CE
0051

97055088
Rev. 01
2020-11

OPTIONAL COMPONENTS AND PACKAGES NewTom 7G

NewTom 7G

Annex to the User Manual code 97055085

EN

NOTES

This document is provided as a means of consultation for the user of the device.

CEFLA s.c. follows a policy of continuous development and updating of the product for which it reserves the right to change the contents of this manual without prior notice.

The original version of this manual is written in Italian.

MANUFACTURER'S NOTE ON MEDICAL DEVICES

The medical device referred to in this manual, consisting of a scanning unit and a control, display and calculation unit (Main Workstation) -as delivered and configured by the technical production and assistance staff- is a radiological device that meets the safety requirements set forth in the Legislative Decree 19 September 1994, no. 626 implementing Directives 89/391 / EEC, 89/654 / EEC, 89/655 / EEC, 89/656 / EEC, 90/269 / EEC, 90/270 / EEC, 90/394 / EEC and 90/679 /EEC concerning the improvement of the safety and health of workers in their workplace and the essential requirements set forth in the Legislative Decree 24 February 1997, no. 46 implementing Directive 93/42 / EEC and subsequent amendments concerning medical devices.

The medical device referred to in this manual is a radiological device that complies with Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Every tampering with, modification, update or change of either hardware[1] or software[2], compared to how the device was released from the factory and installed (and in any case to the specification in the enclosed documentation), may result in the partial or total impossibility of the device to behave as intended. The safety features can also be altered leading to a consequent hazard increase for the patient, the operator and the surrounding environment.

Therefore, if the user must make a change, this must be previously approved in writing by CEFLA s.c.

Any different behaviour from what is established by this note will result in the cancellation of the warranty on the device and the assumption of civil and/or penal liability for any damage and/or accident and/or deterioration of the health of the patient, the operator or of other people, including the surrounding environment, by those who have tampered with the device or its legal representative.

[1] *Adding a memory expansion, a new hardware on the connection bus, a printer or replacing the graphical video interface constitutes a significant change.*

[2] *Including the operating system and the applications already installed when the medical device is delivered. Automatic operating system updates, changes in network connection parameters, modification and/or addition and/or removal of interface software with hardware (device drivers) and/or services (e.g. file and printer sharing services) and/or applications, constitute a significant change.*

Contents

1. INTRODUCTION TO THE MANUAL 4
1.1. CONTENTS 4
1.2. STYLISTIC CONVENTIONS 4
2. OPTIONAL COMPONENTS AND PACKAGES 5
2.1. PACKAGES 5
2.1.1. FULL CONSOLE PACKAGE FUNCTIONS 6
2.1.2. MULTIMEDIA PACKAGE FUNCTIONS 7
2.1.3. CINESCOUT PACKAGE FUNCTIONS 10
2.1.4. LIGHT PANEL PACKAGE FUNCTIONS 11
2.2. POSITIONING TOOLS 12
2.2.1. HEADREST IMMOBILISING DEVICE TOOL FUNCTIONS 12

1. INTRODUCTION TO THE MANUAL

1.1. CONTENTS

This manual has been designed as a means of consultation to provide information and instructions regarding the use of the optional components and packages for the NewTom™ 7G device.

The routine software functions provided for this device (scanning, data processing, reporting and document managing) and the instructions for use for the operator are handled in the “USER MANUAL” and in the document “Acquisition operations with NewTom 7G” attached to the “NNT User Manual”.

The “USER MANUAL” of the device, the “NNT User Manual” and the document “Acquisition operations with NewTom 7G” should be read and understood in all their parts before using the device.

It is recommended to keep this manual together with other documentation and use it as a guide in case new employees need to be instructed about the use of the device.

1.2. STYLISTIC CONVENTIONS

Important safety information and any notes are included in the manual as shown here:

DANGER:
Warns of the presence of a potential danger that could injure a person or that can cause death.

WARNING:
Warns of the presence of a potential danger that could damage the device.

NOTE:
Provides additional information not related to the safety of the device, the patient and the operator.

2. OPTIONAL COMPONENTS AND PACKAGES

This chapter provides an overview of the optional components and packages available for NewTom 7G.
For a comprehensive, complete list of standard accessories, refer to the USER MANUAL.

2.1. PACKAGES

FULL CONSOLE PACKAGE:
Package which allows expanding the device by adding 2 control consoles on the rear side of the device.

MULTIMEDIA PACKAGE:
Package which allows expanding the device by adding a camera to view the patient from the control Workstation and an audio system (speaker / microphone) for the operator-patient communication.

CINESCOUT PACKAGE:
Package which allows expanding the device by adding an external control pedal to perform cinescout examinations and a touch-screen medical monitor on-board the machine to view the examination.

LIGHT PANEL PACKAGE:
Aesthetic panel which allows expanding the device by adding a LED lighting system to illuminate the rear/front cover.

