

BTL-6000 SWT EASY

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.

Please visit our corporate website at <u>http://www.btlnet.com</u> for the latest information on BTL products and services.

Again, thank you for being a BTL customer.

BTL Industries, Ltd.

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1 GENERAL CHARACTERISTICS OF THE DEVICE

The BTL-6000 SWT Easy is a state-of-the-art device allowing the application of therapy using non-invasive shockwaves. Shockwaves are one of the most effective ways to treat pain associated with the musculoskeletal system. Musculoskeletal pain is currently the second-leading cause of absences in the workplace.

The device consists of two parts:

- Main Unit contains the main microcomputer and software for controlling the entire system
- Applicator this ergonomically designed applicator will simplify the course of therapy

1.1 SHOCKWAVE AND ITS CHARACTER

A shockwave is defined as a wave with a rapid increase of pressure within a very short time and then having a gradual decrease of pressure with a small negative pressure phase.

Shockwaves are aimed at the affected areas that are the source of chronic pain. The influence of the shockwaves causes to the dissolution of calcium deposits and leads to better vascularization. The after-effect is relief from the pain.

Outside of the client's body (extra-corporeally), a pressure pulse of high amplitude is generated and its energy is concentrated on the target area. The pressure pulse travels through a liquid medium gel into the client's body and penetrates soft tissue without major energy loss.

The pressure course of the shockwave in real-time in expressively different from the pressure course of the harmonic sound wave. Shockwaves can be compared to ultrasonic waves which are particularly characterized by a pressure jump change, a higher amplitude and non-periodicity.

In the shockwave, the positive amplitude is generally much larger than the negative amplitude. The frequency rate of the shockwaves is usually low (in Hz units) and the eventual cavitation (the disturbance of material consistency and the development of cavities) will relax. Consequently, there is no threat of energy absorption in the cavitations as is the case with continuous ultrasound.

A substantial part of the shockwave energy penetrates into the liquid (of the organism) with a great positive pressure pulse. Its diffusion is only limited by the actual tissue absorption and eventual reflections on acoustic non-homogeneities.

1.2 SHOCKWAVE GENERATION

Several types of generators have been developed for shockwave therapy, each producing shockwaves with varied characteristics. Each type of generation method induces shockwaves with different time progressions and spatial arrangements.

The BTL-6000 SWT Easy uses the ballistic principle of shockwave generation.

1.2.1 BALLISTIC PRINCIPLE OF SHOCKWAVE GENERATION

A pressure wave is formed via a projectile by using accelerated compressed air. The compressed air is generated by an electronically-controlled ballistic pressure compressor. Using elastic impact, the kinetic energy of the projectile is transferred into the probe of the applicator and then into the client's body. Consequently, during the treatment, the end of the applicator must be in direct contact with the skin and subcutaneous tissue.



1.3 INTENDED USE

BTL-6000 SWT is non-invasive therapeutic device intended to be used in case of musculoskeletal system disorders. Application of shockwave energy into the tissue decreases pain sensations and supports local microcirculation what results in local metabolism enhancement. The BTL-6000 SWT uses the ballistic principle of the shockwave generation. The shock wave is formed via a projectile by accelerated compressed air, which is generated by an electronically controlled aircompressor. The kinetic energy of the projectile is transferred into a probe of the applicator and subsequently into the client's body. During the treatment the ending part of the applicator must be in immediate contact with the skin and subcutaneous tissue.

1.4 POSSIBLE SIDE EFFECTS OF SHOCKWAVE TREATMENT

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

1.5 CONTRA-INDICATIONS FOR SHOCKWAVE TREATMENT

- Application to certain tissues: The eyes and the surrounding area, the myocardium, the spinal cord, the gonads, the kidneys and the liver
- Blood disorders, coagulation problems or the use of anticoagulants
- Blood thinning medications (Warfarinization)
- Pregnancy
- Thrombosis
- Tumor diseases
- Polyneuropathy
- Acute inflammation
- Application in proximity to bone growth zone in children
- Therapy using local corticosteroid application in therapy area
- Inapplicable on areas of the body and organs with possible gas content
- Inapplicable on areas in proximity to large nerve bundles, blood vessels, the spinal cord and the head



