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NewTom 5GXL

NewTom 5G XL – USER MANUAL

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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.

The original version of this manual is written in Italian.

MANUFACTURER'S NOTE ON MEDICAL DEVICES

The medical device referred to in this manual, consisting of a scanner and a control, display and calculation unit (Main Workstation) as delivered and configured by the technical production and service personnel, is a radiological device that is subject to the safety requirements of (EU) Regulation 2017/745 on Medical Devices.

The medical 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.

Every tampering with, 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 result in the partial or total impossibility of the device to behave as intended. The safety features can also be altered leading to a consequent hazard increase for the patient, 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.

Any different behaviour from what is established by this note will result in the cancellation of the warranty on the device and the assumption of civil and/or penal liability for any damage and/or accident and/or deterioration of the health of the patient, the operator or of other people, including the surrounding environment, by those who have tampered with the device or its legal representative.

[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 medical 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” model.

The routine software operation set for this device (scanning, data processing, reporting and document management) and the use instructions for the operator are dealt with in the “Acquisition Operations with NewTom 5G XL” annex to the "NNT User Manual" document.

The “USER MANUAL” of the device, "NNT User Manual" and “Acquisition Operations with NewTom 5G XL” should be read and understood in every part before starting to use the device.

We recommend keeping this manual together with the other documentation and using it as a guide if new personnel must be trained on 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 a patient.

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-related information and notes are indicated in the manual as follows:

HAZARD:
Informs about the presence of a potential hazard that may lead to personal injuries or even death.

WARNING:
Warns about the presence of a potential hazard that may damage the device.

NOTE:
Provides further information not concerning the safety of the device, the patient 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 - "SCAN"**.

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.

For operators in Europe: any serious accident occurred in relation to the device must be reported to CEFLA s.c. and to the competent authority of the Member State where the user and/or patient lives.

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 (double pressure).
~	IEC 60417-5032	Alternating current.
	ISO 7000-0434A	Warning.
	ISO 7010-W001	General hazard.
	ISO 7010-W012	Warning: electric current.
	IEC 60417-5019	Protective ground.
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 0051	Directive 93/42/EEC and subsequent amendments	CE marking.
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.
MD	ISO 15223-1	Medical device.
UDI	ISO 15223-1	Unique device identification.
	IEC 60417-5638	Emergency stop.
UA.TR.101		Mark of conformity with technical regulations of Ukraine.

2.3. DEVICE SWITCHING ON AND OFF

The device must be switched on and off as specified in the procedures indicated in par. 4.8 and 4.9.

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 other buttons are located on the sides of the scanning hole, near the signalling keyboards;

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 shut-down must be used only in case of danger such as:

- The X-ray source does not stop emitting x-rays.
- Dangerous conditions that may damage the device and harm people and the environment.
- Conditions where the device indicates an emergency situation.

2.5. SAFETY OF PATIENT AND OPERATOR

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

2.5.1. PATIENT POSITIONING

Make sure the patient is correctly positioned in the scanning area, with the head on the chinrest and that no other part of the body can touch the device or risk to be squeezed during the positioning and the examination.

Make sure that patient's clothes and hair can not remain entangled.

Perform the same check for any catheters, breathing tubes or ECG (Electrocardiography) cables.
Before starting any device movement check that the patient is in the correct position and that there are not obstacles to the device movements.

Refer to par. 6.1.2 - "Positioning the patient and starting the scanning".

2.5.2. DURING THE SCANNING

During the device movement and the patient scanning process **NEVER** leave the device without a supervisor.

Always keep the patient monitored for the entire scanning duration.

WARNING:
NEVER use the device without the operator supervision.

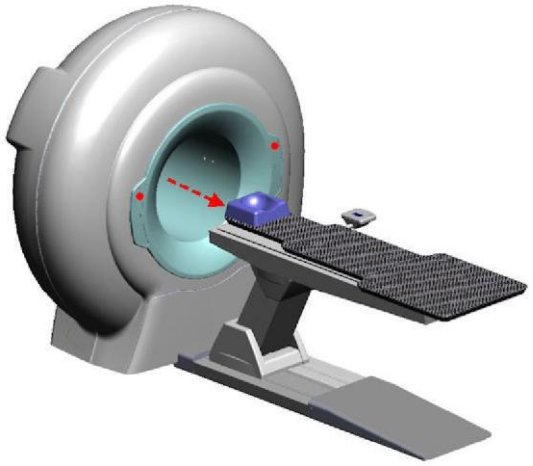
NOTE:
Consider the implementation of an audio/video communication device between the operator and the patient in case the operator controls the device from a protected and remote area.

2.5.3. PATIENT GOING OUT OF THE SCANNING AREA

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

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

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



Below are some general guidelines to remove an unconscious patient or with motion difficulties:

1. Three people are needed, one for each side of the patient and the third one to check and help moving the head.
2. On both sides, place one hand under the patient's shoulder and the other one under the pelvis.
3. From the gantry entrance, remove the headrest cushion with one hand and softly hold the patient's nape
4. Move the patient towards the gantry outer side, checking that the head is always positioned on the headrest plane
5. If the patient can help or partially help, ask him to use his forces to move and make the procedure easier

More effective behaviour for the operator:

- ✓ Avoid bending the back, using the knee flexion;
- ✓ Widen the bearing surface, and therefore the equilibrium conditions, opening and bending the legs transversally or longitudinally depending on the direction of the movement.
- ✓ Move as close as possible to the patient to move;
- ✓ Ensure a good grip of the patient before starting any movement procedure;
- ✓ During movement, explain the instructions using simple words, sentences or gestures.
- ✓ Do not lift the patient

NOTE:
To further move the patient on a stretcher, wheelchair or other mean of transport for unconscious patients or with motion difficulties, please refer to the procedures stated by the organisation.

NOTE:
In case of accidental cut off of the power supply, the maximum distance of motor-driven movement values of the patient table (with maximum rated load applied) are the following:

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

2.6. ARTEFACTS AND SCANNING REPETITION

A scanning process must be repeated **ONLY** if there are important artefacts on a patient's image or if the patient position has clearly changed during the scanning.

2.7. PROTECTION AGAINST IONIZING RADIATIONS

WARNING:
NewTom 5G XL is an X-ray device and therefore it exposes patients and 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 must not be used for routine or screening examinations. For such purposes, use other diagnostic equipment.
The imaging examinations must be justified for each patient 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 patient during the examination.

WARNING:
Never stand near the device during emission.

WARNING:
Based on the recommended dose limits in the local country, please refer to the *"Stray Radiation Map"* to determine the minimum distance to maintain during X-ray emission.
If the operator needs to remain in the room during the examination (e.g. in case of a patient's panic reaction) he/she shall wear suitable lead protection clothes and equipment as defined by the national and local standard [1].

- **Patient**

The user is responsible for the protection of the patient against useless exposure to radiation.

WARNING:
Consider the use of leaded aprons to protect the patient from stray radiation.

WARNING:
When prescribing X-ray examinations to pregnant women or women that could be pregnant, bear in mind the possible radiation consequences on the foetus. When possible, avoid exposing the foetus to radiation.

WARNING:
Consider the possibility to use leaded aprons with thyroid collar to protect the patient from stray radiation.

WARNING:
Possible negative interference of CT X-ray with active implantable or wearable medical devices.
Contact the manufacturer of such devices for further information.

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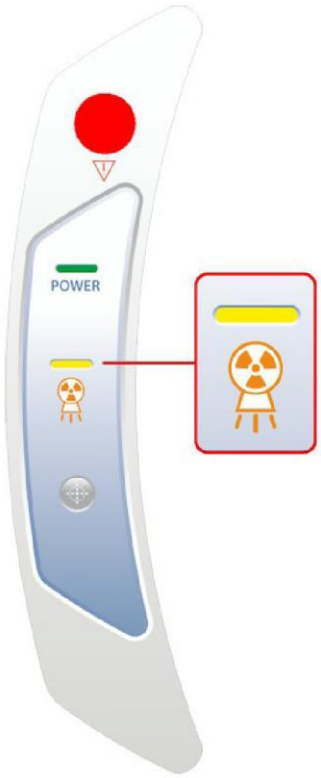
[1] See for example the indications by the department of the Canadian government responsible for public health - *Health Canada "Radiation Protection in Radiology – Large Facilities", par. "Protective Equipment"*

- **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.

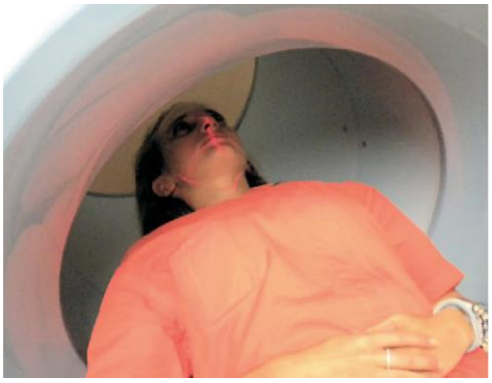
2.8. PROTECTION AGAINST LASER RADIATIONS

The device is provided with three cross lasers to correctly position the patient. 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

Any computer, monitor, printer, mouse, keyboard and any other device connected to the device control workstation MUST be compliant with the ISO and/or IEC and/or EN and/or local standards.
Moreover, the workstation must be compliant with the IEC 60950-1 or EN62368-1 standard.

For further information contact the Manufacturer.

NOTE:
The Manufacturer is not responsible for problems and/or malfunctions of parts and/or components not approved by itself and not installed by qualified technical personnel acknowledged by the manufacturer.

Never eat/drink or leave beverage/food near the device and the console.

2.10.MAINTENANCE INTERVAL

Make sure that the maintenance operations described in par. 3.4 - “Device maintenance" are carried out.

2.11.APPLIED PARTS

The parts of the equipment that, during standard use, necessarily come into contact with the patient, so that the device may carry out its functions correctly, are: patient table pad, head positioning tool cushion and head positioning cushions.

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

3. DEVICE SAFETY AND MAINTENANCE

This chapter includes information on device and environment safety. It also provides general information and procedures concerning the device maintenance.

The user is responsible for a correct use of the device, in compliance with the instructions and procedures provided in this manual. In particular, the operator must observe the following instructions:

- The device can be used **exclusively by authorised personnel, trained** on the machine use and the protection from radiations. Said personnel must also know the standards that regulate the use of X-ray devices.

- The device must never be used in case of evident electric, mechanic or radiological malfunctions. In particular, it must never be used if the warning or emergency switch-off devices do not work properly.

3.1. INSTALLATION REQUIREMENTS

The device must be used in places intended for medical use in accordance with the recommendations of a Qualified Expert Operator.

The equipment must never be exposed to acids, corrosive agents, salt and rain.

Operating temperature:	from +10° to +35° (Celsius)
Humidity conditions during operation:	min 10%, max 85% (without condensate)
Altitude:	≤ 3000m
Pressure:	710 – 1060 hPa
Pollution degree:	2
CTI (Comparative Tracking Index):	IIIb

Minimum size requirements of the installation location: 4.5 x 3 x 2.5 m.
The device must be installed on a horizontal surface.

The power line must be arranged according to the laws in force and the instructions provided in the "User Manual".

Do not use temporary electric connections such as adaptors, extensions, multiple-socket adapters for the connection of the PC or of the peripherals.

The equipment must be connected to the electric system permanently according to the instructions given in the "*Service Manual*".

The medical environment in which the device is installed must be designed by an expert in protection from ionising radiation as required by the national and local laws in force. The national and local laws in force will define the rules to be followed when designing the signals to be applied to the system.

WARNING:
Never move the device after installation as this may pose a hazard to people, the device and the environment.
The device should only be connected to peripherals, computers and cables that comply with the manufacturer's specifications.

WARNING:
Make sure the device is connected to a protective ground power supply.

NOTE:
The computer must be installed outside the patient area.
The connectors connected to the computer cables must be used only to connect the computer.
These connectors must be handled only by authorised and qualified personnel.

3.2. SAFETY GUIDELINES

The device is not protected against liquid and spray penetration. The penetration of liquids can damage the electric and electronic components and generate hazardous situations for the patient, the operator and the environment.

The device safety systems do not reduce the fire-fighting protections installed in the room where the device is used.

- **Electrostatic discharges**

Electrostatic discharges can damage the machine electronic components. As a consequence, the floor of the room in which the device is installed should be made of antistatic materials.

- **Fire-extinguishers**

CO2 fire-extinguishers should be installed in an area easy to be reached.

- **X-ray warning lamp**

The user has the possibility to install an X-ray warning lamp to be used to know both if the X-ray source is ready and if the X-ray emission is active.

- **Switches on doors**

The user has the possibility to install an external switch to stop the emission (usually installed on access doors of the room where the device is used).

- **Electromagnetic compatibility**

For information about the electromagnetic compatibility, refer to APPENDIX A - “Technical Specifications”.

3.3. CYBERSECURITY INFORMATION

Medical devices capable of connecting (eg. Ethernet port) to another device are vulnerable to cybersecurity.
The intended use of the device (generation of radiologic two-dimensional and three-dimensional images) limits for its nature the intended use environment (health care facility, medical facility, hospital, etc.) and the intended users (health care worker, physician, etc.).
This condition limits the probability that the device may be subject to cyber-attack.

In any case, some precautions are recommended:

- the device and the workstations must be used in a controlled access environment (eg. radiology department) so that they are accessible to authorised personnel only;

- the workstations must belong to a medical network, where the cybersecurity countermeasures are correctly and effectively implemented in accordance with national and regional regulations in force:

    - the infrastructure must manage functions for access protection, therefore a login must be executed to access the workstation with correct User ID and Password. The passwords must be maintained reserved, not easily identifiable and they must be changed periodically,
    - the infrastructure must provide the protection from unauthorised accesses with firewall,
    - the infrastructure must manage functions for data protection,
    - the infrastructure must manage functions for logging and detecting accesses.

