CE

97055086
Rev. 05
2025-09

NEWTOM
CONE BEAM 3D IMAGING

NewTom 7G Vet – USER MANUAL

EN

NOTES

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

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

This document, in whole or in part, may not be modified, copied, reproduced, distributed, saved on magnetic or optical media, and published on websites and other on-line services without the written permission of CEFLA s.c.

The original version of this manual is written in Italian.

NewTom 7G is a trademark of CEFLA s.c.
All other products and brand names shown in this document are registered trademarks of their respective manufacturers.

MANUFACTURER'S NOTE ON MEDICAL DEVICES

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

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.

DISCLAIMER

All information, specifications and measurements in this document refer to the device supplied by CEFLA s.c. in the available configurations.
CEFLA s.c. is not responsible for any abnormal operation of the device when used with third-party accessories.

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

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

Contents

1. INTRODUCTION TO THE MANUAL

1.1. CONTENTS

This manual has been designed as a means of consultation to provide information and instructions regarding the use of the NewTom™ 7G device.
The routine software functions provided for this device (scanning, data processing, reporting and document managing) and the instructions for use for the operator are handled in the document “Acquisition operations with NewTom 7G” attached to the “NNT User Manual”.

The “USER MANUAL” of the device, the “NNT User Manual” and the document “Acquisition operations with NewTom 7G” should be read and understood in all their parts before using the device.

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

1.2. STRUCTURE

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

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

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

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

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

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

Chapter 6 – “SCANNING”:
explains the process to position and scan 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 information and any notes are included in the manual as shown here:

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

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

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

2. SAFETY-RELATED INFORMATION

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

To ensure the safety of the animal 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.

2.2. SYMBOLS ON THE DEVICE

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

Symbol	Standard	Description
	IEC 60417-5010	On / Off (pressure-pressure)
~	IEC 60417-5032	Alternating current
	ISO 7000-0434A	Warning
	ISO 7010-W001	General warning sign
	ISO 7010-W012	Caution: hazardous voltage.
	IEC 60417-5019	Protective earthing system.
N	IEC 60445	Connection point of the neutral conductor of a permanently installed device.
L	IEC 60445	Connection point of the line conductor of a permanently installed device.
	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	WEEE (waste electrical and electronic equipment) disposal.
CE		Equipment compliant with the requirements set out by the applied Directives
SN	ISO 7000-2498	Serial number.
	ISO 7000-2497	Date of manufacture.
	ISO 7000-3082	Manufacturer.
	ISO 7000-1641	Operating instructions.
	ISO 7010-M002	Refer to the instruction manual.
#	IEC 60417-6050	Model.
REF	ISO 7000-2493	Catalogue number.
	ISO 7000-3500	The operator’s manual is provided in electronic format.
MD	ISO 15223-1	Medical device.
	IEC 60417-5638	Emergency stop.

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 3 emergency shut-down buttons. The first button in placed on the operator's table. Two further buttons are placed on the sides of the scanning hole

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 ANIMAL AND OPERATOR

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

2.5.1. ANIMAL POSITIONING

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

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

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

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

2.5.2. DURING THE SCANNING

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

Always keep the animal monitored for the entire scanning duration.

WARNING:
NEVER use the device without the operator supervision.

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

2.5.3. ANIMAL LEAVING THE SCANNING AREA

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

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

In case of interruption of the operation of the patient table with stretcher, remove the animal by manually moving the stretcher completely out of the device gantry (after unlocking the latter using the suitable handle at the back of the patient table).

Most effective behaviours for the operator:

- ✓ Do not bend your back but your knees;
- ✓ Increase the support base, thus the balance conditions, by widening and bending your legs, transversally and longitudinally according to the movement direction;
- ✓ Move as close as possible to the animal to move;
- ✓ Ensure a good grip of the animal before starting any movement procedure;
- ✓ Do not lift the animal.

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

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

2.6. ARTEFACTS AND SCANNING REPETITION

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

2.7. PROTECTION AGAINST IONIZING RADIATIONS

WARNING:
NewTom 7G is an X-ray device and therefore it exposes the animal and the operators to the risks deriving from ionising radiations.
It must be used in compliance with the safety standards set forth by the radiological protection standard in force in the country of use.

WARNING:
NewTom 7G must not be used for routine or screening examinations. For such purposes, consider other diagnostic equipment.
The imaging examinations performed on each patient must be justified in order to prove that they provide more benefits than risks.

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

- **Operator**

The operator must follow the examination from a control work station according to the prevailing laws; nobody is allowed to remain near the patient during the examination.

WARNING:
Never remain near the device during the emission.

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

- **Animal**

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

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

WARNING:
Possible negative interaction of CT x-rays with implantable active and worn active devices.
Contact the manufacturer of such devices for further information.

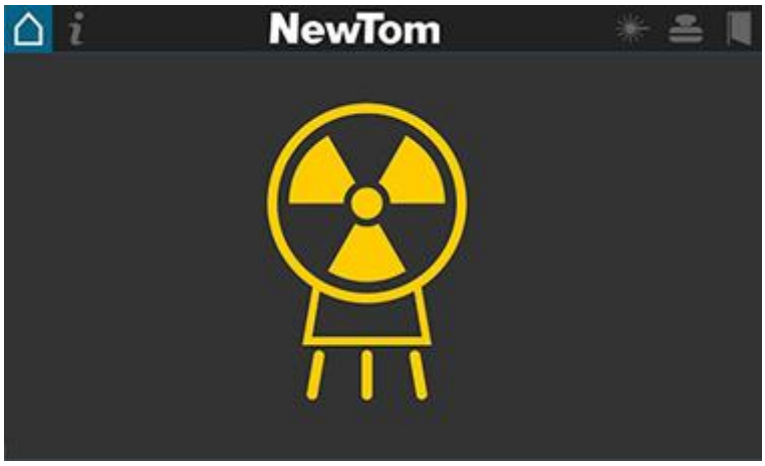
[1] *e.g. Health Canada "Radiation Protection in Radiology – Large Facilities", par. "Protective Equipment"*

- **Emission view devices**

The emission status is clearly identified by:

1. A signal on the display as shown below. Such signal is displayed only after the X-ray emission is started by pressing START on the keyboard or using a mouse (refer to chap. 6 “Scan”) and remains visible for the whole scan duration.

2. An image as the one shown below that is displayed on the page of the control consoles placed on the sides of the device scanning hole (see figure below).
   Such image is displayed only after the X-ray emission is started by pressing START (refer to chap. 6 “Scan”) and remains visible for the whole scan and/or emission duration.



WARNING:
If the emission signals are active when the X-ray emission command has not been given, if they are not active when the emission has been started or if the emission is not interrupted at the end of the preset time, turn off the system and contact the technical service.

2.8. PROTECTION AGAINST LASER RADIATIONS

The device is equipped with three lasers to facilitate animal positioning. The laser radiation is emitted from specific areas located on the internal covering.

The line (A) is drawn by a linear laser source, while lines (B) and (C) are drawn by two cross laser sources on the opposite sides of the opening areas.
The vertical line (A) indicates the central sagittal plane of the reconstructed volume. The horizontal line (B) indicates the central axial plane of the reconstructed volume. The transversal line (C) 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:
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 WORKSTATION

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 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 part of the device that during normal use necessarily comes into contact with the animal for the device to be able to perform its functions is the patient table.
Parts not applied that might come into contact with the animal 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 CONDITIONS

WARNING:
The installation of the device must be carried out by qualified technical personnel and identified by the manufacturer.
The technical description of the device can be found in the “Technical Manual”.

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

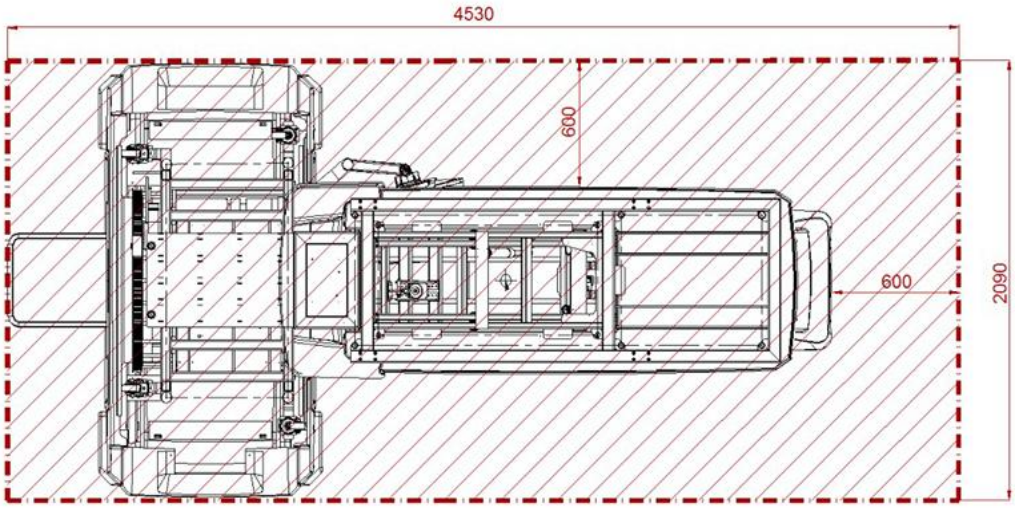
The equipment must not be exposed to acids, corrosive agents, salt and rain.

Operating temperature:	from +10° to +35° (Celsius)
Operating humidity conditions:	min 10%, max 85% (non-condensing)
Altitude:	≤ 3000 m
Pressure:	710 – 1060 hPa
Pollution degree:	2
CTI (“comparative tracking index”) degree:	IIIb
Minimum dimensions of the installation room	5000 x 4000 mm

WARNING:
Make sure that the emergency stop buttons located on operator's console sides can be accessed by the operator without hindrance during device operation.

3.1.1. REQUIREMENTS OF THE ROOM AND FLOOR LOAD-BEARING CAPACITY

WARNING:
Only the user/final customer is responsible for the certification of the capacity, which must be performed by qualified technical personnel.
The manufacturer declines all liability for damage resulting from installation in rooms where the load-bearing capacity declared by the user/final customer does not meet the minimum requirements herein specified for the installation.

Floor load-bearing capacity	**Requirements concerning the room**
< 200kg/sq.m or unknown	Installation NOT allowed. A structural intervention and/or a declaration of conformity by qualified personnel is required according to the current regulation in the country of installation.
200kg/sq.m ÷ 300 kg/sq.m	Comply with the machine perimeter equal to 60 cm without the presence of other static loads (operators and patient only). 
> 300kg/sq.m	No requirement

The device must be installed on a horizontal surface.

The power supply system must be made according to current standards and as prescribed at installation level. The device must also be permanently connected to the electric system as prescribed at installation level (for further details refer to the technical support service).

Do not use temporary electric connections such as, adaptors, extensions, multiple-socket adapters for the connection of the PC or of the peripheral devices in use to the mains.

The medical environment in which the device is installed must be designed by an expert professional and it must be protected against the risk of ionising radiations in compliance with the applicable local and national standards. The applicable local and national regulations will regulate the sign design during installation.

WARNING:
Never move the device after the installation. Moving the device may damage property and be harmful to people and the environment.
Connect only peripheral devices, computers and cables conforming with what specified by the manufacturer to the device.

WARNING:
To avoid the electric shock risk, this device must be connected only to a power supply network with protective earthing system.

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 animal, 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**

CO_2 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, pysician, etc).
This condition limits the probability that the device may be subject to cyber-attack.

In every case some precautions are recommended:

- the scanner and the workstations must be used in a controlled access environment (e.g. 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 animal, 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 modifications or updates of the device must comply with the applicable legislation.

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

WARNING:
The device does not include any repairable part inside it. Never take the covers off the equipment.

WARNING:
The only part that can be repaired by the user is the device's input fuse, located in correspondence with the start-up panel, on the control box side.
The replacement fuse must comply with the manufacturer's specifications.

WARNING:
To ensure protection against risk of fire, use only fuses of the same type and range for the replacement.

- **Standard maintenance**
  Regular maintenance is required to ensure the correct operation of the device, as well as the safety of animal, operator and third parties.

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

WARNING:
If the NewTom 7G device has not been used for scanning patients for a period longer than three months, carry out the X-ray source formation process (for more details, refer to the technical support).

- **Dangerous cleaning agents**
  Certain cleaning agents should be avoided to prevent negative effects on device and persons (see "3.5 Cleaning and disinfection").

- **Preventive maintenance**
  Periodically check the computer-scanner and computer-control box interface cables and the control box power cable. Check the connection cable to the computer, the monitor, the keyboard, the mouse and the printer according to the manufacturer instructions.

- **Storage of components and accessories**
  Components and accessories must be stored and handled with care.
  Any provided components and accessories 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 periodically checked: contact the manufacturer or the distributor to discuss the possibility of a maintenance contract.

- **Device inspection check-list**
  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 system	Check with QA phantom	Weekly
Technical service	Global system	Check with QA phantom	If required for the maintenance and/or check of the performance
	Global system	Centring check of laser targeting modules with QA phantom	If required for the maintenance and/or check of the performance
	Error log	Check	12 months
	All external components	Check for any damage	12 months
	Emergency switch-off	Check of stop system	12 months
	Electrical functionality	Check	12 months
	Mechanical functionality	Check	12 months
Other tests based on local regulations			
Radiation protection expert or another qualified person according to local regulations	Global system	Radiological tests in compliance with local regulations concerning X-ray electromedical equipment. These tests are not the responsibility of operator or local technical service, but they could be required by local regulations.	Radiological 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 required for any disinfection process. Physically scrubbing with detergents and surface-active substances and rinsing with water removes a considerable amount of micro-organisms. If the surface is not first cleaned, the disinfection 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 tuberculocidal (medium-level disinfectant) specific for small surfaces.