2 INSTRUCTIONS FOR OPERATION

2.1 THE FRONT PANEL OF THE BTL-6000 SWT EASY



- 1. control panel
- 2. select knob (to select individual parameters)
- 3. **enter** button
- 4. esc button
- 5. **start/stop** button (to start and stop therapy)
- 6. **on/off** switch (back lit, in blue, when the control unit is "on")

2.2 APPLICATOR FOR BTL-6000 SWT EASY



- 8. hand rest of the applicator
- 9. shock transmitter of the applicator
- 10. shock transmitter screw cap of the applicator
- 11. connector of the applicator
- 12. guide mark of the connector
- 13. applicator button: to start therapy



2.3 THE REAR PANEL OF THE BTL-6000 SWT EASY



- 14. connector for shockwave applicator
- 15. fuse of control unit
- 16. connector for power cable
- 17. power on/off switch
- 18. vessel for collecting condensed water
- 19. type label contains type of the device, manufacturer and safety and warning signs
- 20. venting grid



2.4 ASSEMBLY AND SET-UP

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 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 these vents. Allow a minimum of 4 inches (10 cm) clearance behind the rear panel. Do not place the device on a soft surface (such as a towel) which may obstruct air flow to the bottom cooling vents. 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.

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 - 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:

Turn the applicator so that the red dot on its end is in straight line with the red dot on the output connector and only then plug the connector in.

When disconnecting the connector take the indented part of the applicator connector's end in your fingers and pull slowly towards you to disconnect the connector carefully.

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

- 3. Then switch on the power on/off switch on the rear panel of the device.
- 4. Press the on/off switch located on the front panel of the device.

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 control unit will lock itself into a "secure" mode. If this situation occurs, please contact your authorized BTL distributor.



2.5 BASIC OPERATION

After turning the device on using the **on/off** button (6) on the front panel, the control panel will light up.



2.5.1 CONTROLS FOR SETTING FREQUENCY, NUMBER OF SHOCKS, PRESSURE

Frequency, number of shocks and pressure can be set in two ways.

First, press the button of the desired function (after selecting the therapy program) and when the currently set value begins to blink, the function is active for modification.

Then, either:

- 1. Use the "select" knob: Turn it to the right to increase the value and to the left to decrease the value.
- or
- 1. Press the respective button again to change the set value as follows:
 - Frequency: The frequency will increase by 1 Hz.
 - Number of Shocks: The number will increase by 500 shocks
 - Pressure: The pressure will increase by 0.5 bar

After the user has finished making the changes, the function will be active and blinking for five (5) more seconds. When the blinking stops, the changes are entered.

Whenever setting therapy, first select the program and only then set the values of **frequency**, **number of shock** and **pressure**. The changed values can be saved in the device's temporary memory by quickly pressing the **enter** button or by clicking on the button of another function. These values are saved only temporarily for the therapy you are currently preparing; after the change of the therapy program or switch-off of the device there are again loaded the values saved in the permanent memory for the given program.

After the device is turned off and then turned back on, the control panel will display the last active therapy used with the permanent memory saved values.



2.5.2 CONTROLS FOR SETTING PROGRAM AND MODE

The settings for **program** and **mode** can be changed by pressing the respective button the corresponding number of times until the desired indicator lights up.

2.6 SETTING OPTIONS

2.6.1 PROGRAM

The device contains 8 pre-set programs/therapies:

program	frequency	number of shocks	pressure Bar
manual	8 Hz	1500	1.9
calcar calcanei, plantar fasciitis	10 Hz	2000	2.5
pain in the groin / hip area	10 Hz	2000	2.5
patellar tendinopathy	10 Hz	2000	2.0
achillodynia	10 Hz	2000	2.0
epicondylitis	10 Hz	2000	2.0
painful shoulder	10 Hz	2000	3.0
trigger points	10 Hz	2000	2.0

2.6.2 FREQUENCY

Setting of the frequency of the applicator pulse in Hz.

