

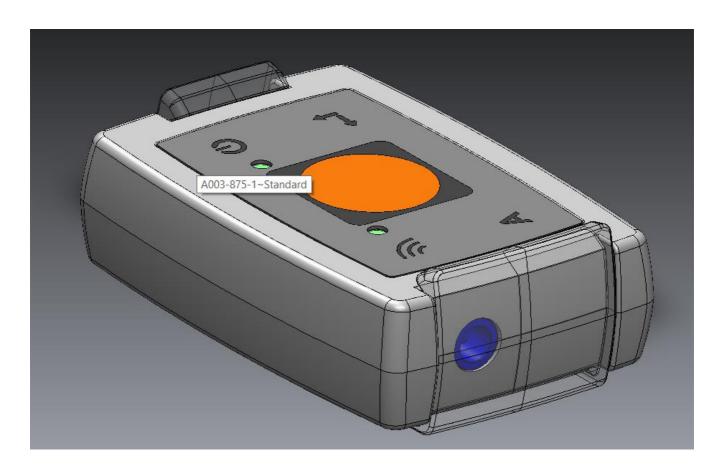
FEEDBACK SENSOR INCL. TOUCH KEY

(MODEL: TT-SENS-14-01)

USER MANUAL

EN

English translation of original user manual









Congratulations!

You've made a great choice by purchasing this feedback sensor incl. touch key. This innovative feedback sensor incl. touch key delivers maximum performance – made in Germany.

This user manual will help you get to know your feedback sensor incl. touch key better. It takes you safely through the functions and use of your new feedback sensor incl. touch key, and also offers plenty of tips and advice for getting the most out of it.

Before using the feedback sensor incl. touch key for the first time, please read and observe chapter 2 "Safety and dangers".

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

EN Ì

We hope you will enjoy keeping active with your feedback sensor incl. touch key.



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1 USER GUIDANCE

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 about the risk of material damage.
- ☐ Warning warns of physical injury.
- Danger warns of danger to life.

Structure of warnings



Type and source of danger!

Action to avoid the danger.

1.2 Notes

Note

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:

- List level 1
- 2. List level 1
 - 2.1 List level 2
 - 2.2 List level 2



1.4 Symbols on the product

r Tol	User manual
	Follow the user manual!
	Manufacturer
	Date of manufacture
CE	Market launch in accordance with Medical Devices Directive 93/42/EEC
SN	Serial number
	Disposal Do not dispose of the product in household waste. Dispose of the product in accordance with local regulations.
☀	Type BF medical device
IP22	Protection against solid foreign objects with a diameter greater than 12.5 mm. Protection against dripping water when the feedback sensor incl. touch key is tilted up to 15°.



2 SAFETY AND DANGERS

	Observe the user manual.
	Only use the feedback sensor incl. touch key if it is completely undamaged and in proper working order.
	If the user has a cardiac pacemaker, consult a doctor before the first training
	session. Do not use the feedback sensor incl. touch key in wet, humid or hot
_	environments.
	Only have trained dealers carry out any repair work.
	In case of damage, malfunctions, etc., of the feedback sensor incl. touch key, contact a trained dealer immediately.
	Make sure that the feedback sensor incl. touch key does not get wet.
	Only use the feedback sensor with incl. touch key if the charging cable is undamaged and in proper working order.
	Only use the USB charger approved by the manufacturer.
	Only use the USB charger for the feedback sensor with the correct supply voltage.
	Leave the feedback sensor incl. touch key at room temperature for 1 hour before using it for the first time.
	Only ever use the charging cable supplied by the manufacturer.
	Disinfect the feedback sensor incl. touch key before every training session.
	The battery in the feedback sensor incl. touch key may only be replaced by a trained dealer.
	The feedback sensor incl. touch key may only be opened by a trained dealer and only modified after consultation with the manufacturer.
	Only ever charge the feedback sensor incl. touch key outside the immediate vicinity of the patient (1.5 metres).
	Faulty/damaged batteries are not suitable for transport. These must be disposed of in accordance with national regulations.
	The feedback sensor incl. touch key must not be returned to the
_	manufacturer with a faulty/damaged battery.
	Ensure that the feedback sensor incl. touch key connected to the THERA-
	Trainer software is connected to the correct THERA-trainer.



