BTL-6000 FSWT

USER’S MANUAL

CONTENTS

1 GENERAL INFORMATION

1.1 INTENDED PURPOSE

BTL-6000 FSWT is a non-invasive therapeutic device using acoustic waves in order to stimulate a local biological response in the treated tissue. The biological response includes a decrease in local pain sensation, muscle relaxation, an increase in blood microcirculation resulting in local metabolism enhancement and local trophic improvement. BTL-6000 FSWT also induces local neovascularization which promotes local trophical improvement.

BTL-6000 FSWT can be used for the treatment of painful conditions of the musculoskeletal system (e.g. chronic tendinopathies, insertional pain, trigger points, myofascial pain syndrome, fasciitis, chronic back pain, bursitis and other painful syndromes), degenerative and overuse conditions of the musculoskeletal system (e.g. arthrosis, arthritis, calcifications and chronic inflammations), spasticity, functional disorders of the pelvic floor region and reproductive organs (e.g. Chronic pelvic pain syndrome/chronic prostatitis, Peyronie´s disease, Erectile disorders), cellulite, open wounds, wounds with disturbed healing, burns, lesions, skin ulcers, scars and other skin disorders connected with impaired skin integrity and/or trophics and bone tissue disorders such as non-healing fractures (pseudoarthrosis).

1.2 USER PROFILE

The device shall be used by medically educated personnel. The user 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, age, weight or height of the patient in general. Nevertheless, manufacturer does not recommend the use of the device on neonates, small infants, children and patients over 65 years. The patient must not show any signs of contraindications determined for the device. The user should take into account a detailed 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 CONTRAINDICATIONS FOR FOCUSED SHOCKWAVE TREATMENT

⚠ 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.

Do not treat (or expose) patients if the following conditions are present:

- Blood disorders, coagulation problems or the use of anticoagulants
- Pregnancy
- Thrombosis
- Cancerous diseases
- Polyneuropathy
- Acute inflammation and/or infection
- Any unstable medical or psychiatric conditions

Treatment must not be applied:

- To certain tissues: The eyes and the surrounding area, the myocardium, the spinal cord, the gonads, the kidneys and the liver
- On areas of the body and organs with possible gas content
- On areas in proximity to large nerve bundles, blood vessels, head and neck
- On areas where the sterile barrier between the applicator and open wound cannot be achieved
- On body areas with sensory deficit
- On areas where any artificial implants such as cardiac pacemakers, implanted defibrillators or implanted neurostimulators are presented
- On areas in proximity to bone growth zone in children
- On areas where therapy using local corticosteroid was applied
- On areas of benign and malignant tissue growth

1.6 POSSIBLE SIDE EFFECTS OF FOCUSED SHOCKWAVE TREATMENT

- Erythema or swelling can temporarily occur in the treated area.
- Loss of bodily sensation, mild pain or itching can temporarily occur in the treated area.
- Hematoma
- Petechiae
- Skin damage after previous corticoid therapy

2 SYMBOLS AND MARKINGS

	Warning
	Caution
	Type B applied part
	Follow instructions for use (user's manual)
	Separate collection for electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
	Serial number
	Batch code
	Catalogue number
	Symbol marking a connector sensitive to electrostatic discharge (ESD)
	CE mark

