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.

\(^1\) 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 Target and Application Field

This manual provides information and instructions regarding the unpacking, moving, and installation operations about the NewTom VGi device - option 7FOV / 3FOV (with “VGi 7FOV” and “VGi 3FOV” are intended the NewTom VG produced from January 2011).

For more details about NewTom VGi, please refer to the “Service Manual” document.

This manual is intended for trained personnel recognized by the manufacturer of the NewTom VGi device. Prior to operating or servicing this device, this manual must be read and understood.

Keep this and other associated manuals for future reference and for new operators or qualified service personnel.
2 Unpacking and moving the equipment

2.1 Inspection and unpacking instructions

Thoroughly inspect the exterior of the crates for damages which might have occurred during shipment. Report any damage to delivering carrier and follow their instructions.

Each crate is equipped with a tilt watch indicator that turns from white to red if the package has tilted during shipment. Check the indicator before opening the crates.

WARNING:
During the process of unpacking, dismounting and remounting the equipment, Electro Static Discharges (ESD) may occur. Please refer to the “Service Manual” document for a proper protection against ESD.

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.
WARNING:
Never try to uncrate and stand up the equipment before unloading from the delivery truck.

Carefully open the crates number 1 and 2 (mechanical structure of the column and the control box), with the help of a hammer and crowbar. Remove all four-side panels.

REMOVE CAREFULLY THE SIDE LOCKING WITH WOOD SCREWS OF THE THE CRATE NUMBER 3 (ROTATING PART). REMOVE ALL THE WOOD SCREWS IN ALL FOUR-SIDE PANELS. REMOVE THE ROTATING PART OF THE SCANNER WITH OWN WOOD SUPPORT.

REBUILD THE CRATE (IT WILL BE NECESSARY TO MOUNT THE ROTATING PART WITH THE MECHANICAL STRUCTURE).

REMOVE THE PACKING LIST AND VERIFY THAT ALL THE LISTED ITEMS ARE INCLUDED IN THE CRATES.

Remove all the packing material and store the component boxes in a safe place. Carefully inspect all components inside the crate for signs of any shipping or internal damage. Do not attempt set-up, installation, or operation of any damaged system.

2.2 Disassembling and moving the equipment

Pay attention to do not scratch the coverings. Keep the screws and the washers in a safe place. Always proceed slowly and carefully while moving the materials from the unloading area to the installation site. Fast movements can damage both the scanner unit parts and the control box. Ensure the access way is as clean as possible.

Pay particularly attention while negotiating doors and corners. Always verify the capacity and size of the elevator if you plan to use one to move the equipment.

Once the equipment (scanner unit and control box) will be placed in the installation site make sure to place the console workstation 1.5 m away from the patient location (electrical safety regulations compliance).
3 Mounting the equipment

NOTE:
To conduct installation and maintenance, the NewTom VGi requires a minimum distance of 25 cm (10 inches) from the rear wall and 25 cm (10 inches) from the sidewalls.

Define the final position of the machine.
Place horizontally the upper part of the scanner unit close to the device final position.

Fix the upper part of the scanner unit to the lower one.

Properly connect the wires from the upper part to M2 terminal.

WARNING:
Wires and terminal numbering must coincide!
Fasten the earth cable from the upper part to the lower earth bar.

Properly connect the MOLEX connectors from the upper part to the lower ones.

**WARNING:**
Wires numbering must coincide!

Mount the actuator to the lower part of the scanner unit.

Fix the other end of the actuator to the upper part of the scanner unit and mount the forelocks.
After mounting the actuator, remove the block plates.

Fix through the proper screws the scanner unit base to the lower chassis part, then screw the 8 feet under the scanner base.

Lift the scanner unit up to a standing position.

Fix the Ethernet cable with a wrapper to the scanner unit lower part.
Place the iron plate on the lower part and fix together the cables, the plate and the legs with two cable tie.

Place the rotating part on the crate.
Move the crate close to the machine to fixing the rotating part to the mechanical structure using 8 M6x30 socket head screws with spring washers (4 screws on each side).

Properly connect the MOLEX connectors (1 and 4).

**WARNING:**
Wires numbering must coincide!

Properly connect the wires to M3 terminal (2).

