BTL-4000 SMART

BTL-4000 PREMIUM

USER'S MANUAL

CONTENT

1 BASIC CHARACTERISTICS OF THE DEVICE

BTL-4000 Smart and BTL-4000 Premium is a series of professional physiotherapy devices. Depending on the required configuration, each device can consist of up to three generators. Four types of generators are available: generators for electrotherapy, ultrasound therapy, laser therapy and magnetotherapy.

Both variants of the device – BTL-4000 Smart and BTL-4000 Premium – are equipped with a colour touch screen which considerably simplifies its operation. The therapy is simply started by a quick selection from a list of most frequently used therapeutic protocols or by selecting from a list of all therapeutic protocols. A sophisticated function of the device is the possibility to select the optimum therapy based on the required therapeutic effect or place of application.

You can easily adjust any therapy parameter using the buttons on the touch screen and/or on the front panel of the device. Throughout the therapy the device keeps you informed on the screen about the applied therapy type, accessories used, remaining therapy time and main therapy parameters.

1.1 INTENDED USE

The intended use depends on the specific device configuration - see Chapter **Types and Models of the Device**.

1.1.1 Electrotherapy

Electrotherapy is a non-invasive therapeutic method based on electrical current flow through human tissues. The electric current is applied with the use of electrodes directly through patient's skin. The use of electrotherapy is accepted in the field of rehabilitation for acute and chronic pain management, treatment of nerve and muscle tissue dysfunctions, treatment of post-traumatic joint mobility impairments, acute and chronic oedema reduction and peripheral blood flow increase.

1.1.2 Ultrasound Therapy

Ultrasound therapy is a non-invasive therapeutic method which uses mechanical energy of longitudinal waves penetrating deep through human soft-tissues resulting in local increase of blood flow and metabolism. The ultrasound therapy is mainly intended for treatment of muscle and connective tissue disorders, reduction of post-traumatic conditions as oedema and healing process acceleration.

1.1.3 Laser Therapy

Low-level laser therapy is a non-invasive therapeutic method based on application of coherent, polarized, monochromatic light in a form of laser beam. The laser beam is absorbed in human tissues and its energy is transmitted to the tissue cells to help restore their normal function. The effect is above all bio-stimulating, regenerating, anti-inflammatory and analgesic, based on the induced photochemical reactions. Low-level laser is useful in the therapy of painful disorders of the musculoskeletal system, in the therapy of inflammatory conditions of skin, mucosa and soft-tissue and in accelerated healing of wounds (e.g. burns, scars) and soft-tissue injuries.

1.1.4 Magnetotherapy

Magnetotherapy is a non-invasive therapeutic method based on application of low-frequency pulsed electromagnetic field. The electromagnetic induction of the field provokes biological effect in tissues such as analgesia, vasodilation and increase of metabolism. Magnetotherapy is intended especially for treatment of post-traumatic conditions, delayed and non-union fractures, soft-tissue, degenerative and rheumatological disorders and post-operative and chronic musculoskeletal pain relief.

1.2 USER PROFILE

The device shall be used by medically educated personnel. The users shall be familiar with all safety precautions, operating procedures and maintenance instructions given in this user's manual.

1.3 OPERATING ENVIRONMENT

The device is intended solely for professional use in medical facilities. The device is designed for indoor use only, not for use in a location where explosion or water intrusion hazards are present, not for use in dusty or humid environment and not to be exposed to direct sunshine. The device is not intended for home-use.

1.4 PATIENT PROFILE

The use of the device is not limited by gender nor age of the patient in general. Weight of the patient is limited to 135 kg only for use with solenoid Ø 70 cm on magnetotherapy couch. Nevertheless, manufacturer does not recommend the use of the device on patients until the epiphyseal closure, especially on neonates and small infants. The patient shall not show any signs of contraindications determined for the device. The user should take into account a detailed patient's medical history, including previous treatment modalities and examine the patient thoroughly to determine whether or not the application of therapy is suitable for the patient.

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 before using the device. It is prohibited to use the device and its accessories in any manner that is not in accordance with the User's Manual.

- If the device is used in compliance with the User's Manual and all operating and maintenance conditions, safety precautions and contraindications are observed, no adverse side effects of electrotherapy, ultrasound therapy, laser therapy and magnetotherapy are known.

- The device can consist of up to three generators. Four types of generators are available – generators for electrotherapy, ultrasound therapy, laser therapy and magnetotherapy. It is allowed to start up to three therapies at a time. The device is certified to perform the therapy on one patient.

- 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.

- The device must be powered exclusively by the power adaptor supplied together with the device (for the type of the power adaptor see **Technical Parameters**). The use of any other power adaptor than stated may cause serious damage to the device and be a risk to the patient's and operator's health. Do not use extension cords with multiple sockets or multi-socket adaptors. To disconnect the device from the mains, detach the power adaptor from the device, unplug the supply cable from the socket or disconnect the supply cable from the power adaptor.

- 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 risks are present or in dusty or humid environments. It is prohibited to use the device in spaces where flammable anaesthetic oxidizing gases (O_2, N_2O) and other flammable gases or vapours are present.

- The device does not include any medicaments or substances to be applied by it. During the storage and operation under the specified conditions the device does not use or emit any dangerous substances, radioactive substances or materials with induced radioactivity.

- Place the device out of direct sunlight and strong electromagnetic fields of nearby devices (diathermy, X-rays, mobile phones and other radio-frequency equipment) to prevent unwanted interference. If unwanted interference occurs, place the device farther from the source of interference or contact the BTL authorized 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 side panels of the device and 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 transferred from a cold environment to a warmer one, wait until temperatures are equalized (at least 2 hours) before plugging it in.
-  No modification of this equipment is allowed! Do not try to open or remove the protective covers or disassemble 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.

- Never use the accessories connector or other connectors to plug in anything else than they are designed for (see **Connection of Accessories**). There is a serious risk of electric shock and serious damage to the device! The device is equipped with a protective system against connecting other accessories than those supplied by the manufacturer, so it does not function with accessories of other manufacturers.
-  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. This includes the electrodes for electrotherapy, applicators for ultrasound therapy and applicators for magnetotherapy. Applicators for laser therapy are not intended to be in touch with a patient and they are therefore not considered as applied parts.
-  The output current or voltage may exceed safe values in connectors marked with this symbol.

- Before starting the therapy make sure that all set parameters match your requirements. Follow the therapy contraindications detailed in the Chapter **Contraindications**.

- When terminating the therapy, do not press the **on/off** button (2), but the **start/stop** button (5). The time interval between switching the device off and switching it on again using the **on/off** button must be at least 3 seconds.

- If the device does not respond and cannot be operated, it is possible to reset it by pressing the **on/off** button (2) for at least 10 seconds. If the device does not respond to pressing the **on/off** button (2) during switching off, unplug the power adaptor from the mains and contact an authorized BTL service.

- The device accessories (ultrasound applicators, laser probes/clusters, electric cables with electrodes) should always be placed properly in the holders when not in use (see **Holders for Accessories**). Improper storage and handling can cause wear of the accessories and/or change of their properties. If more accessories are connected to the device at a time (for example two various ultrasound applicators), do not touch the accessory which is not currently in use during the therapy.

- Before each therapy check carefully the device and its accessories (cables, connectors, electrodes, ultrasound heads, laser probes/clusters, magnetotherapy 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 an 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.

- The device displays system and error messages to inform the user of problems or potential problems with the unit or accessories. These are designed to be self-explanatory. In case of any uncertainties stop using the device and contact an authorized BTL service.

- 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! Never touch the connectors on the rear panel of the device with your hand. Never touch the connectors on the rear panel of the device and the patient simultaneously.

-  The device must be disposed of in a way common for electric and electronic equipment. The removed battery must be disposed of separately according to local hazardous waste disposal requirements. Do not place the device and the battery in municipal waste containers! The device does not contain any toxic materials which could harm the environment if disposed of properly.

- The liability of continuous (at least acoustic) contact with the patient applies to all physical therapy procedures.

- Keep the device out of reach of children.

- Protect the device against unauthorized use.

2.2 SPECIFIC SAFETY PRECAUTIONS FOR ELECTROTHERAPY

- All electrodes supplied with the BTL device for electrotherapy can be used for current intensities and voltages in a manner that is stated in **Technical Parameters of Electrotherapy**. Never use the electric cables without the electrodes connected. We recommend that you check the quality of electrodes periodically. During direct current electrotherapy, electrolysis products accumulate near to the electrodes, so it is necessary to rinse the electrodes in clean water after each therapy. Nevertheless, wear of the electrodes may be faster and their earlier replacement is then necessary.

- When applying electrotherapy, an electrode pad is always used for correct electric current flow, which must be thoroughly moistened with tepid water before each therapy. Water must not drip spontaneously from the moistened electrode pad.

- The electrode pads must be thoroughly washed in tepid water before first use! They are impregnated during production with a special substance to prevent mildew. After the electrode pads have been washed and dried, they harden which is not a defect – they will soften again after they have been moistened. After each therapy the electrode pads must be washed in a manner described in **Maintenance of the Device**. We recommend that the quality of the pads is checked before each use – in case of any signs of wear they have to be replaced.

- When applying direct currents and currents with a direct component, always soak the electrode pads with suitable cathode / anode protective solutions which protect skin against burning! When using anode and cathode protective solutions, always make sure not to confuse them and not to change polarity during therapy! In this case, electrolysis products accumulate in the electrode pads which may result in faster wear. It is necessary to check the electrode pads regularly and replace them earlier if necessary. After each therapy, the electrode pads must be washed thoroughly in tepid water and cleaned in a manner described in **Maintenance of the Device**.

- When applying diadynamic currents without using protective solutions, the therapy time must not exceed 6 minutes. You can change polarity once per therapy and the total therapy time in such case must not exceed 12 minutes. When applying direct (monophasic) pulsed currents (Träbert, Farad, Leduc etc.) the application time without protective solutions should not exceed 15 minutes.

- The maximum safe current density on an electrode is 0.1 mA/cm^2 for direct currents, 1 mA/cm^2 for low-frequency currents and 10 mA/cm^2 for TENS and mid-frequency currents. It thus depends on the electrode surface size (size of the electrode pad) and the type of current! If these values are exceeded, there is a risk of patients' burns!

- The current density values over 2 mA/cm^2 always require special user attention!

- The application of electrodes near to the chest area may increase the risk of arrhythmia. Transthoracal application is generally contraindicated for the use of electrotherapy!

- Connecting the patient to a high-frequency surgical device may result in burns in the locations of electrodes of the electrotherapy device and possible damage to the electrotherapy device.

- Simultaneous connection of the patient to an ECG system may result in temporary outage of the ECG system or may distort the data measured by the ECG system.

- Operating the device near (e.g. 1 m) a short-wave or microwave therapeutic device may cause instability of the device output.

- Electrodes with the prescribed pads must not overlap during application; the optimum placement of electrodes is described in the encyclopaedia of the device for individual therapy protocols. Electrodes must be reliably connected in the prescribed manner (elastic straps, vacuum electrodes); they should not be loaded down by the body segment weight and the patient must not be lying on them.

-  During the therapy the patient and the operator must not touch the electrodes. If you want to adjust the attachment of the electrodes, always interrupt or stop the therapy first.

- Patients are not allowed to manipulate the device or regulate current intensity.

- If the device automatically reduces intensity (during therapy or when the intensity is set) check the condition of the electrodes. This phenomenon is caused by high contact resistance.

- Vacuum electrodes cannot be used for the application of direct currents and currents with a direct component, where the sponges must be soaked in protective solutions and could be damaged by the electrolysis products. Direct currents are not intended for a combination therapy either.

- It is not allowed to run an HVT therapy with vacuum units.

- The use of electrotherapy for the sole purpose of symptomatic analgesic treatment may suppress pain perception which has a protective and informative purpose in human body.

- Electrotherapy contraindications are listed in the Chapter **Contraindications**. The physicians prescribing the therapy despite the contraindications bear full responsibility for such an action.

- The type and size of electrodes should be selected according to the treated area.

2.3 SPECIFIC SAFETY PRECAUTIONS FOR ULTRASOUND THERAPY

- For ultrasound treatment, use an ultrasound head or operator independent HandsFree Sono applicator.

- HandsFree Sono is an operator independent applicator for ultrasound therapy. Before the start of therapy, apply ultrasound gel on the plate of the HandsFree Sono and attach the applicator to the treated area using the fixation straps. After the start of therapy do not manipulate the applicator; the applicator simulates the therapist's movements by means of automatic switching of the ultrasound crystals.

- Always protect the ultrasound heads and HandsFree Sono applicators from hitting their metal parts and housing; any shock can adversely affect their parameters. When not used in therapy, ultrasound heads should be placed in the holders. Do not bend the power cord. Check the applicators for damage (especially cracks) before each therapy. If you find damage, do not continue using the applicator and contact an authorized service.

- During the therapy, hold the ultrasound head in such a way to avoid the contact with its metal part. It is necessary to move the head continuously during the application according to the prescribed therapy type to prevent tissue damage at the maximum intensity. During subaqual application, hold the head so that your hand is not immersed in the water and the ultrasound head is placed about 10–12 cm from the target tissue. When using the HandsFree Sono, ensure sufficient contact between the applicator and the patient's body by fastening the applicator with fixation straps. To let the patient apply ultrasound to himself/herself is a serious infringement of the *lege artis* rules!

- When applying ultrasound by means of any applicator, ultrasound gel shall be used for correct passage of the ultrasound waves. It is recommended to use the BTL ultrasound gel. The applicators have not been tested for use with other gels or oils and can be damaged.

- Use of ultrasound applicators leads to their heating. In sporadic cases the temperature can rise significantly. In such situation the device temporarily decreases the ultrasound intensity for the patient's safety. You will be informed about this situation by the following changes on the display: Change of duty factor to 10% on the screen of running therapy. Change of graphical representation and a message "output power limited" in the text window of MANUAL screen. The parameters are automatically reset to the original values after the temperature decreases again. In case the temperature still increases, the therapy is immediately stopped. The heating of applicators can be limited by using enough gel.. The better the contact, the lower is the heating.

- Ultrasound therapy contraindications are listed in the Chapter **Contraindications**. The physicians prescribing the therapy despite the contraindications bear the full responsibility for such an action.

2.4 SPECIFIC SAFETY PRECAUTIONS FOR LASER THERAPY

The device operates with a class 3B laser beam; failure to observe the following measures and precautions may result in dangerous irradiation! The applicators shall not touch the patients during the therapy; the applicators are not applied parts!

- The device must be located in a special (flank) room with minimum reflective surfaces with beam reflection risk. The room shall be fitted with warning signs. The device must be protected from unqualified use. The laser workplace must be equipped with service regulations approved by a health officer.

- The safety door switch must ensure that the device is automatically switched off once the door is opened. The door switch (not supplied with the device) can be connected in the connector on the rear side of the device; a standard connector of the power jack type is used for the interconnection.

- During the therapy, both the patient and the therapist shall wearprotective laser eyewear, minimum class L3, wavelength 630–850 nm. We recommend using the BTL protective eyewear. Periodically inspect the protective eyewear for any damage. Do not use damaged protective eyewear!

- During the therapy, the laser probe/cluster is just above the treated area, for hygienic reasons it does not touch the body surface. The laser radiation comes out through the aperture at the end of the probe (which is covered by protective glass in case of the laser cluster). Never disconnect the probe/clusters from the device during radiation and never intentionally switch off the device in this situation.

- Protect the laser probe / cluster consistently from shocks! When not used in therapy, they must be placed in the holders. The probe and the cluster are not waterproof.

- Laser therapy contraindications are listed in the Chapter **Contraindications**. The physicians prescribing the therapy despite the contraindications bear full responsibility for such an action.

2.5 SPECIFIC SAFETY PRECAUTIONS FOR MAGNETOTHERAPY

- Never use damaged applicators. Electric shock to personnel or patient may occur.

- Attending personnel should keep away from the patient side of the applicator during the therapy. The relevant channel should be switched off during necessary manipulation.

- Watches, electronic devices and magnetic recording carriers can be damaged when closely exposed to applicators and cables.

- Do not connect anything else to the connectors – there is a danger of injury by electric shock and / or serious damage to the device.

- The device must not be used in the presence of pregnant women!

- Magnetotherapy contraindications are listed in the Chapter **Contraindications**. The physicians prescribing the therapy despite the contraindications bear the full responsibility for such an action.

