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NEWTOM
CONE BEAM 3D IMAGING

Annex to the User Manual code 97050870

NewTom 5G XL Vet - Veterinary applications

EN

NOTES

This document is provided as a means of consultation for the user of the device.

Cefla s.c. follows a policy of continuous development and updating of the product for which it reserves the right to change the contents of this manual without prior notice.

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The original version of this manual is written in Italian.

MANUFACTURER'S INFORMATION NOTICE

The device referred to in this manual is a radiological device that complies with Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Any tampering with or modification, update or change of either hardware [(1)] or software [(2)], compared to how the device was released from the factory and installed (and in any case to the specification in the enclosed documentation), may partially or totally compromise the device expected operation. The safety features can also be altered leading to a consequent hazard increase for the animal, the operator and the surrounding environment.

Therefore, if the user must make a change, this must be previously approved in writing by Cefla s.c.

Failure to comply with what is specified in this informative note will null and void the device warranty and the civil and/or penal responsibility for any consequent damage and/or accident and/or worsening of the animal, operator or other people health (including the surrounding environment) will be borne by the person who tampered with the device or his/her legal representative.

LIABILITY DISCLAIMER

All information, specifications and measurements provided in this document refer to the device supplied by Cefla s.c. in its available configurations.
Cefla s.c. shall not be held liable for any malfunction or abnormal operation of the device when used with third-party accessories.

[1] Adding a memory expansion, a new hardware on the connection bus, a printer or replacing the graphical video interface constitutes a significant change.

[2] Including the operating system and the applications already installed when the device is delivered. Automatic operating system updates, changes in network connection parameters, modification and/or addition and/or removal of interface software with hardware (device drivers) and/or services (e.g. file and printer sharing services) and/or applications, constitute a significant change.

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1. INTRODUCTION TO THE MANUAL

1.1. CONTENTS

This manual has been conceived as a consultation document to provide information and instructions on the use of the NewTom™ 5G series device, “NewTom 5G XL Vet” model.

The routine software functions provided for this device (scanning, data processing, reporting and document managing) and the instructions for use for the operator are dealt with in the document “Acquisition operations with NewTom 5G XL” attached to the “NNT User Manual”.

The “USER MANUAL” of the device, the “NNT User Manual” and the document “Acquisition operations with NewTom 5G XL” should be read and understood in all their parts before using the device.

It is recommended to keep this manual together with other documentation and use it as a guide in case new employees need to be instructed about the use of the device.

1.2. STRUCTURE

The “User Manual” is divided into the following chapters:

Chapter 1 – “INTRODUCTION TO THE MANUAL”:
provides information on the contents, the structure and the conventions used in this document.

Chapter 2 – “SAFETY-RELATED INFORMATION”:
includes information concerning the safety of operators and patients and essential procedures for using the appliance.

Chapter 3 – “DEVICE SAFETY AND MAINTENANCE”:
includes information concerning safety requirements and maintenance operations of the device.

Chapter 4 – “STARTING PROCEDURES”:
provides a general description of the device and its main parts.

Chapter 5 – “PRELIMINARY OPERATIONS”:
explains the procedure for a correct device initialisation.

Chapter 6 – “SCANNING”:
Explains the process to position and scan an animal.

Chapter 7 – “QUALITY CONTROL”:
explains the procedure for a correct Quality Assurance process.

Chapter 8 – “TROUBLESHOOTING”:
Provides a list of malfunctions and possible solutions.

APPENDIX A: TECHNICAL SPECIFICATIONS

APPENDIX B: COMPATIBILITY

APPENDIX C: DEVICE LABELS

1.3. STYLISTIC CONVENTIONS

Important safety information and any notes are included in the manual as shown here:

DANGER:
Warns of the presence of a potential danger that could injure a person or that can cause death.

WARNING:
Warns of the presence of a potential danger that could damage the device.

NOTE:
Provides additional information not related to the safety of the device, the animal and the operator.

2. SAFETY-RELATED INFORMATION

This chapter provides safety-related information the operator must become familiar with before using the device.

To ensure the safety of the patient and of the operator, always follow the instructions provided herein, especially as far as functional tests, electric and mechanical safety and X-ray emission protection are concerned.

In this respect, refer to this chapter, to **Chap. 3 - "DEVICE SAFETY AND MAINTENANCE"** and to **Chap. 6 - "SCANNING"**.

WARNING:
All operators must be familiar with the operative and environmental features of the device and know the procedures to be followed in case of hazard and for emergency switching off.

2.1. APPLICABLE LAWS, JURISDICTION AND COURT OF JURISDICTION

Strictly follow all requirements on device installation, maintenance and use. Refer to the local legislation if it is more severe than the prescriptions contained in this manual.

2.2. SYMBOLS ON THE DEVICE

The following table describes the symbols indicated in the device labels:

Symbol	Standard	Description
	IEC 60417-5010	On / Off (pressure-pressure)
~	IEC 60417-5032	Alternating current
	ISO 7000-0434A	Warning
	ISO 7010-W001	General warning sign
	ISO 7010-W012	Caution: electrical voltage.
	IEC 60417-5019	Protective earthing system.
N	IEC 60445	Connection point of the neutral wire of the permanently installed equipment.
L	IEC 60445	Connection point of the line wire of the permanently installed equipment.
	IEC 60417-5840	Type B applied part, protected against direct and indirect contacts.
	IEC 60878-5909	Ionising radiations.

Symbol	Standard	Description
	Directive 2012/19/EU	Disposal of WEEE (Waste Electrical And Electronic Equipment).
CE		Equipment compliant with the requirements set out by the applied Directives.
SN	ISO 7000-2498	Serial number.
	ISO 7000-2497	Date of manufacture.
	ISO 7000-3082	Manufacturer.
	ISO 7000-1641	Operating instructions.
	ISO 7010-M002	Refer to the instruction manual.
#	IEC 60417-6050	Model.
REF	ISO 7000-2493	Catalogue number.
	ISO 7000-3500	The operator’s manual is provided in electronic format.
	IEC 60417-5638	Emergency stop.

2.3. DEVICE SWITCHING ON AND OFF

Refer to the paragraph with the same title in the “User Manual” document.

2.4. EMERGENCY SWITCHING OFF

The device is equipped with 4 emergency shut-down buttons. The first button in placed on the operator’s table. The second button is on the patient table, under the table movement control console. Two additional buttons are located on either side of the scanning hole, near the signalling keyboards.

NOTE:
Emergency stop button located beneath the patient table control console, available only when the device is equipped with a patient table.

Figure 1: Device emergency stop buttons

If the device is shut down through an emergency stop button emission is immediately stopped and all device motorised movement functions are disabled.

WARNING:
The emergency switching off must be used exclusively in case of hazardous situations, i.e.:

- The X-ray source does not interrupt emission.
- Hazardous conditions that may cause harm to people, the environment, or the device.
- Conditions under which the device signals an emergency situation.

2.5. SAFETY OF ANIMAL AND OPERATOR

Work following the correct procedures and position the animal correctly to avoid risks for the animal and all the involved operators.
Pay special care in case of debilitated animals or with traumas.

2.5.1. ANIMAL POSITIONING

Make sure the animal is correctly positioned within the scanning area, with the head on the chin rest and with no part of the body that may hit the device or at risk of being crushed during the positioning and for the whole duration of the examination.

Make sure that any animal's hairs are not at risk of getting tangled.

Before starting any device movement check that the animal is in the correct position and that there are not obstacles to the device movements.

Refer to Par. 6.1.2 - "Positioning the animal and starting the scan".

2.5.2. DURING THE SCANNING

During device handling and animal scanning, **NEVER** leave the device unsupervised.

Always keep the animal monitored for the entire scanning duration.

WARNING:
NEVER use the device without the operator supervision.

NOTE:
Consider the implementation of an audio/video communication system between the operator and the patient in case the operator controls the device from a protected and remote area.

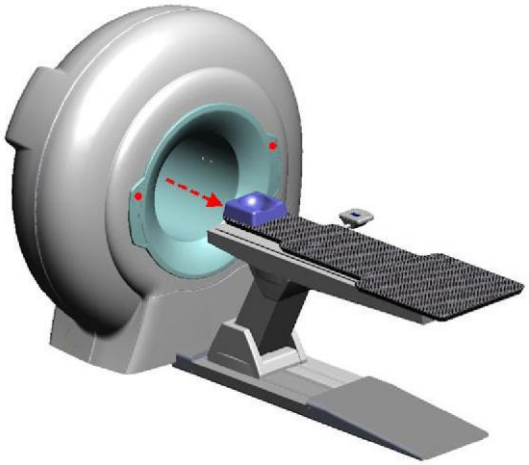
2.5.3. ANIMAL LEAVING THE SCANNING AREA

At the end of the examination or after the emergency stop button has been pressed, it is possible to remove the patient table from the scanning area and allow the animal to leave.

2.5.4. ANIMAL EXIT IN CASE OF FAULT / MALFUNCTION OF THE PATIENT TABLE

NOTE:
Applicable only to devices equipped with patient table, code 96600822.
When using a third-party patient table, refer to the specific user documentation supplied with that product.

In case of interruption of the operation of the patient table with stretcher, remove the animal by manually moving the stretcher completely out of the device gantry.



NOTE:
To further move the animal towards a stretcher, when the animal is unconscious or unable to walk, refer to the procedures set forth by the organisation.

NOTE:
In case of unintentional interruption of the power supply, the maximum distance values of the motorised movements of the patient table (with maximum nominal load applied) are the following:

Longitudinal movement: < 5 mm
Transversal movement: < 10 mm
Vertical movement: < 5 mm

2.6. ARTEFACTS AND SCANNING REPETITION

Refer to the paragraph with the same title in the “User Manual” document.

2.7. PROTECTION AGAINST IONIZING RADIATIONS

WARNING:
NewTom 5G XL Vet is an X-ray device and therefore it exposes the animal and the operators to the risks deriving from ionising radiations.
It must be used in compliance with the safety standards on radiation protection in force in the country of use.

WARNING:
NewTom 5G XL Vet must not be used for routine or screening examinations. For such purposes, use other diagnostic equipment.
The imaging examinations performed on each animal must be justified in order to prove that they provide more benefits than risks.

Strictly follow the applicable radiation protection standards and any prescription provided by a Qualified Expert.

- **Operator**

The operator must supervise the examination from a control workstation in compliance with the applicable laws; nobody is allowed to stand near the animal during the examination.
In case an animal has a panic reaction that requires the intervention of the operator during the examination, the operator shall wear suitable protection clothes and equipment as defined by the national and local standards.

WARNING:
Never stand near the device during emission.

WARNING:
In accordance with the dose limits recommended in the country of use, refer to the "*Stray Radiation Map*" to determine the minimum safe distance to be maintained during X-ray emission. If the operator must remain in the room during the examination (e.g. in the event of a patient panic reaction), suitable lead-lined protective clothing and devices must be worn, as defined by national and local regulations.

- **Animal**

The user is responsible for protecting the animal from useless exposure.

WARNING:
Consider the use of a leaded apron to protect the animal from diffuse radiation.

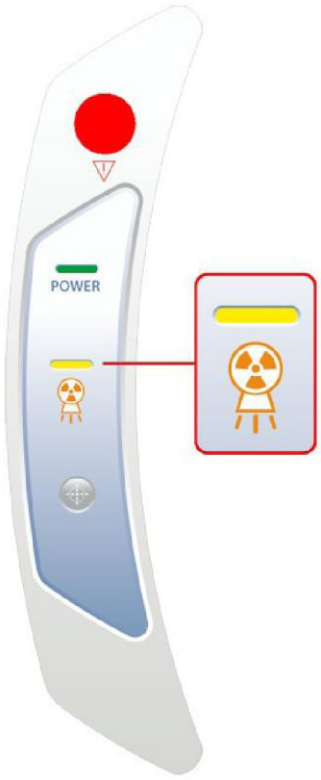
WARNING:
Possible adverse interaction between CT X-radiation and active implantable or wearable electronic devices.
Contact the manufacturer of such devices for further information.

- **Emission view devices**

The emission status is clearly identified by:

1. A signal on the display, as shown below. This signal is displayed only after the X-ray emission has started by pressing the START button on the keyboard or using a mouse (refer to chap. 6 - "Scanning") and remains visible for the entire duration of the scanning.

