BTL-6000 RSWT EASY

USER´S MANUAL

CONTENTS

1 GENERAL INFORMATION

1.1 INTENDED PURPOSE

BTL-6000 RSWT Easy 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 RSWT Easy also induces local neovascularization which promotes local trophical improvement.

BTL-6000 RSWT Easy 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 and functional disorders of the pelvic floor region and reproductive organs (e.g. Chronic pelvic pain syndrome/chronic prostatitis, Peyronie´s disease, erectile disorders).

1.2 USER PROFILE

The device shall be used by medically educated healthcare personnal. The user shall be familiar with all safety precautions and warnings, 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. Do not for use in a location where explosion or water intrusion hazards are present or in oxygen-rich, 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 or weight 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 CONTRAINDICATION FOR 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 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

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2 SAFETY PRECAUTION 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. Use the device and its accessories only in accordance with the User's Manual.
	Do not apply therapy over the head, neck, thorax, over the carotid sinus nerves particularly in patients with a known sensitivity to the carotid sinus reflex, spinal cord and testes.
	Do not apply over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
	Do not apply over, or in proximity to, cancerous lesions.
	Caution is advised when applying therapy directly to an area with impaired arterial blood supply.
	Do not deliver therapy through clothing.
	Keep verbal contact with the patient during therapy. Never leave the patient unattended.
	Before starting therapy, always check the device and its accessories (such as cable, applicators, connectors) for mechanical, functional or other damage. In case of a defect or deviation from normal function, stop using the device immediately and contact a BTL authorized service center. Should any defects be present, do not use the device.
	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.
	Before starting therapy always check the unit has been correctly connected to the mains; the applicator cable is not cross-routed (which may cause damage in the internal wires).
	Before the start of therapy make sure that all set parameters comply with your requirements. Review therapy contraindications.
	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't be determined 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.
	Modifications to the device and its accessories are prohibited. Do not try to open or remove the device protective covers or disassemble the device for any reason. There is a danger of electric shock and serious injury. All servicing must be carried out by an authorized BTL service center; otherwise BTL bears no responsibility for further operation of the device.
	Do not disassemble any covers and connect cables or devices to the USB connectors. They are for service purposes only!

	Never use the accessories' ports or other ports to plug in anything else but what the ports have been designed for. There is a serious risk of electric shock and serious damage to the device! The device is equipped with a protective system against connecting accessories other than those supplied by the manufacturer. The device does not function with accessories from other manufacturers.
	Do not place the applicator close to any part of the device during therapy.
	Protect the device against unauthorized use.
	The applicator can only be plugged in and unplugged when the device is turned off.
	The safety locks must be appropriately locked to secure the connector correctly. If the connector cannot be locked contact the service representative.
	To unplug applicator, release safety locks and pull out the connector. Never pull the applicator cable. Never disconnect the applicator during therapy.
	Use of accessories other than those specified in this manual which may lead to non-function or malfunction of the device. This does not apply to any parts provided by BTL as part of an authorized service. There is a serious risk of electric shock and serious damage to the device! The device is equipped with a protective system against connecting accessories other than those supplied by the manufacturer. The device does not function with accessories from other manufacturers.
	Use of a unit that indicates an Error may pose a risk of injury to the patient, user, or extensive internal damage to the system.
	The device may interfere with other electronic therapeutic devices. Never use another electronic device on the same patient when BTL-6000 RSWT Easy is being applied.
	The device should not be used adjacent to or stacked with other equipment.
	Never replace the transmitter if the device in not switched off.
	Never immerse the applicator in a vessel with water or other liquid.
	Applicator's applied parts must be well cleaned before to start the theprapy. Always place the SWT gel provided by BTL in the treatment area.
	Start the therapy with a lower intensity. Gradually increase to the required value after assurance of patient tolerance.
	RSWT Applicator arm is intended for supporting the applicator throughout the therapy.

	The therapist must control the applicator throughout the whole therapy.
	To terminate operation, do not use the main power switch! Instead, press the **start/stop** button.
	Device displays messages concerning deviations or defects of the device and its accessories. If you are not sure what a message means, stop using the device and contact a BTL service.
	Do not install the device in a place where is possible to be hit by falling objects.
	The mains to which the device will be connected must be installed and revised according to the current standards for electrical installations in healthcare facilities. Make sure voltage parameters of the power supply grid and device requirements match.
	Do not use a different type of fuse that the provided one in section 4.3.
	Transport, store and operate the device in the environment defined in Chapter 8.5. Do not operate the device if there is any danger of explosion or water intrusion into the device. 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 place the device near other devices that produce strong electromagnetic fields (such as diathermy, X-ray, cell phones, and 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 center.
	Do not place the device in direct sunlight or near heat sources. It might lead to an 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. The vents must not be covered. When placing the device, leave at least 10 cm of free space behind the rear panel.
	Do not place any objects that produce heat or objects containing water or other liquids on the device.
	After moving the device from a cold to a warm environment, wait until the temperature equalizes before its connection to the mains (at least 2 hours).
	Keep the device out of reach of children.
	Do not place any objects on the device (including the applicator).
	Don't let the device unattended while it is switched on.
	The device has applied parts of the B.

