CONTROL AND DISPLAY UNIT WITH 10.4" COLOUR SCREEN INCL. TOUCH FUNCTION AND SD CARD

USER MANUAL

EN  English translation of original user manual
Congratulations!

You've made a great choice by purchasing this control and display unit. This innovative control and display unit delivers maximum performance made in Germany.

This user manual will help you get to know your control and display unit better. It takes you safely through the functions and operation, and also offers plenty of tips and advice for getting the most out of your new control and display unit.

Before starting the unit for the first time, please take note of chapter 2 "Safety and dangers".

If you have any further questions or comments, your trained specialized dealer will be happy to help.

We hope you will enjoy keeping active with your control and display unit.
1 USER GUIDE

The user manual and product are marked with a variety of symbols. These symbols and their functions help you to use the product safely and efficiently.

1.1 Warnings

Warning categories

Warnings have different signal words depending on the type of danger:

- **Caution** warns of the risk of material damage.
- **Warning** warns of the risk of physical injury.
- **Danger** warns of the risk of fatal injury.

Structure of warnings

![Warning symbol]

Type and source of danger!

- Action to avoid the danger.

1.2 Notes

Information on the efficient use of the product.

1.3 Symbols in the user manual

Instructions

Structure of instructions:

- Instruction to do something. Presentation of results if required.

Lists

Structure of non-numbered lists:

- List level 1
  - List level 2

Structure of numbered lists:

1. List level 1
2. List level 1
   2.1 List level 2
   2.2 List level 2
1.4 Symbols on the product

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>📚</td>
<td>User manual</td>
</tr>
<tr>
<td>👤</td>
<td>Follow the user manual!</td>
</tr>
<tr>
<td>🏛</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>📅</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>☀️</td>
<td>Market launch in accordance with Medical Devices Directive 93/42/EEC</td>
</tr>
<tr>
<td>🕵️‍♂️</td>
<td>Serial number</td>
</tr>
<tr>
<td>🗑️</td>
<td>Disposal</td>
</tr>
<tr>
<td>🌧️</td>
<td>Protect product from humidity.</td>
</tr>
<tr>
<td>⚭️</td>
<td>Alternating current: The control and display unit uses alternating current</td>
</tr>
<tr>
<td>🚨</td>
<td>This side up</td>
</tr>
<tr>
<td>🍷</td>
<td>Caution fragile</td>
</tr>
<tr>
<td>🌡️</td>
<td>Temperature limit: between -25 °C (-13 °F) and +75 °C (+165 °F)</td>
</tr>
<tr>
<td>🚫</td>
<td>Do not stack</td>
</tr>
</tbody>
</table>
2 SAFETY AND DANGERS

- Observe the user manual.
- Control and display unit:
  - Use exclusively in good and functional condition.
  - Use exclusively under supervision of a trained assistant.
  - Put on even and skid-proof floor.
  - Do not use in wet, humid or hot environment.
  - Have exclusively trained dealers do any repair work.
  - In case of damage, malfunctions, etc. contact a trained dealer immediately.
  - Consult the manufacturer before any modification and modify exclusively with the manufacturer's approval.
  - Position so that power plug is easily accessible and can be pulled out of socket outlet quickly in case of emergency.
  - Use exclusively with undamaged and functional cables.
  - Use exclusively with correctly set supply voltage.
  - Keep away from animals and playing children.
  - Leave at room temperature for 1 hour before using it for the first time.
  - Disinfect before every training session.
- Prior to the initial start-up, have your trained dealer, doctor or therapist show you how to use the product.
- Before starting the training, consult a doctor or therapist and clarify whether the control and display unit can be used without assistance.
- If the user has a cardiac pacemaker, consult a doctor before the first training session.
- Prior to the initial start-up, have a trained dealer, doctor or therapist show your assistant how to use the product.
- Do not smoke while exercising.
- Make sure that the control and display unit does not get wet.
- When laying cables, make sure that
  - The user's movements are not limited.
  - The movements of the control and display unit are not limited.
  - There is no risk of persons falling over or being limited by cables.
- Use the manufacturer's original parts exclusively.
- Remove power plug from power socket after each training session.
- Only use with the medical power supply unit with adapter plug supplied by the manufacturer.
- Use USB ports exclusively with options (USB stick, Bluetooth sensor) approved by the manufacturer. End training session before connecting.
3 INTENDED USE

Control and display unit:
- is designed as a mobile control and display unit in order to use a suitable THERA-Trainer software.

In combination with a THERA-Trainer movement exerciser and a suitable THERA-Trainer software, a control and display unit helps mobilise persons whose mobility is limited due to accidents, surgery or any diseases affecting the locomotor system.