2. Light indicator (LED) inside the signalling keyboards located on the sides of the device scanning hole (see figure below).
   This indicator lights up only after the X-ray emission has started by pressing the START button on the keyboard or using a mouse (refer to chap. 6 - "Scanning") and remains visible for the entire duration of the scanning and/or emission.



WARNING:
If the emission signals are active when the X-ray emission command has not been enabled, if they are not active when the emission has started or if the latter does not stop at the end of the pre-set time, switch off the device immediately and contact the technical customer service.

2.8. PROTECTION AGAINST LASER RADIATIONS

The device is provided with three cross lasers to correctly position the animal. The laser radiation comes out of holes on the internal cover.

The upper vertical line indicates the central sagittal plane of the reconstituted volume. The horizontal lines indicate:

– in case of large field scanning, the occlusal plane.
– in all other fields, the central axial plane of the reconstructed volume.

The lateral vertical line indicates the central coronal plane of the reconstructed volume.

WARNING:
Do not stare at the laser ray, do not look at it directly with optical instruments and avoid the direct exposure. The ray can cause permanent eye damage.

WARNING:
Keep a distance of at least 40mm between the eyes and the laser emission point when the laser ray is active.
If necessary consider the use of suitable protection goggles.

WARNING:
Failure to comply with the prescriptions and procedures described herein may lead to a dangerous exposure to radiations.

2.9. DEVICES CONNECTED TO THE CONTROL CONSOLE

Refer to the paragraph with the same title in the “User Manual” document.

2.10. MAINTENANCE INTERVAL

Refer to the paragraph with the same title in the “User Manual” document.

2.11. APPLIED PARTS

The parts of the equipment that, during standard use, necessarily come into contact with the animal, so that the device may carry out its functions correctly, are: patient table pad cover, patient table with stretcher.

Parts not applied that might come into contact with the animal are the external covers.

3. DEVICE SAFETY AND MAINTENANCE

3.1. INSTALLATION REQUIREMENTS

Refer to the paragraph with the same title in the “User Manual” document.

3.2. SAFETY GUIDELINES

Refer to the paragraph with the same title in the “User Manual” document.

3.3. CHANGES TO THE DEVICE

3.3.1. LIMITS OF RESPONSIBILITY

Refer to the paragraph with the same title in the “User Manual” document.

3.4. DEVICE MAINTENANCE

Refer to the paragraph with the same title in the “User Manual” document.

3.5. CLEANING AND DISINFECTION

3.5.1. CHEMICAL AGENTS TO AVOID

Refer to the paragraph with the same title in the “User Manual” document.

3.5.2. CLEANING

Refer to the paragraph with the same title in the “User Manual” document.

3.5.3. DISINFECTION

Refer to the paragraph with the same title in the “User Manual” document.

3.5.4. STERILISATION

Refer to the paragraph with the same title in the “User Manual” document.

3.6. TRANSPORT AND STORAGE

Refer to the paragraph with the same title in the “User Manual” document.

3.7. DEVICE DISPOSAL

3.7.1. INFORMATION FOR DEVICE OWNER

Refer to the paragraph with the same title in the “User Manual” document.

3.7.2. INFORMATION FOR COLLECTION / DISPOSAL / RECOVERY FACILITIES

Refer to the paragraph with the same title in the “User Manual” document.

3.7.3. BIOCOMPATIBILITY

Cover the parts in contact with the animal with sheets made of biocompatible material.

4. STARTING PROCEDURES

This chapter provides an introduction to the NewTom 5G XL Vet device, the switching on/off procedures and the control devices located on the scanner.

4.1. INTRODUCTION TO THE DEVICE

4.1.1. INTENDED USE

The NewTom 5G XL Vet device is a computerised tomograph that uses the "cone-beam" technology.
It is intended for diagnostic purposes using geometric and radiological density information obtained from two-dimensional and three-dimensional images of anatomical parts and objects in the area under investigation.

4.1.2. INDICATIONS FOR USE

The NewTom 5G XL Vet device is a computerised tomograph that uses the "cone-beam" technology to acquire sequences of images of the anatomic regions according to the system specifications.
The device carries out such operations by reconstructing a 3D matrix of the examined volume and producing two-dimensional views of the volume and then displaying two- and three-dimensional images.
The device is managed and used by radiologists and qualified operators in the veterinary field and by other legally qualified professionals.

This device is intended for veterinary use only.

WARNING:
The NewTom 5G XL Vet is able to produce panoramic reconstructions from CBCT acquisitions. This may reduce the dose if both CBCT and panoramic images are needed.
However, if the device is used to simulate a panoramic image when a CBCT acquisition is not required, the animal may be exposed to an excessive radiation dose.

WARNING:
The imaging Cone Beam must not be used for routine or "screening" examinations.
Other diagnostic tools must be taken into consideration. The imaging examinations must be justified for each animal in order to prove that they provide more benefits than risks.

4.1.3. IMPROPER USE

The NewTom 5G XL Vet device is not intended for the following uses and/or applications (reasonably foreseeable improper use):

- use with animals that cannot stay still for the entire scanning cycle (36 seconds max);
- use with animals that cannot be secured during the scanning;
- use with animals with weight and dimensions exceeding the device specifications: animals laying on the surgical table weighing more than 160kg, animals with anatomic parts that cannot be fitted in the gantry (580mm diameter);
- use by personnel not trained on the device;
- use by personnel not meeting the requirements indicated in the user profile;
- use with removable metallic objects (collars, identification tags, etc.) within the scanning field;
- use in environmental conditions different from the specified ones.

4.1.4. FUNCTIONING

Refer to the paragraph with the same title in the “User Manual” document.

4.2. OPERATION PRINCIPLE

Refer to the paragraph with the same title in the “User Manual” document.

4.3. OVERVIEW

The device consists of three main components: the scanner, the patient table accessory (version with stretcher, code 96600822 - optional) and the main workstation, installed outside the patient area.

Other computers for data processing and storage can be added to the main workstation.

For further information on this topic, please refer to the “NNT User Manual”.

Figure 2: NewTom 5G XL Vet complete device

4.4. SCANNER

4.4.1. SIGNALLING KEYBOARDS AND CONTROLS

The scanner represents the system central unit.
Two signalling keyboards for the light indication of the device switching on status or X-ray emission status are located on the sides of the scanning hole, on the circular ring cover.
The laser module switching on button to be used during animal positioning is also located on the keyboards:

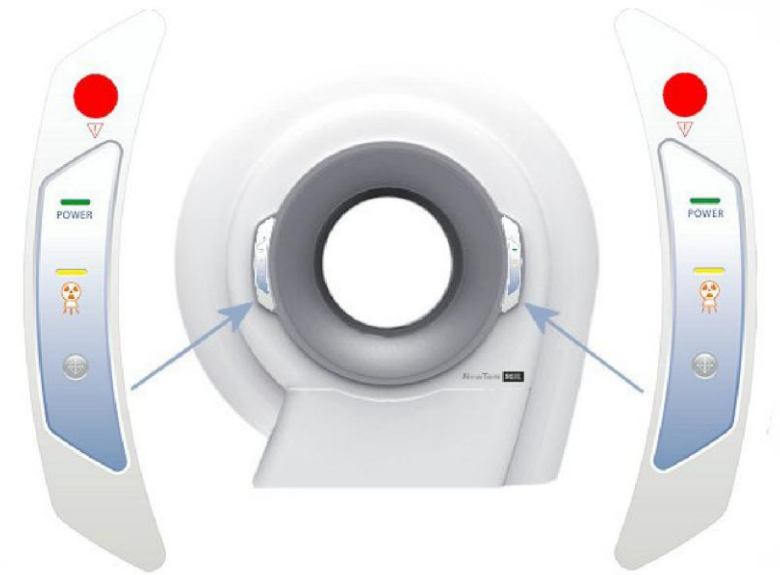


Figure 3: Scanner control panels

Following is a brief description of each indicator / button:

Emergency button:
to be pressed only in case of hazard.
To bring button back to the initial position, turn it towards the printed arrows until hearing a short click.

Device switching on indicator:
A green LED signals the device switching on after the main switch on the scanner is pressed.

X-ray emission indicator:
A yellow LED lights up during device X-ray emission status.

Laser button (L):
to be pressed to switch on/off the positioning laser. The laser switches off automatically after 60 seconds.

4.4.2. MAIN SWITCH AND INPUT PANEL

Refer to the paragraph with the same title in the “User Manual” document.

4.5. PATIENT TABLE WITH STRETCHER

NOTE:

Applicable only to devices equipped with patient table, code 96600822.
When using a third-party patient table, refer to the specific user documentation supplied with that product.

4.5.1. CONTROL CONSOLE OF PATIENT TABLE WITH STRETCHER

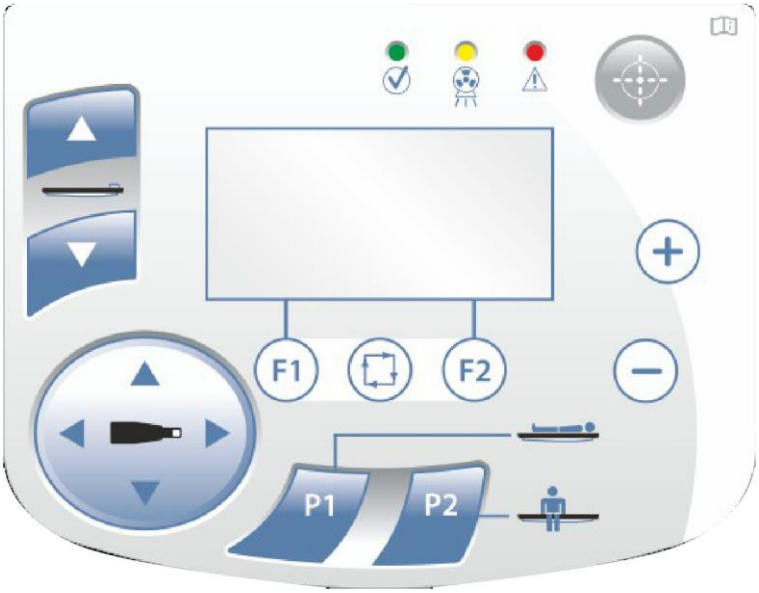
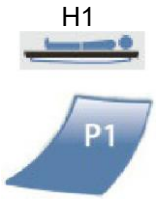
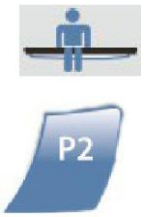


Figure 5: Control console of the patient table with stretcher

Key	Function	Warnings
UP/DOWN 	Table upward and downward movement	The table upward or downward movement is not allowed in case of aided upward movement position. The minimum and maximum movement strokes are limited to pre-set values and by active anti-collision checks.
FORWARD/BACK 	Not available	Not available. The stretcher can be moved only manually.
LEFT/RIGHT 	Transversal movement	The table transversal movement is not allowed in case of aided upward movement position. The minimum and maximum movement strokes are limited to pre-set values and by active anti-collision checks.

Key	Function	Warnings
H1 	Sequence start "Examination Preparation Position"	Operation allowed if the display shows the page representing the symbol P1 (that is if the stretcher is outside the gantry with active limit stop).
H2 	Sequence start "Aided Upward Movement Position"	Operation allowed if the display shows the page representing the symbol P2 (that is if the stretcher is outside the gantry with active limit stop).
* / - 	+ / - keys	The function depends on the current page shown on the display.
LASER 	Laser switching on/off key	The key is active only if the 5G XL/PC communication is active.
F1 / MODE / F2 	Menu browsing keys F1 / MODE / F2	The function depends on the icon shown on the display near the relevant key.
READY 	5G XL/PC connection LED	A green LED lights up when a connection between 5G XL and PC is active
X-RAY EMISSION 	X-ray emission LED	A yellow LED lights up when X-ray emission is in progress
FAULT 	Error LED	A red LED lights up in case of fault. The operator intervention is required

For further information on the available controls and the patient table use, please refer to the attached document "Patient Table User Procedures".

4.6. STANDARD COMPONENTS

Refer to the paragraph with the same title in the “User Manual” document.

4.7. CABLES

4.7.1. OPTIONAL ACCESSORIES

Refer to the paragraph with the same title in the “User Manual” document.

4.8. SWITCHING ON THE DEVICE

Refer to the paragraph with the same title in the “User Manual” document.

4.9. DEVICE SWITCHING OFF

Refer to the paragraph with the same title in the “User Manual” document.