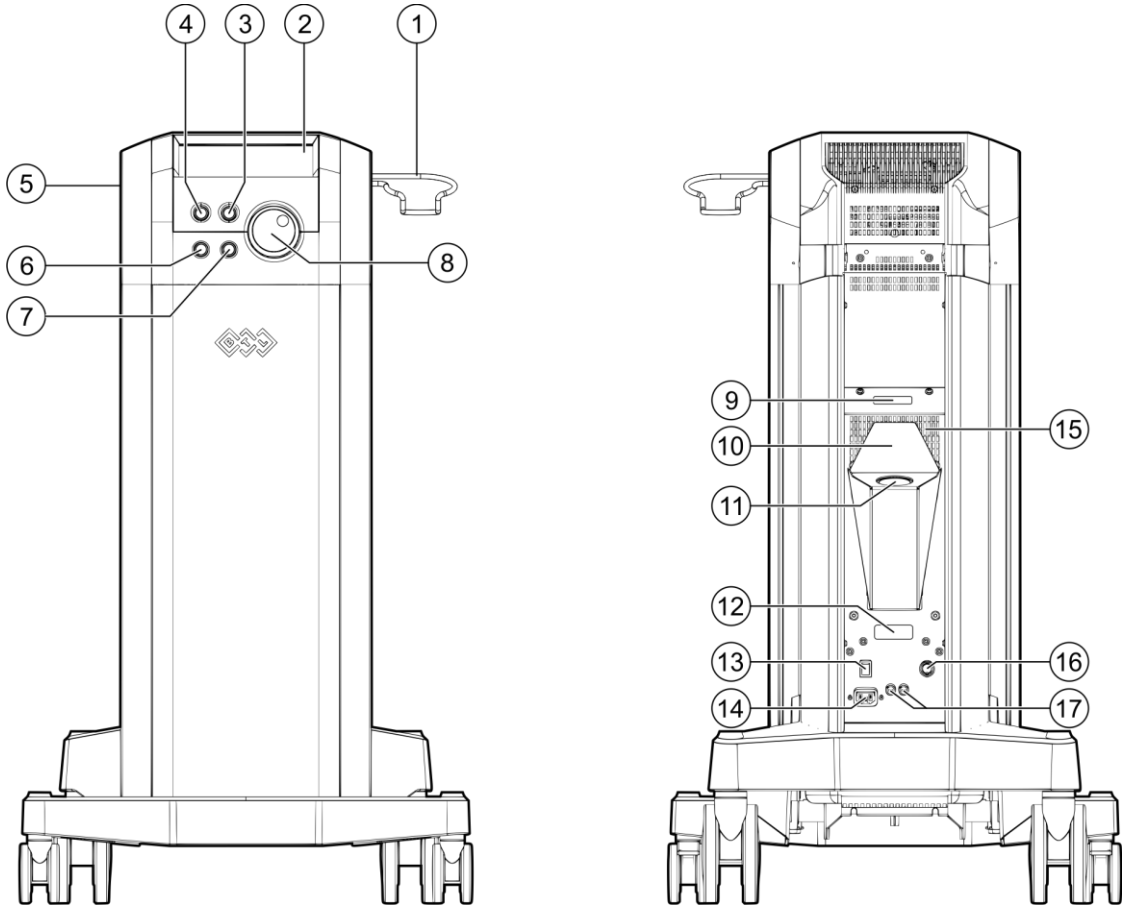
3 GENERAL SAFETY PRECAUTIONS

-  Before operating the unit, please read this User‘s Manual carefully and observe the information contained therein.
-  Do not operate near EM-sensitive interference devices. The device may be emitting EM interference during therapy.
-  The device is intended for operation in a dedicated supply system sufficiently protected by protective earth in accordance with regulations.
-  Portable and mobile high-frequency communication devices (such as mobile phones) may affect the function of the device.
-  Do not use any electrical cables which are to be connected to the device other than those approved and supplied by the manufacturer.
-  The connectors for accessories, as well as the other connectors, must not be used for connecting anything else other than what they are designed for. There is a danger of electrical shock and/or serious damage to the device.
- The device is equipped with a protection system that prevents the connection of accessories other than those supplied by the manufacturer. Consequently it will not operate with equipment from other manufacturers.
-  No modification of this equipment is allowed!
-  Do not try to open, remove protective covers, or dismantle the device for any reason. There is a danger of electrical shock and/or serious injury.
- The device does not contain any components, which can be repaired or replaced by the user. All repairs must be done by an authorized BTL service department.
-  Fuses can only be replaced by an authorized BTL service department using appropriate tools only. Only fuses mentioned in chapter 5 might be used.
-  Fuses can only be replaced while the power cord is unplugged from mains.
-  The device requires the environmental conditions that are stated in the chapter 10 TECHNICAL PARAMETERS. It must not be used in an environment where there is a danger of explosion or of water penetrating the device. The device cannot be in connection with flammable anaesthetics or oxidizing gasses (O2, N2O, etc.).
-  Do not place the device in direct sunlight or near strong electromagnetic fields 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.
-  Check whether the parameters of the main power supply correspond to the requirements of the device according to the 10 TECHNICAL PARAMETERS.
-  Never touch any part of connector on the rear panel of the device and the patient simultaneously.
-  The device must be placed out of the reach of children.

-  Place the device so that it is possible to disconnect the connector of the appliance inlet quickly and easily from the device, or the male plug of the appliance inlet from the mains.
-  Do not treat patients with contraindications.
- The device is not intended to deliver any medications, chemicals or analgesics to the patient.
- We do not recommend applying shockwave to the body parts under local anaesthesia since the effect of the therapy might be reduced.
- The device does not use any drugs, creams, gels or other substances which are an integral part or which are applied by its use.
- The device does not use or emit any toxic substances during its operation, storage or transport under the stated conditions.
-  Note that the shock waves are attenuated in the tissue and that the delivered energy might be absorbed by bone.
-  Avoid the bone in the path of the shock wave therapy unless it is for the purpose of treatment.
-  Before the start of the therapy make sure that all set parameters comply with your requirements.
- To terminate operation, do not use the mains switch! Instead, press the "start/stop".
-  Do not hold the applicator by its cable.
-  Do not disconnect an applicator during therapy.
- The time interval between turning off the mains switch and turning it back on must be at least 3 seconds.
-  Inspect the device thoroughly before each use. Look for loose cables, cracked cable insulation, cracks in the shockwave applicator's housing and functional behavioural differences in the display or the operating elements. Take extra care of the applicator cable. If any anomalies or inconsistencies are found, stop using the device and contact an authorized BTL service department. If the behaviour of the device shows any divergences from the functionality procedures described in this user's manual, stop using the device and contact an authorized BTL service department.
-  If the device shows any defects or if there are any doubts concerning its correct and safe functioning, terminate therapy immediately. If the source of the concern can be determine after a thorough study of the user's manual, then contact an authorized BTL service department immediately. If the device is not used in accordance with this manual or if it is used when the device exhibits functional differences from those stated in this manual, then BTL is not responsible for any damage to or caused by the device.
-  If it is necessary to discard the device, the lithium battery must be removed. The removed battery must be disposed according to local hazardous waste disposal requirements. Do not place the device in municipal waste containers. The device itself does not contain any toxic materials which could harm the environment when disposed of ecologically.
-  Dissipate static electricity by touching a grounded metal object before connecting or manipulating the device connected to the USB connector.

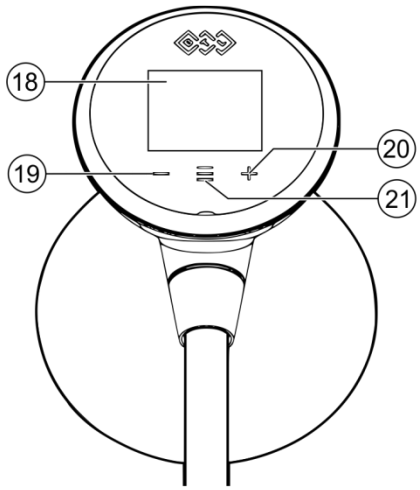
4 DEVICE AND ACCESSORIES

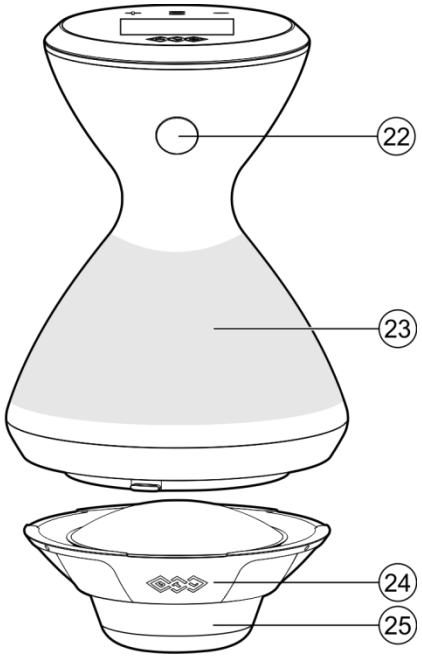
4.1 FRONT AND REAR PANEL OF THE BTL-6000 FSWT