- Use of the magnetotherapy applicators leads to their heating. In sporadic cases the temperature can rise significantly. In this situation the device temporarily decreases the intensity of magnetic field to the half for the patient's safety. You will be informed about this situation by the following changes on the display: Decreased value of the intensity on the touch screen. In the text window of MANUAL screen, the message "applicator power limited" will display. In case the temperature still increases, the device decreases the intensity of the magnetic field to a quarter of the original value. The parameters are automatically reset to the original values after the temperature decreases again.

2.6 SPECIFIC SAFETY PRECAUTIONS FOR COMBINED THERAPIES

 Combination of individual therapies to be simultaneously used on one patient is allowed only for combination of electrotherapy and ultrasound therapy. Other combinations are not recommended by the manufacturer.

Specific safety precautions for combination therapy are the same as for electrotherapy and ultrasound therapy modalities.

 Galvanic currents or currents containing a significant direct (galvanic) component should not be applied during combination therapy because of the need to use protective solutions.

2.7 POSSIBLE SIDE EFFECTS

2.7.1 Possible Side Effects for Electrotherapy

The application of electrodes near the chest area may increase the risk of arrhythmia.

Electrotherapy use for the sole purpose of symptomatic analgesic treatment may suppress pain perception, which has a protective and informative purpose in human body.

If the maximum safe current density values are exceeded, there is a risk of burns.

2.7.2 Possible Side Effects for Ultrasound Therapy

There is risk of burns when high-intensity, continuous ultrasound is used in a stationary application.

There is risk of infection as a consequence of patient cross-contamination when violating the instructions of the transducer head cleaning.

2.7.3 Possible Side Effects for Laser Therapy

Possible side effects for laser therapy include in particular:

- transient tingling
- mild erythema
- skin rash
- burning sensation
- increased pain
- numbness

2.7.4 Possible Side Effects for Magnetotherapy

There are no known possible side-effects for the clinical application of magnetotherapy.

3 CONTRAINDICATIONS

The list of contraindications specifies situations in which the manufacturer does not recommend the application of physiotherapy.

Before the application it is necessary to take the patient's medical history and make a thorough examination to determine whether or not the application of physiotherapy is suitable for the patient.

 If contraindications are not respected, the physicians prescribing therapy and the centre or clinic where the procedure is performed are fully responsible for the treatment and the patient's safety.

3.1 GENERAL CONTRAINDICATIONS FOR PHYSIOTHERAPY

The following contraindications apply to all types of physiotherapy:

- Febrile conditions of any etiology
- Overall cachexia of any etiology (this does not apply to TENS in terminal stages of metastatic tumors)
- Regions of known or suspected malignancy
- Tissues infected with tuberculosis or other forms of virulent bacteria
- Bleeding conditions and hemorrhagic disorders, menses
- Electronic and metal objects in the place and path of the application – active medical implants (e.g. pacemaker, cochlear implants), endoprostheses, splints and bolts, piercing (this does not apply to non-ferromagnetic metals during magnetotherapy)
- Skin inflammation, trophic skin changes in the area of application, irritated or damaged skin (this does not apply to laser therapy)
- Pregnancy (this does not apply to electrotherapy outside the abdominal and pelvis area)
- Area of thyroid gland, gonads and large sympathetic plexuses
- Serious cardiac or respiratory insufficiency
- Sensation disorders (hypesthesia or anesthesia in the area of application)

3.2 SPECIAL CONTRAINDICATIONS FOR PHYSIOTHERAPY

The contraindications listed below expand the list of general contraindications for each type of physiotherapy.

3.2.1 Contraindications for Electrotherapy

- Electroanalgesia without exact diagnose of pain etiology
- Allergies to protective solutions used for sponge covers for electrodes
- Application in the area of chest, heart, eyes
- Cardiovascular diseases
- Sensation disorders in the area of electrode location (relative contraindication)
- Psychopathological syndromes
- Multiple cerebrospinal sclerosis
- Blood vessels and lymphatic vessels inflammation

3.2.2 Contraindications for Ultrasound Therapy

- Application in the area of eyes, brain, chest, heart, spinal cord
- Application over parenchymatous organs – liver, spleen, lungs, endocrine glands, gonads
- Bony bumps under the skin (vertebral spinous processes, ankles, condyles, epicondyles)
- Peripheral nerves under the skin
- Healing fractures, epiphyses of growing bones
- Post-laminectomy conditions
- Allergies to the applied ultrasound gels

3.2.3 Contraindications for Laser Therapy

- Application in the area of eyes – risk of retinal damage
- Application on endocrine glands, particularly the thyroid gland
- Application on tattoo
- Photodermathoses, systemic lupus erythematosus
- Deep vein thrombosis or thrombophlebitis
- Period of 4–6 months after radiotherapy
- Pulse modes (including the infrared lasers) shall not be applied on individuals suffering from paroxysmal disease (epilepsy)
- Be careful when using medications with photosensible substance – some antibiotics, non-steroid antirheumatics, anticoagulants (Warfarin), etc.

3.2.4 Contraindications for Magnetotherapy

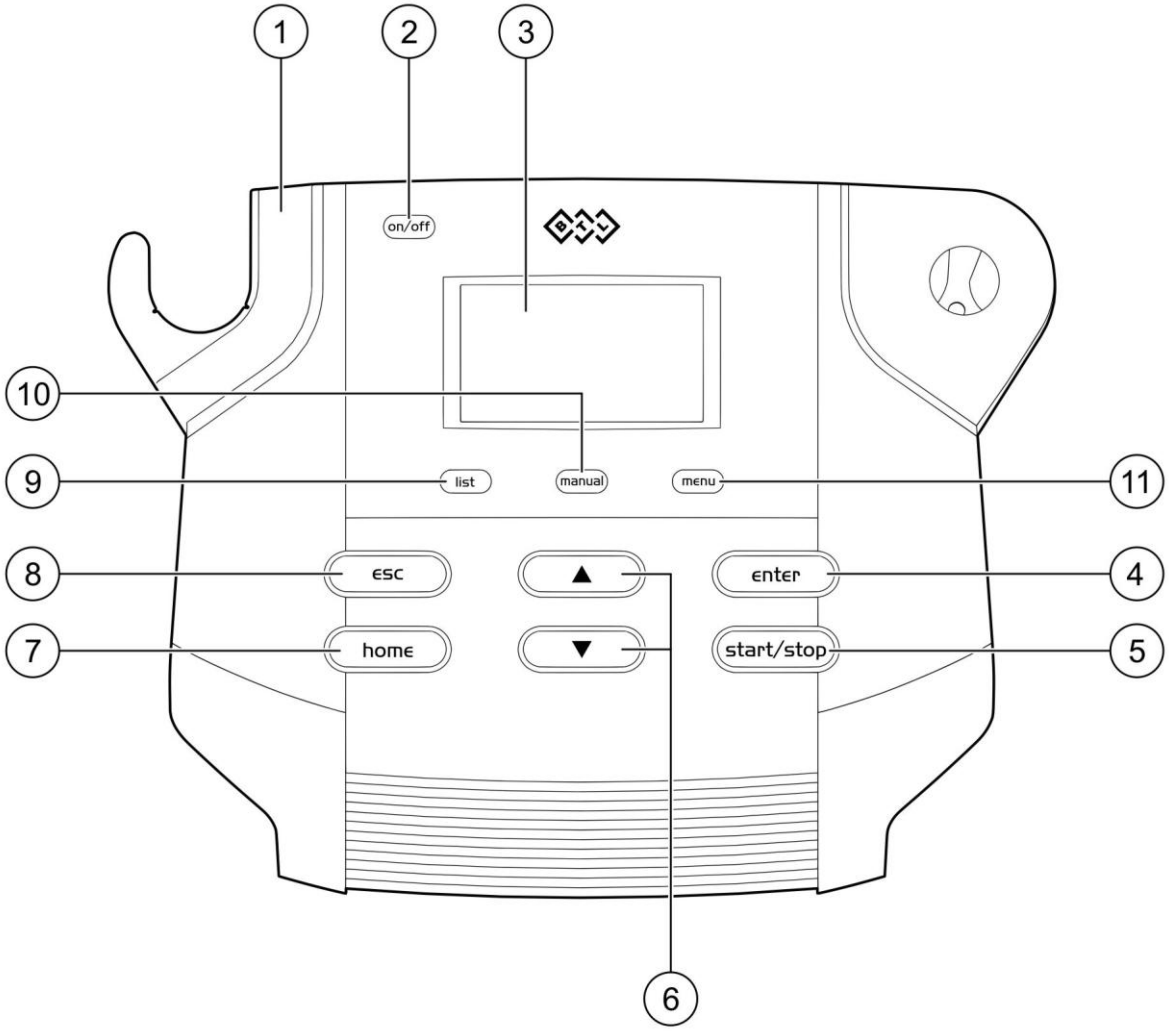
- Implants made of ferromagnetic materials
- Abnormal functions of endocrine glands, myasthenia gravis
- Paroxysmal neurologic diseases
- Psychopathological syndromes
- Severe mycoses, onychomycoses, tissues infected with virulent bacteria
- Special attention has to be paid to patients with hypotension or hypertension and epileptics
- Epiphyses of growing bones
- Juvenile diabetes

4 SYMBOLS AND MARKING OF THE DEVICE

	Warning
	Caution
	Laser equipment warning label. Warning: the values of laser light energy used during therapy may exceed safe values.
	Safety button for the interruption of laser therapy
	Type BF applied part
	Class II equipment
	Before the use of the device read the manual and follow its instructions
	Separate collection for electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
	Serial number
	Batch code
	Catalogue number
	CE mark

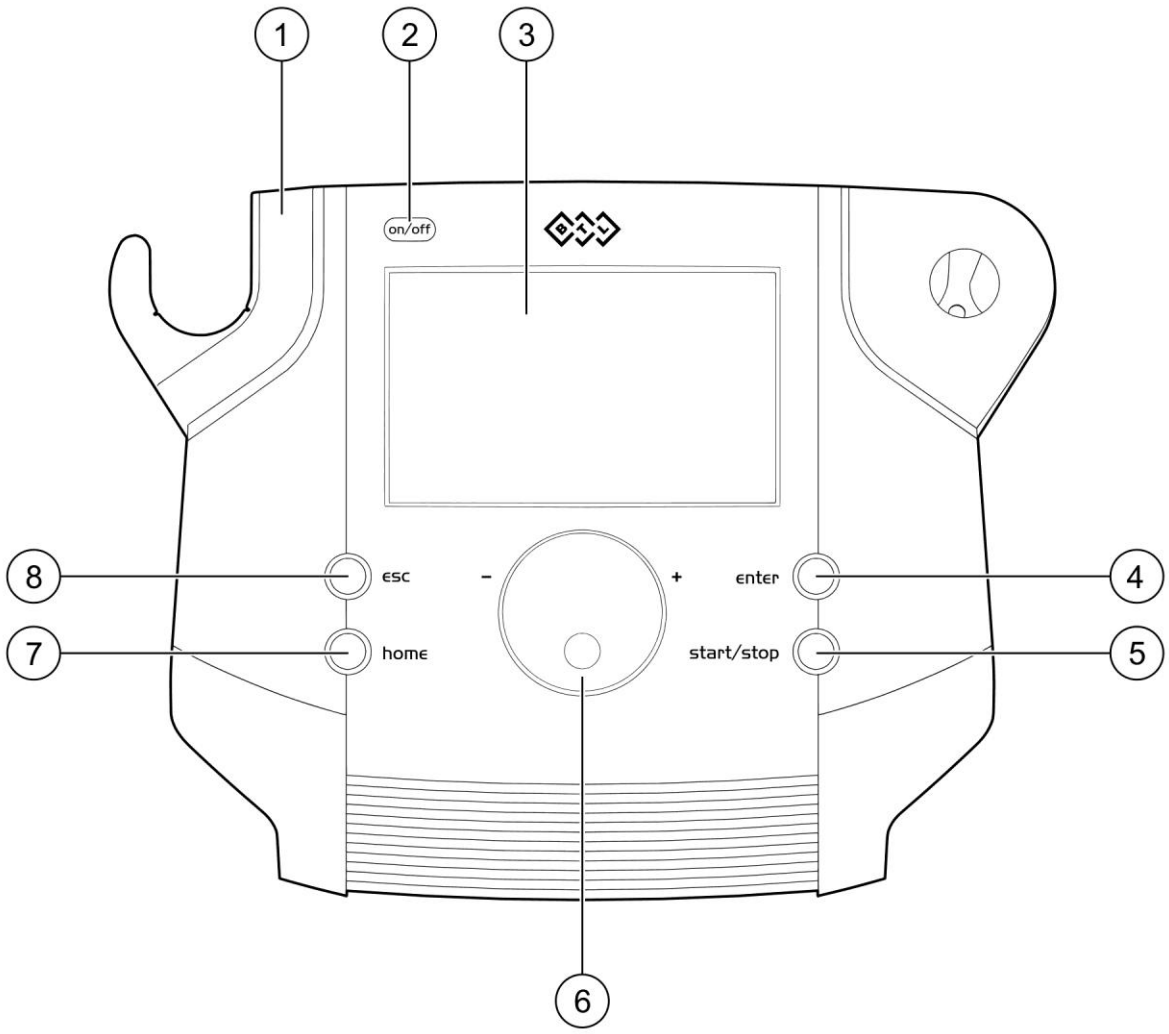
5 INSTRUCTIONS FOR OPERATION

5.1 FRONT PANEL OF THE BTL-4000 SMART



1 accessories holder (the type of the holder depends on the specific device configuration – see Chapter **Accessories Holders**)
2 **on/off** button (to switch the device on/off)
3 4.3" touch screen
4 **enter** button (to confirm the selection)
5 **start/stop** button (to start/stop the therapy)
6 **select** buttons with the indicated **up** and **down** arrows (to move in the device menu and to set the therapy parameters)
7 **home** button (to return to the initial screen)
8 **esc** button (to reject the selection and return to the previous state)
9 **list** button (to set the therapy by selecting the therapeutic protocol)
10 **manual** button (for the user settings of therapy parameters)
11 **menu** button (to set the functions of the device)

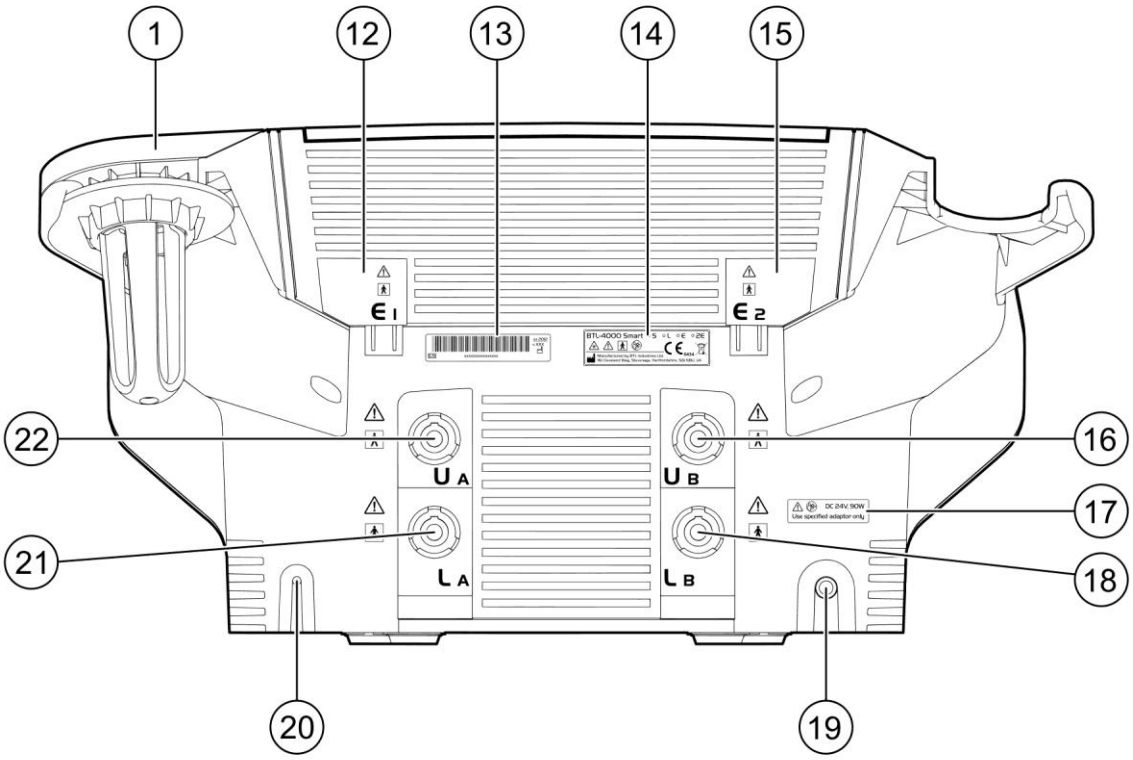
5.2 FRONT PANEL OF THE BTL-4000 PREMIUM



1 accessories holder (the type of the holder depends on the specific device configuration – see Chapter **Accessories Holders**)
2 **on/off** button (to switch the device on/off)
3 7" touch screen
4 **enter** button (to confirm the selection)
5 **start/stop** button (to start/stop the therapy)
6 **select** knob (to move in the device menu and set the therapy parameters)
7 **home** button (to return to the initial screen)
8 **esc** button (to reject the selection and return to the previous state)

