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NEWTOM
CONE BEAM 3D IMAGING

NewTom VGi evo – USER MANUAL

EN

NOTES

This document is provided as a consultation manual intended for the device users.

CEFLA s.c. follows a policy based on the constant development and update of the product. For this reason, it reserves the right to change the content of this manual without prior notice.

The original version of this manual is in Italian.

INFORMATIVE NOTE OF THE MANUFACTURER ON THE MEDICAL DEVICES

The medical device referred to in this manual consists of a scanner and a control, display and calculation unit (Main Workstation). This device, as delivered and configured by the production and service technical staff, is a radiographic equipment compliant with the safety requirements outlined in Regulation (EU) 2017/745 on Medical Devices.

The medical device referred to in this manual is an X-ray device compliant with Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Any tampering with, modification, updating or other change both of hardware[1] and software[2] of the device as supplied and installed by the company (and in the conditions specified in the attached documentation) may partially or totally compromise the device expected operation. This may also alter the safety features with consequent hazard increase for patients, operators and surrounding environment.

For this reason, should the user need to modify the device, he/she must request a written authorisation by CEFLA s.c.

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

[1] *Adding of a new memory expansion, a new hardware on the connection bus, a printer, the replacement of the graphic display interface represents an important modification.*

[2] *Including the operative system and the applications already installed upon medical device delivery. Automatic updates of the operative system, changes to network connection parameters, modification and/or addition and/or removal of interface software with hardware (device driver) and/or services (e.g. file and printer sharing service) and/or applications represent an important modification.*

Contents

1. INTRODUCTION TO THE MANUAL

1.1. CONTENTS

This manual has been conceived as a consultation document to provide information and instructions on the use of the NewTom™ VG series device, “NewTom VGi evo” model.

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

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

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

1.2. STRUCTURE

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

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

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

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

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

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

Chapter 6 – “SCANNING”:
explains the process to position and scan a patient.

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

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

APPENDIX A: TECHNICAL SPECIFICATIONS

APPENDIX B: COMPATIBILITY

APPENDIX C: DEVICE LABELS

1.3. STYLISTIC CONVENTIONS

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

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

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

NOTE:
Provides further information not concerning the safety of the device, the patient and the operator.

2. SAFETY-RELATED INFORMATION

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

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

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

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

2.1. APPLICABLE LAWS, JURISDICTION AND COURT OF JURISDICTION

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

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

2.2. SYMBOLS ON THE DEVICE

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

Symbol	Standard	Description
	IEC 60417-5010	On / Off (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 60417-5841	Type B applied part protected against direct and indirect contacts.
	IEC 60878-5909	Ionising radiations.

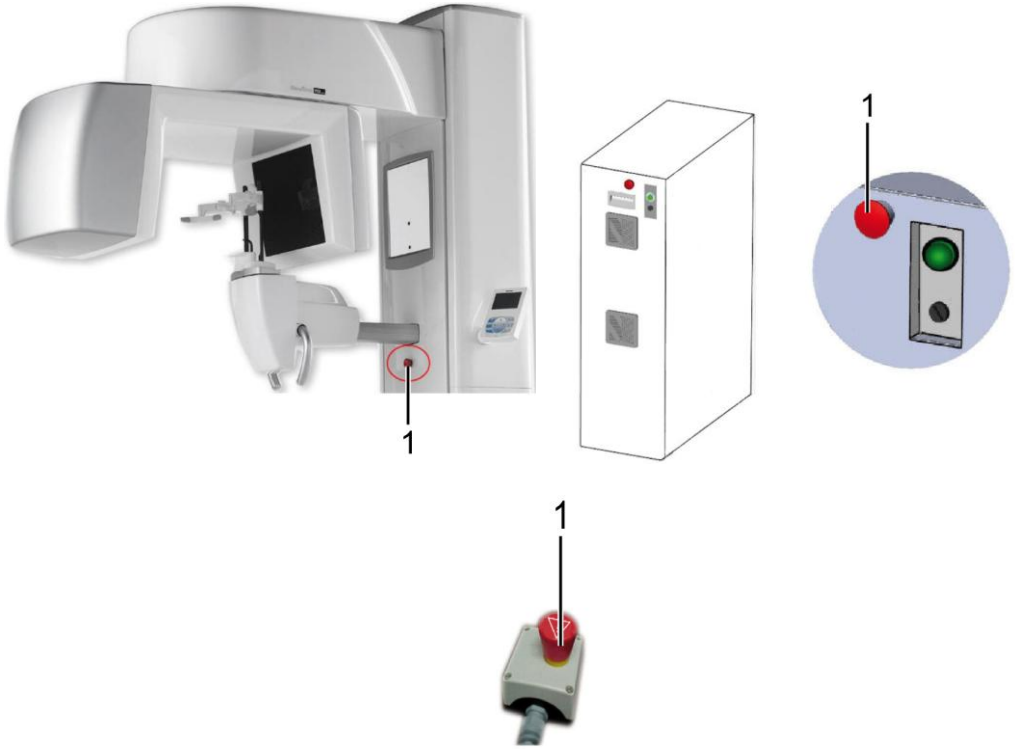
	Directive 2012/19/EU	Disposal of WEEE (Waste Electrical And Electronic Equipment)
CE 0051	(EU) Regulation 2017/745	CE marking.
SN	EN 980:2008	Serial number.
	EN 980:2008	Date of manufacture.
	EN 980:2008	Manufacturer.
	ISO 7000-1641	Operating instructions.
	ISO 7010-M002	Refer to the instruction manual.
	-	Mark of conformity with technical regulations of Ukraine.
	ISO 7000-3500	The operator's manual is provided in electronic format.
MD	ISO 15223-1	Medical device.
#	ISO 15223-1	Model number.
UDI	ISO 15223-1	Unique device identifier.
	IEC 60417-5638	Emergency stop.
	Original symbol required by IEC 60601-1 par. 9	Head collision hazard. In order to avoid any collision, please refer to the Par. 6.1.2 - "Positioning the Patient and Starting the Scanning" for the correct positioning of the patient.

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 provided with 3 emergency switch-off buttons. One is located on the front panel, near the motor-driven chinrest system, the second one near the main switch on the control box and the third one on the operator table.



1- Device emergency buttons.

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

WARNING:

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

- The X-ray source does not stop the emission.
- Situations that can injure people, harm the environment or damage the device.
- Conditions where the device indicates an emergency situation.

2.5. SAFETY OF PATIENT AND OPERATOR

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

2.5.1. PATIENT POSITIONING

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

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

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

Refer to par. 6.1.3 - "Positioning the patient and starting the scanning" and to the attached document **"General guidelines for use of the protocols of New Tom VGi evo".**

2.5.2. DURING THE SCANNING

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

Always keep the patient monitored for the entire scanning duration.

WARNING:
NEVER use the device without the operator supervision.

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

2.5.3. PATIENT GOING OUT OF THE SCANNING AREA

At the end of the examination or after the emergency button has been pressed, it is possible to allow the patient to leave the scanning area without waiting for the rotary arm to return to the initial position.

2.6. ARTEFACTS AND SCANNING REPETITION

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

2.7. PROTECTION AGAINST IONIZING RADIATIONS

WARNING:
NewTom VGi evo is an X-ray device and as such it exposes patients and operators to the risk deriving from ionizing 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 VGi evo 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 "Stray Radiation Map" to determine the minimum distance to maintain during X-ray emission.
In case of the operator needs to remain in the room during the examination (e.g. in case of a patient panic reaction), shall wear suitable lead protection clothes and equipment as defined by the national and local standard[1].

Patient

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

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

WARNING:
When prescribing X-ray examinations to pregnant women or women that could be pregnant, carefully consider the possible radiation consequences on the fetus. When possible, avoid radiation to a fetus.

WARNING:
Consider the possibility to use a leaded apron with collar for thyroid to protect the patient from diffuse radiation.

WARNING:
Possible negative interaction of CT x-rays with implantable active and worn active medical 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

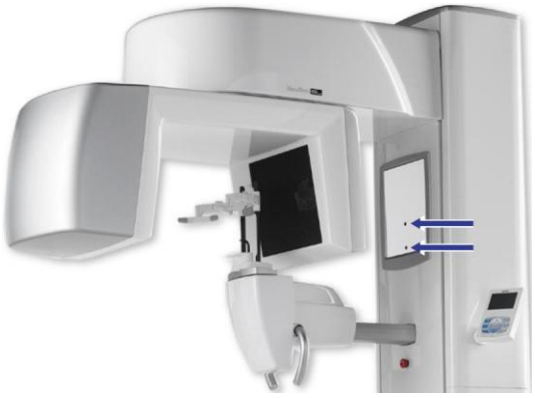
The emission status is clearly identified by:

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. A signal on operator console as shown below. Such signal is displayed on the operator console 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 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 provided with a double laser to correctly position the patient. The laser radiation comes out of two holes on the front cover.

The vertical line indicates the central sagittal plane of the reconstituted volume. The horizontal line indicates the central axial plane of the reconstituted volume.

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

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

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

2.9. DEVICES CONNECTED TO THE CONTROL CONSOLE

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

For further information contact the Manufacturer.

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

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

2.10.MAINTENANCE INTERVAL

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

2.11.APPLIED PARTS

The parts of the equipment that, during standard use, necessarily come into contact with the patient, so that the device may carry out its functions correctly, are: chinrest, bite and hygienic covers, headrest, handles, nose support.

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

3. DEVICE SAFETY AND MAINTENANCE

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

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

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

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

3.1. INSTALLATION REQUIREMENTS

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

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

Operating temperature:	from +10° to +35° (Celsius)
Operating humidity conditions:	min 10%, max 85% (non-condensing)
Altitude:	≤ 3000 m
Pressure:	710 – 1060 hPa
Pollution degree:	2
CTI ("comparative tracking index"):	IIIb

Minimum dimension requirements of the installation room: 2 x 2.5 x 2.5 m.
The equipment must be installed on a horizontal surface.
In case of use with seated patient, make sure that the chair backrest is not higher than 75 cm.

The supply line must be arranged according to the prevailing laws and to the instructions provided in the "Service Manual".

Do not use temporary electric connections like reduction units, extensions, multiple sockets for the connection to the PC network or to other peripheral devices.

The equipment must be connected to the electric system in a permanent way according to the prescriptions provided in the "Service Manual".

The medical environment in which the device is installed must be designed by an expert in ionizing radiation protection as set forth by the prevailing national and local laws. The prevailing national and local laws will define the rules to be followed to design the signals to be applied to the system.

WARNING:
Never move the device after the installation. Moving the device may damage property and be harmful to people and the environment.
The device must be connected exclusively with peripheral units, computers and cables compliant with the manufacturer's specifications.

WARNING:
Make sure the device is connected to an electric line with protective earth.

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

3.2. SAFETY GUIDELINES

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

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

- **Electrostatic discharges**

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

- **Fire-extinguishers**

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

- **X-ray warning lamp**

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

- **Switches on doors**

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

- **Electromagnetic compatibility**

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

3.3. CYBERSECURITY INFORMATION

Medical devices capable of connecting (eg. Ethernet port) to another device are vulnerable to cybersecurity.
The intended use of the device (generation of radiologic two-dimensional and three-dimensional images) limits for its nature the intended use environment (health care facility, medical facility, hospital, etc.) and the intended users (health care worker, 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 patient, the operator and the device.

3.4.1. LIMITS OF RESPONSIBILITY

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

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

3.5. DEVICE MAINTENANCE

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

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

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

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

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

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

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

WARNING:
If NewTom VGi evo 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).

- **Hazardous cleaning agents**
  Some cleaning agents should be avoided to prevent negative consequences on the device and people (see "3.5. Cleaning and disinfecting").

- **Preventive maintenance**

Check the computer-scanner interface cables, the control computer-box and the relevant power supply cables at regular intervals. Check the connection cable to the computer, the monitor, the keyboard, the mouse and the printer according to the manufacturer instructions.

- **Component storage**
  Components must be stored and handled with care.
  Any provided components must be stored and handled in compliance with the relevant technical specifications.

- **Malfunctions**
  In case the device does not work as described in this manual, contact the technical service immediately.

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

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

Manager	Component	Activity	Time interval
Routing testing			
User	Global device	QA Phantom check	Weekly
Local Support Service	Error log	Check	12 months
	Every external part	Damage check	12 months
	Emergency buttons	Emergency test	12 months
	Electrical functioning	Check	12 months
	Mechanical functioning	Check	12 months
Other test depending on local regulations			
Radioprotection expert or other qualified person depending on local regulations	Global device	Radiological test conforming to the local regulation concerning X-ray medical electrical equipment. This tests in not in charge by user or local support service but may be established by local regulations.	Radiological test conforming to the local standard

3.6. CLEANING AND DISINFECTION

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

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

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

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

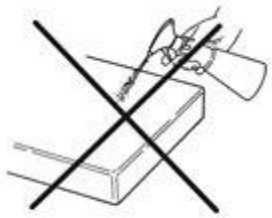
The various drugs and chemical products used in dental surgeries may damage the painted surfaces and the plastic parts. Researches and tests performed show that the surfaces cannot be fully protected against the harsh action of all products available on the market. We therefore recommend protecting with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

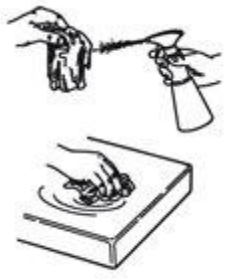
The harsh actions of chemical products also depend on the amount of time they are left on the surfaces. It is therefore important not to leave the product on the surfaces longer than the time specified by the manufacturer.
We recommend to use a specially formulated medium-level disinfectant, STER 1 PLUS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

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

WARNING:

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





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

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

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

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

3.6.1. HYGIENE PROCEDURES FOR PATIENT PROTECTION

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

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

Always replace bite disposable hygienic protections before positioning a new patient.

Disposable hygienic protections must be stored in a dry and clean area and must not be exposed to direct sunlight or UV radiation.
Bite and chin rest can be disinfected by soaking them in a cold sterilising liquid. For sterilisation of such parts, follow the instructions provided by the sterilising product supplier.
Cover with disposable protections all components that will be in contact with dental personnel's hands and might be contaminated by indirect contact with the mouth of the patient. In particular, pay attention while handling equipment control console, mouse and Personal Computer keyboard.