1. holder for the applicator
2. touch screen
3. **enter** button
4. **esc** button
5. USB port – only for sevice pusposes. USB port in the space of the device's grip for use only in compliance with IEC 60950-1
6. **on/off** switch (lights up blue when "on" / lights up orange when "off")
7. **start/stop** button (to start and stop therapy)
8. **select** knob (to select individual parameters)
9. serial number
10. connector cover
11. connector for applicator
12. type label
13. mains switch
14. appliance inlet
15. ventilation
16. connector for foot switch
17. fuseholders

4.2 APPLICATOR FOR BTL-6000 FSWT





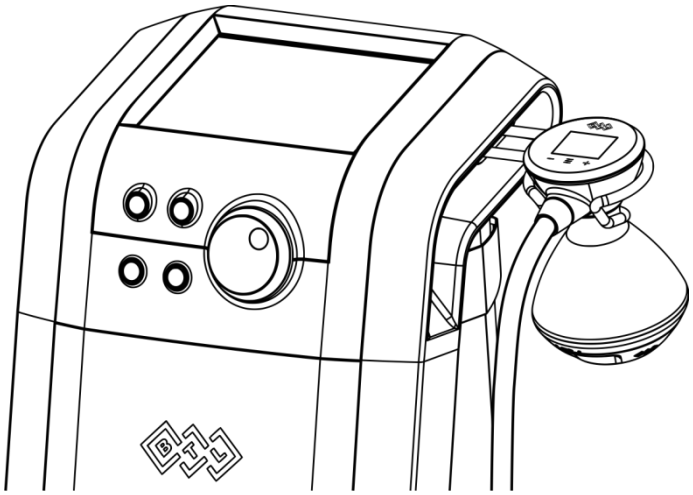
18. display of the applicator
19. button to decrease the value of the selected parameter
20. button to increase the value of the selected parameter
21. button to switch between parameters
22. start/stop button of the applicator
23. holding part of the applicator
24. lock ring
25. coupling pad (applied part type B)

4.2.1 COUPLING PAD VARIATIONS

	Coupling pad size **S**
	Coupling pad size **M**
	Coupling pad size **L**
	Coupling pad **U-shaped**

4.2.2 APPLICATOR'S POSITION IN THE HOLDER

The picture below shows the correct position of the applicator in its holder. It is also possible to put the applicator with its display pointing downwards for easier manipulation with the coupling pads and coupling gel when preparing for the therapy.



5 LIST OF STANDARD AND OPTIONAL ACCESSORIES

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

Standard accessories:

- 1x focused shockwave applicator (cable length 1,8m)
- set of different size coupling pads (S, M, L)
- 1x applicator holder
- 1x gel 1000 ml
- 1x power cord (cable length 3m)
- 2xT2.5AH/250V, tube safety fuse 5 x 20 mm
- 1x user's manual

Optional accessories:

- gel 1000 ml
- foot switch (cable length 2m)
- U-shaped coupling pad

6 DEVICE INSTALLATION

Inspect the box for damage and report any damage to the transport carrier and the distributor. Do not proceed with assembly and set-up if the box is damaged. Keep the original box and packaging to ensure safe future transport of the device.

⚠ When bringing the device from a cold environment into a warm one, do not plug it into the power source until the device has had time to equilibrate to room temperature (minimum 2 hours).

Unpack the device and place it on a stable horizontal surface which is suitable for its weight. Always position the device out of direct sunlight. During operation, the control unit gets warm, so it must not be positioned near direct heat sources. The device is self-cooled by forced air circulation. The cooling vents are located on the rear panel and on the bottom.

⚠ Do not cover or block vents. Allow a minimum of 4 inches (10cm) clearance behind the rear panel. Make sure the connector cover is moving freely (see **Chapter 4.1**).
Do not put any heat-producing devices or any objects containing water or other liquids on the device.
Do not place the device close to appliances producing strong electromagnetic, electric or magnetic field (diathermy, X-rays, etc.), otherwise it could be undesirably influenced.

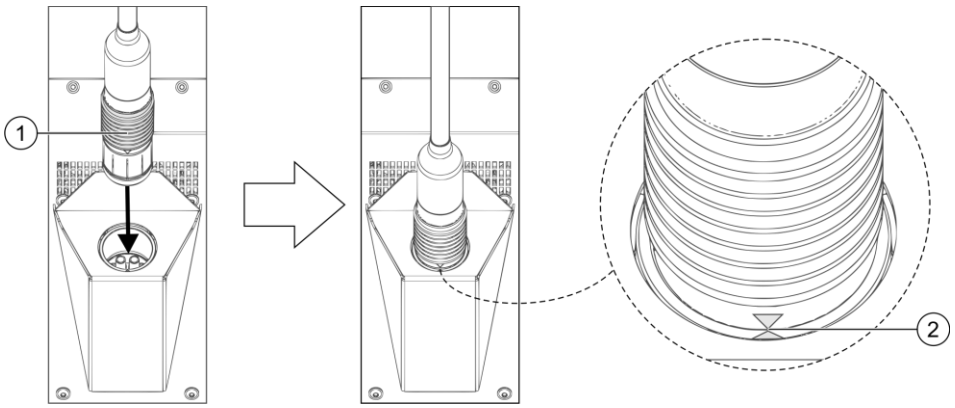
In the event of any questions, please contact an authorized service of BTL devices.

Set-up Procedure:

1. First connect the device in mains by means of the supplied power supply adapter, which you will connect to the connector on the rear panel of the device and to a 100 V or 240 V mains socket. The device detects the voltage automatically.

   Plug the device directly into the mains socket. Do not use any multi-connection extension cables or two-socket adaptors.