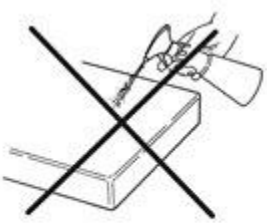
The various drugs and chemical products used in surgeries may damage the painted surfaces and the plastic parts. Researches and tests performed show that the surfaces cannot be fully protected against the harsh action of all products available on the market. We therefore recommend protecting with barriers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

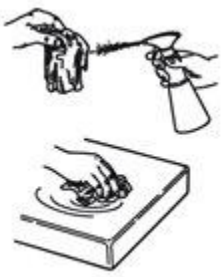
The harsh actions of chemical products also depend on the amount of time they are left on the surfaces. It is therefore important not to leave the product on the surfaces longer than the time specified by the manufacturer.
It is recommended to use the specific medium-level disinfectant, STER 1 PLUS (CEFLA S.C.), which is compatible with painted surfaces, plastic parts and unpainted 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.

- **It is recommended to turn off the equipment prior to cleaning and disinfecting the external parts.**
- **All materials used to clean and disinfect must be thrown away upon completing the procedure.**

- **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 ANIMAL PROTECTION

Disposable hygienic infection control sheaths are the main protection means against cross contamination. **In order to prevent the transmission of infectious diseases, it is essential to always use disposable infection control sheaths. Disposable infection control sheaths are class I equipment and cannot be replaced with other protections having lower specifications.**

Disposable hygienic infection control sheaths must be stored in a dry and clean area and must not be exposed to direct sunlight or UV radiation.
Cover with disposable infection control sheaths all components that will be in contact with dental personnel's hands and might be contaminated by indirect contact with the mouth of the animal. 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.

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.

4. STARTING PROCEDURES

This chapter provides an introduction to the NewTom 7G device, to the switch-on and switch-off procedures and to the control devices positioned on the scanner.

4.1. INTRODUCTION TO THE DEVICE

4.1.1. INTENDED USE

The NewTom 7G device is a computerised tomograph that uses the "cone-beam" technology.
It is intended for diagnostic purposes using geometric and radiological density information obtained from two-dimensional and three-dimensional images of anatomical parts and objects in the area under investigation.

4.1.2. INDICATIONS FOR USE

The NewTom 7G model is a computerised tomographic device using the cone-beam technology which acquires a sequence of images of the head, including ear, nose and throat (ENT), of dental and maxillofacial unit, teeth, mandible and jaw, of the temporomandibular joint (TMJ), cranium and neck with sections of the cervical rachis, sections of the spine, of the upper limbs, including the shoulder, and of the lower limbs, including the hip, 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 managed and used by doctors, dentists, radiologists and other legally qualified professionals.

WARNING:
NewTom 7G 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 X-ray image when a CBCT acquisition is not necessary, the patient could be exposed to an excessive dose of radiations.

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:
Computerised tomography applications of the device must not be used for invasive procedures.

4.1.3. IMPROPER USE

The NewTom 7G device is not intended for the following uses and/or applications (reasonably foreseeable improper use):

- 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 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 the operating theatre;
- use with removable metal objects (collars, identification tags, etc.) in the scanning field;
- use in environmental conditions different from the specified ones.

4.1.4. FUNCTIONING

The animal is placed on the patient table and correctly positioned using 2 laser modules and "scout view" images.

The acquisition device performs a complete rotation around the animal's body 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" technique, the tube-detector system (conical X-ray beam and two-dimensional detector) performs a single rotation around the patient, simultaneously acquiring all the data necessary for volumetric reconstruction.
In practice, the data acquired in each step of the scanning are the digital images corresponding to the relative radiographic projection and the set of data collected (also called raw data) are then used in the process of volumetric reconstruction.

The advantages of this technology compared to traditional systems are:

- Direct reconstruction of any set of points of the scanned object without passing through the axial reconstructions and data reformatting;
- Overall scanning speed related to the acquisition electronics, rather than to the power of the X-ray tube and to mechanical sophistication, and therefore, it tends to be higher;
- For the same total scanning time: lower requirements for generator/tube assembly power and scanning mechanics, resulting in construction and maintenance benefits.

4.3. OVERVIEW

The device consists of three main components: the scanner, the patient table accessory and the main workstation installed outside the patient area.

Other workstations 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 7G complete device

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

4.4. SCANNER

4.4.1. MAIN SWITCH AND INPUT PANEL

On the left side of the device there is the access panel. It is equipped with a switch to turn the device on and off and relevant fuse holder.

On the same panel there are cable glands from which equipment power and control cables as well as Ethernet connectors for the connection of the device to the main workstation / panel come out.

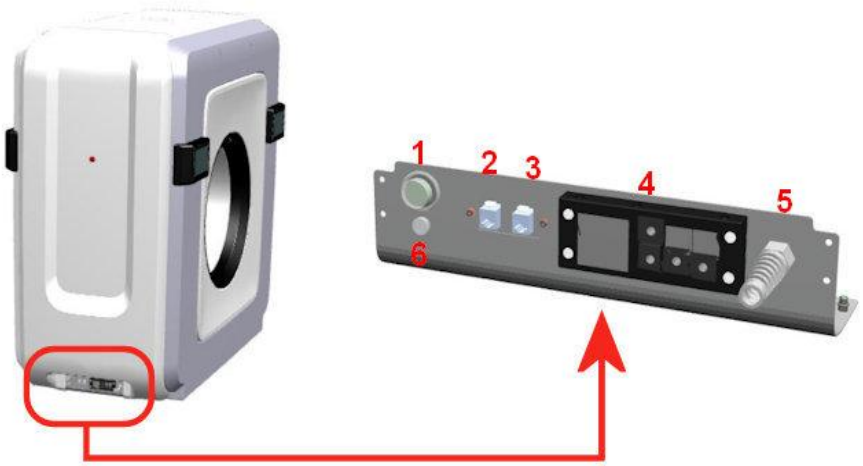


Figure 4: Access panel and relevant connectors

1 - Device main switch

2 - Ethernet connector for workstation
it is possible to make a direct machine - workstation connection or a direct connection to the external data network

3 - Panel Ethernet connector
to download X-ray images: direct machine - workstation connection

4A - Table emergency stop button cable outlet

4B - External lamp 1 (optional)
"Ready" status external lamp contact (24Vdc or 230Vac , max 2.5A)

4C - External lamp 2 (optional)
"X-ray ON" status external lamp contact (24Vdc or 230Vac , max 2.5A)

4D - Door switch (optional)
Input for interruption signal due to open door (interlock) (24Vdc, max 250mA)5 – Cable guide for power supply cable

5 - Cable guide for power supply cable

6 - General fuse holder

4.4.2. CONTROL CONSOLE

The scanner represents the system central unit. On the sides of the scanning hole, there are two control consoles with touch-screen function to

- view the status of the device
- move the patient table and position the animal
- activate the laser modules for animal positioning
- set the type of examination and X-ray parameters

Figure 3: Scanner control panels

Following is a short description of each button / indicator:

Home button:
This button allows displaying the main page where it is possible to select the type of desired examination

Positioning button:
This button allows displaying the positioning page of the patient table.

From this page it is also possible to activate / deactivate the laser

Info button:
This button allows displaying the information page showing some parameters of the device (e.g. IP address of the device etc.)

Laser indicator:
If lit (white) it indicates that the positioning laser is active

Emergency button indicator:
If lit (white) it indicates that the emergency stop button (on the sides of the scanner) is active

Open door indicator:
If lit (white) it indicates that the x-ray room door connected to the device is open, therefore, it is not possible to proceed with the scan

4.4.3. VIRTUAL KEYBOARD

The same functions relevant to the control console, described in the above-mentioned paragraph, are available also in the NNT application by clicking on the relevant key present in the *Scan Manager* panel.

NOTE:
The animal positioning page is available only on the control consoles on-board the machine.

4.5. PATIENT TABLE

The patient table is the device accessory used for animal positioning.
Table movement is carried out by means of the touch-screen control consoles present on the sides of the scanner.

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.

4.7. POSITIONING TOOLS

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

Calibration support:
It is used as a support base for QA Phantom.

4.8. OPTIONAL PACKAGES

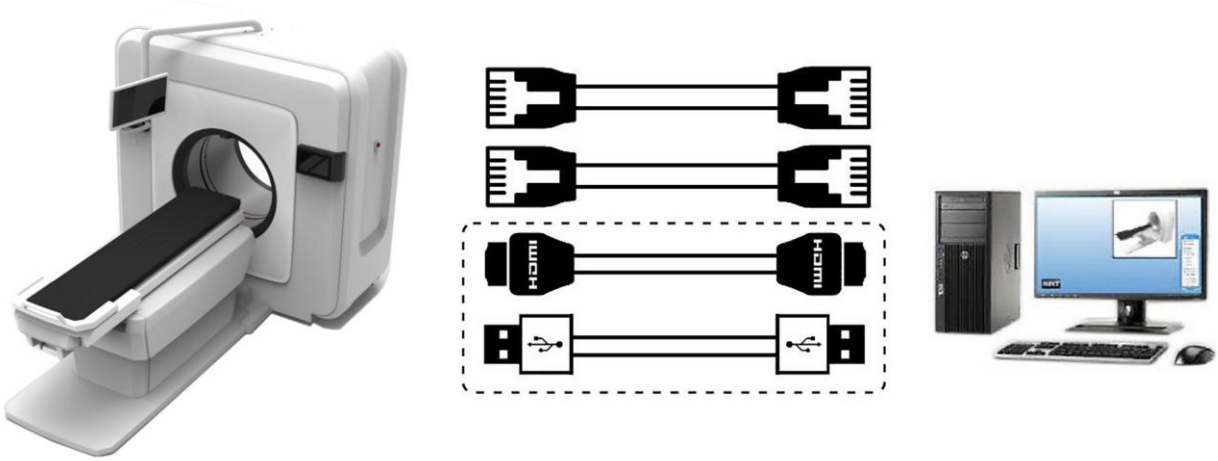
Some optional additional packages are available to expand the device functions.
For further information, refer to the attached document *“Optional components and packages”*.

4.9. CABLES

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

- ✓ 2 Ethernet cables (4 pairs/26 AWG-SFTP-Category 6)
- ✓ Emergency button cable (supplied)
- ✓ 1 HDMI cable (optional - only in case of accessory External Monitor)
- ✓ 1 USB cable (optional - only in case of accessory External Monitor)

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.



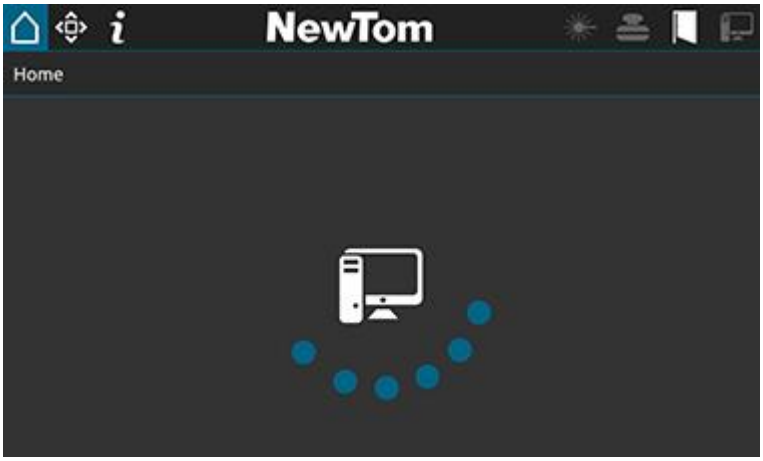
WARNING:
Using components, transducers and cables other than those specified may result in degradation of the electromagnetic compatibility characteristics of the device!

4.10. 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:
Before using the device wait for the correct loading of the NNT application, otherwise the connection will not be established and the following “waiting for connection” page will be displayed



4.11. DEVICE SWITCHING OFF

Following 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 control box input panel.

WARNING:
Switch off the device in case 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 the operations that must be performed on the device before carrying out examinations on the patients.
The operations must be performed without the presence of the animal.
For further information see “NNT User Manual”.

In particular, the operations are the following:

- Daily check;
- Blank acquisition;

The blank acquisition is carried out every 26 weeks, while a Daily check must be run every day before starting the patient examinations.
If such operations are not carried out at the set intervals, the software will block the scanning function showing the following page:

The operating modes are detailed in the relevant chapter of the “NNT User Manual”.

NOTE:
If the ambient temperature is too low or high, it is recommended to bring the latter within the device operating range (+10 ÷ +35 °C) and to wait for a couple of hours until the thermal balance is restored.

5.1. DAILY CHECK

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

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

Figure 6: NNT home page with request for the execution of Daily check

To run a Daily Check click the **"Daily Check"** button on the "Scan Manager" window.

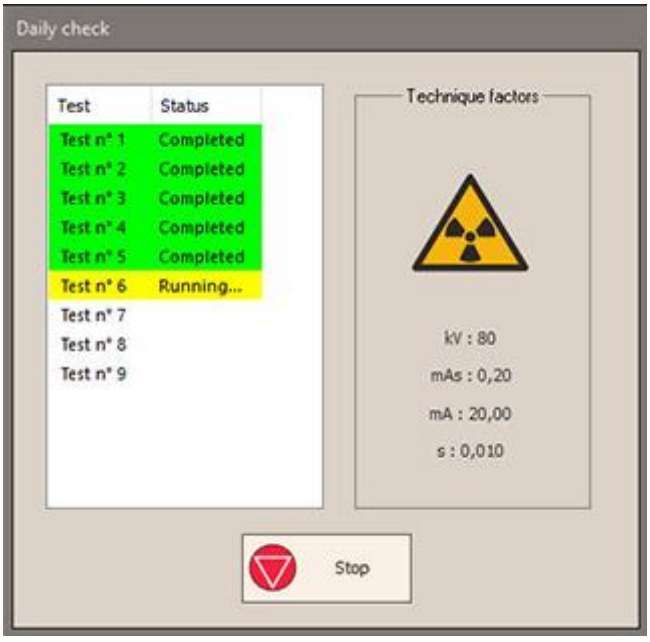


Figure 7: Daily check in progress

The "*Daily check*" window is displayed on screen.

Select "**Start**" to begin the process.

The device will automatically perform each test and display the resulting status in real time.

At this point of the procedure, the program will perform the blank acquisition.

If the "Blank" acquisition is not requested, select the "**Close**" button.

Now it is possible to scan a patient.

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.

WARNING:
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.

