BTL-6000 TR-THERAPY

USER’S MANUAL

CONTENTS

1 BASIC CHARACTERISTICS OF THE DEVICE

BTL-6000 TR-Therapy is a professional physiotherapy device. The device is available in two models BTL-6000 TR-Therapy Elite and BTL-6000 TR-Therapy Pro. It is equipped with a colour touch screen, which considerably simplifies its operation. The on-screen information will guide the user step-by-step through the entire therapy process. The therapeutic parameters are easily set using the touch screen buttons and knobs/keys on the device.

Therapy is simply started by selecting a diagnosis from an alphabetized list of preset therapeutic protocols or the therapy parameters can be manually set using the touch screen buttons. Throughout the therapy the device keeps you informed on the screen about the applied therapy type, remaining therapy time and main therapy parameters.

1.1 INTENDED USE

BTL-6000 TR-Therapy is a non-invasive therapeutic device based on a conversion of a radiofrequency current to heat energy used for treatment of acute, chronic and degenerative muscoloskeletal system disorders and injuries such as sport pathologies of bones, joints and muscles, tendinous, muscular and articular pathologies (e.g. tendinitis, carpal tunnel syndrome, gonarthrosis and gonalgia, ankle distorsion, frozen shoulder connected with pain), neck pain and low back pain, pain in patients with isolated long head biceps tendinopathy, postoperative pain and oedema treatment of femur fractures.

BTL-6000 TR-Therapy is intended for providing treatment effects such as pain relief, myorelaxation (including the local muscle spasms and trigger points relaxation), trophic effect (which is directly connected with supporting tissue regeneration and healing) and antiedematous effect.

1.2 USER PROFILE

The device shall be operated by medically educated personnel. The user shall be familiar with all safety precautions, operating procedures and maintenance instructions. Pregnant women, persons with malignant tumours (cancer in prior 2 years, active cancer treatment) and persons with implanted electronic devices such as cardiac pacemakers, defibrillators and neurostimulators must not operate the device.

1.3 OPERATING ENVIRONMENT

The device is intended solely for professional use. The device is designed for indoor use only. Do not use in a location where explosion or water intrusion hazards are present or in a dusty or humid environment.

1.4 PATIENT PROFILE

The use of the device is not limited by gender nor by age of the patient in general. Nevertheless, manufacturer does not recommend the use of the device on patients until the epiphyseal closure, especially on neonates and small infants. The patient must not show any condition described in the chapter Contraindications. Before application it is necessary to take the patient's medical history and examine the patient thoroughly to determine whether or not the application of the therapy is suitable for the patient.

1.5 CONTRAINDICATIONS

- Pregnancy
- Tissues infected with tuberculosis or other forms of virulent bacteria
- Serious cardiac or respiratory insufficiency
- Acute inflammations
- Sensation disorders (anaesthesia, hypoesthesia or hyperesthesia in the area of application)
- Skin inflammations, trophic skin changes in the area of application, irritated or damaged skin
- Bleeding conditions, haemorrhagic disorders, menstruation
- Regions of known or suspected malignancy (neoplasia, patients undergoing radiotherapy)
- Overall cachexia of any etiology
- Febrile conditions of any etiology
- Infections
- Metal objects or active implantable medical devices in the place and path of the application (pacemaker, endoprosthesis, splints and bolts, piercing, etc.)
- Application over endocrine glands and gonads
- Area of large sympathetic plexuses
- Peripheral nerves close under the skin surface

1.6 POSSIBLE SIDE EFFECTS

Possible side effects for contact radiofrequency current:

- Unpleasant sensation
- Moderate skin irritation

2 SAFETY PRECAUTIONS

2.1 GENERAL SAFETY PRECAUTIONS FOR DEVICE OPERATION

-  Read the User's Manual carefully and become familiar with all its safety requirements, operating procedures and maintenance instructions prior to use of the device. It is prohibited to use the device and its accessory in any manner that is not in accordance with the User's Manual. It is prohibited to use the device in the way that is not in accordance with the Intended use (defined in Chapter **Intended Use**).
- WARNING: Do not modify this equipment without authorization of the manufacturer.
- Before the first plug in of the device, check whether the parameters of the mains meet the device requirements stated in the Chapter **Technical parameters** of this User's Manual. The mains to which the device will be connected must be installed and revised according to the current standards for electrical installations in medical locations.
- Do not connect any cables or devices to the USB connectors. They are for service purposes only!
-  Dissipate static electricity by touching a grounded metal object before connecting or manipulating the device connected to the USB connector.
- The device must be transported, stored and operated in the environment defined in the Chapter **Technical parameters** of this User's Manual. The device is designed for indoor use only. It is prohibited to use the device in a location where explosion or water intrusion risk are present and in dusty or humid environment. It is prohibited to use the device in spaces where flammable anaesthetics oxidizing gases (O_2, N_2O) and other flammable gases or vapours are present.
- Place the device out of direct sunlight, strong electrostatic, magnetic and electromagnetic fields of surrounding devices (diathermy, X-rays, mobile phones and other radio-frequency equipment) to prevent unwanted interference. If unwanted interference occurs, place the device away from the source of interference or contact an authorized BTL service.
- The device heats up during operation and therefore must not be located near devices that heat up or produce heat. The device is cooled by forced air circulation. The cooling vents are located on the rear and bottom panel of the device and they must not be covered. When placing the device, leave at least 10 cm of space behind the rear panel.
- It is prohibited to place any objects that produce heat or objects that contain water or other liquid on the device.
- When the device is placed from cold to warmer environment, wait until temperatures are equalized (at least 2 hours) before plugging it in.
- Do not try to open or remove the protective covers or disassembly the device for any reason. There is a danger of electric shock and serious injury. All service actions must be done by an authorized BTL service only; otherwise BTL bear no responsibility for further operation of the device.
-  The device has applied parts of the BF (Body Floating) type – i.e. parts which come into direct physical contact with the patient during normal device use. Among the applied parts there are all electrodes specified in Chapter **Accessories**.

- Never use the accessories connector and other connectors to plug in anything else than they are designed for (see Chapter **Connecting the Electrodes**). There is a serious risk of electric shock and serious damage to the device!
- When disconnecting the connected accessories from the device, pull them out by the connector, never by the cable itself. Never disconnect the accessories during therapy!
- Do not disconnect an applicator while output is active.
- Before each therapy check carefully the device and its accessories (cables, connectors, applicators, controls, touch screen) for any mechanical, functional or other damage. If any faults or anomalies in the device function are found, stop using the device immediately and contact the authorized BTL service. In case that the device or the accessories are used despite the deviations, the user will be solely responsible for the damages caused by the device.
- Prior to start of the therapy make sure that all set parameters match your requirements. Follow the contraindications of the therapy detailed in the Chapter **Contraindications**.
- Prior to start the therapy, choose high frequency of therapeutic current that does not stimulate nerves or muscles – it only warms the tissue.
- The time interval between switching the device off and switching it on again using the mains power switch must be at least 2 minutes.
- Keep the device out of reach of children.
- Protect the device against unauthorized use.
-  The device must be disposed in a way common for electric and electronic equipment. The lithium battery must be removed and disposed of separately according to local hazardous waste disposal requirements. Do not place the device in municipal waste containers! The device does not contain any toxic materials, which could harm the environment in case of the proper way of disposal.
- The device does not use or emit any toxic substances during its operation, storage or transport under the stated conditions.
- Do not immerse the device in water.
- Follow cleaning instructions defined in Chapter **Maintenance**.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