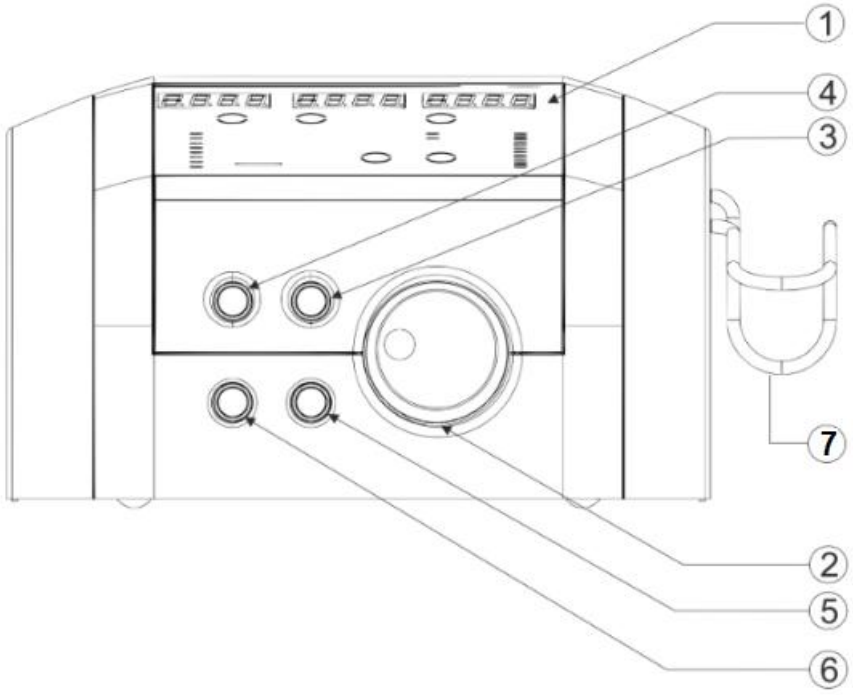
- The device and its accessories must be used in compliance with this manual.
- The device does not contain any components, except for the fuse, parts containing in the sets of shockwave transmitters, and SWT exchangeable kit which can be replaced by the user. Do not remove the cover from the control unit. All repairs must be done by an authorized BTL service.
- If it is necessary to discard the device, the device must be disposed in a way common for electric and electronic equipment. 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.

3 SYMBOLS AND MARKINGS

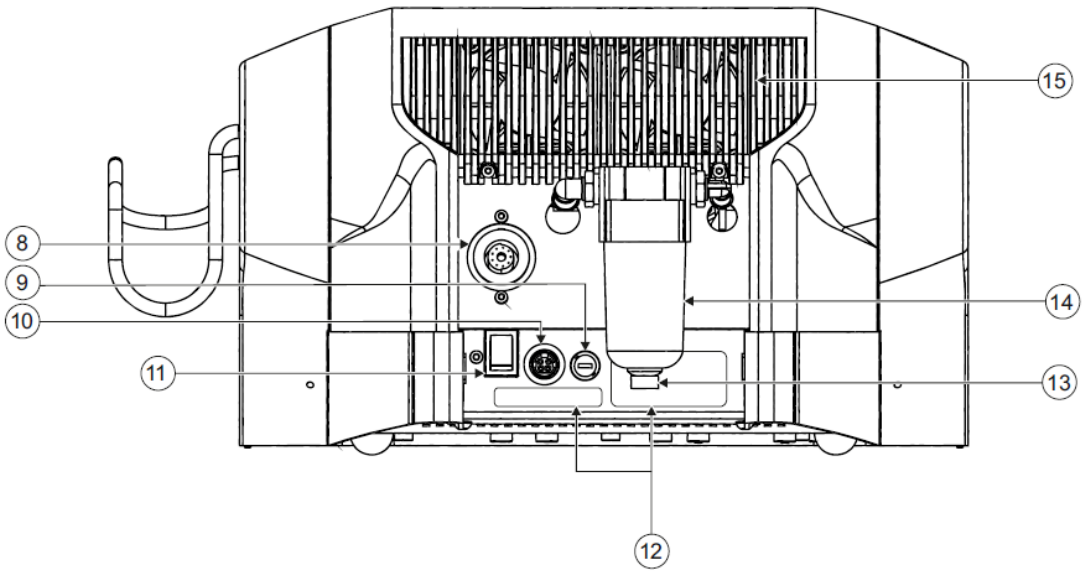
	Warning
	Caution
	Type B applied part
	Follow instructions for use (user's manual)
	Waste electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
	Serial number
	Batch code
	Catalogue number
	Class II equipment
IP22	**For power supply adapter** Protected against solid foreign objects of 12,5 mm ø and greater / Protection against dripping water when tilted at 15°
	Upper limit of working temperature +31 °C
	Equipment is suitable for direct current only
	Indoor use only
	Medical device
	Authorized representative in the European Community
	CE mark

4 INSTRUCTIONS FOR OPERATION

4.1 THE FRONT PANEL OF THE BTL-6000 RSWT 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 button (backlit, in blue, when the control unit is ‘’on’’
7. applicator holder



8. connector for shockwave applicator
9. fuse of control unit
10. connector for power cable
11. power on/off switch
12. type label – contains type of the device, manufacturer and safety and warning signs
13. screw for draw of the water
14. vessel for collecting condensed water
15. venting grid

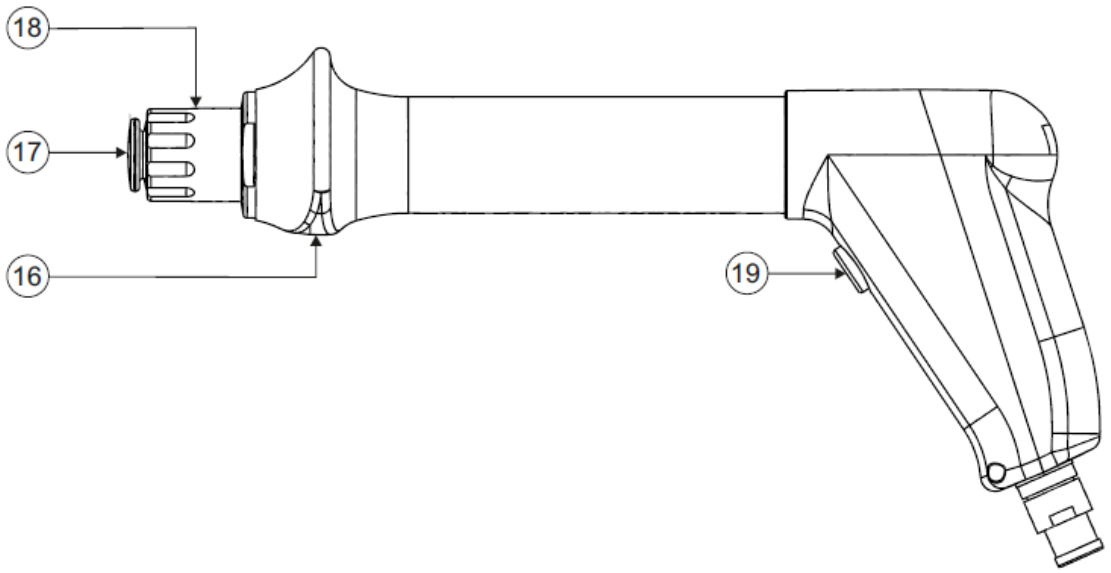
4.2 APPLICATOR FOR BTL-6000 RSWT EASY

Application of shock waves 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.