10 Hz is set by default for each therapy. The maximum settable value of frequency is 15 Hz.

2.6.3 NUMBER OF SHOCKS

It is possible to set 9,999 shocks. For continuous therapy turn the **select** knob to the left. Setting of continuous therapy is indicated by four dashes on the display:



2.6.4 PRESSURE BAR

This function displays the value of pressure. Each program has another preset value of pressure - see Chapter **Program**. The maximum settable value is 4 bar.

Caution!

Always set pressure according to the physician's recommendations and the patient's feeling. The therapy should not cause unpleasant sensation to the patient; that is why the pressure can be modified even during the procedure!



2.6.5 MODE

Setting of the way of control of the start button on the applicator.

continual

First pressing of the button to start the shockwave; second pressing of the button to stop the shockwave.

single

Each pressing of the button makes one shock.

2.7 START, PROGRESS AND END OF THERAPY

After setting of the therapy parameters according to your requirements, press the **start/stop** button on the front panel of the device and then the button on the applicator to start therapy. Depending on your selected mode for the applicator button (continual or single) you can control the progress of the shockwave.

By default, the therapy ends after completion of the set number of shocks; to stop the therapy immediately, press **start/stop**.

To interrupt the therapy, release the button on the applicator (in the single mode) or press it (in the continual mode). To resume the interrupted therapy, press the button on the applicator and hold it pressed (in the single mode) or just press the button again (in the continual mode).

During therapy you can modify the values of pressure, frequency and, if pulses are not being generated, the number of pulses.

2.7.1 APPLICATION OF SHOCKWAVES

Application of shockwaves is provided via a spring-loaded applicator, which:

- Provides proper and exactly specified contact of the applicator with the treated tissue during therapy.
- Minimizes the transmission of reverse shocks to the hand of the therapist due to the built-in air damper.

An integral part of the applicator is the ergonomic hand rest which provides a comfortable grip and prevents unwanted slippage of the hand during therapy. The ergonomic hand rest swivels and can be set into the desired position at any time.

The ergonomically-shaped handle allows the therapist to grip the applicator comfortably in various different positions. The orientation can be varied according to the type of applied therapy and the personal preferences of the therapist whether they are left-handed/right-handed or male/female.

The ergonomic shape of the handle offers the therapist sufficient support during the application. This reduces the tiring of the therapist hands during the course of therapy.



Examples of how to hold the shockwave applicator

These examples illustrate the application of shockwaves in different areas and several of ways of holding the applicator.

Painful shoulder



Trigger-points



Tibial Edge Syndrome





Calcar Calcanei (Plantar Fasciitis)



Epicondylitis



Patellar Tendinopathy (Jumper's Knee)







Trigger points





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2.8 SAVING OF THERAPY

You can change the default values of therapy programs permanently saved in the device's memory.

For each therapy program, you can permanently preset the following parameters: **frequency**, **number of shocks** and **pressure**.

You can set and then save the new parameters for therapy frequency, number of shocks and pressure by pressing the **enter** button and holding it until the backlighting of the buttons blink. The selected settings are saved in the device's permanent memory and will be loaded as presets when the device is turned on the next time.

If you wish to change the program parameters back to the original (default) settings, you should select the therapy to reset then press the **esc** button and hold it until the backlighting of the buttons blink. The values of therapy program will be automatically changed.

2.9 DEVICE SETTINGS

2.9.1 USER SETTINGS

To access the user menu, press the buttons enter + esc + mode simultaneously.

- To switch between functions in the menu, turn the **select** knob.
- To change the on/off setting, press the enter button.
- To exit the user setting menu, press the **esc** button.

2.9.1.1 Sound Volume

Displayed on the control panel: 1 Snd

- **On**: Turns on the audio signalling of the device. A tone will sound at switch-on or switch-off of the device and at the end of therapy.
- Off: Mutes the audio signalling of the device.

2.9.2 ADDITIONAL SETTINGS

2.9.2.1 Brightness Setting

To set the brightness of the backlighting of all buttons, press and hold the buttons **enter + esc** simultaneously and then turn the **select** knob to change the brightness.

2.9.2.2 Firmware Version Display

Press and hold the buttons **enter** + **esc** + **pressure** simultaneously to display the last firmware version loaded in the device.