3 INTENDED USE

The f	feedback sensor incl. touch key:
	is used for wireless transmission of the inclination data to a control and display unit. The biofeedback illustrations of appropriate THERA-Trainer software are controlled on the basis of this inclination data.
THE	feedback sensor incl. touch key is used in conjunction with the appropriate RA-Trainer software and a control and display unit to mobilise persons with ed mobility using exercises.
Obse used	erve the indications of the THERA-Trainer and THERA-Trainer software being Note I.
User	'S
	Persons who have been instructed by expert staff on how to use the feedback sensor incl. touch key and are thus authorised to operate and exercise with the feedback sensor incl. touch key.
	The user is entirely responsible for the safe and correct use of the feedback sensor incl. touch key.
Ехре	ert 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 the feedback sensor incl. touch key, train expert staff regularly.
3.1 ·	Training
Befo	re the equipment is used for the first time:
	Hold training sessions
	- led by trained dealers, doctors or therapists
	 using this user manual as an aid. Check with doctors or therapists whether unsupervised training is possible
	with the feedback sensor incl. touch key.
	Have the assistant trained by trained dealers, doctors or therapists.
3.2	Biocompatibility
using	omponents of the feedback sensor incl. touch key the user will touch when g the unit as intended are designed to meet the biocompatibility requirements e applicable standards.
	For any questions, contact a trained dealer.

FORSEEABLE MISUSE 4

The	feedback sensor incl. touch key is not used for:
	Diagnosis
	Monitoring Measurement
4.1	Misuse
Do n	not use the feedback sensor incl. touch key in:
	combination with other products emitting ionising radiation (e.g. radiation therapy, nuclear medicine, etc.)
	rooms containing
	explosive substancesenriched oxygen
	the presence of
	flammable anaestheticsvolatile solvents
	equipment not approved by the manufacturer.
5	SCOPE OF DELIVERY AND EQUIPMENT
man Depe the f	feedback sensor incl. touch key comes with individual options. This user ual describes all options available for the feedback sensor incl. touch key. ending on the model, the user manual may include options not featured by eedback sensor incl. touch key. If the feedback sensor incl. touch key ures 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
	c equipment of the feedback sensor incl. touch key:
	Feedback sensor incl. touch key Charging cable
	User manual for feedback sensor incl. touch key
5.3	Options
	lable options:
	USB charger for feedback sensor incl. touch key Feedback sensor mounting kit for THERA-Trainer balo
	Feedback sensor mounting kit for THERA-Trainer coro Feedback sensor mounting kit for BALANCE-Trainer
	Bluetooth transmitter for feedback sensor
	feedback sensor incl. touch key can only be used in conjunction with the opriate THERA-Trainer software, a control and display unit, and a Bluetooth

Note

transmitter for the feedback sensor.

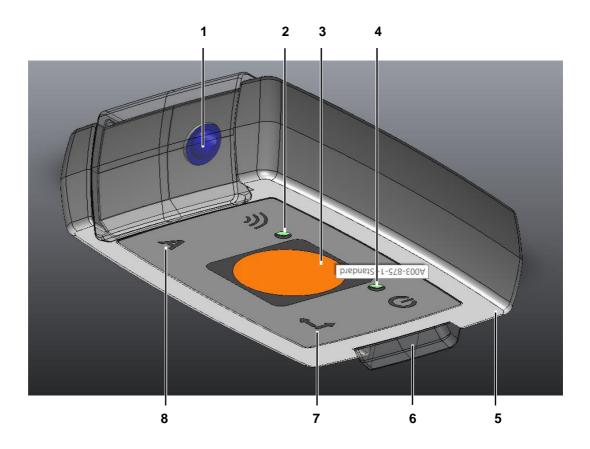


5.3 Removable parts

	Name	Article no.
	Charging cable	A003-891
	USB charger for feedback sensor incl. touch key	A003-980
A004-020	Bluetooth transmitter for feedback sensor incl. touch key	A004-020



OVERVIEW



- Socket for charging cable Connection status indicator

- Touch key
 Activation/charge status indicator
 Feedback sensor incl. touch key (applied part type BF)
 Sensor mounting (not included in the basic equipment)
 Sensor orientation
 Sensor detection (here feedback sensor incl. touch key **Type A**)

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7 FIRST USE

To use the feedback sensor incl. touch key for the first time, remove it from
its packaging and check for damage caused in transit.

☐ Check if delivery is complete.

☐ Report any damage to the supplier or carrier without delay.

■ Before using the equipment for the first time, charge the battery for at least 6 hours.