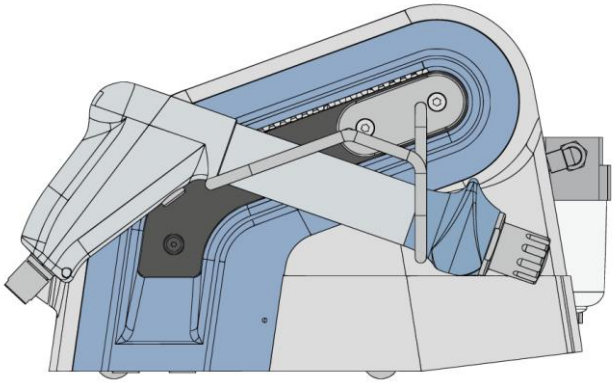
The ergonomically-shaped handle allows the therapist to grip the applicator comfortably in various different positions. The orientation can be varied according to the type of applied therapy and the personal preferences of the therapist whether they are left-handed/right-handed or male/female.



16. hand rest of the applicator
17. shock transmitter of the applicator – Applied part
18. shock transmitter screw cap of the applicator
19. Start / Stop button

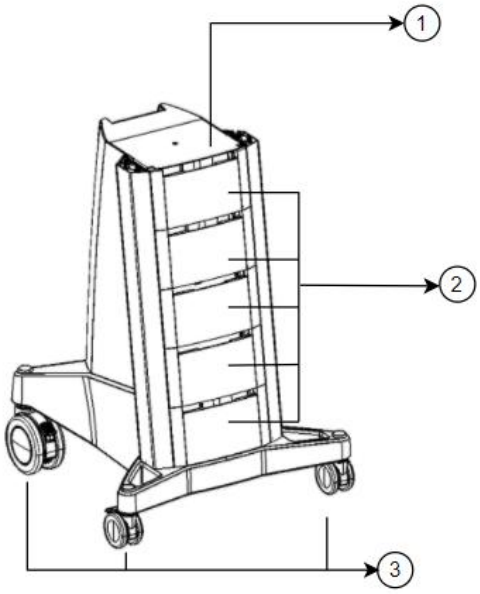
4.2.1 APPLICATOR'S POSITION IN THE HOLDER

When the device is not used, place the applicator in the applicator holder as is shown on the picture below



4.2.2 TROLLEY FOR BTL-6000 SERIES

The trolley is intended for movement and placement of BTL-6000 SWT Pro and BTL-6000 SWT Elite. The trolley is equipped with drawers and retractable castors.



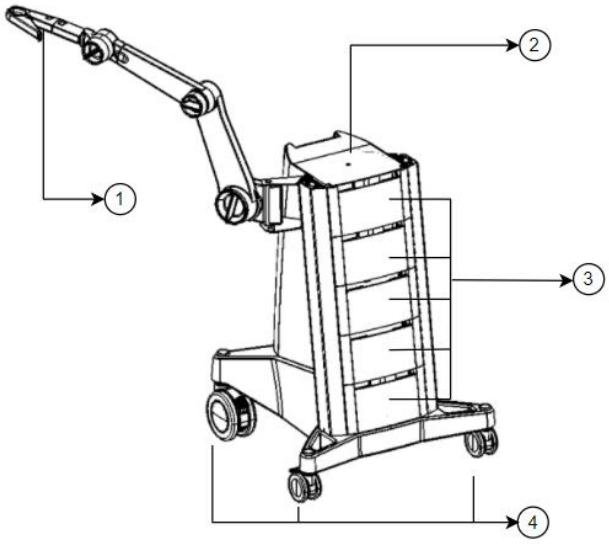
1. Mounting plate for the unit
2. Drawers
3. Retractable castors

4.2.3 TROLLEY WITH RSWT APPLICATOR ARM

The trolley with RSWT Applicator arm is intended for movement and placement of BTL-6000 RSWT Easy, and for supporting the applicator during the therapy.

RSWT Applicator arm is intended for supporting the applicator throughout the therapy.

The therapist must control the applicator throughout the whole therapy.



1. RSWT Applicator arm
2. Mounting plate for the unit
3. Drawers
4. Castors

4.3 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.

Standard accessories:

- 1x shockwave applicator with 15 mm multifocused shock transmitter
- 1x multifocused shock transmitter Ø 9 mm
- 1x focused shock transmitter Ø 15 mm
- 1x set of spare O-rings Ø 13 mm (7 pcs)
- 1x set of spare O-rings Ø 11 mm (7 pcs)
- 1x applicator holder
- 1x gel 300 ml
- 1x power adapter
- 1x power cord
- 1x shell wrench
- 1x bumpnut wrench
- 1x brush
- 1x spare fuse T10AH/250 V
- 1x user's manual

Optional accessories:

- 20 mm vibrating transmitter
- 36 mm vibrating transmitter
- 15 mm multifocused titanium transmitter
- 9 mm multifocused trigger transmitter
- 20 mm titanium transmitter with sanitary cover
- 20 mm transmitter with sanitary cover
- Set of sanitary covers 20 mm (100 pcs)
- SWT exchangeable kit
- Transportation case for BTL-6000
- Gel 300 ml
- Trolley for BTL-6000 SERIES
- RSWT Applicator arm

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 box and packaging to ensure safe future transport of the device.