5. PRELIMINARY OPERATIONS

Refer to the paragraph with the same title in the “User Manual” document.

5.1. DAILY CHECK

Refer to the paragraph with the same title in the “User Manual” document.

5.2. BLANK ACQUISITION

5.2.1. BLANK ACQUISITION INVALIDATION

Refer to the paragraph with the same title in the “User Manual” document.

5.3. COLLIMATOR TEST

Refer to the paragraph with the same title in the “User Manual” document.

6. SCANNING

This chapter describes the procedures to be followed for a correct positioning of the animal (or of the prosthesis) and for a correct execution of the examination.
The description of the scanning procedure is indicated in the specific chapter "*Acquisition operations with NewTom 5G XL*" attached to the "*NNT User Manual*" document.
It is also recommended to refer to chapters 2 - "Safety-related information" and 3 - "Device safety and maintenance".

The scanning procedure can be performed as follows:

- [21x28e] (eFOV scanning) [(2)] (volume diameter 21cm, height 28cm);
- [21x19];
- [18x16];
- [15x22e] (eFOV scanning) [(2)];
- [15x12];
- [15x5];
- [12x8];
- [10x10];
- [10x5];
- [8x8];
- [8x5];
- [6x6];
- [15x5] HiRes (High Resolution);
- [12x8] HiRes;
- [10x10] HiRes;
- [10x5] HiRes;
- [8x8] HiRes;
- [8x5] HiRes;
- [6x6] HiRes.

WARNING:
Use a field of view as small as necessary according to clinical needs.
In general, for small-sized or paediatric patients it is recommended to use smaller FOVs.

NOTE:
Non-HiRes FOVs are characterised by a scanning time ranging from 18 s to 25.8 s and an exposure time between 0.9 and 5.4 s.
HiRes FOVs are intended for examinations for which a more detailed view of bone structures is required (compared with non-HiRes FOVs):

> scanning time (from 18 s to 36 s)
> exposure time (from 3.24 s to 9.0 s)

> examination dose	(approx. 2.5 to 10 times)	*(compared with non-HiRes FOVs, Eco Scan)*
	(approx. 2.3 to 3.1 times)	*(compared with-HiRes FOVs, Regular Scan)*
	(approx. 1.9 to 2.6 times)	*(compared with non-HiRes FOVs, Enhanced Scan)*

Three different scanning options are available for each one of the described fields of view [(3)]:

- **Regular Scan**: default option for image quality, scanning time (from 18 s to 20.2 s) and exposure time (from 3.6 s to 5.4 s).
- **Eco Scan**: recommended for examinations on an animal for whom a low dose is preferable:
  < exposure time (from 0.9 s to 3.24 s)
  < examination dose (approx. 0.1 to 0.6 times) *(compared with Regular Scan mode)*

2 FOV available only in case of software option enabled
3 The "Enhanced Scan" option is not available in case of eFOV scanning

- **Enhanced Scan**: recommended for examinations for which a good image quality is required:

  > scanning time (from 25.8 s to 36.0 s)
  > exposure time (from 5.4 s to 9.0 s)
  > examination dose (approx. 1.6 to 2.3 times) *(compared with Regular Scan mode)*

When performing a Regular or an Enhanced Scan, it is possible to choose one of the following options:

- **Standard Dose**: default option;
- **Boosted Dose**: this option, recommended for thick bone structures, offers better image quality at the expense of a greater dose (up to twice the dose compared to standard dose scans with the same scanning and exposure time).

NOTE:
The ratio of the doses between different FOVs and protocols was determined on the basis of the dose values indicated in the attached document "Dose declaration and acceptance test" considering weighted CTDI values ($CTDI_w$).

WARNING:
Selecting the HiRes / Enhanced Scan / Boosted Dose protocol will entail a dose **6 times** higher than a non-HiRes / Regular Scan /Standard Dose protocol with the same FOV.
The imaging examinations must be always justified in order to prove that they provide more benefits than risks.

NOTE:
“eFOV” fields of view are available only when the device is equipped with patient table, code 96600822.

To choose one of these modes, select the desired scanning mode (FOV) from the "**Scan Manager**" panel located at the bottom right of the software main window:

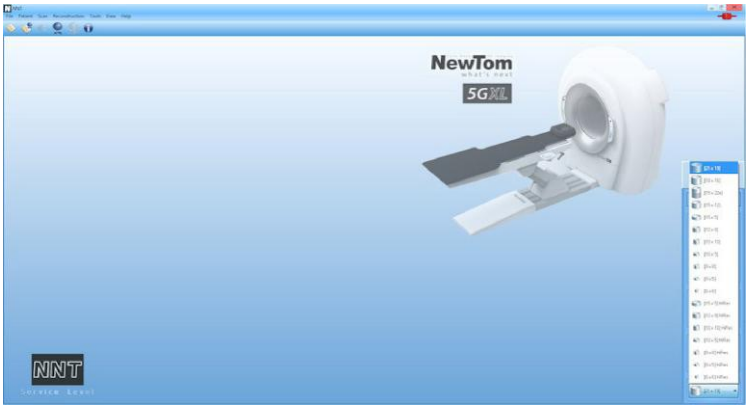


Figure 9: "Scan Manager" panel of the NNT software

6.1. SCANNING AN ANIMAL

6.1.1. PREPARATION OF THE ANIMAL

The preparation of the animal for an examination is an important process which can contribute to the correct execution of the scanning, thus allowing obtaining images of very good quality.
The purpose of this process is to make the animal feel relaxed before and during the examination. Some tips that may contribute to the achievement of this goal are indicated below.

- **Preparation of the room**
  Make sure the scanner is clean and ready to scan the animal ("Daily check" and "Blank acquisition" already performed).

- **Preparing the animal**
  Remove any collar or other objects that may enter the scanning area.

- **Positioning the animal**
  Position the animal on the patient table, adjust the table so as to frame the concerned scanning area and make sure the animal is in a correct position.

- **Avoid delays**
  To relatively reduce the examination execution time, complete all the preliminary procedures before starting the examination.

6.1.2. POSITIONING THE ANIMAL AND STARTING THE SCAN

NOTE:
Applicable only to devices equipped with patient table, code 96600822.
When using a third-party patient table, refer to the specific user documentation supplied with that product.

Below is the description of the operations to be performed to position and centre the animal within the scanning area. Perform these operations in the exact moment signalled by the software.

For further information on how to use the patient table refer to the attached document "Patient Table User Procedures"

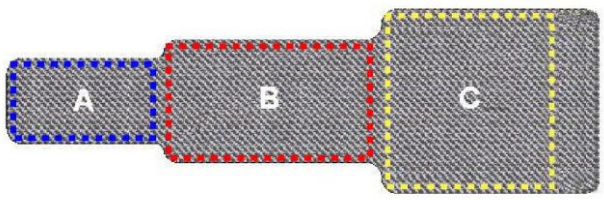
WARNING:
The scanning area where the animal is positioned must remain cleared from objects of any type since they may harm the animal and/or invalidate the results of the examination.

WARNING:
When moving the patient table, pay attention to avoid collisions with present objects and/or people.

NOTE:
Pay attention not to excessively load the parts of the patient table.
The patient table supports a maximum weight of 160Kg (plus 15kg of accessories, if any).
Below is detailed the distribution of the maximum allowed loads:

Patient table with stretcher

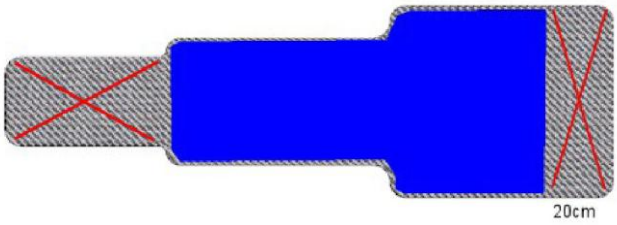
1) Maximum load per area



Stretcher position outside the gantry
Area A: 35 Kg
Area B: 175 Kg
Area C: 175 Kg

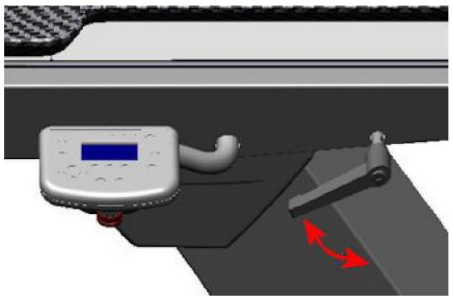
Stretcher position fitted in the gantry
Area A: 35 Kg
Area B: 90 Kg
Area C: 175 Kg

2) Seating areas (maximum weight 160Kg)



NOTE:
If the relevant software option is enabled, scanning in eFOV (extra Field of View) mode is available, namely an acquisition mode that uses 2 adjacent exposures.
The eFOV scanning is characterised by the letter "e" next to the selected FOV (e.g: [15x22e]).
For further details on this acquisition mode, please refer to the “Acquisition Operations with NewTom 5G XL” annex to the "NNT User Manual" document.

1) Upon device switching on, the patient table must be set to the default condition (easy access position).
Make sure the stretcher is completely removed from the gantry and locked with the suitable handle on the table control console side



Then press key P2 of table control console.

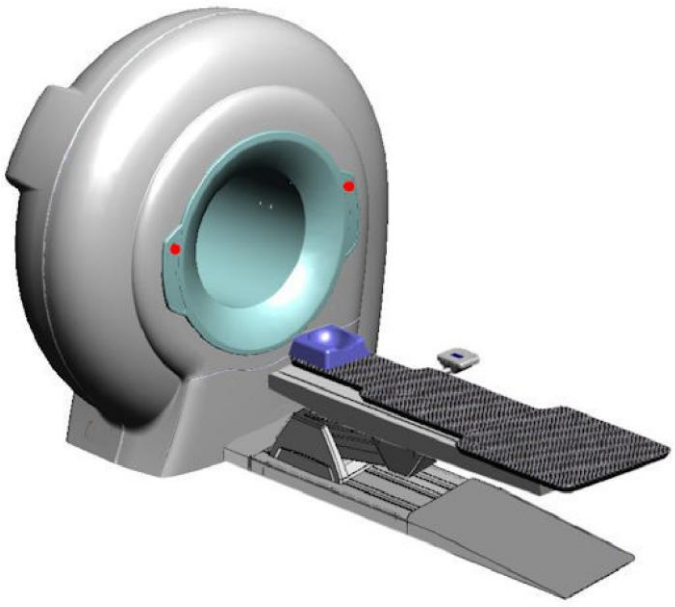


Figure 10: Patient table in easy access position

2) Move the animal to the examination preparation position by pressing P1.

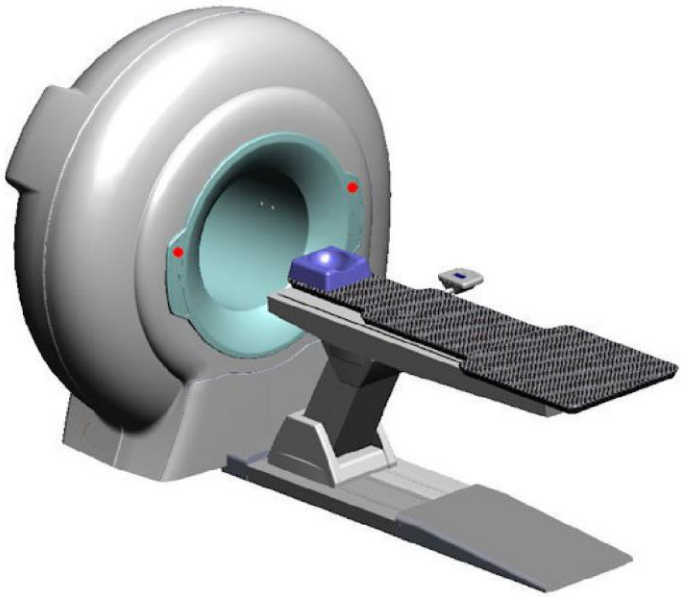


Figure 11: Patient table in examination preparation position

3) Unlock the stretcher and slide it bringing the animal inside the gantry. Then lock the stretcher again.