2.9.2.3 Displaying of the Number of Shot Shocks

After pressing the combination of buttons **enter + esc + number of shocks** you will enter the menu, in which you can view the number of shocks shot by the applicator and/or by the device. For switching between the number of shocks shot by the device and the number of shocks shot by the applicator you can use the **select** knob. Number of shots is displayed in format X.XXX, where dot means that number must be multiplied x1000. For example 1.234 means, that 1 million 234 thousands shots have been applied yet.

To reset the number of shocks of the applicator, hold the **enter** button for 5 seconds. The number of shocks of the device cannot be reset.



2.9.3 ERROR MESSAGES

Unconnected or improperly connected applicator

If the applicator is not connected to the device or is connected improperly, the display shows the following graphics at the option number of shocks:



If the applicator is missing, connect it to the device as described in the Chapter **Assembly and Set-Up**. If the applicator is connected improperly, disconnect it from the device and repeat the connecting process according to Chapter **Assembly and Set-Up**.

The device is ON, but it does not generate shockwave

If the device is ON but cannot generate shockwave because of an internal error, the display shows the following text at the **number of shocks** option:



Switch off the device and contact the authorized service of BTL devices.

The device shows message "Water

After 150,000 shot shocks the device will prompt you automatically by message "Water" to pour out the condensate from the vessel.



Turn the unit OFF. To release the vessel for condensate, screw it out by turning to the left. Unscrew transparent part as whole, do not loosen the blue screw. After pouring the condensate out screw the vessel back into position tightly and press **enter** button. After turning the unit ON the warning message should disappear.





3 LIST OF STANDARD AND OPTIONAL ACCESSORIES

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

The first list is of all standard accessories that are supplied with the device. The second list is of the optional accessories available from BTL.

For more detailed information on individual accessories, see the enclosed leaflet.

Standard accessories:

- 1x shockwave applicator with multi-focus shock transmitter Ø 15 mm
- 1x replaceable multi-focus shock transmitter Ø 9 mm
- 1x replaceable focusing shock transmitter Ø 15 mm
- 1x applicator holder
- 1x gel 300 ml
- 1x adapter
- 1x spare fuse T6.3AL/250 V
- 1x user's manual

Optional accessories:

- transport case for the BTL-6000 SWT
- gel 300 ml



4 MAINTENANCE AND SAFETY INSTRUCTIONS

The service inspection including measurement of all device parameters and possible recalibration must be performed in interval shorter than 30 months after installation and subsequently each 12 months. Shorter intervals can be set by local regulations. The inspection shall be performed by an authorized BTL service facility following a user's order. If the inspection is not performed in required intervals, the manufacturer does not guarantee the technical parameters and safe operation of the product.

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

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 SWT Easy 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!!!

The exterior surface of the shock transmitter can be washed with warm water with its cap on. However, to completely remove all of the contact gel from the shock transmitter, it will be necessary to unscrew the shock transmitter and clean it.

Fuse replacement:

The fuse is placed in the round black boxes on the rear panel. During replacement, check the correctness of the fuse being inserted. This action should only be done by a person acquainted with this procedure!

Before replacement, make sure that the main power switch of the device is in the "0" position and the adapter is unplugged from the unit. Turn the segment of the fuse box to the left using a flathead screwdriver or coin in the slot to remove the fuse. Insert a new fuse and turn it to the right.

Do not use fuses other than those stated above the fuse box!

Servicing of the vessel for condensate:

The vessel for condensate on the rear side of the device shall be emptied and cleaned regularly. After 150,000 shot shocks the device will prompt you automatically by message "Water" (see Chapter **Error Messages**) to pour out the condensate from the vessel. To release the vessel for condensate, screw it out by turning to the left. Unscrew transparent part as whole, do not loosen the blue screw. After pouring the condensate out screw the vessel back into position tightly and press **enter** button.

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 - 240 V.

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 cable 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 **Technical Parameters**.