Follow the indications of the THERA-Trainer movement trainer.

User
- People who are authorised to use the control and display unit and trained to use the control and display unit with appropriate training from specialised staff.
- The user is entirely responsible for the safe and correct use of the control and display unit.

Specialised staff
- Persons who gained their skills and expertise by means of professional training in the medical or medical-technical sector (e.g. doctors, therapists, specialist dealers)
- Persons who due to their professional experience and by means of instruction/training by the manufacturer are able to assess safety-relevant regulations and recognise potential risks in their field of work (e. g. assistants).
- To guarantee safe use of control and display unit, train expert staff regularly.

3.1 Training

Before initial startup:
- Have training
  - By dealers, doctors or therapists trained by the manufacturer.
  - By using this user manual.
- Consult the doctor or therapist and confirm whether the control and display unit can be operated without supervision.
- Have an assistant trained by dealers, doctors or therapists trained by the manufacturer.

3.2 Biocompatibility

All components of the control and display unit that the user will touch when using the unit as intended are designed to meet the biocompatibility requirements of the applicable standards.
- For any questions, contact a trained dealer.
4 FORSEEABLE MISUSE

Control and display unit is not suitable for:

- Diagnosis
- Monitoring
- Measuring

4.1 Misuse

Control and display unit should not be used in:

- combination with other products emitting ionising radiation (e.g. radiation therapy, nuclear medicine, etc.)
- rooms containing
  - Explosive substances
  - Oxygenated air
- the presence of
  - flammable anaesthetics
  - volatile solvents
- devices not approved by the manufacturer.
- outdoors.

5 SCOPE OF DELIVERY AND EQUIPMENT

The control and display unit comes with individual options. This user manual describes all options available for the control and display unit. Depending on the model, the user manual may include options not featured on the control and display unit. If the control and display unit features options not described in the user manual, an appendix will be included.

5.1 Scope of delivery

The delivery note contains all information about the scope of delivery.

5.2 Basic equipment

- Control and display unit with 10.4" colour screen incl. touch function and SD card
- High-resolution colour screen with TFT technology with 10.4" colour screen incl. touch function and SD card
- Medical power supply unit with adapter plug
- USB stick
- Manual control and display unit

5.3 Options

Available options:

- Table holder
- Bluetooth transmitter for feedback sensor

Note: The control and display unit can only be used in combination with suitable THERA-Trainer software and table holder.
### 5.4 Removable parts

<table>
<thead>
<tr>
<th>Name</th>
<th>Article no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control and display unit with 10.4&quot; colour screen incl. touch function and SD card</td>
<td>A002-836</td>
</tr>
<tr>
<td>Table holder</td>
<td>A003-795</td>
</tr>
<tr>
<td>Medical power supply unit with adapter plug</td>
<td>A001-655</td>
</tr>
<tr>
<td>USB stick</td>
<td>A000-626</td>
</tr>
<tr>
<td>Bluetooth transmitter</td>
<td>A004-020</td>
</tr>
</tbody>
</table>
CONTROL AND DISPLAY UNIT WITH 10.4" COLOUR SCREEN INCL. TOUCH FUNCTION AND SD CARD
6 OVERVIEW

6.1 Control and display unit with 10.4” colour screen incl. touch function and SD card and table holder

---

(1) USB ports
(2) Control and display unit with 10.4” colour screen incl. touch function and SD card
(3) Power supply
(4) Table holder
(5) Medical power supply unit with adapter plug
(6) Adapter plug
(7) Power supply plug

---

Damage due to incorrect power supply!

- Only use the original power supply unit from the manufacturer.
7 STARTUP

7.1 Unpacking

Control and display unit and table holder:
- Remove from packaging.
- Check incl. all accessories/options for transport damage.
- Check if delivery is complete.
- Inform supplier or forwarding agent immediately about any damage.

7.2 Installation

Install control and display unit with 10.4" colour screen on table holder

Install the control and display unit on the table holder as follows:
- Install bracket 1 on the control and display unit.
  - Insert bracket in the control and display unit using screw 3.
  - Tighten bracket with lock nuts 2.
- Follow the installation instructions for the table holder.

Connecting the power supply plug

Connect the power supply plug to the control and display unit:
- Insert power supply plug 2 into socket 1 on the control and display unit.
- Make sure that the plug connector audibly clicks into place.

Material damage due to incorrect installation!
- Make sure that the plug is plugged in correctly when connecting the unit.
- Observe position of plug.
Inserting the Bluetooth transmitter for the feedback sensor

- Insert Bluetooth transmitter into a free USB port on the control and display unit.