2.1.1. FULL CONSOLE PACKAGE FUNCTIONS

The “FULL CONSOLE” package allows expanding the device by adding 2 more control consoles on the rear side of the device in addition to the 2 supplied consoles, already featured on the front side.

Consoles are 10” touch-screen panels used to:

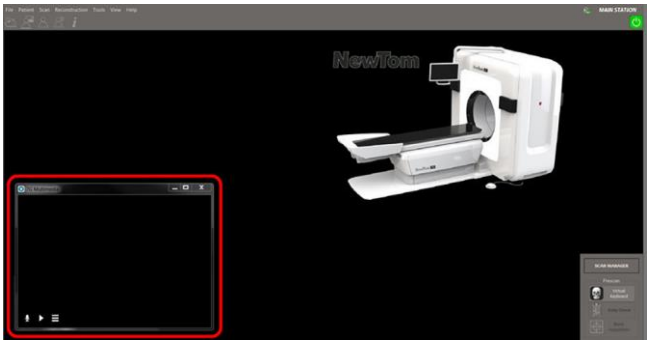
- view the status of the device
- handle the patient table and to position the patient
- activate the laser modules for patient positioning
- set the type of examination and X-ray parameters

For further information on the use of control consoles, refer to Par. “Control consoles” of the “USER MANUAL”.

2.1.2. MULTIMEDIA PACKAGE FUNCTIONS

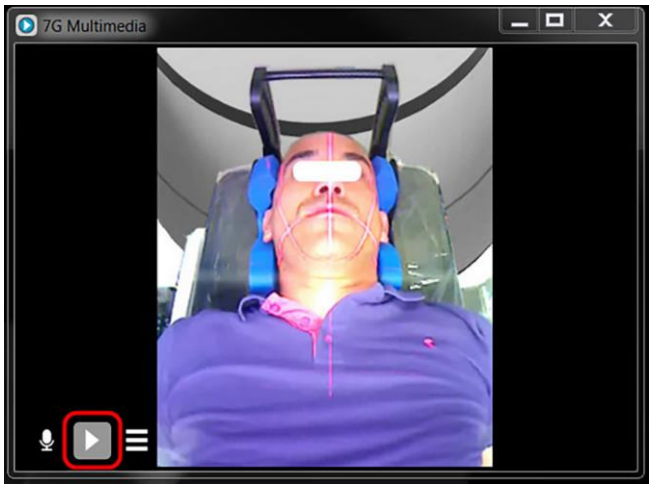
The MULTIMEDIA package allows expanding the device by adding a camera to view the patient from the control Workstation and an audio system (speaker / microphone) for the operator-patient communication

The system is integrated inside the cover of the device near the gantry for patient's access into the unit



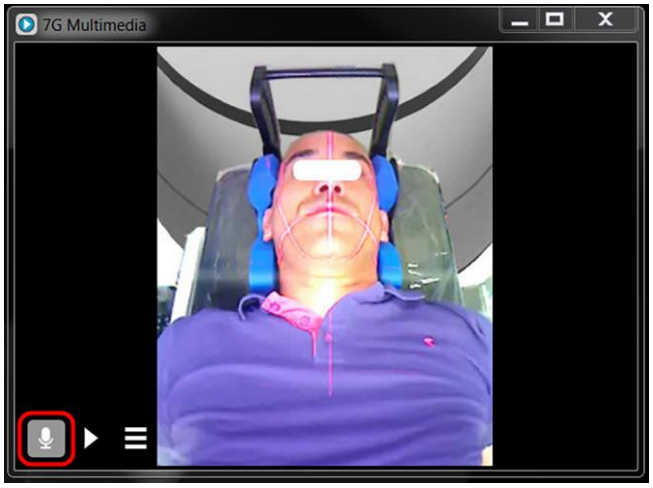
If the functions of the MULTIMEDIA package are enabled, the "*7G Multimedia*" window will be shown when the program is started.

Enabling VIDEO



Press “**PLAY**” to enable the VIDEO connection with the patient inside the window.

