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.
This document cannot be modified, copied, reproduced, distributed, saved on magnetic or optical supports, or published on websites and other online services, in full or in part, without the prior written authorisation of CEFLA s.c.
The original version of this manual is in Italian.
NEWTOM™ 5G is a trade mark of CEFLA s.c.
All other products and trade names mentioned in this document are registered marks of the relevant manufacturers.

INFORMATIVE NOTE OF THE MANUFACTURER ON THE 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.
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1. INTRODUCTION TO THE MANUAL
1.1. CONTENTS

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

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

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

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

1.2. STRUCTURE

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

Chapter 1 - "INTRODUCTION TO THE MANUAL":
Provides information on the contents, the structure and the conventions used in this document.

Chapter 2 – "SAFETY-RELATED INFORMATION":
Includes information concerning the operator and patient safety and fundamental use procedures of the equipment.

Chapter 3 – "DEVICE SAFETY AND MAINTENANCE":
Contains information on the safety requirements and the device maintenance operations.

Chapter 4 – "STARTING PROCEDURES":
Provides a general description of the system and its main parts.

Chapter 5 – "PRELIMINARY OPERATIONS":
Explains the procedure for a correct device initialization.

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

In this regard, refer to chap. 3 - "DEVICE SAFETY AND MAINTENANCE" and Chap. 6 - "SCANNING".

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

2.1. APPLICABLE LAWS, JURISDICTION AND COURT OF JURISDICTION

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

2.2. SYMBOLS ON THE DEVICE

The table below provides a description of the symbols on the device labels:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Symbol" /></td>
<td>IEC 60417-5010</td>
<td>On / Off (pressure-pressure)</td>
</tr>
<tr>
<td><img src="image2" alt="Symbol" /></td>
<td>IEC 60417-5032</td>
<td>Alternating current</td>
</tr>
<tr>
<td><img src="image3" alt="Symbol" /></td>
<td>ISO 7000-0434A</td>
<td>Warning</td>
</tr>
<tr>
<td><img src="image4" alt="Symbol" /></td>
<td>ISO 7010-W001</td>
<td>General warning signal</td>
</tr>
<tr>
<td><img src="image5" alt="Symbol" /></td>
<td>IEC 60878 ISO 3864-B.3.6</td>
<td>Warning: hazardous voltage.</td>
</tr>
<tr>
<td><img src="image6" alt="Symbol" /></td>
<td>IEC 60417-5019</td>
<td>Protective ground.</td>
</tr>
<tr>
<td><img src="image7" alt="Symbol" /></td>
<td>IEC 60445</td>
<td>Connection point of the neutral wire of permanently installed equipment.</td>
</tr>
<tr>
<td><img src="image8" alt="Symbol" /></td>
<td>IEC 60445</td>
<td>Connection point of the line wire of permanently installed equipment.</td>
</tr>
<tr>
<td><img src="image9" alt="Symbol" /></td>
<td>IEC 60417-5841</td>
<td>Applied part of type B, protected against direct and indirect contacts.</td>
</tr>
<tr>
<td><img src="image10" alt="Symbol" /></td>
<td>IEC 60878-5909</td>
<td>Ionizing Radiations.</td>
</tr>
<tr>
<td><img src="image11" alt="Symbol" /></td>
<td>Directive 2012/19/EU</td>
<td>Disposal of WEEE (Waste from Electrical and Electronic Equipment)</td>
</tr>
</tbody>
</table>
# 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 4 emergency switch-off buttons. The first button is located on the operator table. The second button is on the patient table, under the table movement control console. Two other buttons are located on the sides of the scanning hole, near the signalling keyboards;

![Device emergency buttons](image)

**Figure 1: Device emergency buttons**

Switching off the device by pressing an emergency button causes the immediate interruption of the emission and all the motor-driven movement functions of the device.

**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 in which the system indicates an emergency situation.
2.5. SAFETY OF PATIENT AND OPERATOR

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

2.5.1. PATIENT POSITIONING

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

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

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

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

2.5.2. DURING THE SCANNING

During the device movement and the patient scanning process NEVER leave the system 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 system between the operator and the patient in case the operator controls the device from a protected and remote area.

2.5.3. PATIENT GOING OUT OF THE SCANNING AREA

At the end of the examination or after the emergency button has been pressed, it is possible to remove the patient table from the scanning area and allow the patient to leave.
2.5.4. PATIENT EXIT IN CASE OF FAULT / MALFUNCTION OF THE PATIENT TABLE

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

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

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

More effective behaviour for the operator:

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

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

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

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

2.6. ARTEFACTS AND SCANNING REPETITION

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

WARNING:
NewTom 5G XL is an X-ray device and, 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 5G XL 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. In case a patient has a panic reaction that requires the intervention of the operator during the examination, the operator shall wear suitable protection clothes and equipment as defined by the national and local standard.

WARNING:
Never remain near the device during the emission.

• 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 foetus. When possible, avoid radiation to a foetus.

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.

• 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 “Scanning”) and remain visible for the entire scanning duration.
2. Light indicator (LED) inside the signalling keyboards located on the sides of the device scanning hole (see figure below). 
Such light turns on only after the X-ray emission is started by pressing START on the keyboard or using a mouse (refer to chap. 6 - "Scanning") and remain visible for the entire scanning and/or emission duration.

**WARNING:**
If the emission signals are active when the X-ray emission control has not been started, if they are not active when the emission has been started or if the emission is not interrupted at the end of the pre-set time, turn off the system immediately 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 internal cover.

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

- in case of large field scanning, the occlusal plane.
- in all other fields, the central axial plane of the reconstructed volume.
WARNING:
Do not stare at the laser ray, do not look at it directly with optical instruments and avoid the direct exposure. The ray can cause permanent eye damage.

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

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

2.9. DEVICES CONNECTED TO THE CONTROL CONSOLE
Any computer, monitor, printer, mouse, keyboard and any other device connected to the device control workstation MUST be compliant with the ISO and/or IEC and/or EN and/or local standards. Moreover, the workstation must be compliant with the IEC 60950-1 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 that, during standard use, necessarily come into contact with the patient in order for the device to carry out its functions correctly, are: chinrest, bite piece and hygienic protections, headrest, handles and nose protections.