Before positioning the patient for a radiological examination, always cover the bite with a new (non-sterile) plastic protection in order to prevent cross contamination.

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

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

3.6.2. STERILISATION

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

3.7. TRANSPORT AND STORAGE

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

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

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

Pressure:
710 – 1060 hPa

Do not expose to acids, salts, rain.

3.8. DEVICE DISPOSAL

3.8.1. INFORMATION FOR DEVICE OWNER

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

The separate collection of this equipment is organised and managed by the manufacturer. When it is necessary to dispose of this equipment, contact the manufacturer and follow the device 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.

4. STARTING PROCEDURES

This chapter provides an introduction to the NewTom VGi evo 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 VGi evo 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 VGi evo 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, lower and upper jaw, temporomandibular joint (TMJ), other areas of the human cranium and neck with sections of the cervical rachis for diagnostic use.
The device carries out such operations reconstructing a 3D matrix of the examined volume and producing two-dimensional views of the volume (tomographic sections, panoramic and cephalometric projections) and then displays two- or three-dimensional images.
The device is managed and used by doctors, dentists, radiologists and other legally qualified professionals.

Its use is intended on the whole patient population for which radiodiagnostic analyses are usually carried out, according to intended use, instructions for use, medical practice and local regulations.

It can also be used for X-ray analyses on implants, surgical templates and other diagnosis auxiliary tools.

Its use is intended in emergency situations, like first aid situations, only if a non-operation does not pose a hazard for the patient (e.g. if the centre is equipped with other equivalent equipment or a department of radiology).

ONLY FOR CANADIAN MARKET
The NewTom VGi evo 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, lower and upper jaw, temporomandibular joint (TMJ), other areas of the human cranium and neck with sections of the cervical rachis for diagnostic use.
The device carries out such operations reconstructing a 3D matrix of the examined volume and producing two-dimensional views of the volume (tomographic sections, panoramic and cephalometric projections) and then displays two- or three-dimensional images.
The device is managed and used by doctors, dentists, radiologists and other legally qualified professionals.

Its use is intended on the whole patient population for which radiodiagnostic analyses are usually carried out, according to intended use, instructions for use, medical practice and local regulations.

It can also be used for X-ray analyses on implants, surgical templates and other diagnosis auxiliary tools.

Its use is intended in emergency situations, like first aid situations, only if a non-operation does not pose a hazard for the patient (e.g. if the centre is equipped with other equivalent equipment or a department of radiology).

WARNING:
It is recommended to use this device with patients more than 21 kg (46 lb) in weight and more than 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old child.
The studies showed that paediatric patients can be more radiosensitive than adults (for example, the risk of cancer per unit of ionizing radiation dose is higher), therefore, it is necessary to pay special attention to the unnecessary exposure to radiation of paediatric patients.

WARNING:
In particular for paediatric use, it is recommended to consult the general indications described in the existing guidelines for children imaging, e.g. those available in Image Gently (www.imagegently.org) website or in FDA website for "Pediatric X-ray imaging".

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

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

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

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

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

4.1.3. IMPROPER USE

The NewTom VGi evo device has not been designed for the following uses and/or applications (reasonably foreseeable improper use):

- use with patients that cannot stand still during the entire scanning cycle (30 seconds max.);
- use in anatomic regions that are not within the scope of the device intended use (e.g., chest and abdomen);
- use for studying cerebral soft tissues;
- use by staff that have not received training on the device;
- use by staff that do not meet the requirements specified in the user profile;
- use in the operating theatre;
- use with removable metal objects (eye glasses, jewels, rings, necklaces) in the scanning field;
- use in environmental conditions other than the indicated ones.

4.1.4. FUNCTIONING

The patient is approached to the chinrest structure and positioned correctly with 2 laser and "scout-view" image modules.

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

The result of such operation will be the sequence of axial slices that form the reconstituted volume.
At the end of this process, the slices will form the Volumetric Data. These data allow viewing coronal and sagittal sections of the area reconstructed 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 tridimensional 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 device (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 other words, the data acquired at each scanning step are the digital images corresponding to the relevant radiographic projection, and all collected data (also called "raw data") are then used in the volumetric reconstruction process.

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

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

4.3. OVERVIEW

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

The main workstation can be provided with other computers to process and store data.

For further information, refer to the “NNT User Manual”.

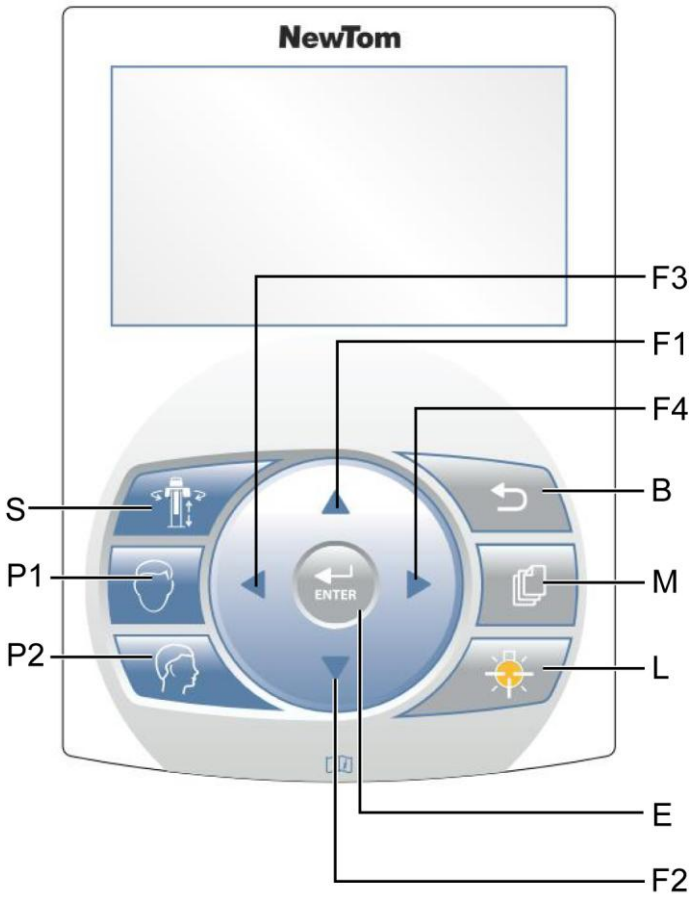
1. Scanner
2. Control box
3. Workstation

4.4. SCANNER

4.4.1. OPERATOR CONSOLE AND CONTROLS

The scanner represents the device central unit.
On the lateral supports (on the right or left side, as required) there is the operator console that allows moving the device and turning on the warning lamp that indicates the device switching on and the X-ray emission in progress.

Following is a short description of each button on the device remote control:



S Scanner movement selection button:
it enables the button operation for the vertical movement and the arm rotation of the scanner.

P1 Chinrest x-y movement selection button:
it enables the button operation for the chinrest device horizontal movement (right / left) and the vertical movement (up / down).

P2 Chinrest transversal movement selection button:
it enables the button operation for the chinrest device transversal movement (depth).

L Laser button:
to be pressed to switch on/off the positioning laser. After 60 seconds the laser switches off automatically.

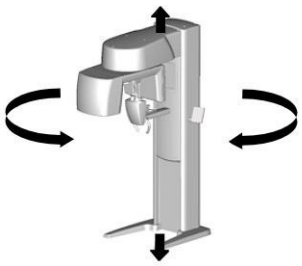
M Menu selection button:
it allows entering the information or service menu.

E Confirmation button:
it allows confirming the items selected in the menus.

B Back button
it allows cancelling the confirmation of the items selected in the menus

F1/ F2/ F3/ F4 Movement buttons:
they allow moving the previously selected device in the desired direction (through buttons S, P1 or P2).
They allow scrolling through the menu items.

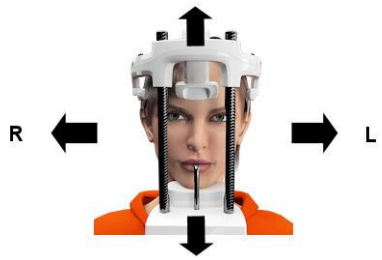
4.4.2. SCANNER MOVEMENT



After pressing the **S button (Scanner movement selection button)** the console screen will display the scanner image.

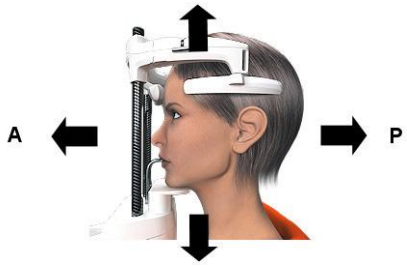
Press the **F1 / F2** arrows to move the unit up/down or **F3 / F4** arrows to rotate the arm clockwise or counter-clockwise.

4.4.3. CHINREST DEVICE MOVEMENT



After pressing the **P1 button (Chinrest x-y movement selection button)** the console screen will show the front view of a patient positioned on the chinrest device.

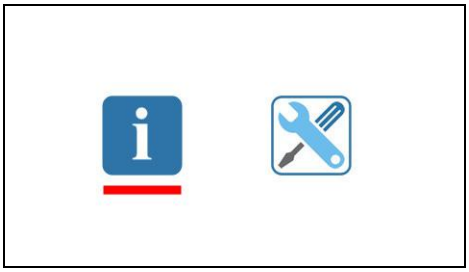
Press the **F1 / F2** arrows to move the chinrest device up/down or **F3 / F4** arrow to move the device to the right/left.

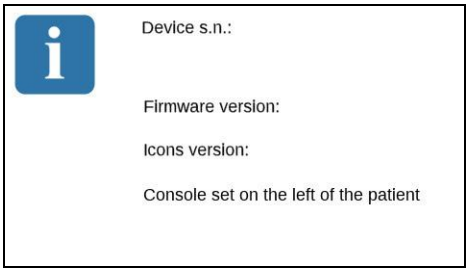


After pressing the **P2 button (Chinrest transversal movement selection button)** the console screen will show the lateral view of a patient positioned on the chinrest device.

Press the **F1 / F2** arrows to move the chinrest device up/down or **F3 / F4** arrow to move the device transversally.

4.4.4. INFORMATION MENU





After pressing the **M button (Menu selection button)** the console screen will show the selection image of the information or service menu.

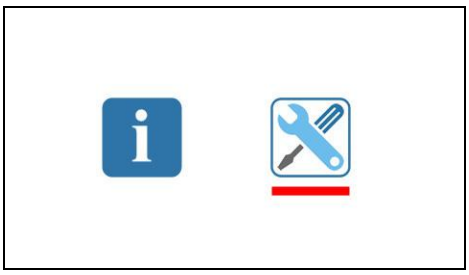
By pressing the **F3 / F4** arrows it is possible to position the selection red cursor under the information menu (marked by letter “i”) and confirm with button **E (Confirmation button).**

The following information will be shown:

- Device serial number
- Console firmware version
- Console icon version
- Console position with respect to the patient

To quit the menu, press button **B (Back button).**

4.4.5. SERVICE MENU



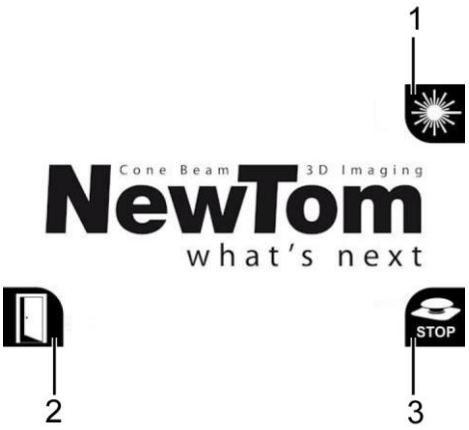
After pressing the **M button (Menu selection button)** the console screen will show the selection image of the information or service menu.

By pressing the **F3 / F4** arrows it is possible to position the selection red cursor under the service menu (marked by a spanner) and confirm with button **E (Confirmation button).**

For further information on the service menu functions, refer to the "Service Manual".

4.4.6. OTHER FUNCTIONS

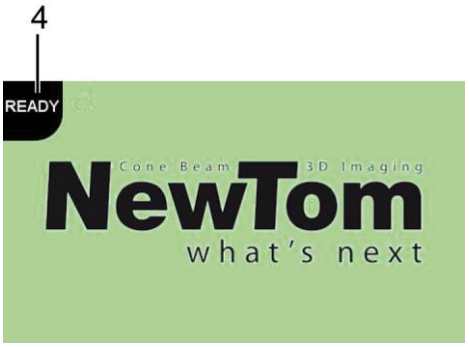
According to the button pressed or the occurred events, the following icons will be displayed on the console screen:



1) **Laser activation icon**
   By pressing the L button (laser button), the device laser rays are activated and the relevant icon is displayed on the upper right corner of the screen.
   By pressing the button again, the laser rays are deactivated and the icon will disappear from the screen.

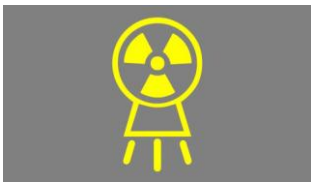
2) **Emergency stop button activation icon**
   By pressing any device emergency button (both on-board the machine or separated from the machine), the relevant icon will appear on the lower right corner of the screen and the device functions will be disabled.
   By releasing the emergency button, the device functions will be available again and the emergency icon will disappear from the screen.

3) **"Open door" warning icon**
   If the "open door" warning function is available, in case of door open, the relevant icon will be displayed on the lower left corner of the screen.



4) **"X-ray ready" icon**
   When the device is "ready" to emit X-rays, the relevant icon will be displayed on the upper left corner of the screen.
   Moreover, the console screens will change colour, from white to green.

4.4.7. X-RAY EMISSION

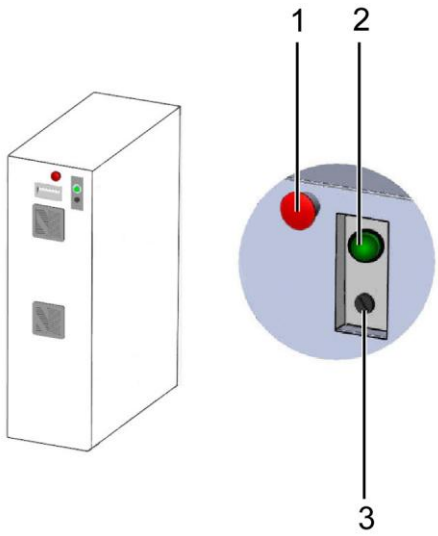


During the scanning process (when the device emits X-rays), the screen will show a page with a grey background and a yellow emission symbol.
At the end of the emission, this page will automatically disappear.