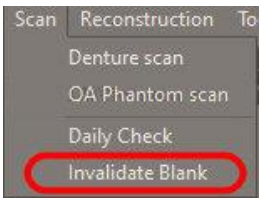
The blank acquisition image will be as shown in the figure.

It is extremely important to ensure that the image does not contain any unusual objects/shadows/marks.
If the above-mentioned spots are present, check that the scan area is actually empty, then click again on “**X-Ray Flash**” and repeat the acquisition procedure.

If the image is correct, select the “**Stop**” button.

5.2.1. BLANK ACQUISITION INVALIDATION

This function applies only to main workstations. To invalidate the blank acquisition follow the instructions below:



To invalidate the blank acquisition select “**Scan**” → “**Invalidate Blank**” from the NNT software.

At the next FOV acquisition selection, the NNT software will request the new Blank acquisition.

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

6. SCANNING

This chapter describes the procedures to be followed for a correct positioning of the animal and execution of the examination.
The description of the scanning procedure is provided in the specific chapter of the document “Acquisition operations with NewTom 7G” attached to the "NNT User Manual".
It is also recommended to refer to Chap. 2 - “Safety-related information” and Chap. 3 - “Device safety and maintenance”.

Upon switching on the device, and after performing the preliminary operations listed before, the following page for the selection of the examination type will be displayed on the control console on the machine and on the Virtual Keyboard inside the NNT application:

CBCT scan:
It allows performing a cone-beam (CBCT) examination

Ray2D scan
It allows performing the Ray2D examination: serial x-ray that allows acquiring a single X-ray image saved on a file.

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.

CineScout scan
It allows performing the CineScout examination: serial x-ray that allows for the dynamic acquisition of a set sequence of X-ray images saved on a video and controlled through an enabling device.

6.1. CBCT SCAN

From the main page, select **CBCT**

6.1.1. SAFEBEAM CBCT AND MANUAL SCAN

Then, select the desired scan mode:

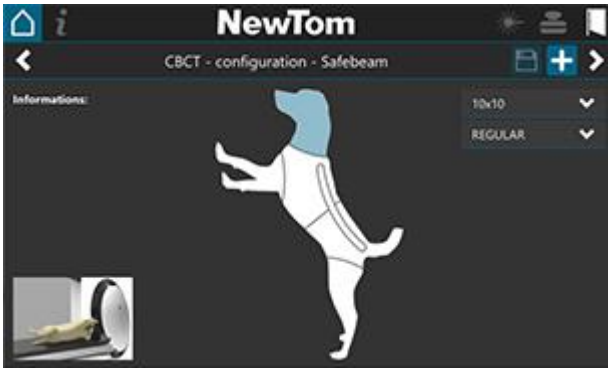
Safebeam:
scan with automatic exposure meter

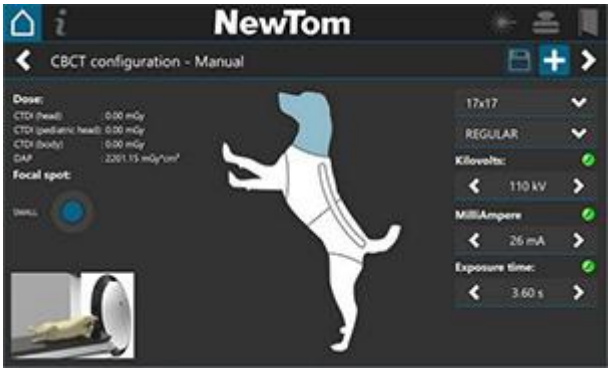
The operating workflow requires an acquisition phase of the scout images that are used to check the animal positioning. These images are used to calculate X-ray parameters to be used during the actual scanning phase.
For further information refer to the "NNT User Manual".

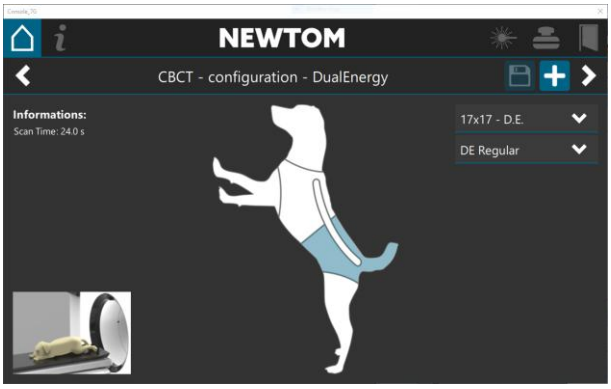
Manual:
scan with X-ray parameters to be set

Dual Energy:
scan with preset X-ray parameters

The relevant configuration panel will be displayed:

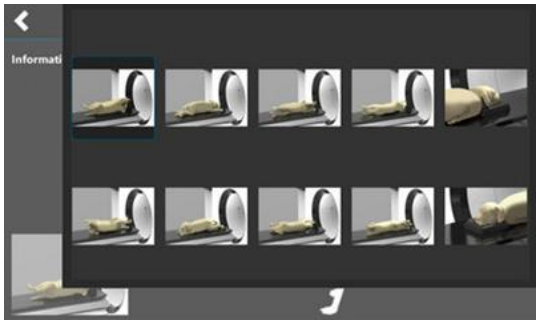






In both modes it is possible to set:

Anatomic area:
on the figure select the desired anatomic area to analyse



Type of positioning:
It is possible to select the following animal positioning modes:

- Head forward, supine
- Head forward, in prone position
- Head forward, in left recumbent position
- Head forward, in right recumbent position
- Paws forward, supine
- Paws in prone position
- Paws in left recumbent position
- Paws in right recumbent position

Type of FOV and acquisition protocol
The required FOV can be selected from the list (volume diameter x volume height)

For the complete list, refer to Appendix A

NOTE:
If the relevant software option is enabled, scanning in eFOV (extra Field of View) mode is available, namely an acquisition mode that uses several adjacent exposures, based on the dimensions of the selected volume. The eFOV scanning is characterised by the letter "e" next to the selected FOV (e.g: [17x32e]).

NOTE:
If the relevant software option is enabled, scanning is available in D.E. mode (Dual Energy Field of View), an acquisition mode that uses preset parameter exposure sequences for high-contrast images.
D.E. FOV scanning can be recognised by the presence of the letters “D.E.” next to the selected FOV (e.g. [17x17]D.E.).

For each above-mentioned FOV, four different scan protocols are available:

- **Low Dose:** protocol to be used to identify / position macrostructures and for secondary check-up examinations
  - Faster protocol
  - Low dose
  - Sufficient resolution

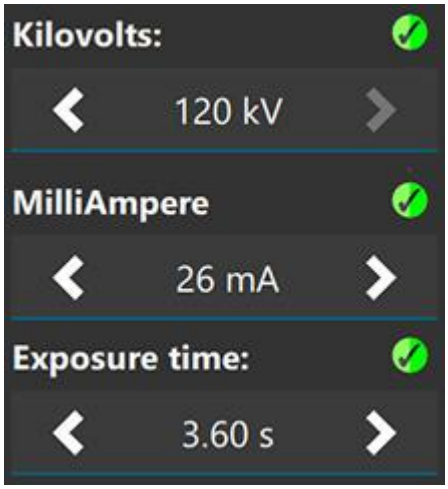
- **Regular**: protocol that offers a good balancing between dose and quality, to be used for first diagnosis without the need of viewing small structures
  - Medium dose
  - Good resolution

- **Enhanced**: protocol to be used for the diagnosis of micro-fractures and small structures
  - High dose
  - High resolution

- **Best**: protocol to be used for the diagnosis of micro-fractures and small structures, endodontic diagnosis…
  - Slower protocol
  - Higher dose
  - Best possible resolution for the chosen FOV

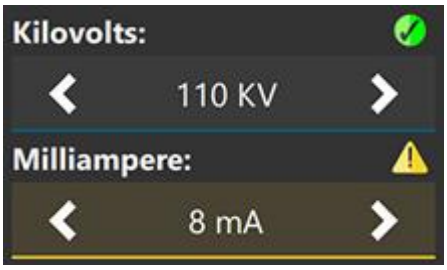
WARNING:
Use the field of view as small as necessary according to clinical needs.
In general, for small-sized animals, it is recommended to use smaller FOVs.

[FOR MANUAL MODE ONLY]

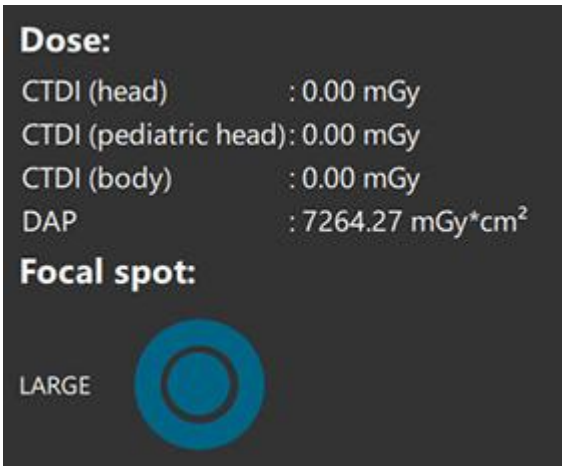


X-ray parameters:
In manual mode, it is possible to vary the scan X-ray parameters (**Kilovolts**, **Milliampere**, **Exposure time**)

If the parameter set is supported by the device, the **green** confirmation symbol will be displayed



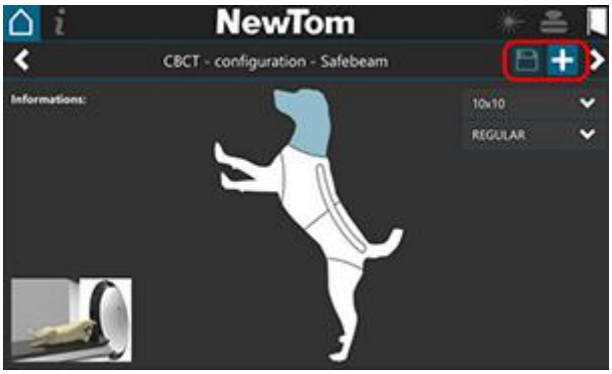
Otherwise, the **yellow** warning symbol will be displayed and it will be necessary to modify the setting of the parameter to carry on



Dose and focal spot:
In manual mode, according to the settings made, the estimated **dose** (**CTDI and DAP**) calculation and the **focal spot** used by the device (**small or large**) will be displayed

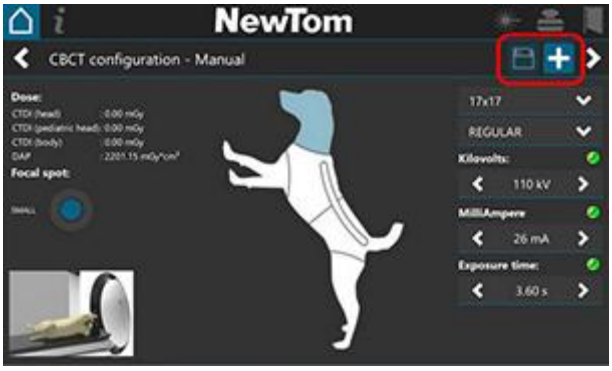
6.1.2. CBCT SCAN WITH CUSTOM PRESET

Besides the Safebeam and Manual modes, it is possible to set customised scan presets

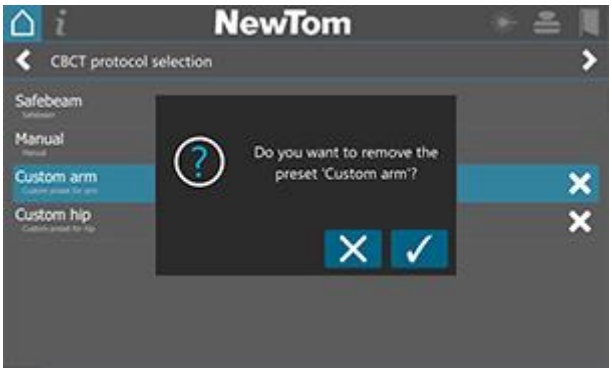


To do this, from the Safebeam or Manual pages, after setting the desired parameters:

- click on the **add** icon
- enter the **preset name**
- click on the **save** button



Now the preset can be recalled from the main page of the scan modes



If the preset needs to be eliminated, simply click on the elimination key next to the name of the preset and confirm

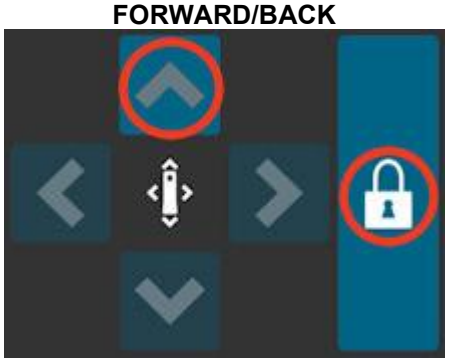
6.1.3. ANIMAL POSITIONING

After selecting the scan mode and setting the relevant parameters, it is necessary to position the animal before starting the scan.

If using the Virtual Keyboard, the message below will be displayed on screen indicating to use the control consoles on-board the machine for the positioning

The positioning page is made up of the following buttons:

Key	Function	Warnings
UP/DOWN 	Table up/down	By pressing these keys continuously and simultaneously the table is moved up or down. The minimum and maximum strokes of the movements are limited to pre-set values and by the active anti-collision controls.

Key	Function	Warnings
FORWARD/BACK 	Longitudinal movement	By pressing these keys continuously and simultaneously the table is moved longitudinally The minimum and maximum strokes of the movements are limited to pre-set values and by the active anti-collision controls.
LEFT/RIGHT 	Transversal movement	By pressing these keys continuously and simultaneously the table is moved transversally The minimum and maximum strokes of the movements are limited to pre-set values and by the active anti-collision controls.
P1 	Sequence execution “Easy Access Position”	By pressing these keys continuously and simultaneously, a sequence of movements is performed to bring the patient table in a position that allows the animal to easily get on the table.
P2 	Sequence execution “Examination Preparation Position”	By pressing these keys continuously and simultaneously, a sequence of movements is performed to bring the patient table in a preliminary position before scanning.

