NOTES
This document is provided as a consultation manual intended for the device technicians.
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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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 hardware1 and software2 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 field application

This document is an attached of the "User Manual" document and provides information and instructions regarding the use of the HELMET accessory (cod. 96600843 / 96600846 / 96600859) associated to the NewTom 5G series Patient Table.

For more information about the use of the NewTom 5G series scanner unit, please refer to the "User Manual" documents.

For a correct use of the patient table please refer to the "Patient Table User Procedures" document.

These documents must be read and understood before you start using the NewTom 5G series.

Keep this and other associated manuals for future reference and for new operators or qualified service personnel.
2 Patient Table version (chair)

2.1 Helmet centered version (Cod. 96600846)

2.1.1 Installation

1) Remove the label for device cleaning
2) The fixing of the tool must be performed from above, by inserting the tool into the carbon support by the appropriate guide. The device remains axially free.

3) To facilitate the device fixing from P2 position, it is possible to act manually on the panel buttons by adjusting the inclination of the carbon support. For more information, please refer to the “Patient Table User Procedures”

2.1.2 Intended use

How to use:
Use with patient sitting:
To facilitate patient comfort, accompany the sliding of the system on the carbon support, during the movement with P2 button.

By lying down with reclining chair (patient lying):
if it is possible, the adjustment of the fixing system can be performed from the back of the device with the patient already lying on the support.
Adjusting the belts:
Use the holes, for the fixing of the forehead, chin or other areas. The belts have 2 different length sizes in order to accommodate various body parts.

The following figures are examples of the use in clinical application
Supplied accessories
Headrest pillow (cod. 97465039)
Velcro belts (cod. 97901516 / 97901517) or disposable belts (cod. 97901522 / 97901523)
Triangular wedges (97465040)

Use the triangular wedges for lateral head immobilization as in figure; place the wedges taking care to leave empty the area for the laser pointer.
Children
For the head positioning, move the shoulders forward until it touches the cap and use velcro belt to immobilize the forehead as shown in figure:

2.1.3 Labeling

Below are shown the visible labels on the support:

Informative label of general warning before use

![Informative label]

Equivalent filtration label

![Equivalent filtration label]

Maximum applicable load label

![Maximum applicable load label]
WARNING label of collision risk with the gantry

Cleaning device label

**WARNING:**
The intended use is the fixing of the head. The maximum applicable load is 12.5Kg centered on the cap, in accordance with IEC60601.

**WARNING:**
Do not use with patients that are not centered on the support or not in balance.

**WARNING:**
Be careful during the use; during the movements, the operator must preside at sight.
Do not use the device by remote handling system as it may cause accidental collisions.

**WARNING:**
Do not perform movements of insertion or removal the patient table from the gantry with the device partially inserted on the carbon support as this could cause accidental collisions (see figure).
2.1.4 Biocompatibility and cleaning

The device cap is made of polycarbonate, biocompatible material according to ISO 10993
Velcro belts are made of biocompatible material according to ISO 10993

Use only neutral non-abrasive and non-aggressive products (no solvent-based, acetone, alcohol, etc.) to clean

Do not sterilize on autoclave.
2.2 Helmet decentralized ENT version (Cod. 96600843)

2.2.1 Installation

As reported above

2.2.2 Intended use

As reported above

Specific use for ENT:
The decentralized system allows to extend the field of use with patient table, to frame of small FOVs for ENT applications.
The displacement of the symmetry axis is 30mm respect centered version

2.2.3 Labeling

As reported above

2.2.4 Biocompatibility and cleaning

As reported above
3 Patient table with stretcher version

3.1 Helmet stretcher version (Cod. 96600859)

3.1.1 Installation

1) Remove the label for device cleaning
2) The fixing of the tool must be made on the narrow end of the stretcher, by placing the base on the carbon support by means of the appropriate guide.

**WARNING:**
If necessary remove and shorten the velcro present at the sides of the stretcher to allow the insertion of the support.

**WARNING:**
The base of the device is to be fixed at the end of the stretcher for not overly restrict the allowed FOV in case of head exams.
3.1.2 Intended use

How to use:
Patient lying down, as shown, with the support surmounted to the stretcher and shoulders resting on the cap.

Adjusting the belts:
As reported above

Supplied accessories:
As reported above

Children:
As reported above

3.1.3 Labeling

As reported above

3.1.4 Biocompatibility and cleaning

As reported above
3.1.5 Disable anticollision system

The device is equipped with an anticollision system that detects the position of the stretcher respect the gantry of the machine, by preventing that the latter not strike the covers during the movements, both from console and from remote (see figure)

It is possible in the exceptional cases, but not recommended, disable the anticollision system, only from the console and under the close supervision of the operator.

It is necessary to be careful not to accidentally bump the casing of the machine.

Please refer to the “Patient Table User Procedures” document, for enabling / disabling the anticollision functionality.

WARNING:
The intended use is the fixing of the head. The maximum applicable load is 12.5Kg centered on the cap, in accordance with IEC60601.

WARNING:
Do not use with patients that are not centered on the support or not in balance.
WARNING:
Be careful during the use; during the movements, the operator must preside at sight.
Do not use the device by remote handling system as it may cause accidental collisions.

WARNING:
Be careful during the movements of the stretcher into the gantry with the anticollision system not activated.
www.newtom.it

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