2.2 SPECIFIC SAFETY PRECAUTIONS FOR BTL-6000 TR-THERAPY

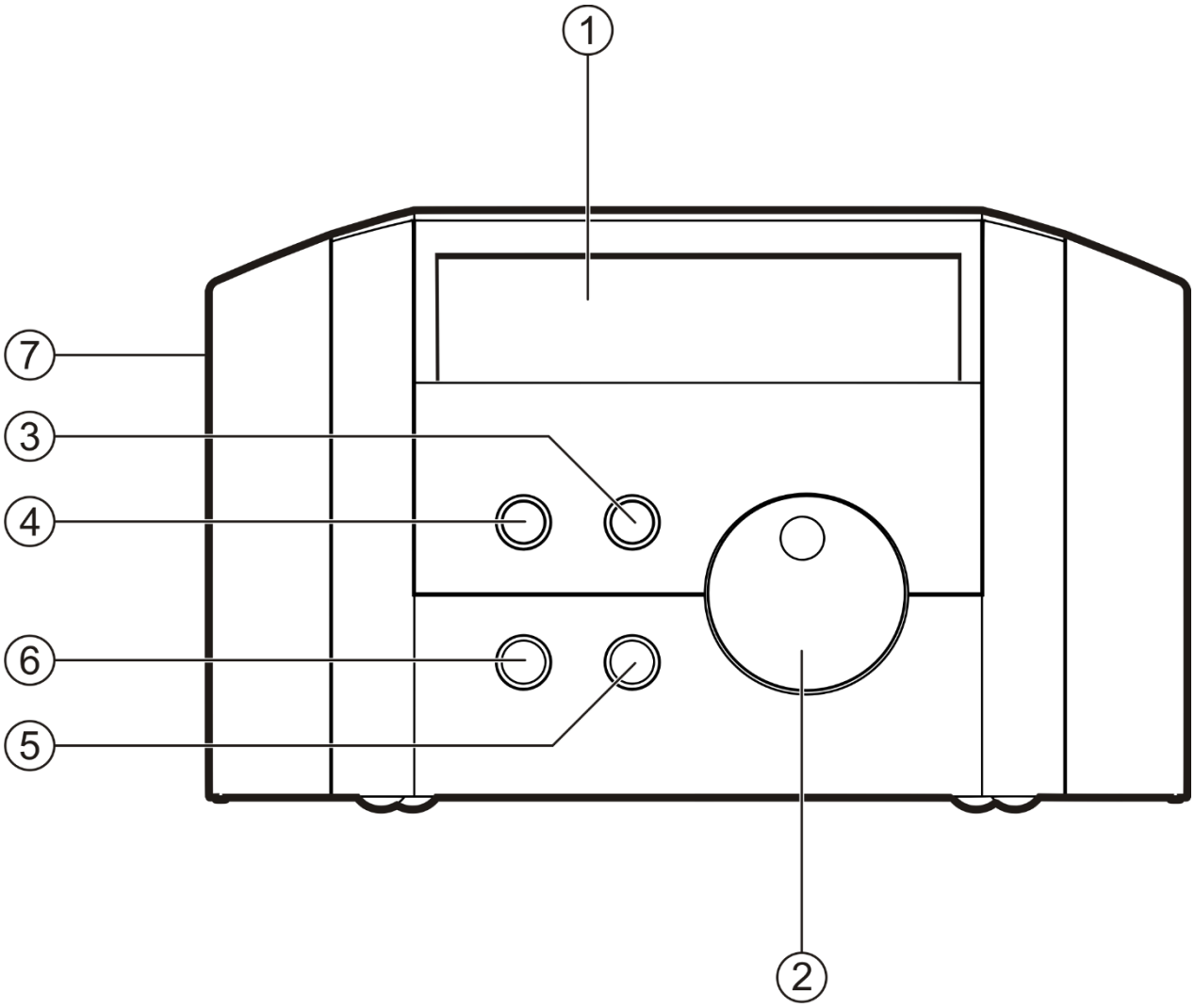
- Never use therapy cream that is not approved by the manufacturer. The approved cream is RF cream, G016.
- Never use scratched capacitive or resistive electrode. The scratched electrodes can cause local discomfort or burns therefore it must be replaced by a new one.
- Never apply the therapy on the anesthetized patient or the patient with elevated pain threshold. Inability of the patient to feel heat or pain can cause his local burns because the operator cannot evaluate reactions of the patient during therapy.
- The unused electrode must be placed in the stand for electrodes during therapy. Avoid placing it on any conductive object.
- During therapy avoid connection of the neutral or active electrode to any conductive object for example metal patient bed, conductive floor cover, etc. The electrodes must be connected only to the patient.
- Keep tight contact of the active electrode on the skin during therapy. The movement when putting the electrode on the skin and taking it away should be quick. Partial contact of the electrode can cause pain or local burns.
- Never use accessory that is not approved by the manufacturer.
- Reference adhesive neutral electrode is for single use only.
- Always respect the feedback of the patient during therapy. Stop the therapy or lower the output power if patient feels discomfort or pain.
- The device emits energy at approximately 500 kHz. Do not use the device in an environment where the 500 kHz electromagnetic signal can disturb other devices or can cause hazardous situation.
- Can cause local burns.

3 SYMBOLS AND MARKINGS

	Follow instructions for use (User's manual)
	Caution
	Warning
	Type BF applied part
	Separate collection for electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
	Serial number
	Class II equipment
	Symbol marking a connector sensitive to electrostatic discharge (ESD)
	Temperature limitation
	Keep away from sunlight
	Use by / Expiration date
	Dispose of waste properly
	Batch code
	Catalogue number
	CE mark