Key	Function	Warnings
	Laser key	By pressing this key the patient positioning laser is activated / deactivated. After the activation the laser will automatically switch off after 60 seconds

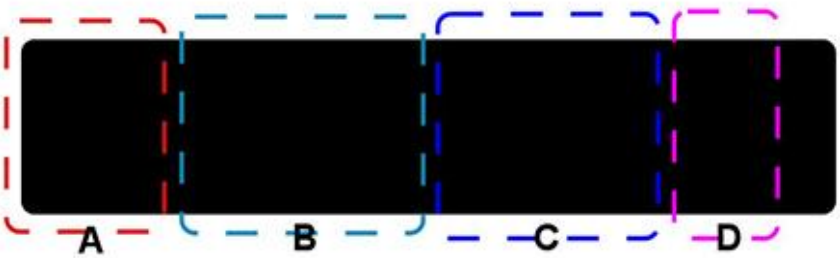
WARNING:
The scanning area where the animal is positioned must remain cleared from objects of any type since they may harm the patient and/or invalidate the results of the examination.

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

WARNING:
Pay attention not to excessively load the parts of the patient table.
The patient table supports patients with a maximum weight of 200Kg (plus 15Kg of accessories, if any).
Below is detailed the distribution of the maximum allowed loads:

1) Maximum load per area and distribution

AREA A	16 Kg	7.4 %
AREA B	120.5 Kg	55.6 %
AREA C	48 Kg	22.2 %
AREA D	31.7 Kg	14.8 %



2) Seating areas (maximum weight 200Kg)

6.1.4. SCAN START

1) The patient table must be set to the default condition (easy access position): press **P1** continuously from the table control panel.

Figure 10: Patient table in easy access position

2) Position the animal.

3) Move the animal to the examination preparation position by pressing **P2** 

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

5) Fine-adjust the animal position using the movement keys present on the control console in the patient positioning page (UP/DOWN - LEFT/RIGHT - FORWARD/BACK) described in the previous paragraph.

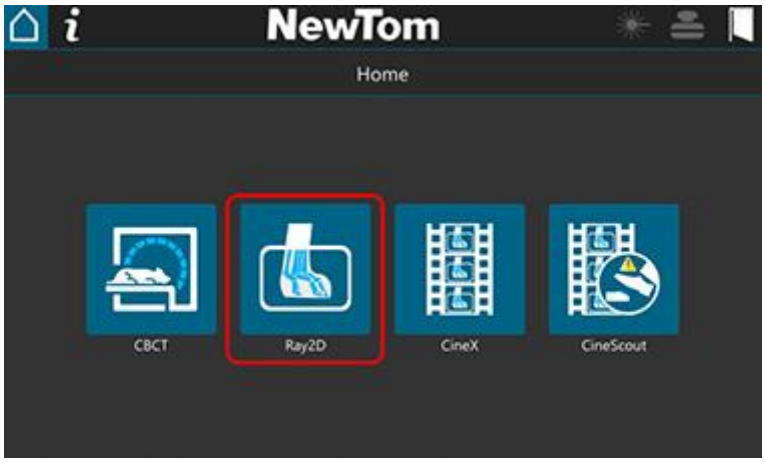
To this end, it is possible to use the laser centring device. To activate it press the LASER key on the control console on board the machine

6) To scan the animal refer to the Par. “Scan” of the document *“Acquisition operations with NewTom 7G”* attached to the "NNT User Manual".

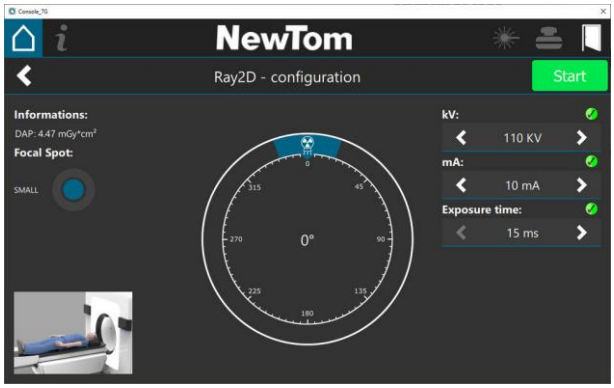
7) Then, press **P1** to bring the animal to the initial position (easy access position) and have the animal leave the room 

6.2. Ray2D SCAN

It allows performing the Ray2D examination: serial x-ray that allows acquiring a single X-ray image saved on a file. From the main page, select **Ray2D**



6.2.1. POSITIONING THE ANIMAL AND STARTING THE SCAN



After selecting the **Ray2D** scan mode, the page to set X-ray parameters will be shown: the operator can choose the position of the X-ray tube with steps of 5 degrees by clicking and rotating the relevant icon.
Moreover, it is possible to set the high voltage and the anode current intensity of the x-ray tube, as well as the exposure time.

Once the setting is complete, press the "**Start"** button.

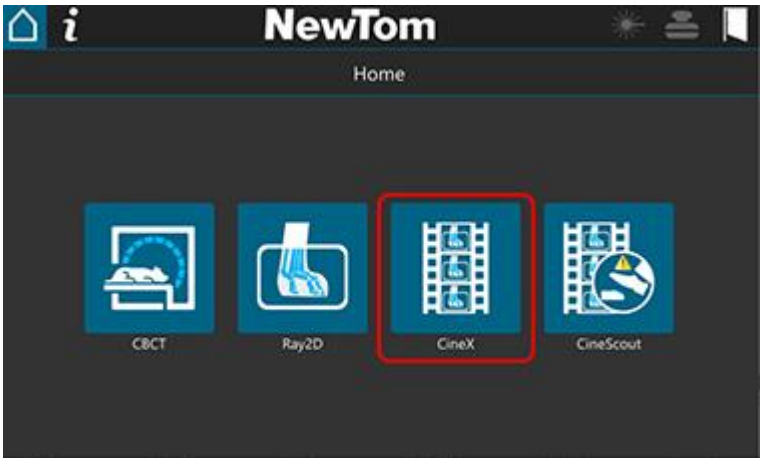
At this point, if not already done so before, it will be possible to enter the animal's data and the relevant positioning.

For further information on animal positioning and preparation, please refer to Par. 6.1.3-6.1.4.

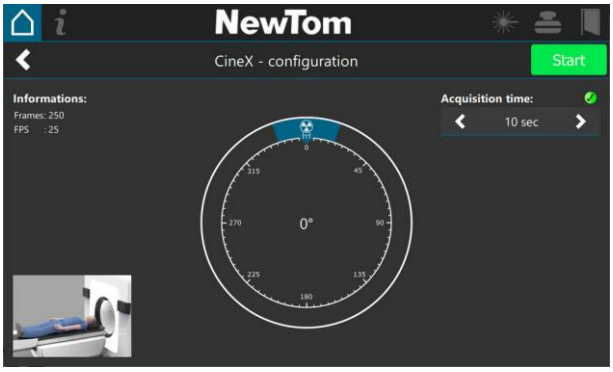
For the complete scanning procedure, refer to the Par. "Ray2D SCANNING OF AN ANIMAL" of the document "*Acquisition operations with NewTom 7G*" attached to the "NNT User Manual".

6.3. 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. From the main page, select **CineX** button.



6.3.1. POSITIONING THE ANIMAL AND STARTING THE SCAN



After selecting the **CineX** scan mode, the page to set X-ray parameters will be shown: the operator can choose the position of the X-ray tube with steps of 5 degrees by clicking and rotating the relevant icon.
Also the exposure time can be set.

Once the setting is complete, press the "**Start"** button

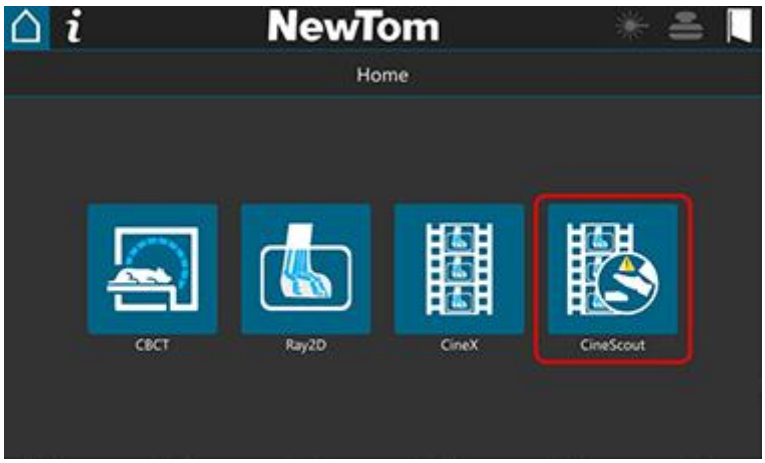
At this point, if not already done so before, it will be possible to enter the animal's data and the relevant positioning.

For further information on animal positioning and preparation, please refer to Par. 6.1.3-6.1.4"

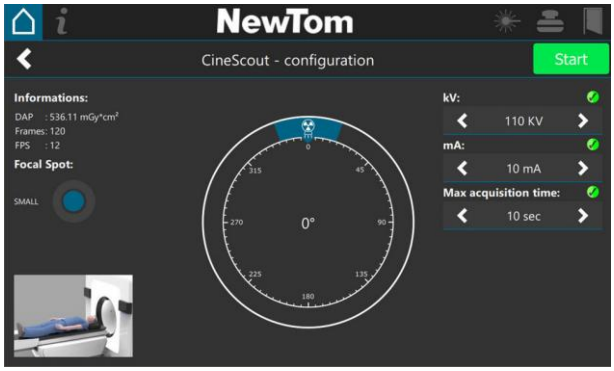
For the complete scanning procedure, refer to the Par. "CineX SCANNING OF AN ANIMAL" of the document "*Acquisition operations with NewTom 7G*" attached to the "NNT User Manual".

6.4. CINESCOUT SCAN

It allows performing the CineScout examination: serial x-ray that allows for the dynamic acquisition of a set sequence of X-ray images saved on a video and controlled through an enabling device.
From the main page, select **CineScout**



6.4.1. POSITIONING THE ANIMAL AND STARTING THE SCAN



After selecting the **CineScout** scan mode, the page to set X-ray parameters will be shown; the operator can choose the position of the X-ray tube with steps of 5 degrees by clicking and rotating the relevant icon.
Moreover, it is possible to set the high voltage and the anode current intensity of the x-ray tube, as well as the exposure time.

Once the setting is complete, press the "**Start"** button

At this point, if not already done so before, it will be possible to enter the animal's data and the relevant positioning.

For further information on animal positioning and preparation, please refer to Par. 6.1.3-6.1.4".

For the complete scanning procedure, refer to the Par. "CineScout SCANNING OF AN ANIMAL" of the document "*Acquisition operations with NewTom 7G*" attached to the "NNT User Manual".

6.5. NOTES FOR USE WITH SMALL-SIZED ANIMALS

Device instructions and specifications

NOTE:
Make sure that collars have been removed. Check that the oral cavity is free.

NOTE:
It is essential that the animal remains still to obtain images of adequate quality. It is recommended to use any measure which could be necessary for stabilising the animal before starting the acquisition procedure.

NewTom 7G can be used to examine small-sized animals, in compliance with the limitations on use shown in the instructions. 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;
- possibility of using fields of view with reduced dimensions, such as: 4x4 (4 cm volume diameter, 4 cm height), 6x6, 8x6, 8x8. Possibility of scanning in “Low dose”, a low-dose protocol characterised by reduced scanning time.

The table below summarises the device functions.

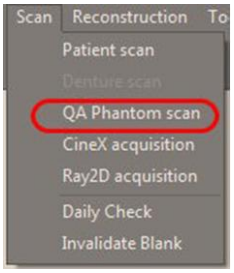
Device features which are relevant for paediatric imaging	**Reference**
Instructions for use	This manual Par. “INTENDED USE”
Protection against radiations	This manual Par. “PROTECTION AGAINST RADIATIONS”
Description of the operation	This manual Par. “HOW TO START”
Protocols available	This manual Par. “SCAN”
Patient positioning	This manual Par. “PATIENT POSITIONING”
Instructions for image quality check	This manual Par. “QUALITY CONTROL” *“Acquisition operations with NewTom 7G”* manual
Dose measurements (CTDI)	*“NewTom 7G - Dose declaration and acceptance test”* manual.

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.

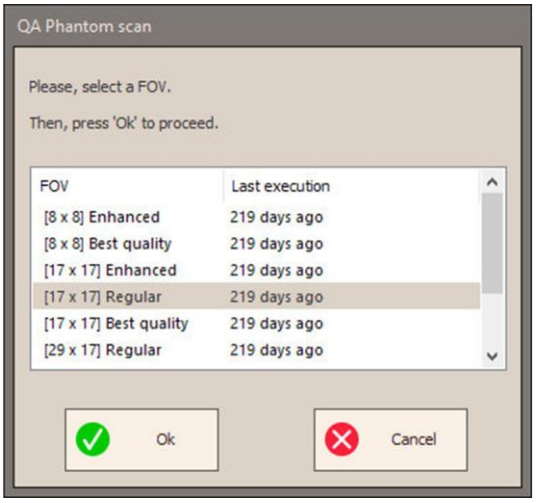
7.1. PHANTOM SCAN



To start the acquisition procedure select ***Scan*** → ***QA Phantom Scan***.

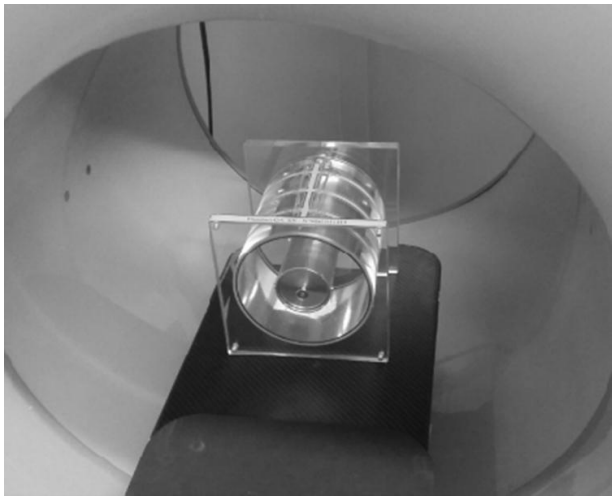
7.1.1. SELECTING THE FOV FOR THE SCAN

Before starting the phantom scan the FOV must be selected.