3.4. CHANGES TO THE DEVICE

Any modifications or updates of the device must comply with the applicable legislation.

WARNING:
It is forbidden to open or tamper with the device with any tool.
Any non-authorised change to the device (hardware and software) is forbidden and may compromise the correct device operation, cause breakages and/or accidents with consequent possible damage to the patient, the operator and the device.

3.4.1. LIMITS OF RESPONSIBILITY

The manufacturer is not responsible for the safety, reliability and performance features in the following cases:

- The installation, maintenance and any change, repair and/or update are not performed by personnel authorised by the manufacturer or the distributor.
- The spare parts have not been approved by the manufacturer or the distributor.
- The environment conditions are not compliant with the requirements described in this manual, the requirements of the applicable laws and the recommendations of a qualified expert.
- The device is not used as described in this manual.

3.5. DEVICE MAINTENANCE

Any change or update of the device must be compliant with the applicable laws.

WARNING:
Always turn off the device before performing any maintenance operation.

WARNING:
None of the internal parts of the equipment can be repaired. Never take the covers off the equipment.

WARNING:
The only part that can be repaired by the user is the device input fuse, located near the switch-on panel.
The spare fuse must be compliant with the manufacturer's specifications.

WARNING:
To ensure the protection against fire, replace fuses only with others of the same type and range.

- **Ordinary maintenance**
  The ordinary maintenance is required to ensure the correct device operation as well as the safety of the patient, the operator and of third parties.

  The device must be exclusively repaired and maintained by personnel authorised directly by the manufacturer or the distributor. All device components must be checked and replaced, if necessary, by qualified personnel.

WARNING:
If the NewTom 5G XL device has not been used to scan patients for more than three months, carry out the X-ray source conditioning process (for more details please contact technical support).

- **Hazardous cleaning agents**
  Some cleaning agents should be avoided to prevent negative consequences on the device and people (see "3.5. Cleaning and disinfecting").
- **Preventive maintenance**
  Regularly check the computer-scanner interface cables and the power lead. Check the connection cable to the computer, the monitor, the keyboard, the mouse and the printer according to the manufacturer instructions.
- **Storage of the components and other parts**
  Components and other parts must be stored and handled with care.
  Any provided components and other parts must be stored and handled in compliance with the relevant technical specifications.
- **Malfunctions**
  In case the device does not work as described in this manual, contact the technical service immediately.

- **Maintenance contract**
  The device should be checked at regular intervals: contact the manufacturer or the distributor to discuss about a maintenance contract.

- **Check-list of the device checks**
  The following check-list indicates the recommended time intervals of the various device checks.
  For further information contact your local distributor.

Manager	Component	Activity	Time interval
Routine test			
Operator	Global device	Control with QA phantom	Weekly
Technical service	Error register	Check	12 months
	All external components	Check for any damage	12 months
	Emergency switch-off	Stop system check	12 months
	Electric part operation	Check	12 months
	Mechanical part operation	Check	12 months

Manager	Component	Activity	Time interval
Other tests according to local standards			
Expert in X-ray protection or other qualified person according to local standards	Global device	X-ray tests in compliance with local standards on X-ray electro-medical equipment. These tests are not to be performed by the operator or the local technical service, but could be stated by the local standards.	X-ray tests in compliance with local standards.

3.6. CLEANING AND DISINFECTION

WARNING:
Always turn off the device before performing any cleaning operation

WARNING:
Cleaning is the first step of any disinfecting process. Physically scrubbing with detergents and surface-active substances and rinsing with water removes a considerable amount of micro-organisms. If a surface is not clean first, the disinfecting process cannot be successful.

If a surface cannot be adequately cleaned, it should be covered with barriers.

The outer parts of the equipment must be cleaned and disinfected using a product for hospital use with indications for HIV, HBV and tubercolocide (medium-level disinfectant) specific for small surfaces.

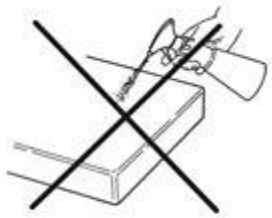
The various drugs and chemical products used in dental surgeries may damage the painted surfaces and the plastic parts. Researches and tests performed show that the surfaces cannot be fully protected against the harsh action of all products available on the market. We therefore recommend protecting with barriers whenever possible.

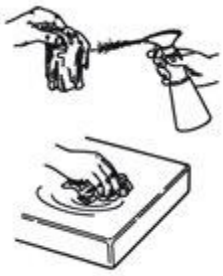
The harsh actions of chemical products also depend on the amount of time they are left on the surfaces. It is therefore important not to leave the product on the surfaces longer than the time specified by the manufacturer.
We recommend to use a specially formulated medium-level disinfectant, STER 1 PLUS (CEFLA S.C.), which is compatible with coated surfaces, plastic parts and uncoated metal surfaces. As an alternative, we recommend to use products containing:

- 96% ethanol. Concentration: maximum 30 g per 100 g of disinfectant.
- 1-Propanol (n-propanol, propyl alcohol, n-propyl alcohol). Concentration: maximum 20 g per 100 g of disinfectant.
- Combination of ethanol and propanol. Concentration: the combination of the two should be maximum 40 g per 100 g of disinfectant.

WARNING:

- Do not use products containing isopropyl alcohol (2-propanol, iso-propanol).
- Do not use products containing sodium hypochlorite (bleach).
- Do not use products containing phenols.
- All products must be used as directed by the manufacturer.
- Do not mix the STER 1 PLUS disinfectant with other products.
- Do not spray the selected products directly on the surfaces.





Clean and disinfect with disposable non-abrasive paper (avoid using recycled paper) or sterile gauze.

- **Turn off the equipment prior to cleaning and disinfecting the external parts.**
- **All materials used to clean and disinfect must be thrown away.**

- **Computer and peripheral devices**
  Follow the manufacturer's instructions to clean the computer and the peripheral devices. If such instructions are not available, refer to the instructions provided in the previous paragraph.

NOTE:
Contact the local distributor for further information about the device safety and maintenance.

3.6.1. HYGIENE PROCEDURES FOR PATIENT PROTECTION

Disposable hygienic protections are the main protection means against cross contamination between patients. **In order to prevent the transmission of infectious diseases between patients, it is essential to always use disposable**

protections. Disposable protections are class I medical equipment and cannot be replaced with other protections having lower specifications.
Disposable protections must comply with standards ISO 10993-1 on biocompatibility and be approved by control bodies where required (e.g. FDA, CE).

Disposable hygienic protections must be stored in a dry and clean area and must not be exposed to direct sunlight or UV radiation.
Cover with disposable protections all components that will be in contact with dental personnel's hands and might be contaminated by indirect contact with the mouth of the patient. In particular, pay attention while handling equipment control console, mouse and Personal Computer keyboard.

Note for Canada users: ask your dental distributor for hygienic protections with suitable size and marketed in Canada according to the local laws.

In compliance with the provisions of Health Canada, bite protections are Class I equipment supplied by authorised distributors as per MDEL database.

3.6.2. STERILISATION

No sterilization is required for the standard use of the equipment.

3.7. TRANSPORT AND STORAGE

During the transport and the storage it is necessary to respect the conditions indicated below.

Transport and storage temperature:
from -20° to +70° (Celsius)

Humidity conditions for transport and storage:
min 10%, max 85% (non-condensing)

Pressure:
710 – 1060 hPa

Do not expose to acids, salts, rain.

3.8. DEVICE DISPOSAL

3.8.1. INFORMATION FOR DEVICE OWNER

This symbol on the device indicates that it must not be disposed of together with other urban waste but it is necessary to collect it separately.

The separate collection of this equipment is organised and managed by the manufacturer. When it is necessary to dispose of this equipment, contact the manufacturer and follow the system that the manufacturer has adopted to allow the equipment separate collection.

The separate collection and recycling of the equipment to be scrapped, contribute to the preservation of the natural resources and ensure that such equipment is scrapped in respect of the environment and of the health.

Illegal equipment disposal carries fines according to the local and regional laws.

To dispose of computers and other peripheral devices, it is necessary to refer to the attached instructions provided by the manufacturer of the same devices.

3.8.2. INFORMATION FOR COLLECTION / DISPOSAL / RECOVERY FACILITIES

Separate the X-ray source, the electronic and mechanical parts, the plastic covers and the computer with the peripheral devices.

The X-ray source contains oil that must be discharged to be disposed of and/or recovered.

The plastic parts must be disposed of with approved methods.

For all other parts for which the manufacturer does not provide specific information, refer to the national and local laws and the guidelines on hygiene, safety at work and environmental protection.

3.9. BIOCOMPATIBILITY

Cover the patient table and any patient positioning tools with sheets made of biocompatible material compliant with standard ISO 10993-1

4. STARTING PROCEDURES

This chapter provides an introduction to the NewTom 5G XL 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 device is intended for diagnostic imaging using cone beam volumetric computed tomography of anatomical regions of the head, neck, lower limbs, upper limbs, spine and musculoskeletal system.

4.1.2. INDICATIONS FOR USE

The NewTom 5G XL device can analyse the regions of the head, including dento-maxillofacial and ENT regions, the cervical spine and the upper and lower limbs. In particular:

- imaging of teeth;
- imaging of upper and lower jaw for implant planning;
- imaging of temporo-mandibular joint (TMJ);
- imaging of middle and inner ear, sinuses, upper respiratory tract (ENT);
- imaging of areas of the dento-maxillofacial complex;
- imaging of cervical spine and spine sections;
- imaging of upper and lower extremities;
- imaging of hand, forearm and elbow;
- imaging of knee, foot and ankle.

The NewTom 5G XL can also be used for X-ray analyses on implants, surgical templates and other diagnosis auxiliary tools.
The device can be used in particular in the following fields: implantology, maxillofacial surgery, orthodontics, periodontology, endodontics, otorhinolaryngology, prosthetics and orthopedics.
The use of the device in emergency situations, like first aid situations, is limited to cases in which non-operation does not pose a hazard for the patient (e.g. if the medical centre is equipped with other equivalent equipment or a department of radiology).

The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.

ONLY FOR CHINESE MARKET

The NewTom 5G XL is a computerised tomographic system using the cone-beam technology which acquires a sequence of images of the head, including ear, dental and maxillofacial unit, teeth, mandible and jaw, temporo-mandibular joint (TMJ), other areas of the human skull and neck with sections of the upper cervical spine for diagnostic use.
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 operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.

ONLY FOR CANADIAN MARKET

The NewTom 5G XL is a cone beam computed tomography x-ray imaging system that acquires sequences of images of the head, including ear, nose and throat (ENT), of dento-maxillofacial complex, teeth, mandible and jaw, temporo-mandibular joint (TMJ), other areas of the human skull with sections of upper cervical spine and of the upper and lower extremities for use in diagnostic support.
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 operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.

ONLY FOR USA MARKET

The NewTom 5G XL is a cone beam computed tomography x-ray imaging system that acquires sequences of images of the head, including ear, nose and throat (ENT), of dento-maxillofacial complex, teeth, mandible and jaw, temporo-mandibular joint (TMJ), other areas of the human skull and neck with sections of upper cervical spine and of the upper and lower extremities for use in diagnostic support.

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 operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.

WARNING:
The NewTom 5G XL 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 necessary, the patient could be exposed to an excessive dose of radiations.

WARNING:
The federal code limits the sale of this device only by or if prescribed by a doctor authorised by the law of the State in which he uses or prescribes the use of X-ray imaging systems 21CFR801.109 (b)

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 patient in order to prove that they provide more benefits than risks.

WARNING:
Where it is likely that an evaluation of soft tissues will be required as part of the patient X-ray evaluation, the appropriate imaging should follow the *"Diagnostic Imaging Referral Guidelines of the Canadian Association of Radiologists"*, instead of using the cone-beam technology.

WARNING:
When prescribing X-ray examinations to pregnant women or women that could be pregnant, bear in mind the possible radiation consequences on the foetus.
Radiation on the foetus must be avoided as much as possible.

WARNING:
This device is especially suitable for patients with a weight higher than 11 kg and height greater than 87 cm; these parameters correspond to the ones of a child with an average age of 3 years.
The studies showed that paediatric patients can be more radiosensitive than adults (for example, the risk of cancer per unit of ionizing radiation dose is higher), therefore, it is necessary to pay special attention to the unnecessary exposure to radiation of paediatric patients.

4.1.3. CLASSIFICATION

Equipment classification according to the rules set out in Annex VIII of (EU) Regulation 2017/745: CLASS IIb.

4.1.4. IMPROPER USE

The NewTom 5G XL device was not intended for the following use and / or applications (reasonably foreseeable misuse):

- use with patients that cannot stay still for the entire scanning cycle (36 seconds max);
- use in anatomic regions not included in the intended use of the device (for example chest and abdomen);
- use for the study of soft tissues;
- use for the study of cerebral soft tissues;
- use by personnel not trained on the device;
- use by personnel not meeting the requirements indicated in the user profile;
- use in operating room;
- use with removable metal objects (glasses, rings, necklaces) in the scanning field;
- use in environmental conditions different from the specified ones.

4.1.5. FUNCTIONING

The patient is laid down on the patient table and positioned correctly inside the scanning area with 3 laser and "scout-view" image modules.

The acquisition system performs a complete rotation around the patient's head and acquires X-ray images that are then automatically processed by the device.

The result of such operation will be the sequence of axial slices that form the reconstituted volume.
At the end of this process, the slices will form the Volumetric Data. Through these data it is possible to visualize coronal and sagittal sections of the reconstructed area in real time.

Starting from the volumetric data and through the definition of a Region Of Interest (ROI), the user starts the examination. The ROIs can be inclined with respect to the volumetric data both to obtain orthogonal images, e.g. at the mandible plane, and to correct positioning errors.

Working on the acquired data, it is possible to create panoramic and transaxial sections and three-dimensional reconstructions. Then it is possible to work on these images to trace distances, angles, add comments etc.
At the end, the new images are saved in the examination section.