*Note*:

*If the Bluetooth transmitter is not inserted, no connection can be made to the feedback sensor with the touch key.*

Connecting the power plug

- Depending on the country, the appropriate plug adapter must be snapped into place on the medical power supply unit.
- Plug power plug 1 into socket outlet.
- Only use with the medical power supply unit with power plug (adapter plug) supplied by the manufacturer.
- Use control and display unit exclusively with correctly set supply voltage.

Control and display unit is ready for use.

### 7.3 Switching on and off

**Switching on**

To switch on control and display unit with 10.4” colour screen:

- Plug power plug into socket outlet.

Control and display unit boots up.

**Switching off**

To switch off control and display unit with 10.4” colour screen:

- Remove power plug from power socket.
7.4 Adjusting the table holder

Adjust the angle and height of the table holder for the control and display unit as follows:

- To adjust the angle of the control and display unit, move it forward or backward.
- To adjust the height of the control and display unit, move it up or down.
- To do so, see the instructions for the table holder.

8 OPERATION

The control and display unit with 10.4” colour screen incl. touch function and SD card can be operated using the touch soft keys.

How to operate the THERA-Trainer software is described in the corresponding user manual.

9 TRANSPORT

Transport control and display unit as follows.

- Remove medical power supply unit plug from power socket.

Control and display unit is ready for transport.
10 CLEANING AND DISINFECTION

Danger to life due to electric shock!
- Prior to any cleaning or disinfection, unplug the power plug.
- Make sure that no cleaning agent or disinfectant gets into the control and display unit.
- If any cleaning agent or disinfectant gets into the control and display unit, contact a trained dealer immediately.

Risk of infection due to contaminated accessories/options!
- Wear gloves for cleaning and disinfection.

Material damage due to incorrect cleaning or disinfection!
- Never use cleaning agents that are aggressive, abrasive or caustic, or contain solvents.
- Use exclusively mild and environment-friendly cleaning agents and disinfectants.
- Use suitable cleaning agent (e.g. for TFT screens, etc.) for the screen.
- Use exclusively disinfectants that conform to country-specific regulations.
- Observe safety instructions by manufacturers of cleaning agents and disinfectants.

Clean/disinfect the control and display unit as follows:
- Remove power plug from power socket.
- Check electronic components for damage.
  - If any damage is found, do not clean but contact trained dealer.
- Make sure that the room is sufficiently aired during cleaning or disinfection.
- Clean surface of control and display unit with a soft damp cloth.
- To clean surfaces of the control and display unit, use exclusively disinfectants approved in accordance with country-specific stipulations.
- Clean foils and stickers with care.
- Leave control and display unit to dry sufficiently.
- Plug power plug into socket outlet.
- Control and display unit boots up.
11 MAINTENANCE AND REPAIRS

Danger to life due to electric shock!

- Prior to any maintenance or repair work, unplug the power plug.

11.1 Maintenance

The control and display unit is maintenance-free.

The manufacturer recommends performing a safety check after 24 months.

11.2 Further use

The control and display unit is suitable for further use by a different customer.

Each time before reusing the control and display unit:

- Clean and disinfect thoroughly (see Chapter 10 Cleaning and disinfection).
- Perform a visual check or a function check.
- Ask the manufacturer for the service instructions for safety control.
- Check if all accessories and options are complete (see delivery note).
12 TECHNICAL DATA

<table>
<thead>
<tr>
<th></th>
<th>Control and display unit with 10.4” colour screen incl. touch function and SD card</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions:</td>
<td>l x w x h</td>
</tr>
<tr>
<td></td>
<td>30-38 cm x 32 cm x 12-31 cm</td>
</tr>
<tr>
<td>Weight:</td>
<td>4.5 kg (incl. table holder)</td>
</tr>
<tr>
<td>Protection class:</td>
<td>II</td>
</tr>
<tr>
<td>Protection category:</td>
<td>IP2x</td>
</tr>
<tr>
<td>Power supply:</td>
<td>230 V~, 50/60 Hz</td>
</tr>
<tr>
<td></td>
<td>115 V~, 50/60 Hz</td>
</tr>
<tr>
<td>Ambient conditions for use:</td>
<td>5 °C to 40 °C</td>
</tr>
<tr>
<td></td>
<td>15 % to 93 % Rh</td>
</tr>
<tr>
<td></td>
<td>700 to 1060 hPa</td>
</tr>
<tr>
<td>Ambient conditions for</td>
<td>-25 °C to 70 °C</td>
</tr>
<tr>
<td>transport/delivery:</td>
<td>15 % to 93 % Rh</td>
</tr>
<tr>
<td></td>
<td>Rh</td>
</tr>
<tr>
<td></td>
<td>700 to 1060 hPa</td>
</tr>
<tr>
<td>Materials used:</td>
<td>steel, stainless steel, plastics (POM, PA6, ABS, PE), rubber</td>
</tr>
<tr>
<td>Control and display unit</td>
<td>7 years</td>
</tr>
<tr>
<td>operating life:</td>
<td></td>
</tr>
</tbody>
</table>