From the field selection window, select the FOV to be used later for the scan:

7.1.2. POSITIONING THE PHANTOM AND STARTING THE SCAN

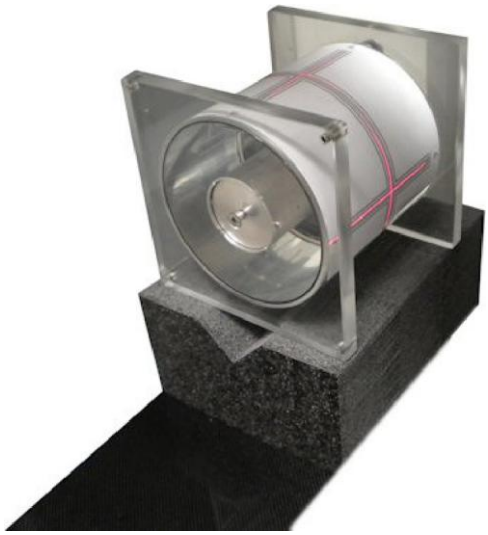


Below is the description of the operations to carry out to position and centre the phantom within the scanning area. Perform these operations in the exact moment signalled by the software.

1) Bring the patient table to the default condition by pressing P1 on the table control panel.

2) Remove the headrest cushion or any positioning tools and move the patient table to the examination preparation position by keeping P2 continuously pressed.

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



4) Fine-adjust the phantom 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.

   Position the phantom by matching the laser crosses on the references on the phantom itself.

5) To scan the phantom refer to the paragraphs “QA Phantom Scan” and “Correction of patient position from workstation” of the document *“Acquisition operations with NewTom 7G”* attached to the "NNT User Manual".

6) After scanning, remove the phantom and relevant support from the patient table, release the stretcher and fully extract it from the scanning area, lock it again and press P2 to bring the table in the initial position (easy access position)

7.1.3. SAVING THE PHANTOM ANALYSES

QA Phantom Report - 1 / 13

Software version : 9.7.6.1
Scan date : 22/05/2019 - 09:50

Device Number : 7G-PRT-18-02
FOV: [29 x 17] Regular

AAP [-1.00 ÷ 1.00 degrees] :	1.00
ALL [-1.00 ÷ 1.00 degrees] :	0.29
Scan duration [14.20 ÷ 14.60 sec.] :	14.42
RNS % [0.00 ÷ 3.50] :	0.43
HDE [59.30 ÷ 60.50 mm] :	60.44
HDI [55.50 ÷ 56.70 mm] :	56.45
VDE [59.30 ÷ 60.50 mm] :	60.19
VDI [55.50 ÷ 56.70 mm] :	56.35
H FWHM [< 0.50 mm] :	0.26
V FWHM [< 0.50 mm] :	0.30
HFD [44.70 ÷ 45.70 mm] :	45.58
VFD [49.50 ÷ 51.00 mm] :	50.01
Min Level (*) :	1017.05
Max Level (*) :	2481.42

(*) Reserved for internal use

22/05/2019 - 09:58

Signature _____

Centers (Reserved for Service)

C1: 575.89 C2: 583.10 C3: 1.00 C4: 0.00 C5: 1323 C6: 13.23
C7: 2600 C8: 26.00 C9: 30.00 C10: 110.00 C11: 8.00 C12: 28.11

When the phantom analysis is completed the table with the results will be automatically displayed.

If a result is out of range, three asterisks will be placed next to the value. In this case contact your local dealer.

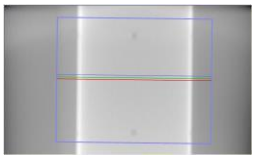
To print the report select ***File → Print.***
It is recommended to always print and store a hardcopy of the phantom analysis.

Any report of the phantom analysis is automatically saved by the software. Then, the reports can be recalled by selecting *“**View**” → “**QA Report**”.*

Once opened, it is possible to scroll through the reports with the PAGE DOWN and PAGE UP keys of the control panel.
It is possible to make copies of the QA Report in PDF format by selecting “***File***” ⟶ “***Save as PDF***”.

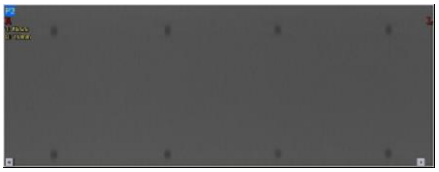
7.2. IMAGE EXAMPLES

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



Lateral view.

Axial section.



Panoramic section.

8. TROUBLESHOOTING

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

9. APPENDIX A: TECHNICAL SPECIFICATIONS

Scanner

Scanning device (cone-beam technology)	Single rotation with volumetric acquisition		
Scanning parameters	Mode CBCT FOVs CineX / CineScout Ray2D		Scanning time / Emission time 7.2÷26 s / 1.4÷8.8 s 1÷36s @ 25fps / 0.25÷9 s 1÷36s @ 12fps / 0.18÷6.48 s 0.015÷0.6 s
	Sampling angle		360°
Patient centring	Fixed position		Positioning laser
Analysed anatomic volume	Cylinder		Ø-max x H-max) [cm x cm] [29x17]; [29x12]; [24x17]; [21x17]; [17x17]; [17x12]; [13x17]; [13x12]; [15x6]; [13x8]; [13x6] [10x10]; [8x8]; [8x6]; [6x6]; [4x4]; extended FOVs (eFOV) [40x17]e; [29x56]e; [29x43]e; [29x30]e; [24x30]e; [21x56]e; [21x43]e; [21x30]e; [17x62]e; [17x47]e; [17x32]e; [17x22]e; [13x62]e; [13x47]e; [13x32]e; Dual Energy FOVs (optional) [17x17]DE;
Dimensions	Scanner	Width	2050 mm / 80.7’’
		Depth	1070 mm / 42.1’’
		Height	2083 mm / 82.0’’
		Gantry opening	770 mm / 30.3’’

	Patient table	Length (max)	2000 ÷ 2200 mm / 78.7'' ÷ 86.6''
		Width (max)	888 mm / 34.9''
		Height (max)	895 mm / 35.2''
		Load (max)	215 kg / 474 lb (200 kg patient + 15 kg components)
Weight		Weight	1050 kg / 2314.8 lb (scanner + patient table with stretcher)

Headrest immobilising device

Equivalent filtration	Max 1 mm	Al eq @ 100kV

Stretcher

Equivalent filtration	Max 1 mm	Al eq @ 100kV

Detector

Pixel	1956 x 1956	Pixel
Pixel size	0.154 x 0.154	mm
Pixel depth	16	bit
S/N	12 – 16 (standard resolution @ 5 nGy) 5 – 9 (HiRes @ 5 nGy)	dB
Frame rate Max	30	F/s

X-ray image scout view

[29x17]

Image pixel	978 x 978	Pixel
Pixel Size	0.308 x 0.308	mm
Pixel depth	16	no.

[24x17]

Image pixel	836 x 978	Pixel
Pixel Size	0.308 x 0.308	mm
Pixel depth	16	no.

[21x17]

Image pixel	750 x 978	Pixel
Pixel Size	0.308 x 0.308	mm
Pixel depth	16	no.

[29x12]

Image pixel	978 x 694	Pixel
Pixel Size	0.308 x 0.308	mm
Pixel depth	16	no.

[17x17]

Image pixel	978 x 978	Pixel
Pixel Size	0.308 x 0.308	mm
Pixel depth	16	no.

[13x17]

Image pixel	746 x 978	Pixel
Pixel Size	0.308 x 0.308	mm
Pixel depth	16	no.

[17x12]

Image pixel	978 x 694	Pixel
Pixel Size	0.308 x 0.308	mm
Pixel depth	16	no.

[13x12]

Image pixel	746 x 694	Pixel
Pixel Size	0.308 x 0.308	mm
Pixel depth	16	no.

[13x8]

Scan protocol	Low dose / Regular	Enhanced / Best quality	
Image pixel	746 x 462	1492 x 924	Pixel
Pixel Size	0.308 x 0.308	0.154 x 0.154	mm
Pixel depth	16		no.

[10x10]

Scan protocol	Low dose / Regular	Enhanced / Best quality	
Image pixel	572 x 572	1144 x 1144	Pixel
Pixel Size	0.308 x 0.308	0.154 x 0.154	mm
Pixel depth	16		no.

[15x6]

Scan protocol	Low dose / Regular	Enhanced / Best quality	
Image pixel	862 x 346	1724 x 692	Pixel
Pixel Size	0.308 x 0.308	0.154 x 0.154	mm
Pixel depth	16		no.

[13x6]

Scan protocol	Low dose / Regular	Enhanced / Best quality	
Image pixel	746 x 346	1492 x 692	Pixel
Pixel Size	0.308 x 0.308	0.154 x 0.154	mm
Pixel depth	16		no.

[8x8]

Scan protocol	Low dose / Regular	Enhanced / Best quality	
Image pixel	462 x 462	924 x 924	Pixel
Pixel Size	0.308 x 0.308	0.154 x 0.154	mm
Pixel depth	16		no.

[8x6]

Scan protocol	Low dose / Regular	Enhanced / Best quality	
Image pixel	462 x 346	924 x 692	Pixel
Pixel Size	0.308 x 0.308	0.154 x 0.154	mm
Pixel depth	16		no.

[6x6]

Scan protocol	Low dose / Regular	Enhanced / Best quality	
Image pixel	346 x 346	692 x 692	Pixel
Pixel Size	0.308 x 0.308	0.154 x 0.154	mm
Pixel depth	16		no.

[4x4]

Scan protocol	Low dose / Regular	Enhanced / Best quality	
Image pixel	230 x 230	460 x 460	Pixel
Pixel Size	0.308 x 0.308	0.154 x 0.154	mm
Pixel depth	16		no.

Reconstructed volume

[40ex17]

Voxel Size	0.600	0.500	mm
Shape	Two overlapping cylinders	Two overlapping cylinders	//
Reconstructed Volume Size	Ø(400 x 290) x H170	Ø(400 x 290) x H170	mm
Image pixel (axial)	672 x 488 (typical)	806 x 586 (typical)	Pixels
Pixel depth	16		bit

[29x56e]

Voxel Size	0.600	0.500	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø290 x H560 (approx.)	Ø290 x H560 (approx.)	mm
Image pixel (axial)	488 x 488 (approx.)	586 x 586 (approx.)	Pixels
Pixel depth	16		bit

[29x43e]

Voxel Size	0.600	0.500	mm

Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø290 x H430 (approx.)	Ø290 x H430 (approx.)	mm
Image pixel (axial)	488 x 488 (approx.)	586 x 586 (approx.)	Pixels
Pixel depth	16		bit

[29x30e]

Voxel Size	0.600	0.500	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø290 x H300 (approx.)	Ø290 x H300 (approx.)	mm
Image pixel (axial)	488 x 488 (approx.)	586 x 586 (approx.)	Pixels
Pixel depth	16		bit

[29x17]

Voxel Size	0.400	0.300	0.240	mm
Shape	Cylinder	Cuboid	Cube	//
Reconstructed Volume Size	Ø290 x H170	E220 x H170	E 161	mm
Image pixel (axial)	732 x 732	734 x 734	672 x 672	Pixels
Pixel depth	16			bit

[29x12]

Voxel Size	0.400	0.300	0.240	mm
Shape	Cylinder	Cylinder	Cuboid	//
Reconstructed Volume Size	Ø290 x H120	Ø290 x H120	E201 x H120	mm
Image pixel (axial)	732 x 732	976 x 976	840 x 840	Pixels
Pixel depth	16			bit

[24x30e]

Voxel Size	0.500	0.400	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø240 x H300 (approx.)	Ø240 x H300 (approx.)	mm
Image pixel (axial)	484 x 484 (approx.)	604 x 604 (approx.)	Pixels
Pixel depth	16		bit

[24x17]

Voxel Size	0.300	0.240	0.180	mm

Shape	Cylinder	Cube	Cube	//
Reconstructed Volume Size	Ø240 x H170	E 161	E 120	mm
Image pixel (axial)	810 x 810	672 x 672	672 x 672	Pixels
Pixel depth	16			bit

[21x56e]

Voxel Size	0.500	0.400	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø210 x H560 (approx.)	Ø210 x H560 (approx.)	mm
Image pixel (axial)	426 x 426 (approx.)	532 x 532 (approx.)	Pixels
Pixel depth	16		bit

[21x43e]

Voxel Size	0.500	0.400	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø210 x H430 (approx.)	Ø210 x H430 (approx.)	mm
Image pixel (axial)	426 x 426 (approx.)	532 x 532 (approx.)	Pixels
Pixel depth	16		bit

[21x30e]

Voxel Size	0.500	0.400	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø210 x H300 (approx.)	Ø210 x H300 (approx.)	mm
Image pixel (axial)	426 x 426 (approx.)	532 x 532 (approx.)	Pixels
Pixel depth	16		bit

[21x17]

Voxel Size	0.300	0.240	0.180	mm
Shape	Cylinder	Cube	Cube	//
Reconstructed Volume Size	Ø210 x H170	E 161	E 120	mm
Image pixel (axial)	710 x 710	672 x 672	672 x 672	Pixels
Pixel depth	16			bit

[17x62e]

Voxel Size	0.500	0.400	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø170 x H620 (approx.)	Ø170 x H620 (approx.)	mm
Image pixel (axial)	346 x 346 (approx.)	432 x 432 (approx.)	Pixels
Pixel depth	16		bit

[17x47e]

Voxel Size	0.500	0.400	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø170 x H470 (approx.)	Ø170 x H470 (approx.)	mm
Image pixel (axial)	346 x 346 (approx.)	432 x 432 (approx.)	Pixels
Pixel depth	16		bit

[17x32e]

Voxel Size	0.500	0.400	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø170 x H320 (approx.)	Ø170 x H320 (approx.)	mm
Image pixel (axial)	346 x 346 (approx.)	432 x 432 (approx.)	Pixels
Pixel depth	16		bit