The examination images can be used to write a report that can be printed and/or saved on electronic support.

For further information, refer to the "NNT User Manual".

4.2. OPERATION PRINCIPLE

In the "Cone-Beam" technology, the detector-tube system (conical X-ray beam and bidimensional detector) performs one rotation around the patient and acquires data necessary for the volumetric reconstruction.
In other words, the data acquired at each scanning step are the digital images corresponding to the relevant radiographic projection, and all collected data (also called "raw data") are then used in the volumetric reconstruction process.

Following are the advantages of this technology compared to the standard systems:

- Direct reconstruction of all scanned points, without going through the axial reconstructions and the data reformatting;
- Total scanning speed usually higher since it is linked with the acquisition electronics rather than with the power of the radiogenic tube and the mechanical sophistication;
- At the same scanning duration: fewer requirements in terms of generator/tube assembly power and scanning mechanic, with consequent structural and maintenance advantages.

4.3. OVERVIEW

The device consists of three main components: the scanner, the patient table (version with stretcher, code 96600822) 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 complete device

NOTE:
The device cannot be extended with parts and components not approved by the manufacturer.

4.4. SCANNER

4.4.1. SIGNALLING KEYBOARDS AND CONTROLS

The scanner represents the device 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 patient positioning is also located on the keyboards:

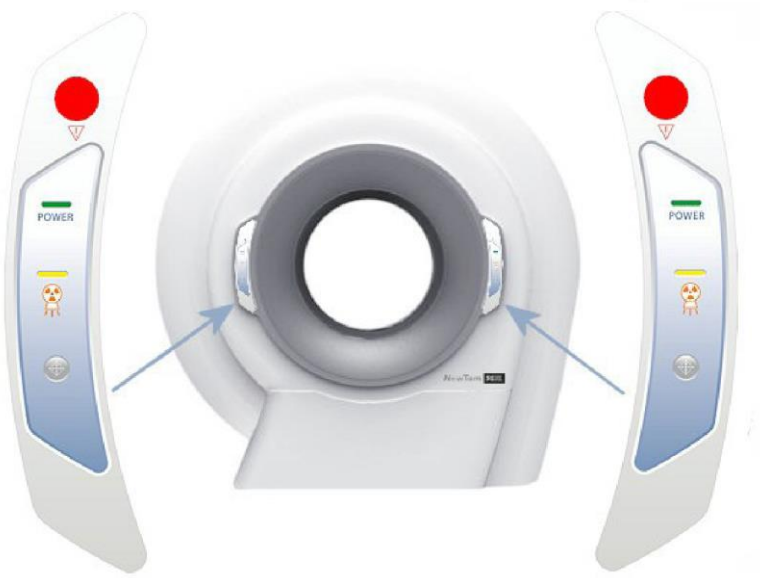


Figure 3: Scanner control panels

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

The control panel that includes the switch for switching the device on or off and its fuse holder are located on the left side of the device.

The panel includes some cable glands used for the power and control cables of the equipment and the CAN Bus and Ethernet connectors for connecting the device to the main workstation.

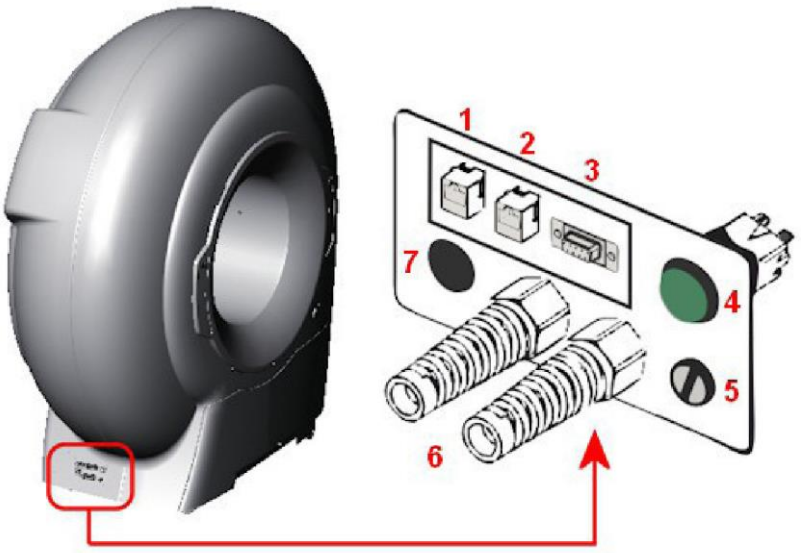


Figure 4: Control panel and relevant connectors

1 - Ethernet connector for workstation
2 - X-ray emission button connector (optional)
3 - CAN bus connector for workstation
4 - Device main switch
5 - Input fuse holder
6 - Cable outlets of power supply line, table emergency stop button cables, external lamp and door switch (optional)
7 - Closing plug for optional outlet openings

4.5. PATIENT TABLE WITH STRETCHER

The patient table with stretcher is the part of the device used for patient positioning.
The control console for table movement and the indicator lights for the device's power status, X-ray emission status and possible activation of the emergency button are located on a special arm.
The laser module switching on button to be used during patient positioning is also located on the control console.

4.5.1. CONTROL CONSOLE OF PATIENT TABLE WITH STRETCHER

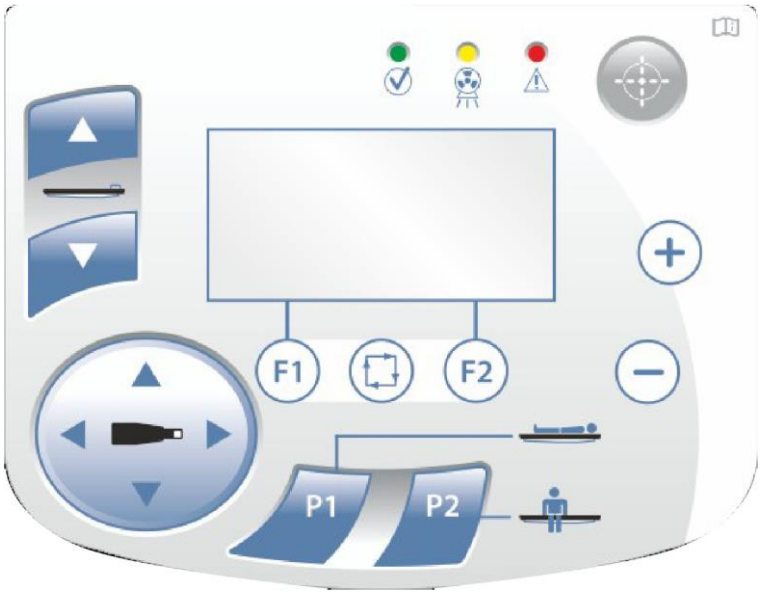
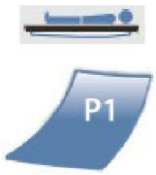
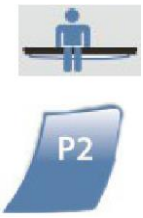


Figure 5: Control console of the patient table with stretcher

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

The device is equipped with some standard components. The main ones are listed below, refer to the local dealer for the full list of available components.

Phantom QA:
It is used to carry out the quality verification procedure.
It is used with the Calibration Support.

Calibration support:
It is used as a support base for QA Phantom on the patient table.

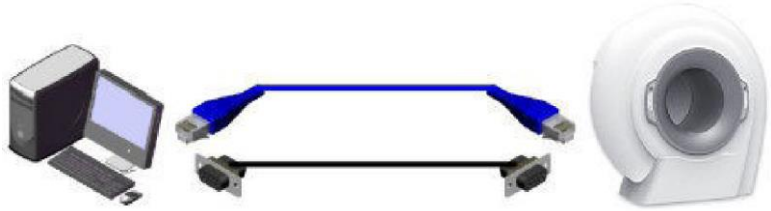
Prosthesis support:
It is used as a resting base for dental prosthesis on the patient table.

4.7. CABLES

The device includes the cables connecting the main workstation to the scanner. These cables are:

- ✔ Ethernet cable (4 pairs/26 AWG-FTP-Category 6)
- ✔ CAN bus cable (2 pairs/24 AWG shielded)

The manufacturer supplies the power cable with one end connected directly to the device and the user is responsible for the mains supply connection during installation.



WARNING:
Using components, transducers and cables other than those specified may result in degradation of the electromagnetic compatibility characteristics of the device!

4.7.1. OPTIONAL COMPONENTS

There are currently no optional components for the NewTom 5G XL.

4.8. SWITCHING ON THE DEVICE

Following is a description of the procedure to correctly switch on the device:

1. Switch the scanner on through the main switch placed on the access panel.
2. Switch the workstation on.
3. Wait for the workstation to load the operating system.
4. Log into the operating system using username and password.
5. Launch the NNT application.

NOTE:
Always switch on the device first. If an attempt is made to use the application before the device has been initialised, the connection will be denied.

4.9. DEVICE SWITCHING OFF

Below is the description of the correct device switching off procedure:

1. Close the NNT software.
2. Stop the operative system and wait for the workstation to switch off.
3. Switch off the device through the suitable main switch located on the input panel.

WARNING:
Switch off the device if it is not used for more than 3 hours.

WARNING:
Always switch off the device at the end of the work day.

5. PRELIMINARY OPERATIONS

This chapter describes all the mandatory operations to be carried out on the device before examining the patients. In detail, the operations are:

- Daily check;
- Blank image acquisition ("Blank acquisition");

This chapter also describes the following function:

- Beam limiter test

The blank image must be acquired every 13 weeks, whereas it is compulsory to start the Daily check every day before starting patients' examinations.
If such operations are not performed within the set intervals, the software will block the scan function.

The operation modes are described in the specific chapter in the "NNT User Manual".

NOTE:
If the environment temperature is too low or too high, it is recommended to bring it within the device operation range (+10 ÷ +35 °C) and wait a couple of hours to restore the thermal balance.

5.1. DAILY CHECK

Through the Daily Check the device checks that all components are working correctly.

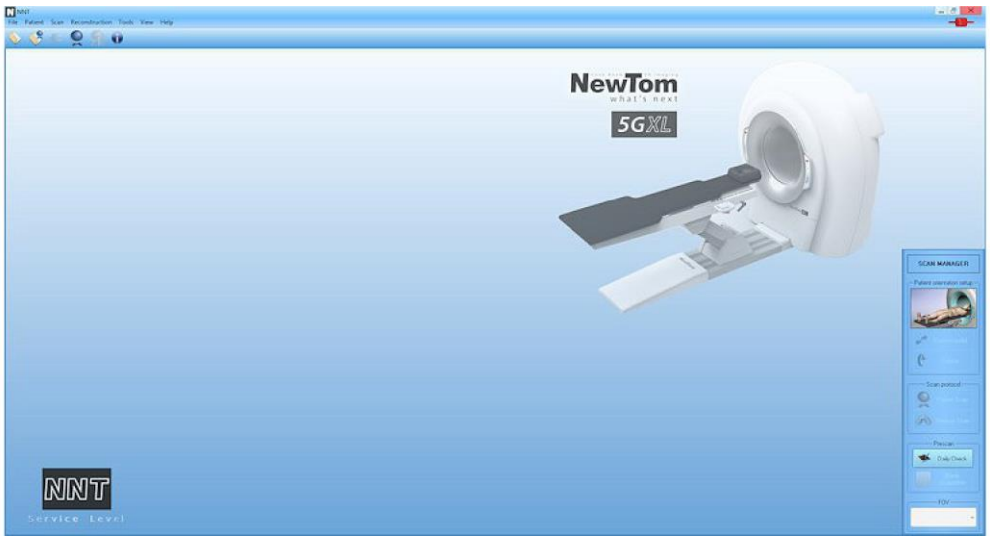


Figure 6: NNT home screen with request of Daily check

WARNING:
Before starting the procedure, make sure that the scanning area is completely empty.
To this end, extract the patient table.

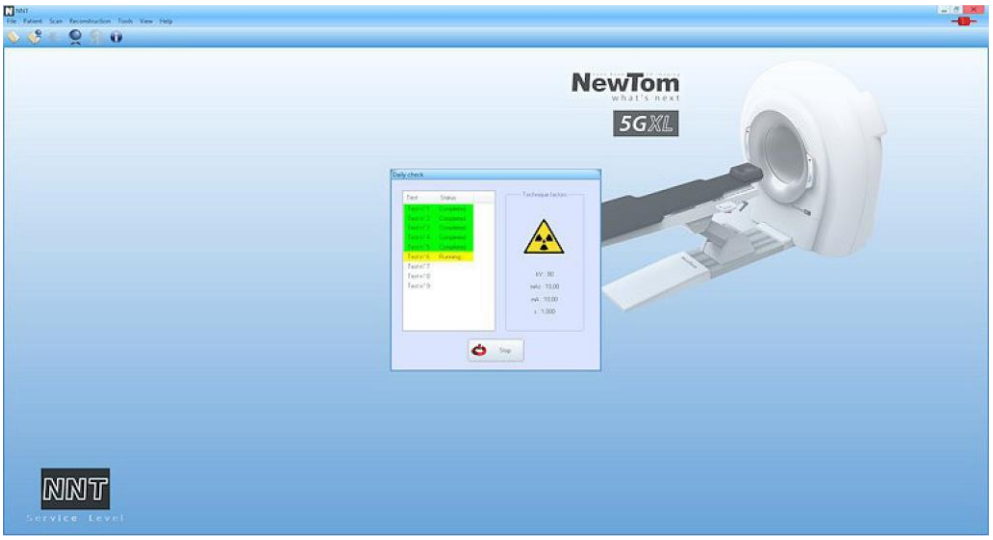
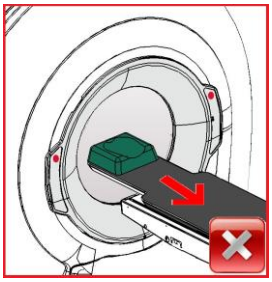


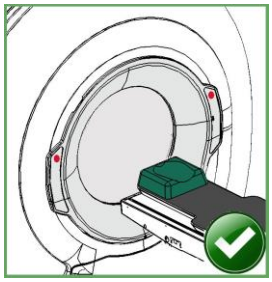
Figure 7: Daily check in progress

5.2. BLANK ACQUISITION

The Blank Acquisition allows optimising the scanning performance through the acquisition of a background image.