After moving 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).

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 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.

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

Do not put any heat-producing devices or any objects containing water or other liquids on the device. Do not put any heat-producing devices or objects containing water or other liquid 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.

Do not place the device in dusty environment.

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

6 BASIC DISPLAYS AND OPERATING OF THE DEVICE

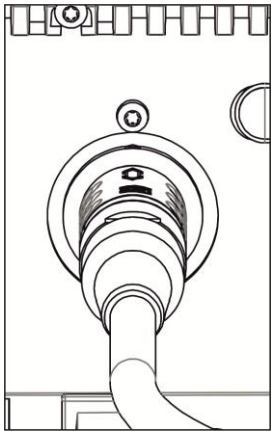
Make sure the marking on the applicator connector's end and applicator connector are pointing against each other and also that they are touching.

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. 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.

Do not turn the entire connected connector by force; otherwise there is a risk of damage to the device!

6.1 DEVICE STARTUP / SHUTDOWN

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 - 240 V mains socket. The device detects the voltage automatically. Plug the device directly in the mains; do not use extension cords with multiple sockets or multi-socket adaptors.
2. Connect the applicator to the connector on the rear panel (8) so the arrow is on top:



3. Switch the mains switch on the rear panel to position "**I**".
4. Press the **on/off** button on the front panel[1].
5. Turn off the device by pressing the **on/off** button.

[1] 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 service.

After turning the device on, the control panel will light up:

6.1.1 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

2. Press the respective button again to change the set value as follows:
    a. Frequency: The frequency will increase by 1 Hz.
    b. Number of Shocks: The number will increase by 100 shocks
    c. 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 **ente**r 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.

6.1.2 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.

6.2 SETTING OPTIONS

6.2.1 PROGRAM

The device contains 7 pre-set programs/therapies + 1 manual

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

6.2.2 FREQUENCY

BTL-6000 RSWT EASY supports range of different frequencies which can be set.
10 Hz is set by default for each therapy. The maximum settable value of frequency is 15 Hz.

6.2.3 NUMBER OF SHOCKS

It is possible to set up to 9,999 shocks. For continuous therapy turn the **select** knob (2) to the left. Setting of continuous therapy is indicated by four dashes on the display:

6.2.4 PRESSURE BAR

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

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!

6.2.5 MODE

The device supports different modes of control of the applicator.

- **continual**
  First press of the button starts continual generating of shocks; second press of the button stops it.
- **single**
  Each press of the button makes one shock.

6.3 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 therapy.

Make sure the marking on the applicator connector's end and applicator connector are pointing against each other and also that they are touching.

Therapy should be performed with the front of the transmitter in front of the treatment area. Not allowed treatment with the edge of the transmitter or otherwise.

Therapy should start with low intensity and observing the user's response. During therapy, the intensity can be increased according to the patient's sensation.

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 shocks.

Press the **on/off** button to turn off the device.

Push the rear main switch to **O** to switch off the device.

6.3.1 APPLICATION OF SHOCKWAVES

Once the **start/stop** button on the front panel is pressed, the device is ready to start delivering shocks. Press the button on the applicator and shocks will start to be delivered from the applicator. Be sure to do so before placing the applicator on to the treated area.

Delivering of shocks to the patient is conditioned by the permanent and sufficient contact of the active part of the applicator and the treated area.

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

6.3.2 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.

6.4 DEVICE SETTINGS

6.4.1 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.

6.4.1.1 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.

6.4.2 ADDITIONAL SETTINGS

6.4.2.1 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.

6.4.2.2 Firmware Version Display

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

6.4.2.3 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.

6.4.3 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

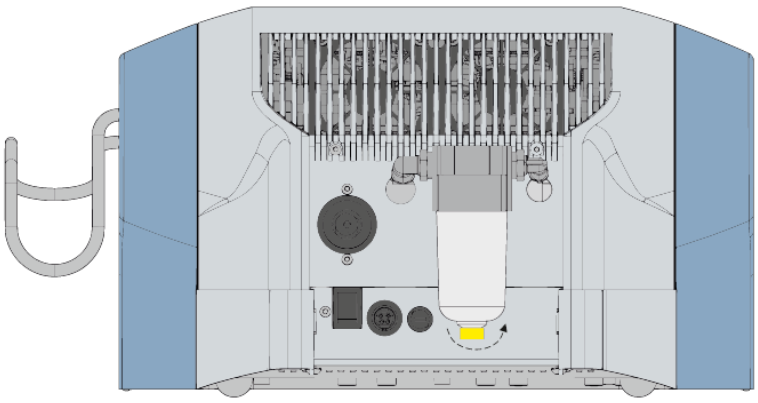
If the device is ON but cannot generate shockwave because of an internal error, the display shows the following text at the **number of shocks** option:

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

The device shows message "Water"

After 100,000 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 the grey part until open the vessel hole. After pouring the condensate out screw the vessel back into position tightly and press **on/off** button. After turning the unit ON the warning message should disappear.



7 TROUBLESHOOTING

The device is designed with user and patient safety in mind. During each start-up, the device carries out self-diagnostics of the internal circuits and functions. If there is any unacceptable deviation, the device will display message **error**. If the problem persists after device restart (turn the device off and on using the main switch), call an authorized BTL service center.

The following table serves as a guideline to solve some common problems that may occur during the operation of the device.