The non-applied parts that may come into contact with patient are the external covers and the chinrest structure.
3. DEVICE SAFETY AND MAINTENANCE

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

The user is responsible for a correct use of the system, 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 system must be used in rooms used for medical purposes in compliance with the recommendations of a Qualified Expert.

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

<table>
<thead>
<tr>
<th>Operating temperature:</th>
<th>from +10° to +35° (Celsius)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating humidity conditions:</td>
<td>min 10%, max 85% (non-condensing)</td>
</tr>
<tr>
<td>Altitude:</td>
<td>≤ 3000 m</td>
</tr>
<tr>
<td>Pressure:</td>
<td>710 – 1060 hPa</td>
</tr>
<tr>
<td>Pollution degree:</td>
<td>2</td>
</tr>
<tr>
<td>CTI (&quot;comparative tracking index&quot;):</td>
<td>IIIb</td>
</tr>
</tbody>
</table>

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 its installation as this may lead to dangers for people, the device 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. CHANGES TO THE DEVICE

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

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

3.3.1. 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.

3.4. DEVICE MAINTENANCE

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

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

**WARNING:**
None of the internal parts of the equipment can be repaired. Never take the covers off the equipment.
WARNING: The only part that can be repaired by the user is the device input fuse, located near the switch-on panel. The spare fuse must be compliant with the manufacturer's specifications.

WARNING: To ensure the protection against fire, replace 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 system components must be checked and replaced, if necessary, by qualified personnel.

WARNING: If the NewTom 5G XL device has not been used to scan patients for more than three months, carry out the X-ray source generation process (see “Acquisition Operations with NewTom 5G XL” annex to the “NNT User Manual” document).

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

• Preventive maintenance
Regularly check the computer-scanner interface cables and the power lead. Check the connection cable to the computer, the monitor, the keyboard, the mouse and the printer according to the manufacturer instructions.

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

• Malfunctions
In case the system 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 system checks
The following check-list indicates the recommended time intervals of the various system checks. For further information contact your local distributor.

<table>
<thead>
<tr>
<th>Manager</th>
<th>Component</th>
<th>Activity</th>
<th>Time interval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Routine test</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operator</td>
<td>Global system</td>
<td>Control with QA phantom</td>
<td>Weekly</td>
</tr>
<tr>
<td>Technical service</td>
<td>Error register</td>
<td>Check</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>All external components</td>
<td>Check for any damage</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>Emergency switch-off</td>
<td>Stop system check</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>Electric part operation</td>
<td>Check</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>Mechanical part operation</td>
<td>Check</td>
<td>12 months</td>
</tr>
</tbody>
</table>
### Other tests according to local standards

<table>
<thead>
<tr>
<th>Manager</th>
<th>Component</th>
<th>Activity</th>
<th>Time interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert in X-ray protection or other qualified person according to local standards</td>
<td>Global system</td>
<td>X-ray tests in compliance with local standards on X-ray electro-medical equipment. These tests are not to be performed by the operator or the local technical service, but could be stated by the local standards.</td>
<td>X-ray tests in compliance with local standards.</td>
</tr>
</tbody>
</table>

### 3.5. 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 microorganisms. 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.

3.5.1. HYGIENE PROCEDURES FOR PATIENT PROTECTION

Disposable hygienic protections are the main protection means against cross contamination between patients. In order to prevent the transmission of infectious diseases between patients, it is essential to always use disposable protections. Disposable protections are class I medical equipment and cannot be replaced with other protections having lower specifications.
Disposable protections must comply with standards ISO 10993-1 on biocompatibility and be approved by control bodies where required (e.g. FDA, CE).
Disposable hygienic protections must be stored in a dry and clean area and must not be exposed to direct sunlight or UV radiation.
Cover with disposable protections all components that will be in contact with dental personnel’s hands and might be contaminated by indirect contact with the mouth of the patient. In particular, pay attention while handling equipment control console, mouse and Personal Computer keyboard.
Note for Canada users: ask your dental distributor for hygienic protections with suitable size and marketed in Canada according to the local laws.
In compliance with the provisions of Health Canada, bite protections are Class I equipment supplied by authorised distributors as per MDEL database.

3.5.2. STERILISATION

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

3.6. 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.
3.7. DEVICE DISPOSAL
3.7.1. INFORMATION FOR DEVICE OWNER

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

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

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

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

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

3.7.2. 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 5G XL device, the switching on/off procedures and the control devices located on the scanner.

4.1. INTRODUCTION TO THE SYSTEM
4.1.1. INTENDED USE
The device NewTom 5G XL is a cone beam computed tomography X-ray system. It is intended for diagnostic use obtaining geometric information and radiologic density from two-dimensional and three-dimensional images of anatomic particulars and objects in the examined area.

4.1.2. INDICATIONS FOR USE
The NewTom 5G XL is a computerised tomographic system using the cone-beam technology which acquires a sequence of images of the head, including ear, nose and throat (ORL), of dental and maxillofacial unit, teeth, mandible and jaw, temporomandibular joint (ATM), other areas of the human cranium and neck with sections of the cervical rachis and of the upper and lower limbs 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 and then displays two- or three-dimensional images.

The device is managed and used by doctors, dentists, radiologists and other legally qualified professionals.

**WARNING:**
The NewTom 5G XL is able to produce panoramic reconstructions from CBCT acquisitions. This may reduce the dose if both CBCT and panoramic images are needed. However, if the system is used to simulate a panoramic image when a CBCT acquisition is not necessary, the patient could be exposed to an excessive dose of radiations.

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

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

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

**WARNING:**
When prescribing X-ray examinations to pregnant women or women that could be pregnant, bear in mind the possible radiation consequences on the foetus. Radiation on the foetus must be avoided as much as possible.
**WARNING:**
This device is especially suitable for patients with a weight higher than 11 kg and height greater than 87 cm; these parameters correspond to the ones of a child with an average age of 3 years.
The studies showed that paediatric patients can be more radiosensitive than adults (for example, the risk of cancer per unit of ionizing radiation dose is higher), therefore, it is necessary to pay special attention to the unnecessary exposure to radiation of paediatric patients.