This procedure is automatically performed by the software whenever necessary.





Before starting the procedure, make sure that the scanning area is completely empty.

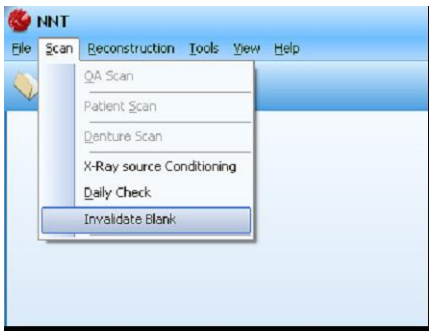
For this purpose, if not previously carried out, extract the patient table.

The blank acquisition image will be as shown in the figure.

It is extremely important to ensure that the image does not contain any unusual objects/shadows/marks.

5.2.1. BLANK ACQUISITION INVALIDATION

This function is only available for the main workstations. To invalidate the blank acquisition, follow the instructions below:



From the NNT software, select "**Scan**" → "**Invalidate Blank**".

Upon next selection of the acquisition FOV, the NNT software will request the next Blank acquisition.

WARNING:
If the test has been performed correctly but has not been completed successfully, please contact our Technical Support.

5.3. BEAM LIMITER TEST

This function allows the user checking the correct beam limit.
The beam limiter positions are pre-set by the manufacturer and cannot be changed by the user.

1. From the main bar of the NNT software, select Tools → Scanner Test.

2. From the service window bar, select Tools → Beam Limiter Test. Select the desired FOV.

3. Set the appropriate X-ray parameters according to the FOV in use (SFS, 6 mA, 15 msec, KV = 110)

4. Start an acquisition

5. Check that the beam is limited within the indicated margins

- The green rectangle must be completely inside the acquired grey area.

- The grey rectangle sides must pass through the drawn red line pairs.

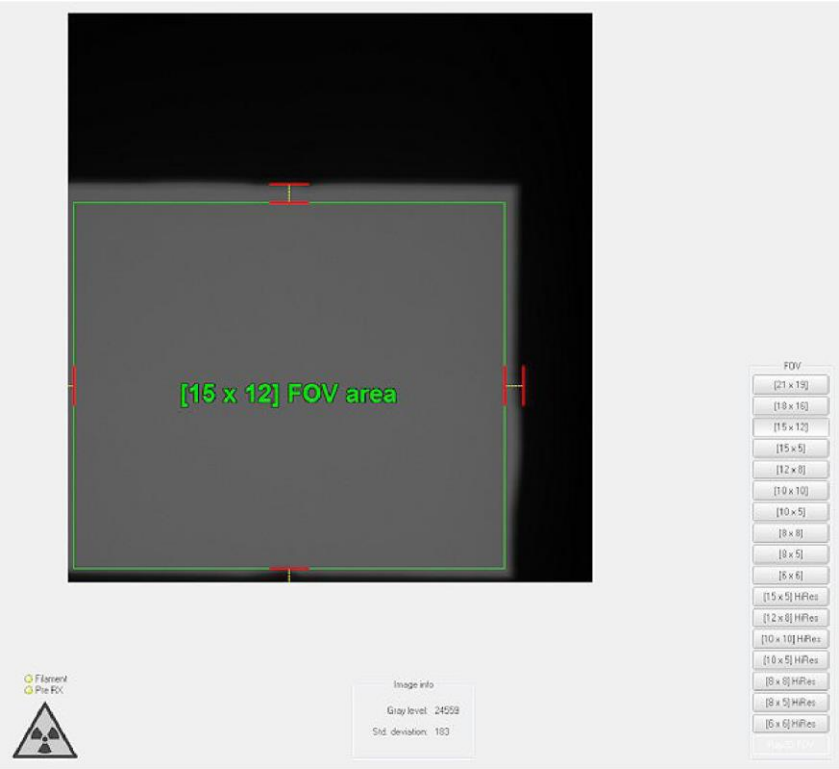


Figure 8: Beam limiter test

WARNING:
If the acquired grey image is not correctly limited by the two red lines, contact the Technical Support

6. SCANNING

This chapter describes the procedures to be followed for a correct positioning of the patient (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:

- [21x19] (volume diameter 21cm, height 19cm);
- [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 non-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 a patient 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:
For paediatric patients [4] (children, but also small-sized patients) it is recommended to use the lowest-dose mode available: ECO SCAN.

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.

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4 "Paediatric patient" means patients more than 11 kg (24 lb) in weight and more than 87 cm (34.25 in) in height; these height and weight measurements approximately correspond to that of an average 3-year-old child.

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:

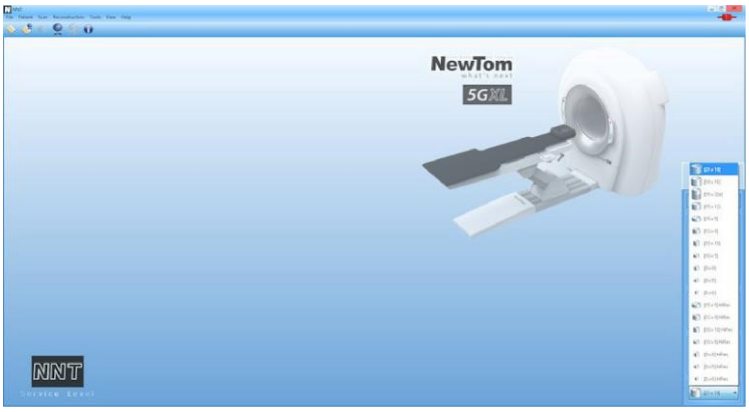


Figure 9: "Scan Manager" panel of the NNT software

6.1. SCANNING A PATIENT

6.1.1. PREPARING THE PATIENT

The preparation of a patient for an examination is an important process that can contribute to the correct execution of the scanning and to obtain high-quality images.
The purpose of such process is to make the patient feel at ease and relaxed before and during the exam. Following are some recommendations to reach such purpose.

- **Room preparation**
  Make sure that the scanner is clean and ready to scan the patient ("Daily check" and "Blank Acquisition" already performed).

- **Preparing the patient**
  Ask the patient to remove any pieces of jewellery (earrings, necklaces, piercings), glasses and removable metallic prostheses, hair clips.

- **Positioning the patient**
  After positioning the patient on the patient table, move him to the scanning area, adjusting the table so as to frame the concerned scanning area, and ensure the patient's bust and neck are in a correct position.

- **Explaining the examination**
  Shortly explain to the patient the examination procedure, including the data entering, positioning and scanning phases.

- **Problematic patients**
  A special attention must be paid in case the patient is a child, an old person, a claustrophobic or another person with a psycho-physic disability.

- **Correct breathing**
  Ask the patient to breathe slowly during the examination (a slow and continuous breath helps avoiding swallowing).

- **Relaxing**
  Ask the patient to keep the dental arches closed without gnashing the teeth.

- **Avoid delays**
  To have relatively reduced examination times, complete all preliminary procedures before starting the examination.

- **Oral instructions**
  Tell the patient any oral instructions that the operator may have to use during the scanning.

6.1.2. POSITIONING THE PATIENT AND STARTING THE SCANNING

Below is the description of the operations to be performed to position and centre the patient 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”

The guidelines for patient positioning during the examination of different anatomic regions are outlined in the attached document "General guidelines for use of the protocols of NewTom 5G series" in the dental and medical environment.

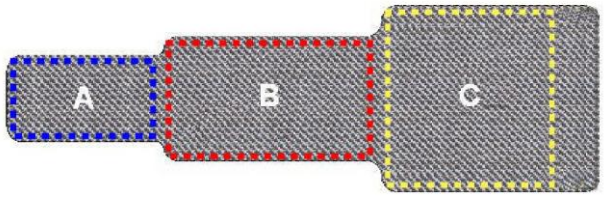
WARNING:
The scanning area where the patient is positioned must remain cleared from objects of any type since they may harm the patient and/or invalidate the results of the examination.

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 patients with a maximum weight of 160Kg (plus 15kg of components, if any).
Below is detailed the distribution of the maximum allowed loads:

Patient table with stretcher

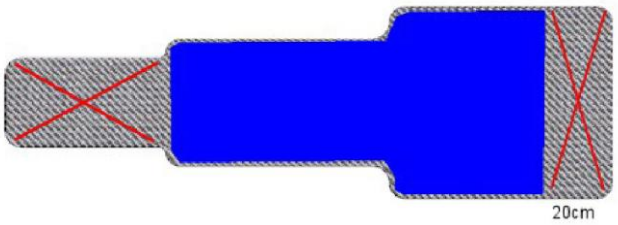
1) Maximum load per area



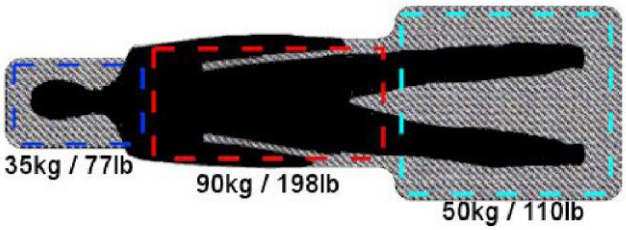
Stretcher position outside the gantry
Area A: 35 Kg
Area B: 175 Kg
Area C: 175 Kg

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

2) Seating areas for adult patient (maximum weight 160Kg)

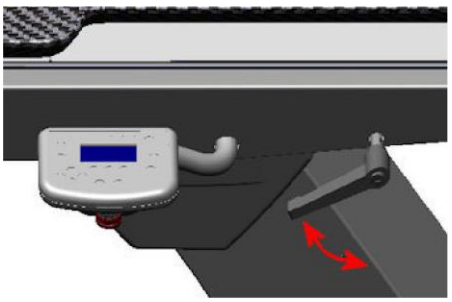


3) Distribution of maximum rated load 175kg (160Kg + 15Kg components)



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.

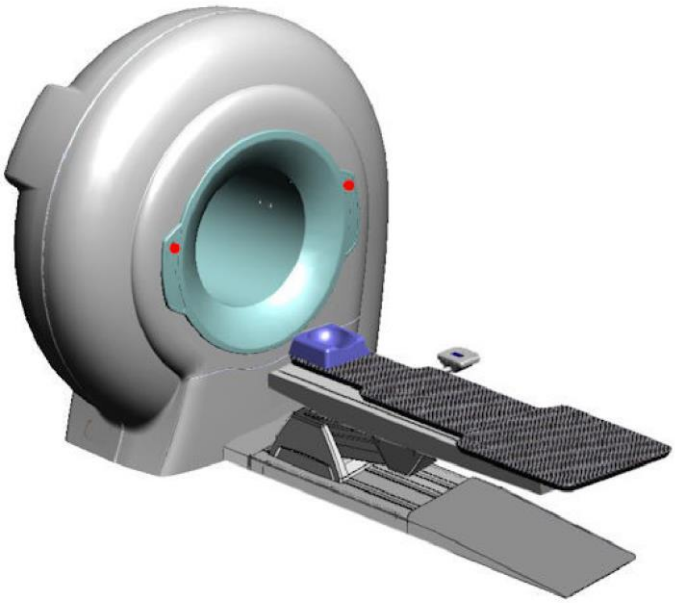


Figure 10: Patient table in easy access position

2) Have the patient sit, with the nape on the headrest cushion.

3) Move the patient in the examination preparation position by pressing P1.

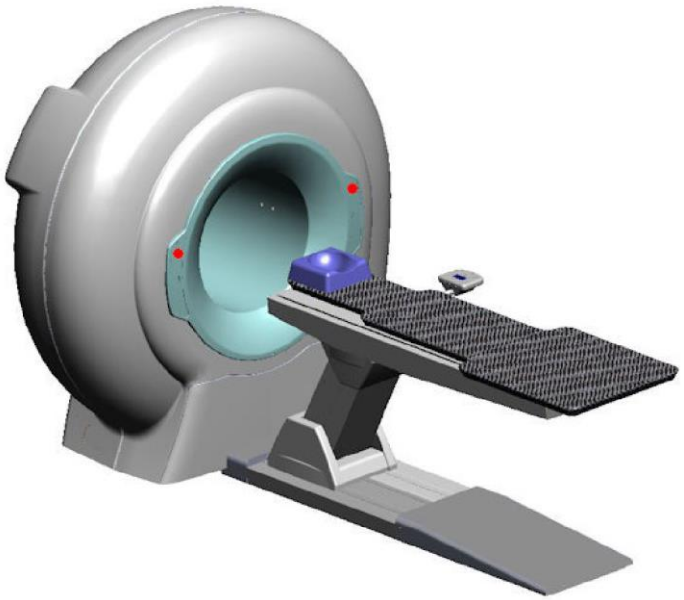


Figure 11: Patient table in examination preparation position

4) Unlock the stretcher and slide it bringing the patient inside the gantry. Then lock the stretcher again.