7.1 Fitting the feedback sensor to the THERA-Trainer balo

Fit the feedback sensor incl. touch key to a THERA-Trainer balo (or BALANCE-Trainer with a current table unit) using the feedback sensor mounting kit for the THERA-Trainer balo. To fit it, follow the instructions below:

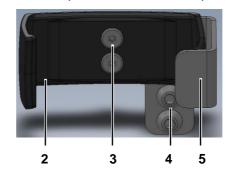
- Mount the sensor holder to the system bracket with two bolts using a suitable tool.
 - Fit the sensor holder on the system bracket using the correct orientation (wider side facing left).
 - Insert two bolts through the holes and secure each one with a nut.
- ▶ Bolt the system bracket to the swivel plate under the table unit of the THERA-Trainer balo (left-hand side) with a suitable tool using two bolts.
- ► Clip the feedback sensor incl. touch key into the sensor holder.
 - Ensure that the sensor orientation arrows point forwards and upwards.

7.2 Fitting the feedback sensor to the THERA-Trainer coro

Fit the feedback sensor incl. touch key to a THERA-Trainer coro using the feedback sensor mounting kit for the THERA-Trainer coro. To fit it, follow the instructions below:

- ▶ Mount the sensor holder **2** to the system bracket **5** with two bolts **3**, using a suitable tool.
 - Fit the sensor holder on the system bracket using the correct orientation (wider side facing left).
 - Insert two bolts through the holes and secure each one with a nut.
- ► Mount the sensor holder **5** on the height adjustment clamp **1** on the Theratrainer coro (right-hand side) with two bolts **4**, using a suitable tool.
- ► Clip the feedback sensor incl. touch key into the sensor holder.
 - Ensure that the sensor orientation arrows point forwards and upwards.





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7.3 Fitting the feedback sensor to the THERA-Trainer

The feedback sensor BALANCE-Trainer mounting kit is required for all BALANCE-Trainers with previous table units.

This affects serial numbers up to:- BT 00xxxxxxx

- 7001-001-03-xxxxxxxx

7017-002-02-xxxxxxx



Previous table unit for BALANCE-Trainer

- Mount the sensor holder to the system bracket with two bolts using a suitable tool.
 - Fit the sensor holder on the system bracket using the correct orientation (wider side facing left).
 - Insert two bolts through the holes and secure each one with a nut.
- ▶ Bolt the system bracket under the table unit to the vertical tube of the BALANCE unit (left-hand side) with the half-shell and two bolts, using a suitable tool
- Clip the feedback sensor incl. touch key into the sensor holder.
 - Ensure that the sensor orientation arrows point forwards and upwards.

To fit the feedback sensor incl. touch key to a BALANCE-Trainer with a current table unit (such as the THERA-Trainer balo), follow the instructions in Chapter 7.1 "Fitting the feedback sensor to the THERA-Trainer balo".

The feedback sensor incl. touch key is now ready for operation.

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Note

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8 OPERATION

8.1 Charging the battery

	Caution	Inco	Prrect use will result in damage! Handle batteries with care. Do not open the batteries. Protect batteries from extreme heat or fire. Always have the battery replaced by a trained dealer.	
	e feedback senso um-ion 3.6 V/68		cl. touch key is fitted with a maintenance-free rechargeable h battery.	
•	Only use USB	char	gers recommended by the manufacturer.	
Sta	Available from - Is not a me - Do not use	the redical with cially	or feedback sensor incl. touch key: manufacturer as an option. l-device USB charger for the feedback sensor. in 1.5 metres of the immediate vicinity of the patient. r-available USB charger (with CE marking).	USB charger
	- Do not use	with	in 1.5 metres of the immediate vicinity of the patient.	
This	s can be used to	chai	cl. touch key is supplied with a charging cable as standard. Trige the battery from a USB interface (computer, control thout a feedback sensor USB charger.	Charging cable
	e service life of that age temperature		ttery depends on its charging/discharging cycles and	
Pos	Approx. 1,000	partia sensa	ance of batteries: al discharges or incl. touch key is fitted with over-discharge protection	Operating period
Wh	30%, the activation when the remainstance.	aining ation aining	harged: g charge (based on the capacity still available) is under /charge status LED will flash green-red. g charge (based on the capacity still available) is under /charge status LED will flash red.	Charging requiremen ts

If the battery is fully discharged, the activation/charge status LED will be off.



Operating period

An operating period of approx. 10 hours per charging cycle can be obtained depending on the conditions of use.

The battery capacity will decline over time.

