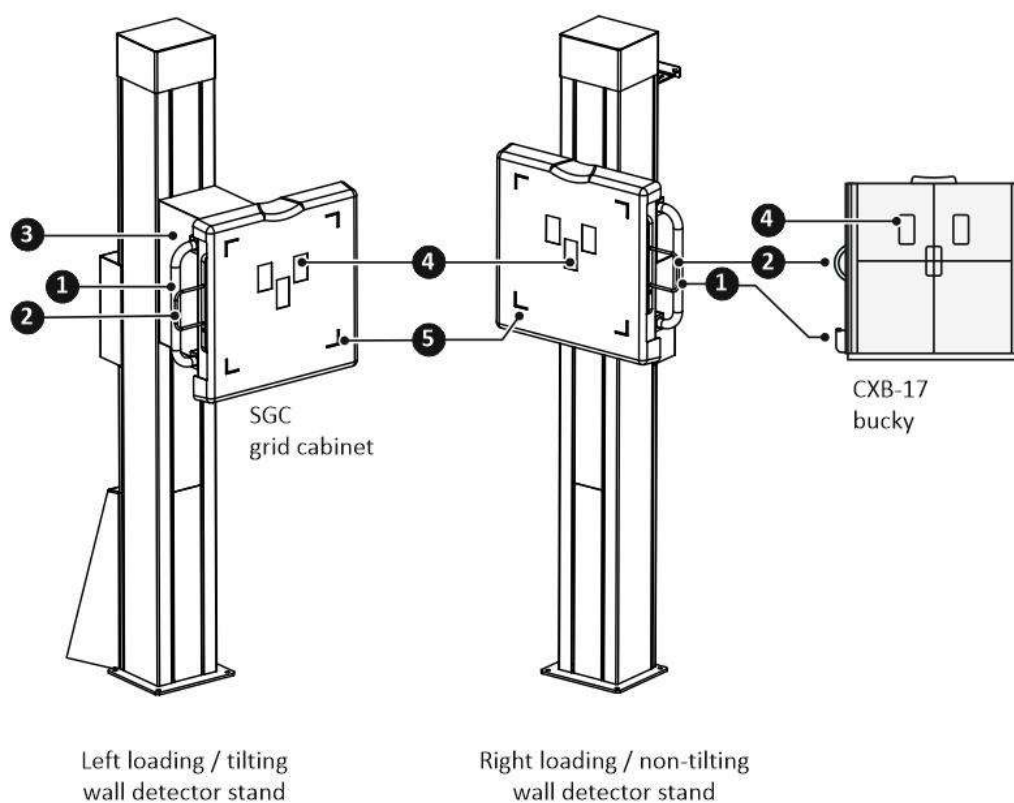
ATTENTION!

4.6 WS99N WALL BUCKY STAND

F100 F200 F300 F400 C100 C200 C300 C400

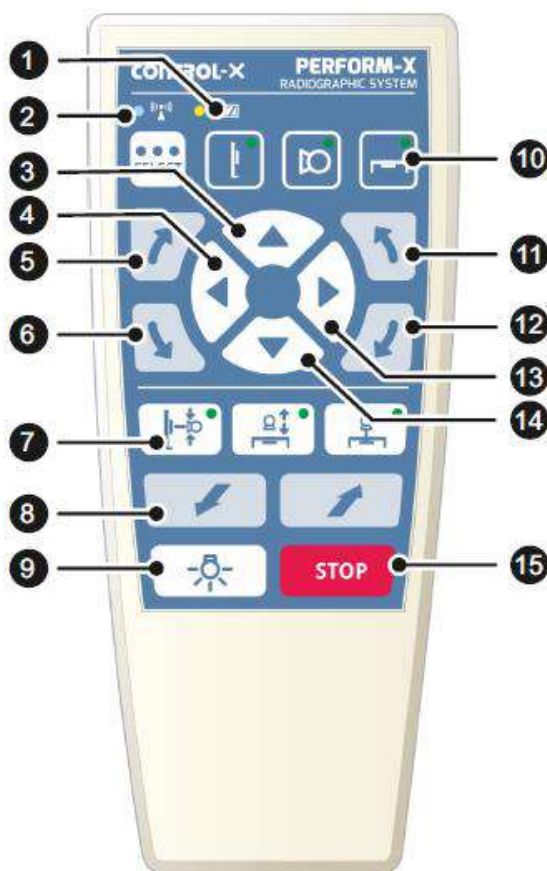
The wall bucky stand operator controls:

- vertical brake release pushbutton
- bucky tilt mechanical fastener (with option T-type and M-type tilting device)
- the handle of the cassette tray (film-based, CR or cassette size portable flat panel only)



- 1 VERTICAL brake release pushbutton
- 2 Detector CASSETTE HANDLE – *ONLY for film-based, CR or DR portable detectors*
- 3 Detector TILT release – *ONLY with option T-type tilting device (manual)*
- 4 AEC field markers
- 5 IMAGE edge indicators

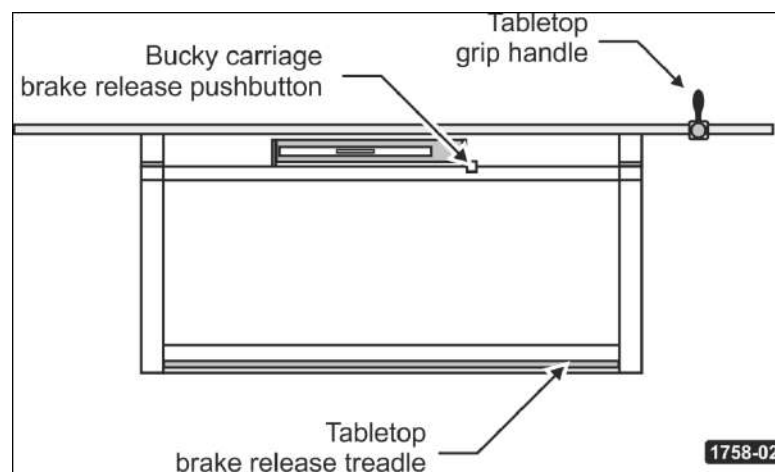
4.7 REMOTE CONTROLLER



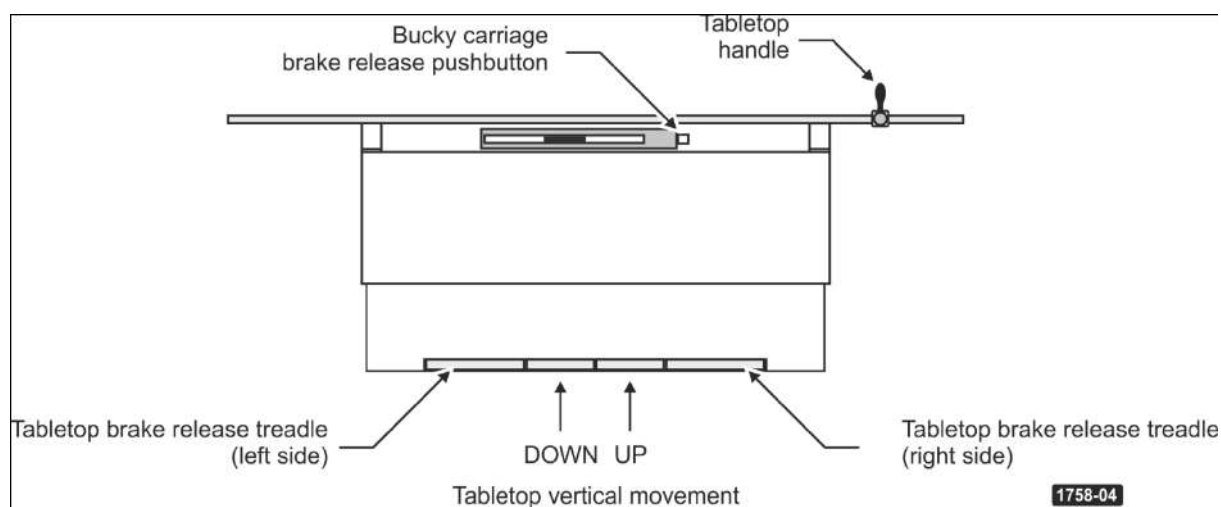
- 1 Battery low indicator / charging (*Bluetooth wireless type only*)
- 2 Connection status (*Bluetooth wireless type only*)
- 3 Vertical movement control (UP) for tabletop / X-ray tube / wall receptor
- 4 X-ray tube or table receptor longitudinal movement control (LEFT)
- 5 X-ray tube rotation around the horizontal axis (CLOCKWISE)
- 6 X-ray tube rotation around the horizontal axis (COUNTERCLOCKWISE)
- 7 Automatic movement functions enabled/disabled
 - Wall stand auto-tracking
 - Constant SID over the table receptor
 - Table receptor auto-centering
- 8 Transversal movement controls (FORWARD / BACK) for the X-ray tube
- 9 Collimator light field on / off
- 10 Equipment selection button with indicators (wall receptor / X-ray tube / table receptor)
- 11 X-ray tube pivot around the vertical axis (COUNTERCLOCKWISE)
- 12 X-ray tube pivot around the vertical axis (CLOCKWISE)
- 13 X-ray tube or table receptor longitudinal movement control (RIGHT)
- 14 Vertical movement control (DOWN) for tabletop / X-ray tube / wall receptor
- 15 STOP (cancels all motorized movement)

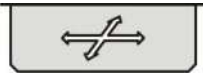
4.8 RADIOGRAPHIC TABLE

4.8.1 Stylix fixed height radiographic table:



4.8.2 Phoenix elevating radiographic table:

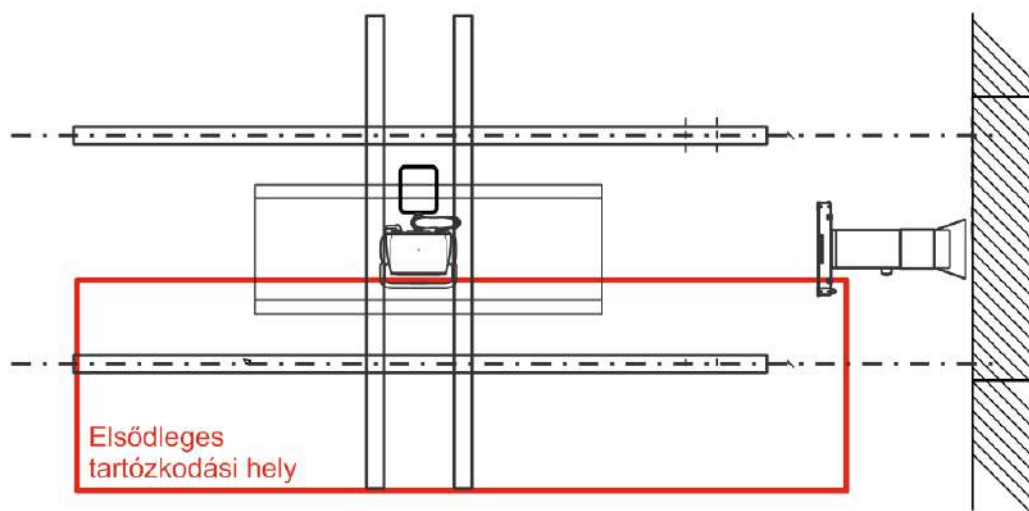
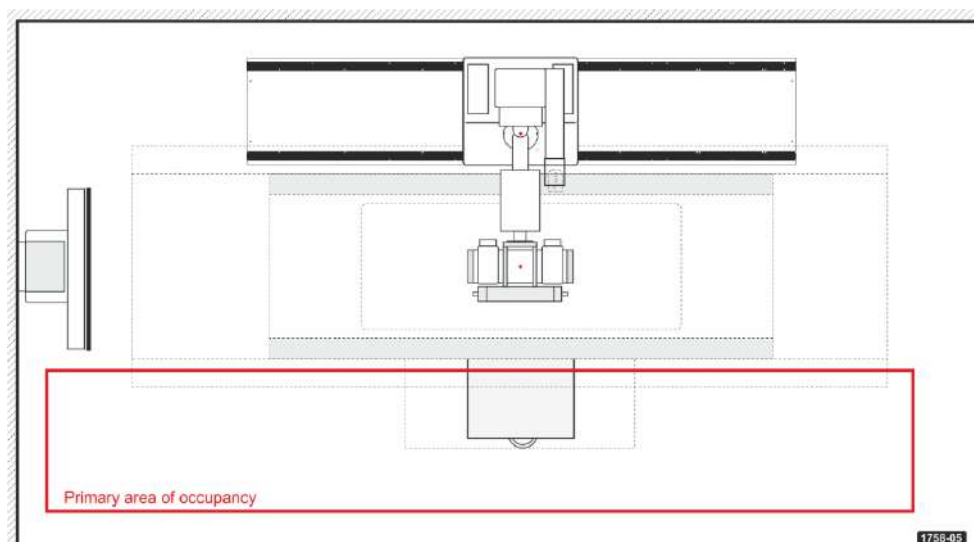


Symbol	Operation
	Foot pedal for tabletop LONGITUDINAL and TRANSVERSAL movement
	Foot pedal for UPWARD table motion
	Foot pedal for DOWNWARD table motion

	EMERGENCY STOP Switch Push it to fully switch off the table. Turn the knob to the right to switch the table back again.
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4.9 SIGNIFICANT ZONE OF OCCUPANCY

During operation, the significant zones of occupancy for the floor and ceiling mounted systems are as follows:



The following operations are performed in the significant zone of occupancy:

- Patient positioning;
- Radiation source and receptor positioning;
- Beam limiting;
- Removing / inserting grid and / or cassette as needed.

Exposure initiation is to be performed from a protected area at the X-ray generator console (this area is not shown – refer to the X-ray generator user manual for further information).

5 USING THE PERFORM-X SYSTEM

5.1 TURNING ON/OFF

The system must be powered up from a main wall disconnect box (not supplied). Please contact your service representative for details.



CAUTION!

With the power turned OFF the tabletop is not fixed by the electromagnetic brakes and **may move without operating the movement controls**, including as a result of unintentional movements (e.g. when the equipment is leaned on).

The powered ON state is indicated on the:

1. E-box (system control box);
2. generator console;
3. tube stand console;
4. tube console SID / inclination displays and brake ON LEDs.

The Perform-X System does not need to be powered OFF between exposures. Following the general practice in radiology, the system is to be powered ON at the start of day and is powered OFF at the end of the day.

The system is usable immediately after power-up, there is no need to wait for warm-up or special initialization / calibration procedure.



WARNING!

Reconnect (power ON) the mains only after safe usage conditions are ensured.

Most moving / movable parts, like the detector holders and X-ray tube (with the exception of the tabletop) are secured with permanent electromagnetic brakes. These brakes will hold the moving parts securely in place when the Perform-X system is powered OFF.

5.2 USING THE WALL STAND

5.2.1 Vertical Receptor Movement

The wall bucky is equipped with an electromagnetic brake to fix the receptor in the desired position. For vertical position adjustment, press the brake release pushbutton located on the side of the bucky or in the bucky handle. Release the pushbutton once the bucky is in the desired position.



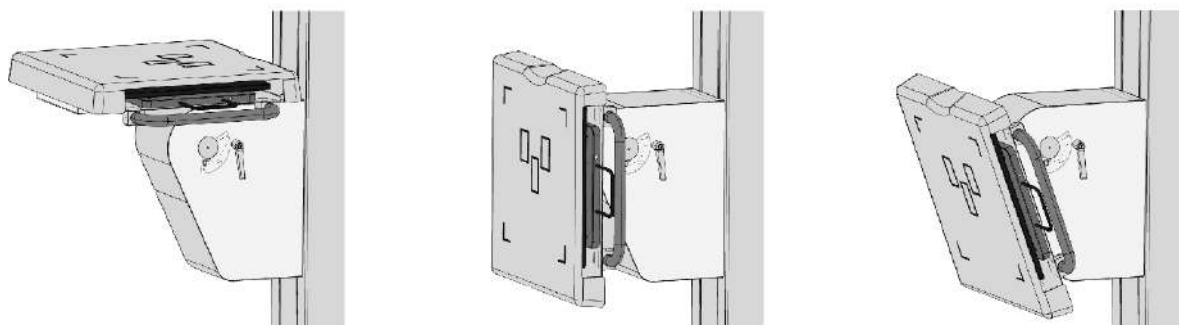
CAUTION!

Use caution when releasing the brake as **counter-balancing** of the wall detector holder **may be off** and the detector holder or the X-ray tube may suddenly start moving up or down. Counter-balancing will also be different with the **portable receptor and / removable grid in and out** of the holder.

5.2.2 Wall Bucky Tilting (with option T-type and M-type tilting device)

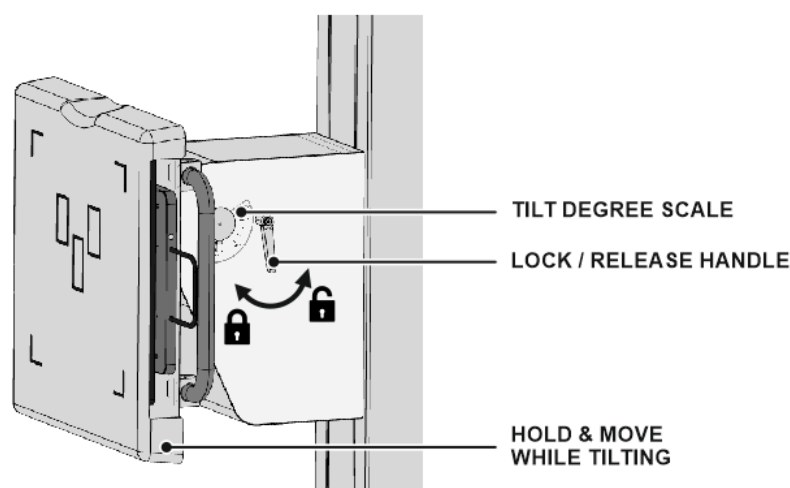
The tilt of the detector can be adjusted between +90 and -25 degrees.

- +90°: receptor is horizontal;
- 0°: receptor is vertical;
- -20°: receptor lower edge closer to column (oblique position).



Wall stand receptor tilt positions: +90° / 0° / -20° (manual version shown)

Manual tilting mechanism operation (with option T-type)



Manual tilt mechanism

1. Release the handle by turning it counter-clockwise while holding the receptor holder at the bottom. The receptor holder is counterbalanced in the entire tilt range, but the presence or lack of the grid and cassette may result in slight imbalance.
2. Tilt the receptor holder. The degree of tilt can be read on the tilt scale next to the handle. The +90°, 0° and -20° positions of the receptor holder are marked with mechanical detents.
3. Fasten the handle by turning it clockwise once the desired tilt is adjusted.

5.3 USING THE RADIOGRAPHIC TABLE

5.3.1 Tabletop Positioning

The radiographic table is equipped with electromagnetic locks, which hold the tabletop in the required position. To release the locks for repositioning a patient, activate the foot pedal marked with the four-way arrow (Phoenix elevating table) or on the single foot treadle (Stylis fixed height table).

While moving, the tabletop automatically stops in its transversal center position. After about three seconds you can move the tabletop further if you desire. For easier positioning, use the handgrip inserted in the tabletop accessory rail. The location of the handgrip can be adjusted by releasing the grip with the knob and sliding to position in the rail.



ATTENTION!

To prevent accidental movement, the Phoenix table can be configured to release the brakes **only after stepping on the foot pedals twice** (double-kick feature). Please contact your service representative to activate / deactivate this feature.

5.3.2 Vertical Tabletop Positioning (*Phoenix elevating table only*)



To control the vertical movement, press one of the vertical foot control pedals to move the table up or down. The table moves in the desired direction until it reaches the radiographic position where it stops automatically for approximately 3 seconds. If you do not desire to move the table further, simply remove your foot from the foot pedal. Otherwise the table will resume moving after the three seconds elapse.

The radiographic position is an optimal height where radiographic exposures can be conveniently taken.



WARNING!

To prevent accidental movement, the Phoenix elevating table can be configured to release the brakes **only after stepping on the foot pedals twice** (double-kick feature). Please contact your service representative to activate / deactivate this feature.

The Phoenix elevating table features a safety mechanism to stop vertical (downward) movement when the tabletop touches with an object in its path (e.g. wheelchair).

NOTE (PHOENIX 2 elevating table ONLY):

Upon touching an obstruction while moving downward, the Phoenix 2 table will automatically stop and move upwards about 2 centimeters for additional safety.

By default, exposures can be initiated at any table height. Upon request, the Phoenix table (*PHOENIX 1 table ONLY*) can be configured to provide an interlock to allow exposures only at a specific height (radiographic position), which is selectable during installation. The recommended tabletop-floor distance for the radiographic position is 750 mm.

Please note that the vertical travel is disabled if activating both up and down direction pedals at the same time.



The Phoenix elevating table is not designed for continuous vertical movement operation. To prevent damage to the equipment and to reduce risk of fire, the table can only be moved for a **maximum of 60 seconds every**

WARNING! **5 minutes.** (There must be a 4 minute pause after each 1 minute movement, giving a 20% duty cycle.). See warning label located on the side of the Phoenix radiographic table.



WARNING!

When driving the table down, the front cover of the table will approach the operator's foot to 55 mm. The Phoenix table provides a **loud audible warning sound** (beeping) when the table is within 100 mm of the foot pedal while moving down.

5.3.3 Positioning the Table Receptor

The Phoenix table is shipped with a cassette tray for portable receptors or a fixed detector built in the bucky or grid cabinet. Use the release pushbutton to disengage the magnetic lock and move the receptor to the desired position. The release pushbutton is a momentary switch – to lock the receptor in the required position, release the button.

5.3.4 Removing or Replacing the Grid (optional)

In some configurations, the anti-scatter grid may be removed (e.g. for hand / wrist and similar studies). To remove the grid, slightly lift the grid frame and pull it out. To insert the grid, slowly slide in the grid frame and once it is completely inserted, push it down to lock it in place.



WARNING!

Note that **when removing the anti-scatter grid, the patient dose is increased** and the image quality may degrade due to the scattered radiation.

The absence of the grid is clearly visible in the grid slot.

5.4 WORKING WITH FIXED AND PORTABLE RECEPTORS

5.4.1 Fixed Receptors

FIXED, non-removable receptors (DR detectors / flat panels) are typically used in wall stands. The active (image) area of most fixed receptors is 43 x 43 cm. Rotation of the receptor between portrait and landscape orientation is not necessary and not possible. *Please contact your service representative about manually or automatically rotating the acquired images using the image acquisition software.*

5.4.2 Cassette Trays

For portable / removable receptors, the receptor holders (bucky or grid cabinet) on the wall stand and in the table may be equipped with a versatile CASSETTE TRAY, which can hold a number of different sized films / CR cassettes from 13 to 43 cm. To insert the cassette, pull it out, open the cassette locks and place the cassette in the center of the tray. The cassette is fixed in position once the locks are released.