4.1 SHOCK TRANSMITTER REPLACEMENT PROCEDURE

The shock transmitter can be replaced as necessary. Three shock transmitters are included as part of the BTL-6000 SWT Easy standard accessories:

- 1x replaceable multi-focus shock transmitter (Ø 15 mm)
- 1x replaceable multi-focus shock transmitter (Ø 9 mm)
- 1x replaceable focusing shock transmitter (Ø 15 mm)

Replacement procedure:

1. Use the transmitter nut wrench [1a] (included in the package) to unscrew the screw cap of the shock



2. Take the shock transmitter (including both O-rings) out from the applicator.



3. Insert the selected shock transmitter "as is" to the applicator, including the mounted O-rings



4. Put the screw cap back in place and TIGHTEN THE SCREW CAP FIRMLY using the transmitter nut wrench [1a].

!ATTENTION! If the screw cap is not TIGHTENED FIRMLY, the projectile may get jammed after mere few thousand shocks!





4.2 PROCESS OF REPLACEMENT OF OLD APPLICATOR KIT

If after some time the applicator stops working correctly, it is possible to replace the old tube and projectile kit by means of the replacement kit, which is included in the supplied BTL-6000 SWT Easy package. Do not use damaged applicators! There is a risk of injury to the operating staff or the client.

The replacement kit package includes:

- 1x exchangeable kit
- 1x transmitter nut wrench [1a] (to screw / unscrew the cap of the shock transmitter)
- 1x body nut wrench [3a] (to screw / unscrew the cap of the cartridge)
- 1x set of spare O-rings

Replacement procedure:

1. Disconnect the applicator from BTL-6000 SWT Easy device. Use the transmitter nut wrench [1a] (included in the package) to unscrew the screw cap of the shock.



2. Take the shock transmitter (including both O-rings) out from the applicator.



3. Use the body nut wrench [3a] (included in the package) to unscrew the screw cap of the cartridge, follow the pictures.





4. Pull the old kit out from the applicator cartridge.



- 5. Take the new replacement kit from its plastic covering.
- 6. Carefully insert the new kit "as is" into the cartridge of the applicator in the direction as shown in the picture. Do not touch the rear cover behind the spring, as it is coated with a thin layer of lubricant from the factory.



7. The front cover of the replacement kit must be set to the position shown in the picture and pushed inside flush with the outer edge of the applicator case (push the kit slightly into the applicator case). The replaced kit must move freely (spring)!



- 8. After inserting the new kit, firmly screw the screw cap of the cartridge back in place using the body nut wrench [3a] and the reverse process.
- 9. During the replacement of the applicator kit we also recommend replacing the O-rings on the shock transmitter of the applicator. Spare O-rings are included in the accessories.
- 10. Put the shock transmitter with both O-rings replaced back in place and TIGHTEN THE SCREW CAP FIRMLY using the transmitter nut wrench [1a].

!ATTENTION!

If the screw cap is not TIGHTENED FIRMLY, the projectile may get jammed after mere few thousand shocks!



11. Connect the applicator back to BTL-6000 SWT Easy. To reset the counter of the number of shocks of the applicator hold the **enter** button for 5 seconds. The counter will be set to zero.

!!The warranty does not cover the damages caused by improper installation!!



4.3 GENERAL SAFETY PRECAUTIONS

- Before turning on the device for the first time, read this manual carefully.
- The device may only be used under the supervision of the physician prescribed the treatment.
- All personnel must be properly trained before using the device. This training should include the servicing technique, maintenance, verification of proper functioning and safety precautions associated with using the device.
- Shockwave therapy requires direct bodily contact, therefore do not use it on damaged skin!
- Do not apply shockwave therapy: To areas of the body with gas-containing organs, close to large nerve bundles or blood vessels, on the spinal cord or on the head!
- We do not recommend applying shockwave to the body parts under local anaesthesia.
- 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 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.
- Only the power supply adapter approved and supplied by the manufacturer, complying with the specifications listed in the Chapter **Technical Parameters**, may be connected to the device.
- Portable and mobile high-frequency communication devices (such as mobile phones) may affect the function of the device.
- The electrical cables which are to be connected to the device must be installed and tested according to the existing valid standards. If it is not known whether cables are safe and/or correct, then they should be checked and/or upgrade by an inspection engineer.
- Check whether the parameters of the main power supply correspond to the requirements of the device according to Chapter **Technical Parameters**.
- The device requires the environmental conditions that are stated in the Chapter **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.
- 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. 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.