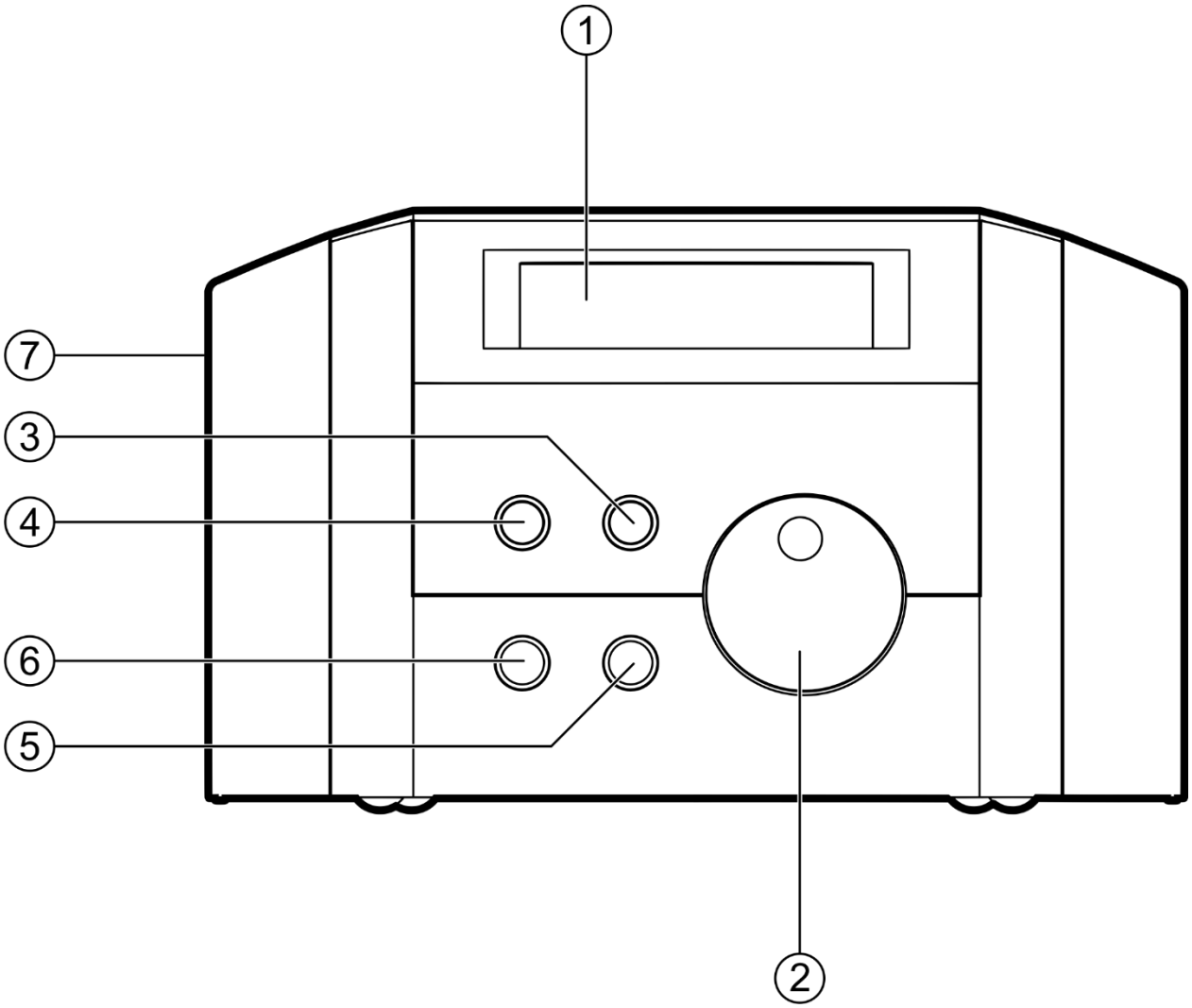
4 INSTRUCTIONS FOR OPERATION

4.1 FRONT PANEL OF BTL-6000 TR-THERAPY ELITE



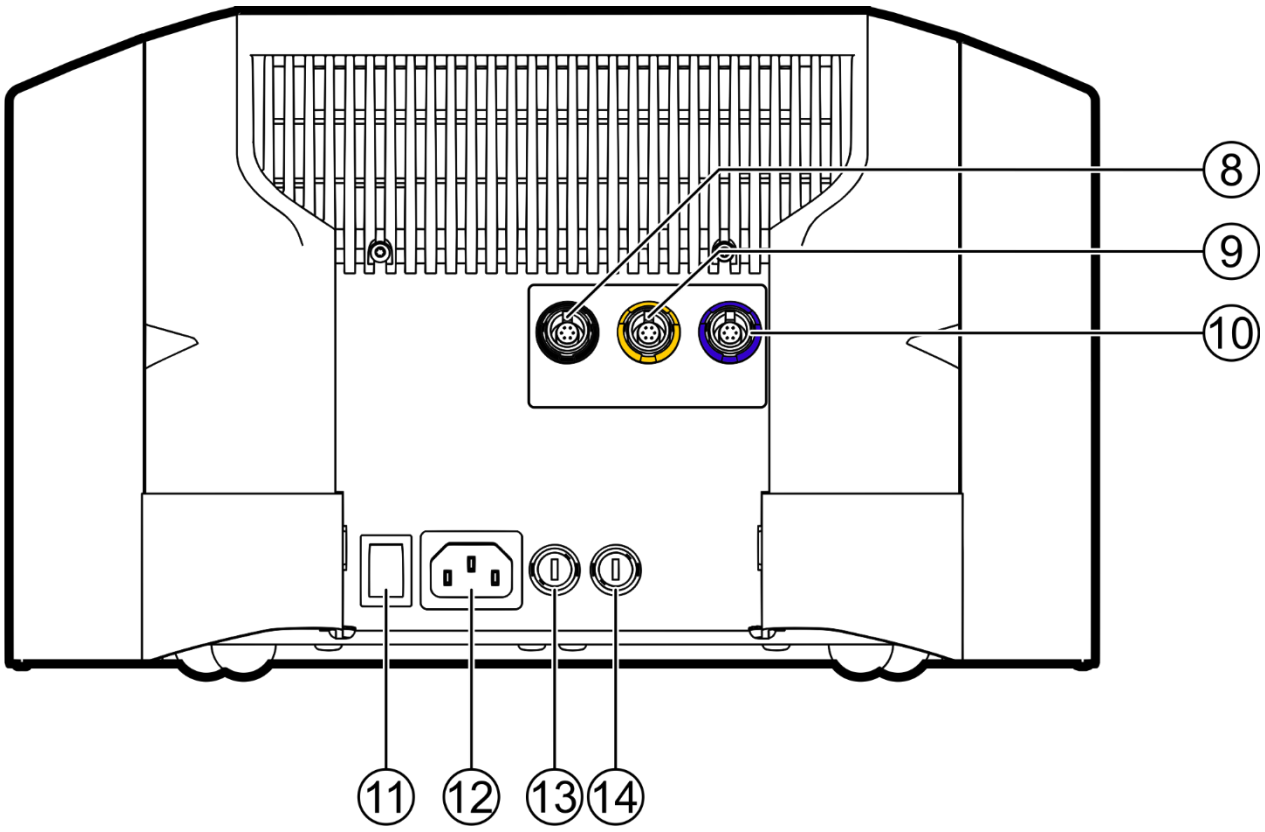
1. 8.4” colour touch screen
2. **select knob** (to move in the device menu and set the therapy parameters)
3. **enter** button (to confirm the selection)
4. **esc** button (to reject the selection and return to the previous state)
5. **start/stop** button (to start/stop the therapy)
6. **on/off** button (to switch the device on/off)
7. The USB Port: Located in the space used for gripping and lifting the device. For use only in compliance with IEC 60950-1. The USB port is used ONLY for technician service purposes such as the uploading of firmware. It is not designed for therapy use!

4.2 FRONT PANEL OF BTL-6000 TR-THERAPY PRO



1. 5.7” colour touch screen
2. **select knob** (to move in the device menu and set the therapy parameters)
3. **enter** button (to confirm the selection)
4. **esc** button (to reject the selection and return to the previous state)
5. **start/stop** button (to start/stop the therapy)
6. **on/off** button (to switch the device on/off)
7. The USB Port: Located in the space used for gripping and lifting the device. For use only in compliance with IEC 60950-1. The USB port is used ONLY for technician service purposes such as the uploading of firmware. It is not designed for therapy use!

