BTL-6000

SUPER INDUCTIVE SYSTEM ELITE

USER’S MANUAL

BEFORE YOU START

Dear customer,

Thank you for purchasing BTL technology. All of us at BTL wish you every success with your system. We pride ourselves on being as responsive as possible to our customers' needs.

Your suggestions and comments are always welcome since we believe an ongoing relationship with our customers is critically important to our future product line.

While we would like you to start using your new equipment right away, we encourage a thorough reading of this manual in order to fully understand the operational features of the system.

Again, thank you for being a BTL customer.

BTL Industries Limited

CONTENTS

1 GENERAL INFORMATION

1.1 INTENDED USE

BTL-6000 Super Inductive System is a non-invasive therapeutic device. The device produces electromagnetic field that interacts with the tissues of the human body. Mainly affected structures are muscular and neuronal tissue. Results of the interaction with the tissue include muscular contraction, depolarization of neuronal cells and influence on blood circulatory system. BTL-6000 Super Inductive System can be used to treat chronic and acute disorders of the musculoskeletal and neuronal system and of the soft tissues of the body, e.g. muscle and joint pain.

1.2 USER PROFILE

The device shall be operated by medically educated personnel. Its users shall be familiar with all safety requirements, operating procedures and maintenance instructions. The device must not be operated by pregnant women.

1.3 OPERATING ENVIRONMENT

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

1.4 PATIENT PROFILE

The patient must not show any signs of the conditions defined in the **Chapter 1.6**. Before application it is necessary to take the patient's medical history and examine the patient thoroughly to determine whether or not the application of therapy is suitable for the patient.

1.5 DESCRIPTION OF THE DEVICE

The BTL-6000 Super Inductive System (hereafter referred to as device) is equipped with a colour touch screen with wide view angle that significantly facilitates the use of the device. The on-screen information guides the user step-by-step through the entire therapy procedure. The therapeutic parameters are easily set using the touch screen, buttons and knob on the device. Therapy is started by selecting a pre-set protocol from the list or by setting the parameters manually using the touch screen controls. During the therapy the device keeps information about the applied therapy type, remaining therapy time and main therapy parameters on the screen. Therapy can be applied through clothes.

1.5.1 Pulse Quality Monitor

As the electromagnetic pulses are generated with the use of high voltages and very high currents, parameters of each generated pulse are evaluated. In case of any mismatch with the expected values, the therapy is stopped to protect the device. Unwanted change in pulse parameters is most often caused by presence of huge metallic or ferromagnetic objects in the application field. For Pulse Quality Monitor settings see the **Chapter 6.4.3.3**.

Pulse Quality Monitor is not intended for protection of the operator and patient. If the device operation and safety instructions stated in this User's Manual are not respected, the device can be damaged and operator or patient can be seriously injured.

1.5.2 Intensity Predictor

Very high currents used for generation of electromagnetic pulses together with their super high induction cause generation of heat and its accumulation in the applicator. The generated heat is proportional to intensity of generated pulses, their repetition rate and therapy time. As the device offers wide range of user parameters and therapies (see the **Chapter 6.5.4**), the Intensity Predictor feature was developed to calculate and predict maximal intensity for currently running therapy. Feature informs the user about maximum intensity in percents (0–100 %) that can be achieved during the running therapy. Intensity value is calculated and displayed on the screen. Maximum achievable intensity of the therapy depends on the combination of therapy parameters (amplitude modulation, frequency modulation and therapy time settings) and current applicator temperature. Intensity Predictor value is available only during the running therapy.

Intensity Predictor does not indicate nor recommend optimal intensity for current therapy. Intensity must be adjusted to patient´s condition (see the **Chapter 6.5.6.**).

1.5.3 Therapy Targeting Mode

Therapy targeting mode helps to position the patient. If it is enabled, after the therapy is started, the low repetition rate pulses are continuously generated to target the treatment area. Running therapy targeting mode is announced with flashing heading on the screen.

Therapy targeting mode is time limited. If the time for patient positioning exceeded, therapy is stopped and message box appears on the screen.

1.6 CONTRAINDICATIONS

- cardiac pacemakers
- implanted defibrillators
- implanted neurostimulators
- electronic implants
- application in the area of growth plate
- pulmonary insufficiency
- metal implants
- drug pumps
- application in the head area
- haemorrhagic conditions
- anticoagulation therapy
- application in the heart area
- heart disorders
- malignant tumour
- fever
- pregnancy

1.7 POSSIBLE SIDE-EFFECTS AND ADVERSE EVENTS

The adverse effects may include, but are not limited to:

- muscular pain
- temporary muscle spasm
- temporary joint or tendon pain
- local erythema or skin redness

2 USED SYMBOLS AND MARKINGS

	Warning
	Type BF applied part
	Warning, magnetic field
	Follow instructions for use
	No access for persons with pacemakers
	No pushing
	Waste as electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
	Serial number
	Class II equipment
	Caution
	Dangerous voltage
	Marking a connector sensitive to electrostatic discharge
	Fuse
	Batch code
	Catalogue number
	CE mark

3 SAFETY PRECAUTIONS AND WARNINGS

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 not allowed to use the device and its accessories in any manner other that is in accordance with the User's Manual. It is prohibited to use the device in the way that is not in accordance with the Intended use (defined in the **Chapter 1.1**).

Therapy is strictly prohibited to persons with pacemakers.

Ensure that persons with pacemakers are not present in vicinity of the device in operation.

The therapy must not be delivered to patients with metal implants.

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.
Make sure that voltage parameters of the power supply grid correspond with the device requirements as stated in the **Chapter 8.**

The device must be transported, stored and operated in the environment defined in the **Chapter 8.** It is strictly forbidden to operate the device if any danger of explosion or of water penetration into the device can occur. The device cannot be in contact with flammable anaesthetics or oxidizing gasses (O_2, N_2O, etc.). The device is not intended for exterior use!

Do not connect any cables or devices to the USB connectors. They are for service purposes only!

Dissipate static electricity by touching a grounded metal object before connecting or manipulating the device connected to the USB connector.

It is strictly forbidden to place any ferromagnetic or metallic materials, data carriers (credit or debit cards, USB flash drives etc.), electronic devices (mobile phones, tablets, watches, PCs etc.) and other device's applicators or accessories in the vicinity (less than 1 meter) of the applicator in use during the therapy.