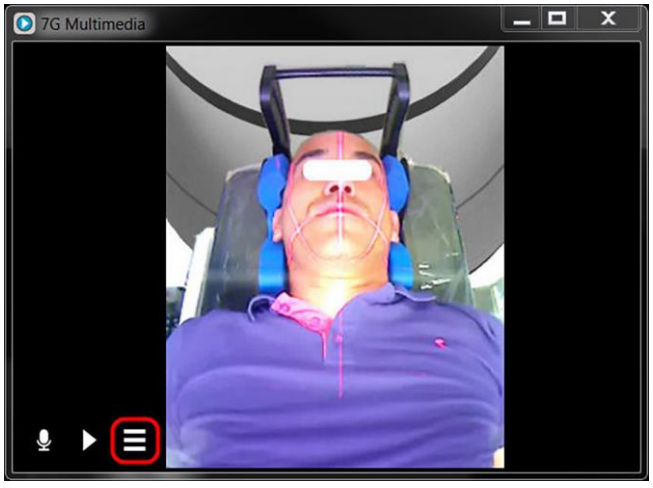
Enabling AUDIO



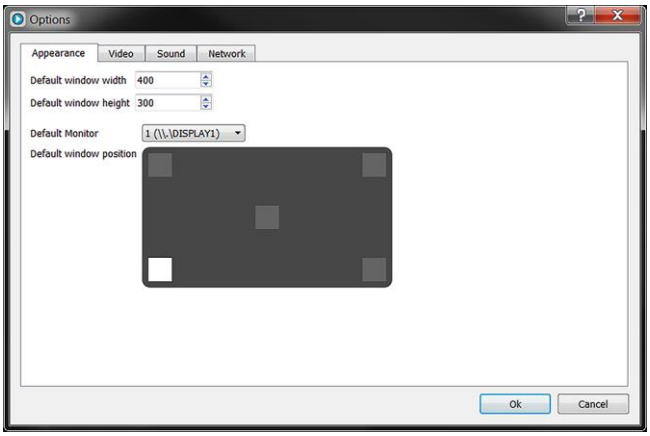
Press “**MIC**” continuously to enable the AUDIO connection between operator and patient.

NOTE:
To listen / talk to the patient, it is required that an appropriate audio system (e.g.: headset, speaker with microphone, etc.) is connected to the control workstation.
The patient’s audio is always available to the operator without having to press the button.
To talk with the patient, the operator should press the button and hold it down during the communication

Settings



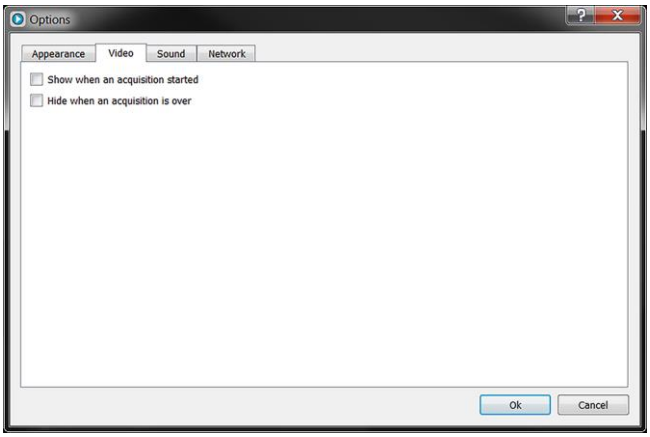
Press the “**SETTINGS**” key to configure the audio / video flow properly:



"**Appearance**" tab:

It is possible to set

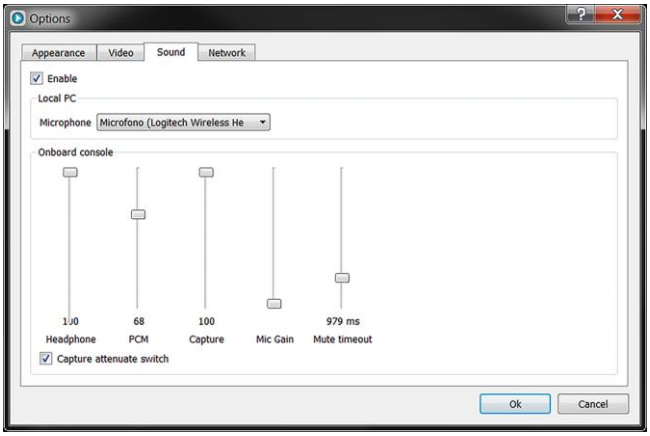
- width / height of the monitor window where the window is shown;
- position of the window on the screen.



"**Video**" tab:

It is possible to set

- if the window is to be shown when an acquisition process has started;
- if the window is to be hidden after completing an acquisition process.



"**Audio**" tab:

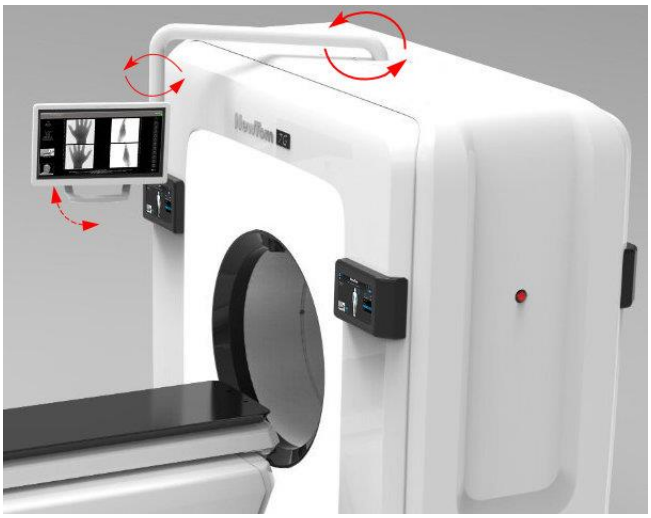
It is possible to set

- the audio source connected;
- the audio volume equalisation.