4.3 REAR PANEL



8. output connector for the neutral electrode (black)
9. output connector for the capacitive applicator / patient cable for capacitive electrode (yellow)
10. output connector for the resistive applicator / patient cable for resistive electrode / patient cable for static application (blue)
11. mains power switch
12. mains cable connector
13. fuse box
14. fuse box

4.4 PUTTING THE DEVICE INTO OPERATION

Always inspect the packaging for damage when you receive the device. Do not proceed with assembly and set-up if the packaging is damaged and return the device to the distributor. Keep the original packaging to ensure safe future transport of the device.

Unpack the device and place it on a firm and stable horizontal surface, which is suitable for its weight, or place it on an original BTL trolley. Place the device in accordance with the instructions listed in the Chapters **Technical Parameters** and the **Safety Precautions** (operating conditions, undesirable interference with other devices etc.)

Prior to switching the device on, carefully read the information related to the connection to the mains in the Chapters **Technical Parameters** and **Safety Precautions**. In case of any doubts, please contact an authorized BTL service.

After plugging the power cord to the mains, the device is put into the standby mode which is indicated by the orange backlighting of the **on/off** button (6) on the front panel of the device. If the **on/off** button (6) does not shine, re-check the connection of the power cord and, if necessary, contact an authorized BTL service.

To put the device into operation press the **on/off** button (6). Switching on the device is indicated by blue backlighting of this button.

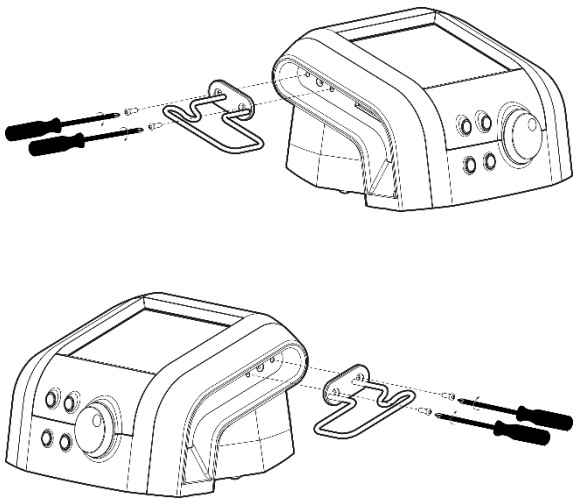
If the test of internal functions is passed, the display shows the initial screen and the device is ready for operation. If the device finds any discrepancy during the test of internal functions, it warns of it and, if necessary, locks itself in the secure mode. In such case it is necessary to contact an authorized BTL service.

To switch off the device, press the **on/off** button (6). Switching off the device is indicated by orange backlighting of this button. At the end of every working day, and especially in case of a longer planned pause in the use of the device, it should be disconnected from the mains socket.

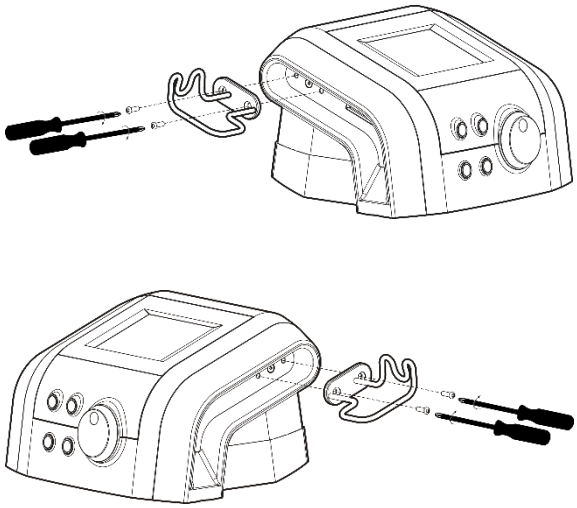
4.4.1 Connecting the Holders

The device is equipped with a set of holders, either holders for the applicators, or holders for the patient cables. The process of connection of the holders to the device is depicted below:

Set of holders for the applicators:



Set of holders for the patient cables:



4.4.2 Trolley Connection

BTL-6000 TR-Therapy can be mounted on the trolley specially designed for the device, as specified in the Chapter 5 List of Accessories. The trolley is designed for movement and placement of physiotherapeutic device BTL-6000 TR-Therapy

For detailed information please refer to instructions for use of the trolley BTL-040-05 (supplied together with the trolley).

4.4.3 Connecting the Electrodes

4.4.3.1 Types of Electrodes and Their Use

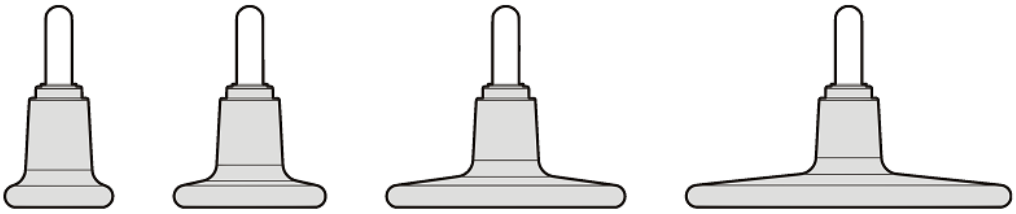
The device uses three types of electrodes: active electrodes, neutral electrodes and electrodes for static application. Active electrodes can be either capacitive or resistive, each of them in four different sizes. The active electrodes are used for the treatment. The neutral electrode is used as a reference electrode.

Before starting the therapy, apply a sufficient amount of RF cream on the neutral electrode and spread it all over its surface. Do not apply RF cream on the active electrodes. Better apply the cream directly on the treated area.

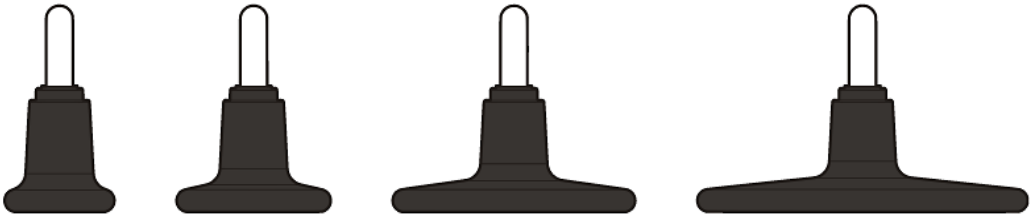
The use of the cream during the RF therapies allows to reduce the contact impedance between the electrodes and the skin. The high conductivity ensures the best results both in the capacitive phase and in the resistive phase of the treatment.

Place the neutral electrode under the patient's body nearby the area selected for the treatment and use the active electrode to treat the area. The static electrodes are intended for static application. Connect one of the static electrodes to the patient cable for neutral electrode and the other one to the patient cable for static application and adhere both electrodes to the patient's body.