Do not place the device near other devices that produce strong electromagnetic fields (diathermy, X-ray, cell phones, radiofrequency) in order to prevent mutual functionality influence. If this happens, move the device further away from the source of interference or contact an authorized BTL service department.

Do not place the device in direct sunlight or near heat sources. It might lead to excessive temperature increase and possible risk for the patient and the device. The device heats up during operation and therefore must not be located near direct heat sources. The device is cooled by forced-air circulation. The cooling vents are located on the rear panel of the main unit and on the sides of the applicator. The vents must not be covered. When placing the device, leave at least 10 cm of free space behind the rear panel.

It is prohibited to place any objects that produce heat or objects containing water or other liquid on the device.

After bringing the device from cold to warm environment, wait until the temperature equalizes before its connection to the mains (at least 2 hours).

No modifications of the device and its accessories are 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 bears no responsibility for further operation of the device.

Never use the accessories connector or other connectors to plug in anything else than what they are designed for (see the **Chapter 4.3**). 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. It does not function with accessories of other manufacturers.

Before starting a therapy always check the device and its accessories (the cable, the applicator, the connectors, the touch screen) for a possible mechanical, functional or other damage. In case that a defect or deviation from normal function is found, stop using the device immediately and contact the BTL authorized service. In case that the device is in use despite the presence of defects, the person solely responsible for any damage caused by the device is the user.

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. For detailed specifications see the **Chapter 8**.

The output voltage values can exceed safe values in connectors marked with the depicted symbol.

Prior to start of the therapy make sure that all set parameters match your requirements. Follow the therapy contraindications detailed in the **Chapter 1.6**.

The hand-held applicator must always be attached to the arm and must not be held in hand during the therapy. The applicator cable must be always fixed in a cable holder during the therapy.

The device and applicator must not be used in other than defined position (see the **Chapter 5**).

Do not place the applicator close to another hand-held applicator or any part of the device during the therapy.

Surface of the applicator and cable may be hot when the therapy is running or during cooling process after the therapy is finished. Never turn the device off before the cooling process is finished.

The device displays messages that inform about deviations or defects of the device and its accessories. These messages are designed in such way that their interpretation is obvious. If you are not sure of the interpretation, stop using the device and contact BTL authorized service.

To unplug the applicator, release the safety locks and pull out the connector. Never pull the applicator cable. Never disconnect the applicator during therapy (see the **Chapter 6.1**).

Always keep verbal contact with the patient when the therapy is running. Never leave the patient unattended.

Protect the device against unauthorized use.

The applicator can only be plugged in and unplugged when the device is turned off.

Keep the device out of reach of children.

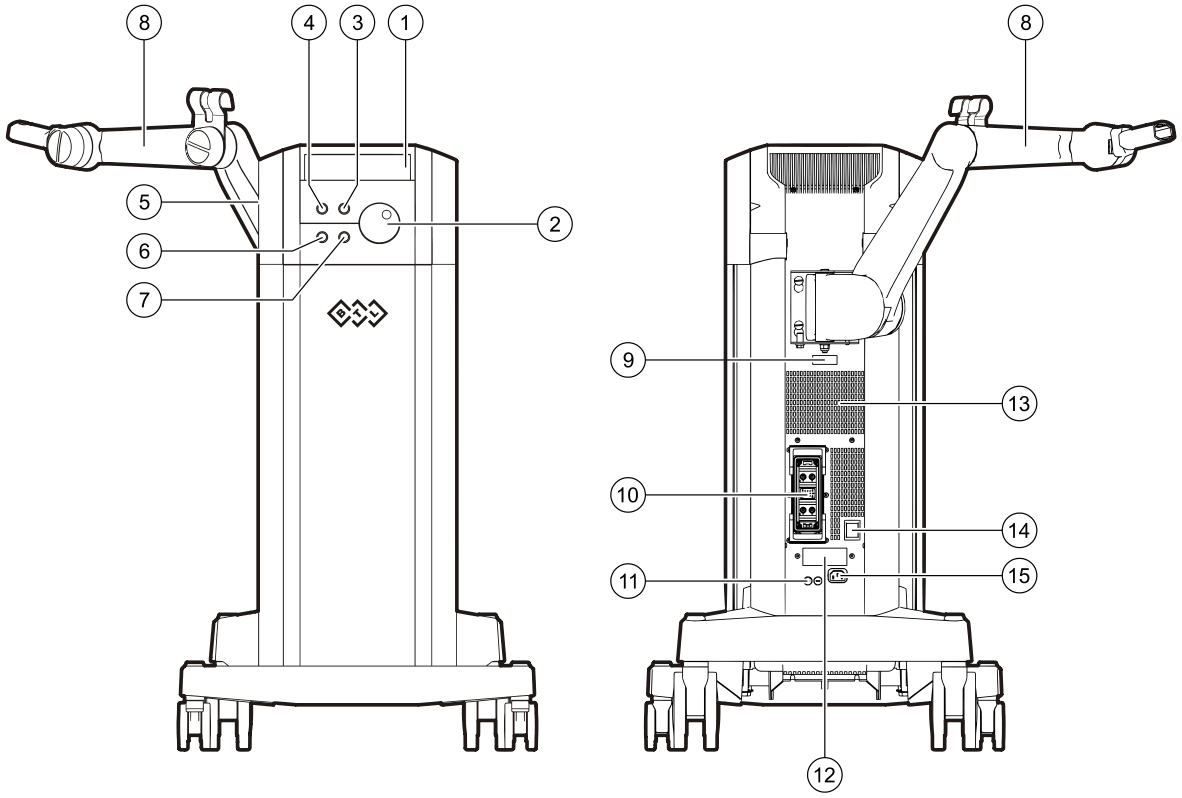
The hand-held applicator always has to be disconnected from the applicator arm during the device transfer.

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

This device does not contain any drugs or substances as an integral part or to be given to the user or patient. This device does not use or emit any toxic or radioactive substances during its operation, storage or transport under the stated conditions.