5.4.3 Docking Stations

For 35 x 43 cm active area portable / removable receptors (especially for wireless DR flat panel detectors), the receptor holders (bucky or grid cabinet) on the wall stand and in the table may be equipped with a DOCKING STATION. To insert the cassette, pull it out, and push the far edge of the cassette against the 2 plastic retainers with springs and insert the opposite edge to the single fixed plastic holder in the center. The docking station tray can be rotated 90 degrees to allow portrait and landscape orientation. The portrait and landscape positions are locked in place with mechanical detents.



ATTENTION!

The docking station **tray shall only be pushed when locked in the landscape or portrait position**. Forcing the tray in any other position may result in damaging the receptor.



CAUTION!

Use caution when connecting the optional **charging cable** to a portable receptor **while in the cassette tray or docking station**. Make sure the cable does not obstruct equipment movement and is away from operator / patient traffic.

5.5 USING THE TUBE STAND



CAUTION!

Use caution when releasing the brakes as **counter-balancing** of the X-ray tube **may be off** and the X-ray tube may suddenly start moving up or down.

5.5.1 Adjusting the Beam Direction

Adjustment of the X-ray tube stand is performed in three steps:

- directing the X-ray beam to the required image receptor;
- centering the X-ray beam to the image receptor;
- setting the appropriate SID (source-to image-distance).

Directing the X-ray beam into vertical, horizontal and the optional transversal positions are the most frequently performed adjustments. The beam pointing vertically to the table receptor is the basic position of the X-ray tube.

The X-ray tube position is secured by electromagnetic brakes. To perform any positioning, press the appropriate brake release pushbutton. The brake release pushbuttons are located on the two sides of the tube stand console near to the handles within reach. The LED lights next to each brake release button are lit when the corresponding brake is ON (engaged).

5.5.2 X-ray Tube Rotation



The X-ray tube can be rotated around the horizontal axis. The rotating axis is perpendicular to the axis of the X-ray tube and crosses its focus point, when the tube is rotated around this axis the focus will not be set off.

Due to the inflexibility of the high-voltage cables, the X-ray tube can only be rotated approximately $\pm 120^\circ$ in both (right and left) directions.

The rotation of the X-ray tube can be fixed in any position by releasing the membrane switch (with an electromagnetic lock). Additionally, mechanical detents help to position the tube precisely in vertical and horizontal directions. The tube inclination is always available on the LED display of the tube stand console.

The mechanical detents of the arm rotation provide accurate main beam direction (0 and 90 degree) positioning. Contact your service representative for calibration in case the readouts are inaccurate in these positions.

5.5.3 Vertical and Horizontal Movement



The vertical and the horizontal position of the X-ray tube can be adjusted by pressing either of the three brake release buttons. The switches release, respectively, the horizontal, vertical or both brakes.

Upon reaching the desired position, release the switch to lock the tube stand and the vertical carriage.

The SID (source image distance) for both vertical and horizontal beam direction is displayed on the upper LED display of the tube stand console. The vertical / horizontal SID is automatically selected based on the tube rotation between 40...50°.

Please note that:

*For systems with option R or X type floor carriage – ROTATING COLUMN: The **SID measurement is not available for lateral exposures** (whenever the column is rotated from its default position over the table).*

*The **SID is always calculated horizontally or vertically** in perpendicular projection for oblique procedures. In such positions, the collimator tape measure used in the line of X-ray beam may yield a value different from the digital SID display.*



WARNING!

The digital SID display of the TS99N tube stand is NOT a primary measuring feature. Always make sure the proper SID is adjusted using the **built-in tape measure** of the collimator.

5.5.4 Transversal Movement (with T-type tube arm)



The transversal position of the X-ray source is adjustable by pressing the button marked with a diagonal arrow.

Upon reaching the desired position, release the switch and the movement will stop.

A mechanical detent helps to position properly the X-ray tube to the center of the table and wall detector. Be sure the receptor installed in the radiographic table is aligned with the center of the table. Under table exposures should be taken in the center position of the cross-arm (tube centered over the table).

5.5.5 Column Rotation (with R and X type floor carriage)

The column rotation of the tube stand allows taking lateral exposures on the table or even (when rotated 180°) vertical exposure on a stretcher or mobile X-ray table.

To rotate the tube stand, release the COLUMN ROTATION lock release and turn the X-ray tube stand column in the desired direction. Mechanical detents are located at 0, left 90° and right 90°. Once the column is out of the detent position and is between two detents, disengage the brake release button. Slowly turn the column towards the detent position. The column will automatically lock into position at the detent.

To direct the X-ray beam in the required position, the tube can be rotated independently of

the position of the column and the vertical and longitudinal travel can be activated at any time as well.

*Please note that after activating the column lock release, the **column stays unlocked for 3 seconds**. After 3 seconds, the locks will automatically activate for safety reasons and to protect the locking mechanism.*

5.6 TRACKING FUNCTIONS AND AUTOMATIC POSITIONING

F100 F200 F300 F400 C100 C200 C300 C400



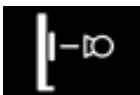
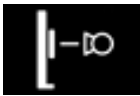
WARNING!

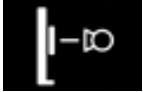
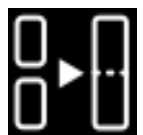
In order to avoid injuries and damage, before initiating any automatic movement on the system always make sure the movement area is clear (e.g. there is no risk of collision with patient or any object).

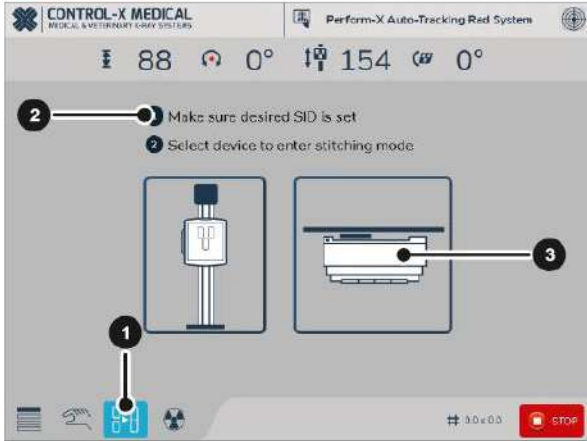
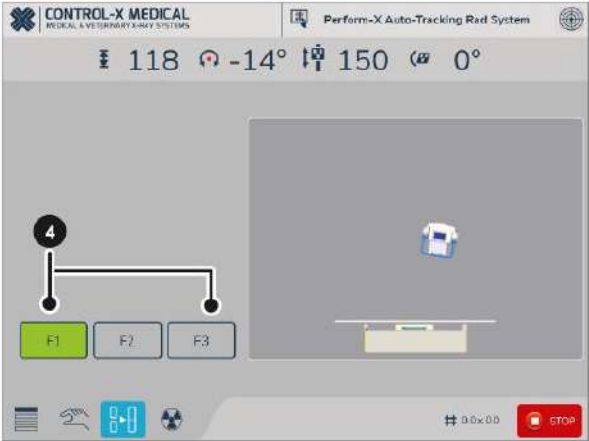
In case of emergency any system movement can be stopped by pushing the following buttons:

- Brake release buttons on the tube stand handle
- Stop button on the LCD display (if applicable)
- Stop button on the remote control (if applicable)

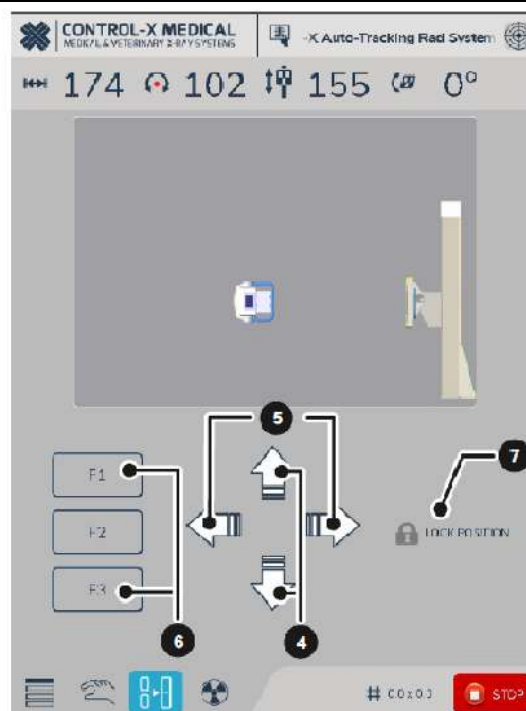
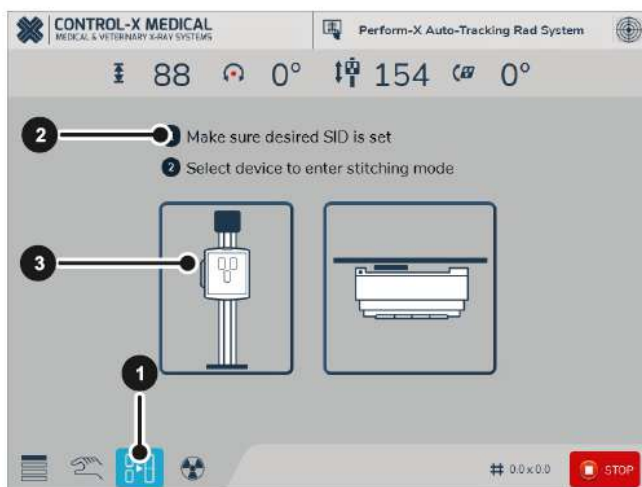
Based on configuration, the Perform-X system is equipped with a number of automatic tracking and positioning functions:

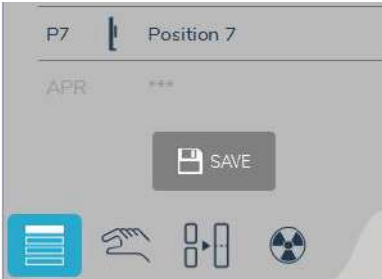
Function	Operation	System requirements
Wall detector: vertical auto-tracking 	The tube immediately follows the wall detector upon vertical movement. The X-ray beam is automatically centered with the detector center. <i>Works with horizontal X-ray beam only – not suitable for oblique projection centering.</i>	Auto Tracking or higher
Wall detector: two-way vertical auto-tracking 	a) The tube immediately follows the wall detector upon vertical movement. The X-ray beam is automatically centered with the detector center. b) The wall detector immediately follows the tube upon vertical movement. The detector is automatically centered with the X-ray beam center. The two device are equivalent, the functions can be simultaneously used (the manually controlled device is the temporary 'Master'). <i>Works with horizontal X-ray beam only – not suitable for oblique projection centering.</i>	- Auto Tracking or higher - Motorized vertical wall detector movement

Function	Operation	System requirements
Wall detector : 3D vertical auto-tracking 	a) The tube immediately follows the wall detector upon vertical movement. The X-ray beam is automatically centered with the detector center. b) The wall detector immediately follows the tube upon vertical movement. The detector is automatically centered with the X-ray beam center. c) When in oblique projection, changing the horizontal SID the X-ray tube centers with the detector The two device are equivalent, the functions can be simultaneously used (the manually controlled device is the temporary 'Master'). This tracking function can be used with any arbitrary beam-detector angle.	• Auto Tracking or higher • Motorized vertical wall detector movement
Table detector: vertical auto-tracking (constant vertical SID) 	While adjusting the table height, the X-ray tube follows the table top and keeps the original vertical SID constant. Can be used with both vertical and oblique beam directions.	• Auto Tracking or higher • Elevating radiographic table
Table detector: automatic detector centering 	When moving or rotating the X-ray tube, the motorized table detector automatically follows the beam center. Can be used with both vertical and oblique beam directions.	• Auto Tracking or higher • Elevating radiographic table • Bucky Auto Centering
Automatic horizontal stitching 	The horizontal auto-stitching positioning supports stitching together 3 images taken on the table receptor. The systems automatically positions the individual frames with an overlap. To achieve ideal stitched output, the frames are taken with a constant focal point. 1. Select the stitching screen tab 2. Make sure the desired SID is set 3. Select the Table detector as device 4. Select the position of the first image to be take (F1 / F3) (the button pushed will turn green) 5. At this point it is still possible to change SID with the footswitch of the table. If the SID is changed the previously selected frame button will turn gray again, so it is needed to be pushed again. 6. Make the first exposure. Once the exposure is taken, push F2 to move the system to the next position. 7. Make the second exposure. Once the exposure is taken, push F3. Wait for the system to position itself then make the last exposure.	• Motorized table detector • Motorized tube rotation • Stitching SW option • <i>Recommended: automatic motorized collimator</i>

Function	Operation	System requirements
Automatic vertical stitching 		
	The vertical auto-stitching positioning supports stitching together 3 images taken on the wall receptor. The systems automatically positions the individual frames with an overlap. To achieve ideal stitched output, the frames are taken with a constant focal point. 1. Select the stitching screen tab 2. Make sure the desired SID is set 3. Select the Wall stand as device 4. Set the height of WS for the first frame according to patient height 5. If needed, SID distance also can be adjusted 6. Select the position of the first image to be taken (F1 / F3) (when pushed, the button turns blue) 7. Push Lock position button. After this button is pushed, it is not possible to change height or SID (the button for the actual frame turns green). <i>Note: If the setting is not correct for the desired examination, click on any icon (other than stitching screen) on the bottom left corner then start again from step 1.</i> 8. Make the first exposure. Once the exposure is taken, push F2 to move the system to the next position. 9. Make the second exposure. Once the exposure is taken, push F3. Wait for the system to position itself then make the last exposure.	• Auto Stitching or higher • Motorized tube rotation • Wall Detector movement • Auto Stitching SW option • <i>Recommended: stitching stand</i> • <i>Recommended: automatic motorized collimator</i>

Function	Operation	System requirements
APR Auto Positioning	The X-ray tube and the detector moves into a default position according to the APR selected inside the generator control software on the workstation. When using an automatic collimator, the light field size is also programmable. In case this function is enabled, the P8 position on the preferred position screen becomes an APR position. The APR position has three states: • Until there is no new APR selection after the startup the APR row is disabled (gray coloured) • If an APR program was selected on the workstation, the APR position will get the same name as the APR program inside the APEX software. Until it is not saved, the name will be displayed in blue colour. After saving it will became red. • In case an already saved APR is selected inside APEX, the APR name will automatically displayed in red, so there is no need to save it again. In order to move the system components to the position that is determined by the APR, click on the triangle in the equipment position display	• APEX (v18.1 or later) software with CXGI interface enabled • Remote APR Option • <i>Recommended: automatic motorized collimator</i>



Function	Operation	System requirements
		

5.7 POSITIONING THE PATIENT



WARNING!

During positioning the patient, always **wear appropriate protective devices** according to procedures prescribed by your healthcare institution.

Adjust the position of the patient / body part according to the exposure and projection.

5.7.1 Wall Bucky Exposures

Recommended procedure:

1. Adjust the film-focus (source-image) distance;
2. Release the wall receptor brake using the brake release pushbutton and move the receptor vertically into the approximate exposure height;
3. (In case of tilting receptor) adjust the tilt angle of the receptor if necessary. The tilt angle is indicated on the inclination scale located on the tilting mechanism;
4. Adjust the patient into the desired position and set the final receptor height. Make sure that the region of interest is centered on the receptor;
5. When performing chest studies / screening, use the chin rest located on the top of the bucky or grid cabinet;
6. After positioning the patient, adjust the center and the size of the beam using the collimator.

5.7.2 Table Exposures

Recommended procedure for table exposures:

1. If necessary, move the X-ray tube aside so that the patient can easily and safely climb onto the table;
2. In case of Phoenix table, adjust the table height for convenient patient transfer onto the table (especially for elderly and disabled patients);
3. (*Phoenix only*) After positioning the patient, move the tabletop into the vertical exposure position (the tabletop automatically stops for convenient default exposure height);
4. Adjust the SID, the beam center and light field size. Use the tabletop longitudinal and transverse movements as necessary;
5. Make sure that the receptor is centered using the centering line of the collimator.

When working with portable digital detectors or film / CR cassettes, it is possible to take exposures directly on the tabletop (e.g. extremities studies). In this case, the SID scale located

higher on the tube stand column must be observed for SID distances (except for special procedures).

The recommended procedure for on-the-tabletop exposures:

1. If necessary, move the X-ray tube aside so that the patient can easily and safely climb onto the table;
2. In case of Phoenix table, adjust the table height for convenient patient transfer onto the table (especially for elderly and disable patients);
3. *(Phoenix only)* After position the patient, move the tabletop into the vertical exposure position (the tabletop automatically stops for convenient default exposure height);
4. Position the cassette / detector under the region of interest as desired;
5. Adjust the SID, the beam center and size. Use the tabletop longitudinal and transverse movements as necessary.

5.8 TAKING EXPOSURES

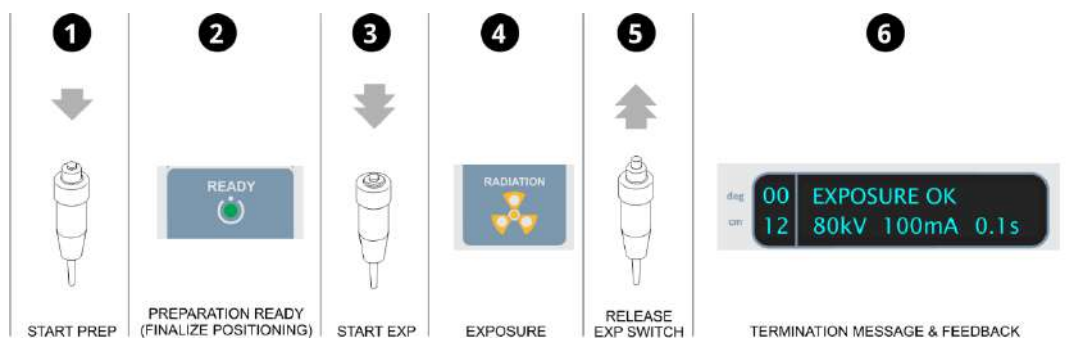
Depending on system configuration, the X-ray parameters can be monitored and adjusted:

- on the image acquisition workstation screen (in exposure mode);
- on the dedicated generator control console (e.g. Milestone or CMP-200 desktop console) or
- on the tube stand 10" LCD touch screen display *(requires LCD Console and integrated generator control sw. module)*.

Please refer to the generator operating instructions for details on APR selection and adjusting X-ray parameters.

The exposure can only be initiated using the 2-step exposure hand switch or the built-in PREP / EXP buttons on the dedicated generator control console.

1. Press the 2-step exposure hand- or footswitch. The first step prepares the generator and the X-ray tube for the exposure. The preparation ready state will be indicated by a visual and/or audible READY signal. Any final positioning (instructions to patient, controlling breathing etc.) should be done at this time.
2. Press the second step of the exposure switch to take an exposure. During the exposure, the yellow exposure symbol will light up on the console(s) and an audible signal will also be heard. **Make sure you do not release the exposure switch prematurely!**
3. Alternatively, if patient position is not required right before the exposure, the 2-step exposure switch can be pushed all the way at once, without pausing between the steps.
4. After the exposure, the measured feedback values and a termination (or error) message will be displayed on the generator console. The feedback message will be on display depending on generator type and setup. In case of any errors during the exposures, the error message will appear on the generator console. Contact your service representative and be prepared to give details on the error conditions and messages.
5. On DR systems, the image appears on the image acquisition workstation in a few seconds after a successful exposure. On CR and conventional X-ray systems, follow the CR / film processing protocol to develop the image.



Exposure sequence (Milestone generator control console indicators shown)



WARNING! The **exposure sequence can be interrupted immediately at any time** in case of an emergency, when patient movement is detected or if other problem occurs.

5.9 EXPOSURE INTERLOCKS

In certain situations, exposures may be disabled by an external interlock (e.g. tube overheat, door switch etc.). Refer to the X-ray generator user manual for further information.

5.10 ERROR MESSAGES AND ERROR CONDITIONS

The stands and radiographic table components of the Perform-X system do not have error message displays. For error messages and conditions related to the X-ray generator, please refer to the operating instruction shipped with the X-ray generator.

6 MAINTENANCE

The Perform-X radiographic system requires regular maintenance to ensure safe operation and to increase the operating life of the equipment. The operator shall check the equipment for functional defects or any deviation from the normal operation. In case of deviation, the unit shall be turned off and your service representative must be notified. The equipment shall not be used until the defect is repaired.

6.1 DAILY ROUTINE CHECK

Check the operating elements (X-ray tube, receptor, tabletop, brakes etc.) for proper functioning. In case of unusual noises or sounds while positioning or slower elevating speed (Phoenix table), contact your service company immediately.

6.2 WEEKLY CHECK

The floor rails must be clean for proper operation and smooth horizontal travel. If necessary, clean the rails with a lint-free cloth.

6.3 PERIODIC MAINTENANCE

To ensure safe and trouble free operation the system shall be checked by your service representative, at least annually. Please refer to the *Maintenance* section of the installation manual.



ATTENTION!

Each failing component which effects the safe operation of the equipment, shall be replaced with **original spare parts**.

Parts of the equipment are treated with anti-corrosion agents. To prevent wear, the manufacturer applied lubricants and under normal circumstances there is no need for further lubrication. Contact your service representative if lubrication becomes necessary.

6.4 CALIBRATION

Some of the components require periodic calibration:

- The X-ray tube must be calibrated every 12 months to compensate for tube aging and ensure accurate operation (refer to the X-ray generator technical manual for calibration instructions);
- If the system is shipped with a DAP (dose area product) meter, the DAP meter is factory calibrated. The calibration certificate is included in the DAP packaging. Recommended frequency of recalibration is 5 years and must be carried out based on the included DAP user manual.

For detailed information, please refer to the installation manual.

6.5 CLEANING AND DISINFECTION

The Perform-X System does not require special cleaning or sterilization. However, it is recommended to clean from time to time:

- the tube stand console and its handles;
- the tabletop;
- wall bucky / grid cabinet cover and brake release handles.

For cleaning without disinfecting, you may use mild soapy water or an equivalent cleaning solution. Apply some solution with lint free cloth or paper towel and wipe down the surface. If for some reason, the handles or other surfaces require disinfection, you may use Actichlor (contains Sodium Dichloroisocyanurate, a form of chlorine) or equivalent with a 3 to 5% Hypochlorite concentration.