- 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. Even the replacement of the lithium battery and the air micro-filter must be done an authorized BTL service department only!
- 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 does not use or emit any toxic substances during its operation, storage or transport under the stated conditions.
- Before the start of therapy make sure that all set parameters comply with your requirements.
- To terminate operation, do not use the main power switch! Instead, press the **start/stop** button.
- The time interval between turning off the main power switch and turning it back on must be at least 3 seconds.
- Place the device so that it is possible to disconnect the connector of the power supply adapter quickly and easily from the device, or the male plug of the power supply adapter from the mains. To disconnect from the mains, unplug the male plug of the power supply adapter from the mains socket outlet.
- 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.
- The device and its accessories must be used in compliance with this manual.
- The device must be placed out of the reach of children.
- The device does not contain any components, except for the fuse and parts containing in the shockwave transmitter replacement kit, which can be repaired or replaced by the user. Do not remove the cover from the control unit. All repairs must be done by an authorized BTL service department.
- Do not disconnect an applicator during therapy.



4.4 USED SYMBOLS

\checkmark	General warning sign
†	Type BF applied part
•	Follow instructions for use (user's manual)
X.	Waste electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
SN	Serial number
	Class II equipment
LOT	Batch code
REF	Catalogue number



5 TECHNICAL PARAMETERS

Name	BTL-6000 SWT		
Model	BTL-6000 SWT Easy		
Operating conditions			
Ambient temperature	+ 10 °C to + 31 °C		
Relative humidity	30 % to 75 %		
Atmospheric pressure	700 hPa to 1060 hPa		
Position	horizontal on legs		
Type of operation	permanent		
Transport and storage conditions			
Ambient temperature	- 10 °C to + 55 °C		
Relative humidity	25 % to 85 %		
Atmospheric pressure	650 hPa to 1100 hPa		
Position of the main unit	horizontal		
	transport only in the original container		
Power supply			
Maximum input	120 W		
Mains voltage	~ 100 V to 240 V		
Frequency	47 Hz to 63 Hz		
Equipment protection class	II (acc. IEC 536)		
External exchangeable fuere	1xT6.3AL/250 V, tube safety fuse 5 x 20 mm,		
External exchangeable fuses	in accordance with IEC 60127-2		
Power switch	On the back of device, positions 0 (off) and I (on). To disconnect from the mains, unplug the male plug of the power supply adapter from the mains socket outlet.		
Design			
Weight main unit	max 7.0 kg		
Weight applicator	max 900 g including cable		
Main unit dimensions (w x h x d)	320 x 190 x 280 mm		
Applicator dimensions $(w x h x d)$	40 x 280 x 140 mm		
IP Code	IP 20		
Display elements			
Control panel	3x LED display		
Buttons	5x top panel, 4x front panel		
Indicator lights	1x orange, 9x blue, 22x yellow-green		
Classification			
Applied part type	BF		
Class according to MDD 93/42/EEC	lla		
Adjustable values			
Shock intensity	1 - 4 bar		
Shock frequency	1 - 15 Hz		
Number of shocks	0 - 9999 shocks		
Increments of adjustable values			
Frequency	1 HZ		
lotal number of shocks per therapy	TWO by the select knob, 500 by pressing the number of shocks button		

Technical parameters of the Switching Power Supply Adapter:

Name	BTL-4000 Adaptor 150W
Design	
Weight	960 g approx.
Dimensions (w x h x d)	207.6 x 76 x 43.7 mm
Covering grade according to EN 60 529	IP20
Class according to IEC 60601-1	11
Type of operation	permanent
Power supply	
Maximum input	~ 100 V to 240 V
Input current	1.63 – 0.7 A
Frequency	47 Hz to 63 Hz
Power switch according to IEC 60601-1	To disconnect from the mains, unplug the male plug of the power supply adapter from the mains socket outlet.
Environmental specification	

Operating temperature Storage temperature Relative humidity 5 % to 95 % non-condensing

0 °C to + 60 °C - 40 °C to + 85 °C



5.1 EMC INFORMATION

Medical electrical equipment should be used with precautions according to EMC, 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 SWT Easy is suitable for use in the specified electromagnetic environment. The purchaser or user of BTL-6000 SWT Easy 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 SWT Easy 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 Easy 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	Not applicable			
Voltage fluctuations / Flickers IEC61000-3-3	Complies	BTL-6000 SWT Easy is suitable for use in establishments directly connected to a public low voltage mains network.		