5.3 REAR PANEL OF THE DEVICE – MODEL WITHOUT MAGNETOTHERAPY

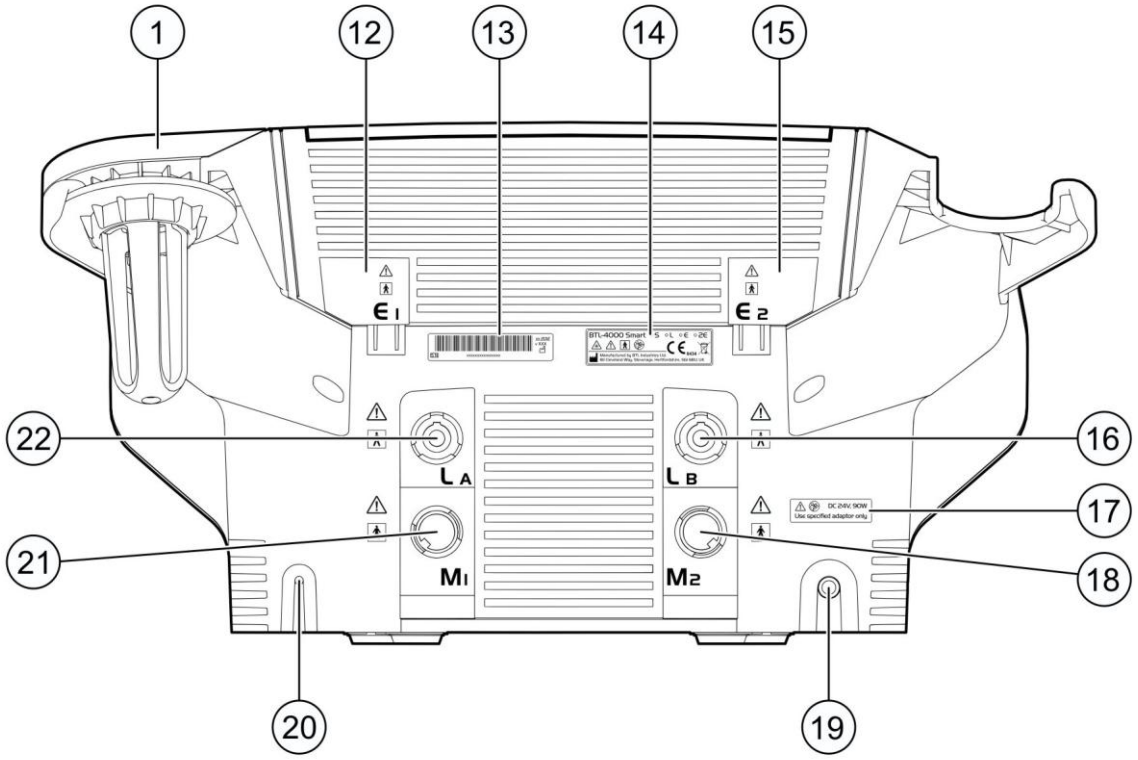
Configuration of the device with the generators for electrotherapy, ultrasound therapy and laser therapy.



1 accessories holder (the type of the holder depends on the specific device configuration – see Chapter **Accessories Holders**)
12 **E_1** output connector for the connection of electrotherapy accessories on channel 1
13 manufacturing label of the device containing the serial number
14 device type label
15 **E_2** output connector for the connection of electrotherapy accessories on channel 2
16 **U_B** output connector for the connection of ultrasound therapy accessories
17 power supply label
18 **L_B** output connector for the connection of laser therapy accessories
19 power supply connector (exclusively for the use of the power adaptor mentioned in Chapter **Technical Parameters)**
20 connector of the laser therapy door switch
21 **L_A** output connector for the connection of laser therapy accessories
22 **U_A** output connector for the connection of ultrasound therapy accessories

5.4 REAR PANEL OF THE DEVICE – MODEL WITH 2 CHANNEL MAGNETOTHERAPY

Configuration of the device with the generators for electrotherapy, laser therapy and magnetotherapy. The distribution of the output connectors on the rear panel of the device may vary depending on the combination of the generators in the device.



1 accessories holder (the type of the holder depends on the specific device configuration – see Chapter **Accessories Holders**)

12 **E_1** output connector for the connection of electrotherapy accessories on channel 1

13 manufacturing label of the device containing the serial number

14 device type label

15 **E_2** output connector for the connection of electrotherapy accessories on channel 2

16 **L_B** output connector for the connection of laser therapy accessories

17 power supply label

18 **M_2** output connector for the connection of magnetotherapy accessories on channel 2

19 power supply connector (exclusively for the use of the power adaptor mentioned in the Chapter **Technical Parameters)**

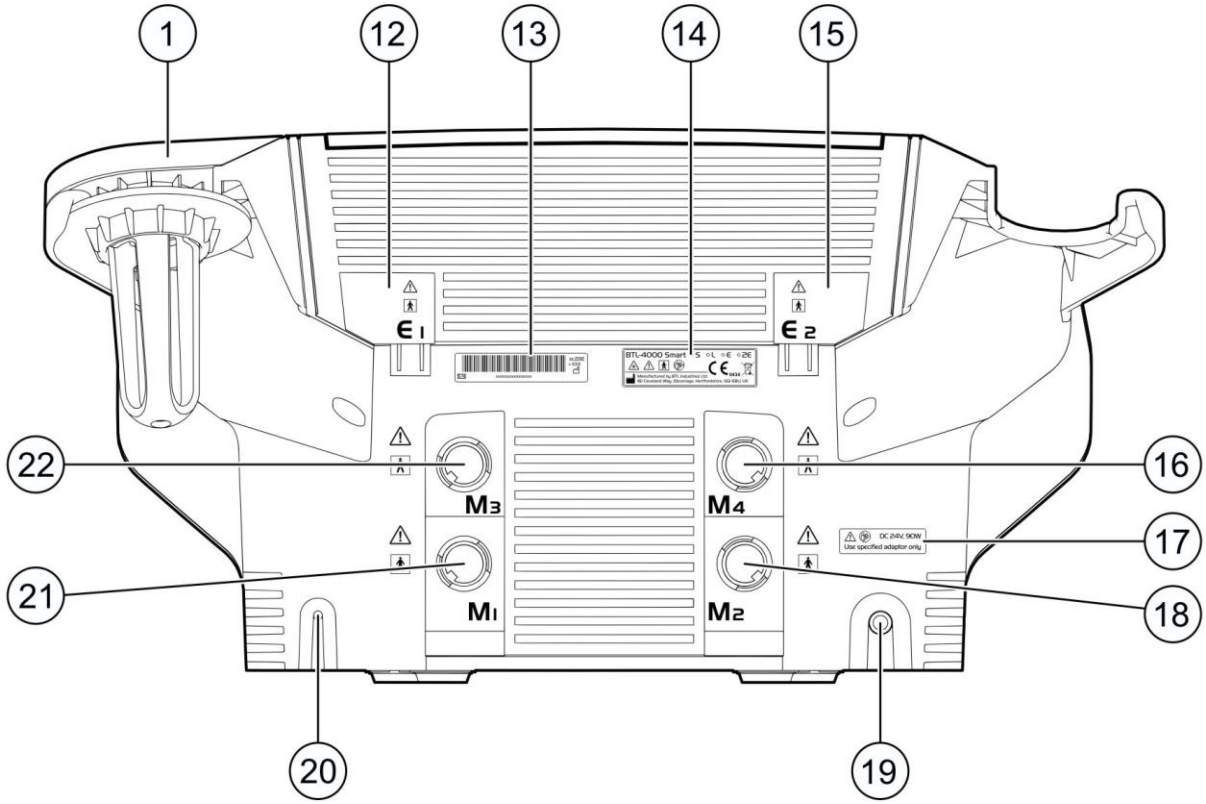
20 connector of the laser therapy door switch

21 **M_1** output connector for the connection of magnetotherapy accessories on channel 1

22 **L_A** output connector for the connection of laser therapy accessories

5.5 REAR PANEL OF THE DEVICE – MODEL WITH 4 CHANNEL MAGNETOTHERAPY

Configuration of the device with the generators for electrotherapy and magnetotherapy.



1 accessories holder (the type of the holder depends on the specific device configuration – see Chapter **Accessories Holders**)

12 **E_1** output connector for the connection of electrotherapy accessories on channel 1

13 manufacturing label of the device containing the serial number

14 device type label

15 **E_2** output connector for the connection of electrotherapy accessories on channel 2

16 **M_4** output connector for the connection of magnetotherapy accessories on channel 4

17 power supply label

18 **M_2** output connector for the connection of magnetotherapy accessories on channel 2

19 power supply connector (exclusively for the use of the power adaptor mentioned in the Chapter **Technical Parameters)**

20 connector of the laser therapy door switch

21 **M_1** output connector for the connection of magnetotherapy accessories on channel 1

22 **M_3** output connector for the connection of magnetotherapy accessories on channel 3

5.6 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 **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**. Connect the device to the mains only by means of the power adaptor supplied together with the device! In case of any doubts, please contact an authorized BTL service.

Putting the Device into Operation

After plugging the power adaptor in the mains, the device is put into the standby mode which is indicated by the orange backlighting of the **on/off** button (2) on the front panel of the device. If the **on/off** button (2) does not shine, re-check the connection of the power adaptor and, if necessary, contact an authorized BTL service.

To put the device into operation press the **on/off** button (2). Switching on the device is indicated by blue backlighting of this button and – for the BTL-4000 Premium – also by blue backlighting of all buttons on the front panel of the device.

If the test of internal functions is passed OK, 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.

In case of units with laser generators it is necessary (according to the standards) to enter a password, which is pre-set to **0000,** before opening the initial screen. Press **enter** to confirm the password. It is recommended to change the password at the first use of the device, so as to protect the device from unauthorized use. The password can be changed in the device menu (menu – unit settings – password).

With units without laser generators the use of a password is not required but is recommended. The password use can be activated in the device menu (menu – unit settings – password).

To switch off the device, press the **on/off** button (2). 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.

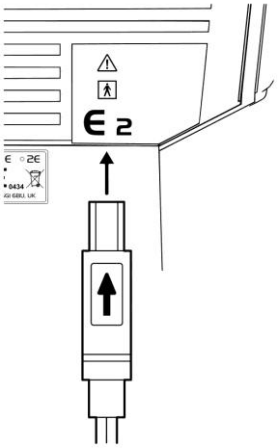
5.6.1 Connecting the Accessories

The supplied accessories have to be connected in the output connectors on the rear panel of the device (for the description of the connectors see **Rear Panel of the Device**). The device does not allow the use of other manufacturers' accessories.

The output connectors are marked with the letter of the generator and the number of the channel, or if need be, with the letter of the output.

Connectors **E_1** and **E_2** (12, 15) are the outputs of the 1st and 2nd channel of electrotherapy, designed for the connection of electric cables with electrodes. The electric cable of channel 1 is light grey with a press-on marked "1". The electric cable of channel 2 is dark grey with a press-on marked "2".

The connectors of the electric cables intended for the connection into the device are marked with an arrow indicating the direction of connecting.

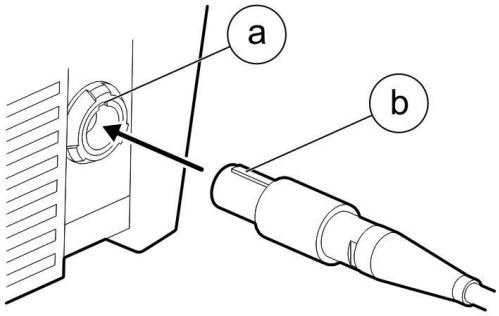


Never connect any USB equipment in the electrotherapy connectors!

Connectors **U_A** and **U_B** (16, 22 on the model without magnetotherapy) are the outputs of the ultrasound therapy channel, intended for the connection of the ultrasound therapy applicators (ultrasound heads and HandsFree Sono).

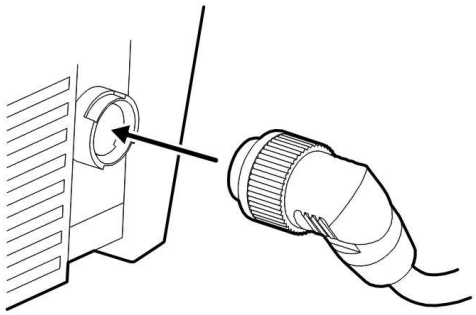
Connectors **L_A** and **L_B** (18, 21 on the model without magnetotherapy; 16, 22 on the model with 2-channel magnetotherapy) are the outputs of the laser therapy channel, intended for the connection of the laser therapy applicators (laser probes and laser clusters).

The connectors of ultrasound and laser accessories 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

Connectors **M_1**, **M_2** (18, 21 on models with 2-channel magnetotherapy) and **M_1**, **M_2**, **M_3**, **M_4** (16, 18, 21, 22 on models with 4-channel magnetotherapy) are the outputs of the magnetotherapy channels, intended for the connection of the magnetotherapy applicators (solenoids, discs, ring and linear applicator):



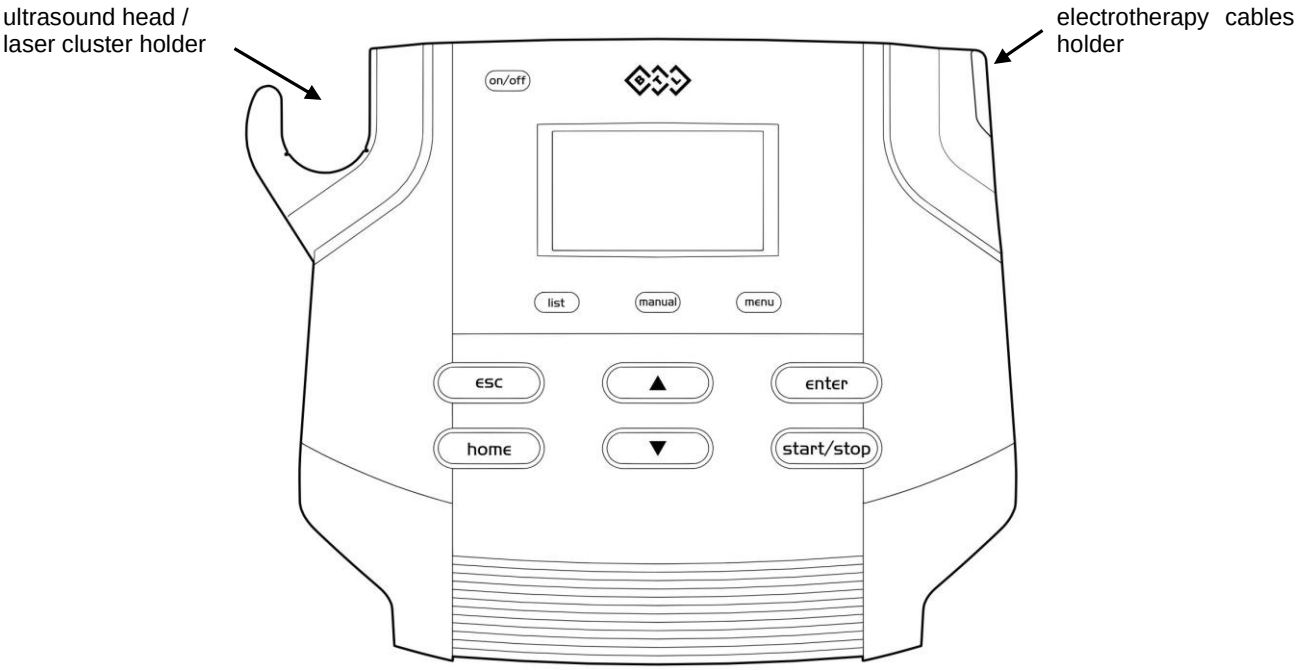
The device detects the accessory, determines its type and displays it on the therapy parameter screen - see **Selection of Accessories**.

When disconnecting the accessories from the device, pull them out by the connector, never by the cable itself!