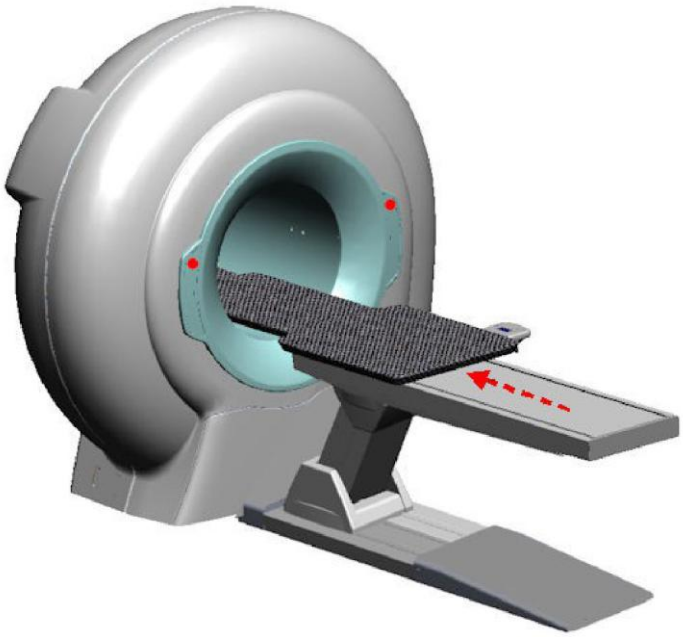
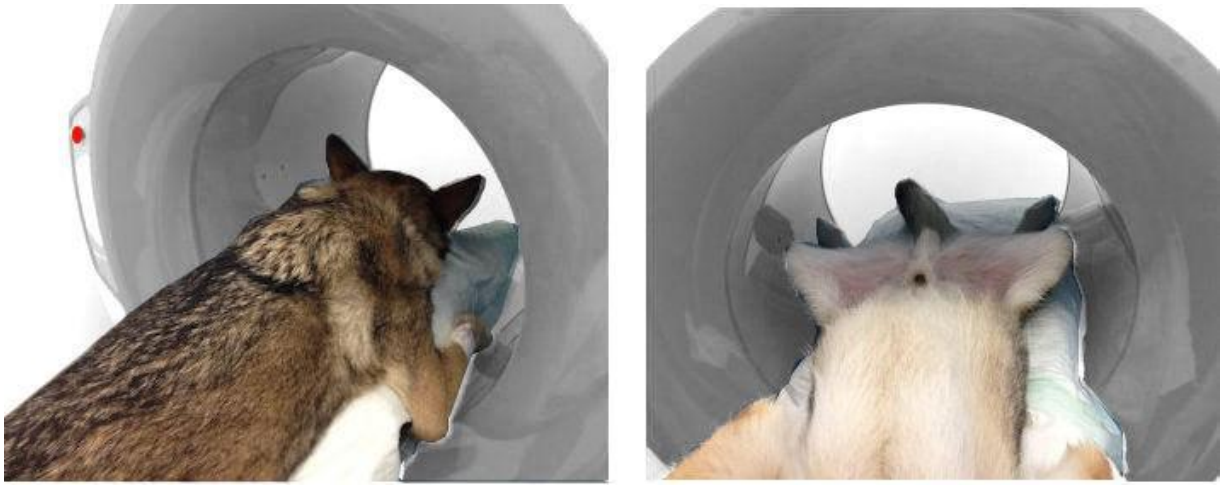


Figure 12: Patient table with fitted stretcher

4) Make sure that the animal maintains a correct position.



5) Fine-adjust the animal position using the movement keys (UP/DOWN - LEFT/RIGHT).
To this end, it is possible to use the laser centring device. To activate it, press the LASER key on the control console (the NNT software must be run) or on the control panels placed on the sides of the scanner.

6) To scan an animal, please refer to paragraphs "Scanning a patient" and "Patient position adjustment from workstation" of the “Acquisition Operations with NewTom 5G XL” annex to the "NNT User Manual" document.

7) At the end of scanning, unlock the stretcher, remove the animal from the gantry by moving the stretcher outwards, and then lock the stretcher again.

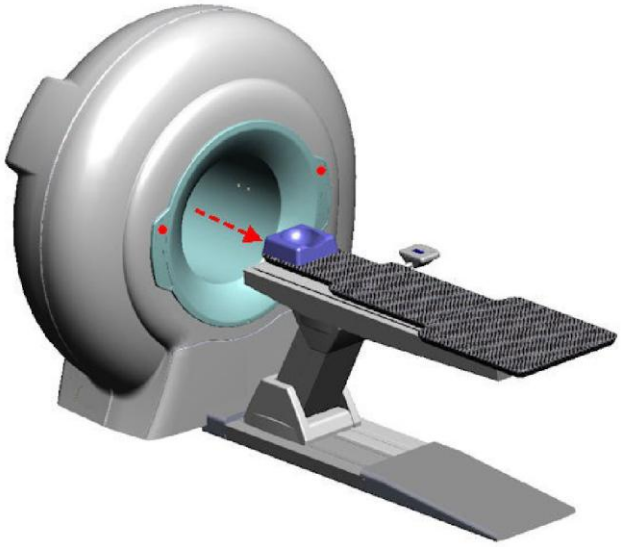
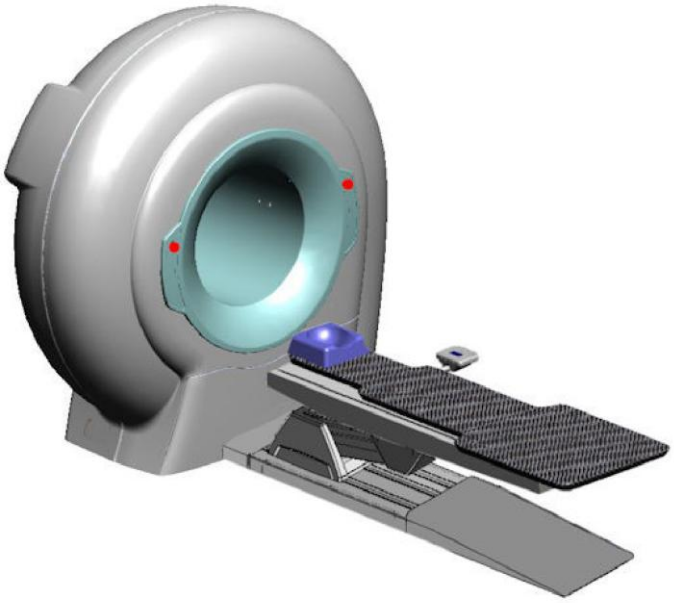


Figure 13: Patient table with removed stretcher

8) Then press P2 to bring the animal to the initial position (easy access position) and have the animal leave the room.



7. QUALITY CONTROL

Refer to the paragraph with the same title in the “User Manual” document.

7.1. PHANTOM POSITIONING

Refer to the paragraph with the same title in the “User Manual” document.

7.2. IMAGE EXAMPLES

Refer to the paragraph with the same title in the “User Manual” document.

7.3. SAVING THE PHANTOM ANALYSES

Refer to the paragraph with the same title in the “User Manual” document.

8. TROUBLESHOOTING

Refer to the paragraph with the same title in the “User Manual” document.

9. APPENDIX A: TECHNICAL SPECIFICATIONS

Scanner

Scanning device (cone beam technology)	Single rotation with volumetric acquisition		
Scanning parameters	Mode FOVs CB3D CineX Ray2D		Scanning time / Emission time 18÷36 s / 0.9÷10.4 s 1÷20s @ 20fps / 0.2÷4s 21÷36s @ 15fps / 3.15÷5.4s 0.064÷3.2 s / 0.01÷0.5 s
	Sampling angle		360°
Patient centring	Fixed position		Positioning laser
Analysed anatomic volume	Cylinder		Standard Resolution: (Ø-max x H-max) [cm x cm] [21x28e] (eFOV) [21x19] [18x16] [15x22e] (eFOV) [15x12] [15x5] [12x8] [10x10] [10x5] [8x8] [8x5] [6x6] High Resolution: (Ø-max x H-max) [cm x cm] [15X5] HiRes [12X8] HiRes [10X10] HiRes [10X5] HiRes [8X8] HiRes [8X5] HiRes [6X6] HiRes
Dimensions	Scanner	Width	1750 mm
		Depth	850 mm
		Height	1780 mm
		Gantry opening	580 mm
	Patient surgical table with stretcher (optional)	Length (max)	3600 mm
		Width (max)	840 mm
		Height (max)	900 mm
		Load (max)	175Kg (160Kg patient + 15Kg accessories)
Weight		Weight	660 Kg (400 kg scanner + 260 kg patient surgical table with stretcher)

Detector

Pixel	1560 x 1440	Pixel

Pixel size	0.184 x 0.184	mm
Pixel depth	16	bit
S/N	9.2 – 14.2 (standard resolution) 17.1 – 21.3 (HiRes)	dB
Frame rate Max	30	F/s

X-ray image scout view

[21x28e]

Image pixels	2 x (720 x 780)	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[21x19]

Image pixels	720 x 780	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[18x16]

Image pixels	650 x 666	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[15x22e]

Image pixels	2 x (590 x 500)	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[15x12]

Image pixels	590 x 500	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[15x5]

Image pixels	590 x 208	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[12x8]

Image pixels	476 x 326	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[10x10]

Image pixels	400 x 416	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[10x5]

Image pixels	400 x 208	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[8x8]

Image pixels	320 x 326	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[8x5]

Image pixels	320 x 208	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[6x6]

Image pixels	234 x 246	Pixel
Pixel depth	16	no.
Pixel Size	0.368 x 0.368	mm

[15X5] HiRes

Image pixels	1180 x 416	Pixel
Pixel depth	16	no.
Pixel Size	0.184 x 0.184	mm

[12X8] HiRes

Image pixels	952 x 652	Pixel
Pixel depth	16	no.
Pixel Size	0.184 x 0.184	mm

[10X10] HiRes

Image pixels	800 x 832	Pixel
Pixel depth	16	no.
Pixel Size	0.184 x 0.184	mm

[10X5] HiRes

Image pixels	800 x 416	Pixel
Pixel depth	16	no.
Pixel Size	0.184 x 0.184	mm

[8X8] HiRes

Image pixels	640 x 652	Pixel
Pixel depth	16	no.
Pixel Size	0.184 x 0.184	mm

[8X5] HiRes

Image pixels	640 x 416	Pixel
Pixel depth	16	no.
Pixel Size	0.184 x 0.184	mm

[6X6] HiRes

Image pixels	468 x 492	Pixel
Pixel depth	16	no.
Pixel Size	0.184 x 0.184	mm

Reconstructed volume

Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø210 x H190	Ø210 x H280	mm
Voxel Size	0.500	0.400	mm
Image pixels	422 x 422	528 x 528	Pixel
Pixel depth	16		bit

[21x19]

Shape	Cylinder	Cube	Cube	//
Reconstructed Volume Size	Ø210 x H190	E 168	E 134	mm
Voxel Size	0.300	0.250	0.200	mm
Image pixels	704 x 704	672 x 672	672 x 672	Pixel
Pixel depth	16			bit

[18x16]

Shape	Cylinder		Cube	//
Reconstructed Volume Size	Ø180 x H160		E 134	mm
Voxel Size	0.300	250	0.200	mm
Image pixels	610 x 610	732 x 732	680 x 680	Pixel
Pixel depth	16			bit

[15x22]e

Shape	Cylinder	//
Reconstructed Volume Size	Ø150 x H220	mm
Voxel Size	0.300	mm
Image pixels	512 x 512	Pixel
Pixel depth	16	bit

[15x12]

Shape	Cylinder			//
Reconstructed Volume Size	Ø150 x H120			mm
Voxel Size	0.300	0.250	0.200	mm
Image pixels	512 x 512	614 x 614	764 x 764	Pixel
Pixel depth	16			bit

[15x5]

Shape	Cylinder			//
Reconstructed Volume Size	Ø150 x H50			mm
Voxel Size	0.300	0.250	0.200	mm
Image pixels	510 x 510	612 x 612	764 x 764	Pixel
Pixel depth	16			bit

[12x8]

Shape	Cylinder			//
Reconstructed Volume Size	Ø120 x H80			mm
Voxel Size	0.300	0.250	0.200	mm
Image pixels	410 x 410	492 x 492	614 x 614	Pixel
Pixel depth	16			bit

[10x10]

Shape	Cylinder			//
Reconstructed Volume Size	Ø100 x H100			mm
Voxel Size	0.300	0.250	0.200	mm
Image pixels	344 x 344	412 x 412	516 x 516	Pixel
Pixel depth	16			bit

[10x5]