Directive and declaration of manufacturer – Electromagnetic immunity				
BTL-6000 SWT Easy is suitable for use in the specified electromagnetic environment. The purchaser or user BTL-6000 SWT Easy should assure that it is used in an electromagnetic environment as described below.				
Immunity test	IEC601-1-2 test level	Compliance level	Electromagnetic environment	
Electrostatic discharge (ESD) IEC 61000-4-2	±6 KV contact ±8 KV air	±6 KV contact ±8 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 for power supply lines ±1 KV for input/output lines	Not applicable	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	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U _T (>95% dip) for 0.5 cycle; 40% U _T (60% dip) for 5 cycles; 70% U _T (30% dip) for 25 cycles; <5% U _T (>95% dip) for 5 sec.	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment. If the user of BTL-6000 SWT Easy requires CLINICAL UTILITY during power mains interruptions, it is recommended that parts of the BTL-6000 SWT Easy system where applicable be powered from an uninterruptible power supply.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/or hospital environment.	
Note: U_T is the nominal voltage of mains.				

Directive and declaration of manufacturer – Electromagnetic immunity				
BTL-6000 SWT Easy is suitable for use in the specified electromagnetic environment. The purchaser or user of BTL-6000 SWT Easy should assure that it is used in an electromagnetic environment as described below.				
Immunity test	IEC 601-1-2 test level	Compliance level	Electromagnetic environment	
Conducted RF IEC 6100-4-6	3 V _{eff} 150 KHz – 80 MHz	Not applicable	Portable and mobile RF communications equipment a used no closer to any part of BTL-6000 SWT Easy, including cables, than the Recommended Separation Distance calculated the formula written below. Recommended Separation Distance: $d=1.17\sqrt{P}$ $d=1.17\sqrt{P}$; (80 MHz – 800 MHz) $d=2.34\sqrt{P}$; (800 MHz – 2.5 GHz) where: P is the highest radiated power disclosed by the manufacturer of transmitter [W]; d is the recommende separation distance [m].	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.5 GHz	3 V/m		
1. note: in case of frequency 80 MHz or 800 MHz, the formula for the higher range is applicable.				
2. note: These are guidelines. Actual conditions may vary.				

Recommended separation distance

BTL-6000 SWT Easy is intended to be used in electromagnetic environment with controlled RF disturbances. The purchaser or user of BTL-6000 SWT Easy may help to reduce electromagnetic disturbances by defining the separation distance between the transportable or mobile RF telecommunication equipment (transmitters) and BTL-6000 SWT Easy, depending on the highest output power of the telecommunication equipment.

The highest output	Separation distance in function of the nequency of the transmitter [m]			
power of the transmitter [W]	150KHz – 80MHz d=[3,5/V₁]√P	80MHz – 800MHz d=[3,5/E₁]√P	800MHz – 2,5GHz d=[7/E₁]√P	
0,01	Not applicable	0,12	0,23	
0,1	Not applicable	0,38	0,73	
1	Not applicable	1,2	2,3	
10	Not applicable	3,8	7,3	
100	Not applicable	12	23	

If this table does not contain the highest output power of the transmitter, the d separation distance [m] can be calculated by the formula, depending on the frequency of the transmitter, where P is the rated highest output power of the transmitter [W].

1. note: in case of frequency 80MHz or 800 MHz, the formula for the higher range is applicable.

2. note: These are guidelines. Actual conditions may vary.



5.2 MANUFACTURER

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

E-mail: sales@btlnet.com

http://www.btlnet.com

This product is distributed in Canada by: BTL Medical Technologies Canada, Inc. 170 Wicksteed Ave Toronto, ON M4G 2B6 Tel: +1-855-285-8188 E-mail: info@btlnet.com

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

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