[17x22e]

Voxel Size	0.400	0.300	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø170 x H220 (approx.)	Ø170 x H220 (approx.)	mm
Image pixel (axial)	432 x 432 (approx.)	576 x 576 (approx.)	Pixels
Pixel depth	16		bit

[17x17]

Voxel Size	0.300	0.240	0.180	mm
Shape	Cylinder	Cylinder	Cube	//
Reconstructed Volume Size	Ø170 x H170	Ø170 x H170	E 120	mm
Image pixel (axial)	576 x 576	720 x 720	672 x 672	Pixels
Pixel depth	16			bit

[17x17] DE

Voxel Size	0.332	mm
Shape	Cylinder	//
Reconstructed Volume Size	Ø170 x H170	mm
Image pixel (axial)	512 x 512	Pixels
Pixel depth		bit

[17x12]

Voxel Size	0.300	0.240	0.180	mm
Shape	Cylinder	Cylinder	Cube	//
Reconstructed Volume Size	Ø170 x H120	Ø170 x H120	E 120	mm
Image pixel (axial)	576 x 576	720 x 720	672 x 672	Pixels
Pixel depth	16			bit

[13x62e]

Voxel Size	0.500	0.400	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø130 x H620 (approx.)	Ø130 x H620 (approx.)	mm
Image pixel (axial)	264 x 264 (approx.)	330 x 330 (approx.)	Pixels
Pixel depth	16		bit

[13x47e]

Voxel Size	0.400	0.300	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø130 x H470 (approx.)	Ø130 x H470 (approx.)	mm
Image pixel (axial)	330 x 330 (approx.)	440 x 440 (approx.)	Pixels
Pixel depth	16		bit

[13x32e]

Voxel Size	0.400	0.300	mm
Shape	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø130 x H320 (approx.)	Ø130 x H320 (approx.)	mm
Image pixel (axial)	330 x 330 (approx.)	440 x 440 (approx.)	Pixels
Pixel depth	16		bit

[13x17]

Voxel Size	0.300	0.240	0.180	mm
Shape	Cylinder	Cylinder	Cube	//
Reconstructed Volume Size	Ø130 x H170	Ø130 x H170	E 120	mm
Image pixel (axial)	440 x 440	550 x 550	672 x 672	Pixels
Pixel depth	16			bit

[13x12]

Voxel Size	0.300	0.240	0.180	mm
Shape	Cylinder	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø130 x H120	Ø130 x H120	Ø130 x H120	mm
Image pixel (axial)	440 x 440	550 x 550	732 x 732	Pixels
Pixel depth	16			bit

[13x8]

Scan protocol	Low dose / Regular			Enhanced / Best quality			
Voxel Size	0.300	0.240	0.180	0.150	0.120	0.090	mm
Shape	Cylinder	Cylinder	Cylinder	Cylinder	Cube	Cube	//
Reconstructed Volume Size	Ø130 x H80	Ø130 x H80	Ø130 x H80	Ø130 x H80	E 80	E 60	mm
Image pixel (axial)	440 x 440	550 x 550	732 x 732	880 x 880	672 x 672	672 x 672	Pixels
Pixel depth	16						bit

[10x10]

Scan protocol	Low dose / Regular			Enhanced / Best quality			
Voxel Size	0.300	0.240	0.180	0.150	0.120	0.090	mm
Shape	Cylinder	Cylinder	Cylinder	Cylinder	Cube	Cube	//
Reconstructed Volume Size	Ø100 x H100	Ø100 x H100	Ø100 x H100	Ø100 x H100	E 80	E 60	mm
Image pixel (axial)	340 x 340	424 x 424	566 x 566	680 x 680	672 x 672	672 x 672	Pixels
Pixel depth	16						bit

[15x6]

Scan protocol	Low dose / Regular			Enhanced / Best quality			
Voxel Size	0.300	0.240	0.180	0.150	0.120	0.090	mm
Shape	Cylinder	Cylinder	Cylinder	Cylinder	Cuboid	Cube	//
Reconstructed Volume Size	Ø150 x H60	Ø150 x H60	Ø150 x H60	Ø150 x H60	E100 x H60	E 60	mm
Image pixel (axial)	510 x 510	636 x 636	848 x 848	1020 x 1020	840 x 840	672 x 672	Pixels
Pixel depth	16						bit

[13x6]

Scan protocol	Low dose / Regular			Enhanced / Best quality			
Voxel Size	0.300	0.240	0.180	0.150	0.120	0.090	mm
Shape	Cylinder	Cylinder	Cylinder	Cylinder	Cuboid	Cube	//
Reconstructed Volume Size	Ø130 x H60	Ø130 x H60	Ø130 x H60	Ø130 x H60	E100 x H60	E 60	mm
Image pixel (axial)	440 x 440	550 x 550	732 x 732	880 x 880	840 x 840	672 x 672	Pixels
Pixel depth	16						bit

[8x8]

Scan protocol	Low dose / Regular			Enhanced / Best quality			
Voxel Size	0.300	0.240	0.180	0.150	0.120	0.090	mm
Shape	Cylinder	Cylinder	Cylinder	Cylinder	Cylinder	Cube	//
Reconstructed Volume Size	Ø80 x H80	Ø80 x H80	Ø80 x H80	Ø80 x H80	Ø80 x H80	E 60	mm
Image pixel (axial)	274 x 274	342 x 342	456 x 456	548 x 548	684 x 684	672 x 672	Pixels
Pixel depth	16						bit

[8x6]

Scan protocol	Low dose / Regular			Enhanced / Best quality			
Voxel Size	0.300	0.240	0.180	0.150	0.120	0.090	mm
Shape	Cylinder	Cylinder	Cylinder	Cylinder	Cylinder	Cube	//
Reconstructed Volume Size	Ø80 x H60	Ø80 x H60	Ø80 x H60	Ø80 x H60	Ø80 x H60	E 60	mm
Image pixel (axial)	274 x 274	342 x 342	456 x 456	548 x 548	684 x 684	672 x 672	Pixels
Pixel depth	16						bit

[6x6]

Scan protocol	Low dose / Regular			Enhanced / Best quality			
Voxel Size	0.300	0.240	0.180	0.150	0.120	0.090	mm
Shape	Cylinder	Cylinder	Cylinder	Cylinder	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø60 x H60	Ø60 x H60	Ø60 x H60	Ø60 x H60	Ø60 x H60	Ø60 x H60	mm
Image pixel (axial)	208 x 208	260 x 260	346 x 346	416 x 416	520 x 520	692 x 692	Pixels
Pixel depth	16						bit

[4x4]

Scan protocol	Low dose / Regular			Enhanced / Best quality			
Voxel Size	0.300	0.240	0.180	0.150	0.120	0.090	mm
Shape	Cylinder	Cylinder	Cylinder	Cylinder	Cylinder	Cylinder	//
Reconstructed Volume Size	Ø40 x H40	Ø40 x H40	Ø40 x H40	Ø40 x H40	Ø40 x H40	Ø40 x H40	mm
Image pixel (axial)	140 x 140	174 x 174	232 x 232	280 x 280	348 x 348	464 x 464	Pixels
Pixel depth	16						bit

X-ray parameters

IAE X-ray tube mod. RTM 70 H 0.3/0.6 (rotary anode)

Documentazione Tubo a raggi X
Tube Documentation
Documentation du Tube

RTM 70 H 0.3/0.6

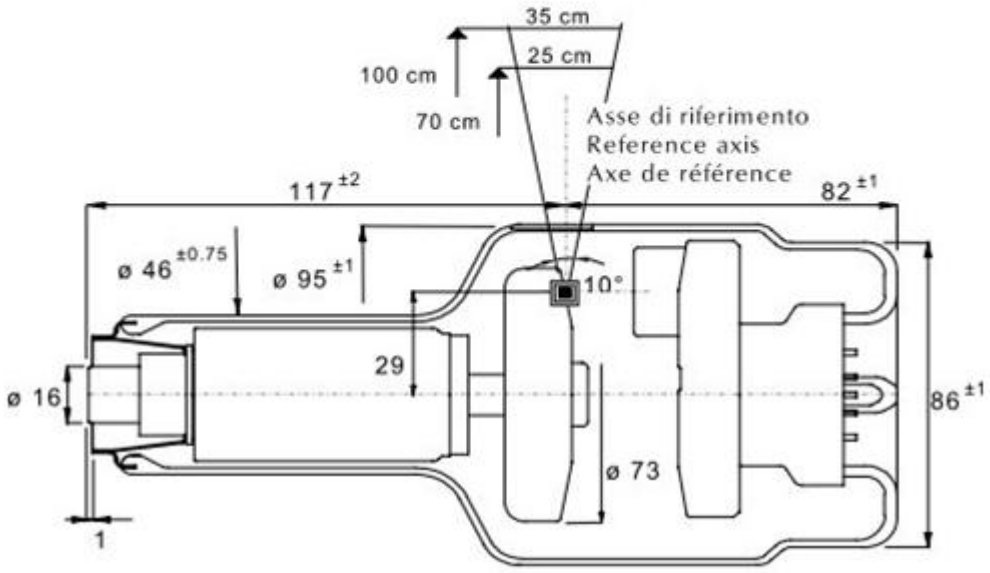
Caratteristiche - Specifications - Spécifications

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}		
Potenza anodica nominale Nominal anode input power Puissance anodique nominale	■ 6 kW ■ 25 kW		(IEC 613, EN 60613)
Diametro anodico Anode diameter Diamètre de l'anode	73 mm		
Materiale anodico Anode material Matériau de l'anode	RTM		
Angolo anodico Anode angle Pente de l'anode	10 °		
Campo di radiazione Radiation field Champ de rayonnement	a 70 cm 25 cm a 100 cm 35 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	225 kJ	300 kHU	
Dissipazione termica continua Continuous heat dissipation Dissipation thermique continue	750 W	60 000 HU/min	
Dissipazione termica massima Maximum heat dissipation Dissipation thermique maximale	1300 W	104 000 HU/min	
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		

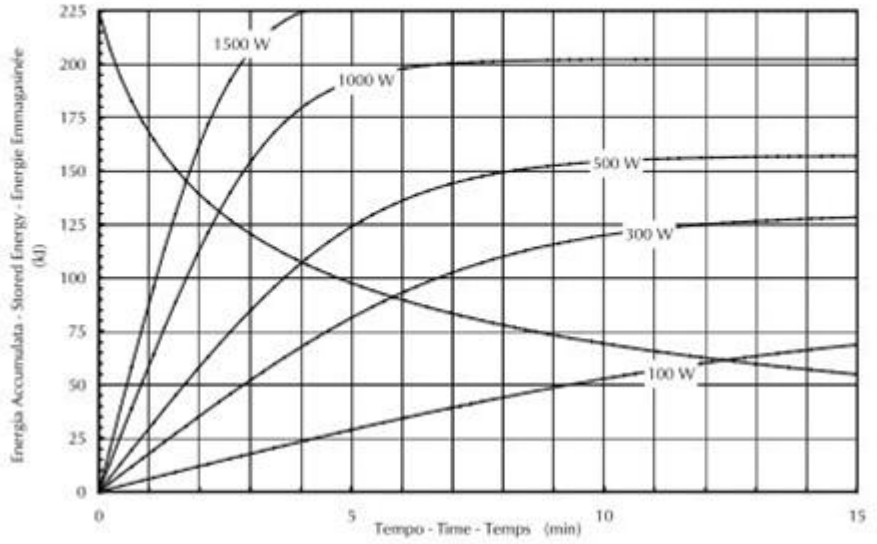
I dati forniti nella presente documentazione si intendono riferiti a:
The data indicated in this documentation refer to:
Les données indiquées dans cette documentation sont calculées pour:

Potenza anodica di equilibrio termico Equivalent anode input power Puissance anodique d'équilibre thermique	100 W =	% della capacità termica anodica % of maximum anode heat content % de chaleur max. accumulée dans l'anode	38%

Dimensioni - Dimension - Dimensions

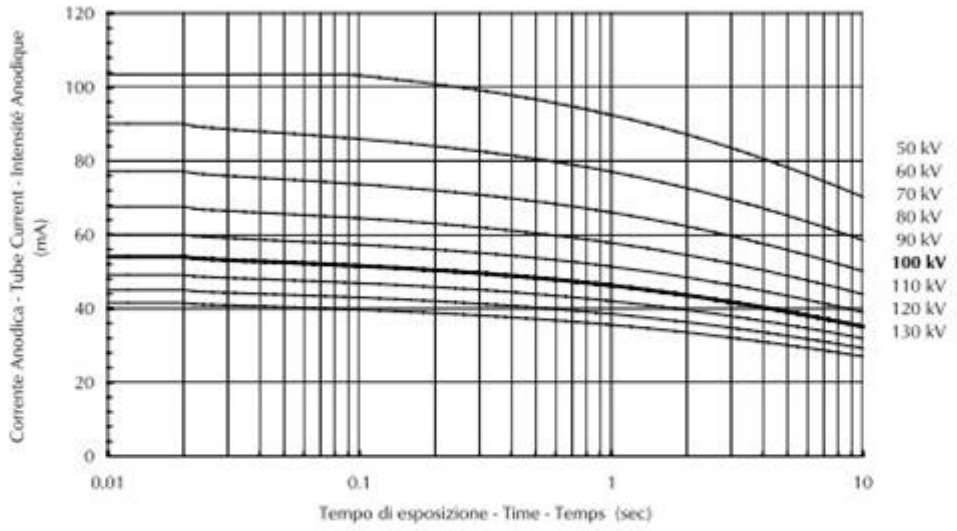


Curve di riscaldamento e raffreddamento dell'anodo
Anode heating and cooling curves
Courbes d'échauffement et de refroidissement de l'anode