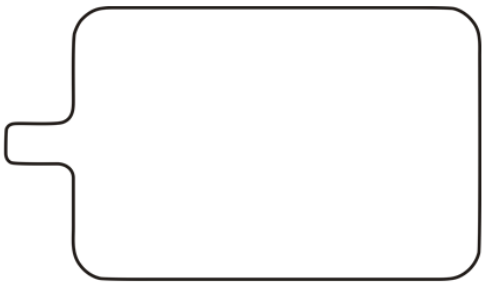
4 sizes of resistive electrodes (diameter 20, 30, 50 and 70 mm):



4 sizes of capacitive electrodes (diameter 20, 30, 50 and 70 mm):



Neutral electrode:

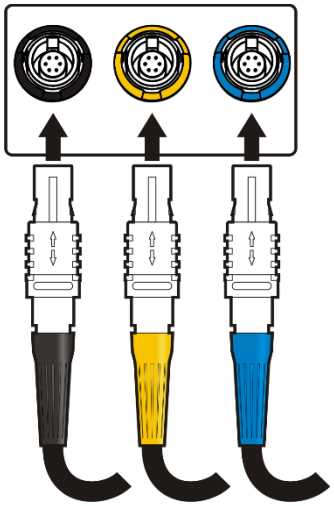


4.4.3.2 Types of Connections

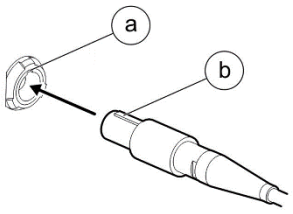
There are three types of connections – for capacitive applicator / patient cable, resistive applicator / patient cable / patient cable for static application and patient cable for neutral electrode. For interconnection of the parts, observe the type of the connector and the colour of each part.

4.4.3.3 Connecting Cables to the Device

For connecting the cables to the device, the output connectors are marked with the colour of the ring which corresponds to the colour marking on the cable. The cable for neutral electrode is marked black, the applicator / patient cable for capacitive electrode is marked yellow and the applicator / patient cable for resistive electrode / patient cable for static application is marked blue.



The connectors are equipped with a locking tongue which sets the correct connector position when connecting it.



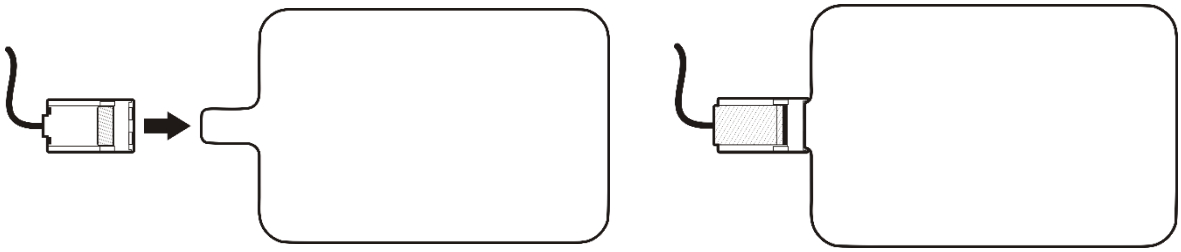
a) guiding groove of the output connector on the rear panel of the device

b) locking tongue on the accessories connector

4.4.3.4 Connecting the Electrodes with the Cables

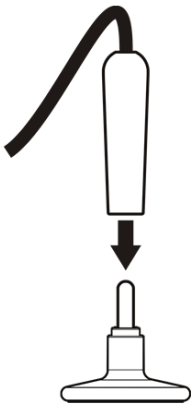
For connecting the electrodes to the applicators / patient cables observe the type of the connector and the colour of each part.

Patient cable for neutral electrode / patient cable for static application has flat connector with lock mechanism. Insert the neutral electrode / adhesive neutral electrode / adhesive electrode for static application while the lock is in upright position. Secure the electrode by closing the lock.

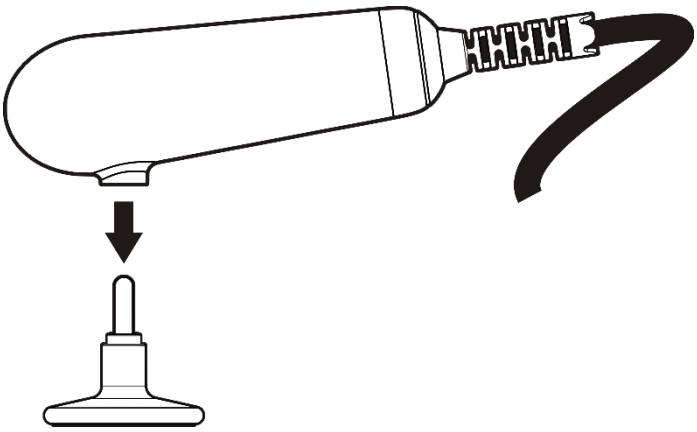


Applicators / patient cables for capacitive and resistive electrodes end with connectors, to which the electrodes can be connected.

Patient cable for capacitive / resistive electrode:



Capacitive / resistive applicator:



4.5 DESCRIPTION OF THE DEVICE CONTROL

4.5.1 Touch Screen

The touch screen displays graphical elements which can be pressed and activated, and other graphical elements which are only informational. The buttons on the screen can be pressed with a finger or any stylus without a sharp point (do not use pencils or pens, for example).

The BTL-6000 TR-Therapy Elite and the BTL-6000 TR-Therapy Pro devices have a bar with device control buttons at the upper edge of the touch screen:

to display the list of preset therapeutic protocols

to display the preset therapeutic protocol quick-selection screen

to display the therapy parameter screen

to set the device functions

to return to the initial screen

4.6 THERAPY – PRINCIPLE OF SETTINGS

4.6.1 Setting a Therapy by Selecting from the List of Preset Therapeutic Protocols – LIST

The list of all preset therapeutic protocols is displayed after pressing the **list** button on the touch screen. After saving your own *user therapeutic protocol*, the item user therapeutic protocols appears, including all of the saved protocols. Each of the user therapeutic protocol is marked by a card icon.

To move in the list of preset therapeutic protocols, use the arrows on the right side of the touch screen or turn the **select** knob (2). A protocol can be also quickly found by pressing the required alphabet letter on the bottom bar. After finding the required protocol, select it by touching its name on the screen or pressing the **enter** button on the touch screen or the **enter** button (3) on the device front panel.

After the selection of the required protocol the device displays the therapy parameters screen (see below – MANUAL screen), from which the therapy can be started directly by pressing the **start** button on the touch screen or **start/stop** (5) on the front panel of the device.

4.6.1.1 Body Parts Navigation

For the BTL-6000 TR-Therapy Elite, the LIST screen offers the function of filtering the preset therapeutic protocols by the body region. Pressing the button with the figure symbol will open the BODY PARTS screen indicating ten human body regions. Pressing the button with the required region displays the list of preset therapeutic protocols relevant for the respective region.

4.6.1.2 Encyclopaedia

After the selection of the required preset therapeutic protocol it is possible to find detailed information for the selected protocol by pressing the button with the encyclopedia symbol  on the therapy parameters screen.

The encyclopedia also includes a graphical part – pressing the button  on the touch screen will display the recommended placement of neutral electrode and the recommended application area treated with the capacitive and the resistive electrode.

Note: The preset therapeutic protocols (including the suggested parameters) serve only as a guide or a therapy proposal and by no means can they replace the professional consideration and experience from the clinical practice.