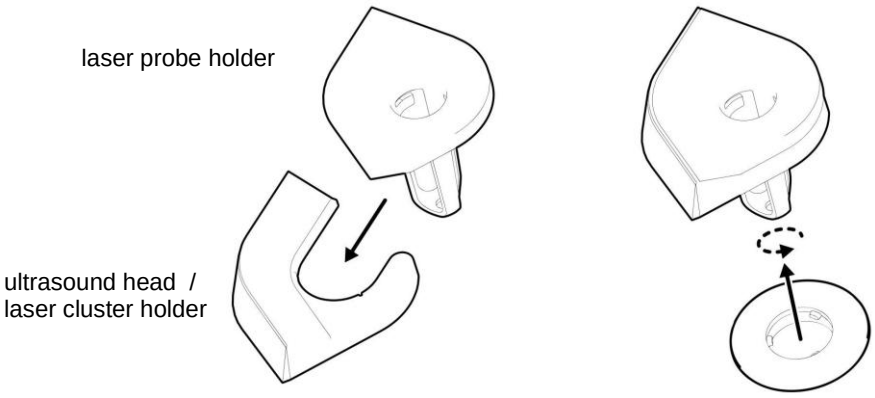
5.6.2 Accessories Holders

The device is equipped with holders for various accessories – ultrasound heads, laser probes or clusters and electrotherapy cables (1). When not in use, the accessories have to be stored in these holders, to prevent their wear and change of properties. The type of holders depends on the specific device configuration.

The ultrasound head / laser cluster holder and the electrotherapy cables holder are located in the upper corners of the device front panel:



The laser probe holder (is supplied within the accessories of the device and can be fixed in the ultrasound head / laser cluster holder by a ring screwed on the bottom of the holder):



5.7 DESCRIPTION OF THE DEVICE CONTROL

5.7.1 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 touch screen is basically layered to the channel tabs at the bottom edge of the screen which contain the letters indicating what generators the device includes. The tabs are marked with the letter “E” for electrotherapy (E1 for the first electrotherapy channel and E2 for the second one), “U” for ultrasound therapy, “L” for laser therapy, “M” for magnetotherapy (M1 for the first magnetotherapy channel and M2 for the second one on the model with 2 channels for magnetotherapy, M1+M3 for the first and third magnetotherapy channels and M2+M4 for the second and fourth magnetotherapy channels on the model with 4 channels for magnetotherapy). The number and type of these tabs (channels) depends on the specific device configuration.

Although the BTL-4000 Smart/Premium devices with more generators allow running up to three therapies simultaneously, only one therapy can be controlled at any given moment; this therapy is selected on the initial HOME screen or by touching the respective tab. The tab of the selected channel is highlighted and all information on the screen and all controls refer to that channel. The most important information about the therapies performed on the other channels remains visible in their tabs.

The BTL-4000 Premium device has a bar with device control buttons at the upper edge of the touch screen:

to display the list of therapeutic protocols

to display the therapeutic protocol quick-selection screen

to display the therapy parameter screen

to set the device functions

to return to the initial screen

In case of the BTL-4000 Smart, these buttons (except the **quick** button) are not located on the touch screen, but on the device front panel (9, 10, 11).

5.7.2 Initial HOME Screen – Screen for the Selection of Therapy Type

The initial HOME screen, which is displayed after switching on the device by the **on/off** button (2), offers the basic selection of the therapy type. Depending on the specific configuration of the device, the buttons on this screen may offer to select the first and second channels of electrotherapy, ultrasound therapy, combination therapy, laser therapy and up to four channels of magnetotherapy.

In case of devices containing only one generator of ultrasound or laser therapy, the initial HOME screen is not displayed and after switching on the device the screens for starting the therapy – LIST, QUICK or MANUAL – are displayed; see below. In such case the **home** button (7) takes you back to one of these screens.

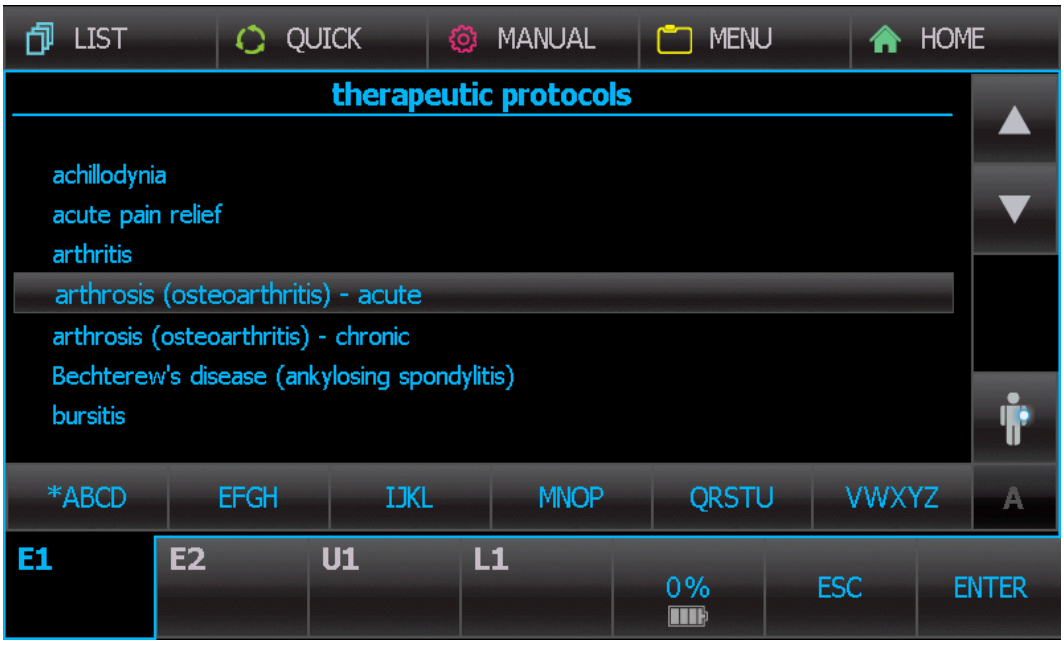
After selecting the therapy type on the initial screen, the BTL-4000 Premium displays the therapeutic protocols quick-selection screen and the BTL-4000 Smart displays the MANUAL therapy parameters screen. At the same time the selected channel is highlighted on the tabs. The type of screen to be displayed in this step can be modified in the device menu (menu – unit settings – advanced settings – HOME screen mode).

5.8 PRINCIPLES OF THERAPY SETTING

5.8.1 Setting a Therapy by Selecting from the List of Therapeutic Protocols – LIST Screen

The list of all therapeutic protocols is displayed after pressing the **list** button (on the touch screen for the BTL-4000 Premium, on the device for the BTL-4000 Smart). For each therapy type there is a list of all available therapeutic protocols. The saved user protocols are marked in the list of therapeutic protocols by a card icon.

To move in the list of therapeutic protocols, use the arrows on the right side of the touch screen; for the BTL-4000 Smart by pressing the **select** buttons with the indicated **up** and **down** arrows (6) and for the BTL-4000 Premium by turning the **select** knob (6). 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 (4) on the device front panel. If the therapeutic protocol offers more therapy options – i.e. the treatment can be performed by several different types of current – their list is displayed after the selection of the therapeutic protocol. Select the current type you require and press **enter** (4) again. For magnetotherapy you can choose from three types of magnetic field.



After the selection of the required therapeutic 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** on the front panel of the device (5).

5.8.1.1 BODY PARTS – Filtering the Therapeutic Protocols by the Body Region

For the BTL-4000 Premium, the LIST screen offers the function of filtering the 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 therapeutic protocols relevant for the respective region. This function is not available for BTL-4000 Smart.

5.8.1.2 Encyclopaedia

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

The encyclopaedia also includes a graphical part – pressing the respective button on the touch screen will display the recommended placement of electrodes or the place of application of ultrasound or laser therapy for every therapeutic protocol.

Note: the therapeutic protocols (including the suggested times, intensities, doses and other 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.

5.8.2 Quick Therapeutic Protocol Selection – QUICK Screen

After pressing the **quick** button on the touch screen of the BTL-4000 Premium the device displays the therapeutic protocol quick-selection screen – QUICK (in the BTL-4000 Smart this screen is not available).

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

Instead of the QUICK screen and the pre-set therapeutic protocols it is possible to display the screen for the selection of therapy by the program number; this option can be set in the device menu (menu – unit settings – advanced settings - QUICK screen mode). The program screen allows starting a therapy by selecting the program number which is assigned to every therapeutic protocol. The program numbers can be found in the protocol description in the encyclopaedia. To set the program value, press the required element on the touch screen and then use the **select** buttons/knob (6) or the numerical keyboard. The screen for the selection of therapy by the program number can be also displayed by pressing the **list** button twice.

To start the therapy using the selected therapeutic protocol from the therapy parameters screen (see below – MANUAL screen), press the **start** button on the touch screen or **start/stop** on the front panel of the device (5).

After the selection of one of the pre-set therapeutic protocols on the QUICK screen it is possible to find the detailed information for the selected protocol by pressing the button with the encyclopaedia symbol on the therapy parameter screen.

5.8.3 User Settings of Therapy Parameters – MANUAL Screen

Pressing the **manual** button on the touch screen or on the device (10) 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 pre-set therapeutic protocols of the LIST or QUICK screens.

In case of electrotherapy and combination therapy, the current selection screen is always displayed first before the therapy parameters screen after pressing the **manual** button on the touch screen or on the device (10). In case of magnetotherapy, the selection of continuous or pulsed magnetic field is always displayed first. Select the required current or the type of the magnetic field and press **enter** (4) on the front panel of the device or on the touch screen. If you want to select another current or another type of magnetic field for the therapy later, it will be necessary to open the current selection screen again by pressing the **manual** button.

The therapy parameters screen allows setting the most important parameters of the required therapy (time, intensity etc.) 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/buttons (6).

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/buttons (6) and confirm it by pressing **enter** (4) or cancel it by pressing **esc** (8) 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 icon below the text window displays symbolically the waveform of the electric current, ultrasound waves, laser radiation or magnetic field.

The figure and bell symbols inform about the behaviour of the device during the therapy (this signalization is not available for magnetotherapy):

Set up these functions by pressing menu-specific settings – contact loss signalization/check contact during therapy.

 In case of electrotherapy the device measures the right contact of the electrodes; if the contact is lost it interrupts the therapy and warns the user. In case of a bad contact of the applicator during ultrasound therapy the device interrupts the therapy time countdown. For combination therapy the figure is always crossed when the contact is lost the therapy time countdown is never interrupted.

 In case of electrotherapy the device does not interrupt the therapy at the loss of the electrode contact (e.g. withdrawing of the electrode during dynamic application or combination therapy). In case of a bad contact of the applicator during ultrasound therapy the device does not interrupt the therapy time countdown.

 In case of electrotherapy, ultrasound and combination therapy the device indicates the loss of contact by a sound signal. In case of laser therapy the device warns by a sound signal that the therapy is in progress (in compliance with the applicable standards, this function cannot be switched off in the device menu).

 In case of electrotherapy, ultrasound and combination therapy the device does not indicate the loss of contact by a sound signal.

To start the therapy according to the selected parameters from the therapy parameter screen, press the **start** button on the touch screen or **start/stop** on the front panel of the device (5).

5.8.3.1 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 (e.g. it allows setting the amplitude modulation of the currents, frequency sweep of the currents, synchronization of the electrotherapy channels, ultrasound therapy, laser therapy and magnetotherapy signal waveforms etc.).

By pressing the **save** button on this screen you can save therapy parameters as a user-defined therapeutic protocol, which may be assigned to a specific client (available only in BTL-4000 Premium).

This screen does not allow starting the therapy directly; it is necessary to confirm the set parameters by pressing the **enter** button (4) and return to the MANUAL therapy parameter screen with the **start** button.

5.8.3.2 Applicator preheating

For higher patient comfort during ultrasound or combination therapy use the applicator preheating function. The ultrasound applicator is heated to a comfortable level and a contact of cold applicator head with the patient´s body is avoided.

This option is available for ultrasound heads (1 cm^2, 5 cm^2), not for operator independent applicators HandsFree Sono.

For setting press the “flame symbol” on screen, than press “applicator preheating” and choose on/off. To confirm press enter.

Preheating in progress is signalized by:

- sign “applicator preheating: on” in the text window of the MANUAL screen
- “flame symbol” in the ultrasound tab
- faster blue flashing of ultrasound head

When the preheating is in progress, do not touch the applicator head – ultrasound is generated.

The preheating can run only if contact is not detected. Always remove the gel from the ultrasound head after finishing the therapy.

You can also set preheating in device MENU (menu-specific settings-applicator preheating).

5.8.4 Setting of the Therapy Time

The therapy time is pre-set for every therapy and therapeutic protocol so that after entering the therapy parameters screen it is possible to start the therapy directly by pressing the **start** button on the touch screen or **start/stop** on the front panel of the device (5). If you want to set a different therapy time, you can modify it directly using the **select** knob/buttons (6). Repeated pressing of the **time** button on the touch screen will open the dialog window for the setting of time. Enter the required time using the **select** knob/buttons (6) or the numerical keyboard and press **enter** (4) to confirm.

You cannot modify the therapy time when the therapy is in progress. For electrotherapy, ultrasound therapy and magnetotherapy the time can be modified after pressing **pause** or **start/stop**. For laser therapy this option is not available.

5.8.5 Setting of the Therapy Intensity / Dose

For electrotherapy it is possible to set the intensity by means of the **intensity** button on the touch screen after starting the therapy by turning the **select** knob (6) in case of the BTL-4000 Premium or by repeated pressing of the **select** buttons with the **up** and **down** arrows (6) in case of the BTL-4000 Smart.

For ultrasound therapy it is possible to set the intensity on the therapy parameter screen, when the therapy is not in progress, on the screen during therapy and in the pause. For setting the value use the **intensity** button on the touch screen. To change the value, turn the **select** knob (6) in case of the BTL-4000 Premium or repeatedly press the **select** buttons with the **up** and **down** arrows (6) in case of the BTL-4000 Smart.

For magnetotherapy it is possible to set the intensity on the therapy parameter screen, when the therapy is not in progress and in the pause. For setting the value use the **intensity** button on the touch screen. To change the value, turn the **select** knob (6) in case of the BTL-4000 Premium or repeatedly press the **select** buttons with the **up** and **down** arrows (6) in case of the BTL-4000 Smart. When setting the intensity on the device model with 4-channel magnetotherapy, the **intensity** button applies to the accessory chosen via the button **accessory**. In this case you can set the intensity value for one applicator or simultaneously for two applicators. When you are setting the intensity value simultaneously for two applicators, the intensity for each applicator is automatically recalculated.

For laser therapy, the laser radiation dose can be set only on the therapy parameter screen when the therapy is not in progress. To change the value, turn the **select** knob (6) in case of the BTL-4000 Premium or repeatedly press the **select** buttons with the **up** and **down** arrows (6) in case of the BTL-4000 Smart. The laser dose modification button is not available on the screen either during the therapy or during the pause.

