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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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\textsuperscript{1} and software\textsuperscript{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.

\textsuperscript{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.

\textsuperscript{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

1.1 Contents

This document is an attachment of the “Service Manual” and has been designed as a guide for a correct installation of the “NewTom 5G XL” device.

Together with the “Service Manual” of the device it has to be read and fully understood prior to operate on the equipment.
2 Unpacking and moving the equipment

2.1 Scanner inspection and unpacking instructions

Thoroughly inspect the exterior of the crates for damages that 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.

![Tilt Watch Indicator Image]

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

1. Carefully open the crate with the help of a hammer and crowbar. Remove the top and all four-side panels.

![Crate Opening Image 1]

![Crate Opening Image 2]

2. Remove all the packing materials and store all the 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.
3. From the base of the crate remove the two lifting tubular bars, the two flat junctions bar and the four “T” shaped lifting screws.

4. Remove the bubble wrap protection from the scanner.

5. Remove the “Front Panel Thermoformed Carter” (97465033)
   Remove the M4x20 hex. socket screw on the left side of the Front Panel Thermoformed Carter (see following image)

   ![Diagram of removal process]

   Lower the Front Panel Thermoformed Carter (1) in order to unhook it from the top, therefore pull the panel (2) to unhook it from the right side.
6. Remove the anterior “Plastic Ring” (97465075).

Remove the self-tapping screw on the plastic ring (1), gently pull the plastic ring from the top and disconnect the keyboards and the emergency buttons (2). Once done pull the ring completely out (3).

7. Removing the “Plastic Cylinder” (97465076).

Remove the Plastic Cylinder from the inside of the gantry. Grab the cylinder from above and accompany while it get out (see photo).

8. Remove the posterior “Plastic Ring” (97465075)

Remove the self-tapping screw on the plastic ring (1) and then gently pull the plastic ring completely out (2).
9. Remove the “Anterior Thermoformed Carter” (97465031)
   Remove the 8 bolts that hold the carter (1) and then gently pull the carter completely out (2).

10. Remove the “Posterior Thermoformed Carter” (97465032)
    Remove the input plate (1), then remove the 8 bolts that hold the carter (2) and then gently pull the carter completely out (2). Pay attention to slowly pass the power cable through the carter while moving it.

11. Remove the block-chassis plate (1) from the main structure (see picture below).
12. Unlock the counterweight of the cable chain by removing the M8x80 hex screw (2) (see picture below).

13. Unscrew 4 nuts from the bottom of the crate base, then remove the 4 M10x210 hex screws from the 4 wood spacer supports, located below the holes designed for the adjustment of the device feet.

14. Place the two tubular lifting bars below the device base and verify they match with the by main structure tubular. The lifting bars include references for a correct positioning (verify they are not positioned below the electronic plate).
15. Install the front and rear junction flat bar using 4 M5 screws provided with the equipment. These bars connect the two lifting bar together, forming a rigid and solid frame.

**WARNING:**
It is very important to properly mount the two junction bars in order to stabilize the device during the lifting process.

16. Mount the four “T” shaped lifting screws on the lifting bars, and position the 4 plastic feet.

17. Slowly lift the device by equally screwing the four “T” shaped lifting screws, until the wood spacer supports can be removed.

*Be careful to do not tilt too much the equipment during the lifting process.*
18. Remove the base of the crate, paying attention to do not bang into the 4 lifting screws.

19. Slowly lower the device by equally unscrewing the 4 “T” shaped lifting screws, until it rests on the wheels. 
   **Be careful to do not tilt too much the equipment while lowering it.**

20. Remove the “T” shaped lifting screws, the plastic feet, the junction bars and the lifting tubular bars.
### 2.2 Moving the device

Once the machine rests on the wheels (without any cover mounted) it can be carefully moved to the final position.

**WARNING:**
In case the device needs to travel through a ramp, move it down sideway. Maximum admitted inclination is 10%.

In case the device needs to be lifted with the aid of a a crane, it is possible to roped it up using belt with 1000 Kg (2204 lb) capacity, secured to the front and rear side of the main structure as shown in the following picture.

Alternately, four M12 threaded holes are provided in order to mount 4 lifting rings (see following picture).
Once the device is in the final position the wheels must be replaced with the provided support feet.