Shape	Cylinder			//
Reconstructed Volume Size	Ø100 x H50			mm
Voxel Size	0.300	0.250	0.200	mm
Image pixels	344 x 344	412 x 412	516 x 516	Pixel
Pixel depth	16			bit

[8x8]

Shape	Cylinder			//
Reconstructed Volume Size	Ø80 x H80			mm
Voxel Size	0.300	0.250	0.200	mm
Image pixels	276 x 276	330 x 330	414 x 414	Pixel
Pixel depth	16			bit

[8x5]

Shape	Cylinder			//
Reconstructed Volume Size	Ø80 x H50			mm
Voxel Size	0.300	0.250	0.200	mm
Image pixels	276 x 276	330 x 330	414 x 414	Pixel
Pixel depth	16			bit

[6x6]

Shape	Cylinder			//
Reconstructed Volume Size	Ø60 x H60			mm
Voxel Size	0.300	0.250	0.200	mm
Image pixels	206 x 206	246 x 246	308 x 308	Pixel
Pixel depth	16			bit

[15X5] HiRes

Shape	Cylinder	Cuboid	Cuboid	//
Reconstructed Volume Size	Ø150 x H50	E110 x H50	E80 x H50	mm
Voxel Size	0.150	0.125	0.100	mm
Image pixels	1020 x 1020	880 x 880	800 x 600	Pixel
Pixel depth	16			bit

[12X8] HiRes

Shape	Cylinder	Cuboid	Cube	//
Reconstructed Volume Size	Ø120 x H80	E87 x H80	E67	mm
Voxel Size	0.150	0.125	0.100	mm
Image pixels	820 x 820	700 x 700	672 x 672	Pixel
Pixel depth	16			bit

[10X10] HiRes

Shape	Cylinder	Cube	Cube	//
Reconstructed Volume Size	Ø100 x H100	E84	E67	mm
Voxel Size	0.150	0.125	0.100	mm
Image pixels	688 x 688	672 x 672	672 x 672	Pixel
Pixel depth	16			bit

[10X5] HiRes

Shape	Cylinder		Cuboid	//
Reconstructed Volume Size	Ø100 x H50		E80 x H50	mm
Voxel Size	0.150	0.125	0.100	mm
Image pixels	688 x 688	824 x 824	800 x 800	Pixel
Pixel depth	16			bit

[8X8] HiRes

Shape	Cylinder		Cube	//
Reconstructed Volume Size	Ø80 x H80		E67	mm
Voxel Size	0.150	0.125	0.100	mm
Image pixels	552 x 552	662 x 662	672 x 672	Pixel
Pixel depth	16			bit

[8X5] HiRes

Shape	Cylinder			//
Reconstructed Volume Size	Ø80 x H50			mm
Voxel Size	0.150	0.125	0.100	mm
Image pixels	552 x 552	662 x 662	828 x 828	Pixel
Pixel depth	16			bit

[6X6] HiRes

Shape	Cylinder			//
Reconstructed Volume Size	Ø60 x H60			mm
Voxel Size	0.150	0.125	0.100	mm
Image pixels	412 x 412	492 x 492	616 x 616	Pixel
Pixel depth	16			bit

X-ray parameters

IAE X-ray tube mod. RTM 30 HS 0.3/0.6 (rotary anode)

Documentazione Tubo a raggi X
Tube Documentation
Documentation du Tube

RTM 30 HS 0.3/0.6

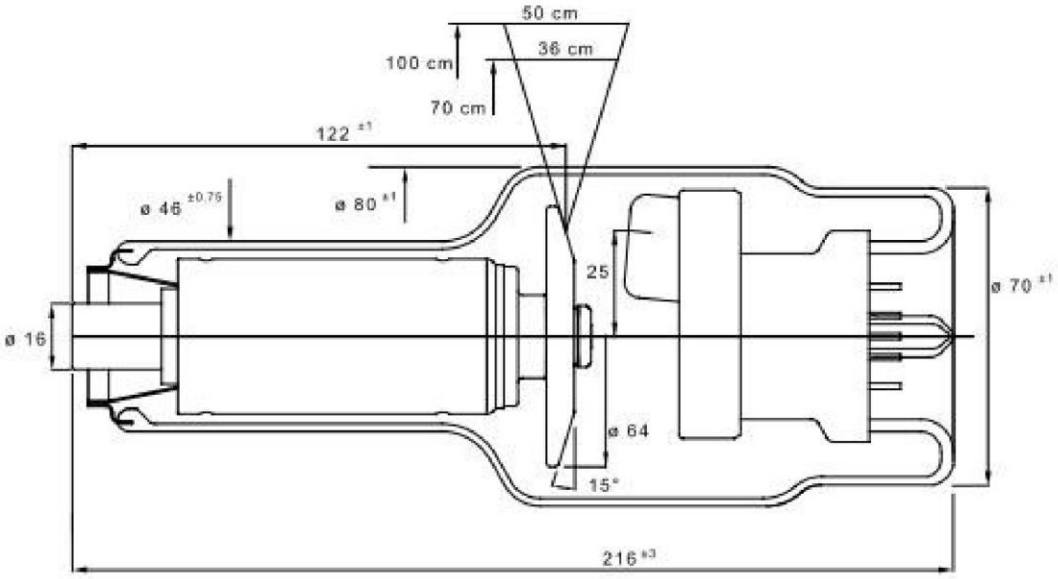
Caratteristiche - Specifications - Spécifications

Macchie focali Focal spot Foyer	■ 0.3 ■ 0.6			(IEC 336, EN 60336)
Velocità di rotazione dell'anodo Anode speed Vitesse de l'anode		3000 min^{-1}	10000 min^{-1}	
Potenza anodica nominale Nominal anode input power Puissance anodique nominale	■ ■	3.8 kW 10 kW	6.5 kW 18 kW	(IEC 613, EN 60613)
Diametro anodico Anode diameter Diamètre de l'anode		64 mm		
Materiale anodico Anode material Matériau de l'anode		RT-TZM		
Angolo anodico Anode angle Pente de l'anode		15 °		
Campo di radiazione Radiation field Champ de rayonnement		a 70 cm 36 cm à 100 cm 50 cm		
Filtrazione inerente Inherent filtration Filtration inhérente		0.7 mm Al eq		(IEC 522)
Capacità termica anodica Maximum anode heat content Chaleur maximale accumulée dans l'anode		80 kJ	107 kHU	
Dissipazione termica continua massima Maximum continuous heat dissipation Dissipation thermique continue maximale		300 W		
Alta tensione nominale Nominal X-ray tube voltage Haute tension nominale		130 kV		
Massima corrente di filamento Max. filament current Courant dans le filament max.		5.4 A		

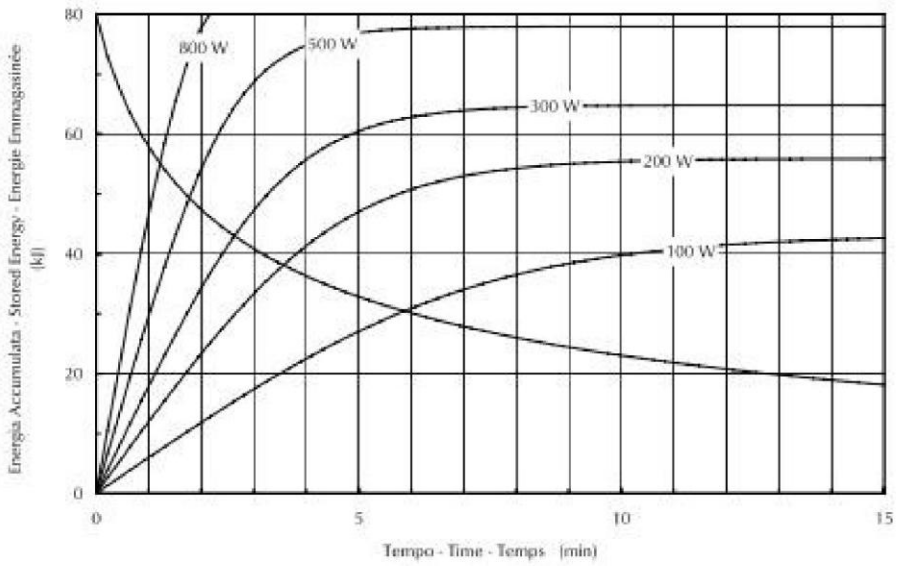
I dati forniti nella presente documentazione si intendono riferiti a:
The data indicated in this documentation refer to:
Les données indiquées dans cette documentation sont calculées pour:

Potenza anodica di equilibrio termico Equivalent anode input power Puissance anodique d'équilibre thermique	75 W =	% della capacità termica anodica % of maximum anode heat content % de chaleur max. accumulée dans l'anode	48%

Dimensioni - Dimensions - Dimensions

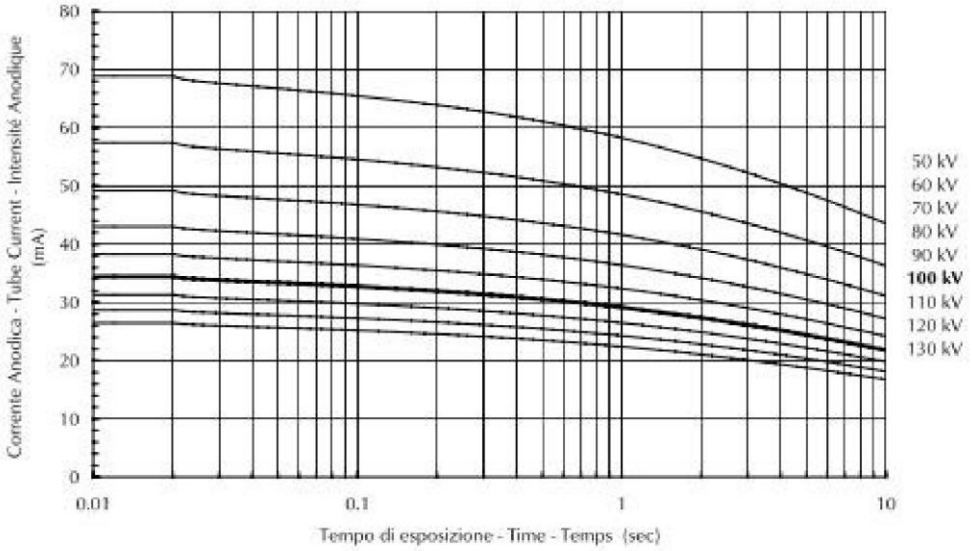


Curve di riscaldamento e raffreddamento dell'anodo
Anode heating and cooling curves
Courbes d'échauffement et de refroidissement de l'anode



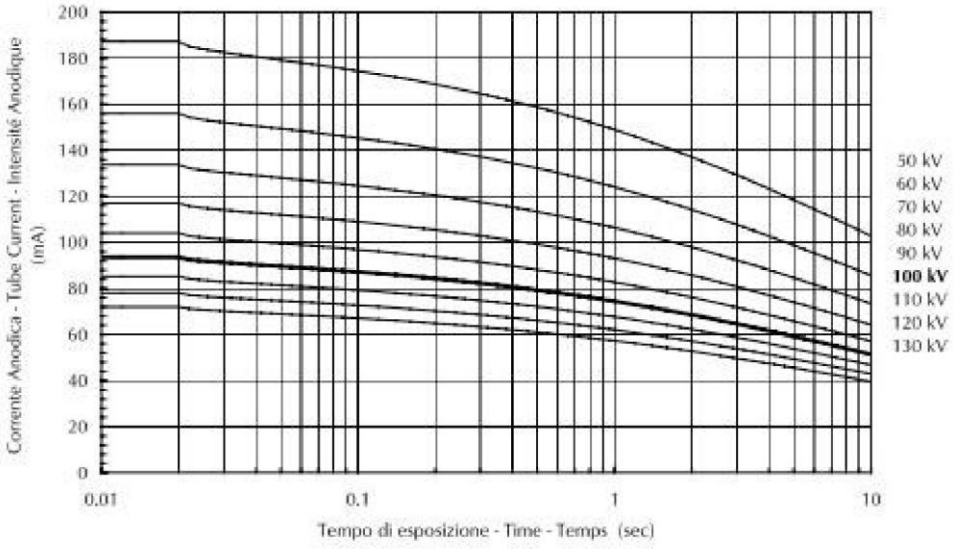
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