4.6.2 Quick Therapeutic Protocol Selection – QUICK

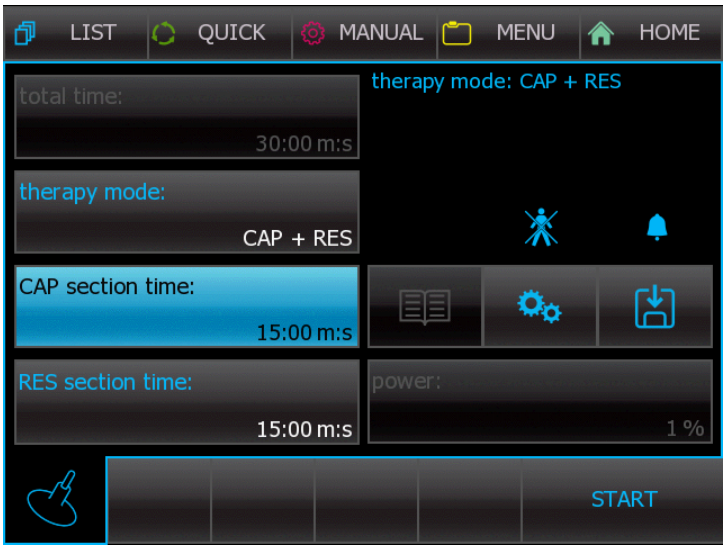
After pressing the **quick** button on the BTL-6000 TR-Therapy Elite touch screen the device displays the therapeutic protocol quick-selection screen – QUICK.

The QUICK screen serves as a quick starting point of a therapy without the need to browse the entire list of all preset therapeutic protocols. To select a protocol press the respective button. If you use other protocols than those preset in the factory more frequently, you can modify the protocol list in the device menu (menu – specific settings – QUICK screen protocols).

After the selection of the required preset therapeutic protocol from the QUICK screen, the device displays the therapy parameters screen (see below – MANUAL screen), from which the therapy can be started directly by pressing the **start** button on the touch screen or **start/stop** (5) on the front panel of the device.

4.6.3 User Setting of Therapy Parameters – MANUAL

Pressing the **manual** button on the touch screen displays the MANUAL therapy parameters screen in which it is possible to set the therapy parameters completely according to the user's requirements and from which the therapy can also be started immediately.



This screen is also displayed every time before the start of a therapy by selecting one of the preset therapeutic protocols of the LIST (BTL-6000 TR-Therapy Elite and BTL-6000 TR-Therapy Pro) or QUICK screens (BTL-6000 TR-Therapy Elite).

The therapy parameters screen allows setting the most important parameters of the required therapy. To change the parameters, press the specific button (the selected button is backlit according to the current colour scheme) and then use the **select** knob or buttons on the touch screen.

Repeated pressing of the buttons will open a dialog window allowing a more detailed setting of the parameter. Enter the required value using the **select** knob (2) and confirm it by pressing **enter** (3) or cancel it by pressing **esc** (4) on the front panel of the device or on the touch screen.

The text window displays supplementary information about the set therapy and, possibly, the name of the selected protocol.

The figure and bell symbols inform about the behaviour of the device during the therapy.

The icon of floppy disk  allows you to save therapy parameters as a user therapeutic protocol, which may be assigned to a specific client.

4.6.3.1 Setting the Therapy Mode

On the MANUAL screen choose from four available therapy modes. Select the mode pressing the button **therapy mode** on the touch screen. Choose CAP+RES, RES+CAP, CAP or RES for the treatment.

4.6.3.2 Setting the Therapy Time

According to the selected therapy mode, set the therapy time: CAP section time and RES section time. Total time of the therapy is shown in the button total time in the upper part of the MANUAL screen.

4.6.3.3 Setting the Therapy Power

You cannot set the therapy power on the MANUAL screen. The power of the therapy is set only on the screen of the running therapy.

4.6.3.4 Screen of Advanced Therapy Parameters EDIT

If you want to set the therapy parameters in more detail than offered by the MANUAL therapy parameter screen, press the **edit** button  on this screen. This will display the screen of advanced therapy parameters.

This screen does not allow starting the therapy directly; it is necessary to confirm the set parameters by pressing the **enter** button (3) and return to the MANUAL therapy parameter screen with the **start** button.

4.7 PROCESS OF TREATMENT

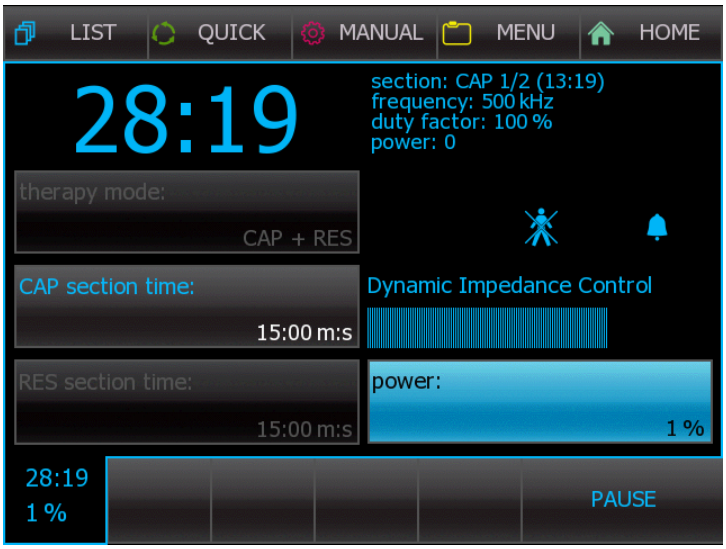
4.7.1 Start/Stop – Interruption of the Therapy

To start the therapy after selecting one of the preset therapeutic protocols or after setting the therapy parameters on the MANUAL screen, press the **start** button on the touch screen or **start/stop** (5) on the front panel.

4.7.2 Screen During Therapy

During the therapy the screen shows buttons with the main therapy parameters, similarly to the MANUAL therapy parameters screen.

- The running time value is highlighted to provide an instant overview of the course of the therapy.
- Set the power of the therapy with rotary knob **select.**
- When needed, change the CAP section time and the RES section time by pressing the respective buttons on the touch screen (therapy is paused) and use the knob **select** to change the value.
- The text window shows you the important therapy parameters of the currently running section.
- Power parameter represents the power delivered to treated area. It is equivalent to power in watts ±20 % for rated load 100 Ω. Accuracy of power measurement is affected by impedance of treated area. This parameter should not be used for any clinical purposes; it is intended only for relative reference.
- Dynamic Impedance Control™.
- The tab on the left bottom edge of the screen indicates the running time value and the value of the set power.



4.8 USER SETTINGS – MENU

After pressing the **menu** button on the touch screen you can browse the following menus of the device function settings:

- user settings / database
- unit settings
- specific settings

4.8.1 User Settings / Database

Selecting the **user settings / database** item displays a menu with items referring to the data saved by the user:

- clients
- user therapeutic protocols
- recent therapies

4.8.2 Unit Settings

Selecting the **unit settings** item displays a menu with items referring to the setting of the unit:

- language
- date & time
- sound settings
- colour schemes
- screen saver and auto switch-off
- password
- unit information
- accessories information
- advanced settings

4.8.2.1 Advanced Settings

This submenu allows setting the following parameters:

- HOME screen mode
- QUICK screen mode
- user accounts
- time of usage (available only when the function “user accounts” is enabled)
- touch panel calibration
- display contrast
- button backlight
- service functions
- dialog history
- setting of HW key

4.8.3 Specific Settings

Selecting the **specific settings** item displays a menu with items referring to following functions:

- QUICK screen protocols
- check contact during therapy
- contact loss signalization
- default therapy setting
- test of the applicator

5 ACCESSORIES

The device is not designed for use with any accessories or medical equipment other than those stated in this manual. The following table contains a list of all standard and optional accessories that can be supplied with the device.