4 DEVICE AND ACCESSORIES

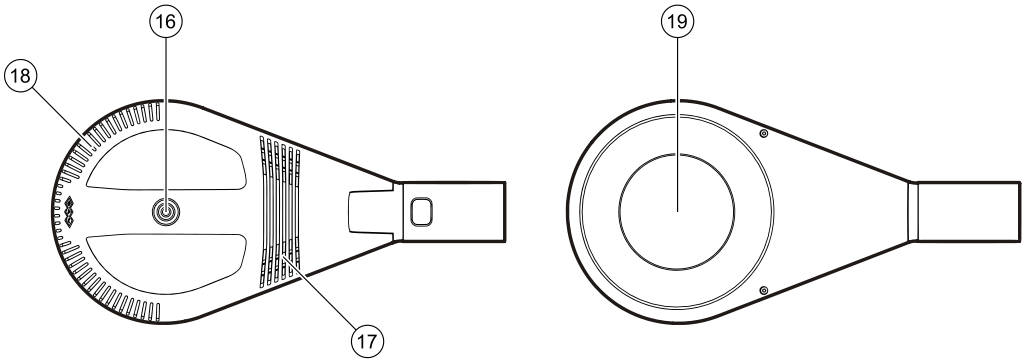
4.1 FRONT AND REAR PANEL OF THE MAIN UNIT



1. touch screen
2. **select** knob (choose and set parameters)
3. **enter** button (confirm the choice/settings)
4. **esc** button (reject the selection, return to previous state)
5. USB port located in the grip space of the device, for use only in accordance with IEC 60950-1; the USB port is intended ONLY for technical service purposes, e.g. loading firmware; it is not intended for therapeutic use.
6. **on/off** button (switch the device on/off)
7. **start/stop** button (start/stop the therapy)
8. applicator attachment arm with cable holder
9. production label (with serial number)
10. applicator connector
11. two fuses
12. type label
13. ventilation grid
14. mains power switch
15. mains cable connector

4.2 HAND-HELD APPLICATOR

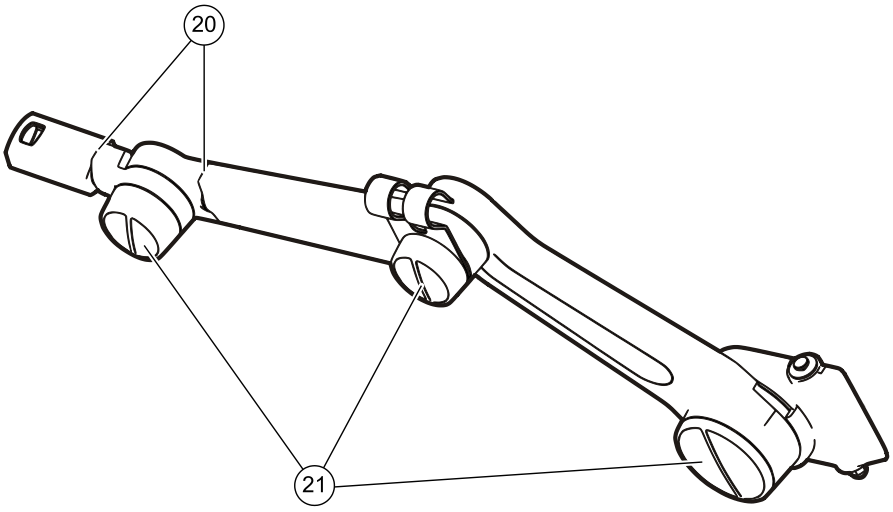
Applicator consists of a handle with marked spot showing the coil centre (16), air vents (17, 18) and therapy application area on the bottom side (19). Applicator is attachable to the arm, which significantly simplifies therapy application. According to standard IEC 60601-1 the hand-held applicator is classified as BF type applied parts. The hand-held applicator may be in contact with the patient, although the therapy is primarily non-contact.



The hand-held applicator must always be attached to the arm and must not be held in hand during the therapy. The applicator cable must always be fixed in cable holder during the therapy.

Applicator Arm

The applicator arm comprises of 3 knobs for adjusting and fixing the arm position (21), 2 rotary joints (360°) for adjusting the applicator position (20), 1 rotary joint (180° on the middle knob) for adjusting the arm position and cable holder.



4.3 LIST OF STANDARD ACCESSORIES

This device is not designed for use with any accessories or medical equipment other than those stated in this manual.

The following list contains all standard accessories that can be supplied with the device.

Standard accessories:

- Focused field applicator / BTL-299-2
- Applicator arm with cable holder
- Arm installation set
- User's manual
- Touch screen pen pointer
- Power cord
- Mains fuses

5 DEVICE INSTALLATION

Always inspect the packaging for damage. If the packaging is damaged, do not proceed with assembly and set-up and return the device to the distributor. Keep the original packaging to ensure safe future transport of the device.

After bringing the device from cold to warm environment, wait until the unit temperature equalizes to the ambient room temperature before connecting it to the mains (at least 2 hours).

Unpack the device and place it on a stable horizontal surface, which is suitable for its weight.

Always place the device out of direct sunlight. The device gets warm during operation, so it must not be positioned near direct heat sources. The device is cooled by forced-air circulation. The cooling vents are located on the rear panel and on the applicator and they must not be covered. Do not place any heat-producing devices or any containers with water or other liquids on the device. Do not place the device close to appliances emitting strong electric, electromagnetic or magnetic fields or X-rays, otherwise the device could be undesirably influenced.

For any questions you may have, please contact an authorized BTL service.

5.1 INSTALLATION OF THE HAND-HELD APPLICATOR

The following components (supplied with the device) are required for installation of the arm and the applicator:

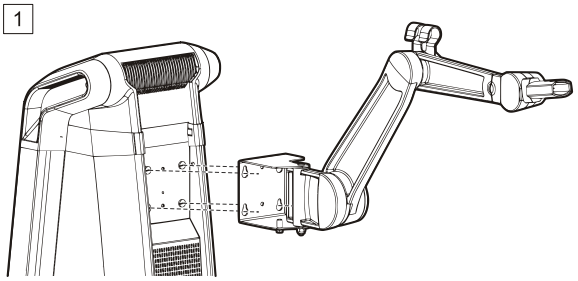
- 1x applicator arm with cable holder
- 1x arm installation set
- 1x applicator

For safe operation with the applicator arm, always hold the arm with one hand and loosen the knob with the other hand to prevent an injury or damage to the arm. Before starting the therapy always make sure that the knobs are tightened and the arm will not move during the therapy.