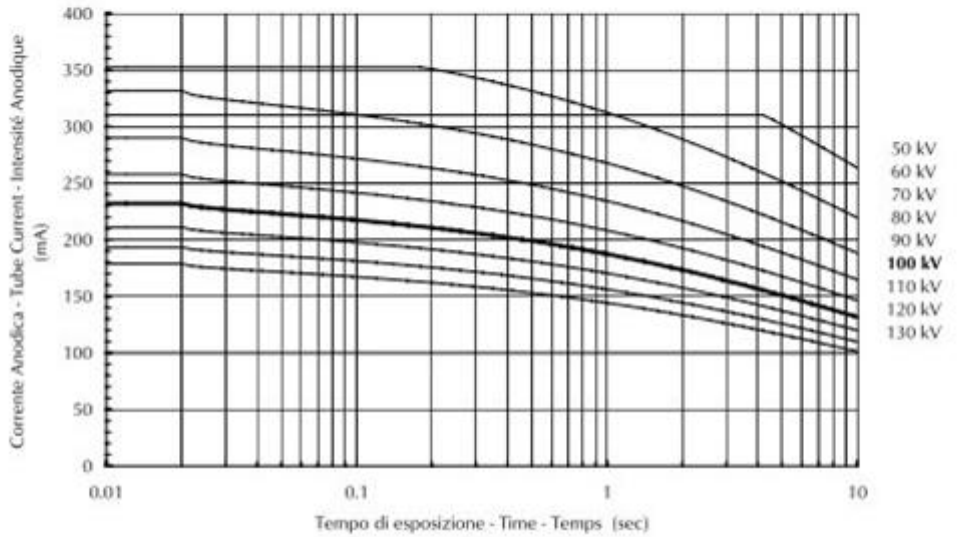
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



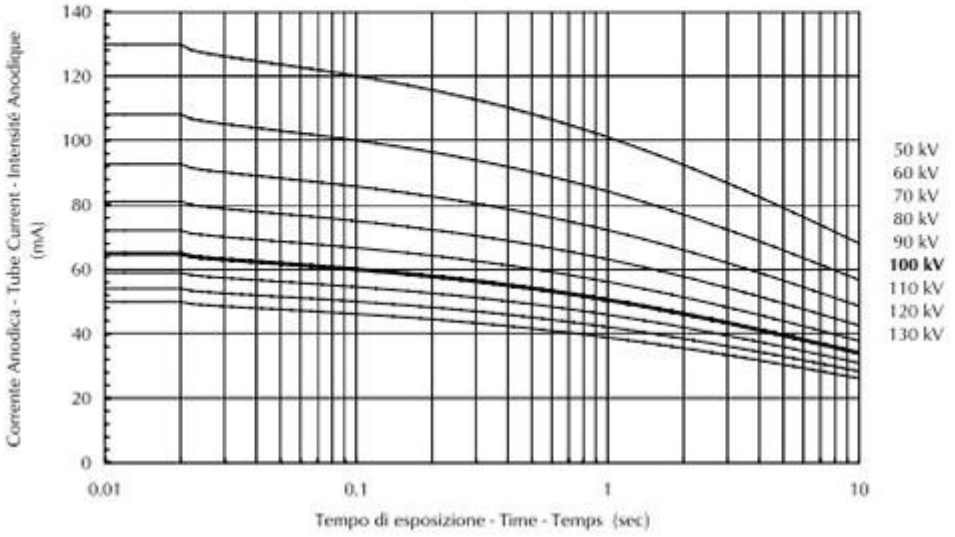
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



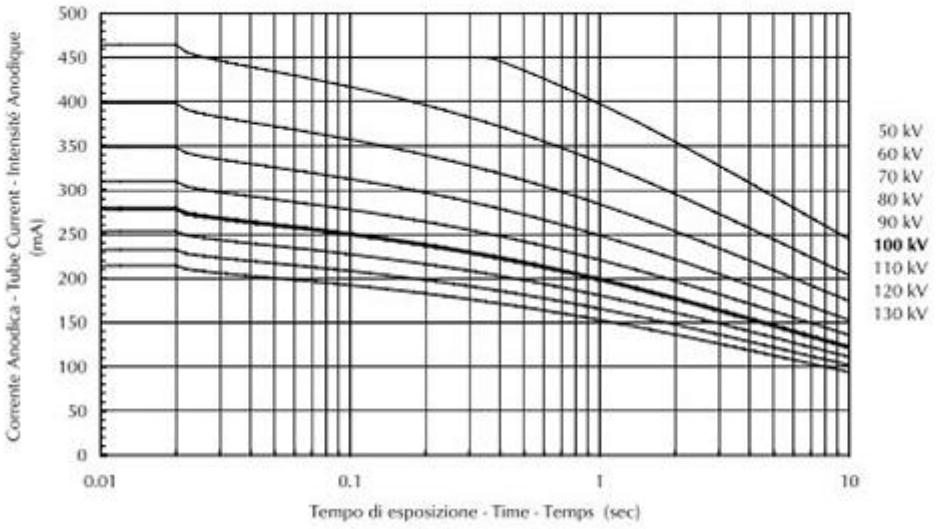
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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

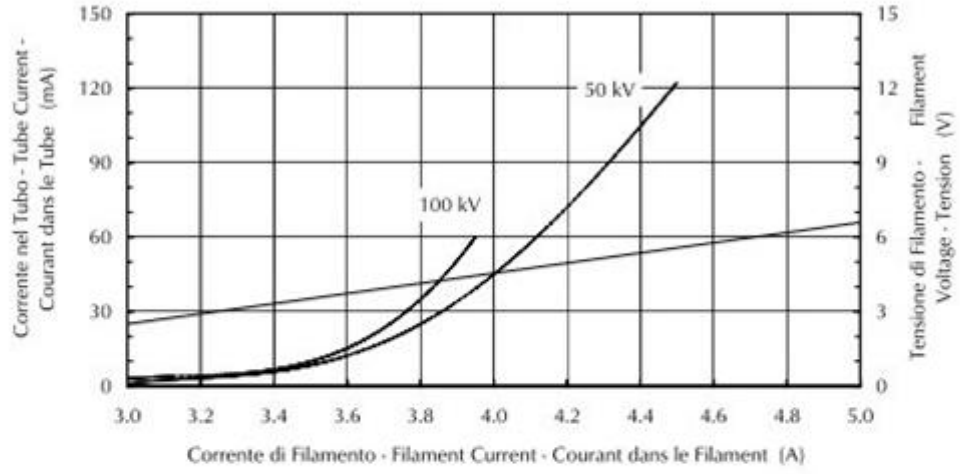


CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

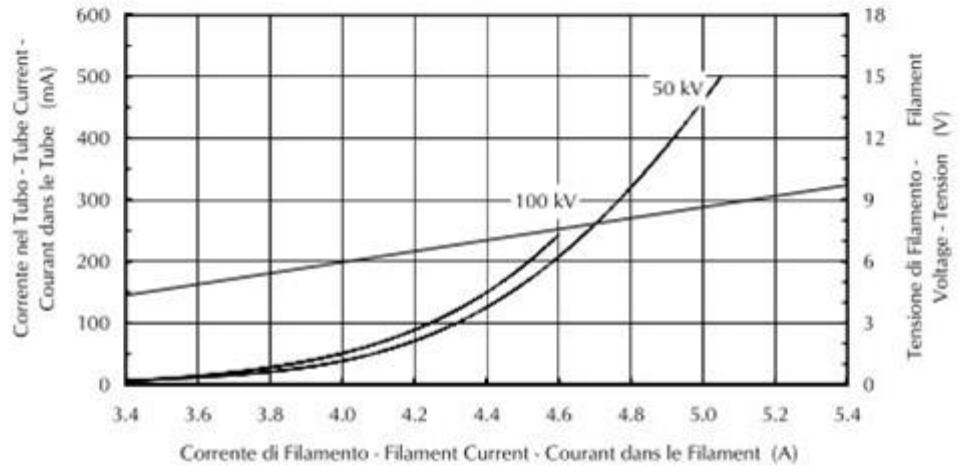
0.6 - 3 ~ - 3000 min^{-1}



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)



X-ray generator-tube-sheath assembly

Model	C31
X-ray tube	IAE RTM 70 HS 0.3/0.6
Source-detector distance	980 mm
Source-skin minimum distance	200 mm
Total filtration	21 mm Al @ 70kV (1 mm Al Inherent filtration)
Cone beam maximum dimension	301 mm x 301 mm (detector area)
Radiation reproducibility [4]	Δ < 10%
Voltage accuracy at the tube [5]	< 10%
Current accuracy at the tube [6]	< 20%
Radiation linearity [7]	< 20%
Emission time accuracy	< 10% + 1 ms
mAs accuracy[9]	< 10% + 0.2 mAs
Maximum continuous anode input power[10]	120 W

Stray radiation (uGy/mAs) according to IEC 60601-2-44 Par. 203.13.

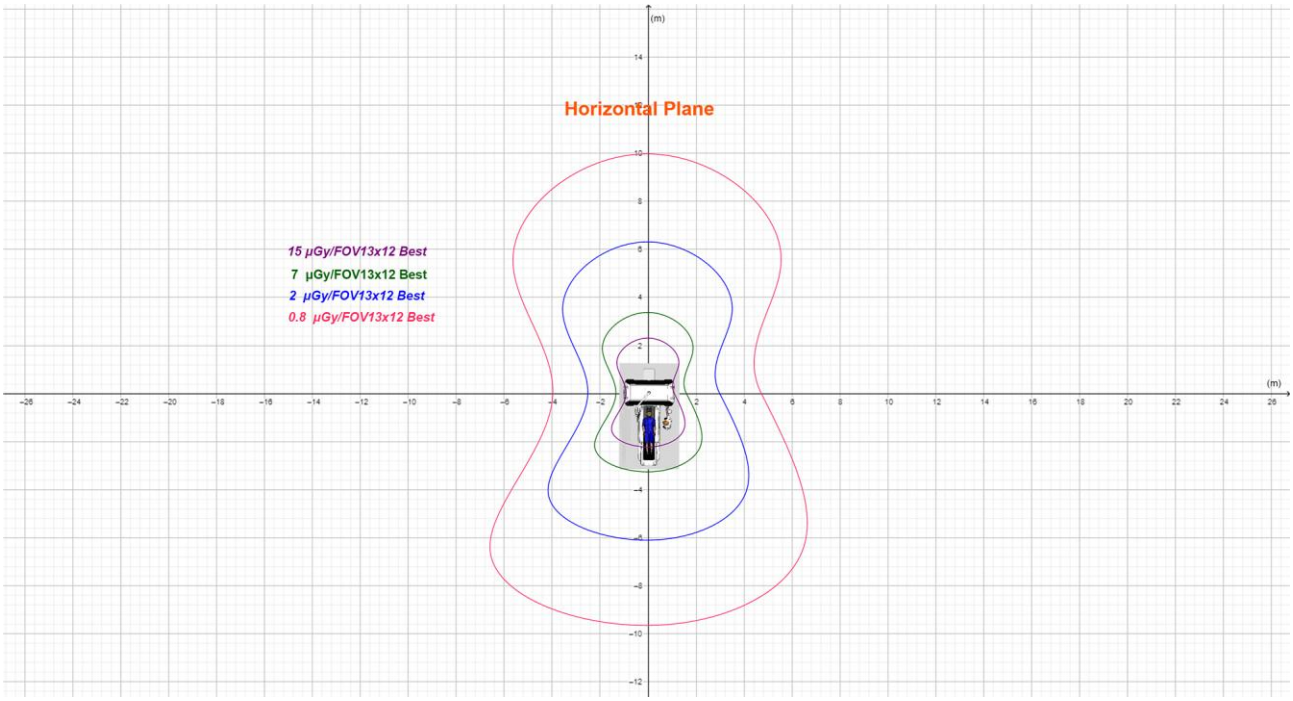
[4] According to IEC 60601-2-44:2009 + A1:2012 + A2:2016, par. 203.6.3.2
[5] According to IEC 60601-2-63:2012, par 203.6.4.3.102.2
[6] According to IEC 60601-2-63:2012, par 203.6.4.3.102.3
[7] According to IEC 60601-2-63:2012, par 203.6.3.1.101
[9] According to IEC 60601-2-63:2012, par 203.6.4.3.102.5
[10] 120kV 5mA 8ms FOV 17x17 REGULAR

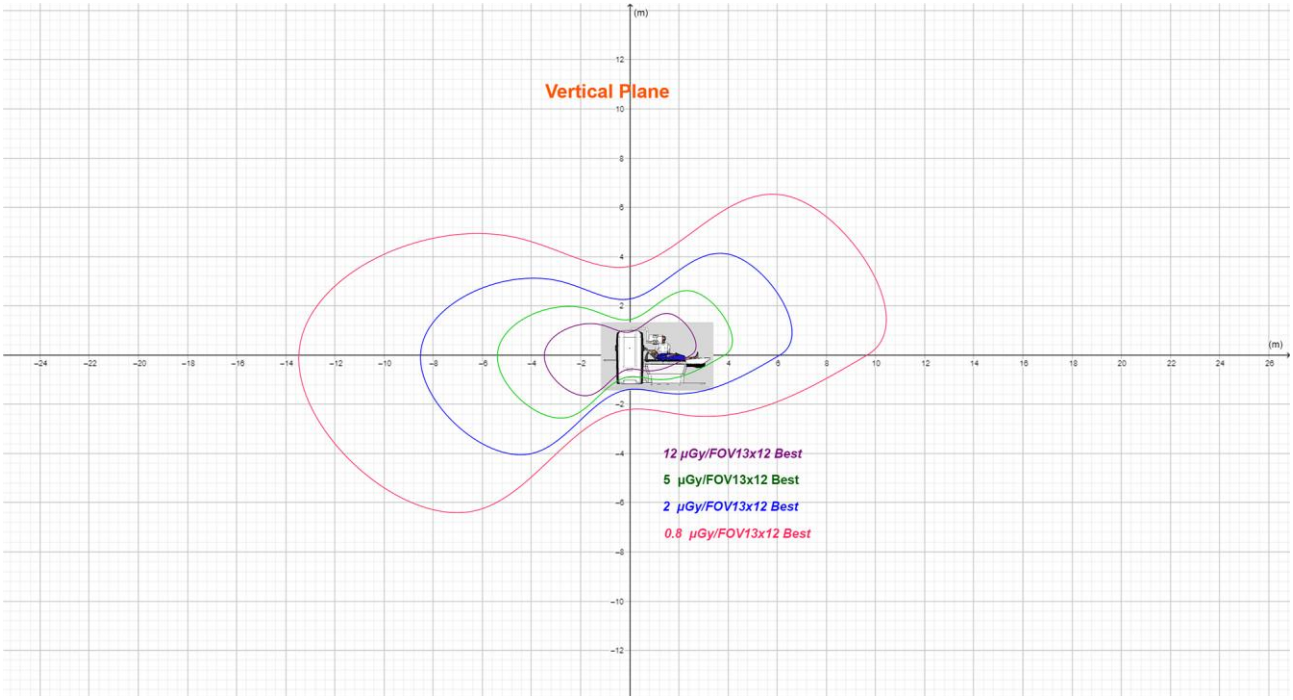
Dose declaration
Please refer to the attached document **"Dose declaration and acceptance test"**

Dispersed Radiation Map
Measured using "head phantom" according to IEC 60601-2-44 Par. 203.108.