Note

The manufacture recommends having the battery replaced by a trained dealer after 2 to 3 years, depending on the number of charging cycles.

Charging process



Faulty charging cable connection due to cable being plugged in incorrectly!

- Make sure that the charging cable plug is correctly positioned in the charging socket when it is connected.
- □ Observe position of plug.
- Only use a charging cable approved by the manufacturer.

Charging the battery:

- Remove the feedback sensor incl. touch key from the sensor holder.
- Switch off the feedback sensor incl. touch key before charging (see Chapter 8.2).
- ▶ Ensure that the feedback sensor incl. touch key is switched off while charging.
- Plug the charging cable into the charging socket in the feedback sensor incl. touch key.
- ▶ Insert the USB plug of the charging cable into a USB interface.

OR

- ► Insert the USB plug of the charging cable in the USB interface of the USB charger for the feedback sensor.
- Insert the plug of the USB charger for the feedback sensor into the socket.

Note

The USB charger for the feedback sensor available optionally from the manufacturer is not a medical-device USB charger. Charging must take place outside a 1.5-metre radius of the immediate vicinity of the patient.

Charging process begins.

☐ The LED of the charge/activation status indicator shows the status of the charging process.

LED flashes green:

Battery charging.

LED lights green:

Battery is fully charged.

Note

During the charging phase of the battery, the feedback sensor incl. touch key is inoperable and cannot therefore be used for training.

Storage

Batteries are leak-proof if handled and stored correctly.

Store the battery in a cool place if not used for an extended period.

Replacing the battery

- Have batteries replaced exclusively by a trained dealer.
- ► To have batteries replaced, contact a trained dealer.

Disposal

When batteries are replaced by a trained dealer, dispose of them in accordance with national regulations.

Warranty

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The battery warranty is subject to legal regulations:

- ☐ 24 months
 - 6 months full warranty
 - 18 months with reversal of burden of proof

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8.2 Switching the feedback sensor incl. touch key on/off

To switch the feedback sensor incl. touch key on:

- The battery must be charged.
- Press the touch key until the activation/charge status indicator shows a status.

The LED of the charge/activation status indicator lights up green.

The feedback sensor incl. touch key is trying to establish a connection with the control and display unit.

- ► The LED of the connection status indicator flashes green while the connection with the control and display unit is being established.
- ▶ When the LED of the connection status indicator lights up with a steady green, a connection has been established.
- If a connection cannot be established, the LED of the connection status indicator flashes red.

To switch the feedback incl. touch key off:

Press the touch key until the activation/charge status indicator no longer shows a status.

The LED of the charge/activation status indicator will go out.

When the feedback sensor incl. touch key is switched off, the LED of the activation/charge indicator flashes every few seconds to indicate the remaining charge of the battery.

If the remaining charge is more than 30%:

□ LED flashes green.

If the remaining charge is under 30%:

■ LED flashes green-red.

If the remaining charge is under 15%:

□ LED flashes red.

8.3 Establishing a connection

After the feedback sensor incl. touch key has been switched on, a wireless connection is established between the feedback sensor incl. touch key and the control and display unit.

In order for a wireless connection to be established, a Bluetooth transmitter for the feedback sensor must be plugged in to the control and display unit. Only use the Bluetooth transmitter approved by the manufacturer (item no. A004-020). If a different Bluetooth transmitter is used, no wireless connection can be established.

The LED of the connection status indicator indicates the following statuses:

LED flashes green (slowly):

- A connection is being established between the feedback sensor incl. touch key and the control and display unit.
- ☐ This can take several seconds.

LED lights green:

A connection exists between the feedback sensor incl. touch key and the control and display unit.

Switching on

Switching off

Remaining charge display

Note



LED flashes red:

- □ No connection exists between the feedback sensor incl. touch key and the control and display unit.
- ► Check whether the feedback sensor incl. touch key is too far away from the control and display unit.
 - The wireless connection has a range of about 5 metres.
- ► Check whether the control and display unit is switched on.
- Check whether a Bluetooth transmitter for the feedback sensor is plugged in to the control and display unit.
- ► Check whether the correct Bluetooth transmitter for feedback sensor is plugged in (article no. A004-020).
- Check whether the feedback sensor incl. touch key is already registered with the control and display unit.
 - If no registration exists, follow the user manual for the relevant THERA-Trainer software.

