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.

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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.

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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 System overview

1.1 Introduction

The NewTom VGi consists of three main parts:

- The CB3D scanner unit;
- A control box containing most electronic circuitry;
- Main computer workstation (with monitor and necessary peripherals)

1.2 Cables

Cables are provided with NewTom VGi for connection between Computer and Scanner Unit, and between Computer and Control Box.

There are:

- 2 cables that connect the Control Box with the Computer (CANBUS and ETHERNET cables).
- 1 cable for the external emergency button
- 1 power supply cable for the Scanner Unit
- Interconnection cables between Scanner Unit and Control Box

CANBUS cable (10m, 15 or 20m / 33ft, 49ft or 66ft) used for the I/O between Computer and Scanner Unit;

ETHERNET cable cat. 5E (10m, 15 or 20m / 33ft, 49ft or 66ft) used for transmission of acquired data between Scanner Unit and Computer.

EXTERNAL EMERGENCY BUTTON cable used for emergency shut-down. This button is meant to be installed at a site easily reachable by the operator while a scan is being performed, e.g. on the table near to the computer.

A bundle of signal cables exit to the Control and connects it to the Scanner Unit.
The standard set of cables is 10m (33 ft) long. Optionally, 15m (49 ft) or 20m (66ft) can be requested when ordering the system.

For compliance with electrical safety standards, the computer must not be touchable by the patient (i.e. must be outside the “patient’s area”), hence it should be located at least 1.5m (5 ft) away from the patient, or separated by a partition wall.

The cables connecting the equipment and computer have connectors at both extremities; for this reason, make sure that the proper routing path for the cables is available. To pass through a wall a 5x5cm (2”x2”) hole is sufficient.

An approved mains power cable, 10m (33ft) long, is supplied already connected scanner unit.

On the mains connection side the cable is un-terminated but prepared for permanent connection into a terminal block with a dedicated circuit breaker before it.

It’s the responsibility of the installer, in coordination with the customer, to arrange the permanent wiring to the terminal block and dedicated circuit breaker.

**PC Workstation hardware**

The system is supplied with a PC Workstation (Windows-based PC, with high-speed 2 quad core processors and high performance VGA board).

The computer is equipped with two network adapter cards: one for general computer networking, the other specially and exclusively devoted to the exclusive connection with the Scanner Unit via the supplied Ethernet cable.

Please note that the Hard Disk with which computer is equipped is NOT intended to satisfy the needs for long term mass storage.

It is the responsibility of the user to identify and implements methods and equipment for long term mass storage and archival of patient imaging data (such as, for instance, networking to an external mass storage device, backing-up with removable external removable HDs, and/or storage on a collection of DVDs), which best fit the specific needs of his/her practice.

No office furniture is delivered with the computer hardware! A suitable accommodation needs to be available for the standard-tower-style computer (dimensions approx. 18”x 6.5”x 18”), and for the 19” flat panel monitor.

A flat surface must be available to accommodate keyboard and mouse.

The system is supplied with International-English keyboard. The user can replace it by any other style keyboard of choice.
1.3 CB3D Equipment Dimensions

The minimum footprint required for the scanner can be determined from the drawings hereunder. Minimum height is 90.3" (229.4 mm). The minimum width of passages for moving in the equipment parts at installation must be at least 28" (700 mm). The device must be installed on a flat horizontal floor.

The CB3D scanner weights approximately 600 lbs.

The unit is supported by its legs and can be free-standing.

However, when possible it is recommended - for further rigidity, stability, and safety - that the unit is also fastened to a wall via the provided brackets, with 4 bolts of a type suitable for the specific wall. See side picture for position of the mounting holes.
The maximum load that each fixation must be capable to withstand is not critical since the bolts mainly have the purpose to stabilize, but the load is mostly born by the legs.

In case of installation in an environment subject to significant vibrations, the bolts could be fit with rubber vibration-dumping pads. Rubber bumpers can also be used underneath the legs.
1.4 Control Box

The control box contains electronic circuitry and components that manage the operation of the system. The main switch to turn the system ON/OFF is located on the external left side of the box.

There is also an emergency button (red mushroom shaped), to stop and shut down the system in emergency, accessible from close to the “Patient Area”.

On the same side as the main switch there is the panel from which cables depart to the power supply, to the Scanner and to the CAN bus interface on the computer.

Connections are available to optionally hook-up a signal lamp that lights up during x-ray emission, and a safety door-switch that would shut-down x-rays if engaged.
The control box may be placed at either side of the scanner within a 2.5m (9 feet) distance. As a reference, see the following example of a typical installation.
For patient seat (i.e. patient in wheelchair) see the following reference drawing.

1.5 X-Ray Radiation Protection

The system must be installed in an environment suitable for medical purposes. NewTom VGi is a radiological device and must be used according to safety regulations stipulated by the applicable local laws and regulations.

Always carefully adhere to applicable regulations about radiation protection, and follow the directions of an accredited Radiation Protection Specialist. Only they can determine whether and what additional radiation shielding barriers may be required for each specific case.