2. Connect the applicator to the connector on the rear panel as follows:



3. Hold the intended part of the applicator connector's end (number 1 on the picture above) and plug it into the applicator connector
4. Make sure the arrows on the applicator connector's end and applicator connector (number 2 on the picture above) are pointing against each other and also that they are touching.
5. When disconnecting the connector take the intended part of the applicator connector's end in your hand and pull slowly towards you to disconnect the connector carefully. Before disconnecting the connector make sure the device is switched off by mains switch on the rear panel of the device and the power cord is unplugged from the mains.

⚠ **CAUTION! DO NOT TURN THE ENTIRE CONNECTED CONNECTOR BY FORCE; OTHERWISE THERE IS A RISK OF DAMAGE TO THE DEVICE!**

The device detects the accessory, specifies its type and displays it on the screen in the appropriate tab. If you connect an improper accessory by mistake, the display shows a message with a help where to connect the given accessory.

6. Plug in the footswitch into its connector (see **Chapter 4.1**). If you want to unplug the footswitch make sure the device is switched off by mains switch on the rear panel of the device and the power cord is unplugged from the mains.
7. Then switch on the power on/off switch on the rear panel of the device.
8. Press the **on/off** switch located on the front panel of the device.
9. Perform functional check of device (see **Chapter 8**).

Note:
After switching the device on, the device will run a self-diagnostic of its internal circuits and its functions for about 10 to 15 seconds. If any fault is detected, the screen will display a warning message. If necessary; the control unit will lock itself into a “secure” mode. If this situation occurs, please contact authorized BTL service department.

7 BASIC DEVICE OPERATION

7.1 DEVICE STARTUP / SHUTDOWN

1. Plug the power cord (supplied with the device) in the connector of the device and in the mains. Plug the device directly in the mains; do not use extension cords with multiple sockets or multi-socket adaptors.
2. Switch the mains switch on the rear panel to position "**I**".
3. Press the **on/off** button on the front panel.
4. Turn off the device by pressing the **on/off** button**.**

7.2 NAVIGATION CONTROLS

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

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

7.3 DEVICE MENU

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

- user settings / database
- unit settings
- specific settings

7.3.1 USER SETTINGS / DATABASE

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

- clients
- user therapeutic protocols
- recent therapies

7.3.1.1 Clients

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

7.3.1.2 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.

7.3.1.3 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.

7.3.2 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

7.3.2.1 Language

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

7.3.2.2 Date & Time

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

7.3.2.3 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.

7.3.2.4 Colour Schemes

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

7.3.2.5 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.

7.3.2.6 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.

7.3.2.7 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.

7.3.2.8 Accessories Information

This option displays information about the connected accessories.

7.3.2.9 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 preset protocols or programs)
- **LIST** screen mode (displaying of list of preset protocols)

- user accounts
- touch panel calibration
- display contrast
- buttons backlight
- service functions
- dialog history
- setting of HW key
- unlock code

7.3.3 SPECIFIC SETTINGS

7.3.3.1 QUICK Screen preset protocols

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

7.3.3.2 Counters

This option enables the user to monitor the total shock count on the device and the applicator, respectively.

7.3.3.3 Shock quality test

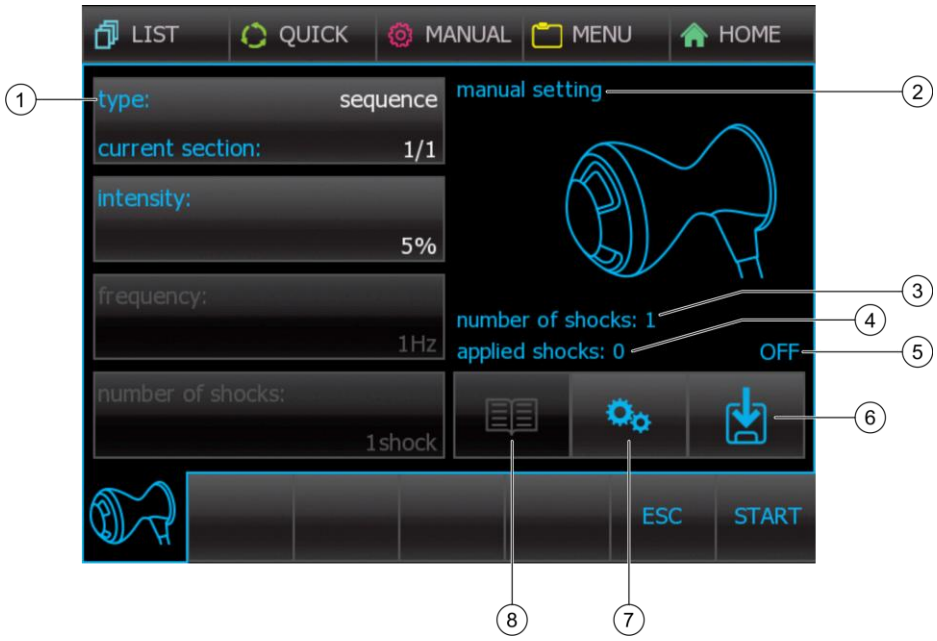
This option enables the user to make sure the device is functioning properly within the full range of its intensity and frequency.

7.4 SETTING THE THERAPY

7.4.1 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.