0.3 - 1~ - 3000 min^{-1}



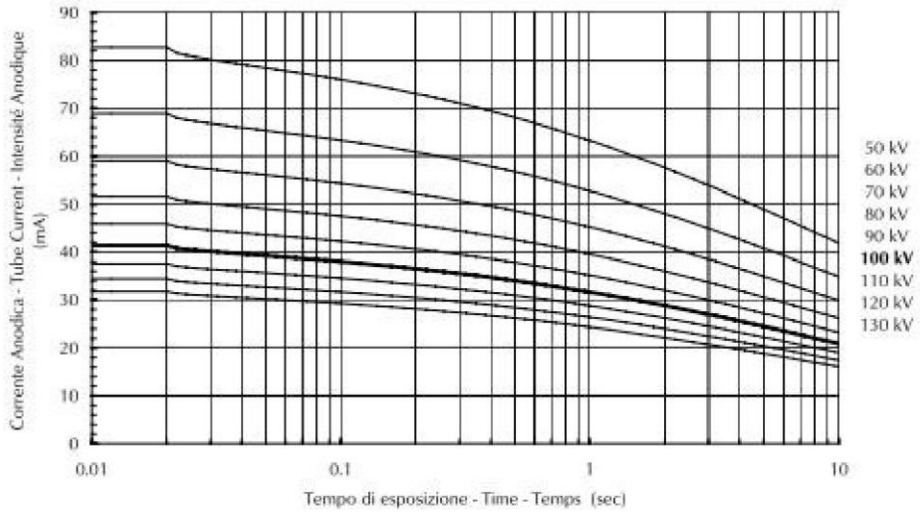
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

0.6 - 1~ - 3000 min^{-1}



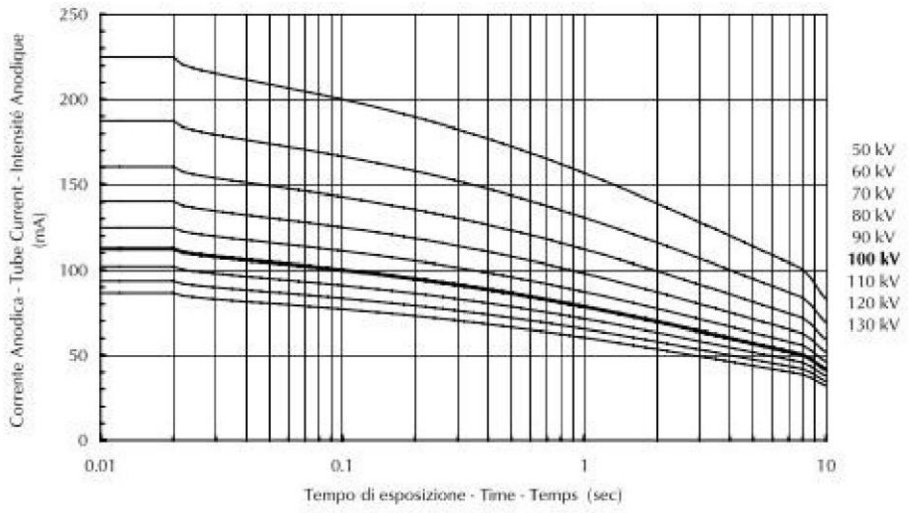
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

0.3 - 3 ~ - 3000 min^{-1}



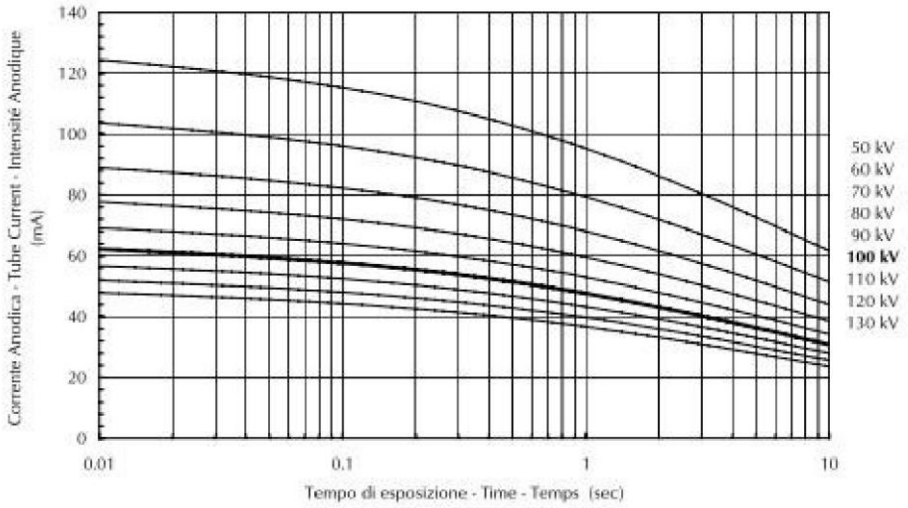
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

0.6 - 3 ~ - 3000 min^{-1}



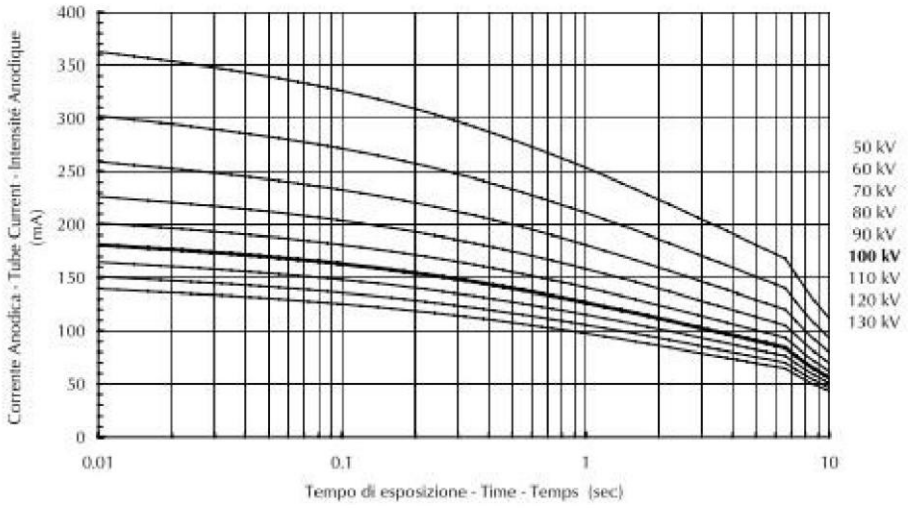
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

0.3 - 1 ~ - 10000 min^{-1}



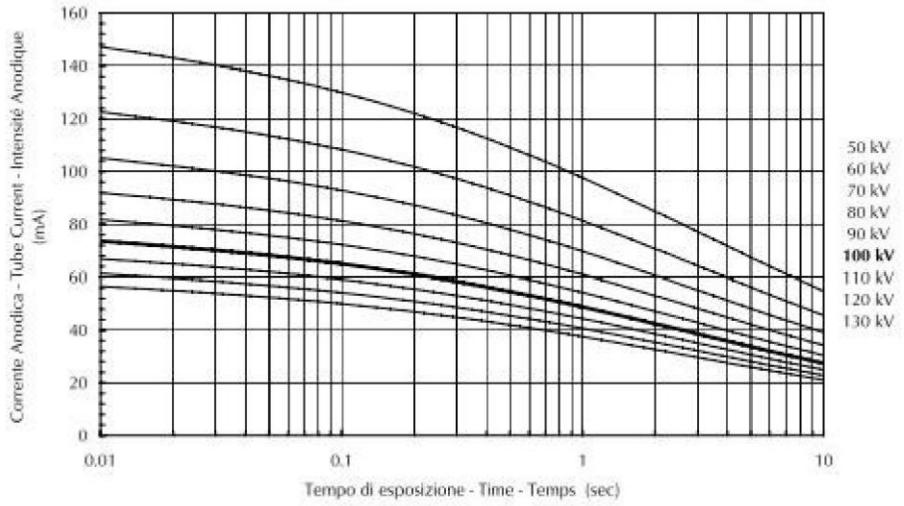
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

0.6 - 1 ~ - 10000 min^{-1}



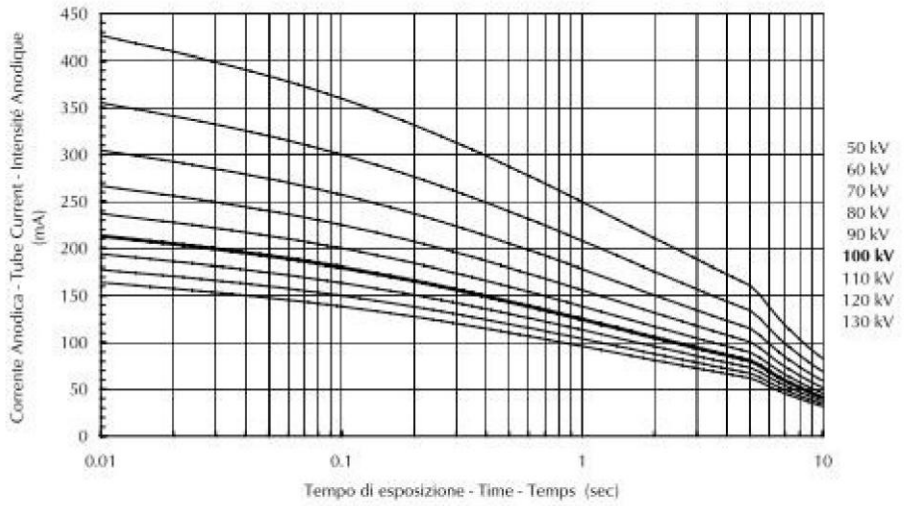
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

0.3 - 3 ~ - 10000 min^{-1}

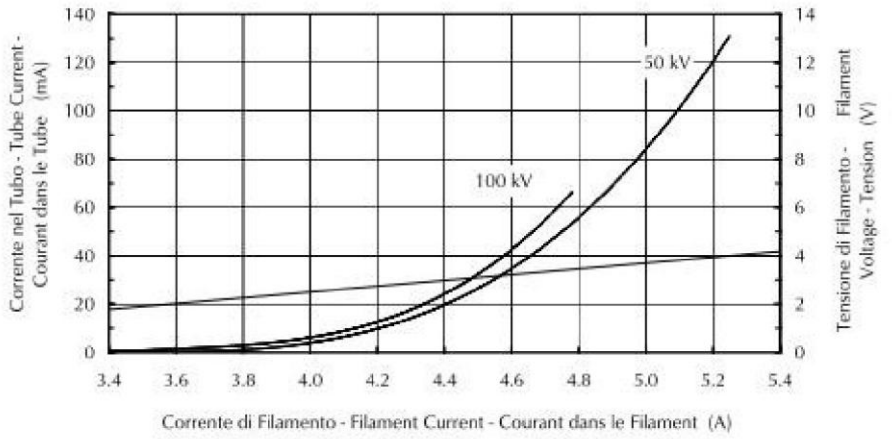


CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

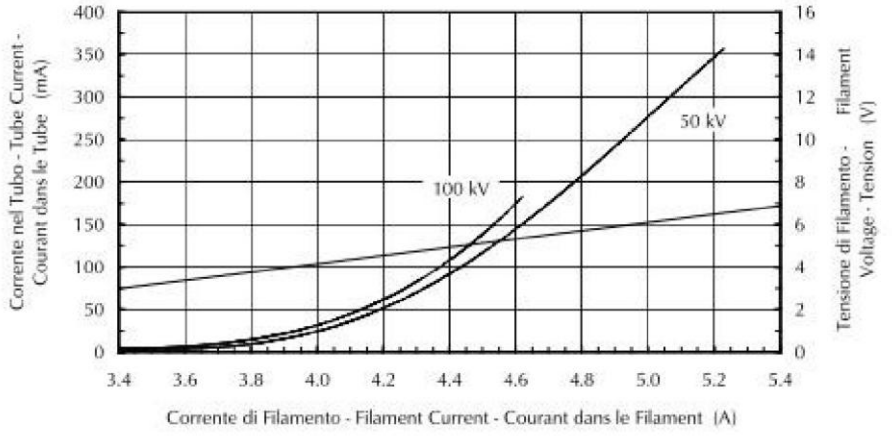
0.6 - 3 ~ - 10000 min^{-1}



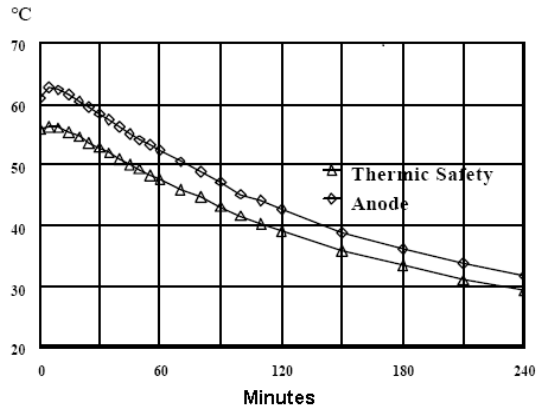
Caratteristica di emissione del catodo
Cathode emission characteristic
Caractéristique d'émission de la cathode
0.3 - 3 ~ - (± 0.2 A)