Method of disinfection:

1. Turn OFF the system completely (using the wall disconnect switch);
2. Use 50/50 disinfectant / water solution;
3. Apply (e.g. spray) the disinfectant on a lint free cloth. Make sure the **cloth is only damp and not wet**;
4. **Do NOT apply the disinfectant directly** on the surfaces as the substance may get into the equipment;
5. Wipe the surfaces carefully with the cloth;
6. Before turning the equipment on again, make sure that the disinfectant has evaporated.



WARNING!

To clean / treat the surfaces, only **acid-free, non-corrosive, non-abrasive** substances shall be used.

Only such disinfecting methods shall be used that correspond to the relevant regulations and rules as well as the protection from explosion.

The use of disinfecting spray is not recommended because it can get inside the equipment.



WARNING!

Make sure that **no water or other liquids** enter any component of the Perform-X system. Such liquids may cause short circuit in electrical components and / or corrosion on surfaces.

7 DISPOSAL AND DECOMMISSIONING

X-ray machines do not present a radiation hazard when they are not in operation. However, many structural components are built with materials that may be considered hazardous (e.g., lead, tungsten) for disposal purposes. These materials must be segregated and disposed of according to the regulatory agency having jurisdiction.

Dismantling and disposing the X-ray equipment may be subject to **clearance by a radiological survey**.



WARNING!

All dismantling and decommissioning activities related to the Perform-X system must be performed by **organizations authorized** to perform such tasks.



WARNING!

During decommissioning and disposal, **serious injury may occur** when dismantling:

- The **glass inside the X-ray tube** may break and can cause injuries;
- Skin may come into contact with **hazardous substances** (lead, tungsten);
- **Weights and heavy parts** can become loose when disassembling.



WARNING!

The Perform-X is a permanently installed equipment with material that may contain **hazardous materials**. These include but are not limited to:

- Lead (in the X-ray tube and the collimator);
- Tungsten (in the X-ray tube);
- X-ray film and film processing agents (not supplied by the manufacturer).

REVISION HISTORY

Version	Date	Change	Pages
01	2020.07.03	Original version	Entire document
02	2020.09.11	Corrected typos and updated wording to 'receptor'	Several pages
03	2020.10.28	Added information for F200-400 and C100-C400	Several pages

PERFORM-X CLASSIC

RADIOGRAPHIC SYSTEM

SIMPLICITY, PERFORMANCE AND SAFETY

Designed to withstand the rigors of the heaviest of caseloads, the Perform-X Classic offers performance, quality and durability at an exceptional price. The system combines hospital-grade components, DR features, a selection of durable elevating or fixed height radiographic tables into a pragmatic solution for a complete modern radiographic suite.

An integrated, easy to use, state of the art acquisition system, with wide selection of high-resolution digital receptors, provides superior image quality for quick diagnoses. A convenient, easily accessible fingertip control with digital display supports trouble free beam positioning and exposure preparation.

An anatomically programmed (APR), ultra-high frequency generator supports low-dose exposures and makes parameter set-up and preparation quick and easy. Optional Automatic Exposure Control (AEC) ensures optimum patient dose while providing excellent image quality.



Integrated generator control and image acquisition



Stylix 2 Fixed Height Table



THE PERFORM-X CLASSIC SYSTEM IS THE RIGHT SOLUTION FOR DIGITAL IMAGING ON A LIMITED BUDGET.

SPECIFICATIONS

TUBE AND WALL STAND

Vertical travel of x-ray tube (beam center):	35 cm - 185 cm / 14" - 73"
Vertical travel of wall receptor (centerline):	38 cm - 187 cm / 15" - 73 2/3"
Longitudinal travel of tube:	180 cm / 71" (with 247 cm / 97 1/4" rails), 290 cm / 114 1/4" (with 360 cm / 141 3/4" rails)
Fixed grid (optional bucky):	80 l/cm / 200 l/in, 10:1 ratio (other grids also available)

RADIOGRAPHIC TABLE PHOENIX 1 (ELEVATING) / STYLIX 2 (FIXED HEIGHT)		HIGH FREQUENCY GENERATOR	
Tabletop size:	220 cm x 81 cm (86" x 32") optional 185 cm / 73" length	Output Power:	32, 40 or 50 kW
Longitudinal travel:	110 cm / 43"	mA Range:	10-630 mA
Transverse travel:	±12 cm / 4 3/4" (optionally ±14 cm / 5 1/2")	kVp Range:	40-150 kV
Vertical travel range (Phoenix 1):	55 cm – 85 cm / 21 2/3" - 33 1/2"	Stored energy generators are available up to 50 kW power	

X-RAY TUBE	COLLIMATOR
300 kHU 0.6-1.2 mm focal spots (other tubes available)	Manual, Laser Guided LED collimator

DIGITAL DETECTORS

Detector options:	43x43 cm / 17"x17" or 35x43 cm / 14"x17" fixed or wireless panels with various resolutions available
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INTEGRATED GENERATOR CONTROL AND IMAGE ACQUISITION

- Single console seamless workflow
- Full DICOM compatibility
- Optional integrated DAP reporting
- Sophisticated image processing features
- Grid suppression or gridless imaging
- Detector status indicators
- Optional Mini PACS is available



SYSTEM FOOTPRINT		POWER REQUIREMENTS (SYSTEM)	
Space requirement:	8 m ² ; 2.5 m x 3.2 m (86.1 sq. ft.; 8.2' x 10.5') with 247 cm (97 1/4") rails, without generator 12.5 m ² ; 2.5 x 5 m (134.5 sq. ft.; 8.2' x 16.4') with 360 cm (141 3/4") rails, without generator	Input Line Voltage: (Your input line voltage may limit the generator power)	1x230V (15A) for stored energy generators 3x230V / 3x400V for three-phase generators
Ceiling height requirement:	245 cm / 96 1/2"		

CERTIFICATIONS

ISO 13485, CE marked and FDA cleared



Please contact us at sales@cxmed.hu
or sales@cxmed.com.

Perform-X Classic System Info Sheet – Version 1.0 – July 2020

Authorized reseller:

PERFORM-X F100 ADVANCED MANUAL RADIOGRAPHIC SYSTEM



The F100 manual setup stuns with its sleek design and advanced features such as digital SID measurement. It can also be customized with a range of available options.

KEY FEATURES:

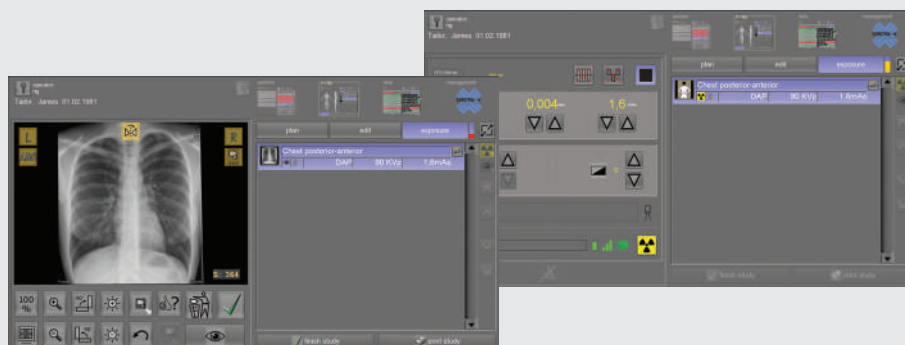
- longitudinal and vertical SID measurement
- manual vertical movement of X-ray tube assembly
- manual horizontal movement of tube stand
- manual tube rotation on the horizontal axis
- manual vertical movement of wall stand
- motorized elevating radiographic table
- optional motorized table receptor auto-centering
- optional manual column rotation
- optional manual transverse tube arm movement
- optional manual receptor tilting for wall stand



We also offer a choice of components such as digital panels, grids, X-ray tubes, collimators, AEC chambers, DAP meters, etc.

INTEGRATED GENERATOR CONTROL AND IMAGE ACQUISITION

- Single console seamless workflow
- Full DICOM compatibility
- Optional integrated DAP reporting
- Sophisticated image processing features
- Grid suppression or gridless imaging
- Detector status indicators
- Optional Mini PACS is available



SPECIFICATIONS

HIGH FREQUENCY GENERATOR

Output Power:	32 – 80 kW
mA Range:	10 – 1000 mA
kVp Range:	40-150 kV
Stored energy generators are available up to 50 kW power.	

X-RAY TUBE

300 kHU 0.6-1.2 mm focal spots (other tubes available)

COLLIMATOR

Manual or Automatic, Laser Guided LED Collimator

DIGITAL DETECTORS

Range of standard cassette sized fixed or wifi panels

GRID

Non-oscillating, 215 lp/inch, 10:1 ratio
(other grids also available)

MECHANICAL DATA AND MOVEMENT RANGES

Recommended room height:	240 cm (depends on vertical travel of tube stand)	Recommended room size:	2,5 m x 3,2 m
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TS99(N) FLOOR-MOUNTED TUBE STAND (X-RAY TUBE)

PHOENIX 2 ELEVATING TABLE (TABLE TOP)

Vertical travel:	154,5 cm (Option: +20cm)	Table top height:	45-90 cm
Vertical movement speed:	15 cm/sec	Vertical movement speed:	2,2 cm/sec
Min. / Max. focus to floor distance:	33,5 / 188 cm	Size (patient surface):	220 x 81 cm
Longitudinal travel (Fix / Rot. Column):	177 / 161 cm (Option: 290 / 274 cm with 360 cm rails)	Longitudinal travel:	60 / 50 cm
		Transverse travel:	+ / - 12,5 cm
Transverse travel "T" version (option):	+ / - 10,2 cm	Table top - image receptor distance:	7 cm
Rotation (around horizontal axis):	330°	Table weight rating:	250 kg
Rotation (around vertical axis – option):	+/-180°	Table detector horizontal travel:	61 cm

WS99(N) WALL STAND (DETECTOR)

Tilt (option):	90° / -25°	Vertical movement speed:	15 cm/sec
Mounting:	Wall & Floor (Option: floor-only)	Min. / Max. center to floor distance:	30 / 183 cm
Vertical travel:	153 cm (Option: +20cm)		

CERTIFICATIONS

ISO 13485, CE marked and FDA cleared



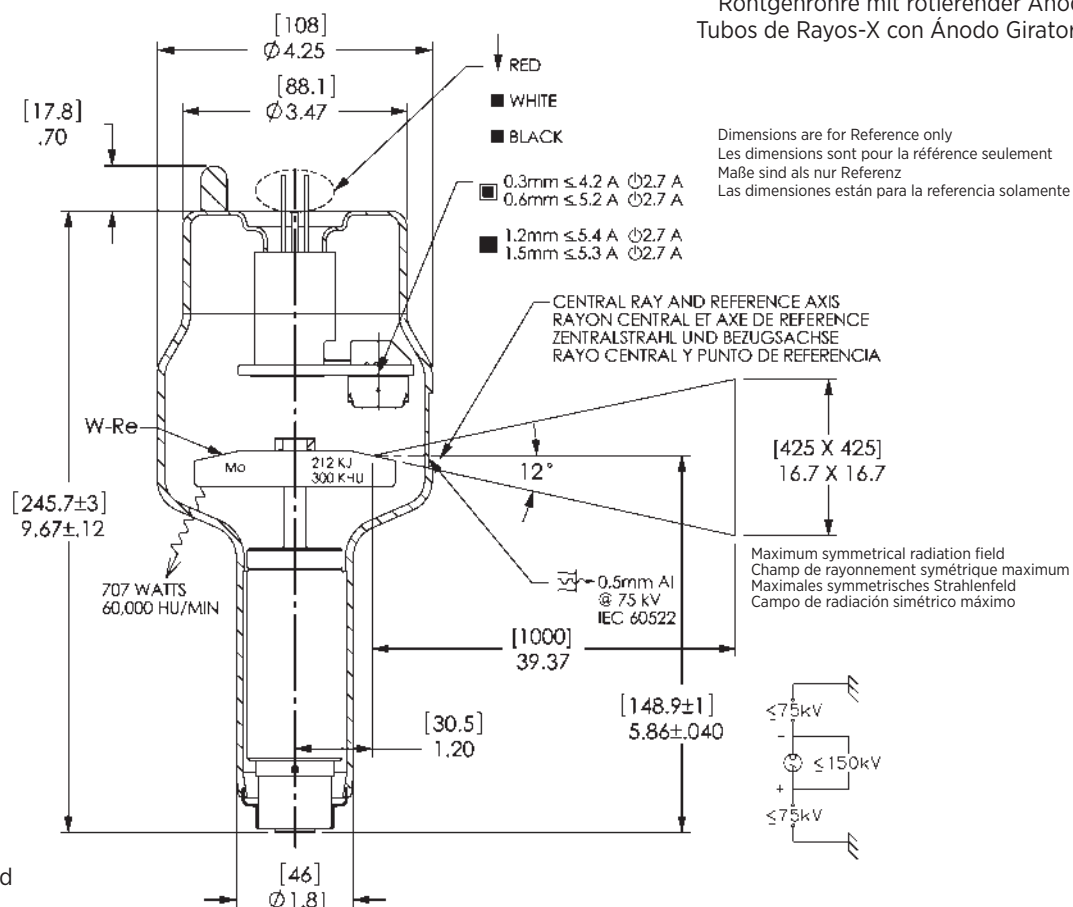
Please contact us at sales@cxmed.hu
or sales@cxmed.com.

F100 Radiographic System Info Sheet – Version 1.0 – April 2021

Authorized reseller:

Rotating Anode X-Ray Tube Tubes Radiogènes à Anode Tournante Röntgenröhre mit rotierender Anode Tubos de Rayos-X con Ánodo Giratorio

- Common - Red
Neutre - Rouge
Neutral - Rot
Común - Rojo
- Large - Black
Grand - Noir
Gross - Schwarz
Largo - Negro
- Small - White
Petit - Blanc
Klein - Weiss
Pequeño - Blanco
- Stand - By
Attente
Bereitschaft
En Espera
- Frame or Chasis
Masse
Chassis
Soporte o Chasis
- X-Ray Tube
Tube Radiogène
Röntgenröhre
Tubo de Rayos X
- Radiation Filter or Filtration
Filtre de rayonnement
Filterung
Filtración de Radiación



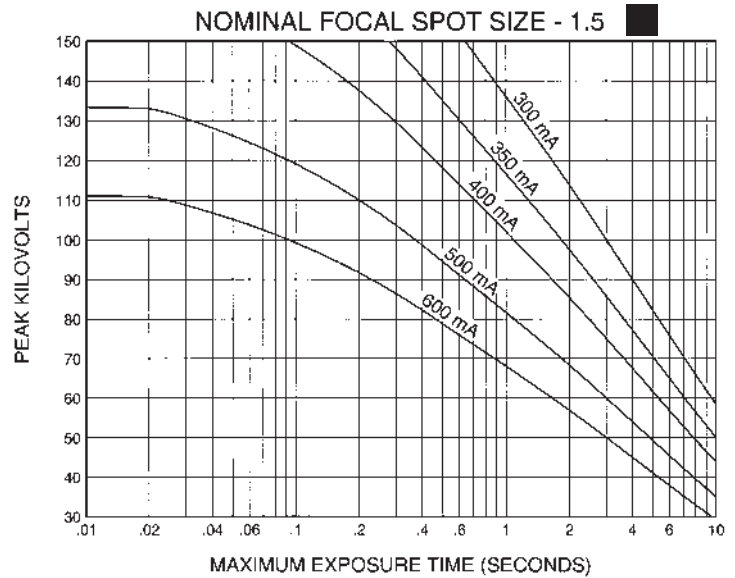
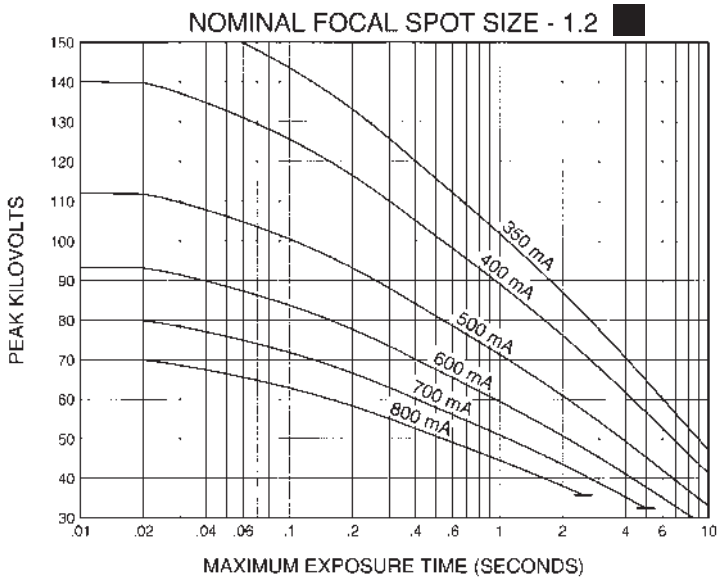
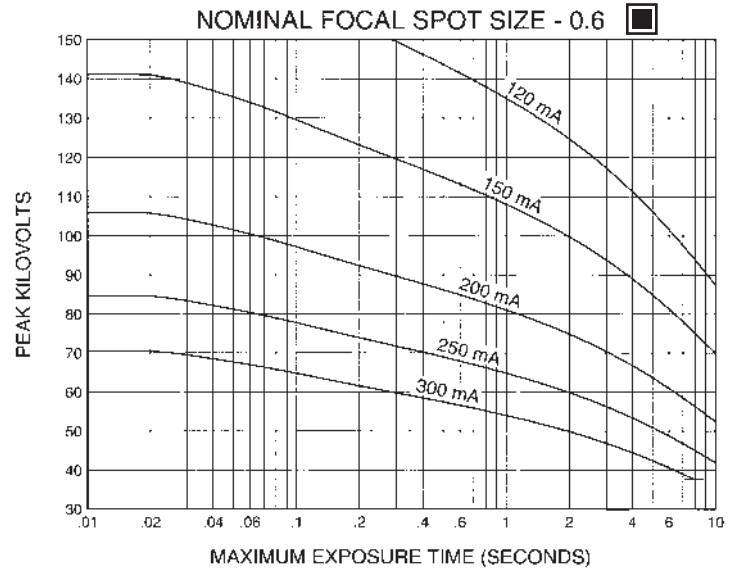
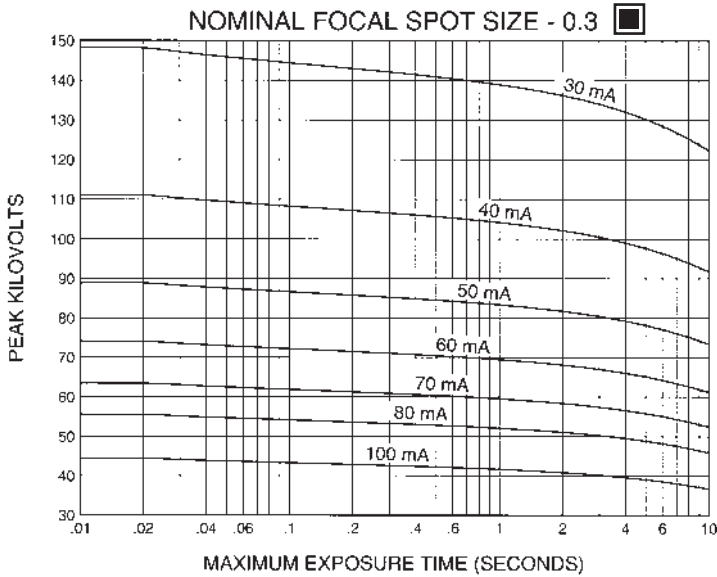
Note: Document originally drafted in the English language.