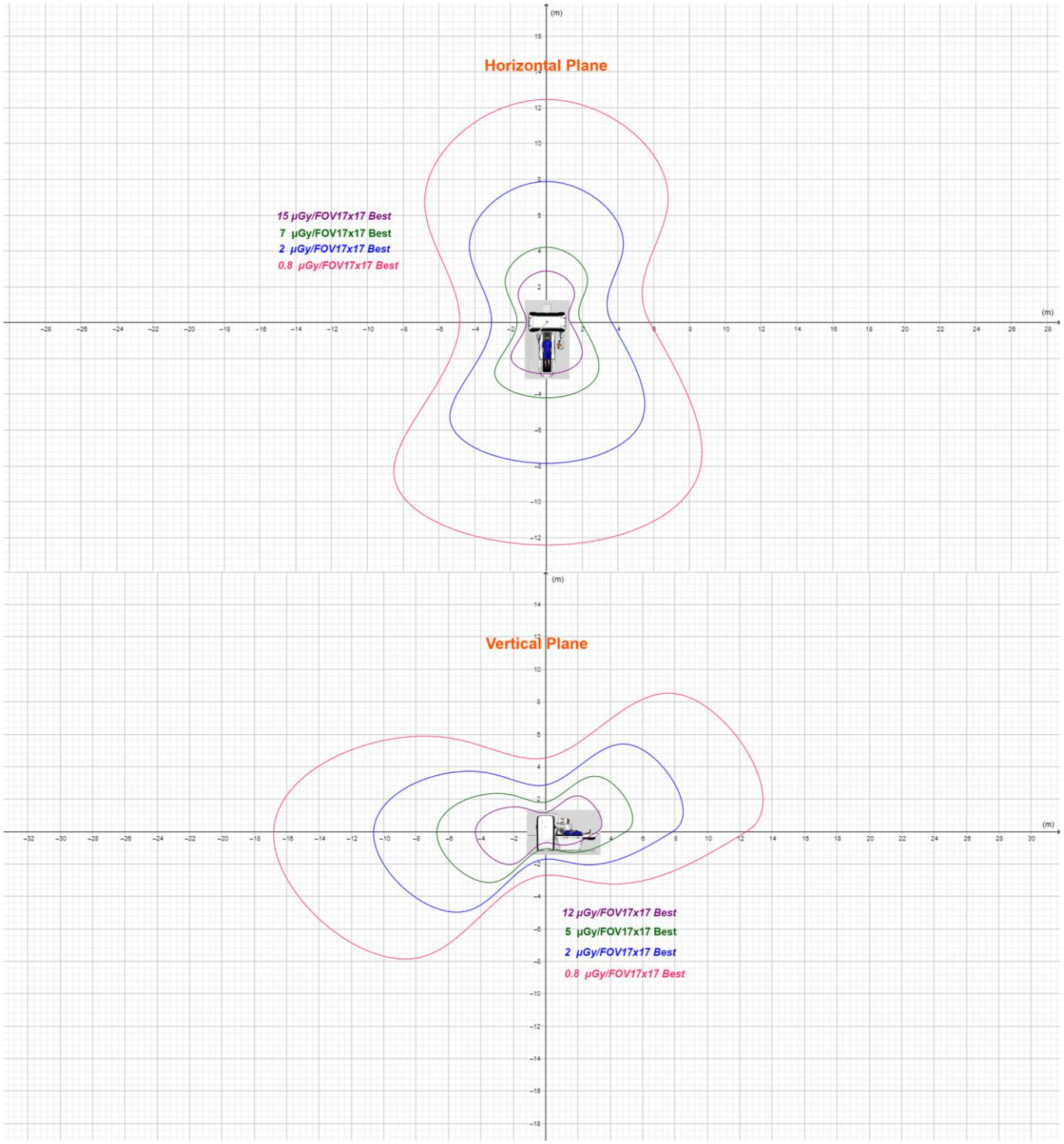
The following curves refer to examinations considered representative for all existing modes:

- FOV 13x12, 120kV, 40mA, 8.16s





- FOV 17x17, 120kV, 40mA, 8.16s



Laser

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

Type	Linear laser source
Output power	0.9 mW
Wave length	635 nm
Beam divergence	58º
Pulse length	Continuous wave
Classification	Class 1 (IEC 60825-1:2014)

Other information

Absorbed power	230 V ~ (± 10%) 50/60 Hz (± 1%) 16 A (during emission) 2 A (in stand-by mode)
Network impedance	≤ 0,5 Ω
Use temperature	+10 ÷ +35 °C
Use humidity	10% ÷ 85 % (non-condensing)
Use altitude:	≤ 3000m
Overvoltage category:	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 equipment present.

<table>
<tr><th>Clause</th><th colspan="2">Guidance and manufacturer's declaration - electromagnetic emissions - for all equipment and systems</th></tr>
<tr><th colspan="3">TABLE: Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><th colspan="3">The NewTom 7G device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom 7G device must ensure that it is used in such environment.</th></tr>
<tr><th>Emission test</th><th>Conformity</th><th>Electromagnetic environment - guide</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The NewTom 7G device uses RF energy only for its internal operation. Therefore, its RF emissions are very low and they probably do not interfere with the electronic devices nearby.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The NewTom 7G device is suitable to be used in all rooms, except the domestic ones, and places directly connected to a public low-voltage line that supplies buildings for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Clause	6.8.3.201 Technical Description - Tab 201 Guidance and manufacturer's declaration - electromagnetic emissions - for all equipment and systems

TABLE: Guidance and manufacturer's declaration - electromagnetic emissions

The NewTom 7G device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom 7G device must ensure that it 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 7G device user requires a continuous operation also in case of blackout, it is recommended to power the NewTom 7G 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 7G device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom 7G device must ensure that it 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) should not be used near the NewTom 7G, including cables, but should be located at the recommended distance calculated with the equation applicable to the transmitter frequency. Recommended distance: d = 1.2 * P d = 1.2 * P from 80 MHz to 800 MHz d = 2.3 * P from 800 MHz to 2.7 GHz where P is the maximum nominal output power of the transmitter in Watt (W) according to the transmitter manufacturer, and d is the recommended distance in meters (m). The field intensity of the fixed RH transmitters, determined based on an electromagnetic* analysis, could be lower than the conformity level in each frequency interval **. Interferences may occur near the devices marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	

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

*The field intensity for fixed transmitters like the base stations for radiophones (mobiles and cordless phones) and radio units, radio amateur devices, AM and FM radio 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 an NewTom 7G device is used exceeds the applicable conformity level mentioned above, the standard operation of the NewTom 7G should be analysed. If abnormal performance is noticed, it may be necessary to implement supplementary measures like a different orientation or position of the NewTom 7G.

**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 7G device is designed to operate in the electromagnetic environment with control of the RF irradiated disturbances. The customer or the operator of the NewTom 7G device could help in preventing electromagnetic interferences ensuring a minimum distance between the RF mobile and portable communication devices and the NewTom 7G 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 rated output power of the transmitter in Watt (W) according to the transmitter manufacturer. Notes: (3) At 80 MHz and 800MHz it is necessary to apply the distance defined for the highest frequency interval (1) These guidelines could not apply to all situations. The electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.			

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

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

WARNING:
The NewTom 7G must not be located directly on another device, and other devices must not be positioned directly on the NewTom 7G.
If this is not possible, observe the NewTom 7G device to check its correct operation in the stacked configuration in which 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 NewTom 7G, including cables specified by the Manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE:
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

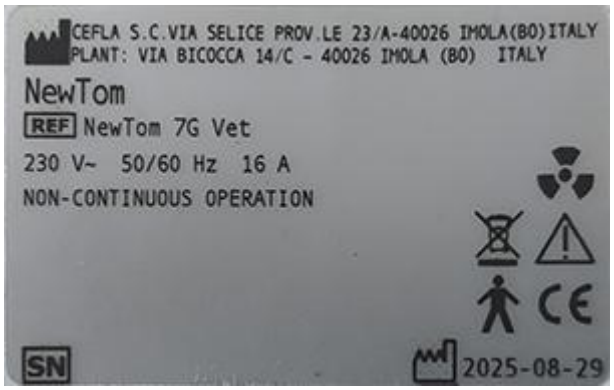
The NewTom 7G has been manufactured in compliance with the IEC standards relating to the safety of similar medical electrical equipment and in particular with the standards:

- IEC 60601-1-2:2014 (4th Ed.) - General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
- IEC 62366-1: 2015 + A1:2020 - Medical devices - Part 1: Application of usability engineering to medical devices.
- IEC 60601-1:2005 + Am1:2012 (ed. 3.1) + Dev CAN-US + Korea - General requirements for basic safety and essential performance.
- IEC 60601-1-3: 2008+ Am1:2013 - Particular requirements for basic safety and essential performance of dental extra-oral x-ray equipment.
- IEC 60601-1-6: 2010 + Am1:2013 / IEC 62366:2007 + Am1:2014 - General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices.
- IEC 60601-2-28:2017 (3rd Ed.) - Particular requirements for basic safety and essential performance of X-ray tube assemblies for medical diagnosis;
- IEC 62366-1: 2015 - Medical devices Part 1: Application of usability engineering to medical devices;
- IEC 60601-2-44:2009 + Am1:2012 + Am2:2016 - Particular requirements for the safety of X-ray equipment for computed tomography;
- IEC 60825-1:2014 - Safety of laser products - Part 1: Equipment classification, requirements and user's guide.
- IEC 60601-2-54:2009 + Am1:2015 + Am2:2018 - Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- AAMI/IEC 60601-1:2005 + AMD1:2012 - US NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements.
- CAN/CSA-C22.2 No. 60601-1:2014 - CA - CANADIAN NATIONAL DIFFERENCES to CAN/CSA-C22.2 No. 60601-1:2014.

IEC 60601-1 CLASSIFICATION	
Type of protection against electric shocks	CLASS I
Applied part classification	TYPE B
IP code (ingress protection)	IPX0
Use with anaesthetic mixtures	This equipment has not been evaluated for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide
Sterilisation and disinfection methods	The device is not subject to sterilization. (See chapter 3.5 “Cleaning and disinfecting”).
Use conditions	Non-continuous operation with intermittent load.
Operating cycle	**15 minutes for a complete operating cycle composed as follows:** Patient table - movements 16% (2.20 min / 15 min) Gantry - movements 14% (2 min / 15 min) X-ray operating 2.9% max 26 sec / 15 min
Intended service life	10 years, following the instructions for use

11. APPENDIX C: DEVICE LABELS

✓ **SCANNER PLATE**



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

✓ **PATIENT TABLE PLATE**

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

✓ **X-RAY WARNING AND DHHS LABEL**

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

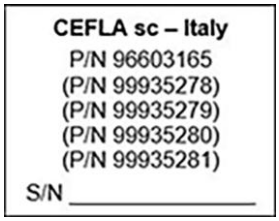
✓ **MAIN SWITCH AND INPUT FUSE LABEL**

Position: on rear plastic cover, LH side of the device, next to the main switch

✓ **LASER DEVICE INFORMATION LABEL**

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

✓ **BEAM LIMITER GLOBAL LABEL**



Position: On “EXTRA FOCAL SUPPORT” of collimator

✓ **BEAM LIMITER ADDITIONAL FILTRATION LABEL**

Position: On “COLLIMATOR FIXING METAL SHEET” of collimator

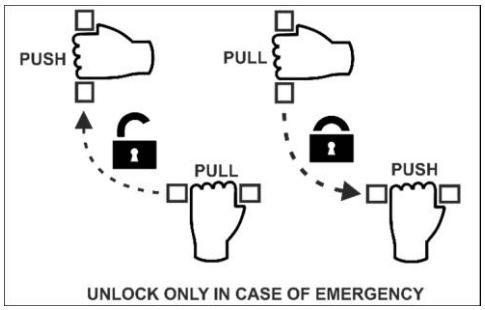
✓ **COVER ADDITIONAL FILTRATION LABEL**

Position: On the internal plastic cover of the scanner (CYLINDER 7G)

✓ **ETHERNET CONNECTOR INDICATION LABEL**

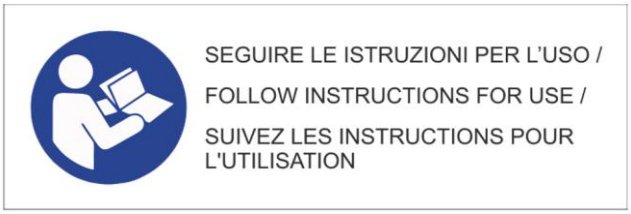
Position: Rear thermoformed cover, bottom LH side, above the Ethernet connectors

✓ **PATIENT TABLE HANDLE LOCKING / UNLOCKING LABEL**



Position: Patient table cover, near the locking / unlocking handle

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



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

✓ **LASER DEVICE WARNING LABEL**

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

✓ **HAND CRUSHING HAZARD LABEL**

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

✓ **MONITOR ARM MAX WEIGHT LABEL**

Position: Monitor support / rotation arm

NEWTOM
CONE BEAM 3D IMAGING
www.newtom.it

NEWTOMTM 7G Vet is manufactured by:

CEFLA s.c.
Headquarters
Via Selice Prov.le 23/A
40026 Imola (BO) Italy

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

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

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