Problem	**Possible reason and solution**
Device does not start.	Check the power cord and the power cord connector. Switch the main switch to ON position ("**I**").
Main switch is on position **I** but the orange light guide of ON/OFF button didn't light and device is not start.	Switch the main switch in **O** position Disconnect the power cord from the mains Check the fuse, if is interrupted change it with the spare one. Connect the device and turn the main switch in position **I** If the problem persists contact BTL service.
Display message **error** after turning on the device.	The device did not pass self-diagnostics. Check that the applicator is connected properly and restart the unit. If problem persists, contact a BTL service.
Therapy stopped unexpectedly due to main unit overheating.	Ensure that all air vents of the device are free. Ensure that the recommended parameters of the therapy and device operating conditions are not exceeded.
Error during applicator calibration.	Turn off the device. Check that the applicator is properly connected. Remove the applicator connector. Make sure the connector mark of the applicator matches the connector mark of the main module. Turn on the device.
Applicator was disconnected from the main unit while in operation.	Switch the device off and reconnect applicator.
Applicator was connected to the main unit while in operation.	Restart the device.
The intensity sensation is lower than usual.	Clean the applicator's shell. Change the transmitter O-rings if they are smashed. If problem persists, contact a BTL service.
Missing the shocks during therapy running.	Clean the applicator's shell If problem persists, contact a BTL service.
Therapy cannot be started.	Check that all accessories are properly connected. If the problem persists after the device restart, follow the instructions and contact a BTL service.
Control buttons are partially or completely irresponsive.	Contact a BTL service.

8 MAINTENANCE AND SAFETY INSTRUCTIONS

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.

8.1 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 RSWT Easy device and its parts. Clean the device one per week.

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.

8.2 CLEANING AND MAINTENANCE OF ACCESSORIES WHICH COME INTO CONTACT WITH THE PATIENT

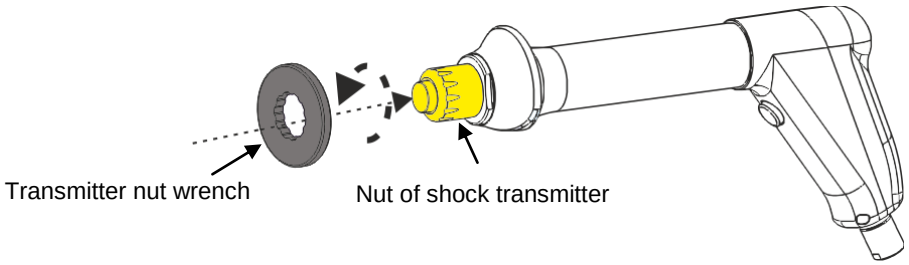
Clean and disinfect after each client using approved cleaning agents. For example, Sekusept, Bacilol, and Incidur Spray can be used. For the cables of accessories, use Incidur Spray and the alike.

Do not use solvents!!!

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

Use the transmitter nut wrench to unscrew the nut of shock transmitter. Clean accurate the nut and transmitter until no gel remain in its surfaces (including internal surface of the nut).

Before to screwing back to the applicator ensure that the nut and transmitter are absolutely dry. It is not allowed to have water drops or gel on them.



Tighten the nut of the shock transmitter until it stops turning. The not well screwed nut will lead to damage the internal components of the applicator!

8.3 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 “O” 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!

8.4 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.

8.5 TRANSPORT AND STORAGE

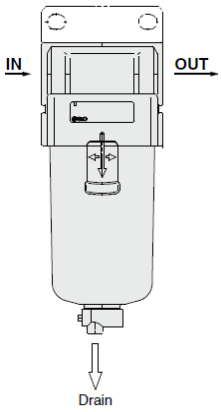
Keep the shipping container and all packaging materials. Transport the unit in original box to ensure maximum protection. Unplug the main power cable and all accessory cables. Take care to avoid shocks or jarring movements to the device during transport. This device should only be transported and stored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

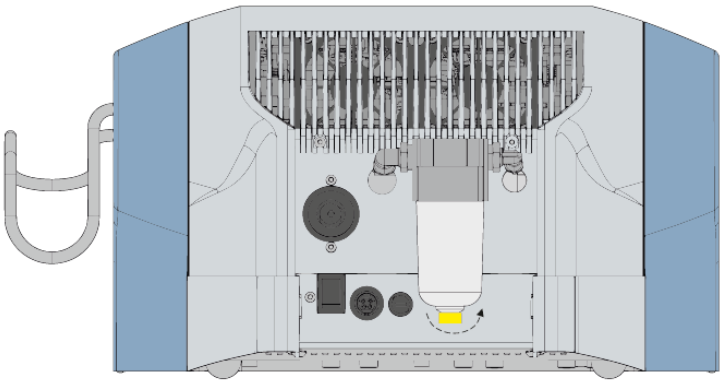
8.6 MAINTENANCE INSTRUCTIONS

8.6.1 REGULAR MAINTENANCE

At the end of each working day, the amount of condensate in the vessel on the rear side of the device should be checked. If not empty, remove all the collected condensate and clean the vessel. Additionally, the device automatically prompts you after 150,000 shot pulses the device to pour out the condensate from the vessel.

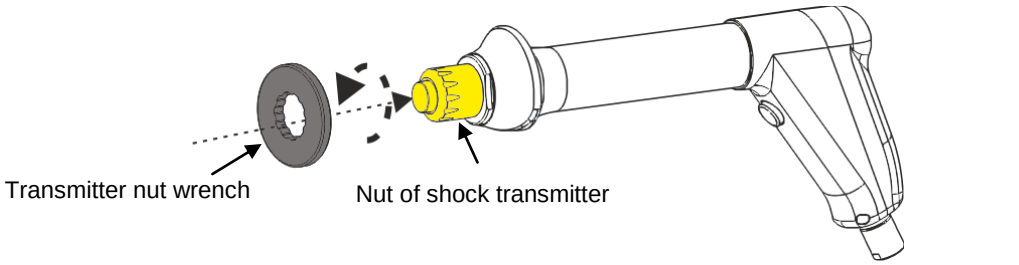
To release the vessel for condensate, unscrew the yellow draining guide by turning to the left. After pouring the condensate out screw the draining guide back into closed position tightly.