Product Description	Description du Produit	Produktbeschreibung	Descripcion del Producto
The RAD-14 is a 3" (80mm), 150 kV, 212 kJ (300 KHU) rotating anode insert specifically designed for general radiographic and fluoro/spotfilm procedures. The insert features a 12° tungsten rhenium molybdenum target and is available in the following focal spot combinations: 0.3 - 1.2 0.6 - 1.2 0.6 - 1.5 IEC 60336 Nominal Anode Input Power Small (0.3) - 7.5 kW IEC 60613 Small (0.6) - 32 kW IEC 60613 Large (1.2) - 77 kW IEC 60613 Large (1.5) - 95 kW IEC 60613 For the equivalent anode input power of 80 Watts	RAD-14 est un tube à anode tournante de 80 mm (3"), 150 kV et 212 kJ (300 KUC) pour usage spécifique en radiologie générale et radio-fluorographie sélective. Il contient une cible composite en tungstène, molybdène et rhenium, à pente de 12° et est disponible avec les combinaisons de points focales suivants: 0,3 - 1,2 0,6 - 1,2 0,6 - 1,5 CEI 60336 Puissance anodique nominale de l'anode Petit foyer (0.3) - 7.5 kW CEI 60613 Petit foyer (0.6) - 32 kW CEI 60613 Grand foyer (1.2) - 77 kW CEI 60613 Grand foyer (1.5) - 95 kW CEI 60613 Pour la puissance anodique d'équilibre thermique de 80 Watts	Die RAD-14 ist eine Röntgenröhre mit rotierender Anode von 80 mm (3"), 150 kV und 212 kJ (300kWE). Sie ist besonders geeignet für die allgemeine Röntgenaufnahme-technik, sowie auch für den Durchleuchtungs- und Zielgerätebetrieb. Die Röntgenröhre ist charakterisiert durch eine 12°-ige Anode, zusammengesetzt aus Wolfram, Rhenium und Molybdän. Folgende Brennfleck-kombinationen ist möglich: 0.3 - 1.2 0.6 - 1.2 0.6 - 1.5 IEC 60336 Nominale Anodenbezugsleistung Klein (0.3) - 7.5 kW IEC 60613 Klein (0.6) - 32 kW IEC 60613 Gross (1.2) - 77 kW IEC 60613 Gross (1.5) - 95 kW IEC 60613 Gilt bei einer Aequivalent - Anodenleistung von 80 Watt	RAD-14 es un tubo de ánodo giratorio de 80 mm (3"), 150 kV, 212 kJ (300 KHU) diseñado específicamente para procedimientos generales en radiografía y fluoroscopia. Consta de un objetivo de tungsteno, renio y molibdeno con 12° de pendiente. Disponible con las siguientes combinaciones de marcas focales: 0.3 - 1.2 0.6 - 1.2 0.6 - 1.5 IEC 60336 Potencia nominal de entrada del anodo Foco fine - 7.5 kW IEC 60613 Foco fine - 32 kW IEC 60613 Foco grueso - 77 kW IEC 60613 Foco grueso - 95 kW IEC 60613 Para una potencia equivalente del anodo de 80 Watts

3 Ø Constant Potential

Radiographic Exposure Charts IEC 60613
Abaques de Charge pour Pose Unique CEI 60613
Brennfleck - Belastungskurven IEC 60613
Diagramas de Exposición Radiográfica IEC 60613

50 Hz - 2,850 RPM



Nominal anode input power for the anode heat content 40%. IEC 60613

Puissance calorifique nominale de l'anode: 40%, CEI 60613

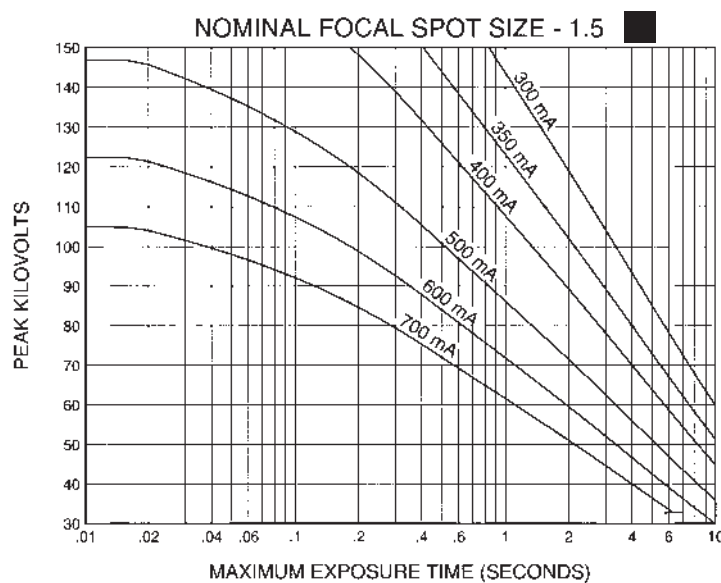
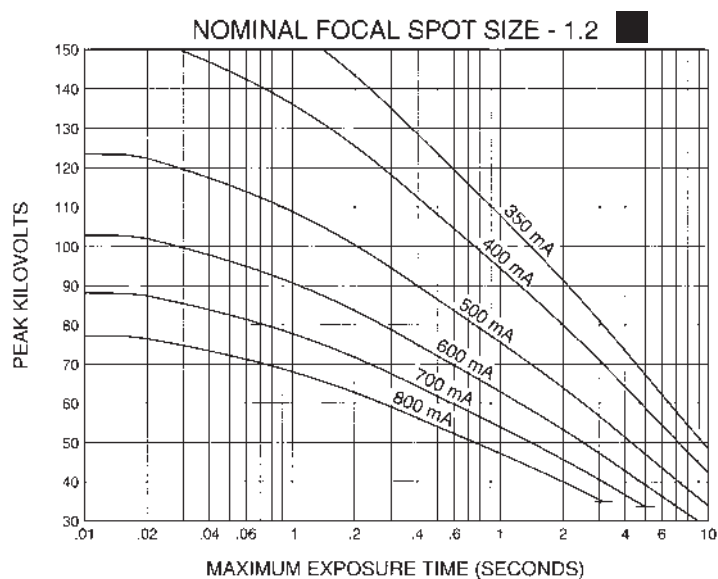
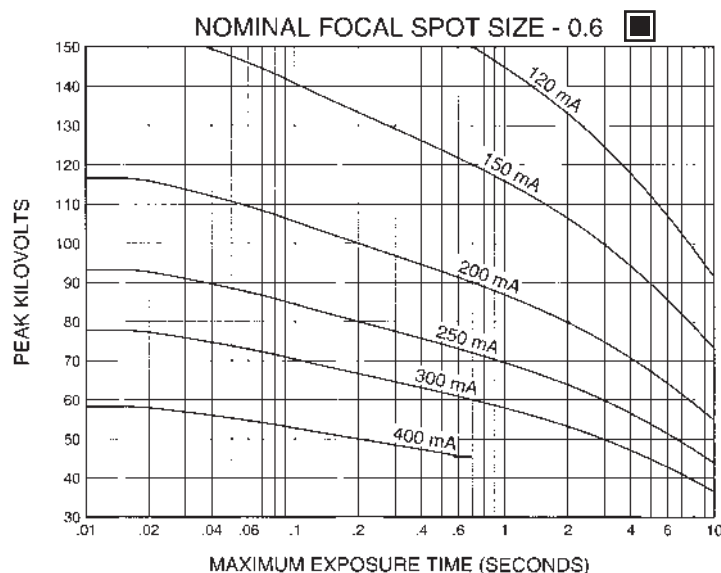
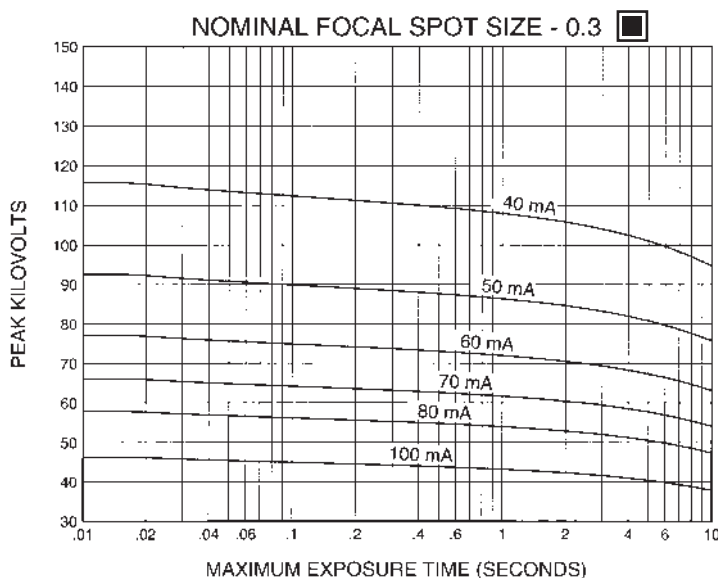
Thermische Anodenbezugsleistung bei einer Wärmespeicherung von 40%. IEC 60613

Aproximadamente el poder de penetración para obtener un almacenaje de calor del anodo de 40%. IEC 60613

3 Ø Constant Potential ==

Radiographic Exposure Charts IEC 60613
Abaques de Charge pour Pose Unique CEI 60613
Brennfleck - Belastungskurven IEC 60613
Diagramas de Exposición Radiográfica IEC 60613

60 Hz - 3,450 RPM



Nominal anode input power for the anode heat content 40%. IEC 60613

Puissance calorifique nominale de l'anode: 40%, CEI 60613

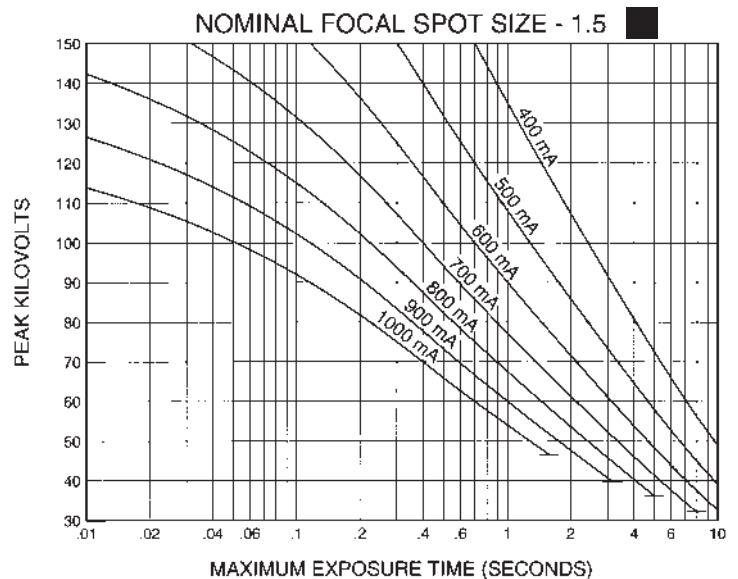
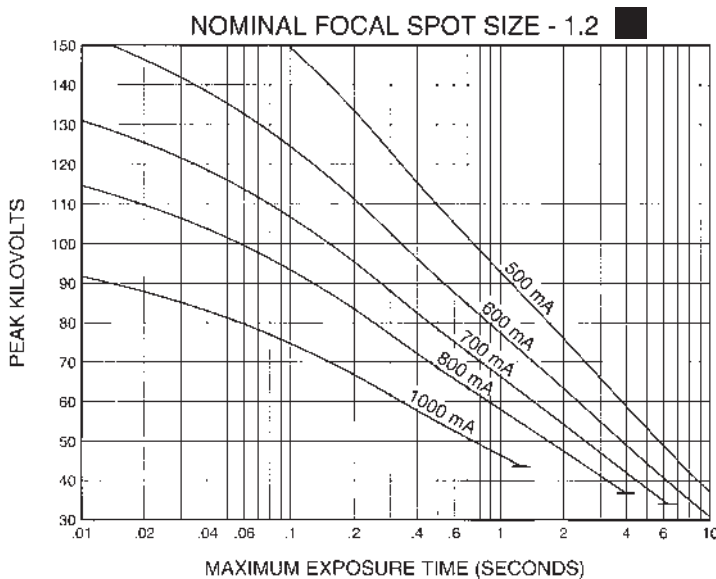
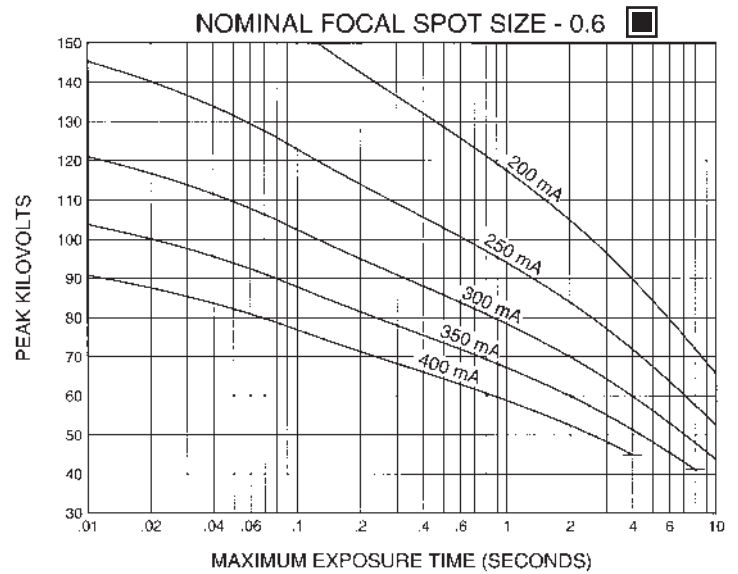
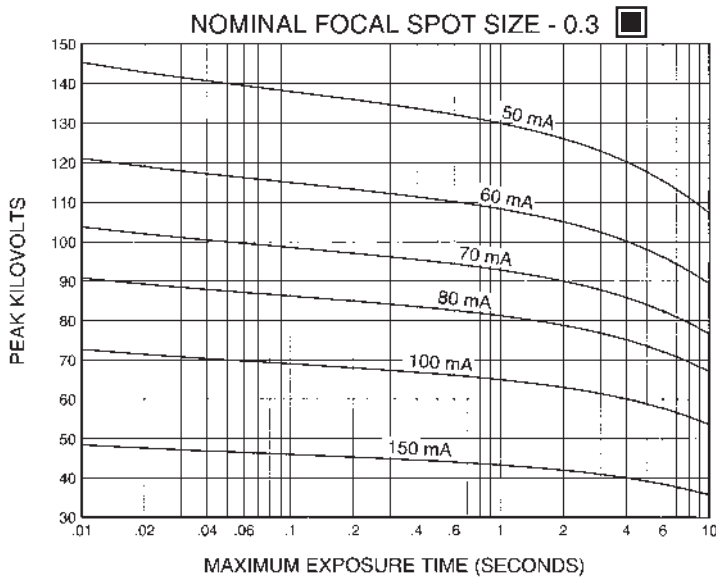
Thermische Anodenbezugsleistung bei einer Wärmespeicherung von 40%. IEC 60613

Aproximadamente el poder de penetración para obtener un almacenaje de calor del anodo de 40%. IEC 60613

3 Ø Constant Potential

Radiographic Exposure Charts IEC 60613
Abaques de Charge pour Pose Unique CEI 60613
Brennfleck - Belastungskurven IEC 60613
Diagramas de Exposición Radiográfica IEC 60613

150 Hz - 8,500 RPM



Nominal anode input power for the anode heat content 40%. IEC 60613

Puissance calorifique nominale de l'anode: 40%, CEI 60613

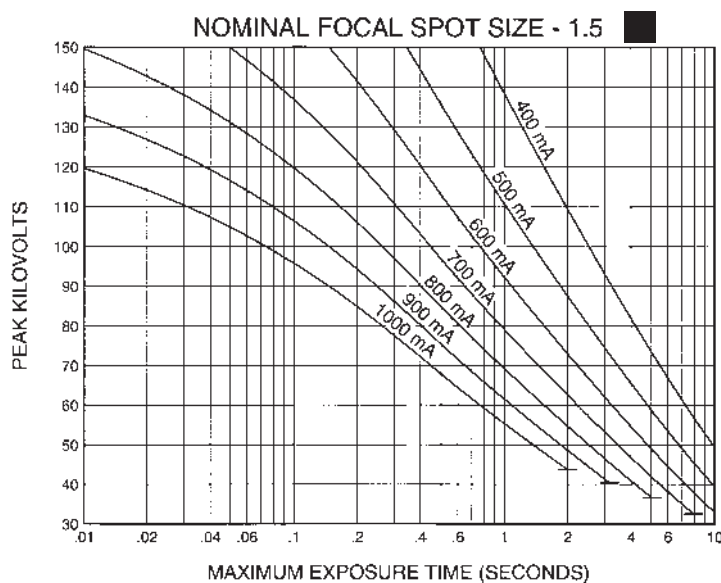
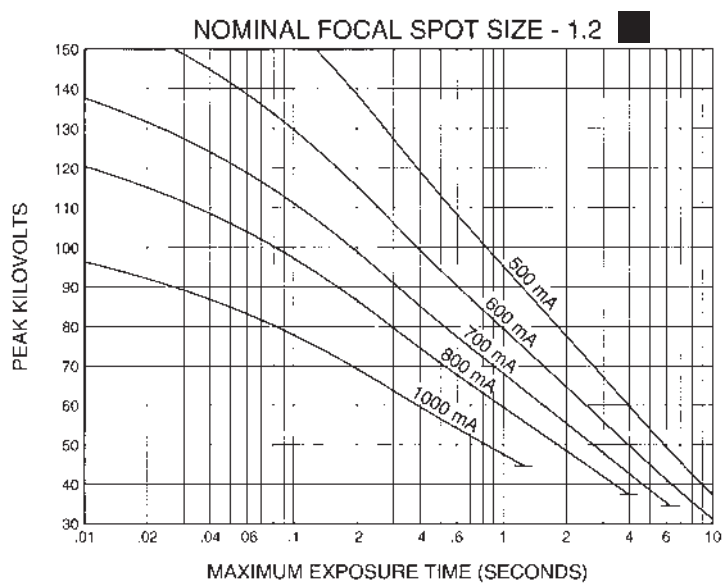
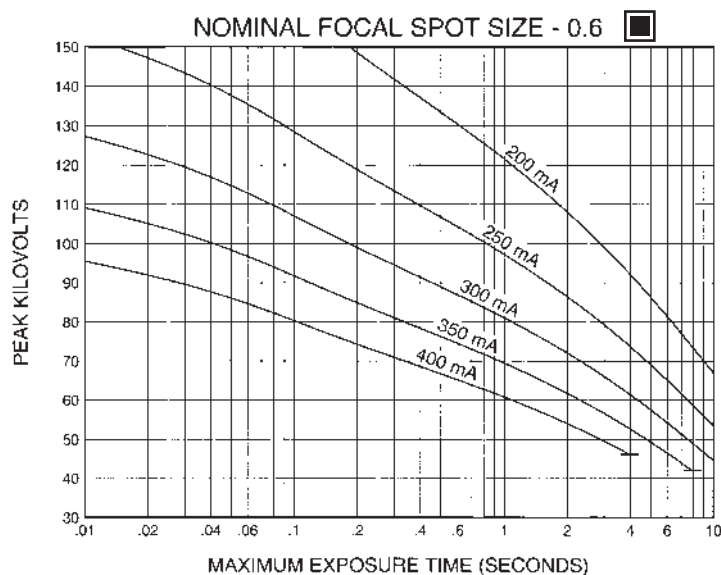
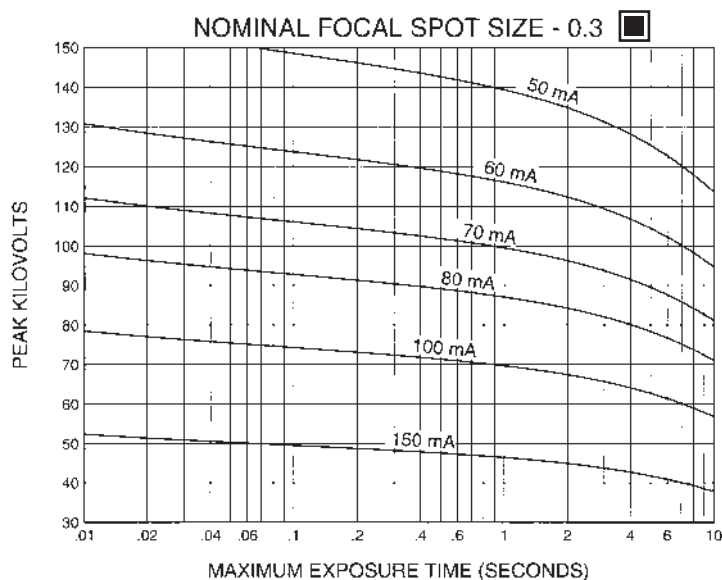
Thermische Anodenbezugsleistung bei einer Wärmespeicherung von 40%. IEC 60613

Aproximadamente el poder de penetración para obtener un almacenaje de calor del anodo de 40%. IEC 60613

3 Ø Constant Potential

Radiographic Exposure Charts IEC 60613
Abaques de Charge pour Pose Unique CEI 60613
Brennfleck - Belastungskurven IEC 60613
Diagramas de Exposición Radiográfica IEC 60613

180 Hz - 10,000 RPM



Nominal anode input power for the anode heat content 40%. IEC 60613

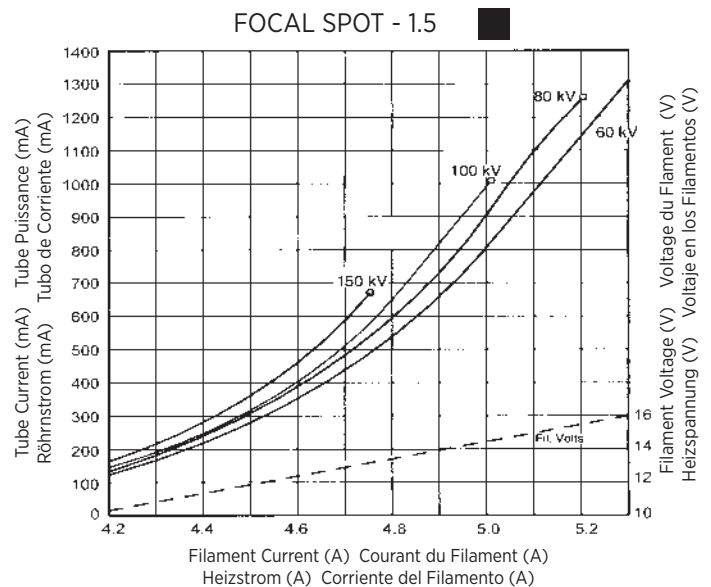
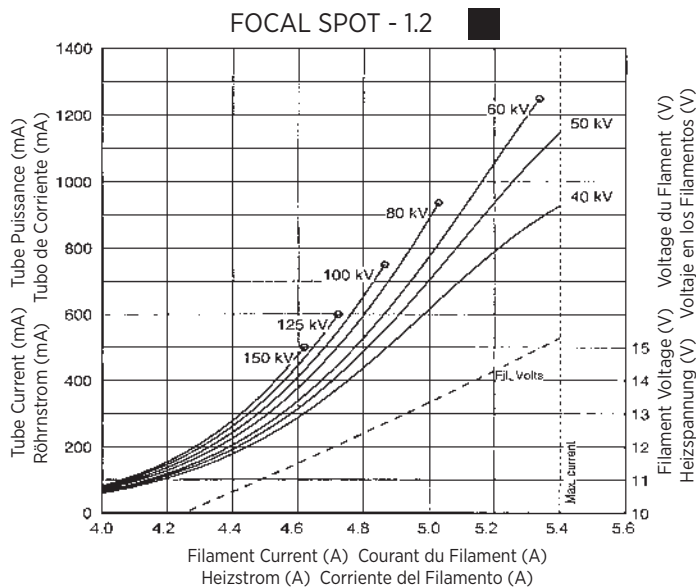
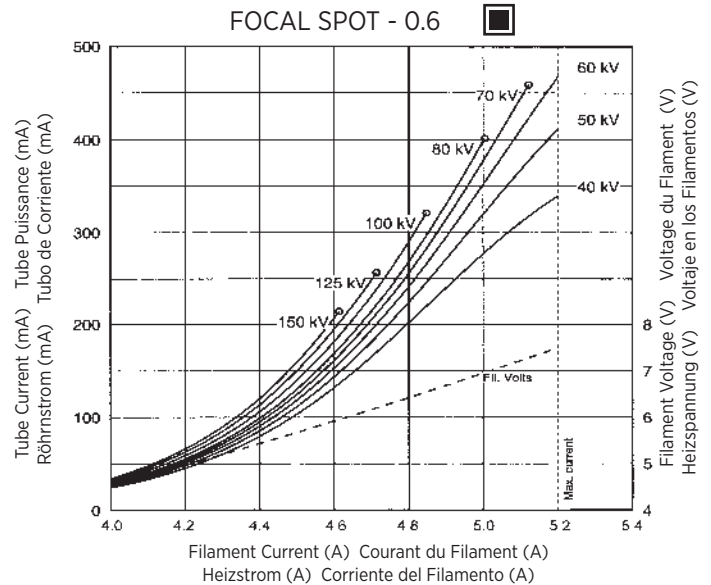
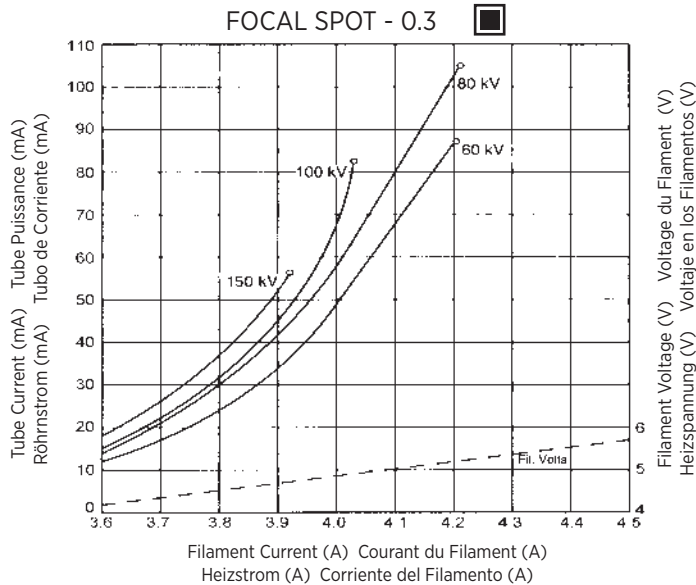
Puissance calorifique nominale de l'anode: 40%, CEI 60613