**WARNING:**
Wires and terminal numbering must coincide!

Fasten the earth cable (3).
4 Connecting the equipment

4.1 Connecting the power supply
For connecting the power supply details refer to the “Service Manual”

4.2 Connecting the console workstation
For connecting the console workstation details refer to the “Service Manual”

4.3 Connecting the external emergency button
For connecting the external emergency details refer to the “Service Manual”

4.4 Connecting the ready state switch (optional)
For connecting the ready state switch details refer to the “Service Manual”

4.5 Connecting the external door switch (optional)
For connecting the external door switch details refer to the “Service Manual”
5 Mounting the equipment covers

1. Fix the “UPPER SLIDING COVER” with 4 M6x20 socket head screws (2 screws on each side). After that centering the laser like last paragraph.

   NOTE:
   In order to remove the cover, make sure to disconnect C30 connector and the black shield (unscrew the red faston from the connectors plate)

   ![Diagram of UPPER SLIDING COVER]

   4 M6x20 round head screws

2. Fix the “SHELF COVER” with 4 M6x20 socket head screws.

   ![Diagram of SHELF COVER]

   2 M6x20 round head screws
   2 M6x20 socket head screws
3. Move the rotating arm as shown in figure.
   Place the "UPPER ROTATING ARM PLATE" and fix it with 4 M6x20 socket head screws.

4. Place the "MOBILE BELLOWS COVER" making sure that the cables are under the cover.
   Fix it with 2 M6x20 socket head screws.
5. Place the “ROUND SHELF COVER” and making sure that the upper translating cover is embedded under the round sliding cover.

Rotate the arm until you can see the holes for the screws. Fix the cover with 4 M6x20 socket head screws.
6. Place the "ROTATING ARM COVER". Fix the cover with 4 M6x16 socket head screws. Use 4 M4x40 screws to fix in the center the lower rotating arm cover with the flat panel surface.
7. Connect the lower and upper parts of the "upright side coverings" (LOWER SIDE COVERS + UPPER SIDE COVERS) and fix them together with 2 M8x20 socket head screws and 2 M8 nuts.

8. Mount the "UPRIGHT SIDE COVERINGS" on the scanner unit chassis.

WARNING: 
Remember to not leave the wires inside the "upright side coverings".

Connect to the proper wires the lateral keypads (see the arrows designed on the connectors)

9. Stick on the keypads in proximity of the holes of the "UPRIGHT SIDE COVERINGS"
10. Mount the column spacers (10 “SHORT SPACERS” (99934522) on the back side, 8 “LONG SPACERS” (99934521) in front)
11. Fix the "upright side coverings" (LOWER RIGHT C. + UPPER RIGHT C. and LOWER LEFT C. + UPPER LEFT C.) with 10 M6x8 roundhead cap screws (rear side) and with 8 M6x8 roundhead cap screws (front side)
VGi Flex

LOWER RIGHT SIDE + UPPER RIGHT SIDE FLEX COVERS (99934721 + 99934591)

LOWER LEFT SIDE + UPPER LEFT SIDE FLEX COVERS (99934722 + 99934592)

10 M6x8 roundhead screws (rear) + 8 M6x8 (front)
12. Mount the “LONGITUDINAL COVER (97465044)” and the “VERTICAL COVER (97465045)” on the motorized head support by pushing the ball studs into the plastic couplings and fix the covers with 2 M4x10 roundhead screws.

13. Fix 2 “HANDLE BARS (99934570)” on the bottom side of the head support with 4 M4x16 flathead screws.
14. Fix the “LOWER CHIN REST PLATE (97465046)” on the UPPER PLATE with 4 M4x10 roundhead screws.

15. Fix the “MOTORIZED HEAD SUPPORT” to the scanner unit with 4 M6x50 socket head screws with 4 M6x18 washers.

   After “head support” fixing, connect C34, C35, C36, C37 connectors on the back of the machine.
16. Lift up the rotating arm to reach the maximum height.

Place the "LOWER FRONT PANEL" making sure that the lower panel is embedded under the steel appendix (joints). Fix the panel with 2 M5x20 roundhead screws.