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

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

4.1.4. FUNCTIONING
The patient is laid down on the patient table and positioned correctly inside the scanning area with 2 laser and "scout-view" image modules.

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

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 three-dimensional reconstructions. Then it is possible to work on these images to trace distances, angles, add comments etc. At the end, the new images are saved in the examination section.

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

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

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

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

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

4.3. OVERVIEW

The system consists of three main components: the scanner, the patient table accessory (version with stretcher, code 96600822) 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 on this topic, please refer to the “NNT User Manual”.

Figure 2: NewTom 5G XL complete system

NOTE:
The system cannot be extended with elements and accessories not approved by the manufacturer.
4.4. SCANNER
4.4.1. SIGNALLING KEYBOARDS AND CONTROLS

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

Figure 3: Scanner keyboards

Hereafter a brief description of each indicator / button is provided:

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

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

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

**Laser button (L):**
to be pressed to switch on/off the positioning laser. The laser switches off automatically after 60 seconds.
4.4.2. MAIN SWITCH AND INPUT PANEL

The input panel which includes the switch for system switching on or off and the relevant fuse holder is located on device LH side.

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

Figure 4: Input panel and relevant connectors

1 - Ethernet connector for workstation
2 - X-ray emission button connector (optional)
3 - CAN bus connector for workstation
4 - Device main switch
5 - Input fuse holder
6 - Power supply line cables outputs, table emergency button, external lamp and door switch (optional)
7 - Hole blanking plug for optional outputs
4.5. PATIENT TABLE WITH STRETCHER

The patient table with stretcher is the system accessory used to position the patient. The control console for table movement and the light indicators of device switching on status, X-ray emission status and any emergency button activation are located on a suitable arm. The laser module switching on button to be used during patient positioning is also located on the control console.

4.5.1. CONTROL CONSOLE OF PATIENT TABLE WITH STRETCHER

![Control console of the patient table with stretcher](image)

**Figure 5: Control console of the patient table with stretcher**

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

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

For further information on the available controls and the patient table use, please refer to the attached document "Patient Table User Procedures".
4.6. STANDARD ACCESSORIES
The device is provided with some standard accessories. The main accessories are listed below. Refer to the local distributor for the complete list of available accessories.

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

**Calibration support:**
Used as bearing surface for the QA Phantom on the patient table.

**Prosthesis support:**
Used as bearing surface for the dental prostheses on the patient table.

4.7. CABLES
The device includes the main workstation to scanner connection cables. I.e.:

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

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

4.7.1. OPTIONAL ACCESSORIES
At the moment there are no optional accessories available for the NewTom 5G XL
4.8. STARTING THE SYSTEM

Below is the description of the correct system switching on procedure:

1. Switch on the scanner through the main switch located on the 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. SYSTEM SWITCHING OFF

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

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

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

**WARNING:**
Always switch off the device at the end of the work day.
5. PRELIMINARY OPERATIONS

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

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

This chapter also describes the following function:

• Beam limiter test

The blank image must be acquired every 13 weeks, whereas it is compulsory to start the Daily check every day before starting patients' examinations.

If such operations are not performed within the set intervals, the software will block the scan function.

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

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

5.1. DAILY CHECK

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

Figure 6: NNT home screen with request of Daily check

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

Figure 7: Daily check in progress
5.2. BLANK ACQUISITION
The Blank Acquisition allows optimising the scanning performance through the acquisition of a background image. This procedure is automatically performed by the software whenever necessary.

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

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

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

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

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

From the NNT software, select “Scan” → “Invalidate Blank”.

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

WARNING:
If the test has been performed correctly but has not been completed successfully, please contact our Technical Support.
5.3. BEAM LIMITER TEST
This function allows the user checking the correct beam limit.
The beam limiter positions are pre-set by the manufacturer and cannot be changed by the user.

1. From the main bar of the NNT software, select Tools → Scanner Test.
2. From the service window bar, select Tools → Beam Limiter Test. Select the desired FOV.
3. Set the appropriate X-ray parameters according to the FOV in use (SFS, 6 mA, 15 msec, KV = 110)
4. Start an acquisition
5. Check that the beam is limited within the indicated margins
   - The green rectangle must be completely inside the acquired grey area.
   - The grey rectangle sides must pass through the drawn red line pairs.

![Figure 8: Beam limiter test](image)

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

This chapter describes the procedures to be followed for a correct positioning of the patient or of the prostheses and for a correct execution of the examination. The description of the scanning procedure is provided in the specific chapter of the “Acquisition Operations with NewTom 5G XL” annex to the “NNT User Manual” document. 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:

- [21x19] (diameter volume 21cm, height 19cm);
- [18x16];
- [15x22e] (eFOV scanning)\(^3\);
- [15x12];
- [15x5];
- [12x8];
- [10x10];
- [10x5];
- [8x8];
- [8x5];
- [6x6];
- [15x5] HiRes (High Resolution);
- [12x8] HiRes;
- [10x10] HiRes;
- [10x5] HiRes;
- [8x8] HiRes;
- [8x5] HiRes;
- [6x6] HiRes.

**WARNING:**

Use 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.

For each of the described modes\(^4\) three different scan options are available:

- Eco Scan: < image quality, < exposure time for every mode
- Regular Scan: default option for image quality, scanning and exposure time
- Enhanced Scan: > image quality, > exposure time for every mode

**WARNING:**

For children it is recommended to use the lowest-dose and fastest scanning mode available: ECO SCAN.

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

![Figure 9: "Scan Manager" panel of the NNT software](image)

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\(^3\) FOV available only in case of software option enabled

\(^4\) "Enhanced Scan" option not available in case of eFOV scan
6.1. SCANNING A PATIENT

6.1.1. PREPARING THE PATIENT

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

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

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

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

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

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

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

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

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

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

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

6.1.2. POSITIONING THE PATIENT AND STARTING THE SCANNING

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.