Thermische Anodenbezugsleistung bei einer Wärmespeicherung von 40%. IEC 60613

Aproximadamente el poder de penetración para obtener un almacenaje de calor del anodo de 40%. IEC 60613

3 Ø Constant Potential ===

Filament Emission Charts IEC 60613
 Abaques d'Émissions des Filaments CEI 60613
 Glühfadenemissionsdiagramm IEC 60613
 Curvas de Emisión de los Filamentos IEC 60613



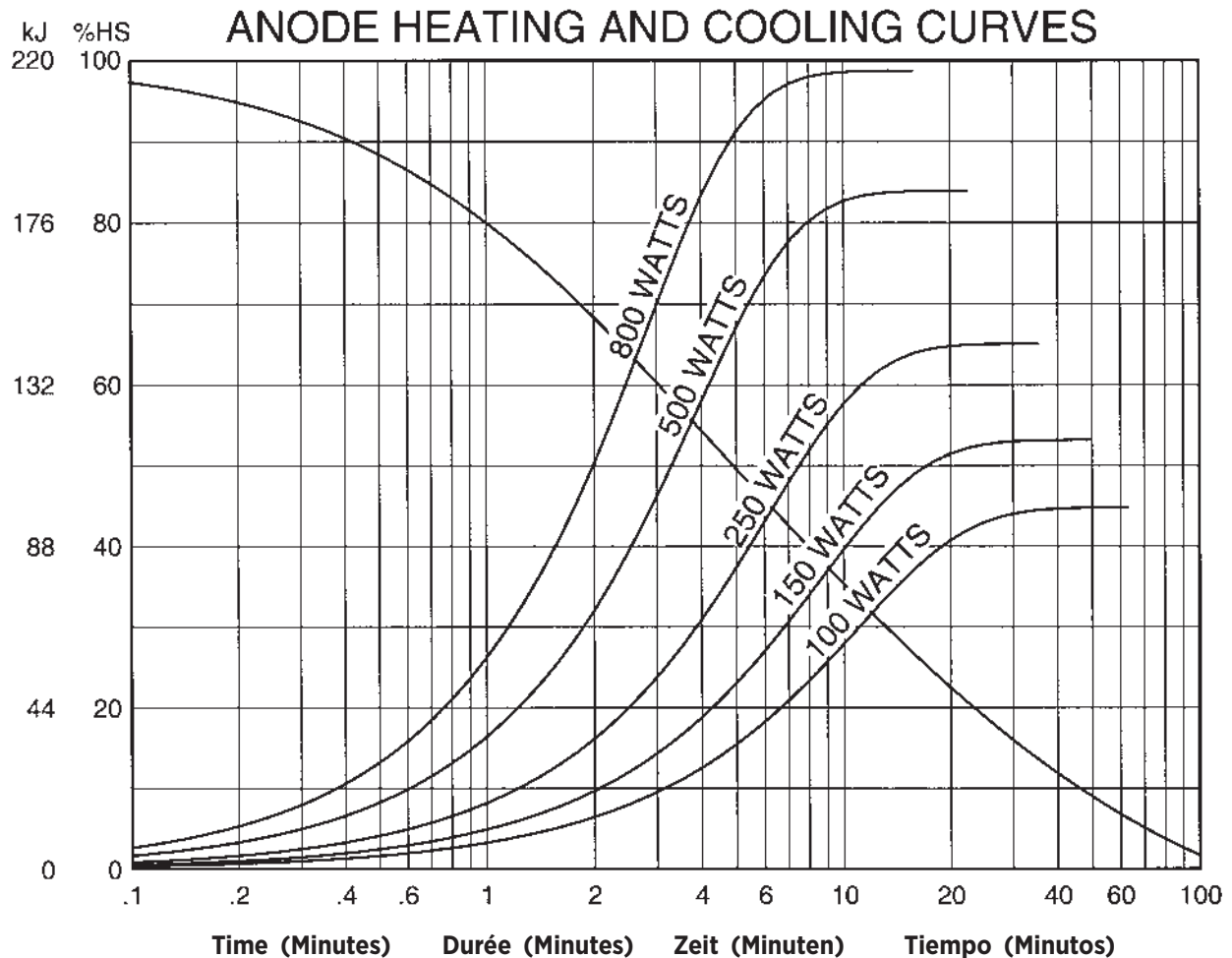
Note: When using these emission curves for trial exposures, refer to the power rating curves shown for maximum kV, tube emission, filament current, exposure time, and target speed.

Remarque: Lors de l'utilisation de ces abaques pour des expositions d'essai, référez-vous aux courbes maximales de kV, d'émission du filament, de temps d'exposition et de vitesse de rotation.

Anmerkung: Wenn Sie diese Emissionskurven für Testaufnahmen verwenden, beziehen Sie sich hierbei auf die entsprechenden Nennleistungskurven für max. kV-Werte, Röhrenemission, Heizström, und Anodendrehzahl.

Nota: Si utiliza estas curvas de emisión para exposiciones de prueba, refiérase a las curvas de gradación de potencia para el máximo de kV, tubo de emisión, corriente en los filamentos, tiempo de exposición, y a las curvas de velocidad del objetivo.

Anode Heating & Cooling Chart
Abaques d'Échauffement et de Refroidissement de L'Anode
Anodenerhitzungs und Kühlungsdiagramm
Curvas de Calentamiento y Enfriamiento del Anodo





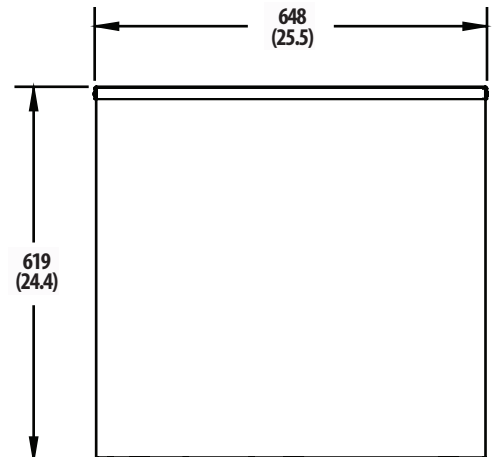
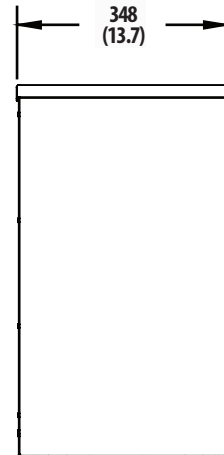
Salt Lake City, UT 1-801-972-5000
Charleston, SC 1-843-767-3005
www.vareximaging.com

Manufactured by Varex Imaging Corporation
Fabrique par Varex Imaging Corporation
Hergestellt von Varex Imaging Corporation
Fabricado por Varex Imaging Corporation

Specifications subject to change without notice.
Spécifications susceptibles d'être modifiées sans préavis.
Technische Daten ohne Gewähr.
Especificaciones sujetas a cambio sin previo aviso.

CMP 200[®] DR

SMALL. COMPACT.
LIGHTWEIGHT.
COST-EFFECTIVE.



DIMENSIONS:
MM
(INCHES)

CMP 200®DR MODELS	40 kW	50 kW	65 kW	80 kW
Application	Radiographic			
Generator Type	High Frequency Output (maximum 450 kHz)			
kV _p Range	40-125 kV (150 kV optional - 3 Φ only)	40-150 kV		
mA Range	10-500 mA	10-630 mA	10-800 mA	10-1000 mA
mAs Range (non-AEC)	0.1-500 mAs	0.1-630 mAs	0.1-800 mAs	0.1-1000 mAs
Rotor Supply	Low Speed Starter (optional Dual Speed Starter)			
Input Phase/Voltage	1 Φ/208-230 VAC 3 Φ/208-230 VAC 3 Φ/400-480 VAC	3 Φ/208-230 VAC (external transformer required for 65 kW) 3 Φ/400-480 VAC		3 Φ/400-480 VAC
High Voltage Ripple	<1 kV @ 110 kV			
Compatible X-Ray Tubes	>300 tube models			
Auto-Tube Calibration	Standard feature			
Exposure Timer Range	Maximum 6.3 s standard (10 s, 20 s, or 30 s optional –consult factory)			
Anatomical Programs (Membrane/Touchscreen Console)	1024/20,000+ techniques			
Supported Console Languages	English, French, German, Italian, Spanish, Chinese, Russian (additional available upon request)			
Image Receptors	Up to 5			
Technique Selection	kV/AEC, kV/mAs, kV/ma/ms or kV/cm thickness (standard console only)			
Tomography Mode	Standard feature			
Auxiliary Collimator Power Supply	Standard feature			
GenWare® Service Software	PC-based diagnostics and technical support			
Documentation	Manuals on CD			
OPTIONS	40 kW	50 kW	65 kW	80 kW
AEC Interface	Ionization or Solid State			
Auxiliary Power with Floating Ground	24 VAC/6.3 A, 150 watts			
Auxiliary AC Power Supply	230 VAC/3A (available on 3 Φ/400-480 VAC models only)			
Digital Radiography Interfaces	CPI RAD VISION™, Canon, IDC, Infimed, CMT, ATS, Konica Minolta, Fuji, Viewworks+others			
Dose Area Product (DAP) Interface	Available			
Dual/Multiple Energy	Available (consult factory)			
Dual Speed Starter	3Φ/400-480 VAC only			
Exposure Switch	Available			
Extended Warranty	Available (consult factory)			
Mini-Console Controller	Available			
Membrane Console Pedestal	Available			
Membrane Console Wall Mount	Available			
Advanced Tomography Mode	Available			
Touchscreen Console	Available			

QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-505-135-1906

The **Directorate of Device Testing and Clinical Engineering (EMKI)**
as a Certification Body with ID No. NAH-4-0096/2016
accredited by the National Accreditation Authority for management system certification
certifies that the quality management system applied by

Control-X Medical Kft.
Öv utca 29.
1141 Budapest
Hungary

meets the requirements of standard

EN ISO 13485:2016

in the field:

Design, development and manufacture of diagnostic X-ray equipment

Registry number of the related audit report: **43-10699-2017**

This certificate is valid until **2022-06-18** supposed that the results of the regular yearly surveillance audits are satisfactory.

The Company has been certified by EMKI since 2017-06-19.

Budapest, 2019-06-19


Head of EMKI



EMKI 2241

The authenticity and validity of the certificate are verifiable at EMKI.

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33

E-mail: cert@emki.hu, Web: www.emki.hu

H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

EMKI

EC CERTIFICATE
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-866-200-1906

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.
certifies that the manufacturer:

Control-X Medical Kft.
Öv utca 29.
1141 Budapest
Hungary

for the products / product category:

Diagnostic X-ray equipment

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **NE/1041/2020**

This certificate is valid until **2024-05-26** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by NEOEMKI LLC as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 4

First issued by the Directorate of Device Testing and Clinical Engineering (EMKI) on 19 June 2019.

Budapest, 2021-01-28


László Imre
Managing Director



EMKI 2664

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu



ATTACHMENT TO EC CERTIFICATE

Page 1 of 2

Additional information for Certificate No. 5-866-200-1906

The certificate is valid for the following products / models:

Diagnostic X-ray equipment

Class

Perform-X radiographic systems including the following configurations:

IIb

- Perform-X F100/F200/F300/F400 Floor Mounted Radiographic System
- Perform-X C100/C200/C300/C400 Ceiling Mounted Radiographic System
- Perform-X Chest Radiographic System
- RadioLogiX Radiographic System

consisting of the following components:

- Milestone HF X-ray generators
- STYLIX and PHOENIX radiographic tables
- WS 99 wall stands
- TS 99 tube stands
- CTM-200 tube stands

Z-Motion radiographic system

IIb

- Z-Motion universal digital radiographic stand
- Milestone HF X-ray generators

Issue: 4

Date: 2021-01-28

First issued: 2019-06-19

László Imre
Managing Director



EMKI

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu





Certificate No. 12965-8-2020

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Two Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer

CONTROL-X MEDICAL, INC.
1755 ATLAS ST.
COLUMBUS, OH USA 43228

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from August 18, 2020 to August 17, 2022.





Certificate No. 12965-8-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Manufacturer

CONTROL-X MEDICAL, INC.
1755 ATLAS ST.
COLUMBUS, OH USA 43228

Name of Product(s)

Name of the Product(s)

PERFORM-X SYSTEM & RADIOLOGIX SYSTEM – CONSISTING OF:
GENERATORS

Milestone 32 kW, 40 kW, 50 kW, 65 kW, 80 kW, 100 kW (MS... Series)

Milestone SE 32 kW, 40 kW, 50 kW (MS... SE Series)

MS 325/350 HF, LC, STR, 100, SE, EU

MS 425/450 HF, LC, STR, 100, SE, EU

MS 525/550 HF, LC, STR, 100, SE, EU

MS 850 HF, STR, 100

MS 1050 HF, STR, 100

APEX 32 kW, 40 kW, 50 kW, 65 kW, 80 kW, 100 kW (APEX... Series)

APEX 325/350 HF, LC, STR, 100, SE, EU

APEX 425/450 HF, LC, STR, 100, SE, EU

APEX 525/550 HF, LC, STR, 100, SE, EU

APEX 850 HF, STR, 100

APEX 1050 HF, STR, 100

CMP Series

CMP200 32 kW, 40 kW, 50, 65, 80 kW (CMP Series)

CMP200DR 32 kW, 40 kW, 50, 65, 80 kW (CMP DR Series)

RADIOGRAPHIC TABLES

STYLIX 2, STYLIX 3 (STX... Series)

PHOENIX, PHOENIX 2 (PHX... Series)

Z-Table

WALLSTANDS

WS 99, WS 99D, WS 99T, AWS 15M, AWS 15T, AWS 15TM

EWS 05, CWS 05

TUBESTANDS

TS 99, TS 99T, TS 05, TS 05R, TS 05RT, ATS 15, ATS 15R

ETS 05, ETS 05T, CTS 05, CTS 05T

Halo, CS31 CTM

COLLIMATORS

Ralco R 108, Ralco R 225

CML-125, CML-150 (CM... Series)

M38 (Series)

X-RAY TUBES

E7239X, E7239FX, E7242X, E7242FX, E7252X, E7252FX, E7254X,

E7254FX (E72... and CXM72... Series)

RAD-8, RAD-74, RAD-13, RAD-14, RAD-68, RAD-68/1,

RAD-21, RAD-56, RAD-60, RAD-90

APEX DIGITAL SOLUTION (SYSTEMS)

DicomPacs DX-R Digital Image Management (Apex Series)

XRP 4336 (APEX PE 4336) PerkinElmer

XRP 4343 (APEX PE 4343) PerkinElmer

FDX 4343 (APEX 4343P) Toshiba

FDX 3543 (APEX 3543) Toshiba

CA 1500Cwe (APEX CA 4336Le) Careray

CA 1500Cw (APEX CA 4336W) Careray

CA1800L (APEX CA 4343T) Careray

CA1800Le (APEX CA 4343Te) Careray

CA1800cW (APEX CA 4343W) Careray

C 750Cw (APEX CA 2430w) Careray

FXRD 1012WB (APEX VI 1012W-G) Vieworks





Certificate No. 12965-8-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

FXRD 1417NAW (APEX VI 4336W-Csl) Viewworks

FXRD 1417WB (APEX VI 4336W-G) Viewworks

FXRD 1717VA (APEX VI 4343T-Csl) Viewworks

FXRD 1717VB (APEX VI 4343T-G) Viewworks

PaxScan 4343W v4 Varex

PaxScan 4343R v3 Varex

PaxScan 4343RC Varex

UNIVERSAL RADIOGRAPHIC SYSTEMS

Z-Motion

Radiographic Systems

Perform-X Classic

Perform-X ATC (C100, C200, C300, C400)

Perform-X ATF (F100, F200, F300, F400)

RadiologiX

Portable System

AMADEO mini

-----END OF PRODUCT LIST-----



CERTIFICATE OF FREE SALE

December 10, 2020

To whom it may concern:

This certificate of Free Sale certifies that Control-X Medical, Incorporated, located at 1755 Atlas Street, Columbus, OH 43228 has represented to us that:

1. They are an authorized and licensed legal corporation in the State of Ohio, with incorporation in the State of Ohio.
2. They are a manufacturer and distributor of X-ray Radiographic Systems and Components and a distributor of Digital Imaging Solutions with manufacturing and distribution facilities at the following locations:
Control-X Medical US 1755 Atlas Street Columbus, OH 43228
Control-X Medical Hungary 29 Öv Street, Budapest H-1141, Hungary
3. The full line of their products is freely sold in the United States per the attached document.
4. The full line of their products is available for export.

The issuance of this Certificate of Free Sale is based on the representation of the facts presented by Control-X Medical, Incorporated, to our satisfaction. This certificate is not to be construed as an expressed or implied endorsement of any of the products of the manufacturer, nor shall it be used for propaganda, advertising or the similar purposed.

Sincerely,



Tracy L. Bloom
Columbus Chamber



12/10/2020


Sworn and subscribed to before me this 10th day of December, 2020

COLUMBUS CHAMBER OF COMMERCE CERTIFICATE OF FREE SALE ADDENDUM



Per the attached Certificate of Free Sale issued by the Columbus Chamber of Commerce, 150 South Front Street, Suite 200, Columbus, Ohio, 43215, USA, regarding articles 3 and 4 of said document, the following is a list of those products manufactured and distributed by Control-X Medical, Incorporated, 1755 Atlas Street, Columbus, Ohio, 43228, USA and so identified in said Certificate of Free Sale and articles. This addendum shall become part and parcel of said Certificate of Free Sale as exhibit A.

<u>Name of the Product(s)</u>	Model Extension
PERFORM-X SYSTEM & RADIOLOGIX SYSTEM – CONSISTING OF:	Single or Combinations are Permissible
<u>GENERATORS</u>	APR, HF, STR, 100, SE
Milestone 32 kW, 40 kW, 50 kW, 65 kW, 80 kW, 100 kW (MS... Series)	
Milestone SE 32 kW, 40 kW, 50 kW (MS... SE Series)	
MS 325/350 HF, LC, STR, 100, SE	
MS 425/450 HF, LC, STR, 100, SE	
MS 525/550 HF, LC, STR, 100, SE	
MS 850 HF, STR, 100	
MS 1050 HF, STR, 100	
PCX 32 kW, 40 kW, 50 kW, 65 kW, 80 kW, 100 kW (PCX... Series)	
PCX (APEX) 325/350 HF, LC, STR, 100, SE	
PCX (APEX) 425/450 HF, LC, STR, 100, SE	
PCX (APEX) 525/550 HF, LC, STR, 100, SE	
PCX (APEX) 850 HF, STR, 100	
PCX (APEX) 1050 HF, STR, 100	
ConRad 30 kW, 40 kW, 50 kW (CR Series)	
ConRad SE 30 kW, 40 kW, 50 kW (CR SE Series)	
Conrad 425/450 HF, LC, STR, 100, SE	
Conrad 525/550 HF, LC, STR, 100, SE	
Conrad 625/650 HF, LC, STR, 100, SE	
CMP200 32 kW, 40 kW, 50 kW (CMP Series)	
CMP200DR 32 kW, 40 kW, 50 kW (CMP DR Series)	
<u>RADIOGRAPHIC TABLES</u>	Elevating
STYLIX 2, STYLIX 3 (STX... Series)	
PHOENIX, PHOENIX 2 (PHX... Series)	
Z-Table	



12/10/2020

COLUMBUS CHAMBER OF COMMERCE CERTIFICATE OF FREE SALE ADDENDUM

<u>WALLSTANDS</u>	S, T	150 South Front St, Suite 220 Columbus, OH 43215
WS 99, WS 99D, WS 99T, WS 15M, WS 15T, WS 15TM		T (614) 221.1321 columbus.org
ETS 05, ETS 05T, CTS 05, CTS 05T		
<u>TUBESTANDS</u>		
TS 99, TS 99T, TS 05, TS 05R, TD 05RT		
ETS 05, ETS 05T, CTS 05, CTS 05T		
Halo, CTM		
<u>COLLIMATORS</u>	LED, CML, Laser, Manual, Certified	
Ralco R 108, Ralco R 225		
CML-125, CML-150 (CM... Series)		
M38		
<u>X-RAY TUBES</u>	X, FX, GX, CX, VAR, NAI	
E7239, E7242, E7252, E7254 (E72... and CXM72... Series)		
RAD-8, RAD-74, RAD-13, RAD-14, RAD-68, RAD-68/1, RAD-21, RAD-56, RAD-60, RAD-90		
<u>APEX DIGITAL SOLUTION (SYSTEMS)</u>	R, RP, Wireless, Tethered	
DicomPacs Digital Image Management (Apex Series)	Viewing License, Modality	
Dicom Worklist		
Dicom Send		
Dicom Print		
Dicom CD burn		
XRP 4336 (APX PE 4336)		
XRP 4343 (APX PE 4343)		
FDX 4343 (APX 4343)		
FDX 3543 (APX 3543)		
CR 1800L (APX CR 4343)		
CR 750Cw (APX CR 2530)		
CR 1500Cw (APX CR 43326)		
<u>UNIVERSAL RADIOGRAPHIC SYSTEMS</u>		
Z-Motion	CR, DR	



COLUMBUS CHAMBER OF COMMERCE CERTIFICATE OF FREE SALE ADDENDUM

COLUMBUS
CHAMBER
OF COMMERCE

High Voltage Cables	HV cable	150 South Front St, Suite 220 Columbus, OH 43215
500-20, 500-25, 500-30, 500-35, 500-40, 500-45,		
500-50, 500-55, 500-60, 500-65		T (614) 221.1321 columbus.org
Bucky	SS, NS	
CXB-17		
Grid Cabinets		
CX-BSGC		
Ion Chambers		
ICX 1153		
Cassette Trays		
QKC, QJC		
Anti-scatter radiation grids		
10310M17, 10310L17, 17810M17, 17810L17,		
21510M17, 21510L17,		
Mobile, Portable X-Ray system	32 kW, 40 kW, 50 kW 6 kW	
	10 kW 3-8 kW	
MobyleX		
TOP-X		
MobyleX Mini		
Amadeo Mini		
Line Matching Transformer		
TP Universal Line	[480/440/380/240/230/220/210]	
	65kVA 60Hz, 60Hz	
SP Universal Line	[208/220/240/380/400]	



12/10/2020

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show CONTROL-X MEDICAL, INC., an Ohio corporation, Charter No. 1665779, having its principal location in Columbus, County of Franklin, was incorporated on December 11, 2006 and is currently in GOOD STANDING upon the records of this office.