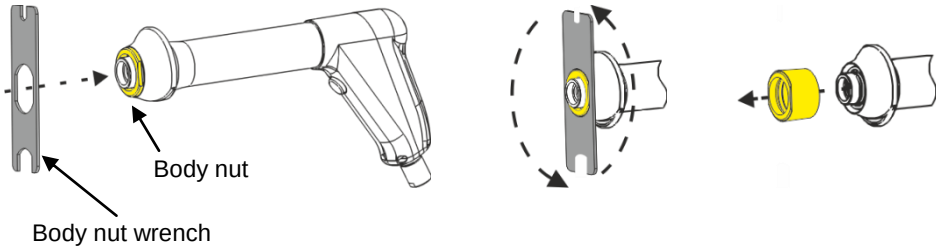




Pay attention during condensate drain. Place a cup under the condensate drain to avoid getting wet on the table, floor or near appliances.

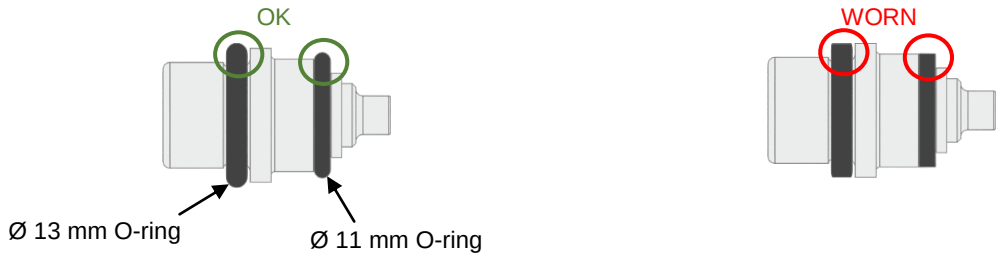
At the end of each working day unscrew nut of the shock transmitter (by transmitter nut wrench) and body nut (by body nut wrench), rinse them in a clear water to remove all residues of contact gel. Clean the shock transmitter as well and remove impurities and residues of contact gel from the gap between applicator's grip and front part of the case. This procedure prevents threads of both nuts from stiffen, what may make unscrewing of the nuts and changing of shock transmitter or case difficult or impossible.





Before to screwing back to the applicator ensure that the nut and transmitter are absolutely dry. It is not allowed to have water drops or gel on them.

Once per month check condition shock transmitter's O-rings. If their outer surface is worn and flattened, they have to be exchanged by the spare ones included in accessories. This will ensure correct transmission of the shock energy and prevent the contact gel from penetration inside the applicator and damage it. Latest together with the applicator kit replacement the O-rings should be exchanged.

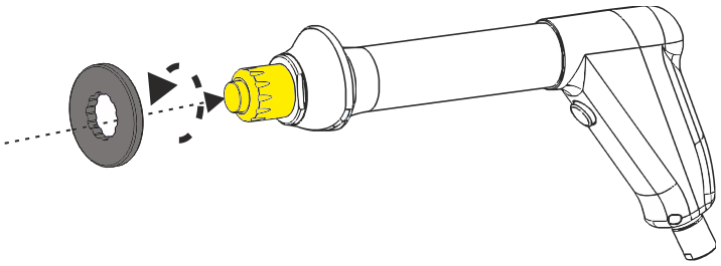


8.6.2 SHOCK TRANSMITTER REPLACEMENT

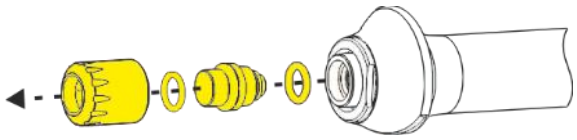
The shock transmitter can be replaced as necessary. Three shock transmitters are included as part of the BTL-6000 RSWT Easy as standard accessories.

Replacement procedure:

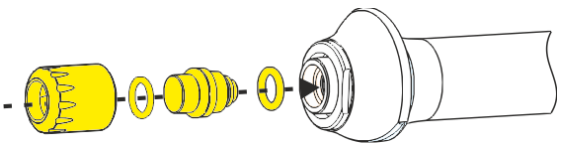
1. Use the transmitter nut wrench (included in the box with applicator) to unscrew the nut of the shock transmitter.



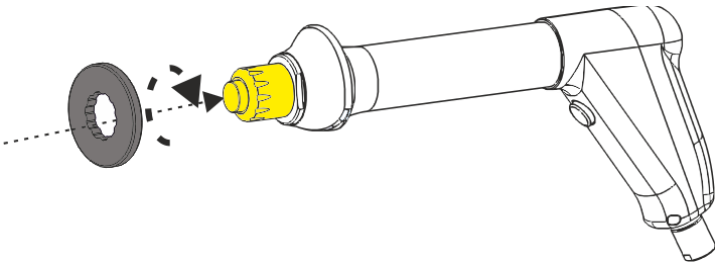
2. Take the shock transmitter together with both O-rings out from the applicator.



3. Insert the selected shock transmitter to the applicator including mounted O–rings.



4. Put the nut back in place and **tighten it firmly** using the transmitter nut wrench.



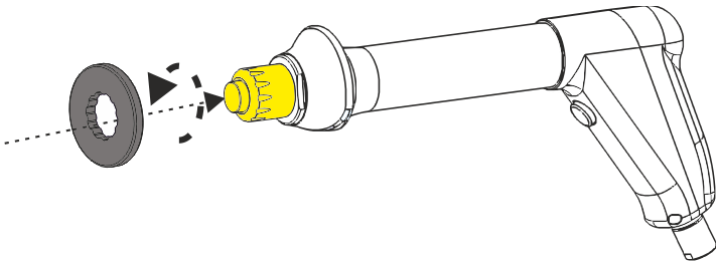
If the nut is not **TIGHTENED PROPERLY**, the projectile may get jammed after mere few thousand shocks!

8.6.3 APPLICATOR SHELL CLEANING

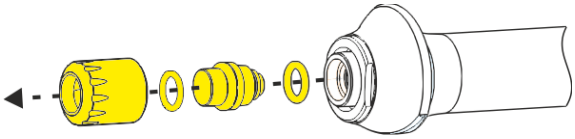
In case the shocks from the applicator are not regular, it is possible to clean the applicator shell by cleaning brush to restore its functionality.