4.5. CONTROL BOX

4.5.1. MAIN SWITCH

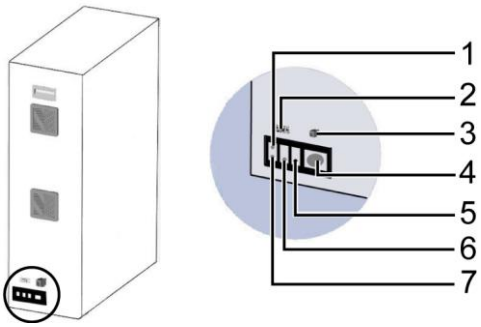
The control box contains the electronic instruments that manage the device operation.
On the outer surface there is the switch that allows switching on/off the device, and the relevant fuse holder is located near the switch.



1 Emergency switch-off
2 Device main switch
3 Input fuse holder

4.5.2. INPUT PANEL

On the main switch opposite side there is the panel with the equipment supply and control cables and the connectors for the connection to the main workstation through CAN Bus as well as for the connection of the X-ray emission button.



1 Optional output for the door switch
2 CAN bus connector for workstation
3 X-ray emission button connector
4 Outlet of control box - scanner connection cables
5 External power supply input
6 Optional output for external lamp
7 Output for table emergency button.

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.

Craniostat:
Fixed to the scanner mechanical structure, it allows the correct positioning of the patient and avoids excessive movements of the patient during the examination.

Chinrest:
Used to position the patient's chin.
It is inserted in the craniostat.

Undernose support
Used to position the patient's nose.
It is inserted in the craniostat.

Bite
Used to stabilise the patient's mouth (bite).
It is inserted in the craniostat.

Calibration support:
Used as bearing surface for the Phantom QA examination.
It is used as an alternative of the craniostat.

Prosthesis support:
It is used as a bearing surface for dental prosthesis on the scanning unit.
It is inserted in the craniostat.

Phantom QA:
Used to perform the quality control procedure.
Used with the Calibration support.

4.6.1. X-RAY EMISSION REMOTE CONTROL

The device is provided with a remote control to enable the X-ray emission, in compliance with the IEC60601-2-63 standard requirements.
For its use, refer to the safety standards set forth by the radiological protection standards in force in the country of use.

The remote control features:

1 A button to confirm the X-ray emission

2. Two luminous LEDs:
   Green (machine ready for the emission)
   Yellow (X-ray emission in progress)

When the device switches to the "Ready" status, it is possible to enable the X-ray emission (green LED steady-on) by pressing the remote control button and keeping it pressed for the entire duration of the X-ray emission.

When the device requires a specific button to be pressed to enable the X-ray emission, an intermittent sound will be activated

The examination is in progress when the yellow LED is activated on the remote control and at the same time a continuous acoustic signal is activated.

Button pressed

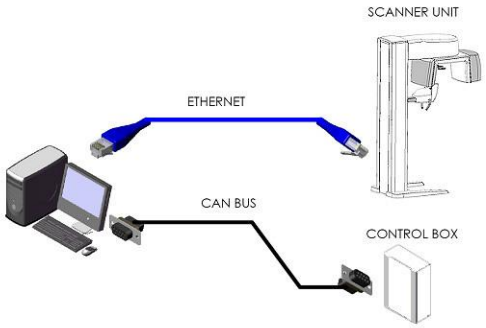
Button released

WARNING:
If the button is released before the examination is completed, the image acquisition will be interrupted.

In compliance with the local laws, the operator must be provided with suitable protection equipment and protected against ionizing radiations during the emission. For further details, refer to the notes provided in Chap. 2.

4.7. CABLES

The device is provided with cables for the connection of workstation/scanner and workstation/control box. I.e.:



- Ethernet cable (4 pairs/26 AWG-FTP-Category 6) (Workstation / Scanner)
- CAN bus cable (2 pairs/24 AWG shielded) (Workstation / Control box)

In addition, there is a cable branch for the control of the scanner at the control box outlet.
The manufacturer provides the supply cable with an end directly connected to the device. The user shall connect the device to the electrical mains during the installation.

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

4.8. SWITCHING ON THE DEVICE

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

1. Switch on the scanner through the main switch located on the control box input panel.
2. Switch on the workstation.
3. Wait for the workstation to load the operative system.
4. Log in the operative system with username and password.
5. Launch the NNT application.

NOTE:
First switch on the device. If you try to use the application before the device has been initialised, the connection will be denied.

4.9. 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

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

This chapter describes the required and/or useful functions:

- Beam limiter test
- Rotary arm complete lowering

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

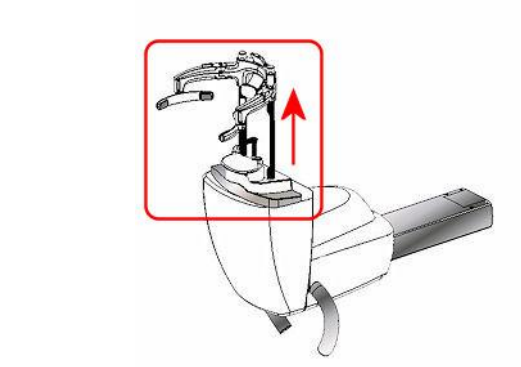
The operation modes are described in the specific chapter in the "NNT User Manual".

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

5.1. DAILY CHECK

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

NNT starting page with request of Daily check.



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

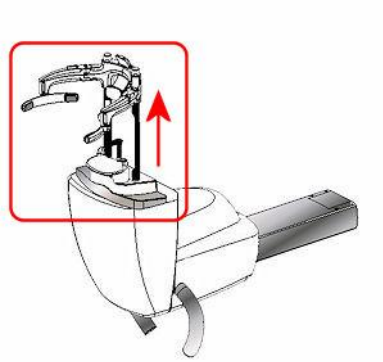
To this end, remove the chinrest structure.

Daily check in progress.

5.2. BLANK ACQUISITION

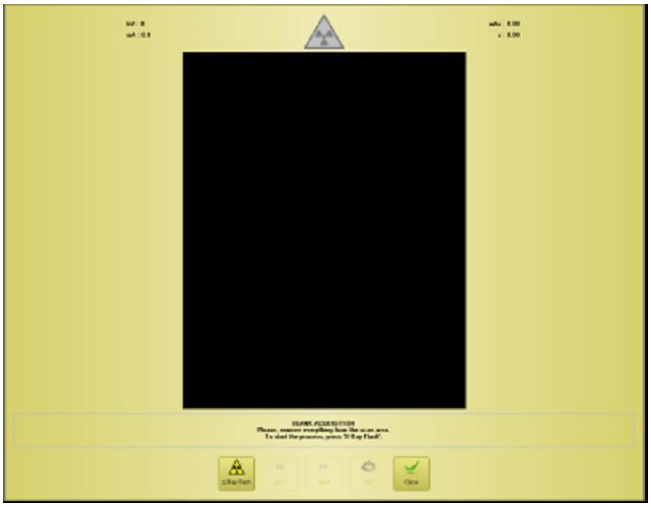
The Blank Acquisition allows optimising the scanning performance through the acquisition of a background image.

This procedure is automatically performed by the software whenever necessary.



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

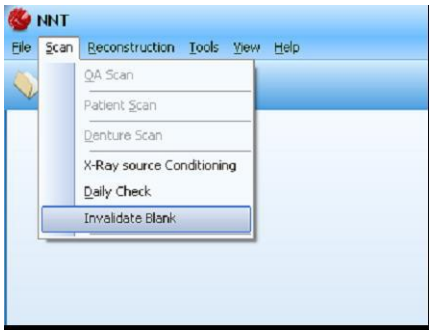
For this purpose, if not previously carried out, remove the chinrest structure.



The blank acquisition image will be as shown in the figure. It is extremely important to ensure that the image does not contain any unusual objects/shadows/marks.

5.2.1. BLANK ACQUISITION INVALIDATION

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



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

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

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

5.3. BEAM LIMITER TEST

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

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

Set the appropriate radiological parameters according to the selected FOV (standard: SFS, 1 mA, 10 msec, KV = 110; HiRes standard: SFS, 6 mA, 10 msec, KV = 110).

Start an acquisition.

Check that the beam is limited within the indicated margins:

- The green rectangle must be completely inside the acquired grey area.
- The grey rectangle sides must pass through the drawn red line pairs.

WARNING:
If the grey image acquired is not correctly collimated within the red lines, please contact our Technical Support.

5.4. LOWERING THE ROTATING ARM COMPLETELY

This function is useful to fully lower the rotary arm. For instance, in case of mobile application, during the transport it is recommended to position the arm completely lowered.

WARNING:
Before using this function make sure that nothing obstacles the arm downward movement!

To lower the rotary arm, follow the instruction below:

1. From the main bar of the NNT software, select "**Tools**" ⟶ "**Scanner Test**".
2. From the service window bar select "**Tools**" ⟶ "**Lift down the rotating arm**".

6. SCANNING

This chapter describes the procedures to be followed for a correct positioning of the patient or of the prostheses and for a correct execution of the examination.
The description of the scanning procedure is provided in the specific chapter of the document "Acquisition operations with NewTom VGi evo" attached to the "NNT User Manual".
We also recommend referring to chapters 2-“Safety-related information" and 3 - "Device safety and maintenance”.

It is possible to perform the scanning procedure as follows:

- [24x19] (diameter volume 24cm, height 19cm);
- [17x19] (diameter volume 17.5cm, height 19cm);
- [16x16] (diameter volume 16cm, height 16cm);
- [15x12] (diameter volume 15cm, height 12cm);
- [15x5] (diameter volume 15cm, height 5cm);
- [12x8] (diameter volume 12cm, height 8cm);
- [10x10] (diameter volume 10cm, height 10cm);
- [10x5] (diameter volume 10cm, height 5cm);
- [8x8] (diameter volume 8cm, height 8cm);
- [8x5] (diameter volume 8cm, height 5cm);
- [5x5] (diameter volume 5cm, height 5cm);

- [15x5] HiRes (High Resolution, diameter volume 15cm, height 5cm);
- [12x8] HiRes (High Resolution, diameter volume 12cm, height 8cm);
- [10x10] HiRes (High Resolution, diameter volume 10cm, height 10cm);
- [10x5] HiRes (High Resolution, diameter volume 10cm, height 5cm);
- [8x8] HiRes (High Resolution, diameter volume 8cm, height 8cm);
- [8x5] HiRes (High Resolution, diameter volume 8cm, height 5cm);
- [5x5] HiRes (High Resolution, diameter volume 5cm, height 5cm);

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

NOTE:
Non-HiRes FOVs are characterized with scanning time from 15 s to 20 s and exposure time from 0.9 s to 3.5 s.
HiRes FOVs are indicated for exams where a better details of bone structures is preferred (respect non- HiRes FOVs):

> scanning time (between 18 and 25 s)
> exposure time (between 1.8 and 6.0 s)

> exam dose
(approx. between 2.4 and 7.3 times) *(compared to non- HiRes Eco Scan)*
(approx. between 3.4 and 3.8 times) *(compared to non- HiRes Regular Scan)*
(approx. between 3.0 and 4.7 times) *(compared to non- HiRes Enhanced Scan)*

For each of the described modes 3 different scan options are available:

- **Regular Scan**: default option for image quality, scanning (from 15 to 18 s) and exposure (from 1.8 to 4.3 s) times

- **Eco Scan**: indicated for exams where a low dose to the patient is preferred
  < exposure time (between 0.9 and 1.8s),
  < exam dose (approx. between 0.2 and 0.7 times) (compared to Regular Scan)

- **Enhanced Scan**: indicated for exams where image quality is preferred
  > scanning time (from 20 to 25 s)
  > exposure time (from 3.5 to 6.0 s)
  > exam dose (approx. between 1.2 and 2.3 times) (compared to Regular Scan)

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

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

WARNING:
For pediatric patient[2] (also called children and small size patients) it is recommended to use the lowest-dose mode available: ECO SCAN.

WARNING:
Selecting a HiRes / Enhanced Scan / Boosted Dose protocol will result in more than 9 times the dose compared to a non-HiRes / Regular Scan / Standard Dose protocol with the same FOV. Imaging examinations must always be justified to demonstrate that the benefits outweigh the risks.

NOTE:
The relative dose informations between different FOVs and protocols was determined on the basis of the dose values reported in the attached document “Dose declaration and acceptance test”, by taking into account the CTDI weighted values.

2 *“Paediatric patient” is the patients more than 21 kg (46 lb) in weight and more than 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5-year-old child.*

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

"**Scan Manager**" panel of the NNT software

6.1. SCANNING A PATIENT

6.1.1. PREPARING THE PATIENT

The preparation of a patient for an examination is an important process that can contribute to the correct execution of the scanning and to obtain high-quality images.

The purpose of such process is to make the patient feel at ease and relaxed before and during the exam. Following are some recommendations to reach such purpose.

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

- **Preparing the patient**
  Ask the patient to remove any metallic objects (earrings, necklaces), glasses or removable metallic prostheses.

- **Positioning the patient**
  After positioning the patient in the scanning area, adjust the scanner and the chinrest device so as to frame the concerned scanning area and ensure the patient's head and neck are in an upright position.

- **Explaining the examination**
  Briefly explain the examination procedure to the patient, including the data entry, positioning and scanning processes.