13 DISPOSAL

To dispose of the control and display unit:

- Observe country-specific regulations and specifications.
- Dispose of metal parts as scrap metal.
- Dispose of plastic parts as prescribed, depending on the type of material.
- Dispose of electric and electronic components as electronic scrap.
14 NOTES ON THE ELECTROMAGNETIC COMPATIBILITY OF CONTROL AND DISPLAY UNIT WITH 10.4” COLOUR SCREEN INCL. TOUCH FUNCTION AND SD CARD

14.1 Lines, line lengths and accessories

The control and display unit may only be operated using the original medical power supply unit.

14.2 Warning notice regarding installation

The control and display unit is not to be used in the immediate vicinity of or stacked with other devices. If it is necessary that the control and display unit is used next to or in a stack with other devices, it should be observed to check if the arrangement permits it to work as intended.

14.3 Level of conformity

The immunity level requirements of DIN EN 60601-1-2 are met.

14.4 Electromagnetic emission

<table>
<thead>
<tr>
<th>Emission measurement</th>
<th>Compliance</th>
<th>Directive for electromagnetic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF emissions according to CISPR 11</td>
<td>Group 1</td>
<td>The control and display unit uses HF energy exclusively for internal functions. This incurs very low HF emissions so it is unlikely to interfere with any nearby electronic devices.</td>
</tr>
<tr>
<td>HF emissions according to CISPR 11</td>
<td>Class B</td>
<td>The control and display unit is designed for use in all kinds of facilities, including:</td>
</tr>
<tr>
<td>Harmonics according to IEC 61000-3-2</td>
<td>Class A</td>
<td>❑ Residential buildings</td>
</tr>
<tr>
<td>Voltage fluctuations/flickers according to IEC 61000-3-3</td>
<td>met</td>
<td>❑ Facilities that are directly connected to a public mains supply which also supplies residential buildings.</td>
</tr>
</tbody>
</table>
## 14.5 Immunity

### Directives and manufacturer’s declaration – Electromagnetic immunity

The control and display unit is designed for operation in an electromagnetic environment as described below. The customer or the user of the control and display unit should make sure that the unit is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>EC 60601 test level</th>
<th>Level of conformity</th>
<th>Directive for electromagnetic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Static discharge (ESD) according to IEC 61000-4-2</td>
<td>± 6 kV contact discharge (indirect)</td>
<td>± 6 kV contact discharge ± 8 kV air discharge</td>
<td>Floors should be wooden, concrete or ceramic tiled. If the floor contains synthetic materials, the relative air humidity must be at least 30 %.</td>
</tr>
<tr>
<td>Fast transient electrical disturbances/bursts according to IEC 61000-4-4</td>
<td>± 2 kV for supply lines ± 1 kV for input and output lines</td>
<td>± 2 kV for supply lines ± 1 kV for input and output lines</td>
<td>The quality of the supply voltage should correspond to that of a typical business or hospital environment.</td>
</tr>
<tr>
<td>Surges according to IEC 61000-4-5</td>
<td>± 1 kV differential mode voltage (symmetrical) ± 2 kV common mode voltage (asymmetrical)</td>
<td>± 1 kV differential mode voltage (symmetrical) ± 2 kV common mode voltage (asymmetrical)</td>
<td>The quality of the supply voltage should correspond to that of a typical business or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and fluctuations of the supply voltage according to IEC 61000-4-11</td>
<td>&lt; 5 % Uₜ for 0.5 periods (&gt; 95 % dip) 40 % Uₜ for 5 periods (60 % dip) 70 % Uₜ for 25 periods (30 % dip) &lt; 5 % Uₜ for 5 s (&gt; 95 % dip)</td>
<td>&lt; 5 % Uₜ for 0.5 periods (&gt; 95 % dip) 40 % Uₜ for 5 periods (60 % dip) 70 % Uₜ for 25 periods (30 % dip) &lt; 5 % Uₜ for 5 s (&gt; 95 % dip)</td>
<td>The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the control and display unit requires continuous functioning in case of power supply interruptions, we recommend using a non-interruptible power system or a battery to supply the control and display unit.</td>
</tr>
<tr>
<td>Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Magnetic fields at mains frequency should correspond to the typical values for business and hospital environments.</td>
</tr>
</tbody>
</table>