LED flashes green (quickly):

- The feedback sensor incl. touch key is being registered with the control and display unit.
 - See the user manual for the relevant THERA-Trainer software

8.4 Error state indicators

LED of the connection status indicator flashes red:

- No connection exists between the feedback sensor incl. touch key and the control and display unit.
 - see Chapter 8.3 "Establishing a connection"

	s alternately green and red:	ashes al¹	icator fl	ge status ind	ı/char	activation/	of the	LED
--	------------------------------	-----------	-----------	---------------	--------	-------------	--------	-----

- The remaining battery charge is under 30%.
- ☐ Charge the battery.
 - see the Chapter "Charging the battery"

LED of the activation/charge status indicator flashes red:

- ☐ The remaining battery charge is under 15%.
- ☐ Charge the battery.
 - see the Chapter "Charging the battery"

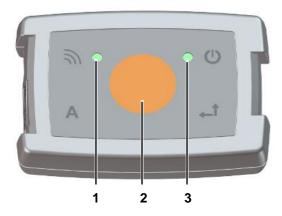


9 TROUBLESHOOTING

If a system fault occurs in the feedback sensor incl. touch key, all the LEDs flash simultaneously. The error code is shown on the control and display unit.

Observe the user manual for the relevant THERA-Trainer software.

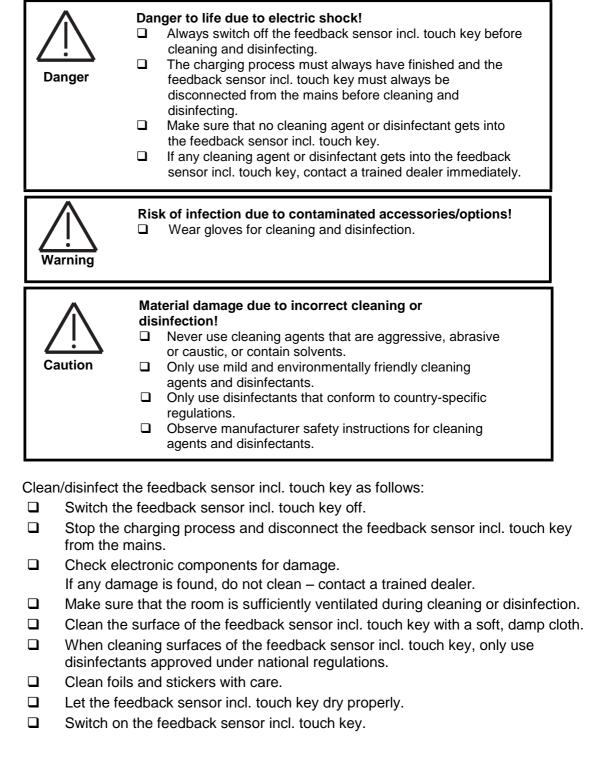
The software version of the feedback sensor incl. touch key is required for troubleshooting. This is shown as follows:



- ▶ Press the touch key 2 until this lights up once.
 - The software version is displayed.
- ▶ The activation indicator 1 lights up successively to indicate the first figure.
 - e.g. 3 times
- ► The touch key lights up once.
 - This means that second figure will now be shown.
- ► The activation/charge indicator 3 lights up successively to indicate the second figure.
 - e.g. 5 times
- ► The touch key lights up once again.
 - The software version display process has finished.

The software version in this example was therefore 3.5.

10 CLEANING AND DISINFECTION





Note

11 MAINTENANCE AND REPAIRS

Danger	 Danger to life due to electric shock! □ Switch off the feedback sensor incl. touch key before all maintenance and servicing work. □ Stop the charging process before all maintenance and servicing work and disconnect the USB plug from the USB interface. □ Only allow trained dealers to carry out this work.
11.1 Maint	enance
The feedback	sensor incl. touch key does not require maintenance.
The manufac	ture recommends having the battery in the feedback sensor replac

11.2 Reuse

cycles.

The feedback sensor incl. touch key is suitable for reuse by a different customer.

by a trained dealer after 2 to 3 years, depending on the number of charging

Before the feedback sensor incl. touch key is reused:

 ore the resultant contest than to do reduced.
Clean and disinfect thoroughly (see Chapter 10 Cleaning and disinfection).
Perform a visual functional check/perform a functional check.
Check if all accessories and options are complete (see delivery note).