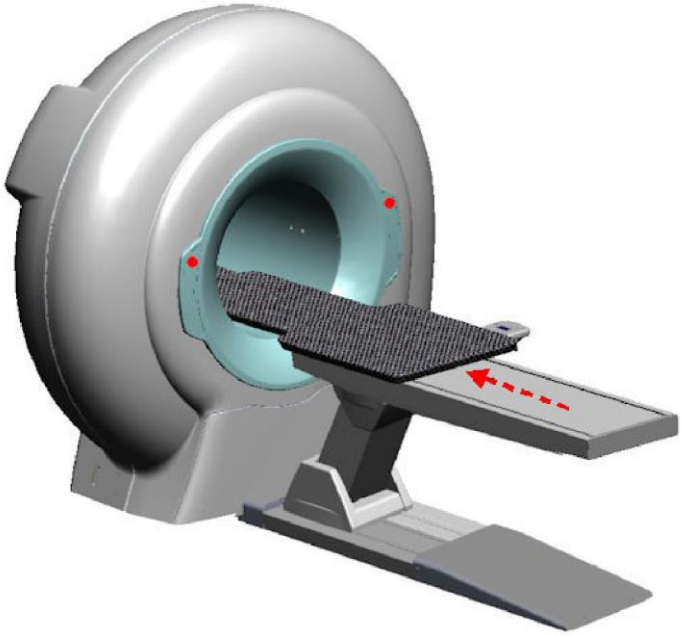
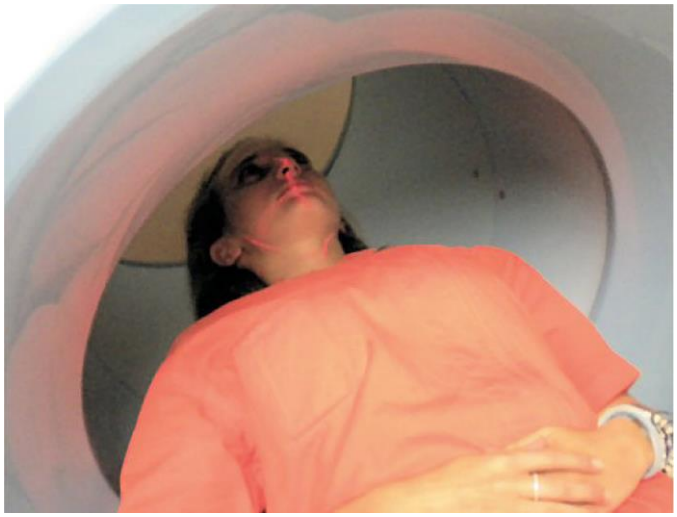


Figure 12: Patient table with fitted stretcher

5) Make sure the patient maintains a correct position, reminding him/her not to grind the teeth and not to swallow. In addition, remind the patient not to move during the positioning phase.
6) Fine-adjust the patient 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.



7) To scan a patient, 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.
8) At the end of scanning, unlock the stretcher, remove the patient from the gantry by moving the stretcher outwards, and then lock the stretcher again.

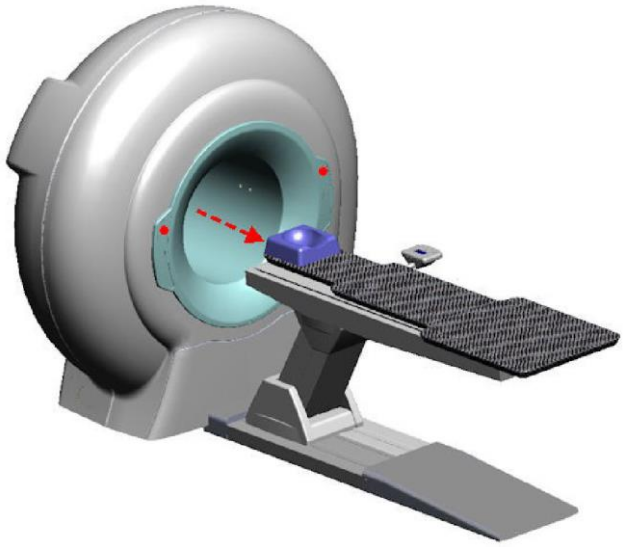
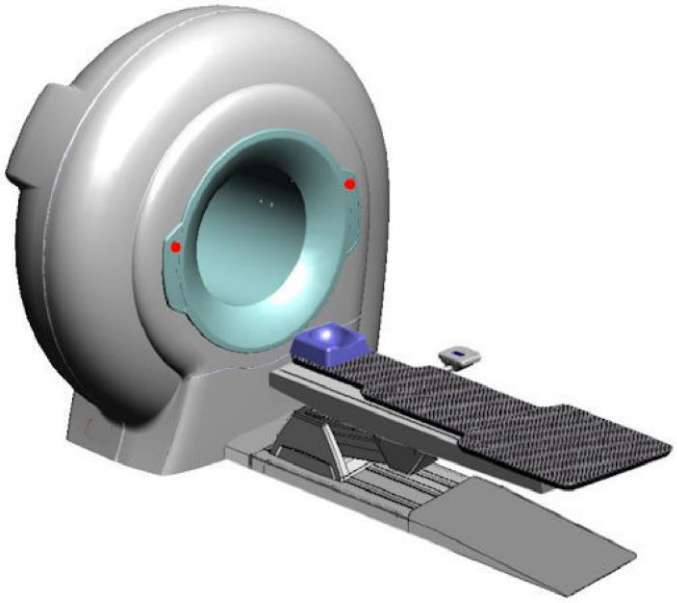


Figure 13: Patient table with removed stretcher

9) Then, press P2 to bring the patient to the initial position (Easy access position) and have the patient leave the room.



6.1.3. NOTES FOR USE WITH PAEDIATRIC PATIENTS OR SMALL-SIZED PATIENTS

WARNING:
Pay special attention to patients, especially paediatric ones, who do not have a typical adult size, such as patients weighing less than 50 kg (110 lb) and who are less than 150 cm (59 in) high, measurements that approximately correspond to those of a 12-year-old boy or those of the 5th percentile adult females in the United States.

NewTom 5G XL has been designed specifically for patients with height exceeding 87 cm (34.25 in) and having a weight exceeding 11 kg (24lb). These weight and height values approximately correspond to that of a 3-year-old child.

Before carrying out X-ray examinations on paediatric patients, their higher sensitivity to ionising radiation must be considered. It is due to several factors, such as: higher life expectancy compared with adult patients, higher risk of cancer per unit dose of radiation, and the impact that radiation might have on organs which are still developing. In addition, using devices or protocols intended for adults or for medium-sized patients can generate a useless exposure to radiation in case of younger patients.
Every X-ray examination must be carried out only if strictly necessary for medical reasons, using protocols characterised by the minimum dose necessary to obtain images of adequate quality (according to the ALARA principle - "As Low As Reasonably Achievable"). It is recommended not to carry out repeated studies in children, unless they are essential for the formulation of a diagnosis. In particular, CBCT technique must be used only when necessary. The indications and patient's medical history must be carefully analysed before performing any X-ray examination.

References for paediatric dose optimisation
In order to ensure a safe use of the device, in case of examinations with children or small-sized patients, it is recommended to consult the following resources dedicated to dental radiology and/or CBCT technique:

- *"National guidelines for dental radiology diagnostics in childhood"* – guideline by Italian Ministry of Health (Italian language):
  http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=3268

- *"Pediatric X-ray Imaging"* - resource by U.S. Food & Drug Administration dedicated to paediatric X-ray imaging (English language):
  http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/ucm298899.htm

- "*Medical X-ray Imaging"* - resource by U.S. Food & Drug Administration dedicated to X-ray imaging (English language)
  https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/default.htm

- *Image Gently* - awareness and educational campaign on correct management of radiological risk for paediatric patients (English language)
  http://www.imagegently.org

- *"Dental Cone-beam Computed Tomography"* - resource by U.S. Food & Drug Administration dedicated to CBCT technique in dental field (English language).
  https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm315011.htm

These resources provide information on the safety of radiation for paediatric imaging and / or on the safety of radiation for computerised tomographs with cone beam.

Device instructions and specifications

NOTE:
Make sure that the personnel is duly trained on how to properly communicate with minors and their relatives.

NOTE:
With the help of the patient's parents, when necessary, make sure that necklaces, hair bobbles, earrings, bracelets, other jewellery and orthodontic devices have been removed. Check that the oral cavity is free from candies or chewing-gums.

NOTE:
It is essential that the patient remains still to obtain images of adequate quality. It is recommended to use any measure which could be necessary for reassuring the child before starting the imaging procedure. If necessary, in order to prepare and perform the examination, plan time intervals suitable for children, longer than those normally required for an adult. If the patient cannot be reassured, postpone the examination.

NOTE:
If possible and necessary, use appropriate protection devices, such as thyroid collar and leaded apron. The lead collar helps to significantly reduce thyroid dose for any dental radiodiagnostic examination. This device is particularly recommended in case of CBCT examinations with extended fields, except when the specialist detects possible risks of artefacts or possible overlapping on concerned anatomic regions.

NewTom 5G XL can be used to examine children and small-sized patients, in compliance with the limitations indicated in the instructions for use. The functions available for this purpose are:

- automatic calculation of minimum X-ray parameters required to carry out an examination, according to the size and the density of the volume to be examined;
- indication of the values of the dose administered during the examination, before the actual scanning;
- need of carrying out examinations with the patient seated or lying on the table, thus reducing the risk of movement;
- availability of adjustable fastening and centring instruments, to secure the patient's head and/or limbs and allow a correct positioning;
- possibility of using fields of view with reduced dimensions, such as: 6x6 (volume diameter 6 cm, height 6 cm), 8x6, 8x8. Possibility of scanning in Eco Scan mode, a low-dose protocol characterised by reduced scanning time.

The table below summarises the device functions which are relevant for paediatric imaging.

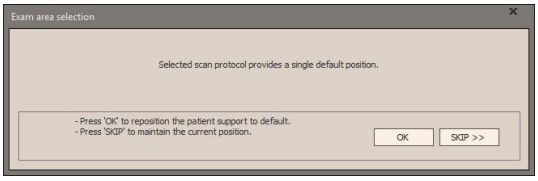
Device features which are relevant for paediatric imaging	Reference
Intended use	This manual Par. "INTENDED USE"
Protection against radiations	This manual Par. "PROTECTION AGAINST IONIZING RADIATIONS"
Description of operation, device overview	This manual Par. "STARTING PROCEDURE"
Protocols available	This manual Par."SCAN"
Patient positioning	This manual Par."SCANNING A PATIENT" "General guidelines for use of the protocols of NewTom 5G series" manual
Instructions for image quality control	This manual Par. "QUALITY CONTROL" "Acquisition operations with NewTom 5G XL" manual
Dose measurements (CTDI)	"NewTom 5G XL - Dose declaration and acceptance test" manual.

6.2. CINEX SCAN

It allows performing the CineX examination: serial x-ray that allows for the dynamic acquisition of a set sequence of X-ray images saved on a video.

To start the CineX scanning procedure click the "**Scan → CineX acquisition**" button in the menu.

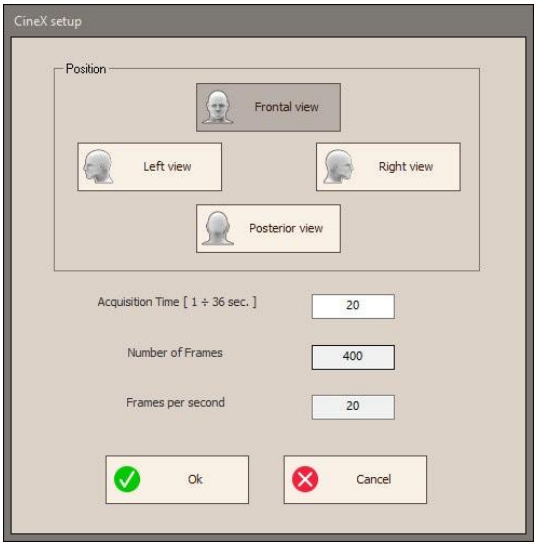
This type of scanning involves only one pre-set view field.



The warning window prompts the operator to reposition the patient arm to the default position.
By pressing "**OK**" the patient arm will be moved automatically and returned to a default position. By pressing the "**SKIP >>**" button the repositioning procedure will be skipped.

If from the last NNT software start-up the repositioning procedure has never been performed, a warning will be displayed. By pressing the "YES" key the operations will carry on, however it will not be possible to use the patient arm movement remote procedure until the reset is performed at least once from the last software start-up.

6.2.1. POSITIONING THE PATIENT AND STARTING THE SCANNING



Once the patient's data have been entered, a window for scanning parameters selection will be displayed.

It is possible to choose between patient side and frontal / rear scanning.

The duration of the exam is freely selectable in the range of 1 - 36 seconds. If the exam lasts between 1 and 20 seconds, the scanning will be carried out by acquiring 20 frames per second; if it is between 21 and 36 seconds, the scan will be carried out by acquiring 15 frames per second.

After selecting the acquisition time and pressing OK, scanning start will be initialised.

For further information on patient positioning and preparation, please refer to Par. 6.1.1-6.1.2

For the complete scanning procedure, refer to the Par. "CineX SCANNING OF A PATIENT" of the document "*Acquisition operations with NewTom 5G XL*" attached to the "NNT User Manual".

6.3. SCANNING A PROSTHESIS

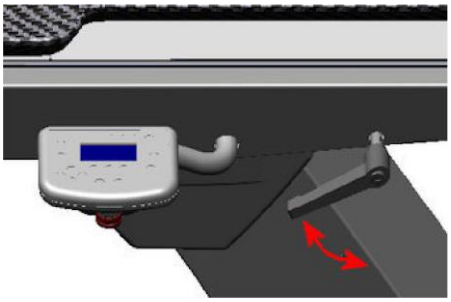
6.3.1. PRELIMINARY OPERATIONS

Following is a description of the operations to be performed to position and centre the prosthesis inside the scanning area. Perform these operations when prompted by the software.

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

6.3.2. POSITIONING THE PROSTHESIS WITH THE PATIENT TABLE WITH STRETCHER

1) Make sure the stretcher is completely removed from the gantry and locked with the suitable handle on the table control console side.