Caratteristica di emissione del catodo
Cathode emission characteristic
Caractéristique d'émission de la cathode
0.6 - 3 ~ - (± 0.2 A)



MONO-BLOCK

Make	IMD s.r.l.
Model	HF1 R
X-ray tube	IAE RTM 30 HS 0.3/0.6 (code XRM.11.X51.001 / IRM.11.280.001)
Classification (IEC 60-601)	Class I Type B
PHYSICAL DATA	
Sheath material	Aluminium
Heat capacity	550 kJ
Maximum continuous thermal dissipation	60 W at 110kV, 3.6 mA, 10 ms, 15 FPS
Maximum temperature	60°
Minimum inherent filtration at 70 kV	1.4 mm Al
Oil volume compensation	410 cu. cm rubber chamber
Dimensions	325 x 145 x 215
Weight	19.5 kg
ELECTRICAL DATA	
Maximum output voltage	120 kV
Cathode-ground	60 kV
Anode-ground	60 kV
Maximum anode current at 110 kV	32 mA
Maximum voltage at the tube at 32 mA	110 kV
Maximum electric power	3.5 kW
Maximum power ripple	<1%
High voltage increase time at maximum power	<0.5 ms
Cooling curve	**COOLING CURVE** 
Rotor	HF1R - Startup 230Vac / 0.8s / 10° - Running 60Vac / 2A
Anode nominal rpm	3000 rpm / 10000 rpm

X-ray generator-tube-sheath assembly

Model	HF1 R
X-ray tube	IAE RTM 30 HS 0.3/0.6
Focus - detector distance	970 mm
Minimum focus-skin distance	150 mm
Total filtration	1.4 mm Al (Inherent filtration) + 9.1 mm Al (Supplementary filtration)
Conical beam maximum dimension	265 mm x 287 mm (detector area)
Radiation reproducibility [5]	Δ < 10%
Tube voltage precision [6]	< 10%
Tube current precision [7]	< 20%
Radiation linearity [8]	< 20%
Emission time accuracy	< 10% + 1 ms
mAs accuracy [9]	< 10% + 0.2 mAs

INVERTER

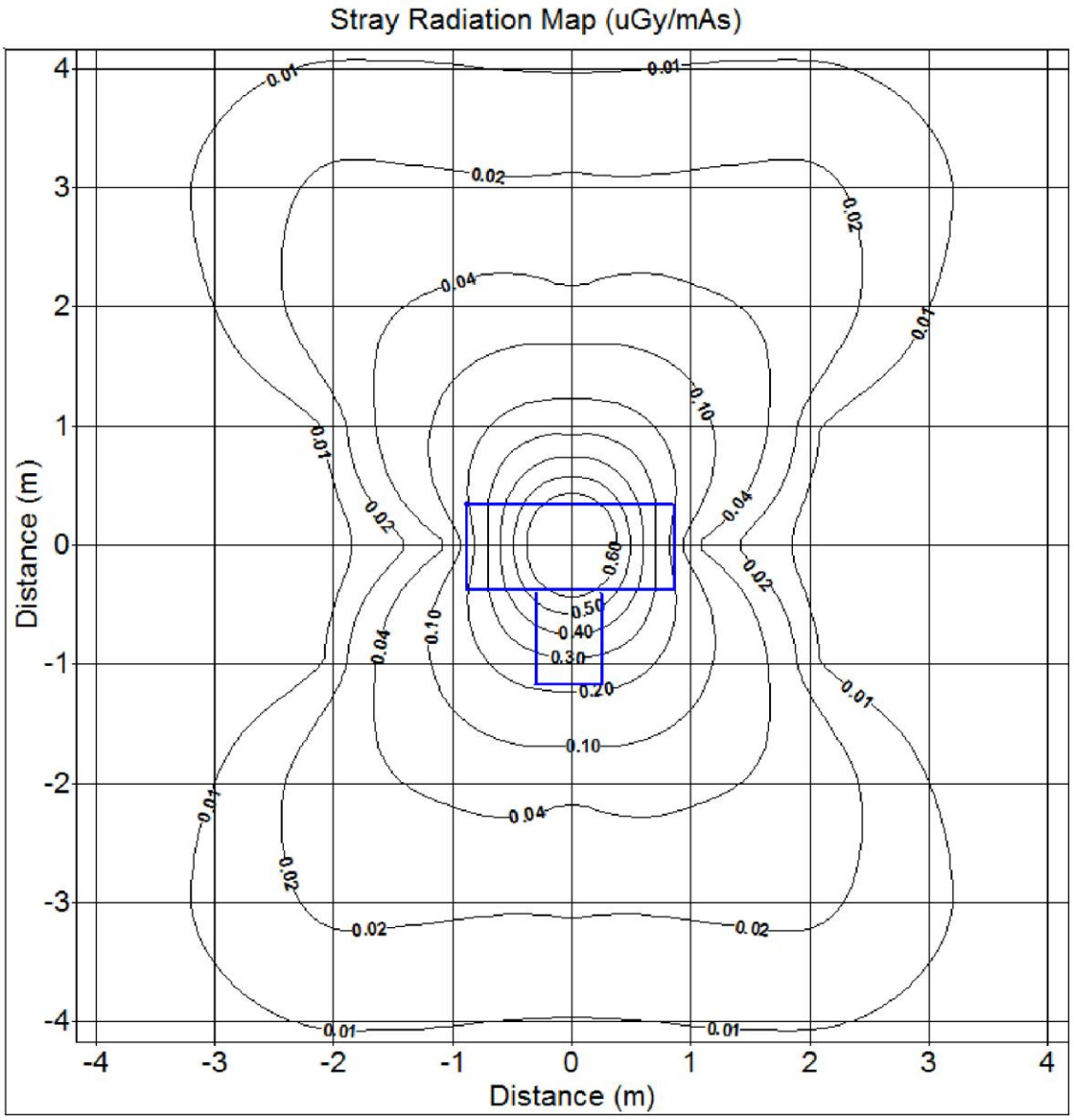
Make	IMD s.r.l.
Model	HF1 3.5kW / HF1 3.5kW PLUS
INPUTS	
Maximum power	3.5 kW
Power supply	230 V~ (± 10%)
Wave shape	Sinusoidal 50/60 Hz
Maximum current	16 A
Power supply apparent resistance	0.35 ohm
OUTPUTS	
Peak voltage	350 Vpk
Maximum peak current	120 Apk Max.
Wave shape	Sinusoidal 20 kHz
PHYSICAL DATA	
Dimensions	160 x 280 x 235 mm
Weight	7 kg

5 According to IEC 60601-2-44:2009, par. 203.6.3.2
6 According to IEC 60601-2-63:2012, par. 203.6.4.3.102.2
7 According to IEC 60601-2-63:2012, par. 203.6.4.3.102.3
8 According to IEC 60601-2-63:2012, par. 203.6.3.1.101
9 According to IEC 60601-2-63:2012, par. 203.6.4.3.102.5

Dose declaration
Please refer to the attached document **"Dose declaration and acceptance test"**

Stray Radiation Map

Stray radiation (uGy/mAs) according to IEC 60601-2-44:2009 Par. 203.13.
Measured using “head phantom” according to IEC 60601-2-44:2009 Par. 203.108.



Laser

Output power	0.9 mW
Wave length	635 nm
Beam divergence	70º
Pulse length	Continuous wave
Classification	Class 1 (IEC 60825-1:2014)

Other information

Absorbed power	100 V ~ (± 10%) / 115 V ~ (± 10%) 50/60 Hz (± 1%) 15 A (during emission) 1.7 A (in stand-by mode)
	200 V ~ (± 10%) 50/60 Hz (± 1%) 12 A (during emission) 1.2 A (in stand-by mode)
	220 V ~ (± 10%) / 230 V ~ (± 10%) 50/60 Hz (± 1%) 10 A (during emission) 1.2 A (in stand-by mode)
	240 V ~ (± 10%) 50/60 Hz (± 1%) 8 A (during emission) 1.1 A (in stand-by mode)
Use temperature	+10 ± +35 °C
Use humidity	10% ± 85 % (non-condensing)
Use altitude:	≤ 3000m
Overvoltage type:	II
Pollution degree:	2
Transport and storage temperature	-20 ± +70 °C
Transport and storage humidity	10% ± 85 % (non-condensing)

Patient table radiotransparency requirements
Max. equivalent filtration 1 mm Al eq. @ 100 kV

WARNING:
For third-party patient tables, the above radiotransparency requirements must be met. Refer to the product-specific documentation for further details.

Electromagnetic compatibility

The device is intended for use in environments recognised as professional health facilities, as described in **IEC 60601-1-2:2014**. The device belongs to CISPR 11 Class A Group 1 and complies with immunity test levels specified by IEC 60601-1-2:2014 for professional health facilities.

Before using any electronic device in health facilities, always check that it is compatible with the other equipment present.

<table>
<tr><th>Clause</th><th colspan="2">Guidance and manufacturer's declaration - electromagnetic emissions - for all equipment and systems</th></tr>
<tr><th colspan="3">TABLE: Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><th colspan="3">The NewTom 5G XL Vet device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom 5G XL Vet device must ensure that is used in such environment.</th></tr>
<tr><th>Emission test</th><th>Conformity</th><th>Electromagnetic environment - guide</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The NewTom 5G XL Vet device uses RF energy only for its internal operation. Therefore, its RF emissions are very low and they probably do not interfere with the electronic devices nearby.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The NewTom 5G XL Vet device is suitable to be used in all rooms, except the domestic ones, and places directly connected to a public low-voltage line that supplies buildings for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not Applicable</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Not Applicable</td></tr>
</table>

Clause	Guidance and manufacturer's declaration - electromagnetic emissions - for all equipment and systems		
TABLE: Guidance and manufacturer's declaration - electromagnetic emissions			
The NewTom 5G XL Vet device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom 5G XL Vet device must ensure that is used in such environment.			
Immunity test	**Test level IEC 60601**	**Conformity level**	**Electromagnetic environment - guide**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV by contact ±15 kV in air	IEC 60601-1-2 Test level	Floors must be made of wood, concrete or ceramic. If floors are covered with synthetic material, the relevant humidity should be at least 30%.
Transients/fast electric trains IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	IEC 60601-1-2 Test level	The network voltage quality should be that of a typical commercial or hospital environment.
Over-voltage IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	IEC 60601-1-2 Test level	The network voltage quality should be that of a typical commercial or hospital environment.
Voltage drops, short blackout or voltage variations on the input supply lines IEC 61000-4-11	Ut = 0% (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) for 0,5 cycles Ut = 0% for 1 cycle Ut = 70% (at 0°) for 25/30 cycles Ut = 0% for 250/300 cycles	IEC 60601-1-2 Test level	The network voltage quality should be that of a typical commercial or hospital environment. If the NewTom 5G XL Vet device user requires a continuous operation also in case of blackout, it is recommended to power the NewTom 5G XL Vet with uninterruptible power supply (UPS) or batteries.
Magnetic field at network frequency (50/60 Hz) IEC 61000-4-8	30 A/m	IEC 60601-1-2 Test level	The magnetic fields at network frequency should feature levels typical of a standard commercial or hospital environment.

Clause	Guidance and manufacturer's declaration - electromagnetic emissions - for all equipment and systems

TABLE: Guidance and manufacturer's declaration - electromagnetic emissions

The NewTom 5G XL Vet device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom 5G XL Vet device must ensure that is used in such environment.