*Witness my hand and the seal of the
Secretary of State at Columbus, Ohio
this 3rd day of September, A.D. 2020.*

A handwritten signature in blue ink, appearing to read "Frank LaRose", written in a cursive style.

Ohio Secretary of State

Validation Number: 202024701968

FOREIGN COUNTRY CERTIFICATION STATEMENT

To Whom It May Concern:

As a responsible official of Control-X Medical, Incorporated, I hereby certify that the company and products identified in the attached Certificate to Foreign Government continues, to the best of my knowledge, to comply with the Federal Food, Drug and Cosmetic Act and all applicable or pertinent regulations enforced by the U.S. Food and Drug Administration. A Photocopy of the Certificate to Foreign Government may be used as long as this original statement is attached.

Signed this 25th day of August 2020

CONTROL-X MEDICAL INC.

Medical and X-RAY Products
1755 Atlas St
Columbus OH 43228



Laszlo Adrovitz
Vice President
Control-X Medical, Inc.

Attachment:
FDA Certificate for Foreign Government

Statement of Partnership & Regulatory Compliance

To Whom It May Concern:

This letter certifies that Control-X Medical, Limited: H-1141 Budapest Őv utca 29, Hungary, is in partnership with Control-X Medical, Incorporated: 1755 Atlas Street, Columbus, Ohio, 43228, USA. The partnership between Control-X components transferred between the companies are of identical quality and built to meet the standards of the International Organization for Standardization (ISO), US FDA and carry CE certifications.

X-ray System Production Synopsis:

Control-X Medical, Limited: Budapest Hungary maintains and oversees the ISO Certification, CE Certification process and the manufacturing process of core x-ray system components, which takes place at a licensed manufacturing facility in Incorporated: Columbus, Ohio, USA. Control-X Medical, Incorporated fabricates these x-ray system components into complete x-ray systems, which comply with the United States Food & Drug Administration (USFDA) guidelines.

Control-X Medical, Incorporated attests to its partnership with Control-X Medical, Limited and is governed by all respective product certifications and requirements.

Signed this June 29th 2020



Laszlo Adrovitz
Vice President
Control-X Medical, Incorporated

CONTROL-X MEDICAL INC.
Medical and X-RAY Products
1755 Atlas St
Columbus OH 43228



X-RAY DOES NOT JOKE!



**RADIATION PROTECTION
APRONS AND RADIOLGY
ACCESSORIES**

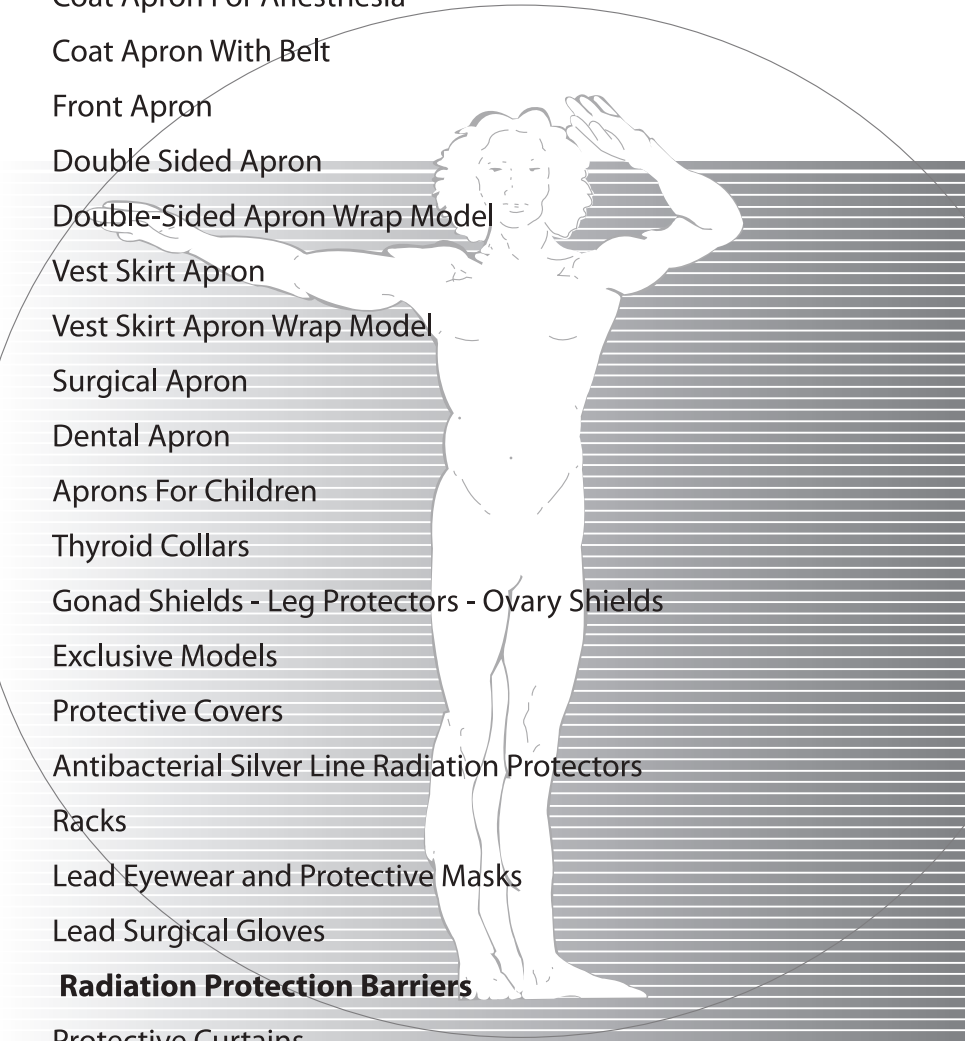


www.aktifxray.com | info@aktifxray.com

**CE
0120**

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Preface

Aktif Dis Ticaret was established in 1993 by the purpose of serving the medical sector.

Our first commercial activity was importing the document microfilm recorder which lets archiving easy to Turkish market. Started to representate world-famous radiology accessories manufacturers in Turkey in 1995.

Meanwhile we specialized in protective aprons by importing and distributing all over to Turkey. By the experience on this area Aktif Dis Ticaret started to manufacture protective lead and leadfree aprons with its own brand Aktif X-Ray since 2002. You can look into our Aktif X-Ray brand protective aprons and accessories, which manufactured by % 100 Turkish capital in Turkey and exported to world with warrant of Aktif Dis Ticaret, in our catalog.

We are at your service with our prioritized customer satisfaction understanding and total quality policy. Aktif X-Ray is registered to Aktif Dis Ticaret by Turkish Patent Institute.

Tel: +90 216 474 46 48 | Fax: +90 216 474 48 19
www.aktifxray.com | info@aktifxray.com

Quality Certificates – (SGS-ISO-UBB Authorization Certificate)



Useful Information and Recommendations

General Information about Protective Aprons

Operator should make the right selection for the protective aprons for maximum protection in order to protect his/her body’s most affected area by radiation. Especially chest, upper body, gonad and thyroid areas should be protected as a priority.

Aktif X-Ray protective aprons and accessories are manufactured by following the latest technology. With the utilization of advanced radiology instruments, we manufacture modern, light-weight, flexible, including rubber mixed lead models which have high protectivity. Aktif x-ray protective aprons and accessories are designed to be favorable for long term treatments to patients.



X-Ray Protection Apron

Points to Consider During Order Process

It is highly important to wear an apron that fits on your body size.

Recommended Sizes;

Chest

- Chest dimensions for Small size 80-90 cm
- Chest dimensions for Medium size 90-104 cm
- Chest dimensions for Large size 104-120 cm

Length

- 90 cm apron is for 1.45 to 1.55 cm length
- 100 cm apron is for 1.55 to 1.60 cm length
- 110 cm apron is for 1.65 to 1.70 cm length
- 120 cm apron is for 1.75 to 1.85 cm length
- 130 cm apron is for 1.85 to 1.90 cm length

Please indicate your color preferences. Pocket, name or logo can be added upon request. Additional snap fastener or rubber belt can be added upon request. (For double sided models)

Certification

As it is directly associated with cell protection, lead and lead free radiation protection aprons are in the scope of Personal Protection Equipment Regulations/Category 3 (complex design) and must be certificated as lead and lead free. Company can add approved notified body number next to CE sign on the product tag after a notified body certificates company’s production models with Article 11 A or 11 B.



X-Ray Protection Apron



Material Used

Protective Aprons and Accessories’ Cover Material

Standard Fabric: Oxford type fabric which is produced especially for x-ray protection aprons with color variations shown below are used in manufacturing. This fabric is long-lasting and easy wiping in term of hygiene.

Fabric Color Options



Color Options

		
Blue	Dark Blue	Gray
		
Pink	Burgundy	Green

Interior Material

The interior lead or lead free polymer rubber material used for Aktif X-Ray Protective Aprons and Accessories is imported abroad and used in accordance to international standards. Our protective aprons received appreciation in Turkey and many other countries with its high quality materials and perfect workmanship.

Our standard protective aprons and accessories are made out of a light compound which contains polymer and protective material mixture. Besides standard 0,125 mm LE, 0,175 mm LE, 0,25 mm LE protective material thicknesses, upon the customer request, we can produce aprons in different protective values.

Light Weight

This protective product we called as light weight is 22% lighter but has the same protective capability as the other brands’ similar products.

Lead Free

We can use nature friendly, easy recyclable lead free material with the same protection level of leaded one in our products upon customer request

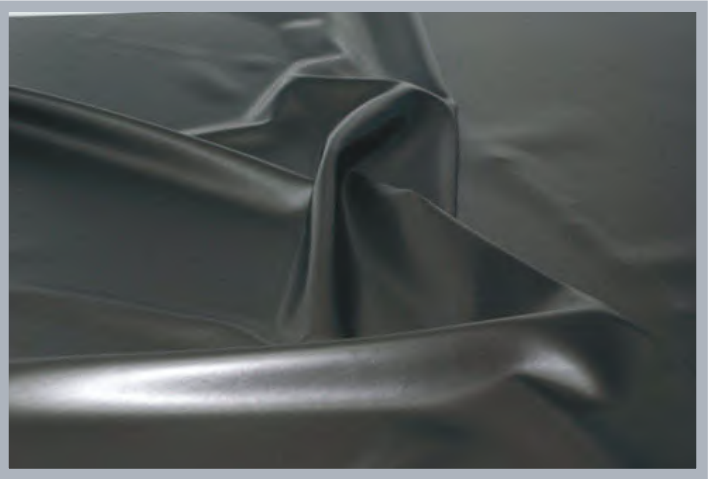
Protection Value

Light Weight and Lead Free protective materials’ protection value is at 80 kV,

0,50 mm Pb protective material protection ratio %99

0,35 mm Pb protective material protection ratio %97

0,25 mm Pb protective material protection ratio %95



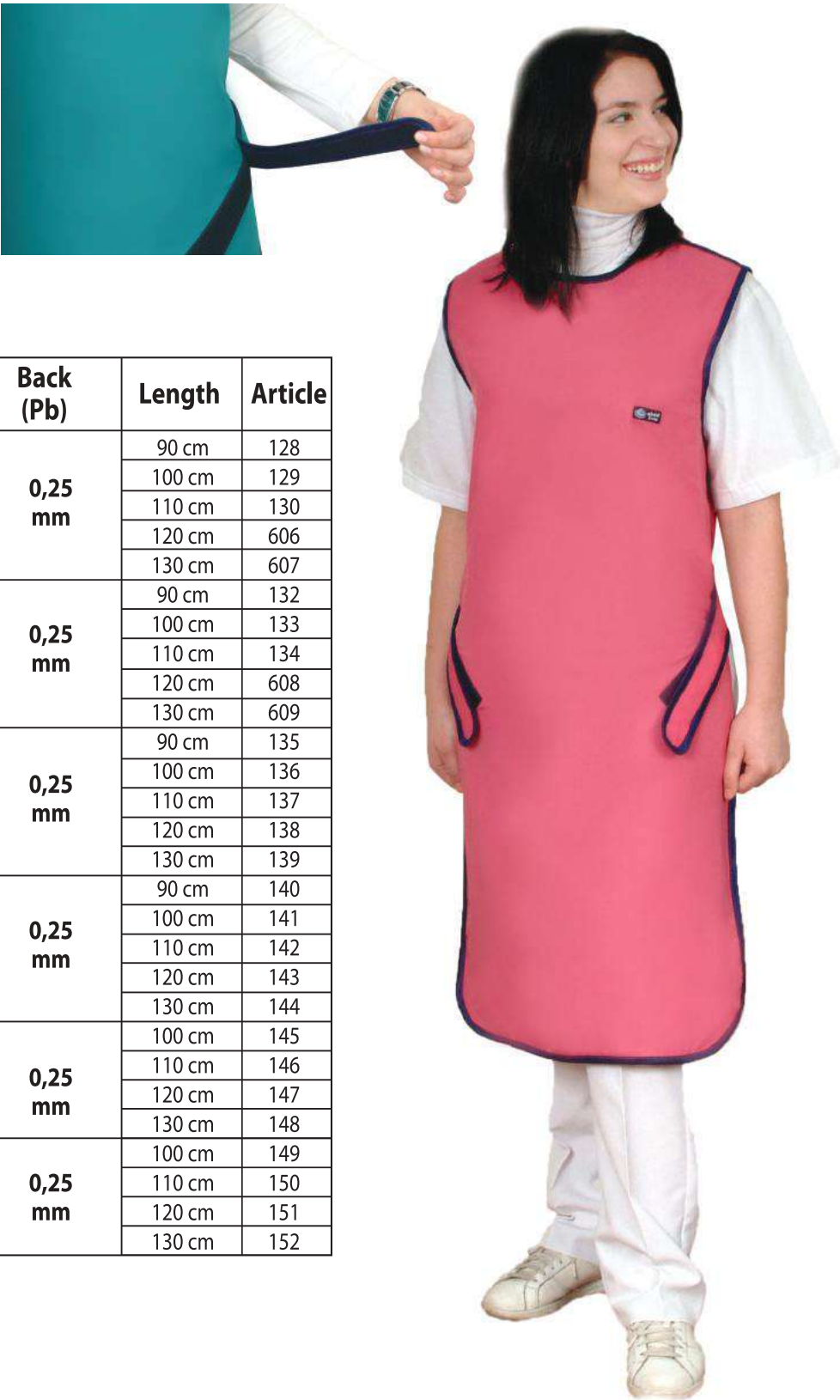
Coat Apron With Velcro

This model is designed for user who are exposed to x-ray for long term. It is an ideal model for protection against scattered x-ray expose. It provides maximum comfort, flexibility and lightness to users by its easy wear and take-off feature.

Thanks to its special design, perfectly covers the shoulder and body and it is adjustable according to user’s body for maximum protection even on shoulder bones.

Lead
LightWeight Lead
LeadFree (optional)

Lead
Front: 0,35 mm Pb or 0,50 mm Pb
Back: 0,25 mm Pb



Size	Front (Pb)	Back (Pb)	Length	Article
SMALL Shoulder Width 40 cm	0,35 mm	0,25 mm	90 cm	128
			100 cm	129
			110 cm	130
			120 cm	606
			130 cm	607
Hip Size 60 cm	0,50 mm	0,25 mm	90 cm	132
			100 cm	133
			110 cm	134
			120 cm	608
			130 cm	609
MEDIUM Shoulder Width 48 cm	0,35 mm	0,25 mm	90 cm	135
			100 cm	136
			110 cm	137
			120 cm	138
			130 cm	139
Hip Size 60 cm	0,50 mm	0,25 mm	90 cm	140
			100 cm	141
			110 cm	142
			120 cm	143
			130 cm	144
LARGE Shoulder Width 53 cm	0,35 mm	0,25 mm	100 cm	145
			110 cm	146
			120 cm	147
			130 cm	148
Hip Size 75 cm	0,50 mm	0,25 mm	100 cm	149
			110 cm	150
			120 cm	151
			130 cm	152

Coat Apron For Anesthesia

It provides very comfortable usage with its 16cm elastic belt and large velcro bands on back protection extension.

Users can keep wearing it during your routine x-ray procedures easily.

Lead
LightWeight Lead
LeadFree (optional)

Lead Equivalent
Front: 0,35 mm Pb or 0,50 mm Pb
Back: 0,25 mm Pb



Size	Front (Pb)	Back (Pb)	Length	Article
SMALL Shoulder Width 40 cm	0,35 mm	0,25 mm	90 cm	153
			100 cm	154
			110 cm	155
			120 cm	156
			130 cm	157
Hip Size 60 cm	0,50 mm	0,25 mm	90 cm	158
			100 cm	159
			110 cm	160
			120 cm	161
			130 cm	162
MEDIUM Shoulder Width 48 cm	0,35 mm	0,25 mm	90 cm	163
			100 cm	164
			110 cm	165
			120 cm	166
			130 cm	167
Hip Size 60 cm	0,50 mm	0,25 mm	90 cm	168
			100 cm	169
			110 cm	170
			120 cm	171
			130 cm	172
LARGE Shoulder Width 53 cm	0,35 mm	0,25 mm	100 cm	174
			110 cm	175
			120 cm	176
			130 cm	177
Hip Size 75 cm	0,50 mm	0,25 mm	100 cm	179
			110 cm	180
			120 cm	181
			130 cm	182

Coat Apron With Belt

This model is mounted to extension of back protection and it is ideal to distribute the load on shoulders for long-term use.

Lead
LightWeight Lead
LeadFree (optional)

Lead Equivalent
Front: 0,35 mm Pb or 0,50 mm Pb
Back: 0,25 mm Pb



Size	Front (Pb)	Back (Pb)	Length	Article
SMALL Shoulder Width 40 cm	0,35 mm	0,25 mm	90 cm	102
			100 cm	103
			110 cm	104
			120 cm	600
			130 cm	601
Hip Size 60 cm	0,50 mm	0,25 mm	90 cm	106
			100 cm	107
			110 cm	108
			120 cm	602
			130 cm	603
MEDIUM Shoulder Width 48 cm	0,35 mm	0,25 mm	90 cm	109
			100 cm	110
			110 cm	111
			120 cm	112
			130 cm	113
Hip Size 60 cm	0,50 mm	0,25 mm	90 cm	114
			100 cm	115
			110 cm	116
			120 cm	117
			130 cm	118
LARGE Shoulder Width 53 cm	0,35 mm	0,25 mm	100 cm	119
			110 cm	120
			120 cm	121
			130 cm	122
			100 cm	123
Hip Size 75 cm	0,50 mm	0,25 mm	110 cm	124
			120 cm	125
			130 cm	126

Front Apron

This more preferred model is designed for ones who are exposed to x-ray for long term. This is an ideal model for scattered x-ray from front side of operators. It gives maximum comfort, flexibility and lightness to operators with easy wear and take-off feature

It can be produced with belt and velcro upon customer request.

Lead
LightWeight Lead
LeadFree (optional)

Lead Equivalent
Front : 0,35 mm Pb or 0,50 mm Pb



Size	Front (Pb)	Length	Article
SMALL Shoulder Width 40 cm	0,35 mm	90 cm	350
		100 cm	351
		110 cm	352
		120 cm	353
		130 cm	354
Hip Size 60 cm	0,50 mm	90 cm	355
		100 cm	356
		110 cm	357
		120 cm	358
		130 cm	359
MEDIUM Shoulder Width 48 cm	0,35 mm	90 cm	360
		100 cm	361
		110 cm	362
		120 cm	363
		130 cm	364
Hip Size 60 cm	0,50 mm	90 cm	365
		100 cm	366
		110 cm	367
		120 cm	368
		130 cm	369
LARGE Shoulder Width 53 cm	0,35 mm	100 cm	371
		110 cm	372
		120 cm	373
		130 cm	374
		100 cm	376
Hip Size 75 cm	0,50 mm	110 cm	377
		120 cm	378
		130 cm	379

Double Sided Aprons

This more preferred model is designed for long term x-ray exposure. It gives maximum comfort, flexibility and lightness to operators with easy wear and take-off feature. It can be produced with belt, thick banded and with Velcro upon customer request.

Lead
LightWeight Lead
LeadFree (optional)

Lead Equivalent
Front : 0,35 mm Pb or 0,50 mm Pb
Back: 0,25 mm Pb

Size	Front (Pb)	Back (Pb)	Length	Velcro	Belt	Snap
SMALL Shoulder Width 40 cm	0,35 mm	0,25 mm	90 cm	228	253	283
			100 cm	229	254	200
			110 cm	230	255	201
			120 cm	612	256	202
			130 cm	613	257	203
Hip Size 90-110 cm	0,50 mm	0,25 mm	90 cm	232	258	204
			100 cm	233	259	205
			110 cm	234	260	206
			120 cm	614	261	207
			130 cm	615	262	208
MEDIUM Shoulder Width 48 cm	0,35 mm	0,25 mm	90 cm	235	263	209
			100 cm	236	264	210
			110 cm	237	265	211
			120 cm	238	266	212
			130 cm	239	267	213
Hip Size 110-125 cm	0,50 mm	0,25 mm	90 cm	240	268	214
			100 cm	241	269	215
			110 cm	242	270	216
			120 cm	243	271	217
			130 cm	244	272	218
LARGE Shoulder Width 53 cm	0,35 mm	0,25 mm	100 cm	245	274	220
			110 cm	246	275	221
			120 cm	247	276	222
			130 cm	248	277	223
Hip Size 125-140 cm	0,50 mm	0,25 mm	100 cm	249	279	225
			110 cm	250	280	226
			120 cm	251	281	227
			130 cm	252	282	284



Double Sided Apron with Belt



Back Side



Double Sided Apron with Snap

Double-Sided Apron Wrap Model

This wrap model apron provides perfect protection for front side of the body because it covers front completely. For the two sided x-ray expose , overall protection level is kepted as 0,25 mm Pb at single front part , so it gives 0,50 mm Pb protection for long term use by a lighter weight apron. It gives maximum protection and preferred by operator of Cardiology department and fields where there is too much x-ray. It has two models with belt and without belt giving maximum protection. It can be weared like a jacket and its cruvaze style overlaps to each other in order to give full protection on front side of human body and gonad region. The shoulder pads decreases the load over the shoulders.