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

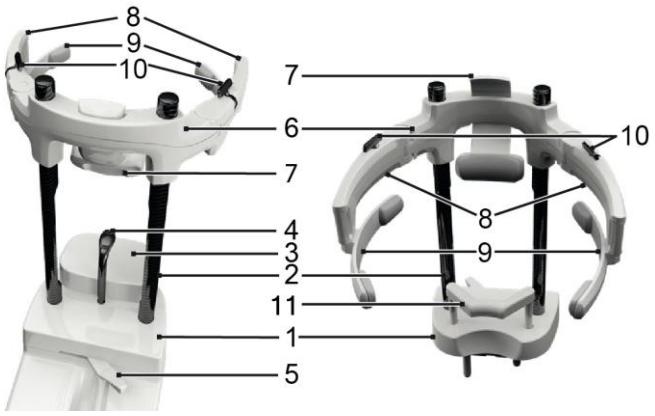
- **Correct breathing**
  Ask the patient to breathe slowly during the examination (a slow and continuous breath helps to avoid swallowing).

- **Relaxing**
  Ask the patients to keep the dental arches closed without grinding their teeth.

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

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

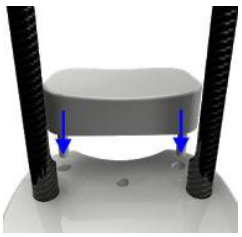
6.1.2. CRANIOSTAT USE



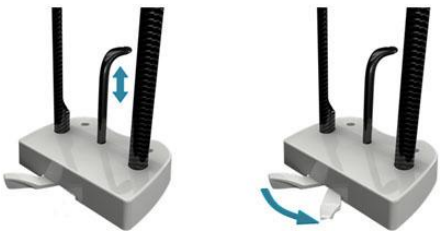
Craniostat components:
1 – Base
2 – Rods
3 – Chinrest
4 – Bite piece
5 – Bite piece block lever
6 – Cross member
7 – Front support
8 – Arms
9 – Anatomic arches
10 – Arms block levers
11 – Undenose support

The craniostat consists of a lower part and an upper one, connected by two carbon rods (2).

The lower part consists of a base (1) which is fitted in the chinrest seat with metal pins and that can be removed by simply pulling upwards.



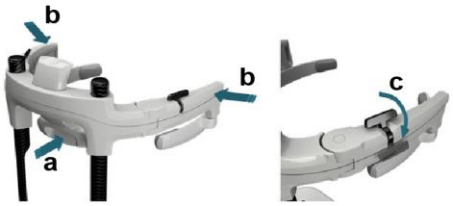
The chinrest (3) is fitted in the dedicated inserts in the base (1) by means of pins and can be removed simply by sliding it upwards.



The bite piece (4) is fitted in the suitable hole of seat (1): once it is set at the desired height, pull the central lever (5) from the left (unlocking position) to the right (locking position) in order to centre it and lock it in place.

Please remember that, in order to remove it, it is necessary to take lever (5) to the unlocking position and to slide it out of its seat.

The upper part consists of a cross member (6) that can slide vertically along the carbon rods (2).
The cross member contains the front support (7) that slides inside its seat in order to adapt it to the patient's anatomy.



After having correctly positioned the patient's head,:

a - push front support (7), making the pad rest against the patient's forehead,. The forehead's pressure on the support will automatically stabilise it.

b - rotate the arms (8) towards the patient's temples, ensuring that the rubber blocks at the ends of arches (9) adhere to the head anatomy.

c - rotate levers (10) downwards to ensure a correct locking.
CAUTION:
Turn down the levers up to the contact with the patient. Do not force the complete closure of the levers

At the end of the exposure, rotate the levers upwards to unlock arms, thus allowing the patient to get out easily In examinations where the undernose support (11) is used, it should be fitted INSTEAD OF THE CHINREST in the inserts in the base and pushed FULLY DOWN INTO PLACE.

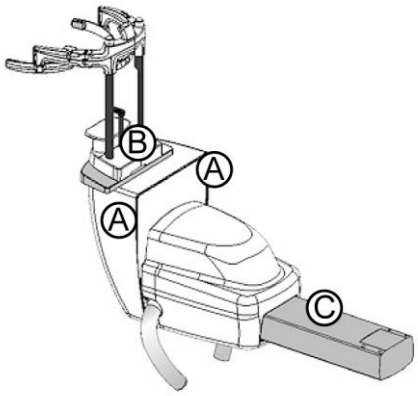
6.1.3. POSITIONING THE PATIENT AND STARTING THE SCANNING

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

The guidelines for patient positioning during examination of the different anatomic regions are outlined in the attached document **"General guidelines for use of the protocols of NewTom VGi evo"**.

WARNING:
The scanning area where the patient is positioned must be free of objects since they could injure the patient and/or invalidate the examination results.

WARNING:
Pay attention during the patient movements since his/her head and shoulders could accidentally impact against the device if the patient is positioned in a wrong way.

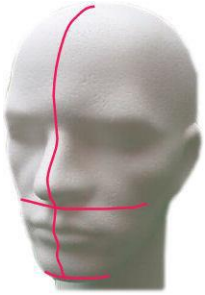


Bring the chinrest device to the default position (the three positioning rulers A, B, C must be set to the default position "0") through the special chinrest buttons on the console (refer to par. 4.4.1 - "Operator console and controls").

Through the suitable buttons on the console, move the rotary arm structure up/down to allow the patient to easily access the scanning area (the chinrest should be approximately at patient's head height).

Bring the patient near the chinrest without touching the structure.

Switch on the positioning laser beams through the suitable button on the remote control.

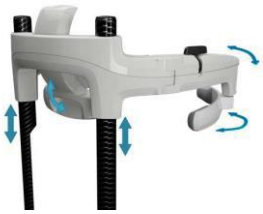


NOTE:
Ask the patient to temporarily close his/her eyes before switching on the positioning laser beams.

The laser vertical line indicates the centre of the scanning volume and corresponds to the patient's sagittal plane.
In case of field scanning [24x19], the upper horizontal line indicates approximately the centre of the scanned volume.
The lower horizontal line indicates (for all FOVs) the lower limit of the scanned volume.

Adjust the scanner height through the suitable buttons on the console to reach the area to be scanned with the laser lines.

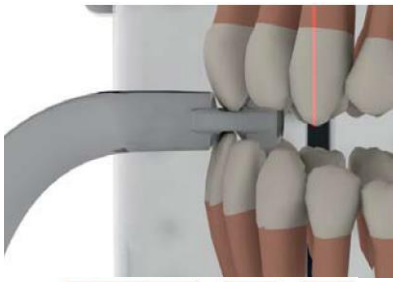
Adjust the chinrest device height so as to bring it to the patient's chin height.

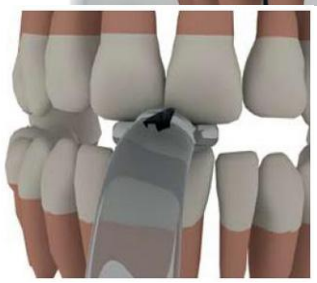


Adjust the craniostat height (as indicated in par. 6.1.2 - “Craniostat use”).

Tell the patient to position in the craniostat recommending him/her to:

- grab with his/her hands the handles on the chinrest structure;



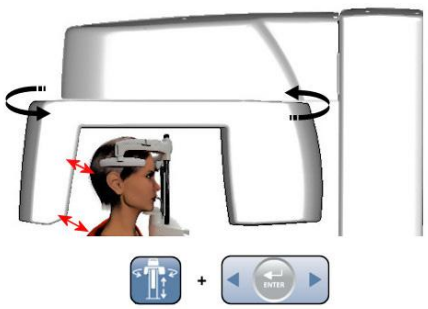


- bite the bite piece (ensuring to have previously inserted the disposable hygienic protection).
  Adjust the bite so that the upper and lower incisor tips are in the suitable groove. The inter-incisor gap must be in the bite medium line.

The bite correct positioning is made easy by the up/down sliding capacity of the relevant support stem.

- Tighten the suitable handgrip to block the bite in the correct position.
- Block the craniostat position (as indicated in par. 6.1.2 - “Craniostat use”).

NOTE:
If the patient is not in a natural position, it will be necessary to further adjust the scanner height.



It is necessary to make sure that the rotary arm does not impact the patient's shoulders or nape: slowly rotate the arm through the operator console.

NOTE:
The check described above must be carried out for each field of view, paying particular attention to the use of the smaller FOVs, since when using them the impact probability of the device with the patient is higher.

Position the patient using the scout latero-lateral (LL) and anteroposterior (AP) images.

6.1.4. SPECIAL CONSIDERATIONS FOR CHILDREN AND SMALL PATIENTS

NewTom VGi evo has been also designed for pediatric patient (also called children and small size patients) is the patients more than 21 kg (46 lb) in weight and more than 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5-year-old child.

It should be noted that all examinations using CBCT should be performed only when necessary to answer a medical question, treat a disease, or guide a procedure.
X-ray exams should use scan protocols that assure the lowest radiation dose that yields an adequate image quality (i.e., radiation doses should be "As Low as Reasonably Achievable" (ALARA)).

The clinical indication and patient medical history should be carefully considered before referring a patient for any X-ray examination.
Because children are more sensitive to radiation, they should have a CT study only if it is essential for making a diagnosis and should not have repeated CT studies unless absolutely necessary.

NewTom VGi evo may be used for children or small patients, but according to the limitations above illustrated.
The features available for this purpose are:

- small fields of view, e.g. FOV: 5x5 cm, 8x8 cm, 10x10 cm;
- ECO SCAN: a low-dose, fast protocol (15 s for Standard modality, 18 s for HiRes modality, ~ -30 % dose vs. a standard protocol);
- automatic calculation of the minimum radiology parameters required for performing the examination, depending on the size and density of the volume to examine (SafeBeam™);
- the indication of the dose values set by the software before the actual scan of the patient;
- the low scan time typical of the CBCT technology that helps provide fast examinations and decreases the chance of movement of the patient;
- possibility to perform exams while the patient is seated, to provide greater comfort and calm for the patient.

The head support tools provided for performing the examination are the same for adult and pediatric patients, as they can be adjusted and suited to the different patients' size.

NewTom VGi evo is equipped with laser pointers and a special device that reads the 3D coordinates for the patient's support position, which helps the user to identify the best position for patients of different sizes before any radiation emission.

Appropriate patient preparation is crucial for image quality. Any measure that can calm the child prior the start of imaging procedure will help keep the child quiet and still during the imaging study.

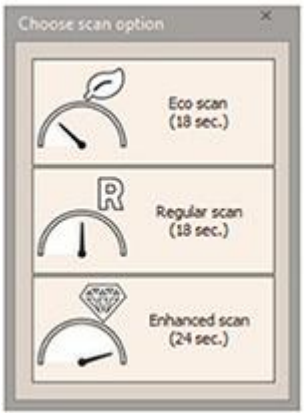
The short scansion examination time (15 seconds for Eco Scan, Standard Modality) helps reduce the possibility of patient movements and increases the comfort.
Patients who cannot remain still during the entire examination time represent an improper use of the machine, as outlined in this user manual.

The guidelines for adult and pediatric patient positioning during examination of the different anatomic regions are outlined in the attached document **“General guidelines for use of the protocols of NewTom VGi evo”**.

6.1.5. RECOMMENDATIONS FOR EXAMS IN THE PRESENCE OF METAL RESTORATIONS

In the case of metal restorations (particularly amalgam fillings), it is advisable to take certain precautions when performing the tomographic examination in order to reduce the artefacts that these metal objects can cause: streak artefacts when the beam passes through a single object, or beam starvation artefacts between two metal objects in close proximity. In these cases, it is advisable to:

1. Position the patient by aligning the upper horizontal light trace with the *Camper's plane* (the plane between the centre of the external auditory canal and the anterior nasal spine);



2. Select the “Regular” or “Eco” modes in the dose profile section to reduce x-ray emission;

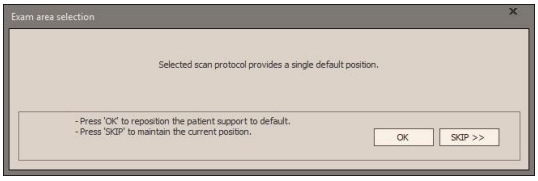
3. Activate the “**MAR**” metal artefact reduction algorithm using the appropriate button (refer to the document *NNT - User Manual*). This is an optional feature that can be activated when the minimum system requirements are met (for more details on minimum and recommended hardware and software requirements, refer to the annex “Minimum and recommended system requirements”).

6.2. CINEX SCAN

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

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

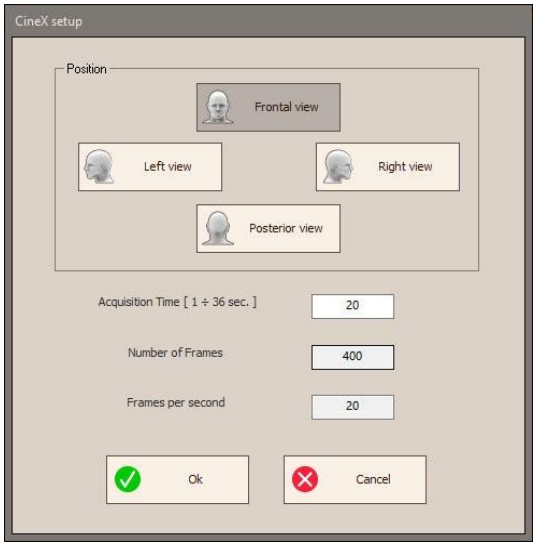
This type of scanning involves only one pre-set view field.



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

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

6.2.1. POSITIONING THE PATIENT AND STARTING THE SCANNING



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

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

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

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

For further information on patient positioning and preparation, please refer to Par. 6.1.2-6.1.3

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

6.3. SCANNING A PROSTHESIS

6.3.1. PRELIMINARY OPERATIONS

Enter the patient's prosthesis data (if not already present in the software database). For further information, refer to the “Acquisition Operations with NewTom VGi evo” annex to the “NNT User Manual” document.

6.3.2. POSITIONING THE PROSTHESIS

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

Remove the chinrest from the relevant structure and the bite.

Insert the prosthesis support between the carbon bars (as indicated in the figure).
Position the prosthesis to the chinrest so that it is in the position (direction) that it would have inside the patient's mouth.

It is possible to obtain a better position of the prosthesis using the anteroposterior (AP) and latero-lateral (LL) scout images.

Once the prosthesis is positioned, perform the scanning as described in the “Acquisition Operations with NewTom VGi evo” annex to the “NNT User Manual” document.