In MANUAL settings you can choose from two different therapy types (see **Chapter 7.4.1.1**)



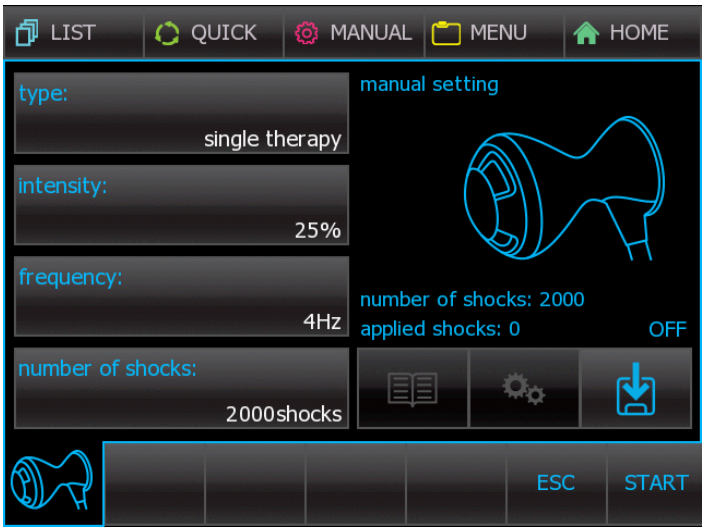
1. Type button for switching between sequence and single therapy mode
2. Manual Setting - allows the user to distinguish between preset protocols or manual settings
3. Number of shocks - allows the user to see the preset amount of shocks
4. Applied shocks - allows the user to see the amount of applied shocks
5. ON/OFF/READY/PAUSE button - allows the user to see if the therapy is on, off, ready or paused
6. Save button allows the user to save the current therapy setting. The therapy is saved as user-defined therapeutic protocol and can be assigned to a specific client.
7. Edit button on this screen allows the user to edit the sequence therapy parameters. When pressed the screen with advanced therapy parameters will be displayed.
8. Detailed information about protocols. Enabled only in preset protocol mode

7.4.1.1 Therapy Types

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

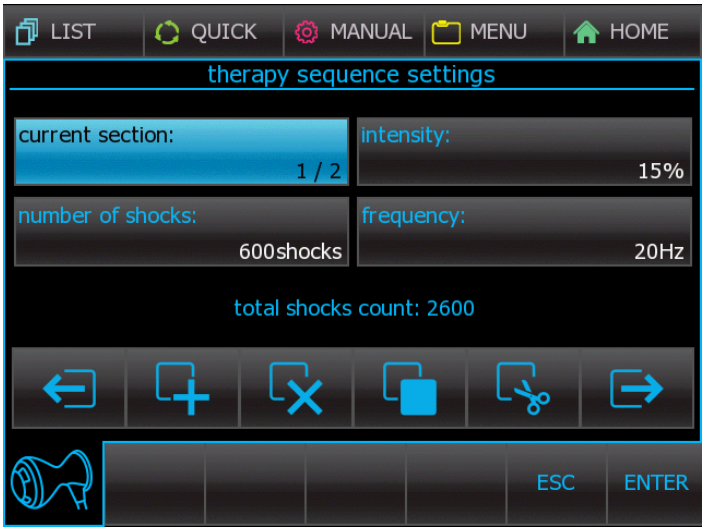
Single therapy mode

This mode enables the user to create single section therapy consisting of adjustable intensity, frequency and number of shocks. In this mode all parameters are adjustable even during running therapy.



Sequence mode

After pressing **edit button** (see **Chapter 7.4.1**) the therapy sequence settings will be displayed. The sequence mode enables creating therapy sequence by setting intensity, frequency and number of shocks of each section in the sequence. The sequence can consist of up to 99 sections. During running therapy intensity is adjustable.



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.
number of shocks	Sets the number of shocks of the current section
intensity	Sets the initial intensity of shocks of the current section
frequency	Sets the frequency of shocks of the current section

7.4.2 SETTING THE NUMBER OF SHOCKS

The total number of shocks for a therapy can be set on screen of the therapy parameters, even during the course of therapy if using single therapy mode. The number can be set either by pressing the button labeled **number of shocks**, or for quick selection, turn the **select** knob.

7.4.3 SETTING THE INTENSITY

The intensity (power) of the focused shockwave therapy can be set on the therapy parameters screen, even during the course of therapy. After pressing the intensity button it is possible to set the intensity either by means of the numeric keypad (see **Chapter 7.4.5**), present values written on the buttons, by the select knob or through the display of the applicator. During application of shocks, the intensity value can only be changed by means of the select knob or through the display of the applicator.

7.4.4 SETTING THE FREQUENCY

BTL-6000 FSWT supports range of different frequencies which can be set by pressing the **frequency** button. After pressing the frequency button it is possible to set the frequency either by means of the numeric keypad (see **Chapter 7.4.5**), present values written on the buttons, by the select knob or through the display of the applicator. For relation between maximal frequency and intensity, see the table below.

Frequency [Hz]	Max Intensity [%]
1 – 10	100
11 - 25	95 - 30

7.4.5 NUMERIC KEYPAD

In addition to setting the numerical values with the **select** knob on all the screens, the "numeric keypad" can be use for the faster or more precise setting of values.

This is the icon for the opening of the numeric keyboard window: 

To use the numeric keypad window press twice the parameter that you wish to adjust. Numeric keypad icon will appear at the upper left corner of the table. Press the numeric keyboard icon and set the required values. Return to the previous screen by pressing the **enter** button. If you do not want to enter any values or change the selected parameter, exit the window with the numeric keypad by pressing the **esc** button.

7.4.6 SETTING THE THERAPY BY SELECTING A PRESET PROTOCOL– LIST SCREEN

The list of all preset protocols is displayed after the **LIST** button is pressed. User protocols saved in the list of preset 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 preset protocol is loaded, the device displays the therapy parameters screen, 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.

Preset protocols

After the required preset protocol is selected, it is possible to view the detailed protocol information by pressing the button with the preset protocols symbol on the therapy parameters screen.

7.4.7 QUICK PRESET PROTOCOL SELECTION – QUICK SCREEN

After the **QUICK** button on the navigation toolbar is pressed, the device displays the preset 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 preset 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 preset protocols on **QUICK** screen, it is possible to find detailed information about the selected protocol by pressing the preset protocols button.

Additionally to the **QUICK** screen and the preset 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 preset protocols. To set the program number, press the required element on the touch screen and then use the **select** knob or the numerical keyboard.

7.5 APPLICATOR SETTINGS

The applicator of BTL-6000 FSWT is equipped with a display which serves as a tool for parameters checking and adjusting. Icons shown on the display represent the intensity, frequency and amount of remaining shocks of the current therapy.