Place the each foot below the corresponding M12x140 screws, then equally tighten each screw in order to lift up the device, until the wheels are free and can be removed (see following picture).

Once all the wheels have been removed lower down the equipment by equally loosing each screw until the two frontal screws responsible for the table coupling, matches with the table holes.

2.3 Patient table inspection and unpacking instructions

For unpacking, moving and preparing the patient table for the installation please refer to the provided “Patient Table Installation Manual”.
3 Mounting and connecting the equipment

3.1 Mounting the equipment

1. Mount the Posterior Thermoformed Carter (97465032)
   First, gently place the carter on the scanner by matching the holes of the carter with the spacers mounted on the structure (see details on image 1).
   Once the carter is in the correct position, fix it with by tightening n°8 6x20 TCEI bolts with M6x24 flat washers (2).

   ![Image 1](image1.png)

   **CAUTION:**
   Do not use the spacers designed for centering the posterior carter, to lift or move the device.

   Remove the surface protection film from the “Posterior Thermoformed Carter”.

2. Mount the Input Main Switch plate fixing it with four M4x20 socket caps screws (see next picture).

   ![Image 2](image2.png)

3. Mount the “Anterior Thermoformed Carter” (97465031)
   First, pass the cables of control panels and emergency button through the dedicated holes on the carter (see following picture).
Gently place the carter on the scanner by coupling it with the posterior carter previously mounted (see details on image 1).

Once the carter is in the correct position, fix it with by tightening n°8 6x20 TCEI bolts with M6x24 flat washers (2).

**CAUTION:** Do not use the spacers designed for centering the posterior carter, to lift or move the device.

Remove the surface protection film from the “Anterior Thermoformed Carter”.

4. Mount the “Posterior Plastic Ring” (97465075).

Mount the ring by aligning 4 bollhoff inserts to the main structure (1). Once ready, gently press the ring (2) to engage the inserts to the structure.

Fix the ring by tightening the M4x20 self-tapping screw located on the top and bottom side of the ring (3).

5. Mount the “Plastic Cylinder” (97465076).
Insert the Plastic Cylinder inside the gantry paying attention to do not reverse the frontal side with the rear side (the laser exit point has to be closer to the front of the scanner. See following picture).

![Image of Plastic Cylinder inside gantry](image1.jpg)

Rotate the cylinder in order to match its notches with the clutches of the plastic ring (see following images).

![Image of rotating cylinder](image2.jpg)

6. Mount the “Anterior Plastic Ring” (97465075).
   While holding the ring, connect the emergency button and control pad cables.

   **CAUTION:**
   Pay attention to do not reverse the control panel connectors (specific label are stuck on each connector).
   Once the device is turned on, “Power ON” led on the control panels must be lighted with green color.
   In case “Power ON” led is yellow, connection is reversed.

![Image of control panel connectors](image3.jpg)

Mount the ring by aligning 4 bollhoff inserts to the main structure (1). Once ready, gently press the ring (2) to engage the insert to the structure.
Fix the ring by tightening the M4x20 self-tapping screw located on the top and bottom side of the ring (3).

7. Coupling the patient table

Couple the patient table to the scanner by matching the two provided screws mounted on the front side of the scanner, with the two holes located on the rear bracket of the patient table, and fixing it with the provided nuts and washers.

Connect connectors C4F, C5F, C6M, C7F located on the front side of the scanner with the corresponding C4M, C5M, C6F, C7M connector of the patient table.

Tie the cables to the provided cable tie mount and verify they won’t interfere with the rotating frame of the scanner.

8. Mount the “Front Panel Thermoformed Carter” (97465033).

Place the carter on the patient table base, then slide it toward the top until it is hooked on the Anterior Thermoformed Carter (1), then press the right side of the carter until it is hooked (2).
Press the right side of the Front Panel Thermoformed Carter until it's hooked on the Anterior Thermoformed Carter.

Fix the plastic by tightening the M4x20 hex socket screw located on the left side of the Front Panel Thermoformed Carter.

Remove the surface protection film from the Front Panel Thermoformed Carter.
3.2 Connecting the equipment

3.2.1 Connecting the power supply

NewTom 5G XL 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 (CE, CSA, ...) are based.

NewTom 5G XL is delivered with a 10m long power cable already assembled and connected to the input terminals and locked with a cable gland (for the Chinese Market please see the note below).