Lead :
LightWeight Lead
LeadFree (optional)

Lead Equivalent
Front: 0,35 mm Pb or 0,50 mm Pb
Back: 0,25 mm Pb



Size	Front (Pb)	Back (Pb)	Length	Article
SMALL Shoulder Width 40 cm	0,35 mm	0,25 mm	90 cm	520
			100 cm	521
			110 cm	522
			120 cm	523
			130 cm	524
Hip Size 90-110 cm	0,50 mm	0,25 mm	90 cm	525
			100 cm	526
			110 cm	527
			120 cm	528
			130 cm	529
MEDIUM Shoulder Width 48 cm	0,35 mm	0,25 mm	90 cm	530
			100 cm	531
			110 cm	532
			120 cm	533
			130 cm	534
Hip Size 110-125 cm	0,50 mm	0,25 mm	90 cm	535
			100 cm	536
			110 cm	537
			120 cm	538
			130 cm	539
LARGE Shoulder Width 48 cm	0,35 mm	0,25 mm	100 cm	541
			110 cm	542
			120 cm	543
			130 cm	544
			100 cm	546
Hip Size 125-140 cm	0,50 mm	0,25 mm	110 cm	547
			120 cm	548
			130 cm	549



Vest Skirt Aprons

This so chick skirt and vest combination model provides ease for movement capability by distributing the weight between shoulders and waist. Skirt and vest model can be produced besides of our standard body size given above according to exact body size of operators upon request.

Lead
LightWeight Lead
LeadFree (optional)

Lead Equivalent
Front : 0,25 mm Pb or 0,35 mm Pb (At the overlapped area in front side, the lead value is double)
Back : 0,25 mm Pb



Size	Front (Pb)	Back (Pb)	Vest Length	Skirt Length	Article
SMALL	0,25 mm	0,25 mm	60 cm	55 cm	415
	0,35 mm				401
MEDIUM	0,25 mm	0,25 mm	60 cm	60 cm	416
	0,35 mm				402
LARGE	0,25 mm	0,25 mm	60 cm	65 cm	417
	0,35 mm				403

Vest Skirt Apron Wrap Model

This so chick skirt and vest combination model provides ease for movement capability by distributing the weight between shoulders and waist. Vest Skirt Apron Wrap Model provides perfect protection by fully covering front of the body with its overlapping panels (0,175 mm / 0,25 mm Pb). For instance, to provide 0,50 mm Pb protection for front of the body, two 0,25 mm Pb panels are arranged to be overlapped. Besides the light weight in long term usage, wrap models also provides highest level of protection. Vest Skirt Apron Wrap Model can be produced besides of our standard body size given above according to exact body size of operators upon request.

Lead
LightWeight Lead
LeadFree (optional)

Lead Equivalent
Front: 0,35 mm Pb or 0,50mm Pb (At the overlapped area in front side, the lead value is double)
Back: 0,25 mm Pb



Size	Front (Pb)	Back (Pb)	Vest Length	Skirt Length	Article
SMALL	0,35 mm	0,25 mm	60 cm	55 cm	430
	0,50 mm				420
MEDIUM	0,35 mm	0,25 mm	60 cm	60 cm	431
	0,50 mm				421
LARGE	0,35 mm	0,25 mm	60 cm	65 cm	432
	0,50 mm				422



Surgical Apron

It can be worn under the surgical gown to provide protection to operators in case of continuous shooting. Doctors do not want to take off it by themselves because they should not risk the hand sterilization. That’s why an assistant can take off the velcro band, so the protection apron drop down. No need to use this apron if the shooting is finished.

Lead
LightWeight Lead
LeadFree (optional)

Lead Equivalent
Front : 0,35 mm Pb or 0,50 mm Pb
Back : 0,25 mm Pb



Size	Front (Pb)	Article
50 x 80 cm	0,25	405
60 x 90 cm		406
60 x 100 cm		407
60 x 110 cm		408
60 x 120 cm		409
50 x 80 cm	0,35	410
60 x 90 cm		411
60 x 100 cm		412
60 x 110 cm		413
60 x 120 cm		414

Dental Aprons

Dentists uses medical radiological examination technics as Panoramic, Periapical, Sefalometric, Sinus graphics very often for diagnostic. That’s why it is necessary to use protective aprons and thyroid collars during the treatment. Specially for children and pregnant it is not allowed to make shooting without protective apron.

Lead	Lead Equivalent
LightWeight	Lead Front: 0,35 mm Pb or 0,50 mm Pb
LeadFree (optional)	Back: 0,25 mm Pb

Size	Front (Pb)	Back (Pb)	Length Width	Article
SMALL	0,35 mm	0,25 mm	60x60 cm	341
	0,50 mm			320
MEDIUM	0,35 mm	0,25 mm	70x60 cm	342
	0,50 mm			321
LARGE	0,35 mm	0,25 mm	75x75 cm	343
	0,50 mm			322



Patient Protection Apron

This model is produced especially for patient under dental treatment. This model eases the usage and has thyroid protector which provides giving maximum protection to user.

Lead
LightWeight Lead
LeadFree (optional)

Lead Equivalent
Front: 0,35 mm Pb or 0,50mm Pb

Size	Pb	Dimensions	Article
STANDARD	0,35 mm	60 x 100 cm	323
	0,50 mm		340



Aprons For Children

Children aprons are produced mostly as front and back protected. They are produced with belt to fit it to the body well and gives maximum safety and ease for usage.

Coat Apron For Children

Lead	Lead Equivalent
LightWeight Lead	Front: 0,50 mm Pb
LeadFree (optional)	Back: 0,25 mm Pb

Size	Front (Pb)	Back (Pb)	Article
3-5 Years	0,50 mm	0,25 mm	501
6-8 Years			502
9-12 Years			503
Set			504



Double- Sided Apron For Children

The models are ease to wear and take off. They are tightened by Velcro bands. This model gives maximum protection and safety for children.

Lead
LightWeight Lead
LeadFree

Lead Equivalent
Front: 0,50 mm Pb
Back: 0,25 mm Pb

Size	Front (Pb)	Back (Pb)	Article
3-5 Years	0,50 mm	0,25 mm	505
6-8 Years			506
9-12 Years			507
Set			508

Thyroid Collars

It is produced in order to protect the thyroid region which is one of the most effected part in human body from x-ray. It has 5 models: Standard, Hat Model, Large Hat Model, Panoramic and Children.

It is recommended operators to have their own private thyroid collar as a matter of hygiene (sweating).

The standard model can be mounted to double-sided aprons by snap fastener. It should be sewed to only Front side closed aprons

Lead
LightWeight Lead
LeadFree(optional)

Lead Equivalent
0,50 mm Pb

Model	Pb	Kod
Panoramic	0,50 mm	316
Large Hat Style		317
Standard		318
Hat Style		319
For Children		328
Hat Style Children		319/1



Hat Style Children



For Children



Standard



Hat Style



Large Hat Style

Ovary Shields and Gonad Shields

Ovary is the most sensitive regions of our bodies – where our genitals are located – to X-RAY.

AKTIF X-RAY ovary shields provides ease for use, comfort and cleanliness and starts from 1.00 mm Pb lead level to provide the maximum protection.
It is produced as 3 different models for 0-9 years , 9-16 years and over 16 years users.

Lead
LightWeight Lead
LeadFree(optional)

Lead Equivalent
1,00 mm Pb

Size	Pb	Article
Small	1,00 mm	312
Medium		313
Large		314
Set		315



Gonad Shields For Males

It must be used to protect gonad region –where our genitals are located-to X-Ray
It is produced as 3 different models for 0-9 years, 9-16 years and over 16 years users.

Lead
LightWeight Lead
LeadFree(optional)

Lead Equivalent
1,00 Pb

Size	Pb	Article
Small	1,00 mm	324
Medium		325
Large		326
Set		327

Leg Protectors

Leg protector is produced according to customer request and it has velcro fastener which enables usage for every size.

Size	Pb	Article
Standard	0,50 mm	329



Lead:
LightWeight Lead
LeadFree (optional)

Lead Equivalent
0,50 mm Pb



Exclusive Models

We offer exclusive production options with high quality materials and perfect workmanship for our customers.

Arm and Wing Protectors

We can provide stitched or snap fastened arm / wing protectors for aprons on demand. It can be produced in six different color options and desired lead equivalent.



Wing Protectors



Arm Protector

Back Relief Belts

Back Relief Belts are needed due to the heavy weight of protective aprons, disfunctioning of belts in time. Contrary to similar belts' loss of elasticity in time, this design provides long term usage. These belts offer safe hold and ease to wear and take off with its nonslip, adjustable buckle or touch and close fastener. It can be produced in 4 different sizes (S,M,L,XL) and 6 different colors on demand.



Breast Shields

These shields are used in spine shoots. Its length can be adjusted with its touch and close fastener. For full spine shoots, it does not contain lead on neck. So it is ideal for scoliosis treatments.



Protective Caps

Perfectly fitted to head caps can be produced in a variety of lead equivalent values. They provide ease for usage with the touch and close fasteners.



Beret Model

Bonnet Model

Samurai Model

Half Aprons

Half aprons can be used for gonad/ovary protector or many other purposes. It is easy-to-use and can be tightened to waist by means of velcro belt.

Lead

LightWeight Lead
LeadFree(optional)

Lead Equivalent

0,50 mm Pb

Size	Pb	Article
20x25 cm	0,50 mm	301
30x30 cm		302
37x40 cm		303
40x50 cm		304
Set		305



Protective Covers

Any of the protective covers below can be used for all radiological environments. The important point is that you should select the proper size for your needs.

Lead

LightWeight Lead
LeadFree(optional)

Lead Equivalent

0,35 mm Pb or 0,50 mm Pb

Size	Pb	Article
60x60 cm	0,35 mm	306
90x60 cm		307
120x60 cm		308
60x60 cm	0,50 mm	309
90x60 cm		310
120x60 cm		311



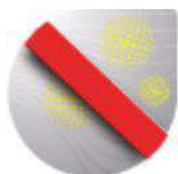


NEW

ANTIBACTERIAL SILVER LINE RADIATION PROTECTORS

PURE SILVER AND PURE PERFORMANCE

Rego X-Ray combines x-ray protection with additional protection against bacteria, odour and offers an anti-static performance as well as a cooling effect.



ANTIMICROBIAL

Protection against growth of bacteria and fungus



ANTI-ODOR

Eliminates odor in a natural way



ANTI-STATIC

Offers protection against electrostatic charge



THERMOREGULATION

Keeps you cooler during a long time treatment



DURABLE

Permanent effect during the whole life of X-ray protection cloth



PURE SILVER AND PURE PERFORMANCE

Our silver line fabrics used in X-Ray protective aprons offers much more advantages when compared with regular ones.

Rego X-Ray silver line fabrics are produced with silver threads as its name suggests.

These silver threads have antimicrobial affect so it provides protection against growth of bacteria and fungus that cause odor. At the same time these threads have anti-static and thermoregulation features.

Fibre surface: no nanotechnology or complex chemical formula, just natural silver



Available in 4 colors: light-blue, navy-blue, emerald green and bordeaux.



SGS



SGS

Racks

It is important to store aprons in proper condition in order to long last their use life. At the same time, easy reach, user friendliness, small size and easy mounting are essential points of storage conditions.

Wall Mounted Apron Rack : (2 arms -3 arms -5 arms):
This user friendly and ergonomic hanger help to long last your apron’s life . Special hooks can be mounted to this model for skirts.



Mobile Apron Rack Stainless Stell (5-10) This mobile racks have metal foots and strong wheels which makes it to move easily. 5-10 aprons can be hanged.

Wall Mounted Rack For Aprons



Wall Mounted Rack For Gloves

This special hanger has very important role for keeping lead gloves lifelong.

Natural Wooden Hanger: Strong wooden body, stainless steel hook part and proper design long lasts your apron’s life. Capacity is only one apron. Color is teak.



Steel Rack



Mobile Apron Rack: With this rack you can store up to 10 aprons by using natural wooden or steel hangers. Please indicate the type and quantity of the hangers with your orders.

Model	Article
Wall Mounted Rack For Gloves	400008
Wall Mounted Rack For Two Aprons	400025
Wall Mounted Rack For Three Aprons	400105
Wall Mounted Rack For Five Aprons	400104
Mobile Rack For Five Aprons Stainless Steel	400011
Mobile Rack For Ten Aprons Stainless Steel	400013
Natural Wooden Hanger	400015
Mobile Apron Rack	400111
Lux Mobile Rack with Shelf	400112

Lead Eyewear and Protective Masks

Lead Eyewear

Our lead eyewear is well-selected and gives the highest protection and comfort of use to operators. Panorama type eyewear is advised to be used in areas where there is radiation expose risk from sides of the head.
PS: According to prescription of user, optically corrected lenses can be produced for panorama model.



Panorama



Ultralite 9935



Ultralite 99



Ultralite 9941



Fitover



Alumilities 99AL

Model	Pb	Article
Panorama	0,75 mm	700
Ultralite 99	0,75 mm	701
Fitover	0,75 mm	702
Ultralite 9935	0,75 mm	704
Ultralite 9941	0,75 mm	705
Alumilities 99AL	0,75 mm	706



Protective Masks

Panoramic Half Protection Mask

A mask of leaded acrylic protection – covering over to almost complete surface of the face-can be applied.
It is ideal for minimum bad –effect of radiation.
It can be cleaned very easily.
It must be kept away from high pressure and temperature.



Panoramic Half Protection Mask

Panoramic Full-Face Protection Mask

Leaded acrylic mask protects the complete face from forehead to chin. It has 20cm length.
Adjustable headband gives use of comfort. It must be kept away from high pressure and temperature.

Model	Pb	Article
Panoramic Half Protection Mask	0,10 mm	707
Panoramic Full-Face Protection Mask	0,10 mm	708



Panoramic Full-Face Protection Mask

Lead Surgical Gloves

These gloves are made of natural dry rubber mixed with lead oxide. The mix of these two raw materials grants high elasticity and softness combined with the best x-ray protective curve without negative peaks typical of other protective materials. Each single gloves is controlled and tested by specialized operators that verify the full conformity to the Standards requisites and to the strictly requirements defined by our Quality Management System.

Models: XP-1* Light Type XP-2** Medium Type XP-3*** Heavy Type

Where To Use :

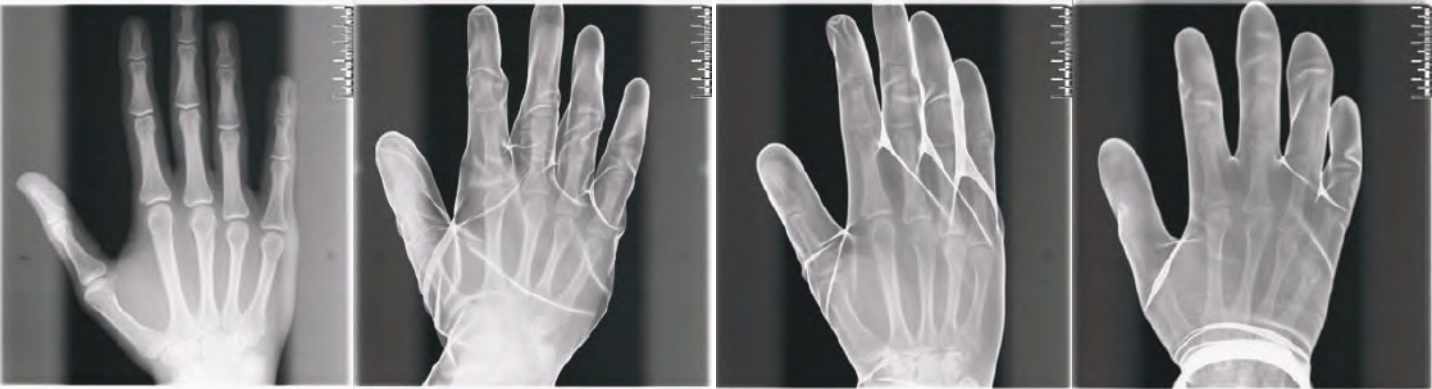
XP-1* Light Type : Gives, maximum touch sense, it is self-lubricated (ease wearing), used more at angiography urology, hematology , gastroenterology, light-simple surgical operations.

XP-2 Medium Type :** Medium thickness, self-lubricated (ease wearing), used more at urology, oncology centers, dentistry, surgery and cardiology.

XP-3* Heavy Type :** It has thicker materials and proper for traumatology and nuclear field.

Size	XP-1* Light	XP-2** Medium	XP-3*** Heavy
6 ½	750	756	762
7	751	757	763
7 ½	752	758	764
8	753	759	765
8 ½	754	760	766
9	755	761	767

Absorbtion and Screening Percentage	60 Kv	80 Kv	100 Kv
XP-1* Light	36%	31%	27%
XP-2** Medium	61%	54%	47%
XP-3*** Heavy	72%	65%	59%



Without Gloves

1 star

2 star

3 star

Lead Gloves

Aktif X-Ray lead gloves are flexible, homogenous and gives maximum safety to operator with 0,50mm Pb lead value.

Model	Pb	Article
Leather Gloves	0,50 mm	772



Protective Curtains

As Aktif X-Ray we produce radiation protective lead curtains which provides ease for apply and usage.

Lead
LightWeight Lead / LeadFree(optional)

Height Adjustable Mobile Protective Shield

This 60x60 cm sized, 0,50 mm Pb panel can be adjusted as 95x160 cm height. With 60 cm diameter aluminum caster system, it provides flexibility and can be immobilized with the 2 brake casters easily. We can produce it in any size and protective value on demand.



Curtains for Tables (Saddle Type)

These curtains can be produced as applicable for all types of tables and with the overlapping panel, it provides ease for usage while opening and closing the curtain. It is suitable for use in surgeries with C arm X-ray units and can be produced in any demanded size.

Lower Body Shields For Operation Tables

It can be mounted to operation table's accessories rail and protecting operator against secondary radiation coming through under secondary table. Table mounted model is designed to protect doctor and other stuff against to radiation during operation. Protective lead material's size is 116 cm x 76 cm , lead equivalent is 0,50mm Pb. Metal part is not magnetic. It can be mounted to both sides of operation table. It can move to front-back direction with ease on table accessory rail giving maximum comfort and safety.



Technical Features

Lead Equivalent: 0,50 mm Pb flexible curtain
Dimensions: Length:116cm xHeight:76cm
Color: Grey
Metal Part: Aluminum

Article	Pb
901	0,25 mm
725	0,35 mm
713	0,50 mm



Leaded Doors and Protective Barriers

Our company produces protective lead doors and protective barriers in any demanded size and provides the mounting service. Our protective barriers produced in high quality and with its featured caster system it provides high mobility compared to its equivalent products. And as our doors are rabbeted, they provide maximum protection against x-ray compared to its equivalent products. Standard color of our doors and doorframes is white/beige. We can also produce sliding doors on demand. Doors and protective barriers can be produced as double leaf and triple leaf. Please demand proposal by notifying the sizes of protective barriers and sizes you need.

Standard Protective Barrier

Dimensions of standard lead protective barrier is 100cm x 200cm. Strong caster system and eye height level lead glass give relax movement capability and wide view perspective to operator.

Standard Protective Barrier With Large Glass

Although the technical characteristics and sizes same as the standard protective barrier with a larger glass offers the user a wider viewing angle.

Model	Size	Pb	Glass Size	Article
Standard Protective Barrier	100x200 cm	2,0 mm	20 x 20 cm	720
Standard Protective Barrier With Large Glass	100x200 cm	2,0 mm	50 x 80 cm	721

Lead Doors

Aktif X-Ray produces custom made leaded doors according to customer needs and gives installation service. Single, double and sliding doorset options are available. Leaded jambs grant a continuous shielding together with wall panels. All doorsets are equipped with high quality handles, heavy duty hinges/sliding system and perfect workmanship. Please send technical drawing with dimensions and protection level when you ask quotation.

Model	Size	Pb	Article
Standard Lead Door	100x200 cm	2,0 mm	716



Standard Paravane



Standard Paravane with Large Glass



LEAD GLASS

Our lead glasses provide high quality transparency and protection. With high amounts of lead and barium substances it provides optimum protection between 100-300 Kv. We produce our lead glasses as 2600 mm x 1300 mm sized polished plates. At the same time, we can cut it in smaller sizes on demand. They are applicable for lamination so, they can be laminated with PV3 (polyvinyl butyral) as double layered. Our lead glasses are audited tightly and they have the certificate of conformity ISO 14001 and also quality standards.

- Benefits Of Med - X

- Protection to 100-300 Kv devices radiation
- Optimum Protection with high lead and barium
- Transparent
- Convenient For Lamination
- Big Sizes
- Up to 2600 mm x 1300 mm standard products .

- Area Of Usage

- Radiography and CT rooms
- Medical Diagnostic Screen
- Protective Window in Laboratories
- Lens of Protective Glasses
- Airport Safety Screens.



Lead Glass



Thickness	Minimum Lead Equivalence (mm) for Stated X-Ray Tube Voltage					
	100kV	110kV	150kV	200kV	250kV	300kV
mm						
5,0-5,5 mm	1,7	1,6	1,5	1,3	1,3	1,3
7,0-8,5 mm	2,3	2,3	2,1	1,8	1,8	1,8
8,5-10,0 mm	2,8	2,8	2,5	2,2	2,2	2,2
10,0-12,0 mm	3,3	3,2	2,9	2,5	2,5	2,5
11,0-13,0 mm	3,7	3,5	3,3	2,8	2,8	2,9
14,0-16,0 mm	N/A	4,7	4,1	3,5	3,6	3,7
16,0-18,0 mm	N/A	N/A	4,6	4	4,1	4,3
	*N/A : Not measured value					

Protective Shields and Ceiling Mounted Systems

Overhead Suspended Shield Model 354

This ergonomically designed shield can be moved partially over a patient and adjusted to provide maximum protection to the practitioner's eyes and upper body. A central joint enables the lead acrylic window to turn and tilt until the optimum position is achieved.

- 0,50 mm lead acrylic with ball & socket joint can be positioned at any angle
- Shield can be placed over the patient for maximum protection
- The decision to locate the cut-out on the left or right can be made during installation, according to its intended use
- A version without the cut-out can be rotated horizontally if a wider shield is required
- Optional flexible 0,50 mm Pb curtains can be factory fitted to either version
- Other sizes available

All of the above shields can be mounted on a ceiling column or on a ceiling track with or without a Surgical Lamp. Or, alternatively, on its own wall mounted.