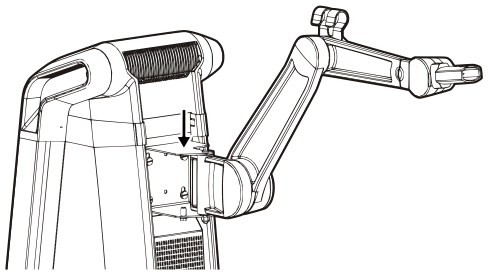
Procedure of Installation (see figures on the following page)**:**

1. Place the arm holder kit to the main unit.
2. Push the arm holder kit down.
3. Screw the arm holder kit to the main unit (use supplied screws and wrench).
4. When needed, adjust turning force of last joint by tube wrench.
5. When needed, adjust turning force of first joint by wrench.
6. Connect the applicator to the arm.
7. Connect the applicator to the main unit and use the safety locks to fix the connector.

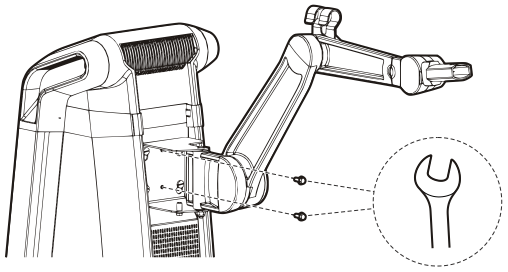
1



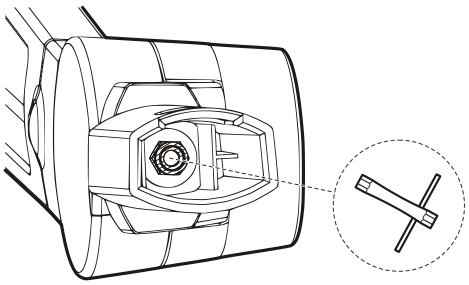
2



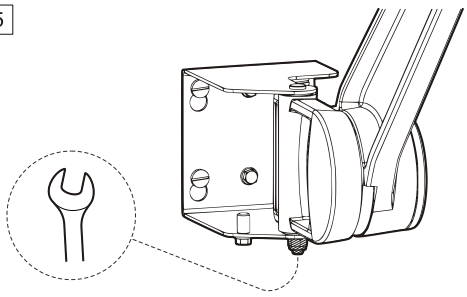
3



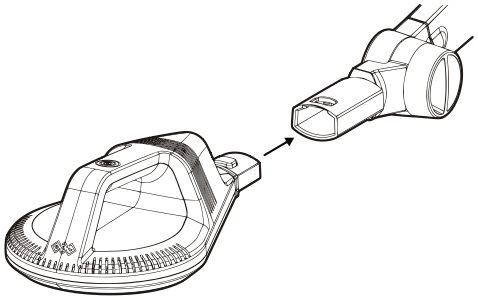
4



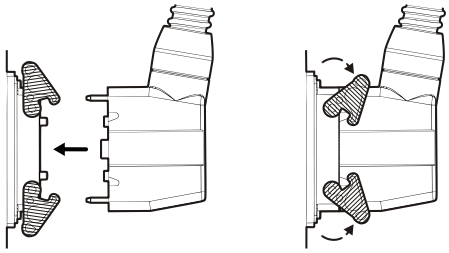
5



6



7



6 BASIC DEVICE OPERATION

6.1 APPLICATOR CONNECTION / DISCONNECTION

The device is provided with detachable applicator. For applicator installation procedure see the **Chapter 5.1**. It is necessary to perform applicator calibration when the applicator is connected (see the **Chapter 6.4.3.2**).

The applicator can only be unplugged when the device is turned off. Never turn on the device when the applicator is disconnected.

6.2 DEVICE STARTUP / SHUTDOWN

1. Plug the power cord (supplied with the device) in the connector (**Chapter 4**, ref.15) of the device and in the mains (see the **Chapter 8**). Plug the device directly in the mains; do not use extension cords with multiple sockets or multi-socket adaptors.
2. Switch the mains switch (**Chapter 4**, ref. 14) on the rear panel to position "**I**".
3. Press the **on/off** button (**Chapter 4**, ref. 6) on the front panel.
4. Turn off the device by pressing the **on/off** button**.** A big amount of thermal energy is accumulated in the applicator at the end of the therapy, thus automatic applicator cooling process has to be completed before the device is turned off. The cooling process can be interrupted by pressing the **esc** button (**Chapter 4**, ref. 4). The unit turns off automatically after the cooling process is completed (when ambient and applicator temperatures are equal).

Always let the automatic cooling process of the device finish before turning the device off. Not respecting the required cooling could cause device damage and operator or patient injury.

Never put two applicators in close proximity when at least one of them is in use. This could cause high voltage risk to the operator and the device can be damaged.

6.3 NAVIGATION CONTROLS

The top part of the touch screen contains a basic navigation toolbar:

	LIST	displays the list of available pre-set protocols
	QUICK	displays the screen for quick selection of pre-set protocols
	MANUAL	displays the screen with therapy parameters
	MENU	enables setting the device functions
	HOME	enables returning back to screen, which is configured as Home (reconfigurable by user, welcome screen by default)

6.4 DEVICE MENU

You can browse through the following menus of function settings and information screens by pressing the **menu** button on the touch screen:

- user settings / database
- unit settings
- specific settings

6.4.1 User Settings / Database

This item displays a menu referring to the data saved by the user:

- clients
- user therapeutic protocols
- recent therapies

6.4.1.1 Clients

This item enables setting up, editing and deleting client information. It is possible to assign therapies from the list of pre-set protocols to any client and to run these therapies after pressing the **load** button.

6.4.1.2 User Therapeutic Protocols

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

6.4.1.3 Recent Therapies

This option displays the list of last performed therapies on the selected tab and enables starting the therapy again after pressing the **load** button.

6.4.2 Unit Settings

The 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

6.4.2.1 Language

This function allows the user to select the language of the displayed text. English is set by default.

6.4.2.2 Date & Time

This function allows the user to set the time and date.

6.4.2.3 Sound Settings

This option allows setting the sound volume and modifying acoustic signalling for key pressing and touching the screen as well as for certain operations such as start of therapy, interruption of therapy, end of therapy etc. Standard sounds are preset by default. Sounds can be completely muted or customized in standard sounds edit.

6.4.2.4 Colour Schemes

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

6.4.2.5 Screen Saver and Auto Switch-off

This option enables setting the type of screen saver. It is also possible to set the idle time, after which the screensaver shall be activated, the screen shall be switched off or the entire device turned off.

6.4.2.6 Password

This menu allows setting or changing the password, which is required after switching the device on. Without entering the password no further work with the device is possible. By default the devices are supplied as "unlocked" – with the password off.