7. QUALITY CONTROL

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

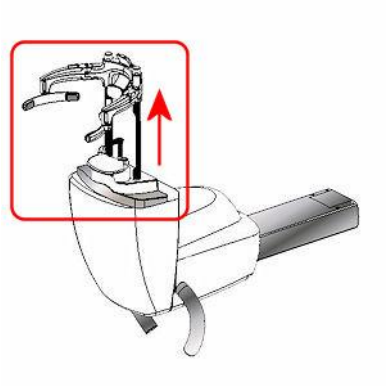
This control, that is recommended at least once a week, ensures the correct operation of the device and the validity of the obtained results.

Before starting the phantom scan the acquisition area must be selected.

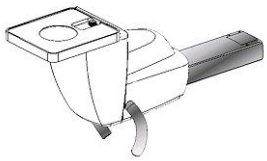
The test procedure is described in the document “Acquisition operations with NewTom VGi evo” enclosed to the “NNT User Manual”.

7.1. PHANTOM POSITIONING

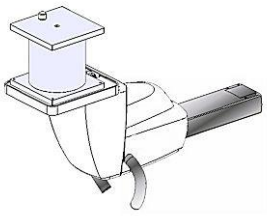
Following is a description of the operations to be performed to position and centre the phantom inside the scanning area. Perform these operations when prompted by the software.



Remove the craniostat from the chinrest device.



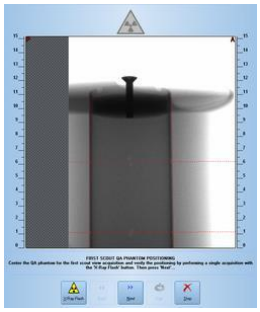
Insert the calibration support.



Position the phantom on the support in the central position.

To facilitate the correct positioning of the phantom, set the chinrest as described below using the relevant buttons on the console (refer to par. 4.4.1 - Operator console and controls).

Ruler A – B - C → "QA" position

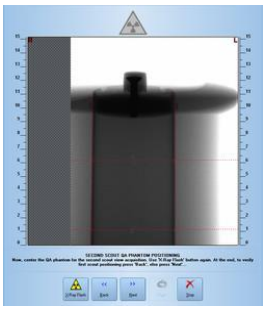


1st scout view.

The first displayed "scout view" image corresponds to the phantom view in the scanning initial position.

Using this image it is possible to further centre the phantom perpendicular to the rotary arm.

Repeat the operation until necessary (the aluminium cylinder should be between the vertical red broken lines, whereas the internal balls must be passed through by the horizontal red broken lines).



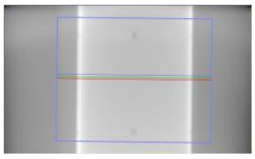
2nd scout view.

To centre the QA phantom from the front side use the second "scout view" obtained with the arm at 90 degrees.
It is therefore possible to scan the phantom.

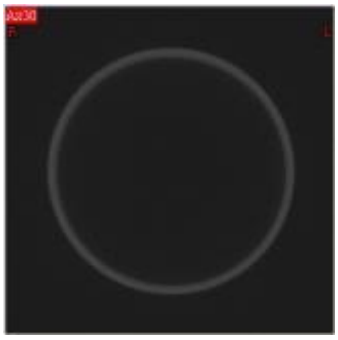
For further details, refer to the “Acquisition Operations with NewTom VGi evo” annex to the “NNT User Manual” document.

7.2. IMAGE EXAMPLES

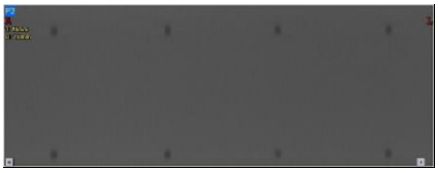
Following are some examples of images acquired during the phantom analysis:



Lateral view.



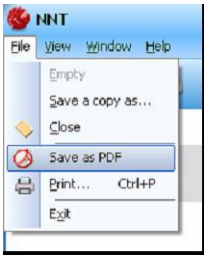
Axial section.



Panoramic section.

7.3. SAVING THE PHANTOM ANALYSES

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



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

8. TROUBLESHOOTING

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

9. APPENDIX A: TECHNICAL SPECIFICATIONS

Scanner

Scanning device (cone beam technology)	Single rotation and volumetric acquisition	
Scanning parameters	Mode:	Time / X-ray emission
	Regular Scan:	
	[24x19]:	15 s / 1.8 s
	[17x19]:	15 s / 1.8 s
	[16x16]:	15 s / 1.8 s
	[15x12]	15 s / 1.8 s
	[15 x 5]:	15 s / 1.8 s
	[12x8]:	15 s / 1.8 s
	[10x10]:	15 s / 1.8 s
	[10x5]:	15 s / 1.8 s
	[8x8]:	15 s / 1.8 s
	[5x5]:	15 s / 1.8 s
	[15x5] HiRes:	18 s / 4.3 s
	[12x8] HiRes:	18 s / 4.3 s
	[10x10] HiRes:	18 s / 4.3 s
	[10x5] HiRes:	18 s / 4.3 s
	[8x8] HiRes:	18 s / 4.3 s
	[8x5] HiRes:	18 s / 4.3 s
	[5x5] HiRes:	18 s / 4.3 s
	ECO Scan:	
	[24x19]:	15 s / 1.2 s
	[17x19]:	15 s / 1.2 s
	[16x16]:	15 s / 1.2 s
	[15x12]	15 s / 1.2 s
	[15 x 5]:	15 s / 1.2 s
	[12x8]:	15 s / 1.2 s
	[10x10]:	15 s / 1.2 s
	[10x5]:	15 s / 1.2 s
	[8x8]:	15 s / 1.2 s
	[5x5]:	15 s / 0.9 s
	[15x5] HiRes:	18 s / 1.8 s
	[12x8] HiRes:	18 s / 1.8 s
	[10x10] HiRes:	18 s / 1.8 s
	[10x5] HiRes:	18 s / 1.8 s
	[8x8] HiRes:	18 s / 1.8 s
	[8x5] HiRes:	18 s / 1.8 s
	[5x5] HiRes:	18 s / 1.8 s
	Enhanced Scan:	20 s / 3.5 s
	[24x19]:	20 s / 3.5 s
	[17x19]:	20 s / 3.5 s
	[16x16]:	20 s / 3.5 s
	[15x12]	20 s / 3.5 s
	[15 x 5]:	20 s / 3.5 s
	[12x8]:	20 s / 3.5 s
	[10x10]:	20 s / 3.5 s
	[10x5]:	20 s / 3.5 s
	[8x8]:	20 s / 3.5 s
	[5x5]:	25 s / 6.0 s
	[15x5] HiRes:	25 s / 6.0 s
	[12x8] HiRes:	25 s / 6.0 s
	[10x10] HiRes:	25 s / 6.0 s
	[10x5] HiRes:	25 s / 6.0 s

Scanning device (cone beam technology)	Single rotation and volumetric acquisition		
	[8x8] HiRes: [8x5] HiRes: [5x5] HiRes: Sharp 2D CineX		25 s / 6.0 s 25 s / 6.0 s 19.2 s / 2.4s 1÷20s @ 20fps / 0.2÷4s 21÷36s @ 15fps / 3.15÷5.4s
	Sampling angle		360°
Patient positioning	Fixed position		Motor-driven chinrest device with laser targeting

Analysed anatomic volume	Cylinder		[24x19]: Ø max 24 cm, h max 19 cm [17x19]: Ø max 17.5 cm, h max 19 cm [16 x 16]: Ø max 16 cm, h max 16 cm [15x12]: Ø max 15 cm, h max 12 cm [15 x 5]: Ø max 15 cm, h max 5 cm [12 x 8]: Ø max 12 cm, h max 8 cm [10 x 10]: Ø max 10 cm, h max 10 cm [10 x 5]: Ø max 10 cm, h max 5 cm [8 x 8]: Ø max 8 cm, h max 8 cm [8 x 5]: Ø max 8 cm, h max 5 cm [5 x 5]: Ø max 5 cm, h max 5 cm [15 x 5] HiRes: Ø max 15 cm, h max 5 cm [12x8] HiRes: Ø max 12 cm, h max 8 cm [10 x 10] HiRes: Ø max 10 cm, h max 10 cm [10 x 5] HiRes: Ø max 10 cm, h max 5 cm [8x8] HiRes: Ø max 8 cm, h max 8 cm [8 x 5] HiRes: Ø max 8 cm, h max 5 cm [5 x 5] HiRes: Ø max 5 cm, h max 5 cm
Weight and size	Scanner	Width (diameter used during the scan)	1284 mm
		Depth (max)	1752 mm
		Height	2330 mm
		Maximum weight	377 Kg / 831 lb
	Control Box	Width	630 mm
		Depth	300 mm
		Height	970 mm
		Weight	95 Kg / 209 lb

Detector

Image pixels	1560 x 1440	dots
Pixel size	0,184 x 0,184	mm
Pixel depth	16	bit
S/N	9.2 – 14.2 (standard resolution) 17.1 – 21.3 (HiRes)	dB
Frame rate Max	30	F/s

X-ray image scout view

[24x19]

Image pixels	720 x 780	dots
Pixel depth	16	bit
Pixel size	0,368 x 0,368	mm

[17x19]

Image pixels	570 x 780	dots
Pixel depth	16	bit
Pixel size	0,368 x 0,368	mm

[16x16]

Image pixels	540 x 678	dots
Pixel depth	16	bit
Pixel size	0,368 x 0,368	mm

[15x12]

Image pixels	518 x 512	dots
Pixel depth	16	bit
Pixel size	0,368 x 0,368	mm

[15x5]

Image pixels	518 x 216	dots
Pixel depth	16	bit
Pixel size	0,368 x 0,368	mm

[12x8]

Image pixels	454 x 342	dots
Pixel depth	16	bit
Pixel size	0,368 x 0,368	mm

[10x10]

Image pixels	410 x 428	dots
Pixel depth	16	bit
Pixel size	0,368 x 0,368	mm

[10x5]

Image pixels	410 x 216	dots
Pixel depth	16	bit
Pixel size	0,368 x 0,368	mm

[8x8]

Image pixels	340 x 342	dots
Pixel depth	16	bit
Pixel size	0,368 x 0,368	mm

[8x5]

Image pixels	340 x 216	dots
Pixel depth	16	bit
Pixel size	0,368 x 0,368	mm

[5x5]

Image pixels	216 x 216	dots
Pixel depth	16	bit
Pixel size	0,368 x 0,368	mm

[15X5] HiRes

Image pixels	1036 x 432	dots
Pixel depth	16	bit
Pixel size	0,184 x 0,184	mm

[12X8] HiRes

Image pixels	908 x 684	dots
Pixel depth	16	bit
Pixel size	0,184 x 0,184	mm

[10X10] HiRes

Image pixels	820 x 856	dots
Pixel depth	16	bit
Pixel size	0,184 x 0,184	mm

[10X5] HiRes

Image pixels	820 x 432	dots
Pixel depth	16	bit
Pixel size	0,184 x 0,184	mm

[8X8] HiRes

Image pixels	680 x 684	dots
Pixel depth	16	bit
Pixel size	0,184 x 0,184	mm

[8X5] HiRes

Image pixels	680 x 432	dots
Pixel depth	16	bit
Pixel size	0,184 x 0,184	mm

[5x5] HiRes

Image pixels	432 x 432	dots
Pixel depth	16	bit
Pixel size	0,184 x 0,184	mm

Reconstructed volume

[24x19]

Shape	Cylinder			
Reconstructed volume size (max)	Ø24 x H19			cm
Voxel size	0,300	0,250	0,200	mm
Image pixels	816 x 816	672 x 672	672 x 672	dots
Pixel depth	16			bit

[17x19]

Shape	Cylinder			
Reconstructed volume size (max)	Ø17.5 x H19			cm
Voxel size	0,300	0,250	0,200	mm
Image pixels	584 x 584	700 x 700	672 x 672	dots
Pixel depth	16			bit

[16x16]

Shape	Cylinder			
Reconstructed volume size (max)	Ø16 x H16			cm
Voxel size	0,300	0,250	0,200	mm
Image pixels	544 x 544	652 x 652	672 x 672	dots
Pixel depth	16			bit

[15x12]

Shape	Cylinder	
Reconstructed volume size	Ø15 x H12	cm

(max)				
Voxel size	0,300	0,250	0,200	mm
Image pixels	515 x 512	614 x 614	764 x 764	dots
Pixel depth	16			bit

[15x5]

Shape	Cylinder			
Reconstructed volume size (max)	Ø15 x H5			cm
Voxel size	0,300	0,250	0,200	mm
Image pixels	510 x 510	612 x 612	764 x 764	dots
Pixel depth	16			bit

[12x8]

Shape	Cylinder			
Reconstructed volume size (max)	Ø12 x H8			cm
Voxel size	0,300	0,250	0,200	mm
Image pixels	410 x 410	492 x 492	614 x 614	dots
Pixel depth	16			bit

[10x10]

Shape	Cylinder			
Reconstructed volume size (max)	Ø10 x H10			cm
Voxel size	0,300	0,250	0,200	mm
Image pixels	344 x 344	412 x 412	516 x 516	dots
Pixel depth	16			bit

[10x5]

Shape	Cylinder			
Reconstructed volume size (max)	Ø10 x H5			cm
Voxel size	0,300	0,250	0,200	mm
Image pixels	344 x 344	412 x 412	516 x 516	dots
Pixel depth	16			bit

[8x8]

Shape	Cylinder			
Reconstructed volume size (max)	Ø8 x H8			cm
Voxel size	0,300	0,250	0,200	mm
Image pixels	276 x 276	330 x 330	414 x 414	dots
Pixel depth	16			bit

[8x5]

Shape	Cylinder			
Reconstructed volume size (max)	Ø8 x H5			cm
Voxel size	0,300	0,250	0,200	mm
Image pixels	276 x 276	330 x 330	414 x 414	dots
Pixel depth	16			bit

[5x5]

Shape	Cylinder			
Reconstructed volume size (max)	Ø5 x H5			cm
Voxel size	0,300	0,250	0,200	mm
Image pixels	176 x 176	210 x 210	264 x 264	dots
Pixel depth	16			bit