2.1.3. CINESCOUT PACKAGE FUNCTIONS

WARNING:
Do not hang anything from the monitor support arm.

The CINESCOUT package allows expanding the device by adding an external control pedal to perform cinescout examinations and a 22'' touch-screen medical monitor on-board the machine to view the examination.



If the functions of the **CINESCOUT** package are enabled, it will be possible to view the X-ray images of the examination on the 22'' touch-screen monitor by "mirroring" the standard monitor of the control Workstation.

It is possible to perform the following movements:

- rotation of the support arm on the RH or LH side of the device
- rotation and inclination of the monitor

For further information on the use of the external pedal and on the CINESCOUT acquisition flow, refer to Par. "CineScout scan" of the "USER MANUAL"

2.1.4. LIGHT PANEL PACKAGE FUNCTIONS

The LIGHT PANEL package allows expanding the device by adding a LED lighting system to illuminate the rear/front cover.

NOTE:
The LED lighting system is supplied as a standard on the front side of the device.

2.2. POSITIONING TOOLS

HEADREST IMMOBILISING DEVICE TOOL
It is used as a fastening system to prevent patient's head from moving during the scan

MAT
It is laid on patient table to ensure greater comfort. It features special folding parts to make Headrest Immobilising Device insertion easier.

2.2.1. HEADREST IMMOBILISING DEVICE TOOL FUNCTIONS

WARNING:
It is intended to fasten patient's head. The maximum load provided for in accordance with IEC60601 is 15kg centred on the skull.

HEIGHT ADJUSTMENT

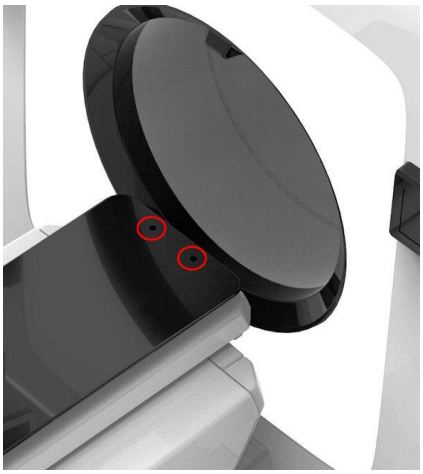
The height of the headrest immobilising device can be adjusted from 0 to 45°.

To perform the adjustment, use the side knobs, unscrewing them so that the headrest is free to slide in the suitable opening.

Position at the desired height (in one of the pre-set suitable positions) and screw the knobs again in order to stabilise the position.

INSERTING THE TOOL INTO THE PATIENT TABLE

Check that the pins located at the bottom of the tool are equipped with the suitable rubber O-rings.



Find the holes on the stretcher of the patient table for the insertion of the tool.

If the Mat is positioned on patient table, fold the upper part so as to make the holes for tool insertion visible.

Insert the pins in the suitable holes of the stretcher until the tool is parallel to the patient table and stable.

NOTE:
To remove the tool, carefully extract the pins from the stretcher, grabbing the tool with both hands in order to balance the effort on both sides.

Now it is possible to position the patient according to the operating flow of the examination to be performed.

For further information, refer to the “USER MANUAL”

www.newtom.it

NEWTOM™ 7G is manufactured by:

CEFLA s.c.
Headquarters
Via Selice Prov.le 23/A
40026 Imola (BO) Italy

Plant:
Via Bicocca 14/C
40026 Imola (BO) Italy

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

U.S.A.	**Cefla North America Inc.** 6125 Harris Technology Blvd. Charlotte, NC, 28269 United States	Phone: +1 704 598 0020 e-mail: info@ceflaamerica.com
РОССИЯ / RUSSIA	Адрес для обращения потребителей на территории РФ: **ООО "Зенит Р.С."** 143051 Россия, Московская обл., Одинцовский р-н, ул. Городок - 17, владение 15, стр.3	Тел.: +7 495 980 13 50; +7 495 234 97 e-mail: sales@zenith-rs.ru website: www.zenith-rs.ru
УКРАЇНА / UKRAINE **UA.TR.101**	Уповноважений представник в Україні: **ТОВ “ДЕНТ ПРО”** Юридична адреса: 62457, Україна, Харківська обл., Харківський р-н, смт Березівка, в’їзд Кооперативний, буд. 4	Тел.: +38(057)-714-07-12, +38(057)-714-07-13 e-mail: dentpro@dentpro.info