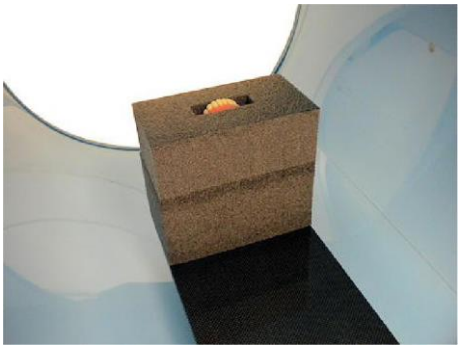


2) Move the patient table to the default position pressing key P2 of the table control console.

3) Remove the headrest cushion and move the patient table to examination preparation position pressing key P1.

4) Unlock the stretcher, slide it inside the gantry, and lock it again.

5) Fit the prosthesis in the suitable opening on the prosthesis support and position the latter on the carbon fibre stretcher of the patient table, as shown in the figure. Pay attention not to reverse the direction of the prosthesis on the support.



6) Fine adjust the prosthesis position using the movement keys (UP/DOWN – LEFT/RIGHT).
To do so, it is possible to use the laser centring device. To enable it, press the LASER key on the control console (it is necessary for NNT software opening) or on the control consoles on the scanner sides.
Position the prosthesis on the laser cross.

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

8) At the end of the scan, remove the prosthesis support from the patient table, unlock the stretcher and completely remove it from the gantry; then lock the stretcher again and press key P2 to move the patient table back to the initial position (aided upward movement position).

9) Position back in place the headrest cushion on the carbon fibre stretcher of the patient table.

7. QUALITY CONTROL

The quality control consists in the execution of the standard examination on a suitable phantom, through an automatic procedure.

This control, that is recommended at least once a week, ensures the correct operation of the device and the validity of the obtained results.

Before starting scanning the phantom it is necessary to select the acquisition field.

The test execution procedure is described in the “Acquisition Operations with NewTom 5G XL” annex to the “NNT User Manual” document.

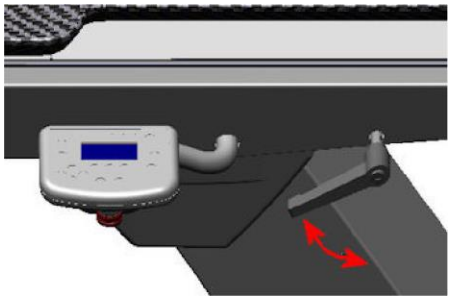
7.1. PHANTOM POSITIONING

Following is a description of the operations to be performed to position and centre the phantom inside the scanning area. Perform these operations when prompted by the software.

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

1) Move the patient table to the default position pressing key P2 of the table control console.

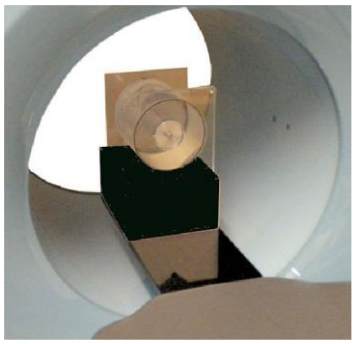
   Before pressing key P2, make sure the stretcher is completely removed from the gantry and locked with the suitable handle on the table control console side.



2) Remove the headrest cushion and move the patient table to examination preparation position pressing key P1.

   Unlock the stretcher, manually fit it inside the scanning area and lock it again.

3) Fit the QA phantom on the phantom support and position the latter on the carbon fibre axis of the patient table, as shown in the figure.

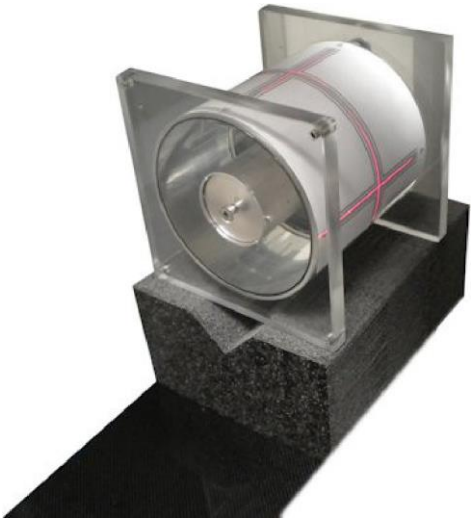


4) Fine adjust the phantom position using the movement keys (UP/DOWN – LEFT/RIGHT)

   To do so, it is possible to use the laser centring device. To enable it, press the LASER key on the control console (it is necessary for NNT software opening) or on the control consoles on the scanner sides.

   Position the phantom matching the laser crosses with the reference marks on the phantom.

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

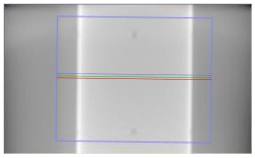


6) At the end of the scan, remove the phantom and the relevant support from the patient table, unlock the stretcher and completely remove it from the scanning area; then lock it again and press key P2 to move the table back to the initial position (aided upward movement position).

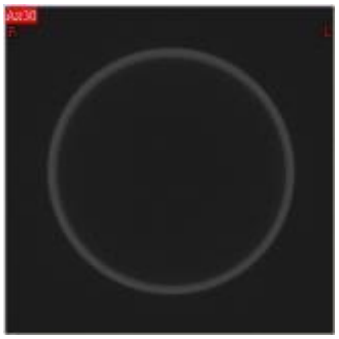
7) Position back in place the headrest cushion on the carbon fibre axis.

7.2. IMAGE EXAMPLES

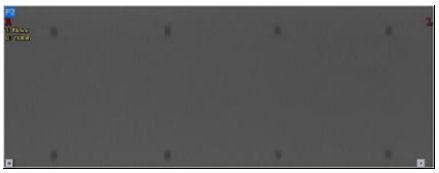
Following are some examples of images acquired during the phantom analysis:



Lateral view.



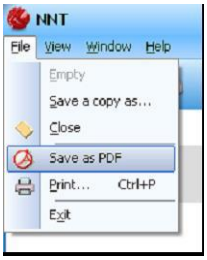
Axial section.



Panoramic section.

7.3. SAVING THE PHANTOM ANALYSES

Each phantom analysis report is automatically saved by the software. Afterwards, the reports can be retrieved by selecting “**View**” → “**QA Report**”.
Once opened, it is possible to scroll through the different reports using the PAGE DOWN, PAGE UP keys on the keyboard.
It is possible to create copies of the QA Report in PDF format by selecting the “**File**” → “**Save as PDF**” menu.



It is recommended to print and keep a paper copy of the Phantom QA analysis.

8. TROUBLESHOOTING

To solve device problems, refer to the “**NNT – Error Guide**” document.

9. APPENDIX A: TECHNICAL SPECIFICATIONS

Scanner

Scanning system (cone beam technology)	Single rotation with volumetric acquisition	
Scanning parameters	Mode	Scanning time / Exposure time
	FOVs CBCT	
	Regular Scan	
	[21x19];	18 s / 3.6 s
	[18x16];	18 s / 3.6 s
	[15x22e];	36 s / 7.2 s
	[15x12];	18 s / 3.6 s
	[15x5];	18 s / 3.6 s
	[12x8];	18 s / 3.6 s
	[10x10];	18 s / 3.6 s
	[10x5];	18 s / 3.6 s
	[8x8];	18 s / 3.6 s
	[8x5];	18 s / 3.6 s
	[6x6];	18 s / 3.6 s
	[15x5] HiRes;	20.2 s / 5.4 s
	[12x8] HiRes;	20.2 s / 5.4 s
	[10x10] HiRes;	20.2 s / 5.4 s
	[10x5] HiRes;	20.2 s / 5.4 s
	[8x8] HiRes;	20.2 s / 5.4 s
	[8x5] HiRes;	20.2 s / 5.4 s
	[6x6] HiRes.	20.2 s / 5.4 s
	Eco Scan	
	[21x19];	18 s / 1.35 s
	[18x16];	18 s / 1.35 s
	[15x22e];	36 s / 2.7 s
	[15x12];	18 s / 1.35 s
	[15x5];	18 s / 1.35 s
	[12x8];	18 s / 1.35 s
	[10x10];	18 s / 1.35 s
	[10x5];	18 s / 1.35 s
	[8x8];	18 s / 1.35 s
	[8x5];	18 s / 1.35 s
	[6x6];	18 s / 0.9 s
	[15x5] HiRes;	18 s / 3.24 s
	[12x8] HiRes;	18 s / 3.24 s
	[10x10] HiRes;	18 s / 3.24 s
	[10x5] HiRes;	18 s / 3.24 s
	[8x8] HiRes;	18 s / 3.24 s
	[8x5] HiRes;	18 s / 3.24 s
	[6x6] HiRes.	18 s / 3.24 s
	Enhanced Scan	
	[21x19];	25.8 s / 5.4 s
	[18x16];	25.8 s / 5.4 s
	[15x12];	25.8 s / 5.4 s
	[15x5];	25.8 s / 5.4 s
	[12x8];	25.8 s / 5.4 s
	[10x10];	25.8 s / 5.4 s
	[10x5];	25.8 s / 5.4 s
	[8x8];	25.8 s / 5.4 s
	[8x5];	25.8 s / 5.4 s
	[6x6];	25.8 s / 5.4 s

	[15x5] HiRes; [12x8] HiRes; [10x10] HiRes; [10x5] HiRes; [8x8] HiRes; [8x5] HiRes; [6x6] HiRes. CineX Ray2D		36.0 s / 9.0 s 36.0 s / 9.0 s 36.0 s / 9.0 s 36.0 s / 9.0 s 36.0 s / 9.0 s 36.0 s / 9.0 s 36.0 s / 9.0 s 1÷20s at 20fps / 0.2÷4s 21÷36s at 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] [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 table with stretcher	Length (max)	3600 mm
		Width (max)	840 mm
		Height (max)	900 mm
		Load (max)	175Kg (160Kg patient + 15Kg components)
Weight		Weight	660 Kg (scanner + patient table with stretcher)

Detector

Pixels	1560 x 1440	Pixels
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

[21x19]

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

[18x16]

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

[15x22e]

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

[15x12]

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

[15x5]

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

[12x8]

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

[10x10]

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

[10x5]

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

[8x8]

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

[8x5]

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

[6x6]

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

[15X5] HiRes

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

[12X8] HiRes

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

[10X10] HiRes

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

[10X5] HiRes

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

[8X8] HiRes

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

[8X5] HiRes

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

[6X6] HiRes

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

Reconstructed volume

[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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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	Pixels
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

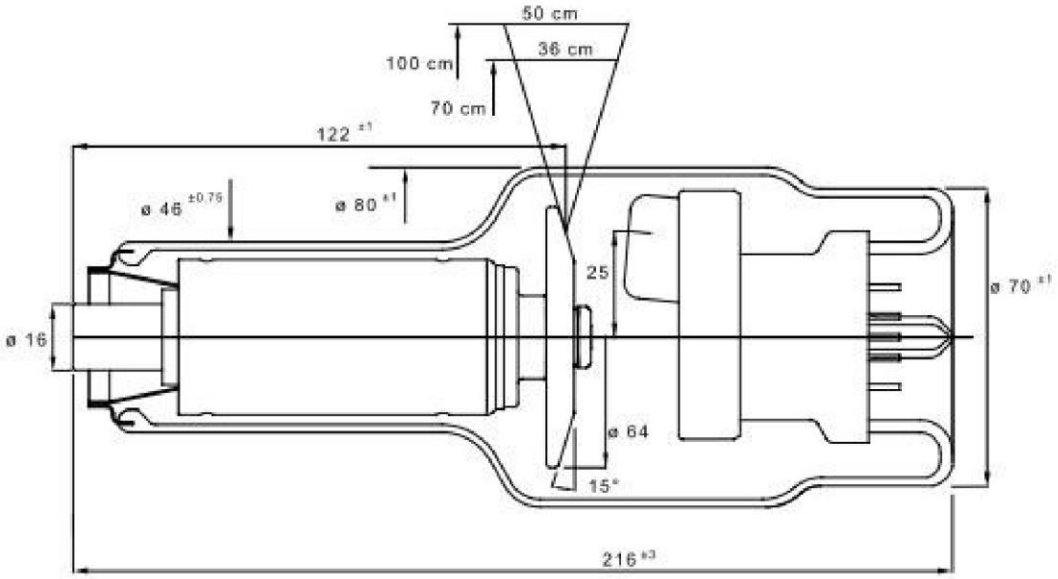
Caratteristiche - Specifications - Spécifications

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 a 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		

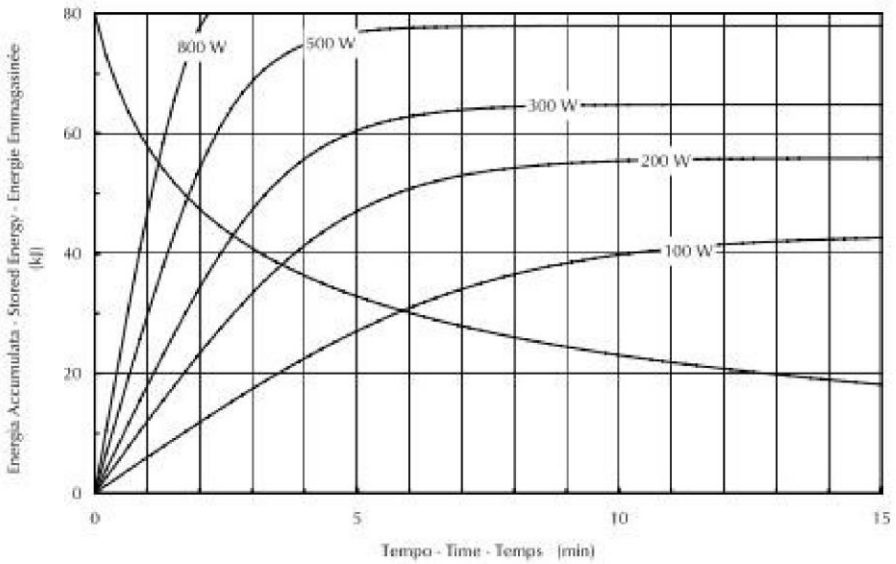
I dati forniti nella presente documentazione si intendono riferiti a:
The data indicated in this documentation refer to:
Les données indiquées dans cette documentation sont calculées pour:

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

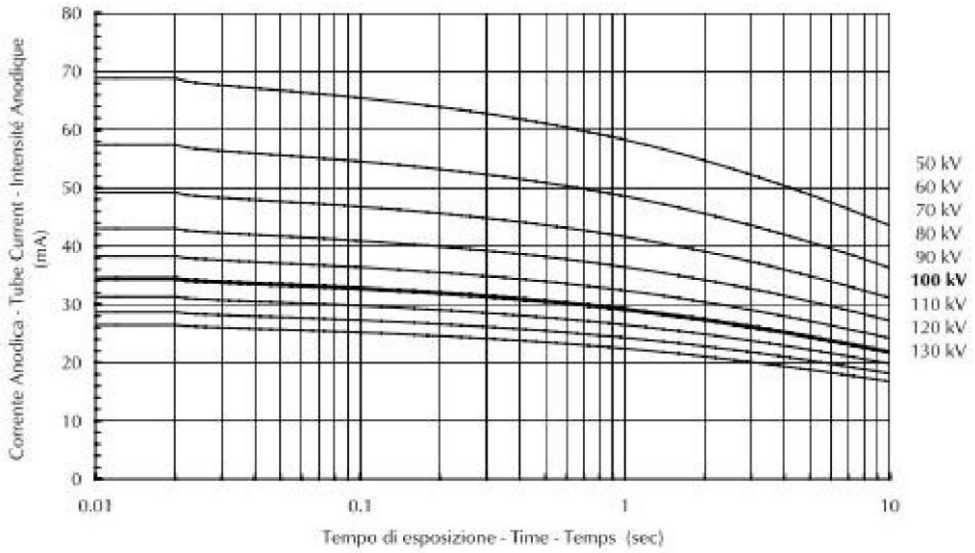


Curve di riscaldamento e raffreddamento dell'anodo
Anode heating and cooling curves
Courbes d'échauffement et de refroidissement de l'anode



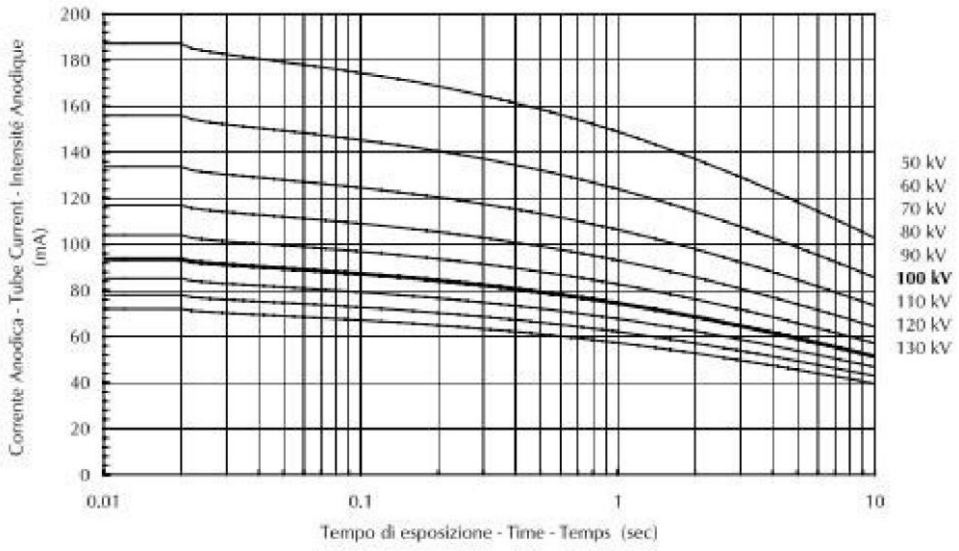
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



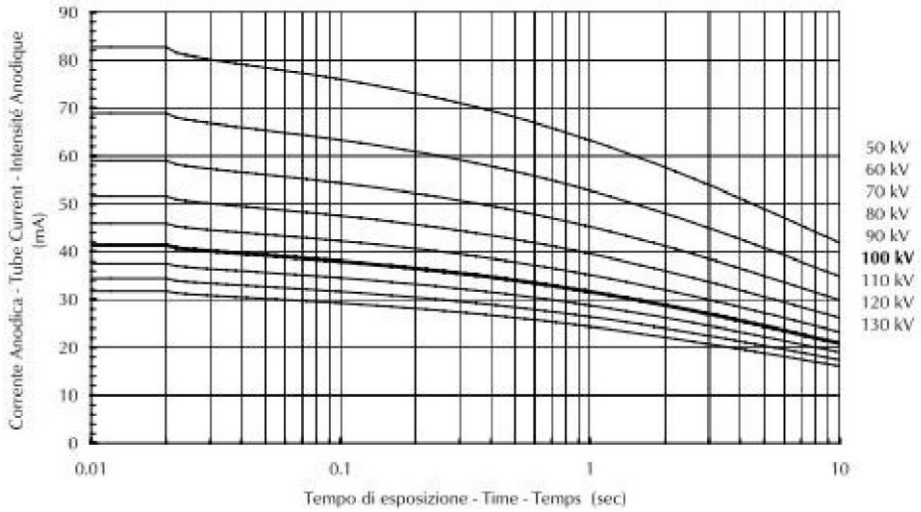
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



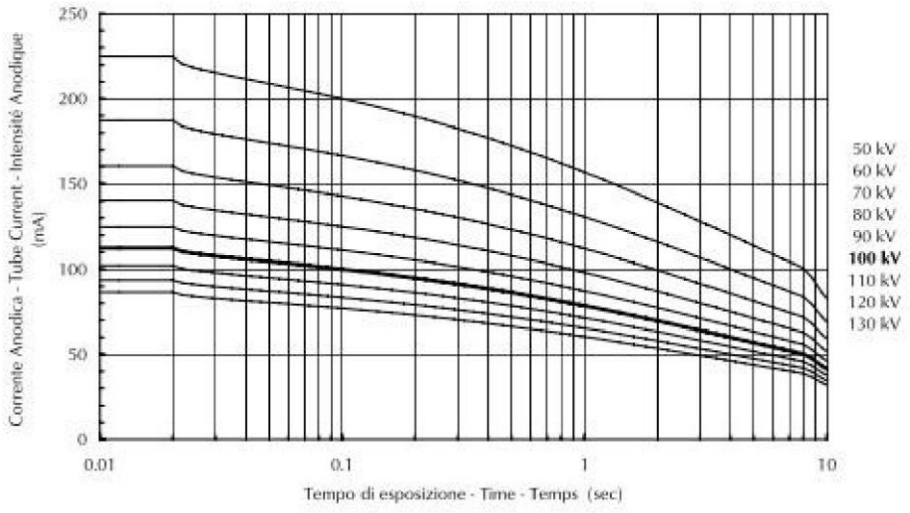
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



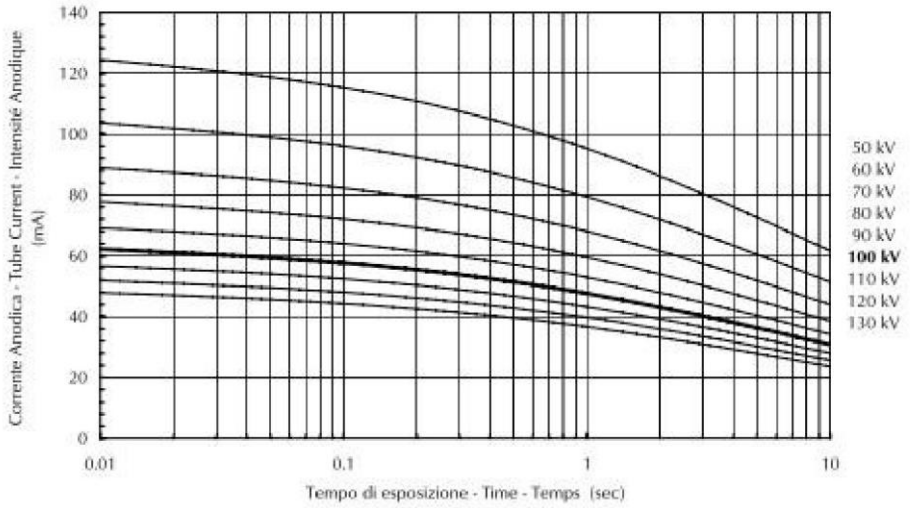
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



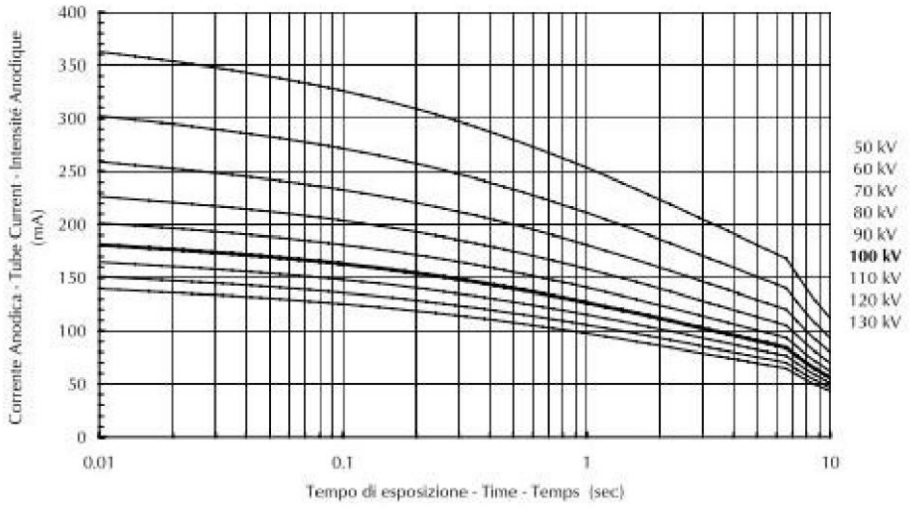
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



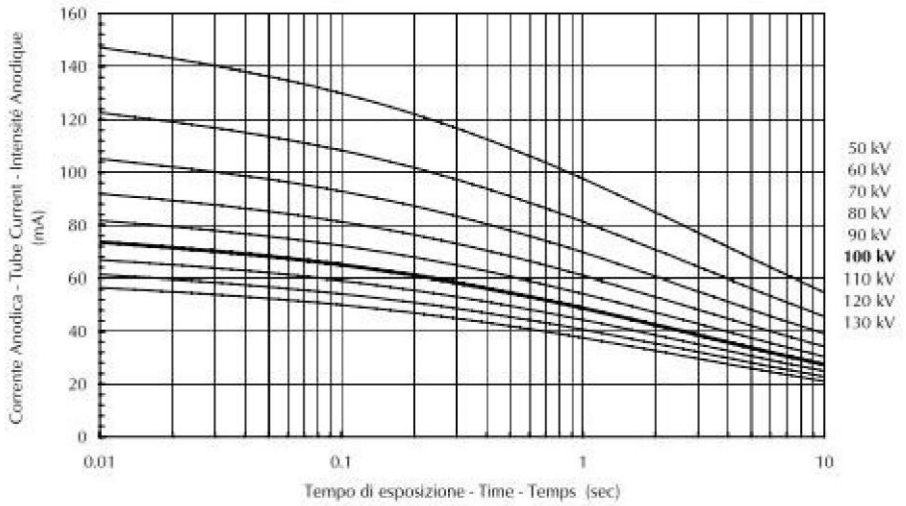
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



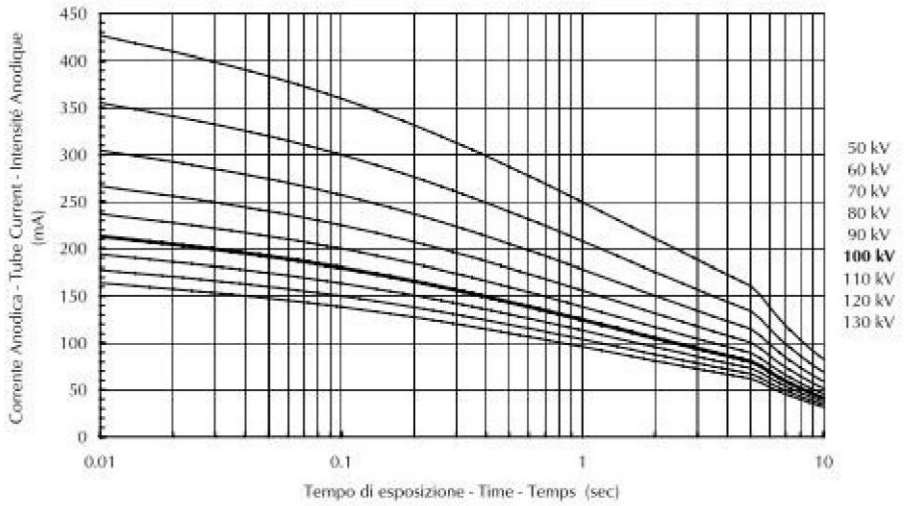
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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