Immunity test	Test level IEC 60601	Conformity level	Electromagnetic environment - guide
Conducted RF IEC 61000-4-6	3 Vrms from 150 kHz to 80 MHz 6 V ISM frequencies	IEC 60601-1-2 Test level	The RF communication devices (portable and mobile) to be used near the NewTom 5G XL Vet device, including cables, should be located at least at the recommended distance calculated with the equation applicable to the transmitter frequency. Recommended distance: d = 1.2 * P d = 1.2 * P from 80 MHz to 800 MHz d = 2.3 * P from 800 MHz to 2.7 GHz where P is the maximum nominal output power of the transmitter in Watt (W) according to the transmitter manufacturer, and d is the recommended distance in meters (m). The field intensity of the fixed RH transmitters, determined based on an electromagnetic* analysis, could be lower than the conformity level in each frequency interval **. Interferences may occur near the devices marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	

Notes:
(1) At 80 MHz and 800MHz it is necessary to apply the distance defined for the highest frequency interval
(2) These guidelines could not apply to all situations. The electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.

*The field intensity for fixed transmitters like the base stations for radiophones (mobiles and cordless phones) and radio units, radio amateur devices, AM and FM radion transmitters and TV transmitters can not be defined theoretically and with precision. To assess an electromagnetic environment caused by fixed RF transmitters, one should consider performing an electromagnetic analysis of the site. If the field intensity measured in the place where a NewTom 5G XL Vet device is used exceeds the applicable conformity level mentioned above, one should analyse the standard operation of the NewTom 5G XL Vet device. If abnormal performance is noticed, it may be necessary to implement supplementary measures like a different orientation or position of the NewTom 5G XL Vet device.

**The field intensity in the frequency interval from 150 kHz to 80 MHz should be lower than 3 V/m

Clause	Guidance and manufacturer's declaration - electromagnetic emissions - for all equipment and systems		
TABLE: Recommended distance between portable and mobile radio-frequency devices and the equipment			
The NewTom 5G XL Vet device is designed to operate in the electromagnetic environment with control of the RF irradiated disturbances. The customer or the operator of the NewTom 5G XL Vet device could help in preventing electromagnetic interferences ensuring a minimum distance between the RF mobile and portable communication devices and the NewTom 5G XL Vet device as indicated below, in relation to the maximum output power of the radio-communication equipment.			
Specified maximum output power of the transmitter, W	**Distance at the transmitter frequency, m**		
	from 150 kHz to 80 MHz d=	from 80 MHz to 800 MHz d=	from 800 MHz to 2.7 GHz d=
0.001	0.037	0.037	0.072
0.1	0.37	0.37	0.72
1	1.2	1.2	2.3
10	37.9	37.9	7.27
100	120	120	23
For transmitters specified for a maximum output power not indicated above, the recommended distance in meters (m) can be calculated using the equation applicable to the transmitter frequency. Where P is the maximum nominal output power of the transmitter in Watt (W) according to the transmitter manufacturer. Notes: (3) At 80 MHz and 800MHz it is necessary to apply the distance defined for the highest frequency interval (1) These guidelines could not apply to all situations. The electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.			

All components, accessories, spare parts must be approved and supplied by Cefla s.c.
In particular, the connection cables must be of the type specified in par. 4.7 - “Cables”.

DANGER:
The use of accessories, transducers and cables different from the specified ones may negatively affect the device characteristics in terms of electromagnetic compatibility!

WARNING:
The NewTom 5G XL Vet must not be located directly on another device, and other devices must not be positioned directly on the NewTom 5G XL Vet device.
If this is not possible, observe the NewTom 5G XL Vet device to check its correct operation in the position it is going to be used!

WARNING:
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING:
The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services.
The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Essential performance
In case a scanning is interrupted because of a temporary or permanent malfunction, the operator will have the possibility to save the data acquired up to that moment.
The quality of the reconstructed images will depend on the quantity of acquired data and will nevertheless be lower than that of images reconstructed based on a standard scanning performed without interruptions.

10. APPENDIX B: COMPATIBILITY

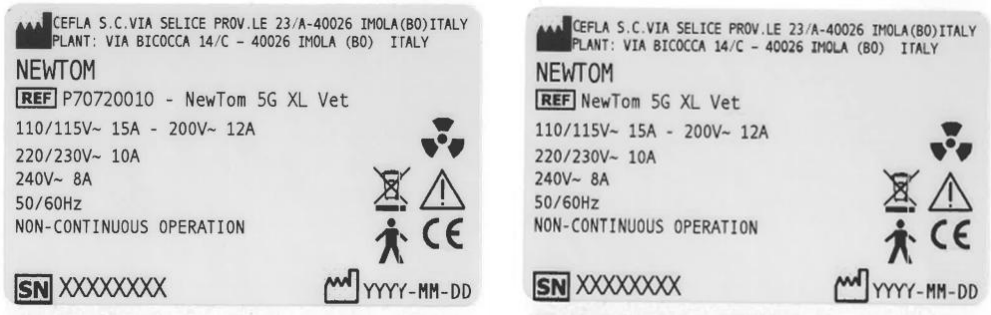
NewTom 5G XL Vet device has been manufactured according to IEC standards for the safety of electrical medical equipment, in particular in compliance with the following standards:

- IEC 60601-1:2005 + A1:2012 - General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 (4th Ed.) - Requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-3:2008 + A1:2013 (2nd Ed.) - Special requirements for basic safety and essential performance of extraoral dental X-ray equipment.
- IEC 60601-2-28:2017 (3rd Ed.) - Special requirements for basic safety and essential performance of X-ray tube assemblies for medical diagnosis;
- IEC 60601-2-44:2009 + A1:2012 + A2:2016 (3a Ed.) - Special requirements for the safety X-ray equipment for computerised tomography;
- IEC 62366-1:2015 + A1:2020 - Medical devices - Part 1: Application of usability engineering to medical devices.
- ANSI/AAMI ES60601-1: 2005 / A2:2010 - USA NATIONAL DEVIATIONS Electrical medical equipment, Part 1: General Requirements.
- CAN/CSA-C22.2 N.60601-1:2014 - CA - CANADIAN NATIONAL DEVIATIONS to CAN/CSA-C22.2 N.60601-1:2014.

IEC 60601-1 CLASSIFICATION	
Class of protection against electric shocks	CLASS I
Degree of protection against electric shocks	TYPE B
IP code (international protection)	IPX0
Use with anaesthetic mixes	This equipment has not been assessed for use in the presence of a mixture of flammable anaesthetic and air, oxygen or nitric oxide
Sterilisation and disinfection methods	Do not sterilize the device. (See chapter 3.5 “Cleaning and disinfecting”).
Conditions of use	Continuous operation with intermittent load.
Operating cycle	**15 minutes for a complete operating cycle consisting of:** Patient surgical table - movements 16% (2.20 min / 15 min) Gantry - movements 14% (2 min / 15 min) X-rays active 2.9% max 26 sec / 15 min for standard resolutions 4% max 36 sec / 15 min for eFOV 4% max 36 sec / 15 min for HiRes resolutions
Expected Service Life	10 years, if used in compliance with the instructions for use

11. APPENDIX C: DEVICE LABELS

✔ SCANNER PLATE



Position: On rear plastic cover, left side of the device on the bottom

✔ X-RAY WARNING LABEL

Position: On rear plastic cover, left side of the device on the bottom

✓ **MAIN SWITCH AND INPUT FUSE LABEL**

Position: On rear plastic cover, left side of the device, next to the main switch

✓ **cMETus CERTIFICATION LABEL (ONLY FOR COMPLETE DEVICE)**

Position: On rear plastic cover, left side of the device, next to the main switch

✔ **LASER DEVICE INFORMATION LABEL (STANDARD USE)**

Position: On rear plastic cover, left side of the device on the bottom, above the scanner plate

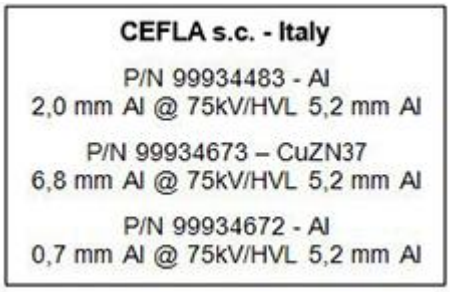
✔ **LASER DEVICE WARNING LABEL**

Position: On the laser support plates, near the laser modules (1 per laser)

✔ **BEAM LIMITER GLOBAL LABEL**

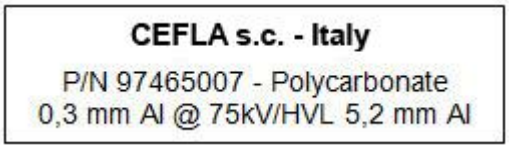
Position: On the “PB EXTRAFOC. SHEET 5G XL” of the collimator

✔ **BEAM LIMITER ADDITIONAL FILTRATION LABEL**



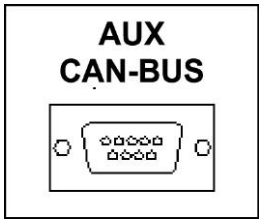
Position: On the "5G XL LASER MIRROR SHEET" of the collimator

✔ **COVER ADDITIONAL FILTRATION LABEL**



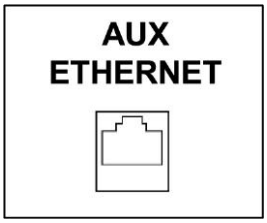
Position: On the internal plastic cover of the scanner (5G XL CYLINDER)

✔ **CAN BUS CONNECTOR INDICATION LABEL**



Position: Rear thermoformed cover, bottom left side, on the right side of the CAN BUS connector

✔ **RJ45 ETHERNET CONNECTOR INDICATION LABEL**



Position: Rear thermoformed cover, bottom left side, above the Ethernet connector

✔ **X-RAY BUTTON CONNECTOR INDICATION LABEL**

Position: Rear thermoformed cover, bottom left side, above the X-ray button

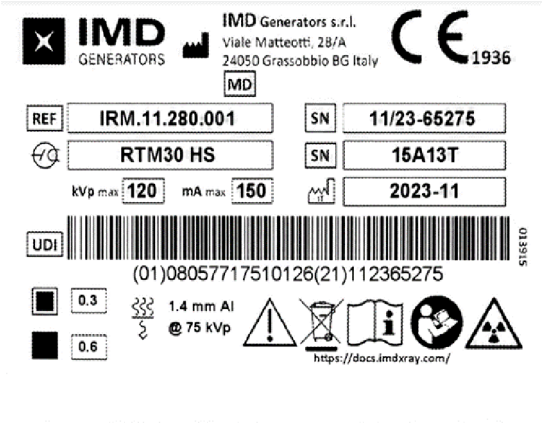
✔ **HAND CRUSHING HAZARD LABEL**

Position: On the device structure, in the points where there is a hand crushing hazard.

✔ **LABEL INDICATING TO REFER TO THE INSTRUCTION MANUAL**

Position: Rear thermoformed cover, bottom left side, above the Input Fuse Main Switch Label.

✔ **LABEL ON X-RAY SOURCE**



Position: On the case of the X-ray source

✔ **INVERTER LABEL**

Position: On the inverter case

NEWTOM
CONE BEAM 3D IMAGING

www.newtom.it

NEWTOM™ 5G XL Vet is manufactured by:

CEFLA s.c.
Headquarters
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40026 Imola (BO) Italy

Plant:
Via Bicocca 14/C
40026 Imola (BO) Italy

Phone: +39 045 8202727
Fax +39 045 8203040
e-mail: info@newtom.it

U.S.A.	**Cefla North America Inc.** 6125 Harris Technology Blvd. Charlotte, NC, 28269 United States	Phone: +1 704 598 0020 e-mail: info@ceflaamerica.com
РОССИЯ / RUSSIA	Адрес для обращения потребителей на территории РФ: **ООО "Зенит Р.С."** 143051 Россия, Московская обл., Одинцовский р-н, ул. Городок - 17, владение 15, стр.3	Тел.: +7 495 980 13 50; +7 495 234 97 e-mail: sales@zenith-rs.ru website: www.zenith-rs.ru
УКРАЇНА / UKRAINE **UA.TR.101**	Уповноважений представник в Україні: **ТОВ "ДЕНТ ПРО"** Юридична адреса: 62457, Україна, Харківська обл., Харківський р-н, смт Березівка, в'їзд Кооперативний, буд. 4	Тел.: +38(057)-714-07-12, +38(057)-714-07-13 e-mail: dentpro@dentpro.info