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

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

**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:**

During patient table movement, pay attention to avoid collisions with objects and/or people.
NOTE:
Pay attention not to excessively load the patient table parts. The patient table stands patients with a maximum weight of 160Kg (plus 15Kg of accessories). Below is the detail of the distribution of the maximum allowed loads:

Patient table with stretcher
1) Maximum load per area

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

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

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

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

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

1) Upon device switching on, the patient table can be moved in the default condition (aided upward movement position).
Make sure the stretcher is completely removed from the gantry and locked with the suitable handle on the table control console side.

Then press key P2 of table control console.

2) Have the patient sit, with the nape on the headrest cushion.
3) Move the patient table to examination preparation position pressing key P1.

Figure 11: Patient table in examination preparation position

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

Figure 12: Patient table with fitted stretcher
5) Make sure the patient remains in a correct position and remind him not to gnash the teeth and swallow. Also remind the patient not to move during the positioning phase.

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

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

8) At the end of scanning, unlock the stretcher, remove the patient from the gantry by moving the stretcher outwards, and then lock the stretcher again.
9) Then press key P2 to bring the patient back to the initial position (aided upward movement position) and let the patient exit the room.
6.2. SCANNING A PROSTHESIS
6.2.1. PRELIMINARY OPERATIONS
Following is a description of the operations to be performed to position and centre the prosthesis inside the scanning area. Perform these operations when prompted by the software.
For further information on the patient table use, please refer to the attached document "Patient Table User Procedures"

6.2.2. POSITIONING THE PROSTHESIS WITH THE PATIENT TABLE WITH STRETCHER
1) Make sure the stretcher is completely removed from the gantry and locked with the suitable handle on the table control console side.

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

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

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

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

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

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

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

9) Position back in place the headrest cushion on the carbon fibre stretcher of the patient table.
7. QUALITY CONTROL
The quality control consists in the execution of the standard examination on a suitable phantom, through an automatic procedure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7.2. IMAGE EXAMPLES
Following are some examples of images acquired during the phantom analysis:

![Lateral view.](image)

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

<table>
<thead>
<tr>
<th>Scanning system</th>
<th>Single rotation with volumetric acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scanning beam</strong></td>
<td><strong>(cone beam technology)</strong></td>
</tr>
<tr>
<td><strong>Mode</strong></td>
<td><strong>Scanning time /</strong></td>
</tr>
<tr>
<td><strong>FOVs CB3D</strong></td>
<td><strong>Emission time</strong></td>
</tr>
<tr>
<td></td>
<td>18÷36 s / 0.9÷10.4 s</td>
</tr>
<tr>
<td><strong>CineX</strong></td>
<td>1÷20s at 20fps / 0.2÷4s</td>
</tr>
<tr>
<td><strong>Ray2D</strong></td>
<td>21÷36s at 15fps / 3.15÷5.4s</td>
</tr>
<tr>
<td><strong>Sampling angle</strong></td>
<td>0.064÷3.2 s / 0.01÷0.5 s</td>
</tr>
<tr>
<td><strong>360°</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Patient centring

- **Fixed position**
- **Positioning laser**

### Analysed anatomic volume

- **Cylinder**
- **Standard Resolution:**
  - \((Ø\text{max} \times H\text{max}) \text{ [cm x cm]}\)
  - [21x19]
  - [18x16]
  - [15x22e] (eFOV)
  - [15x12]
  - [15x5]
  - [12x8]
  - [10x10]
  - [10x5]
  - [8x8]
  - [8x5]
  - [6x6]
- **High Resolution:**
  - \((Ø\text{max} \times H\text{max}) \text{ [cm x cm]}\)
  - [15x5] HiRes
  - [12x8] HiRes
  - [10x10] HiRes
  - [10x5] HiRes
  - [8x8] HiRes
  - [8x5] HiRes
  - [6x6] HiRes

### Dimensions

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Scanner</th>
<th>Patient table with stretcher</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Width</strong></td>
<td>1750 mm</td>
<td><strong>Length (max)</strong> 3600 mm</td>
</tr>
<tr>
<td><strong>Depth</strong></td>
<td>850 mm</td>
<td><strong>Width (max)</strong> 840 mm</td>
</tr>
<tr>
<td><strong>Height</strong></td>
<td>1780 mm</td>
<td><strong>Height (max)</strong> 900 mm</td>
</tr>
<tr>
<td><strong>Gantry opening</strong></td>
<td>580 mm</td>
<td><strong>Load (max)</strong> 175Kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(160Kg patient + 15Kg accessories)</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>660 Kg</td>
<td>(scanner + patient table with stretcher)</td>
</tr>
</tbody>
</table>
### Detector

<table>
<thead>
<tr>
<th>Pixels</th>
<th>1560 x 1440</th>
<th>Pixels</th>
</tr>
</thead>
<tbody>
<tr>
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<td>mm</td>
</tr>
<tr>
<td>Pixel depth</td>
<td>16</td>
<td>bit</td>
</tr>
<tr>
<td>S/N</td>
<td>9.2 – 14.2 (standard resolution) 17.1 – 21.3 (HiRes)</td>
<td>dB</td>
</tr>
<tr>
<td>Frame rate Max</td>
<td>30</td>
<td>F/s</td>
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### X-ray image scout view

#### [21x19]

<table>
<thead>
<tr>
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<tr>
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</table>

#### [18x16]

<table>
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<tr>
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<th>650 x 666</th>
<th>Pixels</th>
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<td>16</td>
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<tr>
<td>Pixel Size</td>
<td>0.368 x 0.368</td>
<td>mm</td>
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</table>

#### [15x22e]

<table>
<thead>
<tr>
<th>Image pixels</th>
<th>2 x (590 x 500)</th>
<th>Pixels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pixel depth</td>
<td>16</td>
<td>no.</td>
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<tr>
<td>Pixel Size</td>
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#### [15x12]

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<th>590 x 500</th>
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</tr>
<tr>
<td>Pixel Size</td>
<td>0.368 x 0.368</td>
<td>mm</td>
</tr>
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#### [15x5]