[15X5] HiRes

Shape	Cylinder			

Reconstructed volume size (max)	Ø15 x H5			cm
Voxel size	0,150	0,125	0,100	mm
Image pixels	1020 x 1020	880 x 880	800 x 800	dots
Pixel depth	16			bit

[12X8] HiRes

Shape	Cylinder			
Reconstructed volume size (max)	Ø12 x H8			cm
Voxel size	0,150	0,125	0,100	mm
Image pixels	820 x 820	700 x 700	672 x 672	dots
Pixel depth	16			bit

[10X10] HiRes

Shape	Cylinder			
Reconstructed volume size (max)	Ø10 x H10			cm
Voxel size	0,150	0,125	0,100	mm
Image pixels	688 x 688	672 x 672	672 x 672	dots
Pixel depth	16			bit

[10X5] HiRes

Shape	Cylinder			
Reconstructed volume size (max)	Ø10 x H5			cm
Voxel size	0,150	0,125	0,100	mm
Image pixels	688 x 688	824 x 824	800 x 800	dots
Pixel depth	16			bit

[8X8] HiRes

Shape	Cylinder			
Reconstructed volume size (max)	Ø8 x H8			cm
Voxel size	0,150	0,125	0,100	mm
Image pixels	552 x 552	662 x 662	672 x 672	dots
Pixel depth	16			bit

[8X5] HiRes

Shape	Cylinder			
Reconstructed volume size (max)	Ø8 x H5			cm
Voxel size	0,150	0,125	0,100	mm
Image pixels	552 x 552	662 x 662	828 x 828	dots
Pixel depth	16			bit

[5x5] HiRes

Shape	Cylinder			
Reconstructed volume size (max)	Ø5 x H5			cm
Voxel size	0,150	0,125	0,100	mm
Image pixels	352 x 352	420 x 420	528 x 528	dots
Pixel depth	16			bit

X-ray Parameters

IAE X-RAY TUBE mod. RTM 30 HS 0.3/0.6 (rotary anode)

Documentazione Tubo a raggi X
Tube Documentation
Documentation du Tube

RTM 30 HS 0.3/0.6

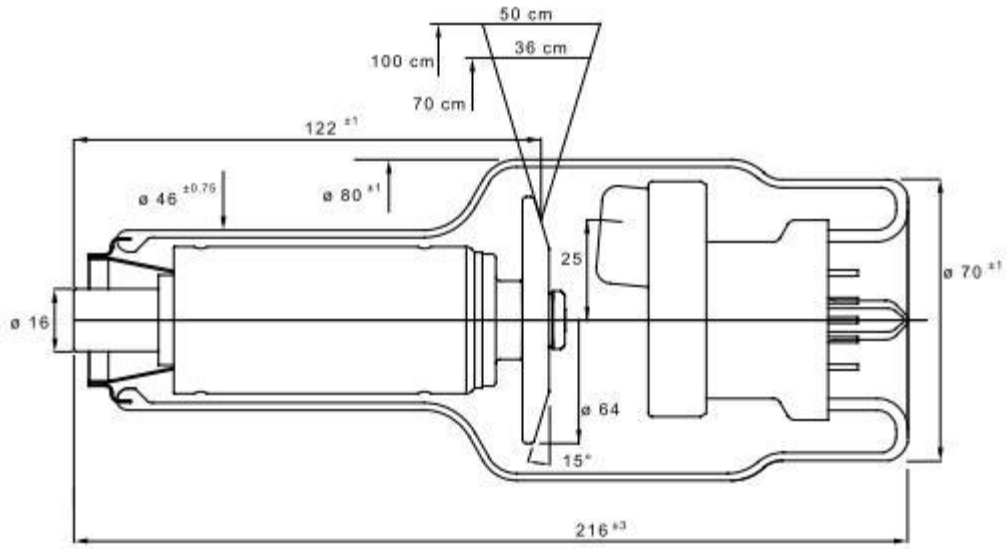
Caratteristiche - Specifications - Spécifications

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

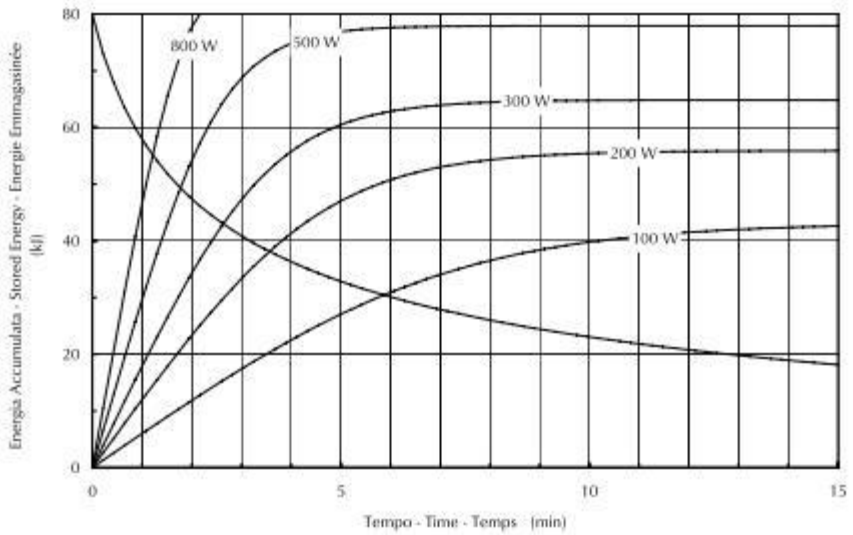
I dati forniti nella presente documentazione si intendono riferiti a:
The data indicated in this documentation refer to:
Les données indiquées dans cette documentation sont calculées pour:

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

Dimensioni - Dimensions - Dimensions

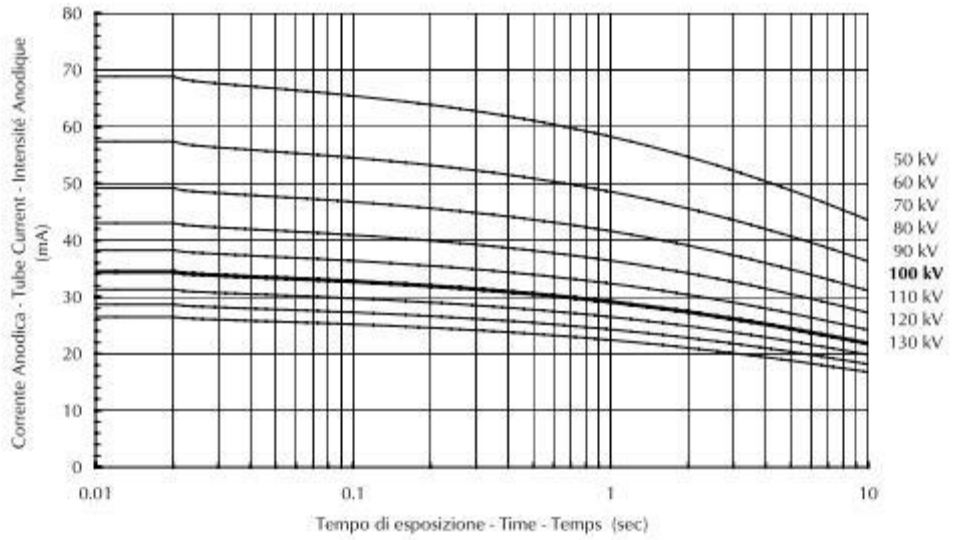


Curve di riscaldamento e raffreddamento dell'anodo
Anode heating and cooling curves
Courbes d'échauffement et de refroidissement de l'anode



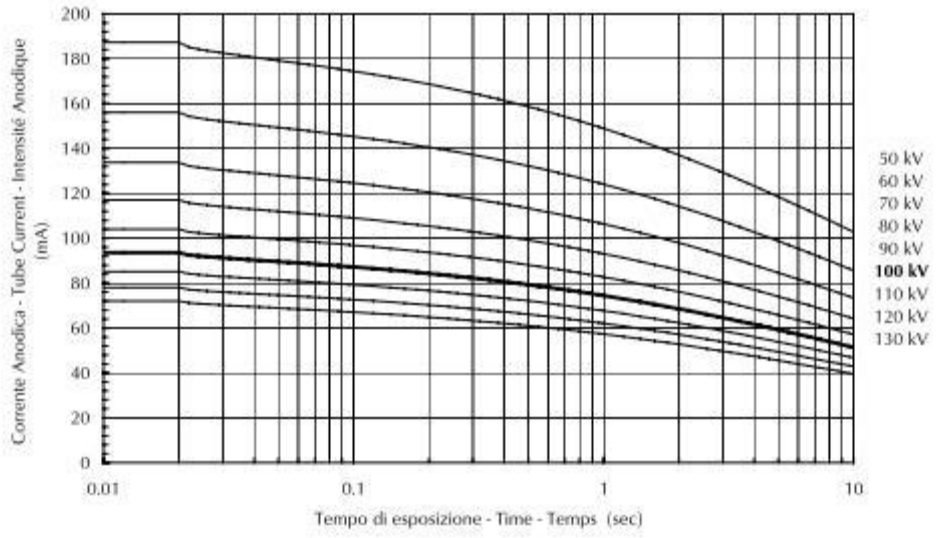
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



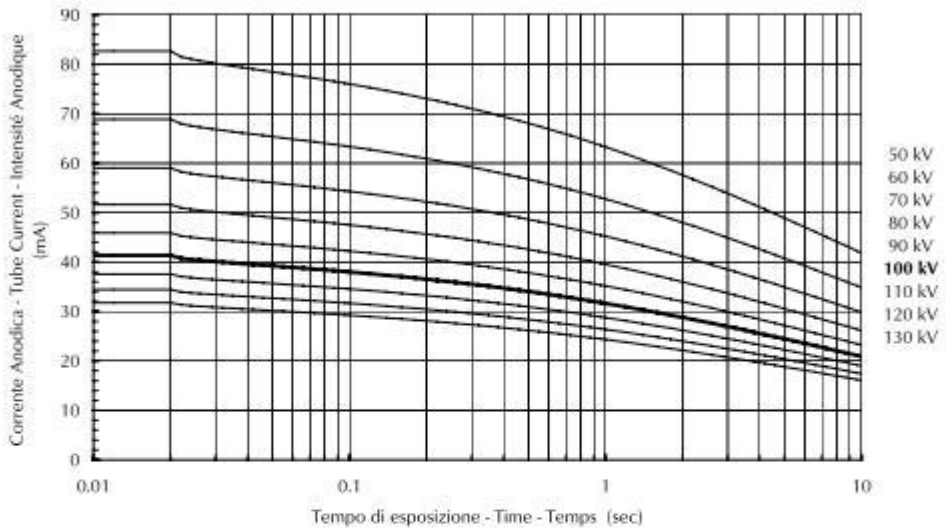
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



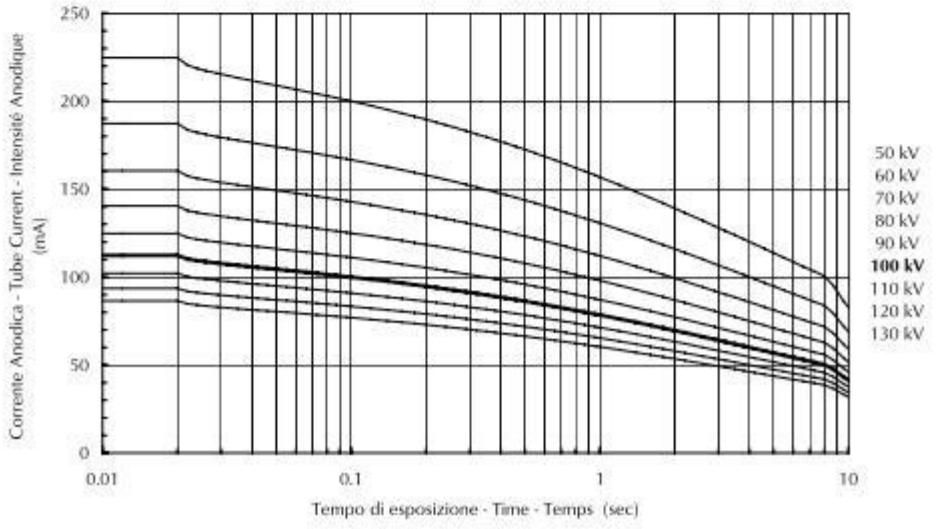
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



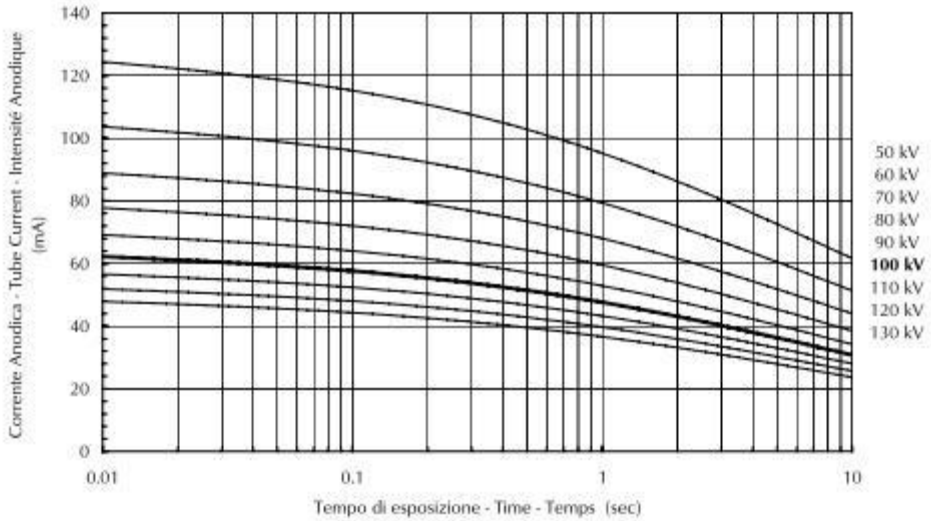
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