5.8.6 Selection of Accessories

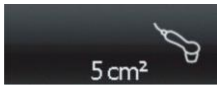
The **accessories** button on the therapy parameters screen displays the symbol of the accessory which is ready for use (for more information about individual applicators see **Accessories** and **Technical Parameters**):

5.8.6.1 Electrotherapy

plate electrodes

vacuum electrodes

5.8.6.2 Ultrasound therapy



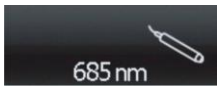
ultrasound head 5 cm^2

ultrasound head 1 cm^2

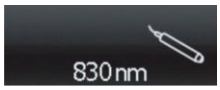
applicator HandsFree Sono 4

applicator HandsFree Sono 6

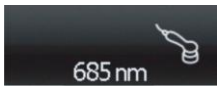
5.8.6.3 Laser therapy



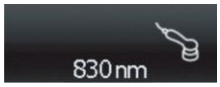
laser probe with red radiation



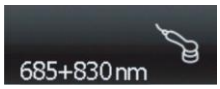
laser probe with infrared radiation



laser cluster with red radiation



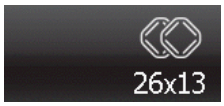
laser cluster with infrared radiation



combined laser cluster with red and infrared radiation

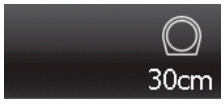
5.8.6.4 Magnetotherapy

disc applicator

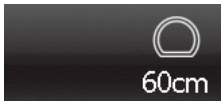


double disc applicator

multi disc applicator

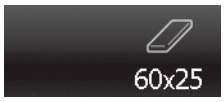


solenoid 30 cm

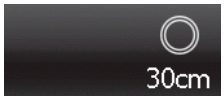


solenoid 60 cm

solenoid 70 cm (only for magnetotherapy couch)



linear applicator



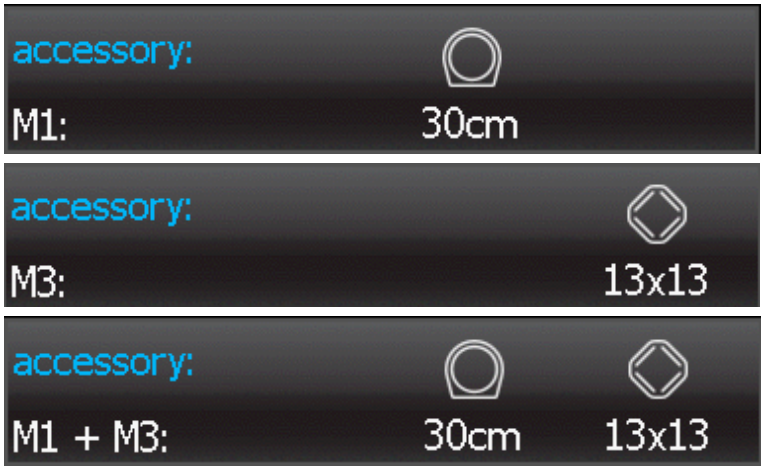
ring applicator

the question mark indicates that no accessories are connected to the chosen channel

If two ultrasound therapy applicators (outputs **U_A** and **U_B**) and/or two laser therapy applicators (outputs **L_A** and **L_B**) and/or up to four magnetotherapy applicators (outputs **M_1** and **M_2** on the device with 2-channel magnetotehrapy, outputs **M_1**, **M_2**, **M_3** a **M_4** on the device with 4-channel magnetotherapy) are connected to the device simultaneously, it is possible to switch between the applicators to be used for the therapy by pressing the **accessories** button. The button always displays the currently selected accessory. For electrotherapy, the accessories button is only informational – switching between the plate and vacuum electrodes can only be done by switching on/off the vacuum on the front panel of the vacuum unit (see the User's Manual of the BTL-Vac II).

5.8.6.5 Selection of Accessories on the Device with 4-Channel Magnetotherapy

At the bottom edge of the screen choose the tab M1+M3 or M2+M4 as described in the Chapter **Description of the Device Control**. By repeated pressing of the **accessory** button you select the applicators on the outputs **M_1+M_3** or **M_2+M_4** according to the chosen tab.



The applicator connected to the M1 output is chosen for the therapy.

The applicator connected to the M3 output is chosen for the therapy.

Applicators connected to the M1 and M3 outputs are chosen for the therapy.

5.8.7 Combination Therapies

If the device is equipped with electrotherapy and ultrasound therapy generators, you can select the **combination therapy** option by pressing the respective button on the initial HOME screen. Thus the first channel of electrotherapy E1 and the channel of ultrasound therapy are selected and their tabs are highlighted.

After the interconnection with electrotherapy, the ultrasound applicator becomes the cathode. The other pole is always the anode – the electrode with a red end connected to the patient. If ultrasound applicators are connected to both outputs U_A and U_B, you can use the **accessories** button on the therapy parameters screen to select which one will be used for the combination therapy.

To start the therapy according to the required parameters after the selection of the required protocol from the therapy parameters screen, press the **start** button on the touch screen or **start/stop** on the front panel of the device (5).

5.9 PROCESS OF TREATMENT

5.9.1 Start – Interruption – End of Therapy

To start the therapy on the selected channel after selecting one of the pre-set therapeutic protocols or after setting the therapy parameters on the MANUAL screen, press the **start** button on the touch screen or **start/stop** on the front panel of the device (5). The therapy can only be started if the therapy parameters screen is displayed on the selected channel.

The therapy can be interrupted at any time by pressing the **pause** button on the touch screen or **start/stop** on the front panel of the device (5) and the interrupted therapy can be resumed by pressing the **start** button on the touch screen or **start/stop** on the front panel of the device (5) or terminated by pressing the **esc** button (8).

In case of laser therapy, the therapy can also be started/interrupted by pressing the button on the probe/cluster.

5.9.2 Screen During Therapy

During the therapy the screen contains buttons with the main therapy parameters, similarly to the MANUAL therapy parameters screen. The running time value is highlighted to provide the instant overview of the course of therapy.

The **accessories** button displays the symbol of the accessory on which the therapy is performed. During the therapy this button is only of informative nature, the accessories cannot be changed when therapy is in progress.

5.9.3 Indication During the Therapy – Energy on the Output

The presence of voltage, ultrasound waves, laser radiation or magnetic field on the output of the device is indicated as follows:

- by the running time value, showing the time remaining until the end of therapy, on the screen during therapy
- by the running time and intensity values on the channel tab
- in the BTL-4000 Premium, by the change of the blue backlighting of the **start/stop** button (5) on the device to yellow; the backlighting of the other buttons remains blue
- in ultrasound therapy, by the blue backlighting of the ultrasound heads and the operator independent HandsFree Sono applicator (the blue light is shining permanently as long as the device is generating therapy)
- in laser therapy, by the green indicator on the probe, aiming beam and acoustic signal (which, in compliance with the applicable standards, cannot be switched off)
- in magnetotherapy (not valid for linear applicator and applicator ring) by the blue backlighting of the controls on the applicators (the blue light is shining permanently as long as the device is generating therapy)

5.10 SAVING A THERAPY

The BTL-4000 Smart/Premium devices enable users to create user therapeutic protocols which may be assigned to specific clients (only for BTL-4000 Premium). The user therapeutic protocols can be saved after setting the therapy parameters exclusively from the EDIT screen of advanced therapy parameters by pressing the **save** button on the touch screen.

When saving a therapy, it is necessary to enter the following:

- name of the therapeutic protocol – it is displayed in the list of user therapeutic protocols under the **list** button on the touch screen or on the device (9)
- program number
- supplementary description of the protocol – it is displayed in the database (menu – user settings / database – user therapeutic protocols)

You can also save the protocol and assign it to a client. The saved protocol will be then displayed also in the list of therapies assigned to the specific client (menu - user settings / database – clients).

In case of the BTL-4000 Premium, user therapeutic protocols may be also displayed on the QUICK screen for the quick selection of therapeutic protocols. The list of the protocols displayed on the QUICK screen may be modified in the device menu (menu – specific settings – QUICK screen protocols).

5.11 DEVICE MENU

After pressing the **menu** button on the touch screen in case of the BTL-4000 Premium or on the device (11) in case of the BTL-4000 Smart you can browse the following menus of the device function settings:

- user settings / database
- unit settings
- specific settings
- electrodiagnostics (only if the device contains electrotherapy generator equipped with electrodiagnostics)

5.11.1 User Settings / Database

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

- clients (only for BTL-4000 Premium)
- user therapeutic protocols
- user sequences (only if the device contains the electrotherapy generator)
- recent therapies

5.11.1.1 Clients

This item enables users to establish, edit and delete information about clients. It is possible to assign therapies from the list of user therapeutic protocols to any client and run these therapies after pressing the **load** button. This function is available only for BTL-4000 Premium.

5.11.1.2 User Therapeutic Protocols

This option allows running user therapeutic protocols after pressing the **load** button and editing or deleting their parameters, names and descriptions. Every generator tab only shows the therapies that have been created on that tab.

5.11.1.3 User Sequences

The user sequences function only applies to the electrotherapy generator.
Selecting the user sequences function allows working with the list of sequences created by the user. The selected sequence can be run, edited and deleted from this menu.
To create a new sequence, select the “sequence” type of current before entering the MANUAL screen. Continue to the EDIT screen of advanced parameters, where you can press the **new sequence** button and then enter the parameters of individual sections which the sequence shall consist of. To save the created sequence, press **save.**

 Limitation of the range of currents in the sequence when the mode without pause between sections is selected:

If the option “**pause between sections**” is set in the sequence, the device stops the generation at the passage to the next section and it is necessary to set the intensity manually again. This allows adding the currents into sequences without limitation and utilizing the full range. We recommend setting this option.

If the option “**pause between sections**” is not set, the device continues generating the current in the next section with the same intensity.

ATTENTION! In this case you shall be very careful when setting the sequences. Each current type has different requirements for the subjective current intensity and therefore it is necessary to include only those currents that the patients perceive similarly. This may include currents with similar pulse length, frequency etc. Never should you mutually combine monophasic and biphasic currents.

5.11.1.4 Recent Therapies

This option will display a list from which you can select one of the last therapies performed on the selected tab and start it again after pressing the **load** button.

5.11.2 Unit Settings

This submenu allows setting the following parameters:

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

5.11.2.1 Language

Selection of the language for the texts on the display. English is set as default.

5.11.2.2 Date & Time

Setting the date and time in the device.

5.11.2.3 Sound Settings

This option allows setting the volume of the sound and modification of the acoustic signals that accompany key pressing, touch screen pressing and some processes (start of therapy, interruption of therapy, end of therapy etc.). The **standard sounds** are set as default from the factory which means the audio signalling of therapy processes. You can mute the sound completely or set your own sound profile by editing the standard sounds.
In the units containing a laser generator the sound during the therapy cannot be switched off (according to the requirements of the standard).

5.11.2.4 Colour Scheme

This option allows selecting one of the pre-set colour layouts of the device and thus changing the colour representation of the elements displayed on the screen.

5.11.2.5 Screen Saver and auto switch-off

Here you can set the type of the screen saver. It is also possible to set the idle time after which the screensaver shall be activated, the screen switched off or the entire device switched off.

5.11.2.6 Password

This menu makes it possible to change the password which the device requires after being switched on. Without entering this password, no further work with the device is possible. By default the devices are supplied as “unlocked” – with the password off. However, in the units containing a laser generator the password cannot be switched off (according to the requirement of the standard) and by default it is pre-set to **0000**.

5.11.2.7 Unit Information

This option displays some information about the unit – the serial number, type of the device, firmware version, HW key etc. If the device function is time-limited, this item contains the information on the date until which the device will be fully functioning.

5.11.2.8 Accessories Information

This option displays the information about the connected accessories.

5.11.2.9 Advanced Settings

This option allows setting less frequent functions of the device:

- HOME screen mode (setting of the type of the screen after the selection of the therapy type)
- QUICK screen mode (displaying of quick therapeutic protocols or programs, only for BTL-4000 Premium)
- battery indication mode
- user accounts
- time of usage
- touch panel calibration
- display contrast
- button backlight
- service functions
- dialog history
- setting of HW key

5.11.3 Specific Settings

This option allows setting the protocols of the QUICK (only for BTL-4000 Premium) screens and additional functions referring only to the selected generator.

5.11.3.1 Electrotherapy

This option allows starting the electrode quality test and setting a sound signalization of contact loss between the patient and the electrode during the therapy.

5.11.3.2 Ultrasound Therapy

This option allows setting the applicator preheating, start the calibration of ultrasound applicators and define the behaviour of the device in case of a loss of contact during therapy, including the form of the contact loss signalling. It also allows setting the change of the recalculation of the applicator output power according to various standards.

5.11.3.3 Laser therapy

This option allows setting the door activity.

5.11.3.4 Magnetotherapy

This option allows starting a test of the connected magnetotherapy applicator and changing the default program time. The change of the default program time will show on the manual therapy parameter screen and will change the time of all programs.

5.11.4 Electrodiagnostics

This option is displayed in the menu only if the device is equipped with the electrodiagnostics functions. It allows performing the muscle motor point detection, measuring the value of the accommodation coefficient and measuring the I/t curve.

5.11.4.1 Motor Point Detection

This allows localizing the motor point of the muscle, i.e. the point in which the muscle stimulation is most significant – the lowest set value of intensity is sufficient to initiate the contraction. For later measurement of the I/t curve it is necessary to set the polarity of the point electrode. The reference electrode is always the plate or vacuum electrode placed proximally or distally on the respective muscle.

To find the motor point, it is recommended to use pulses of a length of approx. 5 ms for healthy muscles and approx. 100 ms for denervated muscles. The pause between pulses should be 1–2 seconds. Having found the motor point, reverse the polarity of the output current (positive polarity → negative) and measure the muscle sensitivity to the reversed polarity of the signal. For further stimulation use that connection of electrodes (polarity) to which the muscle was more sensitive.

5.11.4.2 Accommodation Coefficient

Accommodation coefficient is the ratio between the intensity of the triangular pulse and the intensity of the rectangular pulse. It is measured in the motor point of the muscle using triangular and rectangular pulses and the polarity of the electrodes which was determined as more sensitive at the motor point detection. The pulse width is 1,000 ms and the pause between pulses is 3 seconds. First measure using the rectangular pulse, after saving the result using the **start/stop** button (5) the device automatically switches to the measurement by the triangular pulse. The set intensity is displayed in the upper field on the screen; the lower field displays the current measured value of the accommodation coefficient.

5.11.4.3 I/t Curve

The I/t curve is measured in the motor point of the muscle by triangular and rectangular pulses and with the polarity of the electrodes which was determined as more sensitive at the motor point detection. Before measuring a new I/t curve it is always necessary to enter / select the client for whom the curve will be measured.

5.11.4.3.1 I/t Curve – Options

The **options** button contains the following items:

- edit point: to set the pulse length and pause length quickly and directly
- delete point: to delete the measured point of the curve from the graph
- new curve - rectangular pulses: to add in the graph a new I/t curve to be measured by rectangular pulses
- new curve - triangular pulses: to add in the graph a new I/t curve to be measured by triangular pulses
- delete curve: to delete the curve from the graph
- import curve: to load the I/t curve from the device's memory in the graph
- save curve: to save the I/t curve
- motor point detection
- calculation of chronaxie and rheobase: active only if the graph displays just one curve
- calculation of accommodation coefficient: active only if the graph displays two curves – one measured by triangular pulses and the other by rectangular pulses
- calculation of stimulation: determination of the optimum parameters for the stimulation of the denervated muscle; active only if the graph displays two curves measured by triangular pulses

5.11.4.3.2 I/t Curve – Properties

Available after pressing the **save** button. In this screen you can define the name of the I/t curve and additional supplementary information.

5.11.4.3.3 I/t Curve – Measurement

Use the **select** knob or buttons (6) to move along the time axis of the graph and thus change the length of the measured pulse from 0.1 to 1,000 ms. To start the measurement, press the start button on the screen or **start/stop** (5) on the device; the intensity of the generated pulse can be changed by the **select** knob/buttons **(6);** to insert the currently set intensity value into the graph, press **start/stop**.

The **>>** and **<<** buttons on the screen allow selecting one of the displayed I/t curves as active – that curve will be then handled in the menu, during the measurement etc.

The values of rheobase and chronaxie can be determined from the completely measured I/t curve – see **5.11.4.3** – or it is possible to measure them using this simplified procedure.

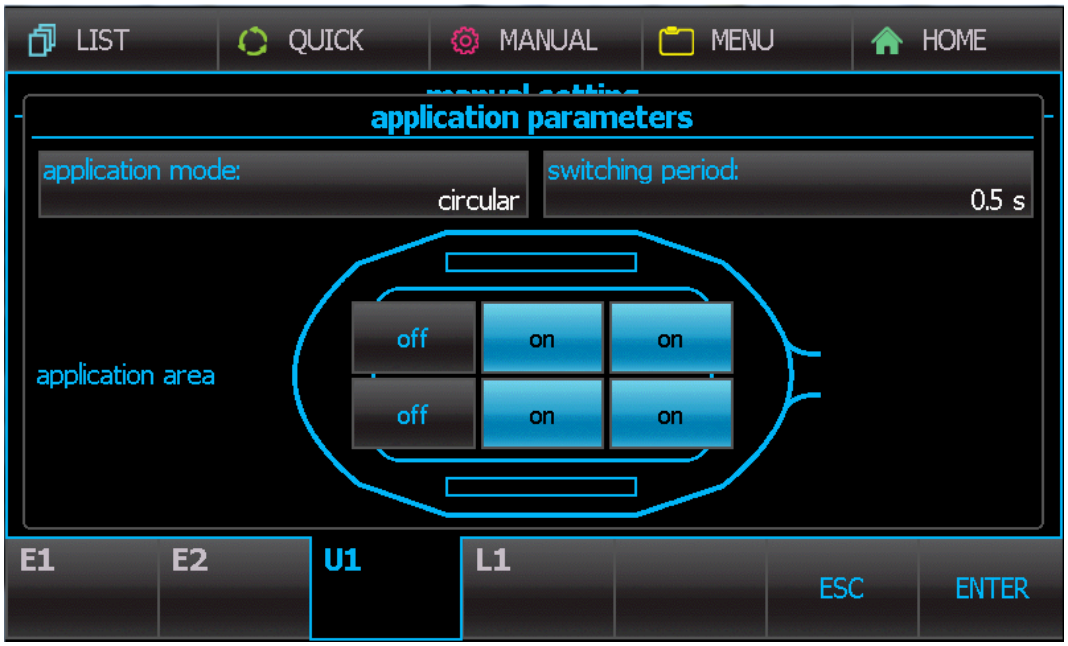
5.12 SETTING OF HANDSFREE SONO APPLICATORS

5.12.1 Applicator HandsFree Sono 6 – six crystals

It is possible to set more options when the HandsFree Sono 6 is connected. Press EDIT button - application parameters and set:

- application mode – circular or random switching between crystals
- switching period – switching between crystals in 0.3 s / 0.5 s / 0.7 s
- application area – activation/deactivation of crystal pairs (at least one pair)

For safety reasons the switching period is fixed to 0.3 s when you choose one pair of crystals.