<table>
<thead>
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<th>590 x 208</th>
<th>Pixels</th>
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<td>Pixel Size</td>
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<td>mm</td>
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<td>Resolution</td>
<td>Image pixels</td>
<td>Pixel depth</td>
</tr>
<tr>
<td>------------</td>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>12x8</td>
<td>476 x 326</td>
<td>16</td>
</tr>
<tr>
<td>10x10</td>
<td>400 x 416</td>
<td>16</td>
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<td>10x5</td>
<td>400 x 208</td>
<td>16</td>
</tr>
<tr>
<td>8x8</td>
<td>320 x 326</td>
<td>16</td>
</tr>
<tr>
<td>8x5</td>
<td>320 x 208</td>
<td>16</td>
</tr>
<tr>
<td>6x6</td>
<td>234 x 246</td>
<td>16</td>
</tr>
<tr>
<td>15x5 HiRes</td>
<td>1180 x 416</td>
<td>16</td>
</tr>
<tr>
<td>Resolution</td>
<td>Image Pixels</td>
<td>Pixel Depth</td>
</tr>
<tr>
<td>------------</td>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>12x8 HiRes</td>
<td>952 x 652</td>
<td>16</td>
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<tr>
<td>10x10 HiRes</td>
<td>800 x 832</td>
<td>16</td>
</tr>
<tr>
<td>10x5 HiRes</td>
<td>800 x 416</td>
<td>16</td>
</tr>
<tr>
<td>8x8 HiRes</td>
<td>640 x 652</td>
<td>16</td>
</tr>
<tr>
<td>8x5 HiRes</td>
<td>640 x 416</td>
<td>16</td>
</tr>
<tr>
<td>6x6 HiRes</td>
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### Reconstructed volume

#### [21x19]

<table>
<thead>
<tr>
<th>Shape</th>
<th>Cylinder</th>
<th>Cube</th>
<th>Cube</th>
<th>//</th>
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<tbody>
<tr>
<td>Reconstructed Volume Size</td>
<td>Ø210 x H190</td>
<td>E 168</td>
<td>E 134</td>
<td>mm</td>
</tr>
<tr>
<td>Voxel Size</td>
<td>0,300</td>
<td>0,250</td>
<td>0,200</td>
<td>mm</td>
</tr>
<tr>
<td>Image pixels</td>
<td>704 x 704</td>
<td>672 x 672</td>
<td>672 x 672</td>
<td>Pixels</td>
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<tr>
<td>Pixel depth</td>
<td>16</td>
<td></td>
<td></td>
<td>bit</td>
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#### [18x16]

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Reconstructed Volume Size</td>
<td>Ø180 x H160</td>
<td>E 134</td>
</tr>
<tr>
<td>Voxel Size</td>
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<td>250</td>
</tr>
<tr>
<td>Image pixels</td>
<td>610 x 610</td>
<td>732 x 732</td>
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<tr>
<td>Pixel depth</td>
<td>16</td>
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</table>

#### [15x22]e

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Reconstructed Volume Size</td>
<td>Ø150 x H220</td>
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<tr>
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<td>Image pixels</td>
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<tr>
<td>Pixel depth</td>
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#### [15x12]

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Reconstructed Volume Size</td>
<td>Ø150 x H120</td>
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<td>Voxel Size</td>
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<tr>
<td>Image pixels</td>
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<td>614 x 614</td>
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<tr>
<td>Pixel depth</td>
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</table>
### [15x5]

<table>
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<tbody>
<tr>
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<td>mm</td>
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<td>0.250</td>
</tr>
<tr>
<td>Image pixels</td>
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<td>612 x 612</td>
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<tr>
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<td>16</td>
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### [12x8]

<table>
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<tbody>
<tr>
<td>Reconstructed Volume Size</td>
<td>Ø120 x H80</td>
<td>mm</td>
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<td>Voxel Size</td>
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<td>0.250</td>
</tr>
<tr>
<td>Image pixels</td>
<td>410 x 410</td>
<td>492 x 492</td>
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<tr>
<td>Pixel depth</td>
<td>16</td>
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### [10x10]

<table>
<thead>
<tr>
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<tbody>
<tr>
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<td>mm</td>
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<tr>
<td>Image pixels</td>
<td>344 x 344</td>
<td>412 x 412</td>
</tr>
<tr>
<td>Pixel depth</td>
<td>16</td>
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### [10x5]

<table>
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<tr>
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<tbody>
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<td>mm</td>
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<td>344 x 344</td>
<td>412 x 412</td>
</tr>
<tr>
<td>Pixel depth</td>
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<td>Cylinder</td>
<td>Cylinder</td>
</tr>
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<tr>
<td>Reconstructed Volume Size</td>
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<th>Cylinder</th>
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<td>Ø80 x H50</td>
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<td>Voxel Size</td>
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### HiRes 12x8

<table>
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<th>Cuboid</th>
<th>Cube</th>
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</thead>
<tbody>
<tr>
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<td>Ø120 x H80</td>
<td>E87 x H80</td>
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</tr>
<tr>
<td>Voxel Size</td>
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<td>0.125</td>
<td>0.100 mm</td>
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</tr>
<tr>
<td>Image pixels</td>
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<td>Pixel depth</td>
<td>16</td>
<td></td>
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<td>bit</td>
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### HiRes 10x10

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<tbody>
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<td>Ø100 x H100</td>
<td>E84</td>
<td>E67 mm</td>
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<td>0.100 mm</td>
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### HiRes 10x5

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<td>E80 x H50</td>
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### HiRes 8x8

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</tr>
</thead>
<tbody>
<tr>
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<td>Ø80 x H80</td>
<td>E67 mm</td>
<td></td>
</tr>
<tr>
<td>Voxel Size</td>
<td>0.150</td>
<td>0.125</td>
<td>0.100 mm</td>
</tr>
<tr>
<td>Image pixels</td>
<td>552 x 552</td>
<td>662 x 662</td>
<td>672 x 672 Pixels</td>
</tr>
<tr>
<td>Pixel depth</td>
<td>16</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### [8x5]|HiRes

<table>
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</tr>
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<td>Ø80 x H50</td>
<td>mm</td>
</tr>
<tr>
<td>Voxel Size</td>
<td>0,150</td>
<td>0,125</td>
</tr>
<tr>
<td>Image pixels</td>
<td>552 x 552</td>
<td>662 x 662</td>
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### [6x6]|HiRes

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<td>492 x 492</td>
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X-ray parameters