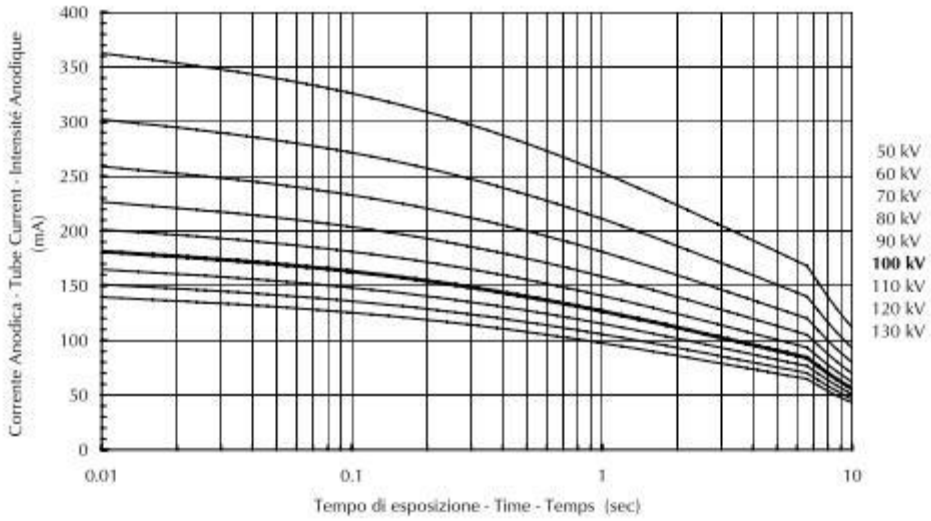
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



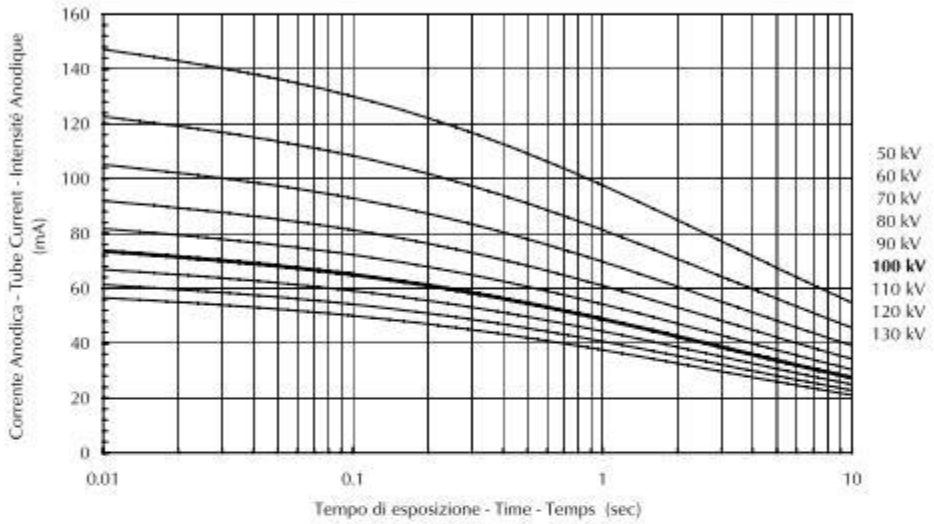
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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



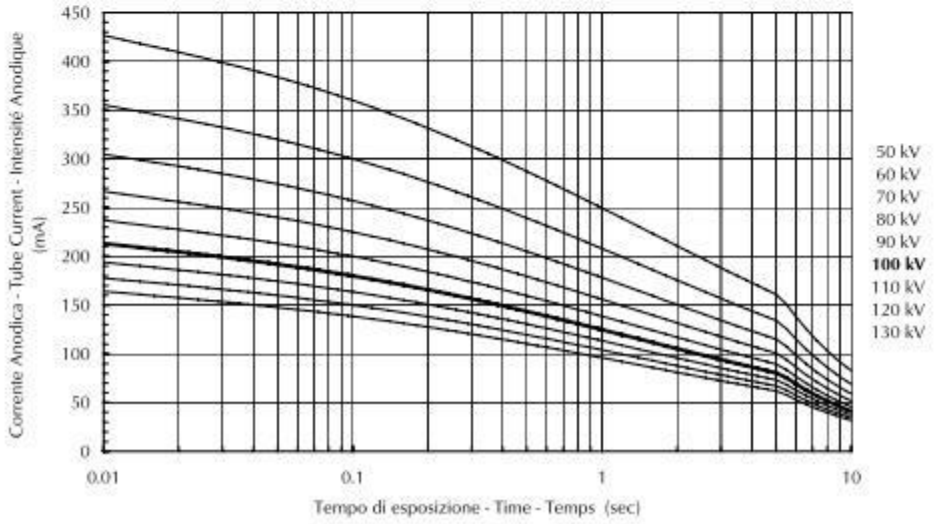
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

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

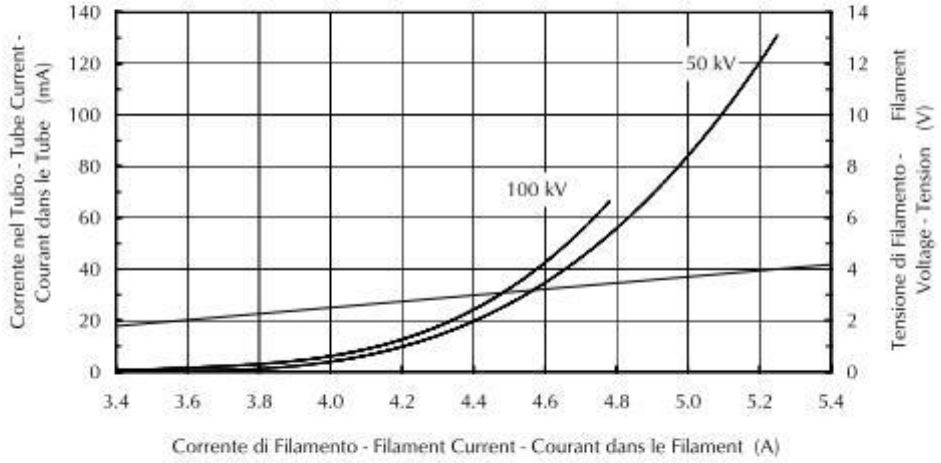


CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

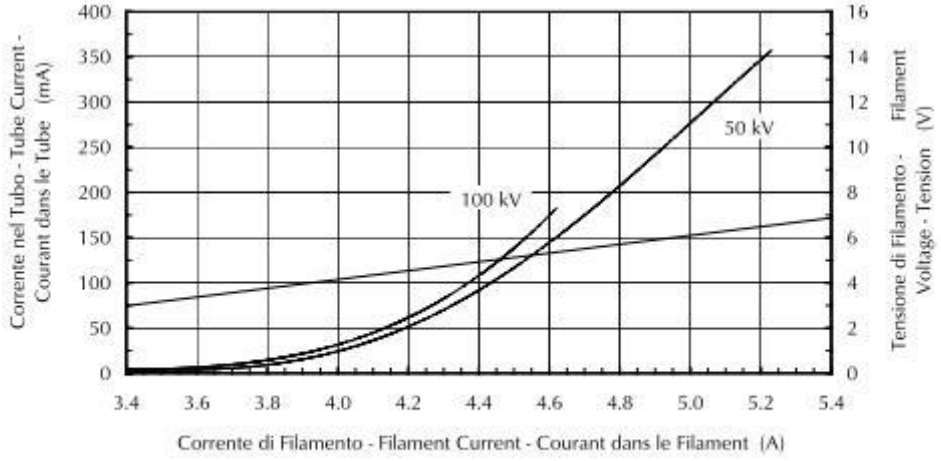
0.6 - 3 ~ - 10000 min^{-1}



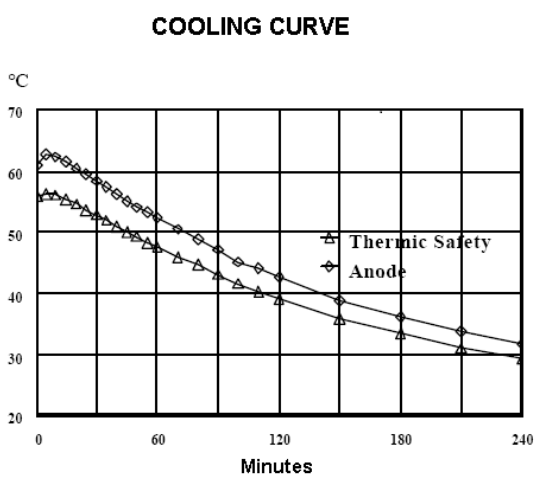
Caratteristica di emissione del catodo
Cathode emission characteristic
Caractéristique d'émission de la cathode
0.3 - 3 ~ - (± 0.2 A)



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



MONO-BLOCK

Make	IMD s.r.l.
Model	HF1 R
X-ray tube	IAE RTM 30 HS 0.3/0.6 (part no. XRM.11.X51.001 / IRM.11.280.001)
Classification (IEC 60-601)	Class I Type B
PHYSICAL DATA	
Sheath material	Aluminium
Heat capacity	550 kJ
Maximum continuous thermal dissipation	60 W at 110kV, 3.6 mA, 10 ms, 15 FPS
Maximum temperature	60°
Minimum inherent filtration at 70 kV	1.4 mm Al
Oil volume compensation	410 cu. cm rubber chamber
Dimensions	325 x 145 x 215
Weight	19.5 kg
ELECTRICAL DATA	
Maximum output voltage	120 kV
Cathode-Ground	60 kV
Anode-Ground	60 kV
Maximum anode current at 110 kV	32 mA
Maximum voltage at the tube at 32 mA	110 kV
Maximum electric power	3.5 kW
Maximum power ripple	<1%
High voltage increase time at maximum power	<0.5 ms
Cooling curve	
Rotor	HF1R - Startup 230Vac / 0.8s / 10° - Running 60Vac / 2A
Anode nominal rpm	3000 rpm / 10000 rpm

X-ray generator-tube-sheath assembly

Mono-block Model	HF1 R
X-ray tube	IAE RTM 30 HS 0.3/0.6
Source-detector distance	721 mm
Source-skin distance (minimum)	150 mm
Total filtration	1.4 mm Al (Inherent filtration) + 10.6 mm Al (Supplementary filtration)
Beam maximum dimension	238 mm x 179 mm (detector area)
Voltage accuracy at the tube [3]	< 10%
Current accuracy at the tube [4]	< 20%
Radiation linearity [5]	< 20%
Emission time accuracy [6]	< 5% + 50 ms
Current-time product accuracy [7]	< 10% + 0.2 mAs

[3] According to IEC 60601-2-63, par. 203.6.4.3.102.2
[4] According to IEC 60601-2-63, par. 203.6.4.3.102.3
[5] According to IEC 60601-2-63, par. 203.6.3.1.101
[6] According to IEC 60601-2-63, par. 203.6.4.3.102.4
[7] According to IEC 60601-2-63, par. 203.6.4.3.102.5

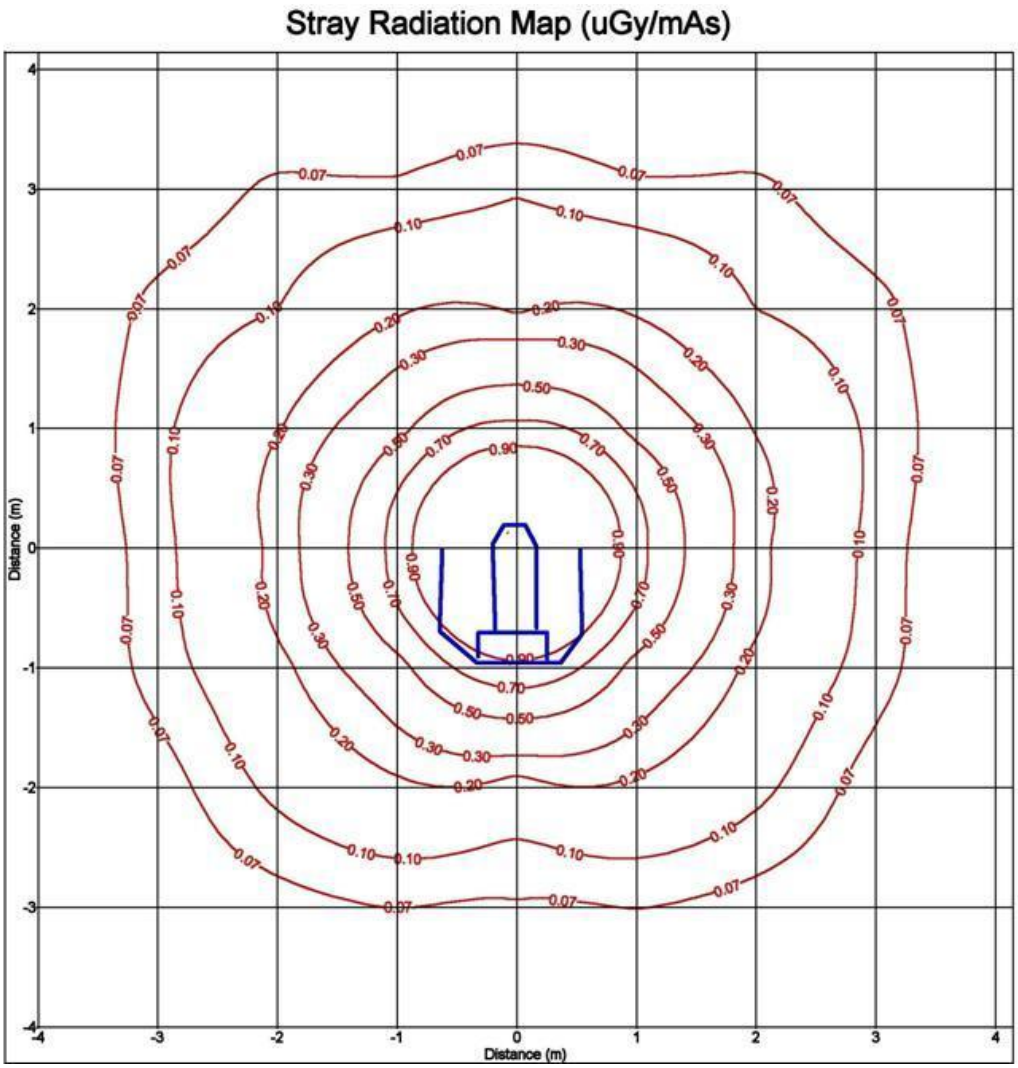
INVERTER

Make	IMD s.r.l.
Model	HF1 3.5kW / HF1 3.5kW PLUS
INPUTS	
Maximum power	3.5 kW
Power supply	230 V~ (± 10%)
Wave shape	Sinusoidal 50/60 Hz
Maximum current	16 A
Power supply apparent resistance	0.14 ohm
OUTPUTS	
Peak voltage	350 Vpk
Maximum peak current	120 Apk Max.
Wave shape	Sinusoidal 20 kHz
PHYSICAL DATA	
Dimensions	160 x 280 x 235 mm
Weight	7 kg