17. Place the "LOWER SLIDING COVER" and fix it with 4 M6x20 socket head screws (see "rear side" figure).

**NOTE:**
The "lower rounded cover" must be fixed from the rear side of the machine.
LOWER SLIDING COVER
(99934329)

4 M6x20 socket head screws
18. Mount the "BELLOWS" and fix the “FIXED BELLOWS COVER” with 2 M6x12 socket head screws.

19. Fix the "BELLOWS" to the "FIXED BELLOWS COVER" and to the base of the structure with 4 M6x12 socket head screws.

**NOTE:**
*The “bellow” must be fixed from the rear side of the machine.*
20. For VGi Standard mount the scanner unit back coverings (CENTRAL BACK COVER, UPPER BACK COVER, LOWER BACK COVER) and fix them with 16 M6x20 roundhead screws (8 screws for CENTRAL BACK COVER, 4 screw for UPPER BACK COVER and LOWER BACK COVER).

VGi Standard

- CENTRAL BACK COVER (99934567) 8 M6x20 roundhead screws
- LOWER BACK COVER (99934566) 4 M6x20 roundhead screws
- UPPER BACK COVER (99934565) 4 M6x20 roundhead screws
For VGi Flex, mount the scanner unit back coverings (CENTRAL BACK COVER, UPPER BACK FLEX COVER, LOWER BACK FLEX COVER) and fix them with 16 M6x20 roundhead screws (8 screws for CENTRAL BACK COVER, 4 screw for UPPER BACK FLEX COVER and LOWER BACK FLEX COVER).
21. Mount the "DETECTOR COVER" and fix it with 2 M4x16 socket head screws (upper side). Pay attention for the joints (lower side).

22. Mount the "X-RAY GENERATOR COVER" and fix it with 3 M4x16 socket head screws (upper side). Pay attention for the joints (lower side).
23. Mount the “UPPER ROUND COVER” and fix it with 3 M6x20 socket head screws and 3 M5x12 socket head screws.

24. Fix the “REMOTE CONTROL SUPPORT (99934349)” to the HEAD SUPPORT (on the right or left side) with 2 M3x10 flathead screws and 4 M3x12 washers. After that, connect the cable of “REMOTE CONTROL” to the HEAD SUPPORT.
25. Mount the “MOBILE HEAD SUPPORT (96600784)” on the motorized head support by using the following parts:

- 2 Carbon Fiber bars (99934556) with plastic plugs (97420059)
- 1 Right bar for temples (97465051)
- 1 Left bar for temples (97465054)
- 1 Right temples support (97465048)
- 1 Left temples support (97465049)
- 1 Chin rest (97465052)
- 1 Bite (97465047) / 1 Edentulous bite (97465065)
- 1 Right lever (97465066) / 1 Left lever (97465067)
5.1 Fixing the device (optional)

The unit can be fastened to a wall via the provided brackets, with 4 bolts of a type suitable for the specific wall. See the figures for position of the mounting holes; (to fix the brackets to the machine use 4 M10x25 socket head screws with washers.

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.
Use 4 M10x25 socket head screws + 4 M10 washers

VGi

VGi Flex
5.2 Testing the equipment

Once the equipment has been installed a few tests must be performed in order to verify the system functionality before calibrating the device.

Refer to the “Service Manual” - Par. “Testing the Equipment” in order to execute the Electrical Safety Checks and other equipment tests.

5.3 Calibrating the system

For the calibration of the system during an installation refer to the “Service Manual”, Chap. “Calibration” for geometric and quality calibration.

5.4 Finishing touches

1. Clean the covers and the head support.

2. Place the “NewTom VGi” logo sticker on the machine.

3. Put the X-Ray source identification stickers on the machine and check that all the other labels are placed where recommended.

4. Empty the error log file.

5. Set the working directories with the correct paths (depends on the configuration of the system).

6. Arrange the cables that connect the machine and control box with the computer.
   Cable have to be sheltered using surface raceways or cable protectors, and should be placed away from walk areas in order to avoid people to trip over it.
At the end of the installation, please compile a copy of "Installation Report" (code 97011121) included in the setup CD, attach the QA report and store with the other registrations of the device.

ONLY FOR USA:
Upon completion of an installation, please fill out and review the manufacturer’s “Installation checklist” (code 97050873) that can be found on the Disk documentation.
www.newtom.it

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