6.4.2.7 Unit Information

By selecting this option, basic system information about the unit are displayed – the serial number, type of the device, Multifirmware ID version, HW key etc. If the device function is time-limited, this item shows the date, until which the device will be fully functional.

6.4.2.8 Accessories Information

This option displays information about the connected accessories.

6.4.2.9 Advanced Settings

This option allows setting less frequent functions of the device:

- **HOME** screen mode (setting the type of the screen after HOME button is pressed)
- **QUICK** screen mode (displaying of quick pre-set protocols or programs)
- **LIST** screen mode (displaying of list of protocols or body parts)
- user accounts
- time of use (disabled by default)
- touch panel calibration
- display contrast
- buttons backlight
- service functions
- dialog history
- setting of HW key

6.4.3 Specific Settings

6.4.3.1 QUICK Screen Protocols

The option enables to set protocols on the **QUICK** screen and additional functions referring only to the selected generator.

6.4.3.2 Applicator Calibration

When the applicator is exchanged and the Pulse Quality Monitor sensitivity is set to *high* (see the **Chapter 6.4.3.3**), the applicator calibration has to be performed for optimal therapy performance and Pulse Quality Monitor function. The applicator has to be cooled down before start of the calibration. All metallic or ferromagnetic objects have to be removed from the applicator area (min. 1 m) before start of the calibration.

6.4.3.3 Therapy Settings

pulse quality monitor	enables switching between low and high sensitivity of Pulse Quality Monitor
pause skipping	enables skipping pause when intensity of the therapy is changed using the knob
therapy targeting mode	enables patient positioning procedure
therapy amplitude alert	enables switching the warning sound signal on/off when current amplitude of the therapy does not match the required value

6.5 THERAPY

6.5.1 Setting the Therapy by Selecting a Pre-set Protocol – LIST Screen

The list of all pre-set protocols is displayed after the **LIST** button is pressed. User protocols saved in the list of pre-set protocols are marked with a card-icon.

After the desired protocol is found, its selection can be made by pressing the selected protocol's row or the **enter** button on the touch screen or on the front panel.

After the desired pre-set protocol is loaded, the device displays the therapy parameters screen (see the **Chapter 6.5.4**), where the therapy can be started directly by pressing the **start** button on the touch screen or the **start/stop** button on the front panel of the device.

If therapy targeting mode is enabled, after pressing **start** button flashing heading "Position the patient. Press ENTER to continue." appears on the screen. Press **enter** button on the touch screen or on the front panel of the device to continue in therapy.

Encyclopaedia

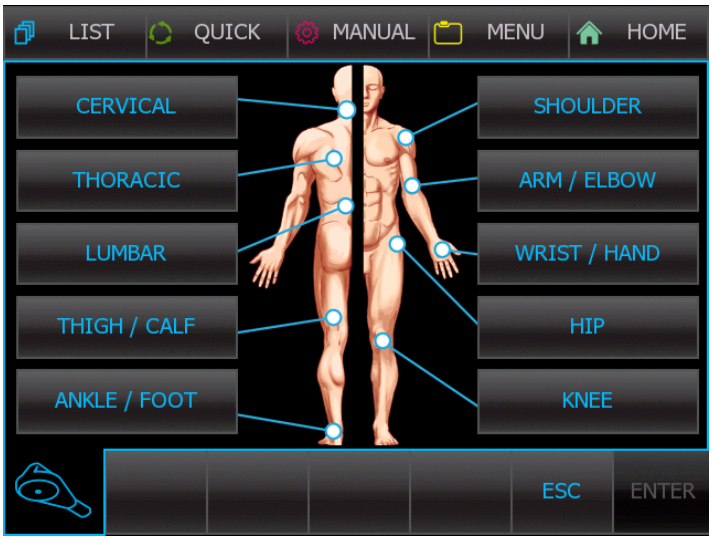
After the required pre-set protocol is selected, it is possible to view the detailed protocol information by pressing the button with the encyclopaedia symbol on the therapy parameters screen.

The encyclopaedia also includes a graphic part – after pressing the respective button on the touch screen, the recommended placement of the applicator will be displayed.

6.5.2 BODY PARTS – Filtering Pre-set Protocols According to Body Area

The device offers a function for filtering the pre-set protocols according to the body area. Pressing the button with the figure symbol opens the **BODY PARTS** screen, where ten areas of human body are depicted.

Pressing the button with the desired region displays the list of pre-set protocols relevant to the area.



6.5.3 Quick Pre-set Protocol Selection – QUICK Screen

After the **QUICK** button on the navigation toolbar is pressed, the device displays the pre-set protocol quick-selection screen.

The **QUICK** screen serves for fast start of the therapy without need to browse through the entire list of protocols. To select a protocol just press the respective button. The list of quick screen protocols can be fully customized (*menu – specific settings – setting of the QUICK screen protocols*).

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

After selecting one of the pre-set protocols on **QUICK** screen, it is possible to find detailed information about the selected protocol by pressing the encyclopaedia button.

Additionally to the **QUICK** screen and the pre-set 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 numbers can be found in the protocol description in the encyclopaedia. To set the program number, press the required element on the touch screen and then use the **select** knob or the numerical keyboard.

6.5.4 Manual Settings of the Therapy Parameters – MANUAL Screen

After the **MANUAL** button from the navigation toolbar is pressed the device displays **MANUAL** therapy parameters screen, where the full range of therapy parameters can be set and the therapy can be started immediately.

This screen also appears always before the start of therapy when one of the pre-set protocols from the **LIST** or **QUICK** screens is selected.

	Press the **edit** button on this screen to edit the therapy parameters. The screen with advanced therapy parameters will be displayed.
	Press the **save** button to save the current therapy settings. The therapy is saved as user-defined protocol and can be assigned to a specific client.

The following symbols on this screen inform about the course of therapy and device behaviour:

	The device alerts that stimulation frequency is too high for the required intensity value (current output amplitude of electromagnetic pulses does not match the required value).
	The device alerts that stimulation frequency is too low for the required intensity value (current output amplitude of electromagnetic pulses does not match the required value).
	Pulse Quality Monitor sensitivity is set to high. Device is sensitive to huge metallic or ferromagnetic objects in applicator vicinity.
	Pulse Quality Monitor sensitivity is set to low. Only the fundamental safety of device power circuits is secured.
	Acoustic indication of therapy alerts is enabled.
	Acoustic indication of therapy alerts is disabled.
	Current applicator temperature and internal device heat level (0–100 %). Values start flashing when the applicator temperature or internal device heat is approaching the limit for safety operation. When values are flashing, the therapy start is blocked.