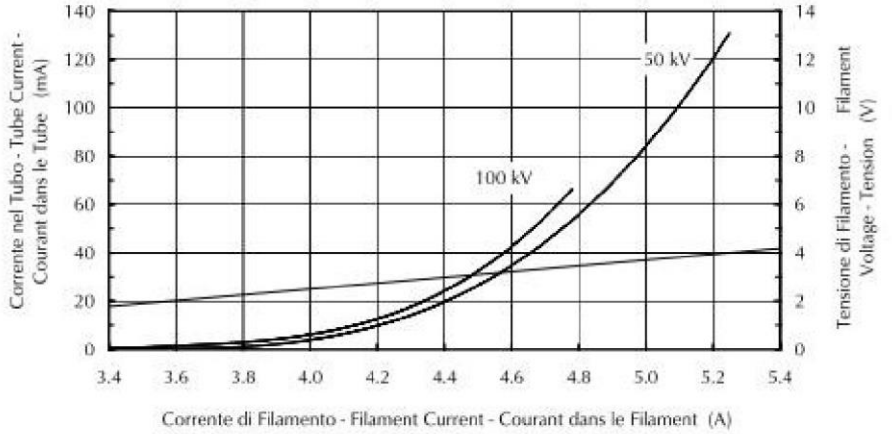


CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

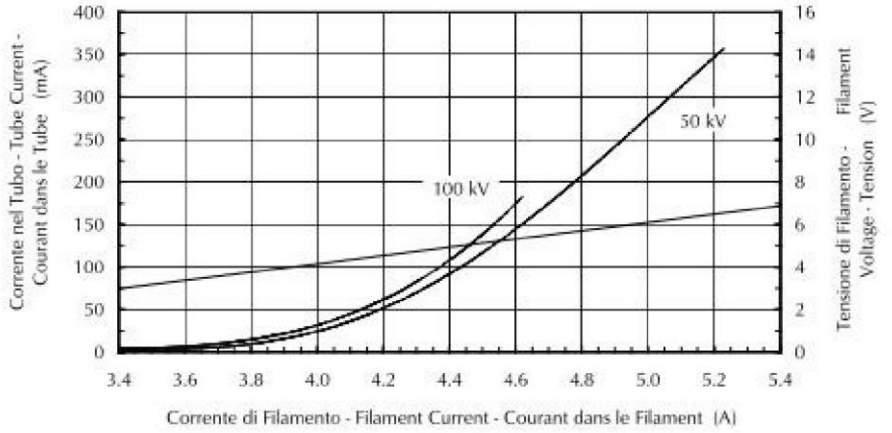
0.6 - 3 ~ - 10000 min^{-1}



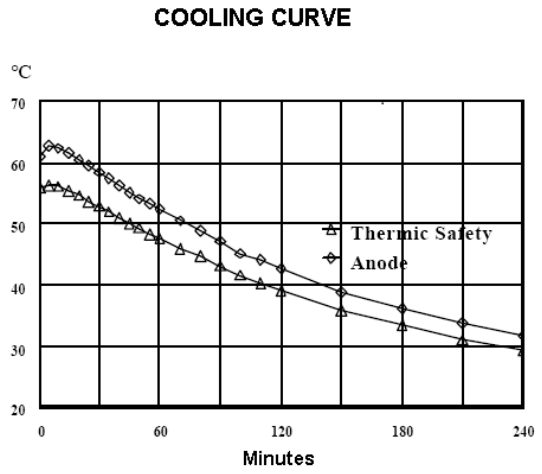
Caratteristica di emissione del catodo
Cathode emission characteristic
Caractéristique d'émission de la cathode
▣ 0.3 - 3 ~ - (± 0.2 A)



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 (part no. XRM.11.H51.001 / 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	
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) + 9.5 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

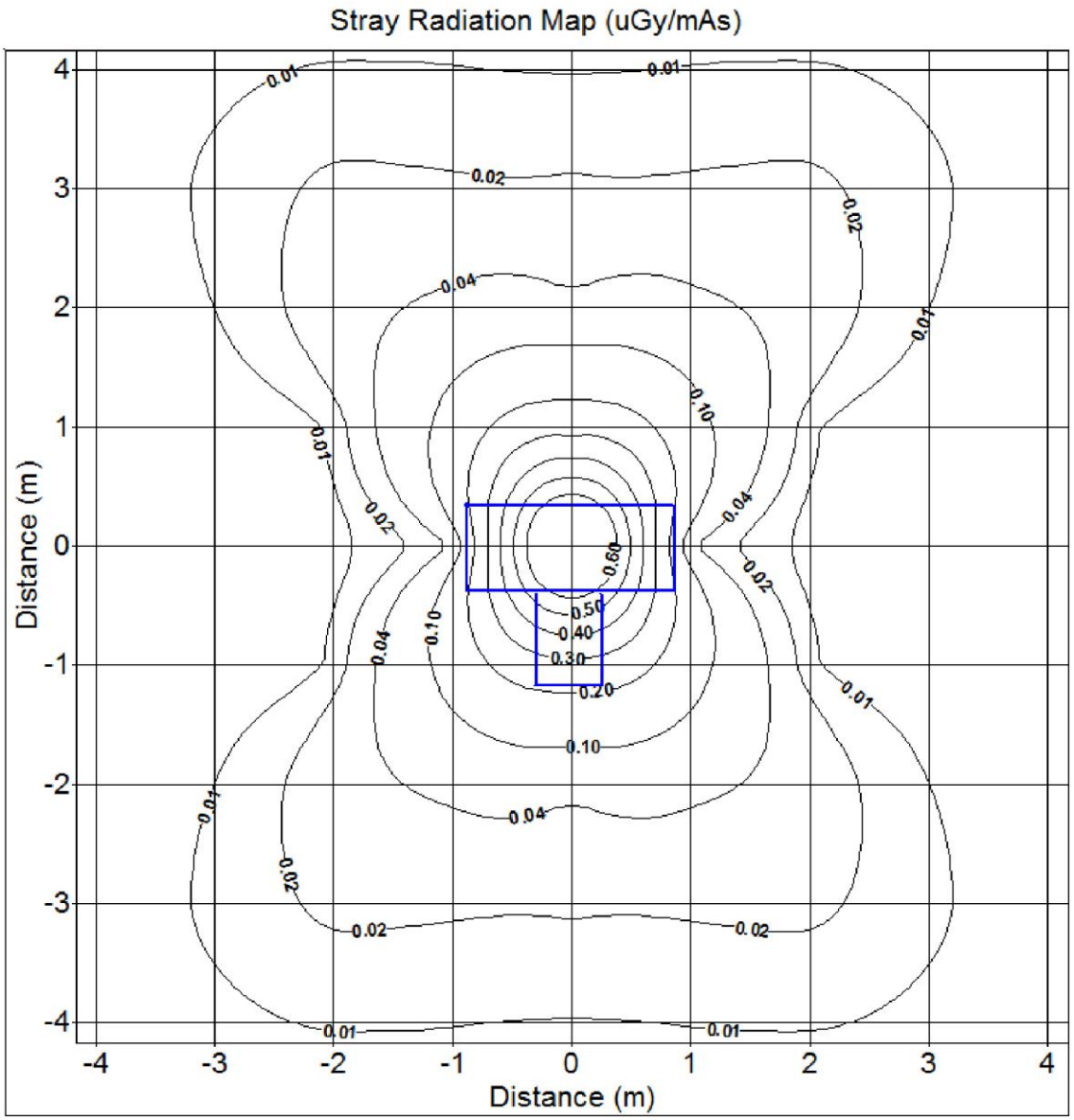
Make	IMD s.r.l.
Model	HF1 3.5kW / HF1 3.5kW PLUS
INPUTS	
Maximum power	3.5 kW
Power supply	230 V~ (± 10%)
Wave shape	Sinusoidal 50/60 Hz
Maximum current	16 A
Power supply apparent resistance	0.35 ohm
OUTPUTS	
Peak voltage	350 Vpk
Maximum peak current	120 Apk Max.
Wave shape	Sinusoidal 20 kHz
PHYSICAL 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
Refer to the attached manual **"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)

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 existing equipment.

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 device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom 5G XL device must ensure that is used in such environment.		
Emission test	Conformity	Electromagnetic environment - guide
RF emissions CISPR 11	Group 1	The NewTom 5G XL 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.
RF emissions CISPR 11	Class A	The NewTom 5G XL 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.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

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 device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom 5G XL 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 device user requires a continuous operation also in case of blackout, it is recommended to power the NewTom 5G XL 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 device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom 5G XL 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 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).
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	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: 

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 device is used exceeds the applicable conformity level mentioned above, one should analyse the standard operation of the NewTom 5G XL 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 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 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 device could help in preventing electromagnetic interferences ensuring a minimum distance between the RF mobile and portable communication devices and the NewTom 5G XL 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, parts, 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 components, transducers and cables different from the specified ones may negatively affect the device characteristics in terms of electromagnetic compatibility!

WARNING:
The NewTom 5G XL must not be located directly on another device, and other devices must not be positioned directly on the NewTom 5G XL device.
If this is not possible, observe the NewTom 5G XL 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

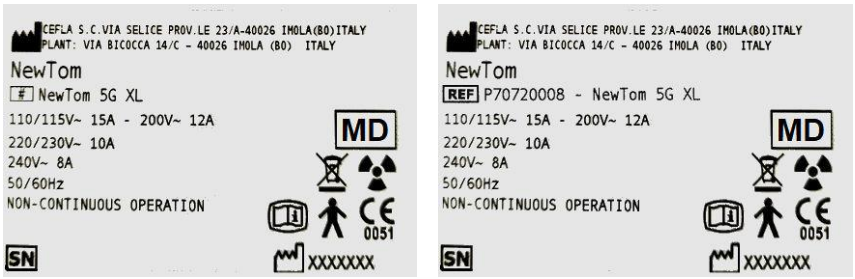
NewTom 5G XL device has been manufactured according to IEC standards for the safety of electrical medical equipment, in particular in compliance with the following standards:

- 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 62304:2006 + A1:2015 (Ed. 1.1) - Medical device software- Software life cycle processes
- IEC 62366-1:2015 + A1:2020 (Ed. 1.1) 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 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
REF code only used for devices sold in Canada.

✔ 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

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

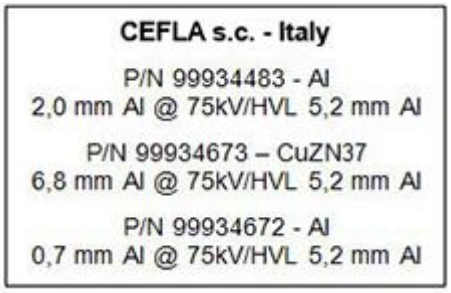
✔ LASER DEVICE WARNING LABEL

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 beam limiter

✔ BEAM LIMITER ADDITIONAL FILTRATION LABEL

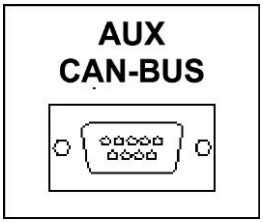


Position: On the "5G XL LASER MIRROR SHEET" of the beam limiter

✔ COVER ADDITIONAL FILTRATION LABEL

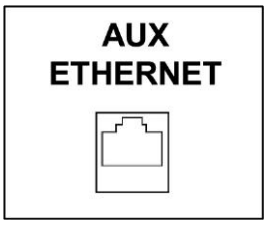
Position: On the internal plastic cover of the scanner (5G XL CYLINDER)

✔ CAN BUS CONNECTOR INDICATION LABEL



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

✔ RJ45 ETHERNET BUTTON 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

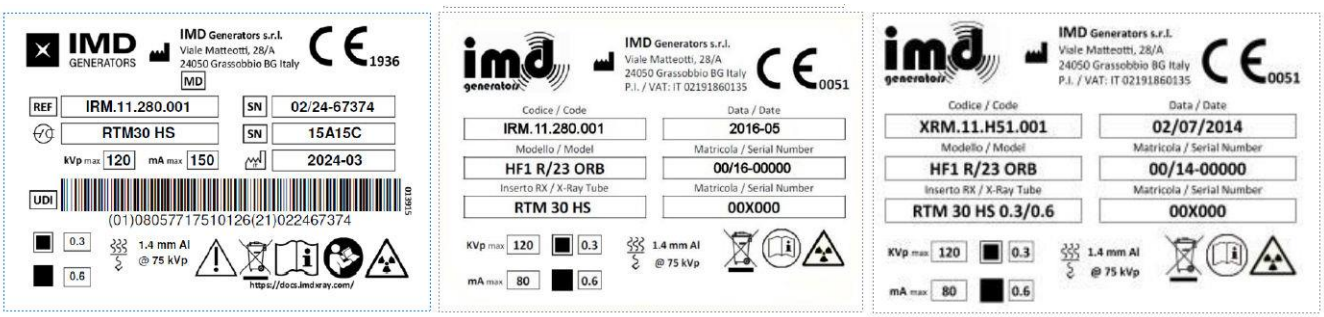
✔ HAND CRUSHING HAZARD LABEL

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

✔ LABEL INDICATING TO REFER TO THE INSTRUCTION MANUAL

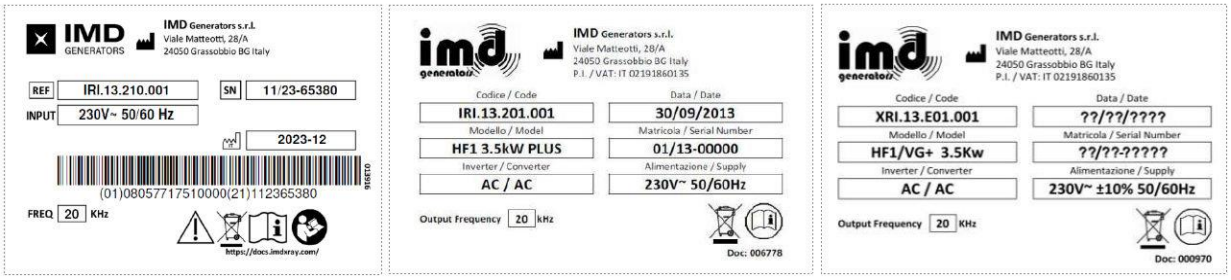
Position: Rear thermoformed cover, bottom left side, above the Input Fuse Main Switch Label.

✔ LABEL ON X-RAY SOURCE



Position: On the case of the X-ray source

✔ INVERTER LABEL



Position: On the inverter case

www.newtom.it

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