Overhead Suspended Shield Model 351

The lead acrylic window of this shield is placed partially over the patient for effective protection against scatter radiation to the eyes and upper body. The wide format provides a safe zone for the practitioner and for personnel assisting close by.

The window can be turned to the most convenient angle or removed immediately for emergency access to the patient.

- 60x80 cm 0,50 mm lead acrylic window ensures protection against scatter radiation to the eyes & upper body
- Wide configuration provides a safe zone for user and personnel close by
- Contoured shield can be placed over the patient for maximum protection
- A version without the cut-out is available
- Optional 0,50 mm Pb flexible curtain can be fitted to either version for additional protection

All of the above shields can be mounted on a ceiling column or on a ceiling track with or without a Surgical Lamp. Or, alternatively, on its own wall mounted.

Overhead Suspended Shield Model 350

These compact shields ensure maximum dose reduction to the eyes by the use of high-quality lead glass, with a lead equivalency of 2,00 mm Pb.

The windows can turn horizontally & vertically until the ideal angle is obtained for protection. This also helps eliminate reflections from lights or other equipment and ensures a clear view of the patient.

- Easy to move overhead shield
- Maximum protection for eyes & thyroid
- Available as 30x40 cm or 40x50 cm
- 2,00 mm Pb lead window with 0,50 mm Pb curtain @150 kV
- Different curtain lengths available

Ceiling Track Mounted Shields & Surgical Lamps

A ceiling track provides maximum positioning flexibility, enabling the shield and/or lamp to be moved easily into the working area. When not in use they can be parked up to 5.5 metres away.

- Ceiling tracks are 2,5 metres long, compact and exceptionally easy to install & use. They can be positioned at any angle across the ceiling.
- Ceiling tracks are useful when static mounts prevent the movement of other equipment.
- The smooth running track carriage will accommodate one or two shields or surgical lamps or a combination of both.
- An additional carriage can be fitted if independent movement of a lamp and shields is required.



Lead Shielding

Radiation safety rules and regulation requires wall of the rooms (Radiography ,tomography , computer aided tomography , radiotherapy , X-Ray) to be leaded isolation. Our company produces also windows and doors of these rooms beside their walls. Please send your inquiry with technical drawing of your room.

What we do;

By our team having 25 years experience;

Shielding for radiography and tomography rooms according to TAEK and World standards.

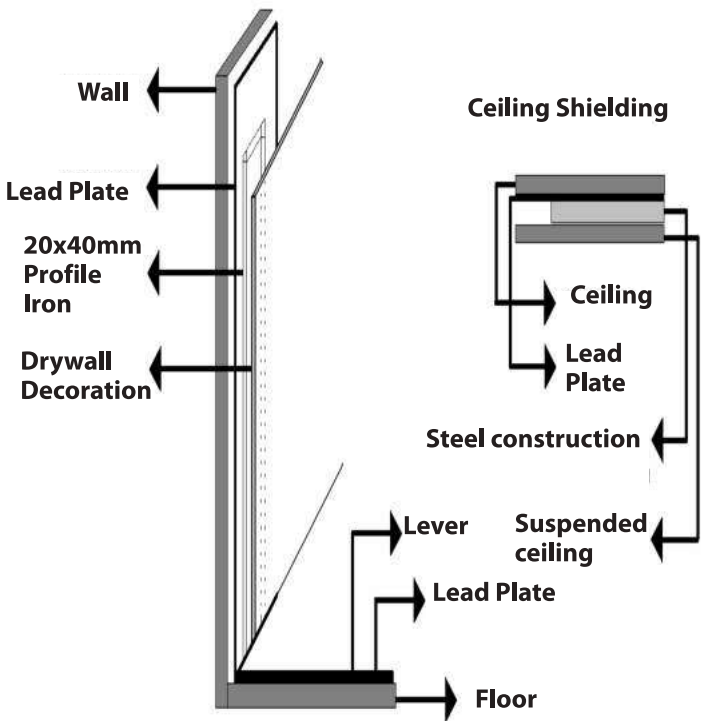
Design and shielding for dental panoramic radiography rooms.

Fully customized leaded doors in different models and sizes

Fully customized protective barrier (fixed , mobile and any size).



Wall and Floor Shielding



WINDOWS – FLOORS – CEILINGS SHIELDINGS

X-Ray Windows Shielding:

X-Ray windows shielding system is made by sliding shutters, made of strong wood box panels with interposed lead , calibrated and brushed .

X-Ray Floor Shielding With Lead Sheets:

For shielding are used lead sheets protected by tarred felt paper .The sheets overflow near the junctions and wall edges to avoid escape radiations outgoing.

X-Ray Ceiling Shielding:

Ceiling shielding is made using X-Ray panels with the same features of wall-panels . Panels fixing is made of wood structure (minimum section cm 6x6) fixed on ceiling by supports.

Rontgen Accessories

Positioning Aids

We have positioning aids set which are used during radiological examination and theraphies. The set includes 9 parts; 2 circular, 1 cylindrical, 1 rectangle, 4 triangle, 1 pyrisma.

Definition	Article
Standard Kit with Bag (uncoated)	614013
Standard Kit with Bag	614113
CT shots model	614118
New Polyetilen Kit with Bag	614213
Multipurpose Pad	666666

Patient Table Pad

It can be produced in customized size upon request.
Width : 60 cm
Height : 200 cm



Patient Table Pad

Computerized Tomography Grayshield Eye and Thyroid Protectors

Grayshield eve and thyroid protectors (1,4 mm thickness) provides 0,125 mm Pb lead equivalent protection.

Grayshield Thyroid Protectors

Grayshield Thyroid Protectors are designed to fit exactly on adam's apple and produced to protect thyroids, which are sensitive to x-rays, during tomography and other radiographies.



Grayshield Eye Protectors

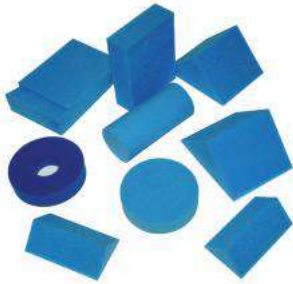
Grayshield Eye Protectors are designed to cover front and side of the eyes and they reduce the x-ray exposure significantly during tomography and radiographies. It is applicable for any face shape by its hypoallergenic adhesive tape.



As Grayshield Tyhroid and Eye Protectors are for single use only, they are prevent contagious diseases. They can be considered as domestic waste because they are composed of barium sulfates.



Positioning Aids



Lead Letters and Warning Signs

We provide a variety of lead letters and numbers. Warning signs are mandatory to use in radiation exposed areas.



Lead Letter and Markers

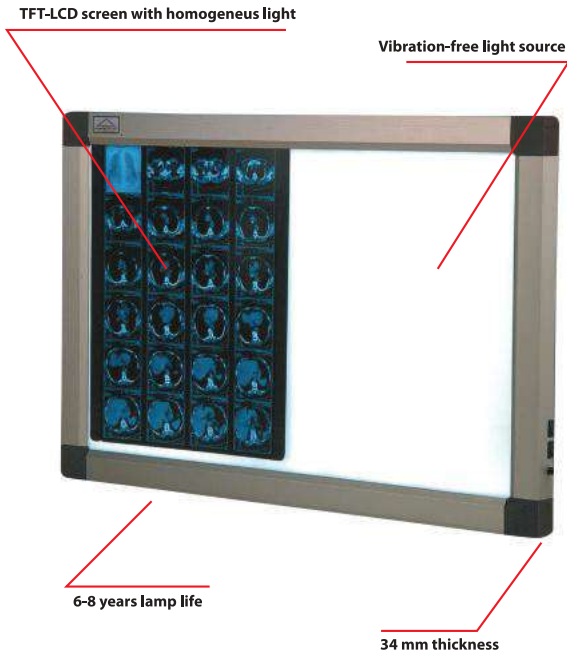


İÇERİ GİRMEYİNİZ
DO NOT ENTER

Negatoscopes

Technical Specifications

- 34 mm thickness
- TFT-LCD screen with homogeneous light
- Special light characteristic for rontgen, mammography, MR and CT films
- Using desired panels
- Special light colors and intensity
- 6-8 years lamp life
- Minimum eye fatigue due to vibration-free light source
- Energy saver lamps (CCFL/LED)
- Use option DC12V or AC 220 V
- Stylish design
- Optional specialized production
- Can be mounted horizontally of vertically
- Can be used on table with back stand
- 2 year warranty

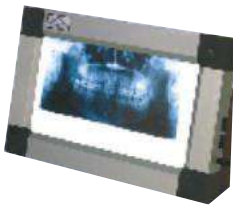


Vertical Negatoscope for Spinal Cord shootings

IRIS Light Type	IRIS Circle	Bright Power	Article
Standard	5-100 mm	70.000 lux	643170
Model - An	5-100 mm	70.000 lux	643171

NOTE: Please ask information about mammography negatoscope.

STANDARD MODELS



Panoramic Negatoscope
(25x40 cm) Article: 643006



Single Negatoscope
(44,7x51,4 cm) Article: 643100



Double Negatoscope
(80,4x51,4 cm) Article: 643101



Triple Negatoscope
(116,4x51,4 cm) Article: 643102



Quadruple Negatoscope
(151,6x51,4 cm) Article: 643103

Colon Set

Instruction For Use

1. Join the application tip and enema bag,
2. Close all clamps,
3. Pour prepared solution to enema bag,
4. Close and tighten the lid of enema bag,
5. Before apply to patient, open clamp on application hose in order to let solution to reach to tip,
6. Lubricate the tip using Vaseline,
7. Locate the tip slightly inside rectum,
8. Squeeze the pump once and inflate the silicon balloon by opening clamp.

A) SLIMLINE – 3 WAYS DOUBLE CONTRAST COLON TIP

1. 18 mm diameter flexible tip and air canal with clamp for dispensing the radioopaque material to body,
2. Silicon balloon and clipped air entry part which keeps tip stuck to body during application,
3. Air entry with clamp for air radiographic shots.

B) SLIMLINE – 1 WAYS DOUBLE CONTRAST COLON TIP

1. 18 mm diameter flexible tip and air canal with clamp for dispensing the radioopaque material to body,
2. Silicon balloon and clipped air entry part which keeps tip stuck to body during application,
3. Air entry with clamp for air radiographic shots.

C) ENEMA BAG

1. Designed specially in order to increase speed of solution flow,
2. It has scale, it can contain 3000 ml solution in fully capacity,
3. Screwed and airy lid,
4. Clamper Extension Hose.

CONSIDERE POINTS

1. Do not use vinyl or latex containing gloves,
2. Take care of not to make pressure to vagus nerve,
3. Do not make fast or deeper the application,
4. Squeeze the pump only once in order to inflate approx. 100cc air, do not give more, it can explode and harm patient.

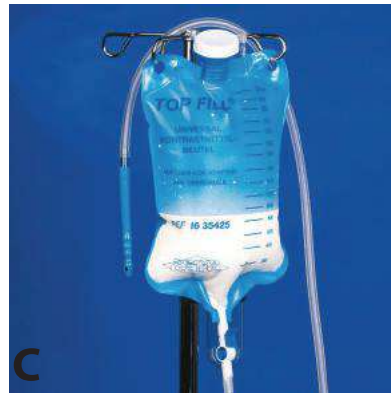
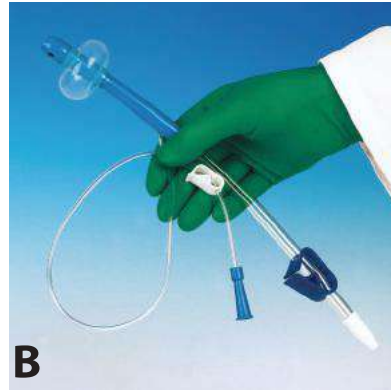
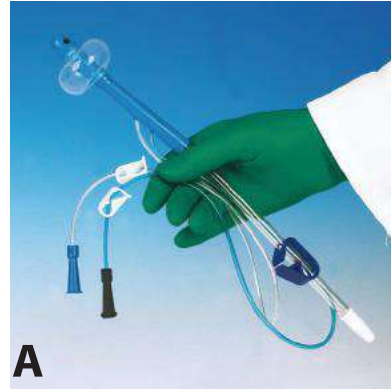
THIS PRODUCT IS APPLICABLE FOR DOUBLE OR SINGLE CONTRAST USAGE. IT IS SINGLE USE. PUMP IS NOT FOR SINGLE USE SO, THE SET DOES NOT CONTAIN PUMP. IT CAN BE PROVIDED ON DEMAND. THE COLON TUBE IS PRODUCED WITH ENVIRONMENT FRIENDLY PLASTIC, PLEASE DISPOSE IT PROPERLY AFTER USAGE.

DO NOT USE IN THE FOLLOWING SITUATIONS:

1. Do not use on patients have colostomy.
2. Pump;
 - a) In rectal anastomosis that don't go in deep,
 - b) In proctitis, inflammatory or neoplastic rectum diseases,
 - c) In first rectal surgery attempts.



Colon Set



Model	Code
Double Contrast Colon Tube	613001
Single Contrast Colon Tube	613002
Medium Bag	613008
Pump	613004

A FEW OF OUR REFERENCES





X-RAY DOES NOT JOKE!

**RADIATION PROTECTION
EQUIPMENTS**

AKTIF DIS TICARET

Altunizade Mah. Kusbakisi Cad.

Asuroglu Sit. D Blok No:25 D:1/2

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Certificate GB18/962221

The management system of

AKTİF DIŞ TİCARET İNŞAAT TURİZM VE TIBBİ ÜRÜNLER SANAYİ LİMİTED ŞİRKETİ

Kuşbakışı Cad. Aşuroğlu, Sitesi 29/1-2, D-Blok
Altunizade Üsküdar, İstanbul, Turkey

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module D

For the following activities

**Manufacturing of X-Ray Protective Lead and Leadfree
products and X Ray Protective Eyewear.**

**Note: All products marked CE0120 must have a valid EU type-
examination certificate issued under Module B or a valid
EC type-examination certificate issued under Article 10
of Directive 89/686/EEC.**

This certificate is valid from 22 December 2020 until 04 July 2023
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 29 June 2023

Issue 3. Certified since 25 October 2018

Authorised by




Digitally signed by Grabazei Alexandru
Date: 2021.05.21 11:43:21 EEST
Reason: MoldSign Signature
Location: Moldova

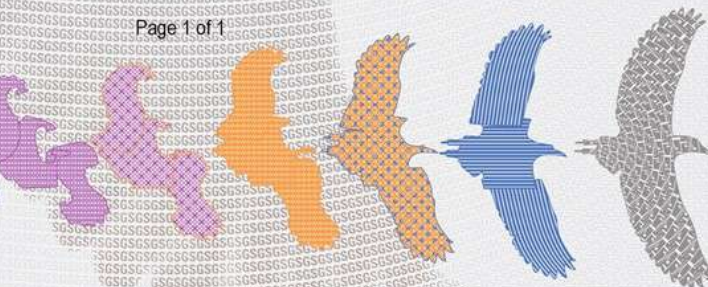


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HC SGS 2016/425 D 0118

Page 1 of 1



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CERTIFICATE



for the management system according to ISO 9001:2015

The proof of the conforming application with the regulation was furnished and in accordance with certification procedure it is certified for the company

AKTIF DIŞ TIC. İNŞ. TURZ. VE TIBBİ ÜRÜNLER SAN. LTD. ŞTİ.

**Kuşbakışı Cad. Aşuroğlu Sit. D Blok No: 29/1-2 34622
Üsküdar – İstanbul / Turkey**

Scope

**Design, manufacture and marketing of x-ray protective products,
shielding of x-ray rooms and installation of x-ray protective
products. Distribution of rotary instruments for dentistry.**

Certificate Registration No.: TIC 15 100 52945

Valid until: 2023-05-29

Valid from: 2020-05-30

Audit Report No.: 3330 25V5 P0

This certification was conducted in accordance with the TIC auditing and certification procedures and is subject to regular surveillance audits.

TÜV Thüringen e.V.
Certification body for
systems and personnel



Jena, 2020-05-05



Deutsche
Akkreditierungsstelle
D-ZM-16006-05-01



Original certificates
are branded with a hologram.

The current validity can be demanded at our homepage www.tuev-thueringen.de.

Zertifizierungsstelle des TÜV Thüringen e.V. • Ernst-Ruska-Ring 6 • D-07745 Jena • ☎ +49 3641 399740 • ✉ zertifizierung@tuev-thueringen.de



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 020011 0048 Rev. 00

Manufacturer:

FUJIFILM Corporation
26-30, Nishiazabu 2-Chome
Minato-Ku, Tokyo
106-8620 JAPAN

EC-Representative:

FUJIFILM Europe GmbH
Heesenstr. 31,
40549 Düsseldorf,
GERMANY

Product Category(ies):

Computed Radiography Console, Diagnostic X-ray
Equipment, Digital Mammography System and
related equipment, Software for Diagnostic
Imaging Workstations, Ultrasound Diagnostic
Imaging Equipment, Endoscopes for medical use
and their related equipment and accessories,
Ultrasound Endoscopes and their related
equipment and accessories

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

JAQ235032836

Valid from:

2018-08-28

Valid until:

2022-11-21

Date,

2018-08-28

Stefan Preiß



Benannt durch/Designated by
Zentralstelle der Länder
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bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 020011 0048 Rev. 00

Facility(ies):

FUJIFILM Corporation

26-30, Nishiazabu 2-Chome, Minato-Ku, Tokyo,
106-8620 JAPAN

FUJIFILM Corporation

798, Miyanodai, Kaisei-Machi, Ashigarakami-Gun,
Kanagawa, 258-8538 JAPAN

-/-

FUJIFILM

FUJI MEDICAL DRY IMAGER

DRYPIX

Lite

(Model : DRYPIX 2000)

Outstanding performance, remarkable efficiency and superb quality satisfy your medical imaging needs



- A New Concept Tabletop Dry Imager
- Supports Multiple Film Size
- Expandable to Two Magazines



Fuji Medical Imager DRYPIX Lite Specifications

Basic Specifications

Standard Component:	Fuji Medical Dry Imager DRYPIX Lite (Model: DRYPIX 2000)
Recording method:	Thermal head transfers heat while in contact with thermal film
Applicable film:	Fuji Medical Dry Film DI-HT 35 x 43 (14 x 17), 26 x 36, 25 x 30 (10 x 12), 20 x 25 (8 x 10)
Film loading:	Daylight film loading
Film magazines:	Up to 2 magazines
Processing capacity:	Approx. 50 sheets/hour 35 x 43 (14 x 17), Approx. 75 sheets/hour 26 x 36, Approx. 65 sheets/hour 25 x 30 (10 x 12), Approx. 90 sheets/hour 20 x 25 (8 x 10)
Pixel size:	84.7µm (300dpi)
Recording gradation:	12 bits
Image memory:	1 GB
Density adjustment:	Automatic
Input channels:	DICOM network input x 1 channel only

Physical Characteristics

External dimensions (W x D x H):	530 x 590 x 365mm (21 x 23 x 14") with Large magazine/ 530 x 470 x 365mm (21 x 19 x 14") with Small magazine 180mm higher with optional sheet-feeder unit
Weight:	32 kg (71 lbs.) / 43 kg (95 lbs.) with optional sheet-feeder unit
Power supply:	Input voltage: AC100-240V / Phase: Single / Frequency: 50-60Hz Rated current: 5-2A

Operating Environment

Temperature:	15-30°C
Humidity:	40-70% RH (at 15°C) to 15-70% RH (at 30°C) (no dew condensation)

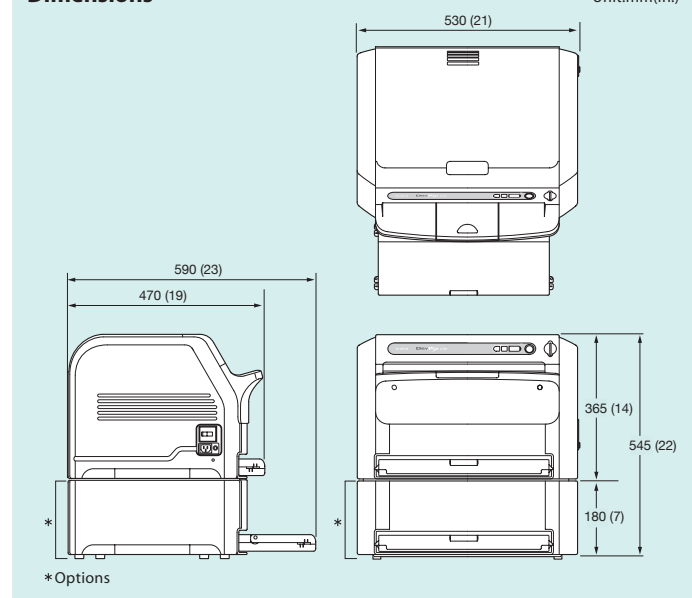
Options

- Optional sheet-feeder unit (*Supply magazine not included [Purchase separately])
- Vehicle mounting kit • Cart (*Cart does not conform to UL requirements.)
- Large magazine • Small magazine

*DRYPIX Lite doesn't come standard with supply magazine. Purchase magazine accordingly.
 *Large magazine can only accommodate 35 x 43 (14 x 17) film size.
 *Small magazine can accommodate either 26 x 36, 25 x 30 (10 x 12) or 20 x 25 (8 x 10) film size.
 To set up the film size to your desired size requires the support of our servicing personnel.
 Once the magazine is set to a film size, you cannot change it to a different one by yourself.
 *Film sizes indicated above required the respective magazines, as desired.

Dimensions

Unit:mm(in.)



Consumables

Fuji Medical Dry imaging Film DI-HT



*DI-HT only for DRYPIX Lite.

- 35 x 43 (14 x 17): 100 sheets/pack
- 26 x 36: 100 sheets/pack
- 25 x 30 (10 x 12): 100 sheets/pack
- 20 x 25 (8 x 10): 100 sheets/pack



DRYPIX Lite shown optional sheet feeder unit and 2magazines

Specifications are subject to change without notice.
 All brand names or trademarks are the property of their respective owners.
 In some countries, regulatory approval may be required to import medical devices.
 For the availability of these products, please contact your local sales representatives.



Medical Dry Imager
 WITH RESPECT TO ELECTRIC SHOCK, FIRE
 AND MECHANICAL HAZARDS ONLY
 IN ACCORDANCE WITH UL60601-1/CAN/CSA C22.2 NO.601-1
 EC: 60601-1-1 5396

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<http://www.fujifilm.com/products/medical>

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