5.12.2 Applicator HandsFree Sono 4 – four crystals

It is possible to set more options when the HandsFree Sono 4 is connected. Press EDIT button - application parameters and set:

- application mode – circular or random switching between crystals

6 ACCESSORIES

The device is not designed for use with any accessories or medical equipment other than those stated in this manual. The following chapters contain the lists of all standard and optional accessories that can be supplied with the device. For more information about individual accessories see the enclosed leaflets or the Chapter **Technical Parameters**.

6.1 ACCESSORIES COMMON FOR BTL-4000 SMART/PREMIUM

- 1x power adaptor (specified in the Chapter **Technical Parameters**)
- 1x user's manual
- 1x touch screen pen pointer
- battery pack (optional)

6.1.1 Power Adaptor

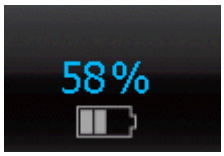
The devices of the BTL-4000 Smart/Premium series can be connected to the mains exclusively via the supplied power adaptor.

It is forbidden to connect any other power adaptor than the above mentioned one to the device.

6.1.2 Battery Pack

The devices of the BTL-4000 Smart/Premium can be extended with a battery pack. The battery pack is not supported in devices containing a magnetotherapy generator. To insert the battery into the device disconnect the device from the mains and proceed according to the manual placed in the package. The tab next to the channels tab shows the battery state.

The device is connected to the battery pack and at the same time to the mains with the power adaptor.



Partially discharged battery.

Fully charged battery.

In the standby mode the connection to the battery is indicated by orange flashing of the **on/off** button on the front panel.

Charge the battery by connecting the device to the mains using power adaptor. In the standby mode the animation is shown in the lower part of the screen. After turning the device on, the animation of battery charging is shown in the tab.

The battery charge is shown in percents of full charge or as remaining time. You can set this option by pressing menu-unit settings-advanced settings-battery indication mode.

It is possible to start up to three therapies at a time when the device is connected to the mains. This is different when the device is powered from the battery pack. Then you can run only electrotherapy or ultrasound therapy or laser therapy. Combination of two electrotherapy channels when using battery pack is possible only in case of 4-pole interference. Combination of electrotherapy and ultrasound therapy when using battery pack is possible only in case of combination therapy.

6.2 ACCESSORIES FOR ELECTROTHERAPY

6.2.1 Standard Accessories

- 1x electrode cable – light grey (twin cable, cable length: 280 ± 6 cm) for channel 1
- 1x electrode cables – dark grey (twin cable length: 280 ± 6 cm) for channel 2
- 4x plate electrodes 7 x 5 cm
- 4x electrode pads for electrodes 7 x 5 cm
- 1x set of elastic straps for the fixation of the electrodes

6.2.2 Optional Accessories

- plate electrodes 12 x 8 cm
- electrode pads for electrodes 12 x 8 cm
- adhesive electrodes 40 x 40 mm, REF PG871/40W
- adhesive electrodes 50 x 50 mm, REF PG871/50W
- adhesive electrodes 75 x 140 mm, REF PG477W
- adhesive electrodes 32 mm, REF PG479/32W
- adhesive electrodes 50 mm, REF PG479/50W
- ball electrode:
  - ball electrode tip – diameter 2 mm
  - ball electrode tip – diameter 6 mm
- vacuum unit BTL-Vac II

6.3 ACCESSORIES FOR ULTRASOUND THERAPY

6.3.1 Standard Accessories

- 1x ultrasound head 5 cm^2 (cable length: 220 ± 1.5 cm)
- 1x ultrasound gel in a 300 ml packing

6.3.2 Optional Accessories

- ultrasound head 1 cm^2 (cable length: 220 ± 1.5 cm)
- HandsFree Sono 4, HandsFree Sono 6 – applicators for operator independent ultrasound therapy (cable length: 220 ± 1.5 cm)
- set of elastic straps for the fixation of the HandsFree Sono applicator, magnetic frame
- ultrasound gel in a 1 l packing
- plastic holder for HandsFree Sono

6.4 ACCESSORIES FOR LASER THERAPY

6.4.1 Optional Accessories

- laser probes – red and infrared (cable length: 220 ± 1.5 cm)
- laser clusters – red, infrared and combined (cable length: 220 ± 1.5 cm)
- optical attachments for laser probes
- laser probe holder
- warning labels
- protective goggles for laser therapy, protection grade L3 and higher

6.5 ACCESSORIES FOR MAGNETOTHERAPY

6.5.1 Optional Accessories

- disc applicator
- double disc applicator
- multi disc applicator
- solenoid 30 cm
- solenoid 60 cm
- solenoid 70 cm (only for the magnetotherapy couch)
- couch with a magnetotherapy applicator
- linear applicator
- ring applicator

7 MAINTENANCE OF THE DEVICE

 **Before any maintenance switch off the device and unplug it from the mains!** Observe all safety principles listed in the 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.

The laser equipment does not require any user settings or adjustment. Its inspection is performed during the periodic recalibration of the device by the authorized BTL service.

7.1 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.

7.2 CLEANING OF THE ACCESSORIES COMING INTO CONTACT WITH THE PATIENT

After each use, the accessories that come into direct contact with the patient's body (electrodes and electrode pads, ultrasound heads and HandsFree Sono ultrasound applicator) shall be cleaned and disinfected with a solution approved for the use in health service. Do not use agents containing chlorine or those with a high alcohol content (more than 20 %). If you do not want to use the electrode pads immediately for next therapy, let them dry completely on a dry and airy place after the cleaning. The ultrasound heads and HandsFree Sono applicators shall be cleaned from remaining ultrasound gel by a paper towel or a soft cloth and rinsed in a clear water at first. In case of HandsFree Sono applicator, the plastic frame covering peripheral part of the active surface shall be also removed before the cleaning.

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. They cannot be sterilized (with the exception of the optical attachments of the laser probes which, if necessary, may be sterilized for 20 minutes at 180 °C).

Clean the laser aperture of laser probes and clusters with a soft cloth. The laser probe/cluster is not waterproof.

7.3 TRANSPORT AND STORAGE

Keep the packaging of the device. Transport the unit in the original packaging 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 **Technical Parameters**.

8 TECHNICAL PARAMETERS

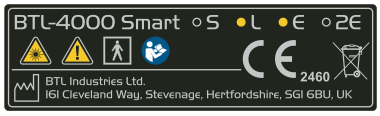
Name	BTL-4000 Smart, BTL-4000 Premium	
Models	see Chapter 8.1	
Operating conditions		
ambient temperature	+10 °C to +30 °C	
relative humidity	30 % to 75 %	
atmospheric pressure	800 hPa to 1,060 hPa	
position	vertical – on legs	
type of operation	continuous	
Transport and storage conditions		
ambient temperature	-10 °C to +55 °C	
relative humidity	10 % to 85 %	
atmospheric pressure	650 hPa to 1,100 hPa	
position	any	
other conditions	transport only in the supplied packaging	
Power supply	external power adaptor	
maximum input	60 W / 90 W	
supply voltage	24 V, DC	
protection class	II for devices with adaptor SA160D-24U-M	I for devices with adaptor HPU101-108
device on/off button	on the front panel, marked **on/off**	
Internal chemical sources		
battery	lithium battery CR2430	
Power adaptors	BTL-4000 Adaptor Model: SA160D-24U-M *alternative* BTL-4000 Adaptor Model: GSM60B24-BTL2	BTL-4000 Adaptor Model: HPU101-108
supply voltage	~ 100 V to 240 V AC	
frequency	50 Hz to 60 Hz	
cable length	150 cm	190 cm
rated voltage / current / input power	24 V / 2.5 A / 60 W	24 V / 4.16 Amax / 90 W
protection class	II	I (Caution: the equipment must always be connected to the protective ground)
fuse	internal	
covering grade	IP20 - protects against penetration of solid objects of a diameter of 12.5 mm and more.	
Reserve battery	Model: 258-BATTPACK	
Design		
weight – device only	max. 3 kg (6.1 lb)	
weight – including packing and accessories	max. 6 kg (13.2 lb)	
dimensions (W x H x D)	380 mm x 190 mm x 260 mm (15“ x 7.5“ x 10.2“)	
packing dimensions (W x H x D)	435 mm x 365 mm x 335 mm (17.1“ x 14.4“ x 13.2“)	
covering grade	IP20 – protects against penetration of solid objects of a diameter of 12.5 mm and more.	
Display elements		
display – BTL-4000 Smart	LCD colour, 480 x 272, diagonal 10.9 cm (4.3“)	
display – BTL-4000 Premium	LCD colour, 800 x 480, diagonal 17.8 cm (7“)	
Classification		
applied parts of type	BF	
class according to MDD 93/42/EEC	IIb	
Therapy time		
for electro and laser therapies	0 to 100 minutes	
for ultrasound therapies	0 to 30 minutes	

step of setting	1 second
accuracy of therapy time	±5 % of the set value
Accuracy of time values	5 seconds per 1 day

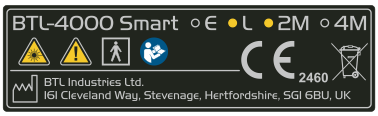
8.1 TYPES AND MODELS OF THE DEVICE

The device comes in two types: BTL-4000 Smart and BTL-4000 Premium. The particular model of the device is shown on the device label; the summary is in the table below. The models which support electrotherapy and have the numeral 5 in their name (e.g. BTL-4625 Smart) contain a HW key extending the portfolio of currents.

Device models containing electrotherapy, ultrasound therapy and laser therapy generators:

Model	Device label	Ultrasound therapy	Laser therapy	Electrotherapy
BTL-4620 Smart, BTL-4625 Smart				x
BTL-4620 Premium, BTL-4625 Premium				x
BTL-4710 Smart		x		
BTL-4710 Premium		x		
BTL-4110 Smart			x	
BTL-4110 Premium			x	
BTL-4820S Smart, BTL-4825S Smart		x		x
BTL-4820S Premium, BTL-4825S Premium		x		x
BTL-4820L Smart, BTL-4825L Smart			x	x
BTL-4800SL Smart		x	x	
BTL-4820SL Premium, BTL-4825SL Premium		x	x	x

Device models containing electrotherapy, laser therapy, 2-channel and 4-channel magnetotherapy generators:

Model	Device label	Laser therapy	Electro therapy	Magneto therapy 2 channel	Magneto therapy 4 channel
BTL-4920 Smart				x	
BTL-4920 Premium				x	
BTL-4940 Smart					x
BTL-4940 Premium					x
BTL-4825M2 Smart			x	x	
BTL-4825M2 Premium			x	x	
BTL-4800LM2 Smart		x		x	
BTL-4800LM2 Premium		x		x	

8.2 TECHNICAL PARAMETERS OF ELECTROTHERAPY

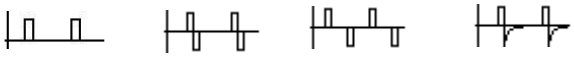
8.2.1 Parameters of the Electrotherapy Generator

Output current in the CC mode*	max. 140 mA (maximum instantaneous value)
Output current in the CV mode*	max. 165 mA (maximum instantaneous value)
Output current at HVT*	max. 10 A (maximum instantaneous value)
Output current at microcurrents*	max. 1,000 µA (maximum instantaneous value)
Output voltage in the CC mode*	max. 200 V (maximum instantaneous value)
Output voltage in the CV mode*	max. 100 V (maximum instantaneous value)
Output voltage at HVT*	max. 500 V (maximum instantaneous value)
Output voltage at microcurrents*	max. 100 V (maximum instantaneous value)
Tolerance of the output amplitude	± 20 %
Tolerance of the time parameters of current	± 20 %
Nominal load impedance	500 to 750 Ω
Internal output resistance in the CV mode	50 Ω ± 10 %
Internal output resistance in the CC mode	1 MΩ ± 10%
Output capacity	typically 150 pF
Output polarity – can be selected	positive / negative / with reversal in the middle of the therapy
Positive polarity	red banana plug = + = anode; black banana plug = - = cathode
Negative polarity	red banana plug = - = cathode; black banana plug = + = anode

*for some currents the maximum value can be limited according to IEC 60601-2-10

8.2.2 Parameters of Individual Therapies – Currents

8.2.2.1 TENS



Type	symmetric, alternating, asymmetric, monophasic
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Pulse	10 to 1,000 µs
Frequency	0.1 to 1,000 Hz
Pulse width modulation	automatic ± 30 %
Modulation	See **Current Modulation** below in this Chapter.
Channel mode	See **Channel Mode** below in this Chapter.

8.2.2.2 4-pole interference

Intensity - CC mode	0 to 100 mA
Intensity - CV mode	0 to 100 V
Carrier frequency	2,000 to 10,000 Hz
AMF	1 to 250 Hz
Spectrum	0 to 250 Hz
Frequency sweep	See **Frequency Sweep** below in this Chapter.

8.2.2.3 2-pole interference

Intensity - CC mode	0 to 100 mA
Intensity - CV mode	0 to 100 V
Carrier frequency	2,000 to 10,000 Hz
AMF	1 to 250 Hz
Spectrum	0 to 250 Hz
Frequency sweep	See **Frequency Sweep** below in this Chapter.

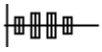
8.2.2.4 Isoplanar interference

Intensity - CC mode	0 to 100 mA
Intensity - CV mode	0 to 100 V
Carrier frequency	2,000 to 10,000 Hz
AMF	1 to 250 Hz
Spectrum	0 to 250 Hz
Frequency sweep	See **Frequency Sweep** below in this Chapter.

8.2.2.5 Interference - dipole vector

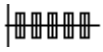

Type	automatic, manual rotation
Intensity - CC mode	0 to 100 mA
Intensity - CV mode	0 to 100 V
Carrier frequency	2,000 to 10,000 Hz
AMF	1 to 250 Hz
Spectrum	0 to 250 Hz
Frequency sweep	See **Frequency Sweep** below in this Chapter.

8.2.2.6 Russian stimulation



Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Carrier frequency	2,000 to 10,000 Hz
Pulse frequency	30 to 150 Hz
Pulse/pause ratio	1:1 to 1:8
Modulation	trapezoid surges or constant frequency (For the parameters see **Current Modulation** below in this Chapter.)
Channel mode	See **Channel Mode** below in this Chapter.

8.2.2.7 Mid-frequency surges

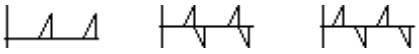


Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Carrier frequency	2,000 to 10,000 Hz
Pulse	0.1 to 50 ms
Pulse frequency	10 to 1,000 Hz
Modulation	See **Current Modulation** below in this Chapter.

8.2.2.8 Rectangular pulses

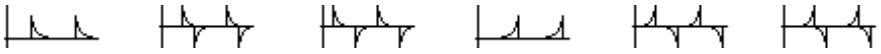
Type	monophasic, symmetric, alternating
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Pulse	0.2 to 1,000 ms
Frequency	0.1 to 1,000 Hz
Modulation	See **Current Modulation** below in this Chapter.

8.2.2.9 Triangular pulses



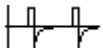
Type	monophasic, symmetric, alternating
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Pulse	1 to 1,000 ms
Frequency (monophasic)	0.1 to 900 Hz
Frequency (symmetric, alternating)	0.1 to 450 Hz
Modulation	See **Current Modulation** below in this Chapter.