Do not use damaged applicators! There is a risk of injury to the operating staff or the client.

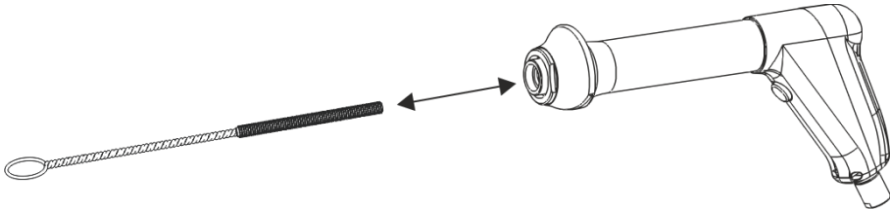
1. Use the transmitter nut wrench (included in the box with applicator) to unscrew the nut of the shock transmitter.



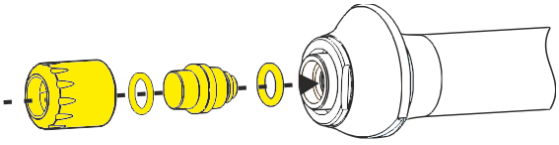
2. Take the shock transmitter together with both O-rings out from the applicator.



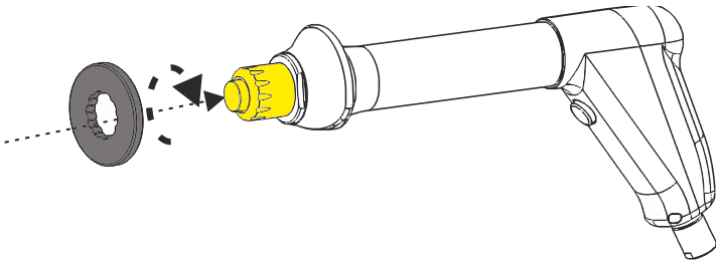
3. Insert the brush into the applicator shell, move it back and forth several times and make sure it reaches the end of the shell.



4. Insert the shock transmitter to the applicator including mounted O–rings.



5. Put the nut back in place and **tighten it firmly** using the transmitter nut wrench.



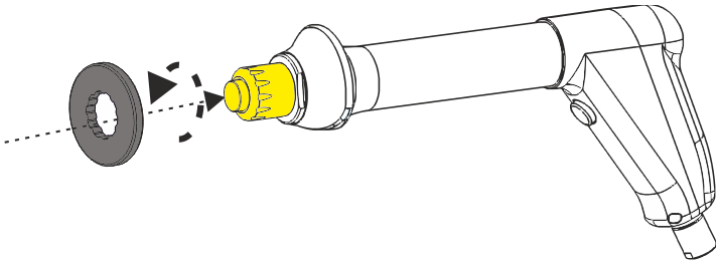
If the nut is not **TIGHTENED PROPERLY**, the projectile may get jammed after mere few thousand shocks!

8.6.4 APPLICATOR SHELL REPLACEMENT

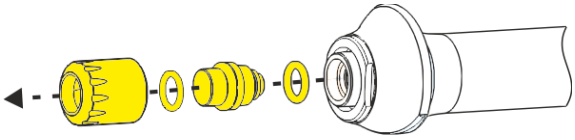
If after some time the applicator stops working correctly, it is possible to try to clean the shell or replace it by the new one from the SWT exchangeable kit.

Do not use damaged applicators! There is a risk of injury to the operating staff or the client.

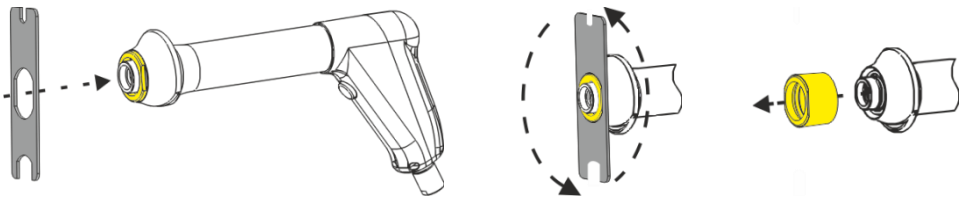
1. Use the transmitter nut wrench (included in the box with applicator) to unscrew the nut of the shock transmitter.



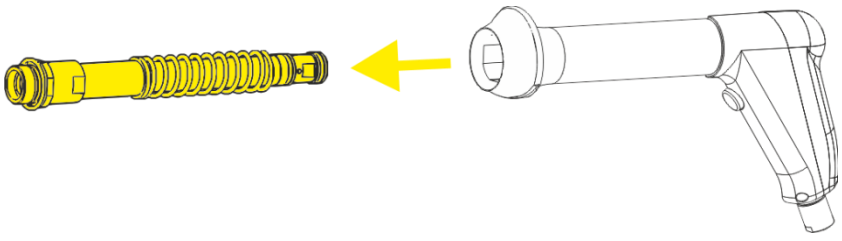
2. Take the shock transmitter together with both O-rings out from the applicator.



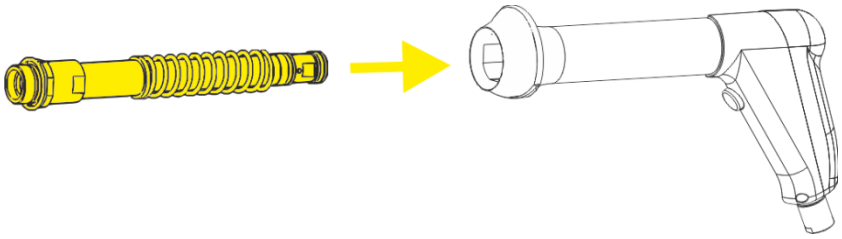
3. Use the body nut wrench (included in the box with applicator) to unscrew the body nut.