Accessory	Model	Model of the device	
		BTL-6000 TR-Therapy Pro	BTL-6000 TR-Therapy Elite
Power cord	-	•	•
Set of two spare fuses	-	•	•
User´s manual	-	•	•
Touch screen pen pointer	-	•	•
Set of capacitive electrodes (4 sizes: 20, 30, 50, 70 mm)	BTL-249-SC4	•	•
Set of resistive electrodes (4 sizes: 20, 30, 50, 70 mm)	BTL-249-SR4	•	•
Neutral electrode (160 x 240 mm)	BTL-249-N1	•	•
Patient cable for neutral electrode	BTL-249-CABN	•	•
Resistive applicator	BTL-249-APR1	o	•
Capacitive applicator	BTL-249-APC1	o	•
Patient cable for resistive electrodes	BTL-249-CABR	•	o
Patient cable for capacitive electrodes	BTL-249-CABC	•	o
Patient cable for static application	BTL-249-CABS	o	o
RF cream	G016	•	•
Adhesive neutral electrode	F7805	o	o
Adhesive electrode for static application 90x148 mm	F7805P	o	o
Trolley[1)]	BTL-040-05	o	o
Transportation case	-	o	o
Set of holders for the applicators	-	o	•
Set of holders for the patient cables	-	•	o
Stand for electrodes	-	•	•
Holder for neutral electrode[2)]	-	o	o

• … standard o … optional

NOTE 1: For using together with BTL-6000 TR-Therapy unit refer to instruction for use supplied together with a trolley.

NOTE 2: Ordered separately from the unit. Designed for mounting to trolley only. For details refer to instruction for use supplied together with the holder.

6 MAINTENANCE

 **Before any maintenance switch off the device and unplug it from the mains!** Observe all safety principles listed in Chapter **Safety Precautions**. Never dismantle the device and its accessories during cleaning!

The recommended intervals for inspection of the device are 24 months after installation, subsequently each 12 months. The intervals may differ according to the local regulations. The inspection shall be performed according to procedure authorized by BTL.

Do not repair the device. All service actions must be done by an authorized BTL service only and only original parts can be use for repair, otherwise BTL bear no responsibility for further operation of the device.

6.1 CLEANING OF THE SURFACE OF THE DEVICE AND ACCESSORIES

For the cleaning of the device and its accessories use a soft cloth slightly moistened with water or a 2 % detergent solution. Never use agents containing alcohol, chlorine, ammonia, acetone, benzine or thinners. The touch screen shall be cleaned very gently using a dry soft cloth. The cloth may be slightly moistened with a commercially available screen cleaner. Never apply the agent cleaner directly onto the screen!

Never use abrasive materials for the cleaning, otherwise the surface of the device or accessories could get damaged.

6.2 CLEANING OF THE ACCESSORIES COMING INTO CONTACT WITH THE PATIENT

The accessories that come into direct contact with the patient's body shall be cleaned after each use with disinfectants approved for the use in health service. Do not use agents containing chlorine or those with a high alcohol content (more than 20 %). The electrodes shall be always cleaned from the remaining cream first. After cleaning, dry all the parts.

After the disinfection it is necessary to rinse the accessories with clean water so as to prevent undesirable allergic reaction!

The device accessories are designed for non-invasive use, therefore they do not need to be sterile.

6.3 TRANSPORT AND STORAGE

Keep the packaging of the device. Transport the unit in the original packaging or in the transportation case to ensure its maximum protection. Unplug the power supply cable and all accessory cables. Avoid strong shocks. The device shall only be stored and transported under the conditions defined in Chapter **Technical Parameters**.

7 TECHNICAL PARAMETERS

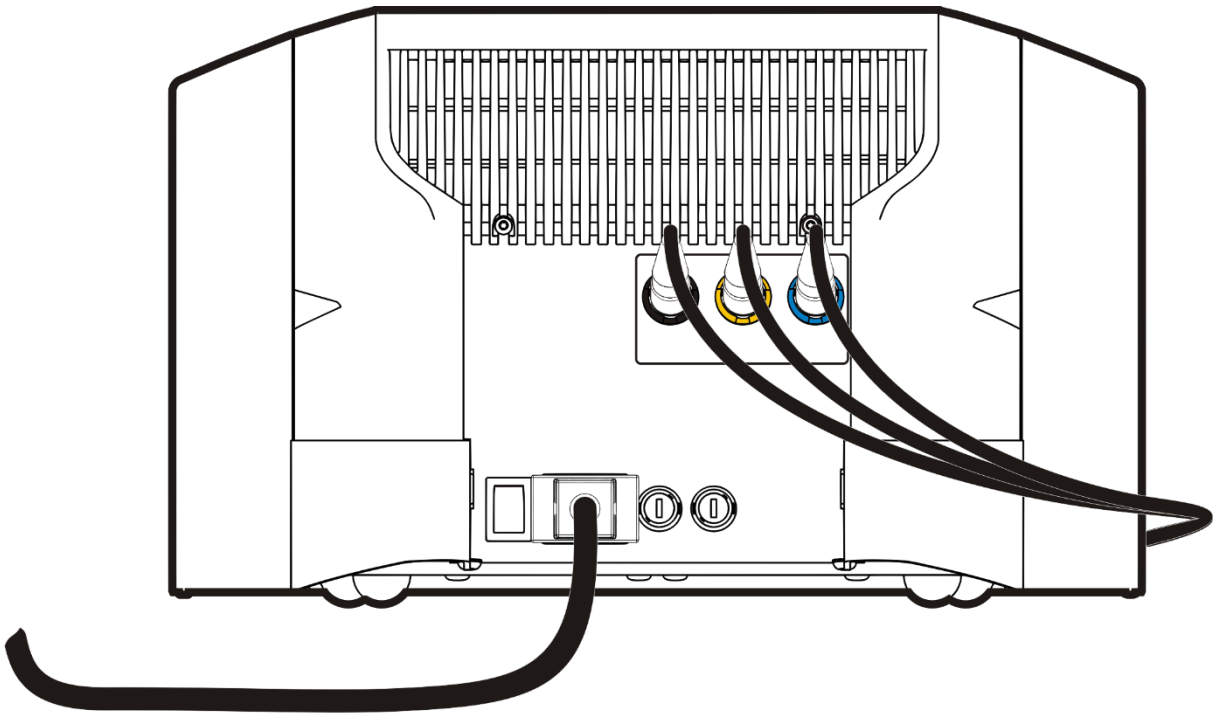
Name	**BTL-6000 TR-Therapy**	
Models	**BTL-6000 TR-Therapy Elite, BTL-6000 TR-Therapy Pro**	
Display BTL-6000 TR-Therapy Elite	LCD colour, diagonal 8.4”	
Display BTL-6000 TR-Therapy Pro	LCD colour, diagonal 5.7”	
Operating conditions	For indoor use	
Ambient temperature	+10 °C to +30 °C	
Relative humidity	30 % to 75 %	
Atmospheric pressure	800 to 1 060 hPa	
Position	Horizontal – on legs	
Type of operation	Continuous	
Storage and transport conditions		
Ambient temperature	-10 °C to +55 °C	
Relative humidity	10 % to 85 %	
Atmospheric pressure	650 to 1 100 hPa	
Position	According to marking on the package	
Other conditions	Transport only in the supplied package	
Power supply		
Supply voltage	Input mains voltage: AC 100 V to 240 V	
Mains frequency	50 to 60 Hz	
Maximum input	400 VA	
Power switch	On the back of device, positions 0 (off) and I (on). To disconnect from the mains, unplug the male plug of the power cord from the mains socket outlet.	
External exchangeable fuses	2x T4AH/250 V, tube safety fuse 5 x 20 mm, in accordance with IEC 60127-2	
Classification		
Type of applied part according to IEC 60601-1	BF (single applied part with two functions)	
Device class	II Device has a connection to protective earth for functional reasons only. The connection does not ensure any protection against electric shock.	
Class according to MDD 93/42/EEC	IIa	
Design		
Weight	Device: 5 kg Including packaging and accessories: 10 kg	
Dimensions (W x H x D)	Device: 325 x 210 x 290 mm Including packaging: 372 x 417 x 392 mm	
Degree of protection acc. to EN 60529	IP20	
Accuracy of parameters		
Therapy time	±5 % of set value	
System time	±5 seconds per day	
Power	Equivalent to output power ±20 % for rated load 100 Ω. For other loads the accuracy may differ.	
Output parameters		
	BTL-6000 TR-Therapy Elite	BTL-6000 TR-Therapy Pro
Output current	Max 1.8 A ± 20 %	Max 1.25 A ± 20 %
Output voltage	Max 180 V ± 20 %	Max 125 V ± 20 %
Output power	Max 324 W ± 20 %	Max 156 W ± 20 %
Nominal load impedance	100 Ω	
Working frequency	480 to 520 kHz	