8.2.2.10 Exponential pulses, pulses with exponential rise



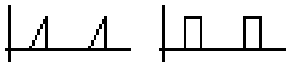
Type	monophasic, symmetric, alternating
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Pulse	1 to 800 ms
Frequency (monophasic)	0.1 to 900 Hz
Frequency (symmetric, alternating)	0.1 to 450 Hz
Modulation	See **Current Modulation** below in this Chapter.

8.2.2.11 Combined pulses



Type	asymmetric
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Pulse	0.2 to 1,000 ms
Frequency	0.1 to 700 Hz
Modulation	See **Current Modulation** below in this Chapter.

8.2.2.12 Stimulation pulses (for stimulation according to electrodiagnostics)



Type	rectangular monophasic, triangular monophasic
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Pulse	0.1 to 1,000 ms
Pause	0.5 to 10 s
Sound of the pulse generation	no sound, click, beep

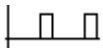
8.2.2.13 Trapezoid pulses

Type	monophasic, symmetric, alternating
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100V
Rise	0 to 250 ms
Pulse	0.1 to 250 ms
Fall	0 to 250 ms
Frequency (monophasic)	0.1 to 900 Hz
Frequency (symmetric, alternating)	0.1 to 450 Hz
Modulation	See **Current Modulation** below in this Chapter.

8.2.2.14 Interrupted pulses

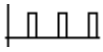
Type	rectangular, triangular (monophasic, symmetric, alternating)
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Frequency of interruption	8,000 Hz
Pulse	1 to 30 ms
Pause (monophasic)	1 to 60 ms
Pause (symmetric, alternating)	1 to 30 ms
Frequency (monophasic)	11.1 to 500 Hz
Frequency (symmetric)	11.1 to 333 Hz
Frequency (alternating)	8.3 to 250 Hz
Modulation	See **Current Modulation** below in this Chapter.

8.2.2.15 Träbert current, Ultra-Reiz, current 2/5



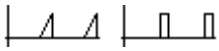
Type	monophasic
Intensity - CC mode	0 to 90 mA
Intensity - CV mode	0 to 100 V
Pulse	2 ms
Pause	5 ms
Frequency	143 Hz
Modulation	See **Current Modulation** below in this Chapter.

8.2.2.16 Leduc



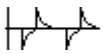
Type	monophasic
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Pulse	1 ms
Pause	9 ms
Frequency	100 Hz
Modulation	See **Current Modulation** below in this Chapter.

8.2.2.17 Farad, Neofarad



Type	monophasic rectangular (Farad), monophasic triangular (Neofarad)
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Pulse	2 ms
Pause	20 ms
Frequency	45.5 Hz
Modulation	See **Current Modulation** below in this Chapter.
Channel mode	See **Channel Mode** below in this Chapter.

8.2.2.18 H-waves

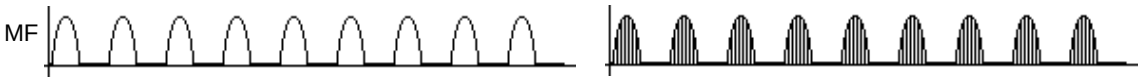


Type	symmetric
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Pulse	2 x 5.6 ms
Frequency	0.1 to 87.7 Hz
Modulation	See **Current Modulation** below in this Chapter.
Channel mode	See **Channel Mode** below in this Chapter.

8.2.2.19 Diadynamics

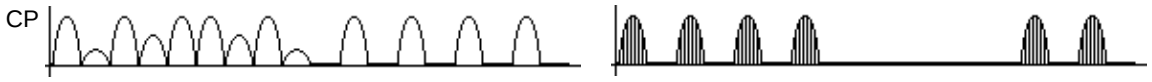
Type	DF, MF, CP, LP, RS, CP-ISO, LP-ISO, MM
Intensity - CC mode	0 to 70 mA
Intensity - CV mode	0 to 100 V
Base (direct component)	0 / 0.5 / 1 / 2 / 5 / 10 / 20 / 30 / 40 / 50%
Basic frequency	50 or 60 Hz
Pulse interruption	8,000 Hz

DF type parameters*: continuous sinusoidal pulses, frequency 100 Hz



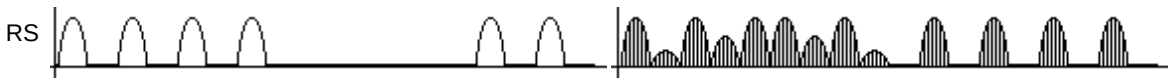
MF type parameters *: continuous sinusoidal pulses, frequency 50 Hz

MM type parameters*: amplitude-modulated MF, continuous sinusoidal pulses, 50 Hz



CP type parameters *: alternation of DF and MF; 1 second DF, 1 second MF

LP type parameters *: alternation of DF with modulation and MF; 10 seconds DF with modulation, 4 seconds MF



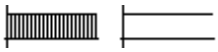
RS type parameters*: alternation of MF and pause; 1 second MF, 1 second pause

CP-ISO type parameters*: alternation of DF and MF with the amplitude 82 % of DF; 1 second DF, 1 second MF

LP-ISO type parameters*: alternation of DF and MF with the amplitude 82 % of DF

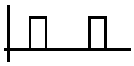
* The parameters are defined at the basic pulse frequency 50 Hz.

8.2.2.20 Galvanic current



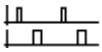
Type	continuous, interrupted 8,000 Hz
Intensity - CC mode	0 to 80 mA
Intensity - CV mode	0 to 100 V
Stimulation mode	continuous interrupted (stimulation 1 to 60 s, pause 1 to 60 s)

8.2.2.21 Microcurrents



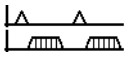
Type	rectangular, triangular, exponential (monophasic, symmetric, alternating) and combined
Intensity in the CC mode	0 to 1,000 µA
Pulse	0.2 to 1,000 ms (rectangular, combined) 1 to 1,000 ms (triangular, exponentional)
Frequency	0.1 to 1,000 Hz (rectangular) 0.1 to 700 Hz (combined) 0.1 to 900 Hz (triangular, exponentional, monophasic) 0.1 to 450 Hz (triangular, exponentional, symmetric and alternating)
Modulation	See **Current Modulation** below in this Chapter.
Note	CC mode only

8.2.2.22 Spastic stimulations - Hufschmidt



Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Pulses	0.1 to 1,000 ms
Delay between channels	10 to 3,000 ms
Frequency	0.1 – 10 Hz

8.2.2.23 Spastic stimulations - Jantsch

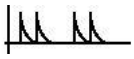


Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Pulses	0.1 to 1,000 ms
Delay between channels	0 to 3,000 ms
Frequency	0.04 - 0.99 Hz
Note	Second channel consist of TENS currents with pulse length 200 µs

8.2.2.24 High voltage therapy (HVT)

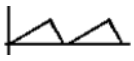
Type	single, double, triple pulses symmetric, alternating
Intensity - CV mode	0 to 500 V
Pulse	the pulse is in the shape of a downward exponential curve, the slope of which depends on the impedance of the patient (the lower the patient's impedance = the faster the decline) the maximum length of one pulse is limited to 50 μs double pulses – two pulses following 60 μs one after the other
Frequency	0.1 to 500 Hz
Modulation	See **Current Modulation** below in this Chapter.
Channel mode	See **Channel Mode** below in this Chapter.
Note	CV mode only

8.2.2.25 NPHV



Type	double pulses (double-pike)
Intensity - CV mode	0 to 100 V
Pulse	300 μs (double pulses, 2 x 50 us peak + 200 us pause)
Frequency	0.1 to 1667 Hz
Modulation	See **Current Modulation** below in this Chapter.
Note	CV mode only

8.2.2.26 IG pulses

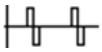


Type	IG30, IG50, IG100, IG150 (monophasic, biphasic symmetric)
Intensity - CC mode	0 to 80 mA
Intensity - CV mode	0 to 100 V
Increase in pulse	30 ms - IG30; 0.3 ms - IG50, IG100 and IG150
Decrease in pulse	10 ms - IG30; 0.1 ms - IG50, IG100 and IG150
Pause between pulses	80 ms - IG30; 5 ms - IG50, IG100 and IG150
Increase in envelope	without envelope - IG30; 25 ms - IG50, IG100 and IG150
Envelope stagnation	without envelope - IG30; 15 ms - IG 50; 65 ms - IG100; 115 ms - IG150
Decrease in envelope	without envelope - IG30; 10 ms - IG50, IG100 and IG150
Envelope pause	without envelope - IG30; 100 ms - IG50; 150 ms - IG100; 200 ms - IG150

8.2.2.27 Modulated pulsed current

Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Carrier frequency	2,000 to 10,000 Hz
Frequency	30 to 150 Hz
Duty factor	1:1 to 1:8
Modulation	trapezoid surges, sine surges or symmetric surges (For the parameters see **Current Modulation** below in this Chapter.)
Channel mode	See **Channel Mode** below in this Chapter.

8.2.2.28 VMS currents

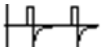


Type	symmetric biphasic
Intensity - CC mode	0 to 140 mA
Intensity - CV mode	0 to 100 V
Frequency	0.1 to 4167 Hz
Pulse width	20 to 1,000 µs
Gap between pulses	0,1 ms – 9,998 ms
Modulation	See **Current Modulation** below in this Chapter.
Channel mode	See **Channel Mode** below in this Chapter.

8.2.2.29 Kotz current

Carrier frequency	2,000 to 10,000 Hz
Intensity - CC mode	0 to 100 mA
Intensity - CV mode	0 to 100 V
Frequency	30 to 150 Hz
Modulation	trapezoid surges (For the parameters see **Current Modulation** below in this Chapter.)
Channel mode	See **Channel Mode** below in this Chapter.

8.2.2.30 EPIR



1. SECTION

Current	TENS
Type	asymmetric
Pulse	150 µs
Frequency	60 Hz
Mode	CC
Modulation	trapezoid surges
Rise/stimulation/fall/pause	2/4/1/23
Time	2 minutes

2. SECTION

Current	TENS
Type	asymmetric
Pulse	150 µs
Frequency	55 Hz
Mode	CC
Modulation	trapezoid surges
Rise/stimulation/fall/pause	2/5/1/22
Time	2 minutes

3. SECTION

Current	TENS
Type	asymmetric
Pulse	150 µs
Frequency	50 Hz
Mode	CC
Modulation	trapezoid surges
Rise/stimulation/fall/pause	2/6/1/21
Time	2 minutes

4. SECTION

Current	TENS
Type	asymmetric
Pulse	150 µs
Frequency	45 Hz
Mode	CC
Modulation	trapezoid surges
Rise/stimulation/fall/pause	2/7/1/20
Time	2 minutes

8.2.2.31 Current modulation

Types:	constant frequency
	random frequency sweep
	burst
	sine surges
	trapezoid surges
	symmetric surges
Random frequency sweep (can not be set for mid-frequency surges):	typically ± 30 %
Burst (cannot be set for HVT):	
number of bursts in pulse:	3 to 10
burst frequency:	0.1 to 100 Hz (acc. to the length and frequency of pulses)
Sine surges:	
surge length:	0.1 to 120 s (for HVT from 3 to 120 s)
pause length:	0 to 120 s (for HVT from 3 to 120 s)
Trapezoid surges:	
rise, fall of surge:	0 to 120 s (for HVT from 3 to 120 s)
time of stimulation:	0.01 to 120 s (for HVT from 3 to 120 s)
pause between surges:	0 to 120 s (for HVT from 3 to 120 s)
Symmetric surges:	
sweep time:	0.01 to 120 s (for HVT from 3 to 120 s)
contour:	1 to 100 %

8.2.2.32 Frequency sweep

Types:	continuous, jump, symmetric
Random frequency selection at the sweep:	yes, no
Continuous sweep:	
rise and fall of frequency:	0.01 to 120 s
frequency standstill:	0 to 120 s
Jump sweep:	
frequency standstill:	0.01 to 120 s
Symmetric sweep:	
sweep time:	0.01 to 120 s
contour:	1 to 100 %

8.2.2.33 Channel Mode

Channel modes:	
Single-channel	single-channel stimulation
Reciprocal	asynchronous stimulation over two current channels with an appropriate delay between the two channels
Co-contract	synchronous stimulation over two current channels

8.3 TECHNICAL PARAMETERS OF ULTRASOUND THERAPY

8.3.1 Parameters of the Ultrasound Generator

Adjustable values

Maximum intensity - continuous operation	0.1 to 2 W/cm^2 ±30 % for the output intensity higher than 0.2 W/cm^2
Maximum intensity - pulse operation	0.1 to 3 W/cm^2 ±30 % for the output intensity higher than 0.2 W/cm^2
Working frequency	1 MHz ± 5 % and 3.1 MHz ± 5 %
Modulation frequency	10 Hz to 150 Hz ± 5 %
Duty factor*	5 % to 100 % ±5 % of the set value
Duty factor - presets	6.25 % (1:16), 12.5 % (1:8), 25 % (1:4), 50 % (1:2), 100 % (1:1) ±5 % of the set value
Maximum output power	13.2 W ± 20 %

*) the duty factor can only be set in the pulse mode, in the continuous mode it is always 100 %

Parameters of pulses

Duty factor	frequency 10 Hz period 100 ms		frequency 50 Hz period 20 ms		frequency 100 Hz period 10 ms		frequency 150 Hz period 6.67 ms	
	pulse length	pause length	pulse length	pause length	pulse length	pause length	pulse length	pause length
50 %	50 ms	50 ms	10 ms	10 ms	5 ms	5 ms	3.33 ms	3.33 ms
25 %	25 ms	75 ms	5 ms	15 ms	2.5 ms	7.5 ms	1.67 ms	5 ms
10 %	10 ms	90 ms	2 ms	18 ms	1 ms	9 ms	0.67 ms	6 ms
6 %	6 ms	94 ms	1.2 ms	18.8 ms	0.6 ms	9.4 ms	0.40 ms	6.27 ms

Steps of the adjustable values

Intensity	0.1 W/cm^2
Modulation frequency	10 Hz
Duty factor	1 %

8.3.2 Parameters of the Ultrasound Applicators

BTL-257-1-13 – Ultrasound head 1 cm^2

Effective radiation area (A_{ER})	
A_{ER} (EN 61689)	0.7 cm^2 ± 20 %
A_{ER} (21 CFR 1050)	0.9 cm^2 ± 20 %
Maximum intensity	3 W/cm^2 ± 30 %
Maximum acoustic power	
for A_{ER} according to EN 61689	2.1 W ± 20 %
for A_{ER} according to 21 CFR 1050	2.7 W ± 20 %
Radiation frequency	1 MHz and 3.1 MHz ± 5 %
Type of beam (1/3 MHz)	divergent/collimated
Beam non-uniformity ratio (R_{BN})(1/3 MHz)	2.2 ± 30 % / 3 ± 30 %
Covering grade	IP67 - protected against dust penetration and temporary immersion in water

BTL-257-5-13 – Ultrasound head 5 cm^2

Effective radiation area (A_{ER})	
A_{ER} (EN 61689)	3.2 cm^2 ± 20 %
A_{ER} (21 CFR 1050)	4.4 cm^2 ± 20 %
Maximum intensity	3 W/cm^2 ± 30 %
Maximum acoustic power	
for A_{ER} according to EN 61689	9.6 W ± 20 %
for A_{ER} according to 21 CFR 1050	13.2 W ± 20 %
Radiation frequency	1 MHz and 3.1 MHz ± 5 %
Type of beam	collimated
Beam non-uniformity ratio (R_{BN})	3 ± 30 %
Covering grade	IP67 - protected against dust penetration and temporary immersion in water

BTL-447-4-13 – HandsFree Sono 4 - four-crystal applicator

Effective radiation area (A_{ER})	
A_{ER} (EN 61689)	4x 3.0 cm^2 ± 20 %
A_{ER} (21 CFR 1050)	4x 4.1 cm^2 ± 20 %
Active area of the applicators	31.5 cm^2
Maximum intensity	3 W/cm^2 ± 30 %
Maximum acoustic power	
for A_{ER} according to EN 61689	9 W ± 20 %
for A_{ER} according to 21 CFR 1050	12.3 W ± 20 %
Radiation frequency	1 MHz and 3.1 MHz ± 5 %
Type of beam	collimated
Beam non-uniformity ratio (R_{BN})	3 ± 30 %
Covering grade	IP67 - protected against dust penetration and temporary immersion in water

BTL-447-6-13 – HandsFree Sono 6 - six-crystal applicator

Effective radiation area (A_{ER})	
A_{ER} (EN 61689)	6x 3.0 cm^2 ± 20 %
A_{ER} (21 CFR 1050)	6x 4.1 cm^2 ± 20 %
Active area of the applicator	31.5 cm^2
Maximum intensity	3 W/cm^2 ± 30 %
Maximum acoustic power	
for A_{ER} according to EN 61689	9 W ± 20 %
for A_{ER} according to 21 CFR 1050	12.3 W ± 20 %
Radiation frequency	1 MHz and 3.1 MHz ± 5 %
Type of beam	collimated
Beam non-uniformity ratio (R_{BN})	3 ± 30 %
Covering grade	IP67 - protected against dust penetration and temporary immersion in water

8.4 TECHNICAL PARAMETERS OF LASER THERAPY

8.4.1 Parameters of the Laser Generator

Indication of the emission of laser radiation	green indicator light on the probe, supplementary lighting of the probe/cluster, sound, therapy time running on the display
Indication of the readiness for emission	indication on the screen
Indication of not being ready for emission	indication on the screen
Additional safety means	warning labels on the device housing and on the probe/cluster
	label on the entrance door of the workplace
	connector of the safety door contact

Connector of the safety door contact

The laser generation is disabled	the connector contacts are open
The laser generation is enabled	the connector contacts are short-circuited

The connector of the door contact is not intended for the connection of potential.