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

<table>
<thead>
<tr>
<th>Caratteristiche - Specifications - Spécifications</th>
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<tbody>
<tr>
<td>Macchie focali</td>
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<tr>
<td>Foyer</td>
</tr>
<tr>
<td>Velocità di rotazione dell’anodo</td>
</tr>
<tr>
<td>Vitesse de l’anode</td>
</tr>
<tr>
<td>Potenza anodica nominale</td>
</tr>
<tr>
<td>Puisance anodique nominale</td>
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<tr>
<td>Diametro anodico</td>
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<td>Diamètre de l’anode</td>
</tr>
<tr>
<td>Materiale anodico</td>
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<td>Angolo anodico</td>
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<tr>
<td>Campo di radiazione</td>
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<td>Champ de rayonnement</td>
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<td>Filtrazione inerente</td>
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<td>Filtration inhérente</td>
</tr>
<tr>
<td>Capacità termica anodica</td>
</tr>
<tr>
<td>Chaleur maximale accumulée dans l’anode</td>
</tr>
<tr>
<td>Dissipazione termica continua massima</td>
</tr>
<tr>
<td>Dissipation thermique continue maximale</td>
</tr>
<tr>
<td>Alta tensione nominale</td>
</tr>
<tr>
<td>Haute tension nominale</td>
</tr>
<tr>
<td>Massima corrente di filamento</td>
</tr>
<tr>
<td>Courant dans le filament max.</td>
</tr>
</tbody>
</table>

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 = 75 W = % della capacità termica anodica
Equivalent anode input power = % of maximum anode heat content
Puisance anodique d’équilibre thermique = 48%
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

0.3 - 3 - 3000 min⁻¹

- 50 kV
- 60 kV
- 70 kV
- 80 kV
- 90 kV
- 100 kV
- 110 kV
- 120 kV
- 130 kV

Tempo di esposizione - Time - Temps (sec)

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

0.6 - 3 - 3000 min⁻¹

- 50 kV
- 60 kV
- 70 kV
- 80 kV
- 90 kV
- 100 kV
- 110 kV
- 120 kV
- 130 kV

Tempo di esposizione - Time - Temps (sec)
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

■ 0.3 - 3 - 10000 min⁻¹

■ 0.6 - 3 - 10000 min⁻¹
### Make
IMD s.r.l.

### Model
HF1 R

### X-ray tube
IAE RTM 30 HS 0.3/0.6 (cod. XRM.11.X51.001 / IRM.11.280.001)

### Classification (IEC 60-601)
Class I Type B

### PHYSICAL DATA

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheath material</td>
<td>Aluminium</td>
</tr>
<tr>
<td>Heat capacity</td>
<td>550 kJ</td>
</tr>
<tr>
<td>Maximum continuous thermal dissipation</td>
<td>60 W at 110kV, 3.6 mA, 10 ms, 15 FPS</td>
</tr>
<tr>
<td>Maximum temperature</td>
<td>60°</td>
</tr>
<tr>
<td>Minimum inherent filtration at 70 kV</td>
<td>1.4 mm Al</td>
</tr>
<tr>
<td>Oil volume compensation</td>
<td>410 cu. cm rubber chamber</td>
</tr>
<tr>
<td>Dimensions</td>
<td>325 x 145 x 215</td>
</tr>
<tr>
<td>Weight</td>
<td>19.5 kg</td>
</tr>
</tbody>
</table>

### ELECTRICAL DATA

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum output voltage</td>
<td>120 kV</td>
</tr>
<tr>
<td>Cathode-ground</td>
<td>60 kV</td>
</tr>
<tr>
<td>Anode-ground</td>
<td>60 kV</td>
</tr>
<tr>
<td>Maximum anode current at 110 kV</td>
<td>32 mA</td>
</tr>
<tr>
<td>Maximum voltage at the tube at 32 mA</td>
<td>110 kV</td>
</tr>
<tr>
<td>Maximum electric power</td>
<td>3.5 kW</td>
</tr>
<tr>
<td>Maximum power ripple</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>High voltage increase time at maximum power</td>
<td>&lt;0.5 ms</td>
</tr>
</tbody>
</table>

### COOLING CURVE

*Cooling curve diagram*

### Rotor
HF1R - Startup 230Vac / 0.8s / 10° - Running 60Vac / 2A

### Anode nominal rpm
3000 rpm / 10000 rpm
### X-ray generator-tube-sheath assembly

<table>
<thead>
<tr>
<th><strong>Model</strong></th>
<th>HF1 R</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>X-ray tube</strong></td>
<td>IAE RTM 30 HS 0.3/0.6</td>
</tr>
<tr>
<td><strong>Focus - detector distance</strong></td>
<td>970 mm</td>
</tr>
<tr>
<td><strong>Minimum focus-skin distance</strong></td>
<td>150 mm</td>
</tr>
<tr>
<td><strong>Total filtration</strong></td>
<td>1.4 mm Al (Inherent filtration) + 9.5 mm Al (Supplementary filtration)</td>
</tr>
<tr>
<td><strong>Conical beam maximum dimension</strong></td>
<td>265 mm x 287 mm (detector area)</td>
</tr>
<tr>
<td><strong>Radiation reproducibility</strong></td>
<td>Δ &lt; 10%</td>
</tr>
<tr>
<td><strong>Tube voltage precision</strong></td>
<td>&lt; 10%</td>
</tr>
<tr>
<td><strong>Tube current precision</strong></td>
<td>&lt; 20%</td>
</tr>
<tr>
<td><strong>Radiation linearity</strong></td>
<td>&lt; 20%</td>
</tr>
<tr>
<td><strong>Emission time accuracy</strong></td>
<td>&lt; 10% + 1 ms</td>
</tr>
<tr>
<td><strong>mAs accuracy</strong></td>
<td>&lt; 10% + 0.2 mAs</td>
</tr>
</tbody>
</table>

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

### INVERTER

<table>
<thead>
<tr>
<th><strong>Make</strong></th>
<th>IMD s.r.l.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model</strong></td>
<td>HF1 3.5kW / HF1 3.5kW PLUS</td>
</tr>
</tbody>
</table>