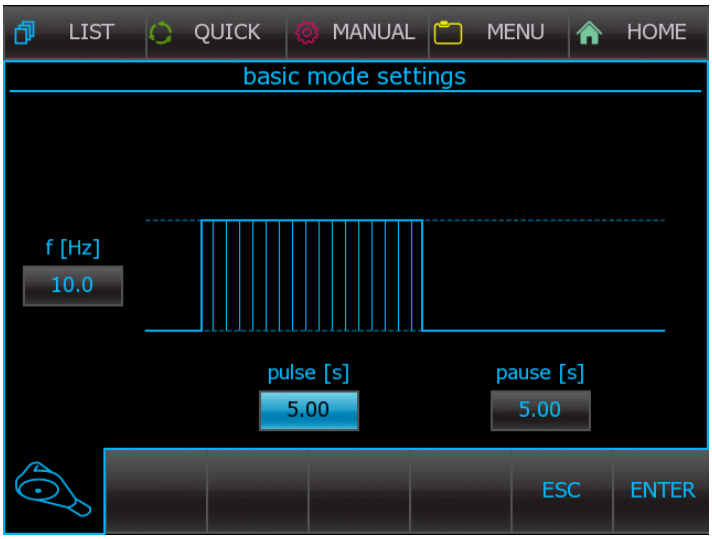
To start the configured therapy, press the **start** button on the touch screen or **start/stop** button on the front panel of the device (if the temperature symbol is flashing, please wait before the applicator is ready for new therapy - temperature symbol stays still).

6.5.4.1 Therapy Types

The device supports three different therapy types, which can be changed by pressing the **type** button: basic, sequence and single.

Basic mode

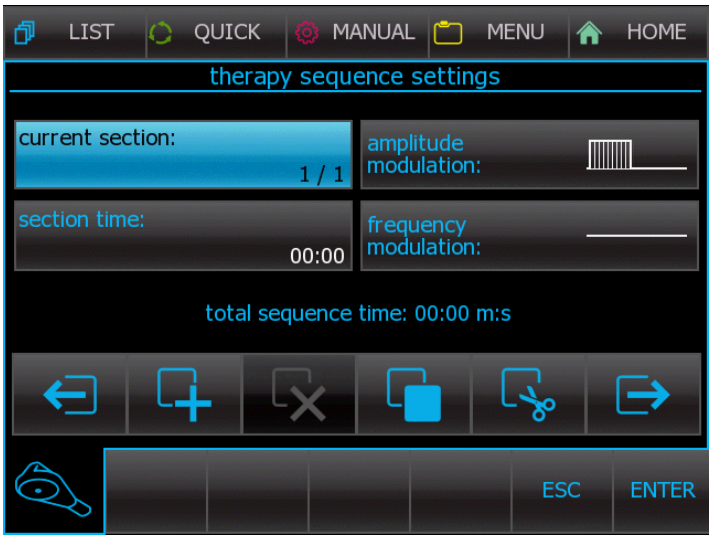
The simplest supported mode, which enables changing pulse repetition rate (frequency), stimulation period and stimulation pause.



Frequency [Hz]	Pulse [s]	Pause [s]
1–150	0.01–60	0–60

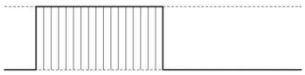
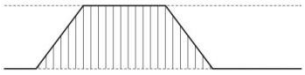
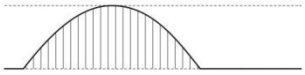
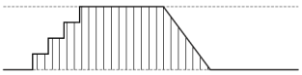
Sequence mode

This mode enables creating therapy sequence by setting amplitude modulation, frequency modulation and time of each section in the sequence. The sequence can consist of up to 99 sections.



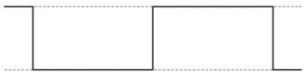
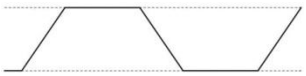
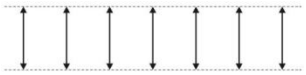
Sequence editor is controlled by the following buttons:

	Shift to the left position in the sections list.
	Shift to the right position in the sections list.
	Add a new section (with default values).
	Delete the current section.
	Create a copy of the current section.
	Cut the current section.
	Place the chosen section before the current one.
	Place the chosen section behind the current one.
current section	Displays current section number and number of sections.
section time	Displays the duration of the current section.
amplitude modulation	Sets the parameters of amplitude modulation.
frequency modulation	Sets the parameters of frequency modulation.

Amplitude modulation		
Type	**Symbol**	**Parameters**
none		pulse [s]: 0.01–60 pause [s]: 0–60 I [%]: 1–100
trapezoid		rise [s]: 0.01–60 hold [s]: 0–60 fall [s]: 0.01–60 pause [s]: 0–60 I1 [%]: 0–99 I2 [%]: 1–100
sine		period [s]: 0.01–60 pause [s]: 0–60 I1 [%]: 0–99 I2 [%]: 1–100
staircase		rise [s]: 0.01–60 hold [s]: 0–60 fall [s]: 0.01–60 pause [s]: 0–60 I1 [%]: 0–99 I2 [%]: 1–100

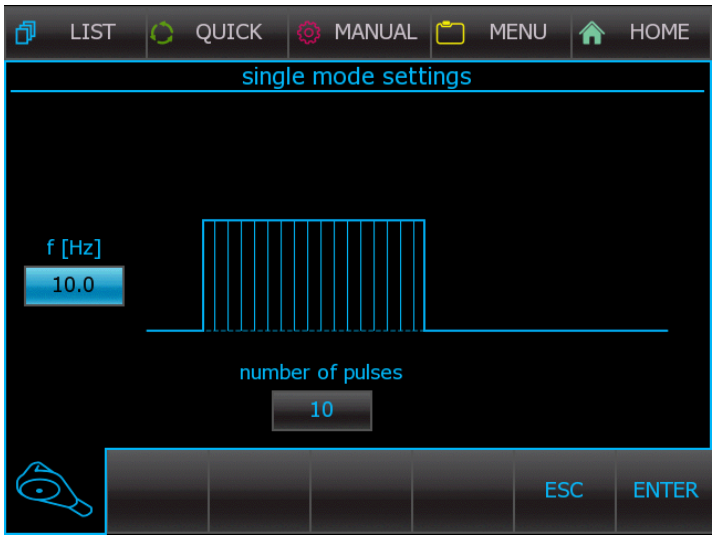
If the falling edge of the amplitude modulation waveform is not corresponding to the expected (configured) shape caused by low stimulation frequency and short falling edge; the falling edge is automatically corrected and the message box appears on the screen (see the **Chapter 6.5.4**).