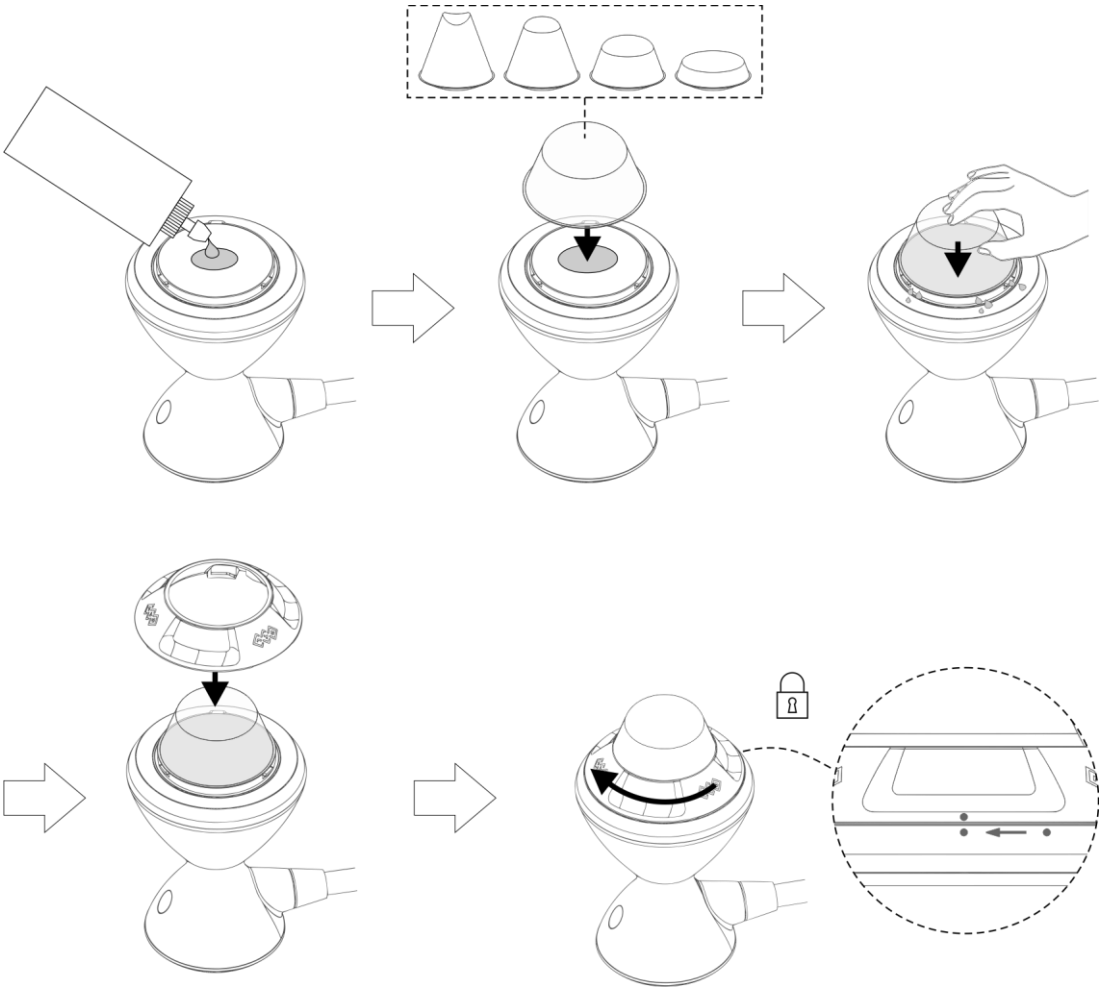
	Intensity icon
	Frequency icon
	Number of shocks icon
	Button to decrease the value of the selected parameter
	Button to switch between parameters
	Button to increase the value of the selected parameter

7.6 COURSE OF THERAPY

7.6.1 PREPARING THE APPLICATOR

Before you start the therapy choose optimal coupling pad size depending on the required penetration depth of the focused point (For information about penetration depth of the focused point of individual coupling pads see **Chapter 10.1.**). Apply a sufficient amount of contact gel between the surface of the applicator and the coupling pad and push out slightly on the coupling pad to avoid any air bubbles. If the air bubbles are still presented the additional amount of contact gel might be applied. Then put the lock ring on and twist clockwise to lock the coupling pad in position as shown on the picture below.

⚠ Use only the gel supplied by the manufacturer



7.6.2 START, INTERRUPTION AND END OF THERAPY

To start the therapy after selecting one of the preset 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. Once the **start** button on the touch screen or **start/stop** button on the front panel is pressed, the device is ready to start delivering shocks. Press the button on the applicator or foot switch and shocks will start to be delivered from the applicator. Be sure to do so before placing the applicator on to the treated area.

⚠ Always start the therapy with lowest intensity and increase it gradually based on the patient perception.

⚠ Delivering of shocks to the patient is conditioned by the permanent and sufficient contact of the active part of the applicator (coupling pad) and the treated area.

⚠ For immediate interruption of the shock therapy, remove the applicator from the treated area.

To interrupt therapy, it is also possible to press the **pause** button on the screen or the **start/stop** button on the panel of the device. Therapy can also be paused by pressing the button on the applicator or the foot switch. To resume the interrupted – paused – therapy press the **start/stop** button on the panel again or press the button on the applicator or foot switch. To stop, press **esc.**

7.6.3 SCREEN DURING THERAPY

Screen during the single therapy mode

During single therapy mode it is possible to adjust intensity, frequency and amount of remaining shocks even while the therapy is running.

Screen during the sequence therapy mode

During sequence therapy mode it is possible to adjust intensity even while the therapy is running

7.7 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 **Chapter 7.4.1**). During the protocol saving, the following data must be inserted: name of the protocol (will be displayed in the list of user protocol 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).*

8 MAINTENANCE

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

⚠ Do not use the device if it is damaged! Before each use, check that the device and its accessories (especially cables) are not mechanically or otherwise damaged. Do not immerse it in any liquid.To keep the device clean, do not store or use it in extremely dusty environment for a long time.