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12 TECHNICAL DATA

	Feedback sensor incl. touch key
Dimensions:	LxWxH
	7.5 cm x 5.5 cm x 2.5 cm
Weight:	80 g
Protection category:	IP22
	(only if the feedback sensor incl. touch key is attached to the sensor holder)
Mains connection of USB charger for feedback sensor	100-240 V~, 50/60 Hz
USB charger voltage for feedback sensor	5 V
USB charger current for feedback sensor incl. touch key	0.5 A
Lithium-ion battery	3.6 V/680 mAh
Nominal battery energy	2.65 Wh
Ambient conditions for	5 °C to 40 °C
use	15% to 93% Rh
	700 to 1,060 hPa
Ambient conditions for	-25 °C to 70 °C
transport/delivery	15% to 93% Rh
	700 to 1,060 hPa
Materials used:	Plastic (POM, PA6, ABS, PE), rubber, rechargeable lithium- ion battery
Operational life:	7 years
Feedback sensor	(not including the battery)
incl. touch key	

13 DISPOSAL

regulations.

To dispose of the feedback sensor incl. touch key:

- 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.
 Dispose of lithium-ion batteries in accordance with national rules and
 - Do not dispose of lithium ion batteries unless the positive and negative terminals have been taped up.



14 NOTES ON ELECTROMAGNETIC COMPATIBILITY OF THE FEEDBACK SENSOR INCL. TOUCH KEY

14.1 Electromagnetic emissions

Connection	Electromagnetic emissions/frequency range (MHz)	Limit	Underlying standard
Housing	Radiation 30230	30 dB(uV/m) quasi-peak value at 10 m distance	CISPR 11
	Radiation 2301000	37 dB(uV/m) quasi-peak value at 10 m distance	
AC mains power	Wired interference 0.15 0.5	66 dB(uV) to 56 dB(uV) quasi-peak value	CISPR 11
supply*		56 dB(uV) to 46 dB(uV) mean value	
		The limit values decrease linearly with the logarithm of the frequency.	
	Wired interference 0.5 5	56 dB(uV) quasi-peak value 46 dB(uV) mean value	
	Wired interference 5 30	60 dB(uV) quasi-peak value 50 dB(uV) mean value	
	Distortion due to harmonics	Not tested.	EN 61000- 3-2
	Voltage fluctuations and flicker	As defined in EN 61000-3-3.	EN 61000- 3-2

^{*} Observance of the limit values and requirements depends largely on the characteristics of the external power supply.



14.2 Electromagnetic immunity

Connection	Test	Underlying standard	Test specification/inte nsity	Assessment criterion
Housing	Electrostatic discharge ESD	EN 61000-4-2 Technical standard EN 60601-1-2	Contact ± 6 kV Intensity 3 air ± 8 kV intensity 3	A
	Emitted electromagnetic fields	EN 61000-4-3	3 V/m 10 V/m (device may go out, no critical status may occur)	A
	Mains-frequency magnetic field	EN 61000-4-8	3 A/m	A
AC mains power supply*	Voltage drop/short-term voltage drop	EN 61000-4-11	0.5 period test voltage level <5% Ut	A
			5 periods test voltage level 40% Ut	
			25 periods test voltage level 70% Ut	
			Voltage interruption <5% duration 5 s	С
	Fast transients	EN 61000-4-4	± 2 kV	Α
	Surge voltage	EN 61000-4-5	Conductor to earth ± 0.8, ± 1 kV and ± 2 kV	A
			Conductor to conductor ± 0.5 and 1 kV	A
	Wired HF signals	EN 61000-4-6	3V intensity 2	A
DC supply	Fast transients	EN 61000-4-4	± 2 kV	Α
connection	Surge voltage	EN 61000-4-5	No requirements	Α
	Wired HF signals	EN 61000-4-6	3V intensity 2	A
Input/output, signal/control lines (call nurse, PC interface)	Fast transients	EN 61000-4-4	± 1 kV on lines longer than 3 m	A
	Wired HF signals	EN 61000-4-6	3V	A

^{*} Observance of the limit values and requirements depends largely on the characteristics of the external power supply.



14.3 User Information acc. To FCC15.21

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

14.4 Statement for Class B digital device acc.to FCC 15.105

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio / TV technician for help.

15 WARRANTY

In accordance with legal regulations, the manufacturer grants a manufacturer's warranty for the feedback sensor incl. touch key if it is handled with due care. This is based on the delivery date.

The manufacturer grants a manufacturer's warranty of 6 months (as of the date of delivery) for the battery if it is handled with due care.

Within this period of time, the manufacturer will replace free of charge any faulty parts of the feedback sensor incl. touch key or repair free of charge the feedback sensor incl. touch key 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.

Note

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

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