The mains power cable 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 CHINESE MARKET
For the Chinese Market NewTom 5G XL is not delivered with power supply cable.
In case of, for any reason, this cable needs to be locally replaced, the replacement cable MUST be CCC (China Compulsory Certification) approved.

In case of, for any reason, this cable needs to be locally replaced, the replacement MUST comply with IEC245 & IEC227 standards, with CE, CSA, VDE, HAR safety and quality marks and with any applicable national certification, and the following directions must be followed:
The minimum section of each wire of the cable must be 2.5mm² (AWG 14), and the color of the conductors must be brown (line) / blue (neutral) / green-yellow (safety ground).
Power supply cord neutral (blue) and line phase (brown) conductors must be connected to M1 I/O Terminal as shown in the picture:

The power input cable must be packed with 3 plastic belts. About the 3 belts position, please see figure.
The two cables to terminal 3 and 5 of M1 should be packed together near end with one belt. Another two cables to terminal 1 and 3 should be packed together near end with one belt. The last belt is used for all the four cables together.

NewTom 5G XL can operate at any of the following nominal mains voltages: 100 / 115 / 200 / 220 / 230 / 240 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. For nominal mains voltage different from 230 VAC, re-adjust the internal connections accordingly (refer to “Mains AC Distribution” diagram, and to the M2 Terminal connectors connections / Toroidal Transformers TOR001 – TOR002 in the “Wiring Tables” attached document making the selection that best fits the actual average mains voltage.

The safety ground (green-yellow) conductor of the power supply cable must be secured under the bottom nut. The wire to the PE (Protection Earth) bar must be secured between the first and second nut. Refer to the the “Wiring Tables” attached document.

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. Consult a certified electrician, skilled with local practices and regulations, to define the specific connection manner.

In general, it MUST be possible to disconnect (break) the electrical supply power externally to NewTom 5G XL. Unless otherwise directed by local electrical safety regulations, or by practical considerations, we recommend that the electrical power cable from NewTom 5G XL be connected (A) via a dedicated local circuit breaker, preferably with maximum-load tripping action, with or without GFCI functionality (Ground Fault Circuit Interrupter).

Alternatively (B) the electrical power cable from NewTom 5G XL can be connected via a simple mains terminal block to a dedicated (=exclusive) line from the scanner unit, if available.

(NOTE: by dedicated line we mean a line from scanner unit the which is individually protected by an existing fuse and/or max. current breaker).
A - Circuit breaker (see picture)

The maximum load (= effective current) absorbed by NewTom during 5G XL execution of an exam, is 10A for the 115V range, 6.3A for 200V and 5A for the 230V range. Therefore, a circuit breaker based upon magneto-thermal action (the most common type) should be rated at the above-mentioned rating. That is also the rating for wires and (retarded-action) fuses. Please note, however, 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 USP devices), they need to be rated higher than NewTom 5G XL effective rating.

B - Terminal block and dedicated line from the Power ON Board

The dedicated line from the Power ON Board must be protected, breakable, and rated to carry at least the load (effective current) specified in the “Wiring Table” attached document (i.e. 15A for the 115V range, 12A for the 200V, 10A for the 230V range, 8A for the 240V range).

NewTom 5G XL is delivered from the factory with F1 mains line fuse. The fuse value depends by mains voltage where the machine will be installed. Possible fuse values are the following:

F1= T8A  for 240V mains voltage
F1= T10A for 220V / 230V mains voltage [factory default setting]
F1= T12A for 200V main voltage
F1= T15A for 100V / 115V mains voltage

If the mains voltage where the machine will be installed isn't 220V / 230V (factory default) please be careful to replace the fuse with one with correct value. Spare fuses are originally delivered with NewTom 5G XL.

All fuses must bear the applicable quality certification marking (e.g. UL/CSA).
3.2.2 Connecting the console workstation
Two cables connect the scanner unit with the console workstation:

Ethernet cable (Cat. 5E), for the transmission of the acquired images between PC and scanner unit
Connect the Ethernet cable with “Intel Gigabit CT Desktop Adapter” Ethernet port located in the back panel of computer (see the picture).