7.1 ESSENTIAL PERFORMANCE OF THE DEVICE

The BTL-6000 TR-Therapy has no essential performance according to IEC 60601-1.

7.2 CABLE ROUTING

To avoid unwanted electromagnetic emission into mains which may influence close-by electronic equipment, please don’t route patient cables and power cord simultaneously. Correct position is with power cord and patient cables routed in opposite directions from the unit. See scheme bellow.



7.3 INTERCONNECTION WITH OTHER DEVICES

The BTL-6000 TR-Therapy is not intended for interconnection with other devices.

7.4 ELECTROMAGNETIC COMPATIBILITY (EMC)

Medical electrical equipment should be used with precautions according to the EMC directive and must be installed in compliance with the EMC notices disclosed in this manual; otherwise the equipment could be adversely affected by mobile RF transceivers.

The use of accessories, transducers and cables other than those specified, with the exception of the transducers and cables sold by the manufacturer as the spare parts for the internal components, may increase the radiation or reduce the durability of the device.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The BTL-6000 TR-Therapy is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 TR-Therapy shall ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The BTL-6000 TR-Therapy is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. **Warning**: The BTL-6000 TR-Therapy is designed for use by medical professionals only. The BTL-6000 TR-Therapy may cause radio interference or disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the BTL-6000 TR-Therapy or shielding the location.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the BTL-6000 TR-Therapy				
The BTL-6000 TR-Therapy is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BTL-6000 TR-Therapy can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BTL-6000 TR-Therapy as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (m)**			
	150 kHz - 80 MHz **$d = [3.5/V_1]\sqrt{P}$**		**80 MHz – 800 MHz** **$d = [3.5/E_1]\sqrt{P}$**	**80MHz - *2.7 GHz*** **$d = [7/E_1]\sqrt{P}$**
	$V_1 = 3V$	$V_1 = 6V$		
0.01	0.12	0.06	0.12	0.23
0.1	0.37	0.18	0.38	0.73
1	1.2	0.6	1.2	2.3
10	3.7	1.8	3.8	7.3
100	11.7	5.6	12	23
For transmitters at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable for the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: In case of a frequency of 80 MHz or 800 MHz, the formula for higher frequency range is applicable. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

Guidance and manufacturer's declaration – Electromagnetic immunity			
The BTL-6000 TR Therapy is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 TR Therapy should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle at 0° 70 % U_T; 25 cycles at 0° 0 % U_T; 250/300 cycle	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle at 0° 70 % U_T; 25 cycles at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE : U_T is the AC mains voltage prior to application of the test level.			

<table>
<tr><th colspan="5">Guidance and Manufacturer's Declaration – Electromagnetic Immunity</th></tr>
<tr><td colspan="5">The BTL-6000 TR-Therapy is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 TR-Therapy shall ensure that it is used in such environment.</td></tr>
<tr><th>Immunity test</th><th colspan="2">IEC 60601
Test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF IEC 61000 -4-6</td><td colspan="2">3 V in 0,15 MHz – 80 MHz

6 V in ISM bands between 0,15 MHz and 80 MHz</td><td>3 V in 0,15 MHz – 80 MHz

6 V in ISM bands between 0,15 MHz and 80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment shall be used no closer to any part of the BTL-6000 TR-Therapy, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = [3.5/V_1]\sqrt{P}$
$d = [3.5/E_1]\sqrt{P}$ 80 MHz to 800 MHz
$d = [7/E_1]\sqrt{P}$ 800 MHz to 2.7 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
The intensities of the fields from fixed high-frequency transmitters, determined by the summary of the electromagnetic characteristics of the location [a], shall be lower than the compliance level [b] in every frequency band.
Interference may occur in the vicinity of a device identified with the following mark:  </td></tr>
<tr><td>Radiated RF
IEC 61000-3-4</td><td colspan="2">3 V/m</td><td>3 V/m
80 MHz to 2.7 GHz</td></tr>
<tr><td rowspan="11">Immunity to proximity fields from RF wireless communications equipment – Table 9. IEC 60601-1-2:2014

Performed according to IEC 61000-4-3</td><td>27 V/m</td><td>385 MHz</td><td>PM 18 Hz</td><td rowspan="11">Note: Compliance level is the same like test level.</td></tr>
<tr><td>28 V/m</td><td>450 MHz</td><td>FM 5 kHz</td></tr>
<tr><td rowspan="3">9 V/m</td><td>710 MHz</td><td rowspan="3">PM 217 Hz</td></tr>
<tr><td>745 MHz</td></tr>
<tr><td>780 MHz</td></tr>
<tr><td rowspan="3">28 V/m</td><td>810 MHz</td><td rowspan="3">PM 18 Hz</td></tr>
<tr><td>870 MHz</td></tr>
<tr><td>930 MHz</td></tr>
<tr><td rowspan="3">28 V/m</td><td>1720 MHz</td><td rowspan="3">PM 217 Hz</td></tr>
<tr><td>1845 MHz</td></tr>
<tr><td>1970 MHz</td></tr>
<tr><td>28 V/m</td><td>2450 MHz</td><td>PM 217 Hz</td></tr>
<tr><td rowspan="3">9 V/m</td><td>5240 MHz</td><td rowspan="3">PM 217 Hz</td></tr>
<tr><td>5500 MHz</td></tr>
<tr><td>5785 MHz</td></tr>
<tr><td colspan="5">NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="5">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BTL-6000 TR-Therapy is used exceeds the applicable RF compliance level above, the BTL-6000 TR-Therapy should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BTL-6000 TR-Therapy.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

8 MANUFACTURER

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