#### INPUTS

<table>
<thead>
<tr>
<th><strong>Maximum power</strong></th>
<th>3.5 kW</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Power supply</strong></td>
<td>230 V~ (± 10%)</td>
</tr>
<tr>
<td><strong>Wave shape</strong></td>
<td>Sinusoidal 50/60 Hz</td>
</tr>
<tr>
<td><strong>Maximum current</strong></td>
<td>16 A</td>
</tr>
<tr>
<td><strong>Power supply apparent resistance</strong></td>
<td>0.35 ohm</td>
</tr>
</tbody>
</table>

#### OUTPUTS

<table>
<thead>
<tr>
<th><strong>Peak voltage</strong></th>
<th>350 Vpk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maximum peak current</strong></td>
<td>120 Apk Max.</td>
</tr>
<tr>
<td><strong>Wave shape</strong></td>
<td>Sinusoidal 20 kHz</td>
</tr>
</tbody>
</table>

#### PHYSICAL DATA

<table>
<thead>
<tr>
<th><strong>Dimensions</strong></th>
<th>160 x 280 x 235 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight</strong></td>
<td>7 kg</td>
</tr>
</tbody>
</table>
Dose statement
Refer to the attached document “Dose statement 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.

<table>
<thead>
<tr>
<th>Laser</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Output power</td>
<td>0.9 mW</td>
</tr>
<tr>
<td>Wave length</td>
<td>635 nm</td>
</tr>
<tr>
<td>Beam divergence</td>
<td>70°</td>
</tr>
<tr>
<td>Pulse length</td>
<td>Continuous wave</td>
</tr>
<tr>
<td>Classification</td>
<td>Class 1</td>
</tr>
</tbody>
</table>
### Other information

| Absorbed power | 100 V ~ (± 10%) / 115 V ~ (± 10%)  
|                | 50/60 Hz (± 1%)  
|                | 15 A (during emission)  
|                | 1.7 A (in stand-by mode)  
| 200 V ~ (± 10%)  
| 50/60 Hz (± 1%)  
| 12.5 A (during emission)  
| 1.2 A (in stand-by mode)  
| 220 V ~ (± 10%) / 230 V ~ (± 10%)  
| 50/60 Hz (± 1%)  
| 10 A (during emission)  
| 1.2 A (in stand-by mode)  
| 240 V ~ (± 10%)  
| 50/60 Hz (± 1%)  
| 8 A (during emission)  
| 1.1 A (in stand-by mode)  |

**Use temperature**  
+10 ± +35 °C  

**Use humidity**  
10% ± 85 % (non-condensing)  

**Use altitude:**  
≤ 3000m  

**Overvoltage type:**  
II  

**Pollution degree:**  
2  

**Transport and storage temperature**  
-20 ± +70 °C  

**Transport and storage humidity**  
10% ± 85 % (non-condensing)

### Electromagnetic compatibility

<table>
<thead>
<tr>
<th>Clause</th>
<th>6.8.3.201 Technical Description - Tab 201 Guidance and manufacturer’s declaration - electromagnetic emissions - for all equipment and systems</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TABLE: Guidance and manufacturer’s declaration - electromagnetic emissions</strong></td>
<td>The NewTom 5G XL device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom 5G XL device must ensure that is used in such environment.</td>
</tr>
<tr>
<td><strong>Emission test</strong></td>
<td><strong>Conformity</strong></td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Compliant</td>
</tr>
</tbody>
</table>
The NewTom 5G XL device is designed to operate in the electromagnetic environment specified below. The customer or user of the NewTom 5G XL device must ensure that it is used in such environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>Test level IEC 60601</th>
<th>Conformity level</th>
<th>Electromagnetic environment - guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 6 kV by contact</td>
<td>6 kV by contact</td>
<td>Floors must be made of wood, concrete or ceramic. If floors are covered with synthetic material, the relevant humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>±8 kV in air</td>
<td>8 kV in air</td>
<td></td>
</tr>
<tr>
<td>Transients/fast electric trains</td>
<td>±2 kV for power supply lines</td>
<td>2 kV</td>
<td>The network voltage quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>±1 kV for input/output lines</td>
<td>1 kV</td>
<td></td>
</tr>
<tr>
<td>Over-voltage</td>
<td>±1 kV differential mode</td>
<td>1kV</td>
<td>The network voltage quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>±2 kV common mode</td>
<td>2kV</td>
<td></td>
</tr>
<tr>
<td>Voltage drops, short blackout or voltage variations on the input supply lines</td>
<td>&lt;5% Ut (&gt;95% drop in Ut) per 0.5 cycles</td>
<td>Compliant</td>
<td>The network voltage quality should be that of a typical commercial or hospital environment. If the NewTom 5G XL device user requires a continuous operation also in case of blackout, it is recommended to power the NewTom 5G XL with uninterruptible power supply (UPS) or batteries.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>40% Ut (60% drop in Ut) per 5 cycles</td>
<td>Compliant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% Ut (30% drop in Ut) per 25 cycles</td>
<td>Compliant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5% Ut (&gt;95% drop in Ut) per 5 sec</td>
<td>Function interruption</td>
<td></td>
</tr>
<tr>
<td>Magnetic field at network frequency (50/60 Hz)</td>
<td>3 A/m</td>
<td>Compliant</td>
<td>The magnetic fields at network frequency should feature levels typical of a standard commercial or hospital environment.</td>
</tr>
</tbody>
</table>
### 6.8.3.201 Technical Description - Tab 201 Guidance and manufacturer’s declaration - electromagnetic emissions - for all equipment and systems

**TABLE: Guidance and manufacturer’s declaration - electromagnetic emissions**

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>Test level IEC 60601</th>
<th>Conformity level</th>
<th>Electromagnetic environment - guide</th>
</tr>
</thead>
</table>
| Conducted RF  | 3 Vrms from 150 kHz to 80 MHz | 3 Vrms | The RF communication devices (portable and mobile) to be used near the NewTom 5G XL device, including cables, should be located at least at the recommended distance calculated with the equation applicable to the transmitter frequency. Recommended distance: 
\[
d = 1.2 \times P
\]
| | **IEC 61000-4-6** | **IEC 61000-4-3** | 3 V/m from 80 MHz to 2.5 GHz | d = 1.2 * P from 80 MHz to 800 MHz  
d = 2.3 * P from 800 MHz to 2.5 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 RF 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   | 3 V/m from 80 MHz to 2.5 GHz | 3 V/m | |
| IEC 61000-4-3 |                                     |       | |

**Notes:**

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

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

**The field intensity in the frequency interval from 150 kHz to 80 MHz should be lower than 3 V/m**
The NewTom 5G XL device is designed to operate in the electromagnetic environment with control of the RF irradiated disturbances. The customer or the operator of the NewTom 5G XL device could help in preventing electromagnetic interferences ensuring a minimum distance between the RF mobile and portable communication devices and the NewTom 5G XL device as indicated below, in relation to the maximum output power of the radio-communication equipment.