CANbus cable used for the I/O between PC and control box
Connect the CANbus cable with “Peak PCAN PCI Express” or “Kvaser PCIEcan HS” board port located in the back panel of the computer through the CAN terminator adapter (see following picture).

3.2.3 Connecting the external emergency button
The external emergency button (see picture on the side) has to be installed near the console that controls the equipment.
Connect the cable of the external emergency button with the M1 connector inside the machine.
The two wires of the cable must be connected with terminal 21 (Blue) and 23 (Gray).
Once the cable is connected fix it to the scanner unit with the cable gland. Be sure the cable is tie.

3.2.4 Connecting the Ready State Switch (optional)
A ready state switch connection is available in the machine.
The switch has to the following specifications:

\[ \text{250Vac, 4A} \quad \text{or} \quad \text{30Vdc, 4A} \]

M1 I/O Terminal provides the connection to the internal switch:

- Connect the cable with the M1 I/O Terminal inside the machine. The two wires of the cable must be connected with terminal 13 (Blue) and 15 (Gray).
Once the cable is connected fix it to the scanner unit with the cable gland. Be sure the cable is tied.

3.2.5 Connecting the X Ray Emission State (optional)
An x-ray emission state switch connection is available in the machine.

The switch has to the following specifications:

\[250\text{Vac}, 4\text{A} \quad \text{or} \quad 30\text{Vdc}, 4\text{A}\]

M1 I/O Terminal provides the connection to the internal switch:

- Connect the cable with the M1 I/O Terminal inside the machine. The two wires of the cable must be connected with terminal 9 (Blue) and 11 (Gray).

Once the cable is connected fix it to the scanner unit with the cable gland. Be sure the cable is tied.

3.2.6 Connecting the External Door switch (optional)
An external door switch can be connected with the machine. This switch inhibits the emission of the X-Ray source when the involved door is open.

The switch’s cable has to be connected with terminal 17 (Blue) and 19 (Gray) of M1 I/O Terminal.

Once the cable is connected fix it to the scanner unit with the cable gland. Be sure the cable is tied.

3.2.7 Connecting the patient table
After the Patient Table installation (for more details refer to the “Patient Table Installation Manual” document), connect C4M, C5M, C6F, C7M patient table connectors to the C4F, C5F, C6M, C7F scanner unit connectors.
3.3 Testing the equipment

3.3.1 Electrical Safety Checks
Please contact the CEFLA S.C. Technical Support for more informations about tests.

WARNING:
The electrical safety checks involve the use of dangerous tensions. It is necessary pay the maximum attention, before, during and after the tests IN ORDER TO AVOID ELECTRICAL SHOCK AND/OR TO CAUSE IRREVERSIBLE DAMAGES AT THE DEVICE

In the following table, in order to execute the electrical safety checks, the normative references and the limits of acceptability for the device are indicated:

<table>
<thead>
<tr>
<th>Protection earth resistance</th>
<th>IEC 60601-1 Ed.2 par. 18 f) IEC 60601-1 Ed.3 par. 8.6.4 a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dielectric strength</td>
<td>IEC 60601-1 Ed.2 par. 20 IEC 60601-1 Ed.3 par. 8.8.3</td>
</tr>
<tr>
<td>Leakage current</td>
<td>IEC 60601-1 Ed.2 par. 19.1, 19.2, 19.3, 19.4 IEC 60601-1 Ed.3 par. 8.7</td>
</tr>
</tbody>
</table>

3.3.2 Other tests
Once the equipment has been installed, a few basic tests need to be carried out in order to verify the system functionality before running the calibration process.

1. Turn on the scanner and the main workstation and verify the software recognize the system and connect without errors.
2. Press the “P2” button on the patient table console in order to set the table to the default position.
3. Perform a motor test
4. Perform a single acquisition in order to verify the acquisition system works properly.

3.4 Device calibration
Please refer to the “Service Manual” document.

3.5 Finishing touches
Perform the following finishing touches once the device has been calibrated:

1. Clean the covers (after the film protections have been removed)
2. Put the x-ray source identification stickers on the machine and check that all the other labels are placed where recommended.
3. Empty the error log file (refer to the “Software Manual” document)
4. Set the working directories with the correct paths (depends on the configuration of the system, please refer to the “Software Manual” document).
5. Arrange the cables that connect the machine with patient table and 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 97050874) that can be found on the Disk documentation.