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

Stray Radiation Map

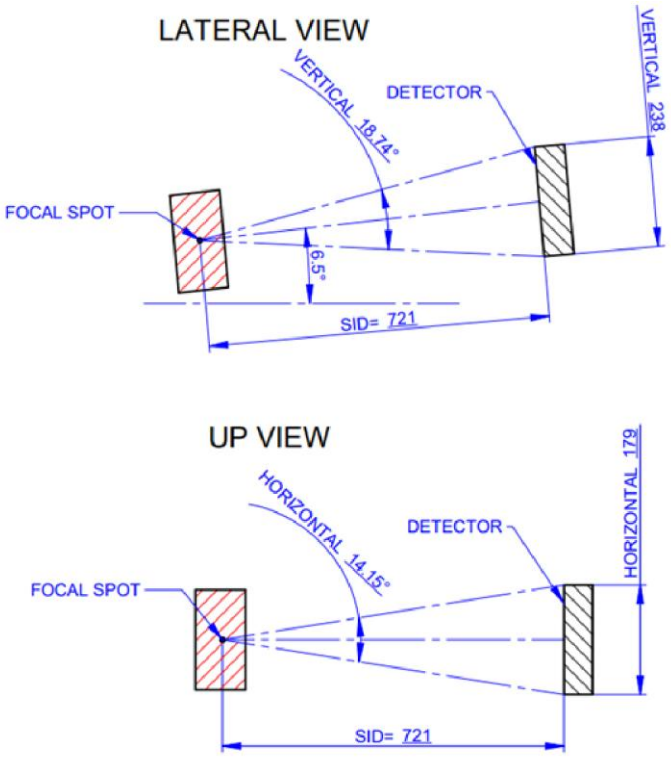
Stray radiation (uGy/mAs) according to IEC 60601-2-44:2009 Par. 203.13.
Measured using “head phantom” according to IEC 60601-2-44:2009 Par. 203.108.



Laser

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

Geometric relationship between the focal spot, the beam size, the patient position and the image reception area.



Other information

Absorbed power	220 V ~ (± 10%) / 230 V ~ (± 10%) / 240 V ~ (± 10%) 50/60 Hz (± 1%) 10 A (during the scan with maximum x-ray load) 0.9 A (in stand-by mode)
	200 V ~ (± 10%) 50/60 Hz (± 1%) 12.5 A (during the scan with maximum x-ray load) 1.1 A (in stand-by mode)
	100 V ~ (± 10%) / 115 V ~ (± 10%) 50/60 Hz (± 1%) 15 A (during the scan with maximum x-ray load) 1.4 A (in stand-by mode)
Network impedance	≤ 0,5 Ω
Use temperature	+10 ± +35 °C
Use humidity	10% ± 85 % (non-condensing)
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.

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

Clause	Guidance and manufacturer's declaration - electromagnetic emissions - for all equipment and systems		
TABLE: Guidance and manufacturer's declaration - electromagnetic emissions			
The NewTom VGi evo device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom VGi evo 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 VGi evo device user requires a continuous operation also in case of blackout, it is recommended to power the NewTom VGi evo 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 VGi evo device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom VGi evo 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 6V ISM frequencies	IEC 60601-1-2 Test level	The RF communication devices (portable and mobile) should not be used near the NewTom VGi evo device, 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 a NewTom VGi evo device is used exceeds the applicable conformity level mentioned above, one should analyse the standard operation of the NewTom VGi evo device. If abnormal performance is noticed, it may be necessary to implement supplementary measures like a different orientation or position of the NewTom VGi evo device.

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

Clause	Guidance and manufacturer's declaration - electromagnetic emissions - for all equipment and systems		
TABLE: Recommended distance between portable and mobile radio-frequency devices and the equipment			
The NewTom VGi evo device is designed to operate in the electromagnetic environment with control of the RF irradiated disturbances. The customer or the operator of the NewTom VGi evo device could help in preventing electromagnetic interferences ensuring a minimum distance between the RF mobile and portable communication devices and the NewTom VGi evo 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, parts, spare parts must be approved and supplied by CEFLA s.c.
In particular, the connection cables must be of the type specified in par. 4.8.1 - "Cables".

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

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

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

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

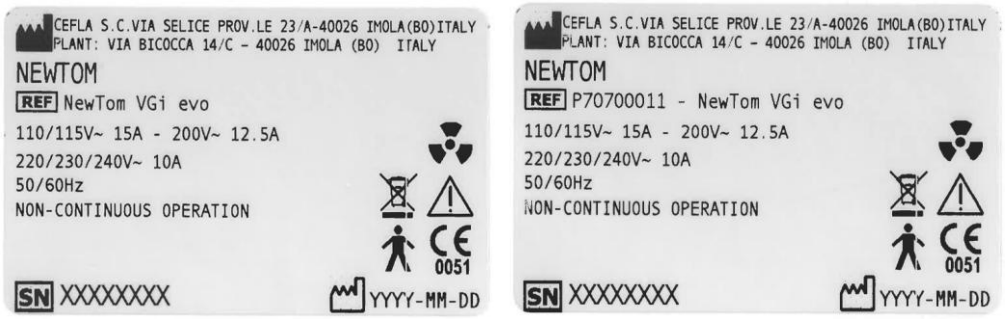
The NewTom VGi evo device has been manufactured in compliance with the IEC standards for the safety of medical electrical equipment, and particularly with the following standards:

- IEC 60601-1: 2005 + AMEND. 1 (2006) + AMEND. 2 (2007) + A1:2012 (Ed. 3.1) - General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 (4th Ed.) - General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-3:2008 + A1:2013 (Ed. 2.1) - Particular requirements for basic safety and essential performance of dental extra-oral x-ray equipment.
- IEC 60601-1-6:2010 + A1:2013 (Ed. 3.1) - General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices.
- IEC 60601-2-63:2012 + A1:2017 (Ed. 1.1) - Particular requirements for basic safety and essential performance of dental extra-oral x-ray equipment.
- IEC 62304:2006 + A1:2015 (Ed. 1.1) - Medical device software - Software life cycle processes.
- IEC 62366: 2007 + A1:2020 (Ed. 1.1) - Medical devices - Application of usability engineering to medical devices.
- IEC 60825-1:2014 - Safety of laser products - Part 1: Equipment classification, requirements and user's guide.
- ANSI/AAMI ES60601-1: 2005 / A2:2010 - US NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements.
- CAN/CSA-C22.2 No. 60601-1:2008 - 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	
Degree of protection against electric shocks	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	Continuous operation with intermittent load.	
Operating cycle	**15 minutes for a complete operating cycle composed as follows:**	
	Device part:	Duration of the operation:
	Column actuator and chinrest motors - movements	Duty cycle: 16% (2.20 min / 15 min)
	Beam limiter motors	Duty cycle: 6% (50 sec. / 15 min.)
	Scan motor - movements	Duty cycle: 14% (2 min / 15 min)
	X-ray emission	Duty cycle: 2% (max 36 sec. pulsed / 15 min) 110 kV-15 ms - 32 mA

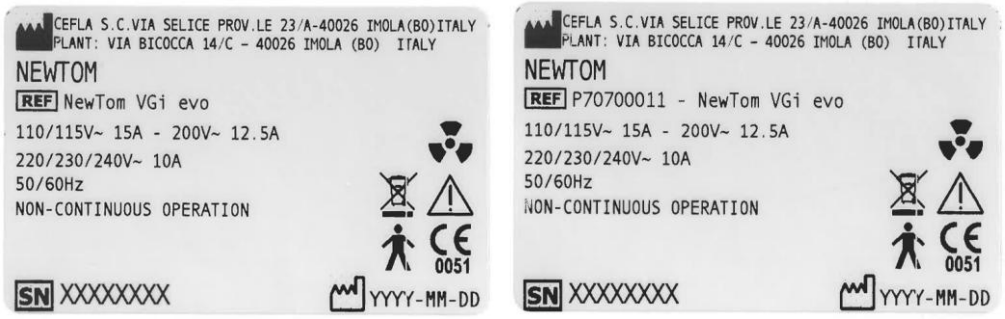
11. APPENDIX C: DEVICE LABELS

PLATE ON THE SCANNER



Position: Right upright of the scanner, lower side

CONTROL BOX PLATE



Position: Left side of the control box

MAIN SWITCH AND INPUT FUSE LABEL

Position: Left side of the control box

X-RAY WARNING AND DHHS LABEL

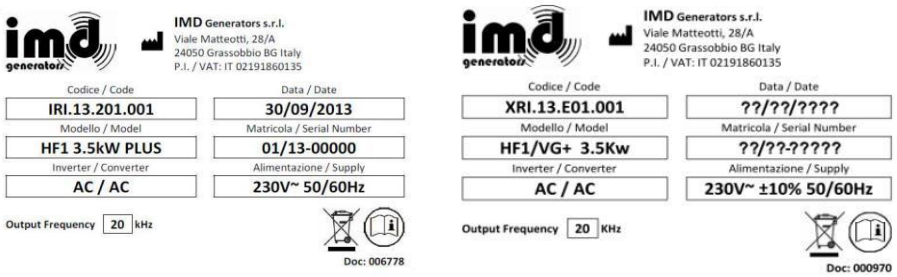
Position: Left side of the control box

APPLIED PART LABEL

Position: on the motor-driven chinrest

CONTROL BOX PLATE

Ray source with rotary anode



Position: On the X-ray source and inverter case

PLATE WITH DEVICE COMMERCIAL NAME

NewTom VGi evo

Position: On the scanner cover, in the lateral central area

NewTom

Position: On the detector case, in central area

cMETus CERTIFICATION LABEL

Position: Left side of the control box, under the laser label

BEAM LIMITER LABELS

BEAM LIMITER GLOBAL LABEL

Position: Near the collimator assembly part no. 96600870

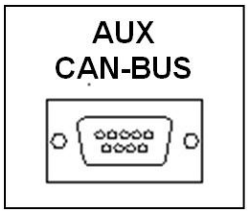
BRASS FILTER LABEL

CEFLA s.c. – Italy
P/N 99934979 – CuZn – 0.15 mm
P/N 99935063 – CuZn – 0.25 mm

10.60 mm Al at 75 kV

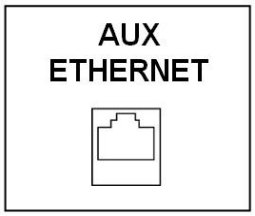
Position: Near brass filters part no. 99934979 and 99935063

CANBUS CONNECTOR INDICATION LABEL



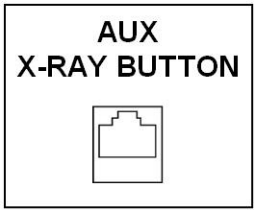
Position: Left side of the control box, at the bottom

X-RAY BUTTON CONNECTOR INDICATION LABEL



Position: Left side of the control box, at the bottom

RJ45 ETHERNET BUTTON CONNECTOR INDICATION LABEL



Position: Left side of the control box, at the bottom

WARNING LABELS FOR LASER DEVICES

Position: Left side of the control box, under the emergency stop button

LASER DANGER LABEL

Position: On the scanner, near laser modules

LABEL INDICATING TO REFER TO THE INSTRUCTION MANUAL

Position: Left side of the control box, at the bottom

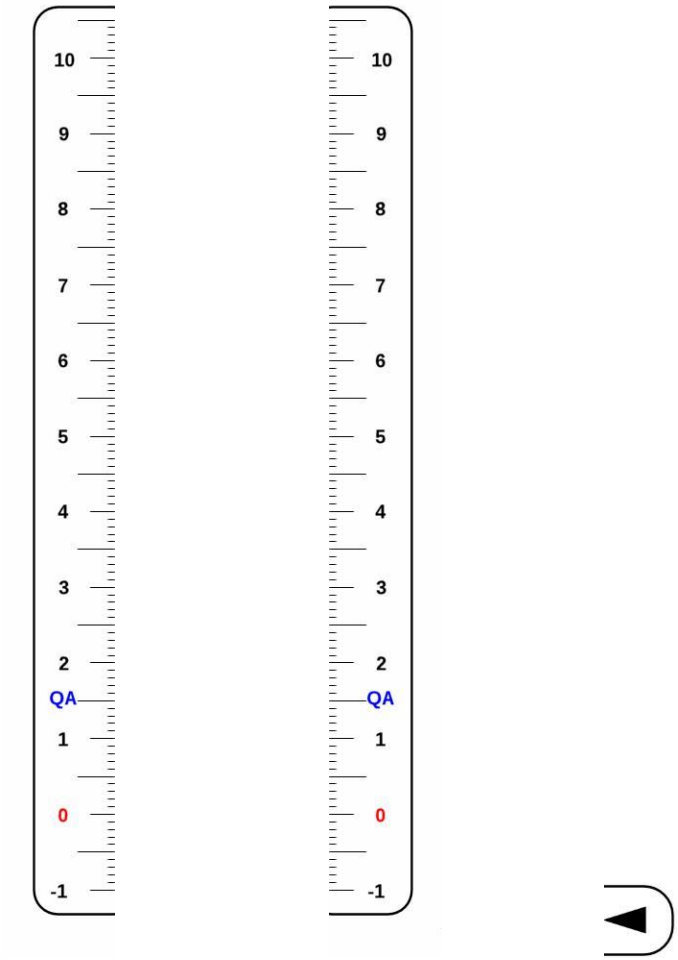
LABEL INDICATING THE HEAD COLLISION HAZARD

Position: On the scanner rotary arm

STOP LABEL

Position: On the emergency stop buttons

CHINREST DEVICE LABELS



Position: On the chinrest covers

NEWTOM
CONE BEAM 3D IMAGING

www.newtom.it

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