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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The original version of this manual is in english.

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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 Unpacking and moving the equipment

1.1 Scanner 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.

![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.
2. Remove all the packing materials 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.

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. Removing the “Front Panel Thermoformed Carter” (97465006)

Unscrew the M4x20 hex socket screw located on the left side of the Front Panel Thermoformed Carter.

Disengage the left side of the Front Panel Thermoformed Carter by sliding it down, therefore grab the top side and pull it toward you until the right side unhooks from the Anterior Thermoformed Carter.

6. Remove the anterior “Plastic Ring” (97465003)

Unscrew the M4x20 self-tapping screw located on the bottom side of the Plastic Ring.

Unhook the Plastic Ring from the 2 top inserts, then disconnect the control panels (C8 and C9 connectors) and the emergency buttons on both left and right side of the gantry.
1 Unpacking and moving the equipment

Then unhook the 2 bottom inserts.
**Pay attention to do not damage the cables.**

7. Removing the “Plastic Cylinder” (97465007)

Remove the Plastic Cylinder by holding its top side with the palm of the hand, and sliding it out of the gantry.
*Be carefully to do not scratch the external surface of the cylinder while sliding it out.*

8. Removing the posterior “Plastic Ring” (97465003)

Unscrew the M4x20 self-tapping screw located on the bottom side of the Plastic Ring.

9. Unhook the Plastic Ring from the 4 back inserts (there are no cables connected to the posterior ring).
10. Removing the “Anterior Thermoformed Carter” (97465004)

Unscrew the 8 M6x16 hex. socket screws and 8 M6x24 washers from the Anterior Thermoformed Carter.

Pull back the control panels and emergency button cables through the dedicated holes on the Anterior Thermoformed Carter (see following picture).

Slide out the Anterior Thermoformed Carter from the 4 spacers and store in a safe place.
11. Removing the “Posterior Thermoformed Carter” (97465005)

Unscrew the 8 M6x20 hex socket screws, 8 M6x24 washers and 8 M6x18 washers from the Posterior Thermoformed Carter.

Slide out the Posterior Thermoformed Carter from the 4 spacers and store in a safe place.

12. Unscrew the M8x25 socket caps screw from the Block-chassis plate (99934481).

13. Remove the block-chassis plate by unscrewing the two M6x20 socket caps screws that hold the plate to the main structure.

14. Unlock the counterweight of the cable chain by removing the M8x80 hex screw.
15. 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.

16. 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).

**WARNING:**
It is very important that the lifting bars are correctly positioned on both the right and left side in order to ensure the device to be balanced during the lifting process.
17. 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.

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

19. 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.**
20. Remove the base of the crate, paying attention to do not bang into the 4 lifting screws.

21. Slowly lower the device by equally unscrewing the 4 “T” shaped lifting screws, until the it rest on the wheels.

   **Be careful to do not tilt too much the equipment while lowering it.**

22. Remove the “T” shaped lifting screws, the plastic feet, the junction bars and the lifting tubular bars.
1.2 Moving the equipment

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 crane, it is possible to rope 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.

Alternatively four M12 threaded holes are provided in order to mount 4 lifting rings (see following picture).
1 Unpacking and moving the equipment

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.

1.3 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”.

![Image of a M12x140 hex screw and SUPPORT FEET]
2 Mounting and connecting the equipment

2.1 Lasers setup

Please refer to the “Service Manual” document.

2.2 Mounting the equipment

1. Mounting the Posterior Thermoformed Carter (97465005)

Lean the “Posterior Thermoformed Carter” to the main structure, center it with the aid of the mounted spacers and fix it using eight M6x20 socket caps screws, eight M6x24 washers and eight M6x18 washers.

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 and four M4 washers (see next picture).

3. Mounting the “Anterior Thermoformed Carter” (97465004)

Run the control panels and emergency button cables through the dedicated holes on the *Anterior Thermoformed Carter* (see following picture).
Lean the Anterior Thermoformed Carter to the main structure, center it with the aid of the mounted spacers and fix it using eight M6x16 socket caps screws and eight M6x24 washers.

**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. Mounting the “Posterior Plastic Ring” (97465003).

Lean the Plastic Ring to the 4 Bollhoff rubber inserts and press it.
Tight the M4x20 self-tapping screw located on the bottom side of the Plastic Ring
5. Mounting the “Plastic Cylinder” (97465007).

Insert the Plastic Cylinder inside the gantry paying attention to do not reverse the frontal side with the rear side (the laser cross painted on the top of the cylinder has to be direct toward the front of the device. See following picture)

Center the Plastic Cylinder by matching its notches with the clutches of the plastic ring.


Lean the Anterior Plastic Ring to the two bottom Bollhoff inserts and connect the two control panels (connector C8 and C9) and the emergency buttons.

Lean the Anterior Plastic Ring to the two top Bollhoff inserts then press the entire ring until it's engaged.

**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.
8. Fix the “Anterior Plastic Ring” by tightening the M4x20 self-tapping screw located on the bottom side.

9. 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.
10. Mounting the “Front Panel Thermoformed Carter” (97465006).

Place the Front Panel Thermoformed Carter on the patient table base, then tilt it and sliding its left side up engage with the Anterior Thermoformed Carter.

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.
2.3 Connecting the equipment

2.3.1 Connecting the electric distribution
Please refer to the “Service Manual” document.

2.3.2 Connecting the console workstation
Please refer to the “Service Manual” document.

2.3.3 Connecting the external emergency button
Please refer to the “Service Manual” document.

2.3.4 Connecting the ready state switch
Please refer to the “Service Manual” document.

2.3.5 Connecting the x-ray emission switch
Please refer to the “Service Manual” document.

2.3.6 Connecting the external door switch
Please refer to the “Service Manual” document.

2.4 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.
2.5 Device calibration

Please refer to the “Service Manual” document.

2.6 Finish touches

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", (reported in the next page), 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 97050872) that can be found on the Disk documentation.
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