In some cases a short-term occurrence of the alarm signal (see the **Chapter 6.5.4**) can be a natural part of the stimulation sequence (especially in time of change between two following sections with different amplitude modulation types and relative intensity parameters).

Frequency modulation		
Type	**Symbol**	**Parameters**
none		f [Hz]: 1–150
alternating		f1 [Hz]: 1–150 f2 [Hz]: 1–150 t1 [s]: 1–60 t2 [s]: 1–60
trapezoid		f1 [Hz]: 1–150 f2 [Hz]: 1–150 t1 [s]: 0.01–60 t2 [s]: 0–60 t3 [s]: 0.01–60 t4 [s]: 0–60
sine		f1 [Hz]: 1–150 f2 [Hz]: 1–150 period [s]: 1–60
random		f_{min} [Hz]: 1–150 f_{max} [Hz]: 1–150 transition time [s]: 1–60

Single Mode

This mode enables creating triggered single bursts composed of defined number of pulses. Pulse repetition rate (frequency) and number of pulses within the burst can be configured.



Frequency [Hz]	Number of pulses
1–150	1–1000

6.5.5 Setting the Time of Therapy

Therapy time is pre-set for every therapy and pre-set protocol. Therapy time on the **MANUAL** screen can be changed by pressing once the **time** button and by rotating the **select** knob. Repeated pressing of the **time** button opens dialog window for time setting. Change the required time using the **select** knob or enter the value through numerical keyboard and press **enter** to confirm.

Therapy time cannot be modified when the therapy is running. Time can be modified only when the therapy is paused (**pause** button) or stopped (**start/stop** button).

6.5.6 Setting the Intensity

The intensity button on the touch screen is automatically selected after the therapy is started. The intensity can be adjusted by the **select** knob. To prevent unexpected increase of intensity for the patient, the stimulation pause can be optionally skipped when the therapy intensity is adjusted (for setting see the **Chapter 6.4.3.3)**. Maximum achievable intensity of the therapy depends on the combination of therapy parameters (amplitude modulation, frequency modulation and therapy time settings) and current applicator temperature. Adjust the intensity according to patient's condition and feedback.

6.5.7 Recommended Therapy Parameters

For optimal device performance and therapeutic effect, it is necessary to follow the recommended therapy intensities for device's NORMAL USE (listed in tab below). Always consider body type and pre-set protocol. Values listed below should be considered as general recommendation, always adjust intensity according to patient´s condition and feedback.

Subjective perception	Intensity (%)
sensitivity threshold	5 (+5)
above the sensitivity threshold	10 (±5)
lower than or up to motor threshold intensity	15 (±5)
motor threshold	20 (±5)
above the motor threshold	25–80

6.6 COURSE OF THERAPY

6.6.1 Therapy Start – Interruption – End

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

If the therapy targeting mode is enabled, after the **start** button is pressed the low repetition rate pulses are continuously generated. The stimulation intensity has to be adjusted according to patient's feedback (see **Chapter 6.5.6**). The therapy targeting mode is finished and therapy continues by pressing the **start** button.

The therapy can be interrupted (and resumed again) at any point by pressing the **pause** button or **start/stop** on the front panel. The interrupted therapy can be terminated by pressing the **esc** button.

6.6.2 Running Therapy

During the running therapy the screen shows buttons with the main therapy parameters, similarly to the **MANUAL** therapy parameters screen. However, buttons are not active (except for the **intensity** button). The remaining time is highlighted to provide an instant overview of the course of the ongoing therapy. During the running therapy the applicator symbol and the current therapy time / intensity are alternating in the therapy tab. The main applicator symbol on the **MANUAL** screen is animated.

Presence of the electromagnetic field during the ongoing therapy is indicated on the device by animation of the applicator symbol and a non-zero intensity value on the **intensity** button on the **MANUAL** screen.

6.7 SAVING THE THERAPY

The device offers function for saving the user-specific protocols. The user´s protocol can be saved (after setting therapy parameters) solely on the **MANUAL** screen by pressing the **save** button on the touch screen (see the **Chapter 6.3**). During the protocol saving, the following data must be inserted: name of the protocol (will be displayed in the list of user protocols under the **list** button), program number and additional description of the protocol (will be displayed in the device database). The protocol can also be assigned to a specific client.

User protocols may be displayed on the **QUICK** screen. The list of protocols displayed on the **QUICK** screen can be modified in the device menu (*menu – specific settings – **QUICK** screen protocols*).

6.8 TROUBLESHOOTING

The device is designed with operator and patient safety as well as device long lifetime in mind. After each start of the device, the self-diagnostics of the internal circuits and functions important for safety is performed. If any unacceptable deviation occurs during the start-up the device always remains safe and the therapy tab is blocked. If this problem persists after the device restart (turn off and on again with the main switch), follow instructions in the **Chapter 7** and call service, please.

The following table serves as guidelines for solving common problems that can occur during the device operation.