<table>
<thead>
<tr>
<th>Specified maximum output power of the transmitter, W</th>
<th>Distance at the transmitter frequency, m</th>
</tr>
</thead>
<tbody>
<tr>
<td>from 150 kHz to 80 MHz d=</td>
<td>from 80 MHz to 800 MHz d=</td>
</tr>
<tr>
<td>0.001</td>
<td>0.037</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>37.9</td>
</tr>
<tr>
<td>100</td>
<td>120</td>
</tr>
<tr>
<td>from 800 MHz to 2.5 GHz d=</td>
<td></td>
</tr>
<tr>
<td>0.072</td>
<td>0.72</td>
</tr>
<tr>
<td>2.3</td>
<td>7.27</td>
</tr>
<tr>
<td>23</td>
<td>23</td>
</tr>
</tbody>
</table>

For transmitters specified for a maximum output power not indicated above, the recommended distance in meters (m) can be calculated using the equation applicable to the transmitter frequency. Where P is the maximum nominal output power of the transmitter in Watt (W) according to the transmitter manufacturer.

Notes:
(3) At 80 MHz and 800 MHz 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.

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 5G XL device has been manufactured in compliance with the IEC standards for the safety of medical electrical equipment, and particularly with the following standards:

- IEC 62304:2006 (1st Ed.) - Medical device software - Software life cycle processes

<table>
<thead>
<tr>
<th>IEC 60601-1 CLASSIFICATION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Class of protection against electric shocks</td>
<td>CLASS I</td>
</tr>
<tr>
<td>Degree of protection against electric shocks</td>
<td>TYPE B</td>
</tr>
<tr>
<td>IP code (ingress protection)</td>
<td>IPX0</td>
</tr>
<tr>
<td>Use with anaesthetic mixtures</td>
<td>This equipment has not been evaluated for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide</td>
</tr>
<tr>
<td>Sterilisation and disinfection methods</td>
<td>Do not sterilise the device. (See chapter 3.5 “Cleaning and disinfecting”).</td>
</tr>
<tr>
<td>Use conditions</td>
<td>Continuous operation with intermittent load.</td>
</tr>
<tr>
<td>Operating cycle</td>
<td>15 minutes for a complete operating cycle composed as follows:</td>
</tr>
<tr>
<td></td>
<td>Patient table - movements 16% (2.20 min / 15 min)</td>
</tr>
<tr>
<td></td>
<td>Gantry - movements 14% (2 min / 15 min)</td>
</tr>
<tr>
<td></td>
<td>X-ray operating 2.9% max 26 sec / 15 min for standard resolutions 4% max 36 sec / 15 min for eFOV 4% max 36 sec / 15 min for HiRes resolutions</td>
</tr>
<tr>
<td>Intended service life</td>
<td>10 years, following the instructions for use</td>
</tr>
</tbody>
</table>
11. APPENDIX C: DEVICE LABELS

✔ **SCANNER PLATE**

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

✔ **X-RAY WARNING LABEL**

Position: On rear plastic cover, LH side of the device on the bottom
✔ MAIN SWITCH AND INPUT FUSE LABEL

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

✔ cMETus CERTIFICATION LABEL

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

✔ LASER DEVICE INFORMATION LABEL (STANDARD USE)

Position: On rear plastic cover, LH side of the device on the bottom, above the scanner plate
✔ LASER DEVICE INFORMATION LABEL (DISTANCE <40MM)

Position: Inside the "5G Bearing", near the laser modules (1 set per side)

✔ LASER DEVICE WARNING LABEL (DISTANCE <40MM)

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

✔ BEAM LIMITER GLOBAL LABEL

Position: On the "PB EXTRAFOC. SHEET 5G XL" of the beam limiter

✔ BEAM LIMITER ADDITIONAL FILTRATION LABEL

Position: On the "5G XL LASER MIRROR SHEET" of the beam limiter
✔ COVER ADDITIONAL FILTRATION LABEL

CEFLA s.c. - Italy
P/N 97465007 - Polycarbonate
0.3 mm Al @ 75kV/HVL 5.2 mm Al

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

✔ CAN BUS CONNECTOR INDICATION LABEL

Position: Rear thermoformed cover, bottom LH side, on the RH side of the CAN BUS connector

✔ RJ45 ETHERNET CONNECTOR INDICATION LABEL

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

✔ XRAY BUTTON CONNECTOR INDICATION LABEL

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

✔ HAND CRUSHING HAZARD LABEL

Position: On the device structure, in the points where there is a hand crushing hazard.
✔ **LABEL INDICATING TO REFER TO THE INSTRUCTION MANUAL**

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

✔ **LABEL ON X-RAY SOURCE**

Position: On the case of the X-ray source

✔ **INVERTER LABEL**

Position: On the inverter case

✔ **USA FEDERAL LAW LABEL**

Position: Rear thermoformed cover, bottom LH side, above the Input Fuse Main Switch Label.
NEWTOM™ is a commercial trademark of CEFLA s.c.

All other products and brand names are registered trademarks or trademarks of their respective companies.

NEWTOM™ 5G series is manufactured by:

**CEFLA s.c.**
Phone: +39 045 8202727
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владение 15, стр.3
Тел.: +7 495 980 13 50; +7 495 234 97
e-mail: sales@zenith-rs.ru
website: www.zenith-rs.ru

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