Exterior cleaning of the device:

Use a soft cloth slightly moistened with water or with a 2% detergent solution to clean the exterior of the BTL-6000 FSWT device and its parts. Never use cleaning agents containing alcohol, ammonia, benzine, thinners, etc. Never use abrasive cleaning materials which will scratch the device's surfaces. No parts of the device require sterilization. Care should be given to prevent water or other liquids from getting inside the device.

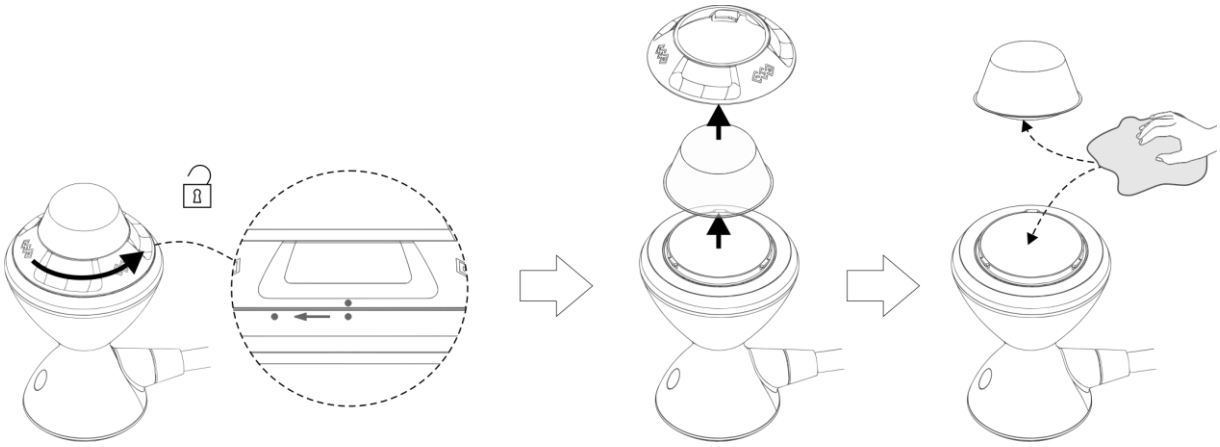
Cleaning and maintenance of accessories which come into contact with the patient:

Clean and disinfect after each client using approved cleaning agents. For example, Sekusept, Bacilol, and Incidur Spray can be used. For the cables of accessories, use Incidur Spray and the alike. DO NOT USE SOLVENTS!!!

Cleaning of the applicator

After each therapy remove the coupling pad and clean it, also clean the bottom surface of the applicator of contact gel using a damp soft cloth.

To remove the coupling pad turn the lock ring counterclockwise as shown on the picture below:



Plugging the device into an electrical outlet:

The device is equipped with automatic voltage detection, so it can be used for voltages within the 100-240V.

Functional check:

Inspect the main unit and applicator for damage. Take a closer look for loose cables, cracked cable insulation, cracks in the shockwave applicator's housing.

Start the device.

Perform **Shock quality test.** Press the "Shock quality test" button in the specific settings menu (see **Chapter 7.3.3.3**) and follow the instructions on the display. You can perform the "Shock quality test" either with or without the coupling pad being attached to the applicator.

The device will automatically and periodically remind the user to perform the test.

⚠ Do not touch the active area of applicator or attached coupling pad during Shock quality test.

Check that testing shocks are successfully counted.

If necessary, the proper function of the applicator can be checked by a color sensitive pressure sensor. For detailed information contact an authorized BTL service.

Transport and Storage:

Keep the shipping container and all packaging materials. Transport the unit in original box to ensure maximum protection. Unplug the main power cord and all accessory cables. Take care to avoid shocks or jarring movements to the device during transport. This device should only be transported and stored under the conditions defined in the chapter 10 TECHNICAL PARAMETERS.

9 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 8** 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**").
Applicator was disconnected from the unit in operation.	Switch the unit off and connect the applicator properly
Applicator was connected to the unit in operation.	Restart the unit.
The patient has no sensation during the therapy.	Make sure you applied a sufficient amount of contact gel between the surface of the applicator and the coupling pad (see **Chapter 7.6.1**). Make sure there are no bubbles between the surface of the applicator and the coupling pad (see **Chapter 7.6.1**).

10 TECHNICAL PARAMETERS

Name	**BTL-6000 FSWT**
Operating conditions	
Ambient temperature	+10 °C to +35 °C
Relative humidity	30 % to 75 % (non-condenzing)
Atmospheric pressure	700 hPa to 1060 hPa
Position	Vertical on castors
Type of operation	Permanent
Transport and storage conditions	
Ambient temperature	-10 °C to +55 °C
Relative humidity	10 % to 85 % (non-condenzing)
Atmospheric pressure	650 hPa to 1100 hPa
Position of the unit	Vertical
Additional conditions	Transport only in the original container
Power supply	
Maximum input	150 VA
Mains voltage	100 V to 240 V AC
Mains Frequency	50 to 60 Hz
Equipment protection class	I (in accordance IEC60601-1)
External exchangeable fuses	2xT2.5AH/250V, tube safety fuse 5 x 20 mm, in accordance with IEC 60127-1
Power switch	On the front of device, button labeled on / off
Mains switch	On back of device, positions 0 (off) / 1 (on)
Design	
Weight main unit	Max. 30 kg
Weight applicator	Max. 880 g excluding cable and coupling pad
Main unit dimensions (w x h x d)	580 x 980 x 550 mm
Applicator dimensions (w x h x d)	120 x 145 x 120 mm
Main unit and applicator IP code	IP 20
Foot switch IP code	IPX5
Display elements	
Graphic colour touch screen	Diag. 8,4" / 21.5 cm, resolution 640 x 480 pixels
Indicators	1x orange, 4x blue
Classification	
Applied part type	B
Class according to MDD 93/42/EEC	IIb
Adjustable values	
Shock intensity	5 to 100%
Shock frequency	1 to 25 Hz
Number of shocks	0 – 9999 shocks
Increments of adjustable values	
Intensity	1%
Frequency	1 Hz
Total number of shocks per therapy	100 shocks

Essential performanceIEC

The BTL-6000 FSWT has essential performance according to IEC 60601-1.
The device shall not display intensity levels improperly.
The device shall not accidentaly emit shock wave energy to the patient.