NOTE: Uₜ is the supply AC voltage before the test level is applied.
**Directives and manufacturer’s declaration – Electromagnetic immunity**

The control and display unit is designed for operation in an electromagnetic environment as described below. The customer or the user of the control and display unit should make sure that the unit is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>EC 60601 test level</th>
<th>Level of conformity</th>
<th>Directive for electromagnetic environment</th>
</tr>
</thead>
</table>
| Conducted HF emissions according to IEC 61000-4-6 | 3 V<sub>eff</sub> 150 kHz to 80 MHz         | 3 V<sub>eff</sub>                             | Portable and mobile radio equipment should not be used closer to the control and display unit (including line) than the recommended protective distance. The equation for the transmission frequency in question is used to calculate it. **Recommended protective distance:**
|                                           |                                            |                     | d = \([3.5/3] \times \sqrt{P}\) = 1.17 \times \sqrt{P} for 80 MHz to 800 MHz d = \([7.0/3] \times \sqrt{P}\) = 2.33 \times \sqrt{P} for 800 MHz to 2.5 GHz with P as the transmitter’s power rating in watts (W) according to the indications of the transmitter manufacturer and as the recommended protective distance in metres (m). An on-site test should show that the field intensity of stationary radio transmitters are below the compliance level with all frequencies. Disturbances are possible in the vicinity of equipment labelled as follows. |
| Radiated HF emissions according to IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz                     | 3 V/m               |                                           |

**NOTE 1:** For 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2:** These guidelines may not be applicable in every case. Buildings, objects and persons influence the propagation of electromagnetic waves by absorption and reflection.

An exact technical estimate of the field intensity of stationary transmitters such as base stations of mobile phones and land mobile radio devices, amateur radio stations, AM and FM radio broadcast and television stations is not possible. In order to determine the electromagnetic environment with regard to stationary transmitters one should consider a survey of the location. If the field intensity measured at the location where the control and display unit will be used exceeds the conformity levels listed above, the control and display unit should be observed in order to check if it is working correctly and as intended. Should any performance irregularities occur, it might be necessary to take additional measures such as modifications or a change of locations for the control and display unit.

In the frequency range between 150 kHz and 80 MHz, the field intensity should be below 3 V/m.
14.6 Recommended protective distances between portable and mobile HF telecommunication devices and the control and display unit with 10.4" colour screen incl. touch function and SD card

The control and display unit is designed for operation in an electromagnetic environment as described below. The customer or the user of the control and display unit can help to prevent electromagnetic disturbances by observing the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the control and display unit as indicated below (depending on the output power of the telecommunication device).

<table>
<thead>
<tr>
<th>Power rating of transmitter [W]</th>
<th>Protective distance depending on transmission frequency [m]</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>d = 1.17 \sqrt{P}</td>
<td>d = 1.17 \sqrt{P}</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
</tr>
<tr>
<td>10</td>
<td>3.7</td>
</tr>
<tr>
<td>100</td>
<td>11.7</td>
</tr>
</tbody>
</table>

The distance for any transmitters of which the nominal power is not indicated in the table above can be determined by means of the equation given. \( P \) is the nominal power of the transmitter in watts (W) as indicated by the transmitter manufacturer.

NOTE 1:
An additional factor \( 10/3 \) was used for calculating the recommended protective distance for transmitters in the frequency range between 80 MHz and 2.5 GHz. This reduces the probability of a mobile/portable communication device that was brought to the user area by mistake causing a disturbance.

NOTE 2:
These guidelines may not be applicable in every case. Buildings, objects and persons influence the propagation of electromagnetic waves by absorption and reflection.

15 WARRANTY

In accordance with legal regulations, the manufacturer grants a manufacturer’s warranty for the control and display unit if it is handled with due care. The basis is the date of delivery.

Within this period of time, the manufacturer will replace free of charge any faulty parts of the control and display unit or repair free of charge the control and display unit in the factory or an authorised workshop.

The following are excluded from the manufacturer’s guarantee:

- Wear parts
- Opened devices
- Third-party installations and attachments
- Devices repaired by persons other than trained dealers.
- Any damage due to incorrect use.
MANUFACTURER:

THERA-Trainer®
a trademark of
medica Medizintechnik GmbH
Blumenweg 8
88454 Hochdorf
Germany
Tel: +49 7355-93 14-0
Fax: +49 7355-93 14-15
Email: info@thera-trainer.de
Internet: www.thera-trainer.de