Adjustable values

Frequency*	0 – 10,000 Hz with the BTL-458 laser probe, 0 – 500 Hz with the BTL-455 laser cluster
accuracy of frequency	± 10 % of the set value
Dose	0.1 – 100 J/cm^2
accuracy of dose	± 20% (according to IEC 60601-2-22)
Area**	0.1 – 100 cm^2
accuracy of area	see BNR
Output**	5.0 – 400 mW (depending on the connected laser probe) 20 – 1,500 mW (depending on the connected laser cluster)
accuracy of output	± 20 % (according to IEC 60601-2-22)
Duty factor ***	35 – 90 %, 100 %
accuracy of duty factor	± 5 % of the range of duty factor

*) Zero frequency means the continuous operation of laser.

**) The stated values are maximum. The actual values depend on the type of the connected accessories.

***) Adjustable only in the pulse mode, in the continuous mode it is always 100 %.

8.4.2 Parameters of the Laser Probes

Laser probes with red radiation:

Type	**BTL-458-03RD**	**BTL-458-05RD**
Output power	30 mW ± 20 %	50 mW ± 20 %
Wavelength	685 nm ± 10 %	685 nm ± 10 %
Laser class*	3B	3B
Beam	divergent	divergent
Aperture	Ø 2 mm	Ø 2 mm
BNR	0.28 rad ± 0.05 rad	0.28 rad ± 0.05 rad
NOHD**	0.2 m	0.2 m

Laser probes with infrared radiation:

Type	**BTL-458-05IC**	**BTL-458-10IC**	**BTL-458-20IC**	**BTL-458-30IC**	**BTL-458-40IC**
Output power	50 mW ± 20 %	100 mW ± 20 %	200 mW ± 20 %	300 mW ± 20 %	400 mW ± 20 %
Wavelength	830 nm ± 10 %	830 nm ± 10 %	830 nm ± 10 %	830 nm ± 10 %	830 nm ± 10 %
Laser class*	3B	3B	3B	3B	3B
Beam	collimated	collimated	collimated	collimated	collimated
Aperture	Ø 4.4 mm	Ø 4.4 mm	Ø 4.4 mm	Ø 4.4 mm	Ø 4.4 mm
BNR	0.015 rad ± 0.005 rad	0.015 rad ± 0.005 rad	0.015 rad ± 0.005 rad	0.015 rad ± 0.005 rad	0.015 rad ± 0.005 rad
NOHD**	8.5 m	12.1 m	12.5 m	16.6 m	19.2 m

*) The laser class is classified according to IEC 60601-2-22:2007 and IEC 60825-1:2007.

**) NOHD – the nominal distance from the laser aperture in which the eye should not be damaged when hit by the laser beam.

8.4.3 Parameters of the Laser Clusters

Laser clusters with red radiation:

Type	**455-C25R02**
Output power	200 mW ± 20 % (4x 50 mW)
Wavelength	4x 685 nm ± 10 %
Laser class*	3B
Beam	4x divergent
Aperture	4x Ø 1.5 mm
Active area	Ø 56 mm (25 cm^2)
BNR	4x 0.35 rad ± 0.05 rad
NOHD**	0.2 m

Laser clusters with infrared radiation:

Type	**455-C25I08**	**455-C25I13**
Output power	800 mW ± 20 % (4x 200 mW)	1,300 mW ± 20 % (4x 325 mW)
Wavelength	4x 830 nm ± 10 %	4x 830 nm ± 10 %
Laser class*	3B	3B
Beam	4x divergent	4x divergent
Aperture	4x Ø 3.5 mm	4x Ø 3.5 mm
Active area	Ø 56 mm (25 cm^2)	Ø 56 mm (25 cm^2)
BNR	4x 0.52 rad ± 0.17 rad	4x 0.52 rad ± 0.17 rad
NOHD**	8.5 m	12.1 m

Combined laser clusters with red and infrared radiation:

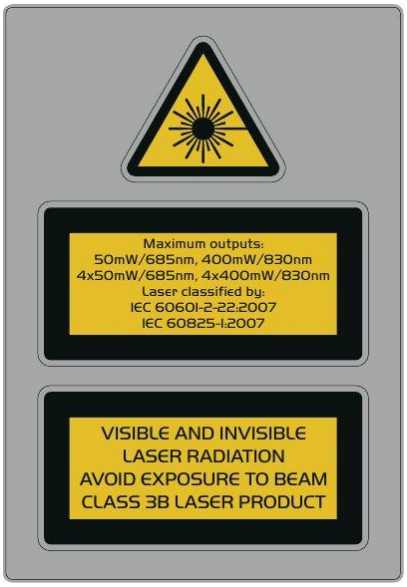
Type	**455-C25RI10**	**455-C25RI15**
Output power	red: 200 mW ± 20 % (4x 50 mW) infrared: 800 mW ± 20 % (4x 200 mW)	red: 200 mW ± 20 % (4x 50 mW) infrared: 1,300 mW ± 20 % (4x 325 mW)
Wavelength	red: 4x 685 nm ± 10 % infrared: 4x 830 nm ± 10 %	red: 4x 685 nm ± 10 % infrared: 4x 830 nm ± 10 %
Laser class*	3B	3B
Beam	8x divergent	8x divergent
Aperture	red: 4x Ø 1.5 mm infrared: 4x Ø 3.5 mm	red: 4x Ø 1.5 mm infrared: 4x Ø 3.5 mm
Active area	Ø 56 mm (25 cm^2)	Ø 56 mm (25 cm^2)
BNR	red: 4x 0.35 rad ± 0.05 rad infrared: 4x 0.52 rad ± 0.17 rad	red: 4x 0.35 rad ± 0.05 rad infrared: 4x 0.52 rad ± 0.17 rad
NOHD**	8.5 m	12.1 m

*) The laser class is classified according to IEC 60601-2-22:2007 and IEC 60825-1:2007.

**) NOHD – the nominal distance from the laser aperture in which the eye should not be damaged when hit by the laser beam.

8.4.4 Warning Labels Placed on the Housing of the Device and on the Applicators

8.4.4.1 Label placed on the housing of the device, warning about the occurrence of visible and invisible radiation of class 3B



8.4.4.2 Label placed on the body of the probe and cluster, warning about the proximity of the aperture of laser and informing about the presence of the "EMERGENCY LASER STOP" button

8.4.4.3 Label for marking the laser workplace, warning about the proximity of 3B-class laser

8.5 TECHNICAL PARAMETERS OF MAGNETOTHERAPY

8.5.1 Parameters of the Magnetotherapy Generator

Adjustable Values

Max. intensity of magnetic field	max. 128 mT / 1280 Gauss* (max. value on the surface of applicator)
Mode of magnetic field	continuous, pulsed, series of pulses
Shape of magnetic pulses	rectangular, rectangular protracted, exponential, triangular, sinusoidal
Pulse frequency	0 to 166 Hz ± 5 %
Modulation	none, burst, sine/ trapezoid/ symmetric surge
Random frequency	yes / no
Accuracy amplitude of magnetic field time parameters	 ± 30 % ± 10 %

*) The stated value is maximum for disc applicator. The actual value depends on the type of the connected applicator and on the settings of the device.

Parameters of Adjustable Values

Parameters of pulses	Pulse lenght	Pause lenght
rectangular	3 to 255 ms ± 10 %	3 to 65000 ms ± 10 %
rectangular protracted	6 to 510 ms ± 10 %	6 to 65000 ms ± 10 %
exponential	6 to 510 ms ± 10 %	6 to 65000 ms ± 10 %
triangular	6 to 510 ms ± 10 %	6 to 65000 ms ± 10 %
sinusoidal	6 to 510 ms ± 10 %	6 to 65000 ms ± 10 %
Parameters of modulation	Surge lenght	Pause lenght
sine surge	1 to 255 s ± 10 %	1 to 255 s ± 10 %
trapezoid surge	1 to 255 s ± 10 %	1 to 255 s ± 10 %
symmetric surge	1 to 255 s ± 10 %	1 to 255 s ± 10 %
Parameters of burst modulation	Number of pulses in burst	Pause lenght between bursts
	3 to 10	1 to 255 s ± 10 %

8.5.2 Parameters of the Magnetotherapy Applicators

BTL-239-1 – Disc Applicator

Dimensions	130 x 130 x 30 mm
Weight	1.05 kg
Intensity of the permanent magnet	23 mT (230 Gauss)
Max. intensity of pulsed magnetic field	105.2 mT (1052 Gauss)
Max. intensity of magnetic field in total	128.2 mT (1282 Gauss)
Resistance of the applicator	4.2 Ω

BTL-239-4 – Double Disc Applicator

Dimensions	2x 130 x 130 x 30 mm
Weight	2.15 kg
Intensity of the permanent magnet	23 mT (230 Gauss)
Max. intensity of pulsed magnetic field	73.6 mT (736 Gauss)
Max. intensity of magnetic field in total	96.6 mT (966 Gauss)
Resistance of the applicator	8.4 Ω

BTL-239-5 – Multi Disc Applicator

Dimensions	4x 130 x 130 x 30 mm
Weight	4.30 kg
Intensity of the permanent magnet	23 mT (230 Gauss)
Max. intensity of pulsed magnetic field	52.6 mT (526 Gauss)
Max. intensity of magnetic field in total	75.6 mT (756 Gauss)
Resistance of the applicator	4.2 Ω

BTL-239-2 – Solenoid 30

Dimensions	340 x 340 x 300 mm
Inner diameter	295 mm
Weight	5.75 kg
Max. intensity of pulsed magnetic field	9.3 mT (93 Gauss)
Resistance of the applicator	3.5 Ω

BTL-239-3 – Solenoid 60

Dimensions	620 x 540 x 300 mm
Inner width	580 mm
Inner height	480 mm
Weight	10.0 kg
Max. intensity of pulsed magnetic field	8.6 mT (86 Gauss)
Resistance of the applicator	6.2 Ω

BTL-239-8 – Solenoid 70 cm (only for magnetotherapy couch)

	Solenoid 70 cm	Magnetotherapy couch	Assembly
Dimensions (L x W x H)	310 x 740 x 740 mm	2000 x 540 x 600 mm	2000 x 740 x 1100 mm
Weight	18 kg	49 kg	67 kg
Max. intensity of pulsed magnetic field	7.6 mT (76 Gauss)	-	-
Resistance of the applicator	8.2 Ω	-	-

BTL-239-6 – Linear Applicator

Dimensions	600 x 290 x 20 mm
Weight	6.1 kg
Max. intensity of pulsed magnetic field	20.4 mT (204 Gauss)
Resistance of the applicator	2.6 Ω

BTL-239-7 – Ring Applicator

Dimensions	325 x 325 x 60 mm
Inner Diameter	280 mm
Weight	2.8 kg
Max. intensity of pulsed magnetic field	33.4 mT (334 Gauss)
Resistance of the applicator	4.2 Ω

8.6 ESSENTIAL PERFORMANCE OF THE DEVICE

 If any of the following functions fails, do not use the device and contact the service.

8.6.1 Essential Performance of the Device with Any Types of Therapy

- Device turn-off.

8.6.2 Essential Performance of the Device with Ultrasound Therapy

- The displayed numerical values of ultrasound therapy parameters (i.e. the values of output power and intensity) correspond to the actual values of the therapeutic output.
- No unwanted ultrasound radiation occurs at the sides of the head.
- The ultrasound radiation intensity does not exceed 3 W/cm^2.
- The ultrasound accessory surface temperature does not exceed the maximum permissible value of 43 °C.

8.6.3 Verification of the Essential Performance of the Device

Once a month it is suitable to check that the device resets after holding the **on/off** button for at least 10 seconds pressed.

Checking of the device including the ultrasound generator is done within the regular service inspections - see **Maintenance of the Device**.

8.7 INTERCONNECTION WITH OTHER DEVICES

The BTL-4000 Smart and BTL-4000 Premium devices with electrotherapy can be interconnected with the vacuum unit BTL-Vac II.
Other combinations are not allowed!

8.8 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.

WARNING: 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.

WARNING: 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.

Guidance and manufacturer's declaration – electromagnetic emissions		
BTL-4000 Smart/Premium is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-4000 Smart/Premium should assure that it is used in such an environment.		
Emissions test	***Compliance***	***Electromagnetic environment – guidance***
RF emissions CISPR 11	Group 1	The BTL-4000 Smart/Premium uses RF energy only for its internal function. Therefore, the emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BTL-4000 Smart/Premium 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity				
The BTL-4000 Smart/Premium intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BTL-4000 Smart/Premium can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BTL-4000 Smart/Premium 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 to 80 MHz $d = [3.5/V_1]\sqrt{P}$ $V_1=3V$	***150 kHz to 80 MHz*** $d = [3.5/V_1]\sqrt{P}$ $V_1=6V$	**80 MHz to 800 MHz** $d = [3.5/E_1]\sqrt{P}$ $E_1= 3$ V/m	***800 MHz to 2.7 GHz*** $d = [7/E_1]\sqrt{P}$ $E_1= 3$ V/m
0.01	0.12	0.06	0.12	0.23
0.1	0.37	0.18	0.37	0.74
1	1.2	0.58	1.2	2.3
10	3.7	1.8	3.7	7.4
100	12	5.8	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to 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** At 80 MHz and 800 MHz, the separation distance for 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.				

Guidance and manufacturer's declaration – Electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	±8 kV contact ±15 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 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	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(s) to line(s) ±2 kV line(s) 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; 1cycle at 0° 70 % U_T; 25 cycles at 0° 0 % U_T; 250/300 cycles	0 % U_T; 0.5 cycle at 0°,45°,90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1cycle at 0° 70 % U_T; 25 cycles at 0° 0 % U_T; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	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 device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th colspan="2">Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V
0.15 MHz – 80 MHz

6 V
ISM bands between 0.15 MHz and 80 MHz</td><td colspan="2">3 V
0.15 MHz – 80 MHz

6 V
ISM bands between 0.15MHz and 80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the device, 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]√ P 0.15 MHz to 80 MHz
d = [3.5/E_1]√ P 80 MHz to 800 MHz
d = [7/E_1]√ 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).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b].

Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz</td><td colspan="2">Compliance in same levels as test levels</td></tr>
<tr><td></td><td colspan="3">Table 9 of IEC 60601-1-2:2014:
27 V/m | 385 MHz | PM 18 Hz
28 V/m | 450 MHz | FM 5 kHz
9 V/m | 710 MHz | PM 217 Hz
9 V/m | 745 MHz | PM 217 Hz
9 V/m | 780 MHz | PM 217 Hz
28 V/m | 810 MHz | PM 18 Hz
28 V/m | 870 MHz | PM 18 Hz
28 V/m | 930 MHz | PM 18 Hz
28 V/m | 1720 MHz | PM 217 Hz
28 V/m | 1845 MHz | PM 217 Hz
28 V/m | 1970 MHz | PM 217 Hz
28 V/m | 2450 MHz | PM 217 Hz
9 V/m | 5240 MHz | PM 217 Hz
9 V/m | 5500 MHz | PM 217 Hz
9 V/m | 5785 MHz | PM 217 Hz</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-4000 Smart/Premium is used exceeds the applicable RF compliance level above, the BTL-4000 Smart/Premium 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-4000 Smart/Premium.</td></tr>
<tr><td colspan="5">b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

9 MANUFACTURER

BTL Industries Ltd.
161 Cleveland Way
Stevenage
Hertfordshire
SG1 6BU
United Kingdom

E-mail: sales@btlnet.com

For service, please contact our service department at service@btlnet.com.

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