To help that determination, a chart is provided hereunder, that reports typical measurement of scattered radiation dose (in µGy/mAs) with a (simulated) patient head. Note that one exam to a human patient typically uses less than 5 mAs.
1.6 Connection to the mains electrical power

NewTom VGi is designed and certified for permanent connection to the electric mains power line. It should NOT be connect via (detachable) power cord with plug and socket, since this might invalidate the conditions upon which certain technical certifications are based.

NewTom VGi is delivered with a 10m (33ft) long power cable already assembled and connected to the input terminals and locked with a cable strain relief.
The mains power cable (3x14 AWG, including ground) provided and pre-connected is Interpower Components Ltd Type SJT 86020620, or equivalent, and complies with the requirements of the certified safety marks CE, CSA, VDE, HAR.

NOTE:
For the Chinese Market, NewTom VGi is not delivered with power supply cable.

NewTom VGi can operate at any of the following nominal mains voltages: 100 / 115 / 200 / 215 / 230 / 240 Vac (except Chinese Market - default setting is 215 Vac).

The equipment can operate (with the rated specification) with a +/-10% tolerance range respect to the nominal mains voltage. The factory default setting is 230 Vac.

Before powering on, check the mains voltage provided, and hook up the wiring selection that best fits the average mains voltage (refer to “Service Manual” for the detailed instructions about how to perform voltage range selection).

<table>
<thead>
<tr>
<th>Voltage Range</th>
<th>Absorbed Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 V ~ (± 10%) / 215 V ~ (± 10%) / 230 V ~ (± 10%) / 240 V ~ (± 10%)</td>
<td>50/60 Hz (± 1%) 5 A max (during x-ray emission)</td>
</tr>
<tr>
<td>100 V ~ (± 10%) / 115 V ~ (± 10%)</td>
<td>50/60 Hz (± 1%) 10 A max (during X-Ray emission)</td>
</tr>
</tbody>
</table>

If UPS (Uninterruptible Power Supply) modules are used, to provide continuity against electrical power black-out, then it is necessary that the output waveform from the UPS is substantially sinusoidal.

In particular the manufacturer recommended an UPS with the follow technical data (or better):

- **Power:** 5000 VA
- **Nominal output voltage:** 220 or 230 or 240 Vac
- **Voltage distortion:** < 3% with linear load / < 6% with non-linear load
- **Output frequency:** 50/60 Hz ± 5 Hz
- **Static variation:** 1.5%
- **Dynamic variation:** ≤ 5% in 20 ms
- **Waveform:** sinusoidal, single-phase

The specific manner by which the power supply cable is connected to the mains power network may depend upon national and local regulations on safety of electrical installations. A certified electrician, skilled with local practices and regulations, has to be to advice about the specific connection manner.

In any case, it MUST be possible to disconnect (break) the electrical supply power externally to NewTom VGi.
It is recommend that the electrical power cable from NewTom VGi be connected via a dedicated local circuit breaker, preferably with maximum-load tripping action, with or without GFCI functionality (Ground Fault Circuit Interrupter), see picture merely as an example of such circuit breaker.

The maximum load (= effective current) absorbed by NewTom VGi during execution of an exam, is 10A for the 115V range, and 5A for the 230V range.

A circuit breaker based upon magneto-thermal action (the most common type) should be rated at least at the above-mentioned rating. That is also the rating for wires and (retarded-action) fuses. Note that these are effective current ratings. Like with most electrical and electronic loads, the maximum instantaneous (peak) current (for duration shorter than one mains pulse) may significantly exceed those values, e.g. at power-up (inrush current) and during x-ray emission. It is impossible to provide absolute guidelines about instantaneous (peak) current, because it depends upon the nature of the local mains power network (mains “stiffness”). If very-fast-acting devices are used (e.g. electronic breakers or UPS devices), they need to be rated higher than NewTom VGi effective rating.

NewTom VGi is delivered from the factory with mains line fuse F1 (see picture) set for 230V, i.e. T5A. In case of mains power in the 100-115V range, fuse F1 must be replaced with a T10A fuse. Spare fuses are originally delivered with NewTom VGi.

All fuses must bear the applicable quality certification marking (e.g. UL/CSA).

1.7 Choice of the device optionals

To select the favorite length of the cables and the other available device options, compile the “NewTom Installation Features” document and return it to CEFLA s.c. before the purchase order.
1.8 Shipping / Packaging

The equipment is shipped in three crates: one for the upper part of the mechanical structure, one for the Control Box, the lower part of Scanner Unit and its accessories and one for the rotating part of scanner unit.

Make sure that enough space is available to uncrate the equipment, and have easy access to the installation site.

Packaging Dimensions:

<table>
<thead>
<tr>
<th>Crate type</th>
<th>Dimensions (width x height x depth)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Column</td>
<td>1770 x 970 x 940 mm / 70.4 x 38.1 x 37 &quot;</td>
</tr>
<tr>
<td>Control Box</td>
<td>1400 x 840 x 940 mm / 55.1 x 33 x 37 &quot;</td>
</tr>
<tr>
<td>Rotating Gantry</td>
<td>960 x 890 x 620 mm / 37.7 x 35 x 24.4 &quot;</td>
</tr>
<tr>
<td>Optional Chair</td>
<td>710 x 610 x 670 mm / 28 x 24 x 26.4 &quot;</td>
</tr>
</tbody>
</table>
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NEWTOM™ VG series is manufactured by:

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

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