Problem	**Possible reason and solution**
Device does not start.	Check power cord and power cord connector. Switch the main switch to ON position ("**I**").
Therapy tab is not available or the therapy start is blocked after the device start.	The device did not pass the self-diagnostics. Check if the applicator is connected properly and restart the unit. If this problem persists after the device restart, please follow instructions in the **Chapter 7** and call service.
Pulse Quality Monitor stopped the therapy.	Remove all metal objects around the applicator. Perform the applicator calibration (see the **Chapter 6.4.3.2**). This problem can persist if environment where the device is operated is strongly electromagnetically polluted. In such case, please change the sensitivity of Pulse Quality Monitor to *low* (see the **Chapter 6.4.3.3**).
Pulse Quality Monitor does not react to metallic object in the applicator area.	Check if the sensitivity of Pulse Quality Monitor is set to *high* (see the **Chapter 6.4.3.3**). Pulse Quality Monitor reacts only to objects, which could cause serious damage to the unit (when the energy loss or the magnetic pulse shape degradation exceed limits safe for the device).
Therapy stopped unexpectedly due to applicator or device overheating.	Ensure that all air vents of the applicator are free. Ensure that the recommended parameters of the therapy (see the **Chapter 6.5.7**) or device operating conditions (see the **Chapter 8**) are not exceeded.
Device does not turn off immediately after **on/off** button is pressed.	Applicator cooling is still running. The device will be turned off automatically when the cooling process finishes.
Error during applicator calibration.	Check if the applicator is connected properly. Remove all metal objects from around the applicator. Restart the unit and repeat the calibration (see the **Chapter 6.4.3.2**).
Applicator was disconnected from the unit in operation.	Switch the unit off and connect the applicator properly (see the **Chapter 6.1**).
Applicator was connected to the unit in operation.	Restart the unit.
Therapy cannot be started and the temperature and device's heat values on the **MANUAL** screen are flashing.	The applicator or device is overheated. Wait until the values stop flashing and try again.
Therapy cannot be started and the temperature and device's heat values on the **MANUAL** screen do not flash. Warning message about generator unavailability appears.	Device is likely to be overheated due to not respecting maximum recommended therapy parameters (see the **Chapter 6.5.7**) or operating conditions (see the **Chapter 8)** or other internal problem occurred. Switch the unit off and let it cool down for at least 30 minutes. If this problem persists after the device restart, please follow instructions in the **Chapter 7** and call service.
It is not possible to achieve the same intensity values in consecutive therapies.	Maximum intensity values may differ in consecutive therapies due to change of ambient temperature and accumulated heat in the applicator (see the **Chapter 1.5.2**).

7 MAINTENANCE

Before any maintenance switch the device off and unplug it from the mains! Observe all safety principles listed in the **Chapter 3**. 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.

7.1 FUSE REPLACEMENT

The fuses for the device are located in the black fuse housing (**Chapter 4**, ref. 11) on the rear panel of the main unit. Ensure that the type and rating of the new and the replaced fuses match (see the **Chapter 8**).

1. Turn off the device and disconnect the power cord from the unit and mains outlet.
2. Remove the fuse housing by using a screwdriver.
3. Remove the burnt fuse.
4. Insert new fuse. Make sure the fuse is properly seated within the fuse housing.
5. Connect the power cable to the unit and to the mains outlet.
6. Turn on the device.

7.2 CLEANING OF THE SURFACE OF THE DEVICE AND ACCESSORIES

The device always has to be turned off using the mains switch when cleaning. Mains power switch has to be in position **OFF** ("**0**").

For 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 cleaner directly on the screen!

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

7.3 CLEANING OF THE ACCESSORIES THAT COME INTO CONTACT WITH PATIENT

Always turn off the device before disinfecting the applicator and accessories. Disinfectant must not reach the air vents.

The applicator that comes into direct contact with patient shall be cleaned after each use with disinfectants approved for the use in health care. Do not use agents containing chlorine or those with a high alcohol content (more than 20 %). For cleaning always use soft cloth slightly moistened with disinfectant.

After disinfection, it is necessary to rinse the accessories with soft cloth slightly moistened 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 and cannot be sterilized.

7.4 TRANSPORT AND STORAGE

Store 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 the **Chapter 8.**

8 TECHNICAL PARAMETERS

Name	**BTL-6000 Super Inductive System**
Model	BTL-6000 Super Inductive System Elite
Operating conditions	
Ambient temperature	+10 °C to +30 °C
Relative humidity	30 % to 75 % (non-condensing)
Atmospheric pressure	800 hPa to 1060 hPa
Position	Vertical – on castors
Type of operation	Continuous
Transport and storage conditions	
Ambient temperature	-10 °C to +55 °C
Relative humidity	10 % to 85 % (non-condensing)
Atmospheric pressure	650 hPa to 1100 hPa
Position	Vertical
Other conditions	Transport only in the supplied packaging
Power supply	
Maximum input	1400 W
Supply voltage	100 V to 240 V AC (mains impedance max. 0.20 Ω)
Frequency	50 to 60 Hz
Protection class	II (connection to protective earth for functional reasons only)
External fuse	2x T10 AH / 250 V, 5x20 mm
Switch	On the front panel, marked **on/off**
Mains power switch	On the rear panel, positions **0** (off) and **I** (on)
Classification	
Applied parts type	BF (see the **Chapter 4.2**) / Single-patient
Class according to MDD 93/42/EEC	IIa
Essential performance according to IEC 60601-1	No essential performance
Design	
Weight	33 kg (73 lb) / 46 kg (101 lb) including package and accessories
Dimensions (w x h x d)	500 x 970 x 580 mm (20 x 38 x 23 in)
Packaging dimensions (w x h x d)	670 x 720 x 1070 mm (26 x 28 x 42 in)
Display	
Graphic colour touch screen	8.4" / 21.3 cm, 640 x 480 px.

Therapy	
Pulse type	Sine, biphasic
Magnetic field pulse width (±20 %)	280 µs
Settable intensity range (±20 %)	0.7–2.5 T, max. dB/dt 28 kT/s (intensity value on the coil surface) *
Intensity settings unit	Relative 0–100 % (therapy pulses are not generated at 0 %)
Pulse repetition rate (accuracy ±5 %)	1–150 Hz
Intensity modulations types	None, trapezoid, sine, staircase
Pulse repetition rate modulations types	None, alternating, trapezoid, sine, random

* Maximum achievable intensity of the therapy depends on the combination of therapy parameters (amplitude modulation, frequency modulation and therapy time settings) and current applicator temperature.

8.1 ELECTROMAGNETIC COMPATIBILITY (EMC)

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

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The 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.		
Emissions test	***Compliance***	***Electromagnetic environment – guidance***
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. **Warning**: The device is designed for use by medical professionals only. The device may cause radio interference or disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the device or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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 $d = 1.17\sqrt{P}$	***80 MHz to 800 MHz*** $d = 1.17\sqrt{P}$	***800 MHz to 2.5 GHz*** $d = 2.34\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1kV – for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	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	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	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	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">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><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V_{rms}
150 kHz to 80 MHz</td><td>3 V</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
$d = 1.17\sqrt{P}$
$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.34\sqrt{P}$ 800 MHz to 2.5 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 2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">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="4">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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.</td></tr>
<tr><td colspan="4">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 service department at service@btlnet.com.

CE 2460

Date of last revision: 13th April 2018

ID: 099-80MANEEN02101