10.1 OUTPUT PARAMETERS

Focal location with coupling pad S

Focus size *4)*	5 mm x 5 mm x 35 mm
Focal point depth	45 mm
Depth of focal zone *3)*	min. 30 - 65 mm

Focal location with coupling pad M

Focus size *4)*	5 mm x 5 mm x 35 mm
Focal point depth	30 mm
Depth of focal zone *3)*	min. 15 - 50 mm

Focal location with coupling pad L

Focus size *4)*	5 mm x 5 mm x 35 mm
Focal point depth	15 mm
Depth of focal zone *3)*	min. 0 - 35 mm

Focal location with coupling pad U-shaped

Focus size *4)*	5 mm x 5 mm x 35 mm
Focal point depth	15 mm
Depth of focal zone *3)*	min. 0 - 35 mm

General output parameters

Energy setting (%)	**5**	**50**	**100**
Peak positive acoustic pressure in focal point (MPa)	3	25	65
Peak negative acoustic pressure in focal point (MPa)	3	7	15
Derived acoustic pulse energy (mJ) *1)*	0.1	1.8	8.3
Derived acoustic pulse intensity integral (mJ/ mm^2) *2)*	0.01	0.12	0.65
Focal radius (mm) *3)*	6.4	5.5	2.9
Focal extent (mm) *3)*	50	42	35

1) Integration limits – Total pulse duration, radius 5 mm
2) Integration limits – Total pulse duration, focal radius (-6dB)
3) -6dB peak positive acoustic pressure contours
4) Approximatelly values

10.2 EMC INFORMATION

Medical electrical equipment should be used with precautions according to EMC standards and must be installed according to the EMC notices disclosed in this manual as mobile RF transceivers could adversely affect it.

Directive and declaration of manufacturer – Electromagnetic Emission		
BTL-6000 FSWT is suitable for use in the specified electromagnetic environment. The user of BTL-6000 FSWT should assure that it is used in an electromagnetic environment as described below		
Emission test	***Compliance***	***Electromagnetic Environment***
Radiated and conducted RF emission CISPR 11	Group 1	The BTL-6000 FSWT 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.
Radiated and conducted RF emission CISPR 11	Class A	The BTL-6000 SWT 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 emission IEC61000-3-2	Class A	
Voltage fluctuations / Flickers IEC61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the BTL-6000 FSWT				
The BTL-6000 FSWT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BTL-6000 FSWT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BTL-6000 FSWT as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter [W]	***Separation distance according to frequency of transmitter [m]***			
	150 kHz – 80 MHz $d = [3.5/V_1]\sqrt{P}$	***150 kHz – 80 MHz*** $d = [3.5/V_1]\sqrt{P}$ ***– ISM bands***	***80 MHz – 800 MHz*** $d = [3.5/E_1]\sqrt{P}$	***800 MHz – 2.5 GHz*** $d = [7/E_1]\sqrt{P}$
0.01	0.12	0.06	0.12	0.23
0.1	0.38	0.18	0.38	0.73
1	1.2	0.58	1.2	2.3
10	3.8	1.88	3.8	7.3
100	12	5.83	12	23
For transmitters at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable for the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: In case of a frequency of 80 MHz or 800 MHz, the formula for higher frequency range is applicable. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

Directive and declaration of manufacturer – Electromagnetic immunity			
BTL-6000 FSWT is suitable for use in the specified electromagnetic environment. The purchaser or user BTL-6000 FSWT should assure that it is used in an electromagnetic environment as described below.			
Immunity test	***IEC60601 test level***	***Compliance level***	***Electromagnetic environment***
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors are wood, concrete or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV/100kHz for power supply lines	±2 kV/100kHz for power supply lines	Mains power quality is that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 KV differential mode ±2 KV common mode	±1 KV differential mode ±2 KV common mode	Mains power quality is that of a typical commercial and/or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/or hospital environment.

Directive and declaration of manufacturer – Electromagnetic immunity			
BTL-6000 SWT is suitable for use in the specified electromagnetic environment. The purchaser or user of BTL-6000 SWT should assure that it is used in an electromagnetic environment as described below.			
Immunity test	***IEC60601 test level***	***Compliance level***	***Electromagnetic environment***
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T in 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% U_T in 1 cycle; 70% U_T in 25/30 cycles at 0°; 0 % U_T in 250/300 cycle	According to test level	Mains power quality is that of a typical commercial and/or hospital environment. If the user of BTL-6000 FSWT requires CLINICAL UTILITY during power mains interruptions, it is recommended that parts of the BTL-6000 FSWT system where applicable be powered from an uninterruptible power supply.
Conducted RF IEC 61000-4-6	3 V_{eff} in 150 KHz – 80 MHz 6 V_{eff} in ISM bands 150 KHz – 80 MHz	3 V 6 V in ISM	Portable and mobile RF communications equipment are used no closer to any part of BTL-6000 FSWT, including cables, than the Recommended Separation Distance calculated the formula written below.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1kHz Including Tab.9. from IEC 60601-1- 2:2014	3 V/m	**Recommended Separation distance:** $d=[3.5/V_1]\sqrt{P}$ $d=[3.5/3\ V/m]\sqrt{P}$; (80 MHz – 800 MHz) $d=[7/3\ V/m]\sqrt{P}$; (800 MHz – 2.7 GHz) where: P is the highest radiated power disclosed by the manufacturer of transmitter [W]; d is the recommended separation distance [m]. WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BTL-6000 FSWT,including cables specified by the manufacturer.
1. Note: U_T is the nominal voltage of mains.			
2. Note: These are guidelines. Actual conditions may vary.			
3. Note: At 80MHz or 800 MHz, the formula for the higher range is applicable.			

10.3 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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