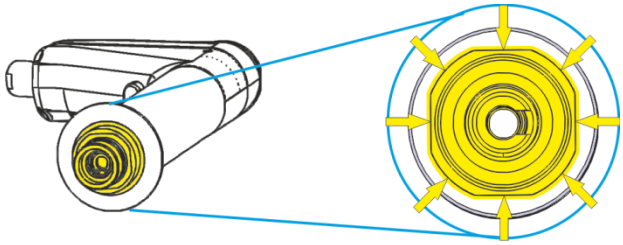
4. Pull the old kit out from the applicator case.



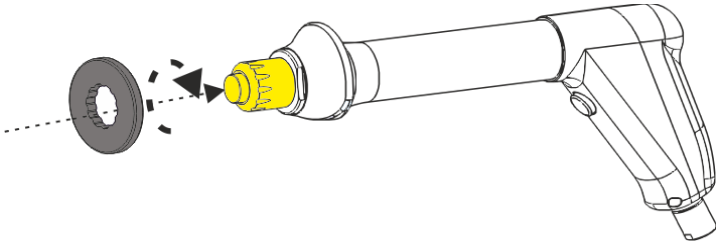
5. Take the new shell from its plastic covering.
6. Carefully insert the new shell "as is" into the case of the applicator in the direction as shown in the picture. Do not touch the rear part behind the spring, as it is coated with a thin layer of lubricant from the factory.



7. The front cover of the shell 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 shell has to move freely (spring)!



8. After inserting the new shell, firmly screw the body nut back in place using the body nut wrench.
9. During the replacement of the applicator shell we also recommend replacing the O-rings on the shock transmitter of the applicator. Spare O-rings are included in the accessories.
10. Insert the shock transmitter to the applicator including the new O-rings. Put the nut back in place and **tighten it firmly** using the transmitter nut wrench.



If the nut is not **TIGHTENED PROPERLY**, the projectile may get jammed after mere few thousand shocks!

11. Connect the applicator back to BTL-6000 RSWT 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!

8.7 TECHNICAL PARAMETERS

Name	**BTL-6000 RSWT**
Model	**BTL-6000 RSWT 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	10 % to 85 %
Atmospheric pressure	650 hPa to 1100 hPa
Position of the main unit	Horizontal
Position of the compressor	Horizontal
Other conditions	Transport only in the original container
External power adaptor specifications	
Safety grade	Medical
Electrical protection class	II According IEC 60601-1
Input voltage	~100 V to 240 V
Input current	2.5 - 1.3 A
Input frequency	50 / 60 Hz
Output voltage	DC 24 V
Output current	Maximum 9.2 A
Output power	Maximum 221 W
Type of operation	Permanent
Dimensions (w x h x d)	210 mm x 85 mm x 46 mm
Weight	1.1 kg
Covering grade according to EN 60 529	IP22
Manifacturer	MEAN WELL
Model	GSM220B24
Ordering No	GSM220B24 -R7B
Fuse	1xT10AH/250 V, tube safety fuse 5 x 20 mm, 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.
Devise mass propertis	
Weight main unit	max 7.0 kg
Weight applicator	max 1.1 kg
Main unit dimensions (w x h x d)	320 mm x 190 mm x 280 mm
Applicator dimensions (w x h x d)	40 mm x 280 mm 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	B
Class according to Regulation (EU) 2017/745	IIa
Adjustable values	
Shock intensity	1.5 – 4 Bar
Shock frequency	1 – 15 Hz
Number of shocks	1 – 9999 shocks
Increments of adjustable values	
Intensity	0.1 Bar
Frequency	1 Hz
Total number of shocks per therapy	100 by the **select** knob, 500 by pressing the **number of shocks** button
Power Supply cord	
Connector	C7 according to IEC60320
Type	H03VVH2-F 0.75mm2
Length	3000 mm +/-50 mm

9 EMC INFORMATION

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

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and manufacturer's declaration – electromagnetic emissions		
BTL-6000 RSWT Easy is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 RSWT Easy should assure that it is used in such an environment.		
Emissions test	***Compliance***	***Electromagnetic environment – guidance***
RF emissions CISPR 11	Group 1	The BTL-6000 RSWT 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.
RF emissions CISPR 11	Class A	The BTL-6000 RSWT 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 emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity				
The BTL-6000 RSWT Easy intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BTL-6000 RSWT Easy can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BTL-6000 RSWT Easy as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter W	***Separation distance according to frequency of transmitter (m)***			
	150 kHz to 80 MHz $d = [3.5/V_1]\sqrt{P}$ $V_1=3V$	***150 kHz to 80 MHz*** $d = [3.5/V_1]\sqrt{P}$ $V_1=6V$	**80 MHz to 800 MHz** $d = [3.5/E_1]\sqrt{P}$ $E_1= 3$ V/m	***800 MHz to 2.7 GHz*** $d = [7/E_1]\sqrt{P}$ $E_1= 3$ V/m
0.01	0.12	0.06	0.12	0.23
0.1	0.37	0.18	0.37	0.74
1	1.2	0.58	1.2	2.3
10	3.7	1.8	3.7	7.4
100	12	5.8	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

Guidance and manufacturer's declaration – Electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment – guidance***
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle at 0°,45°,90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1cycle at 0° 70 % U_T; 25 cycles at 0° 0 % U_T; 250/300 cycles	0 % U_T; 0.5 cycle at 0°,45°,90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1cycle at 0° 70 % U_T; 25 cycles at 0° 0 % U_T; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

<table>
<tr><th colspan="5">Guidance and manufacturer's declaration – Electromagnetic immunity</th></tr>
<tr><td colspan="5">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th colspan="3">IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td colspan="3">3 V
0.15 MHz – 80 MHz

6 V
ISM bands between
0.15 MHz and
80 MHz</td><td>3 V
0.15 MHz – 80 MHz

6 V
ISM bands between
0.15MHz and 80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance
d= [3.5/V₁]√P 0.15 MHz to 80 MHz
d = [3.5/E₁]√P 80 MHz to 800 MHz
d = [7/E₁]√P 800 MHz to 2.7 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

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

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

  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td colspan="3">3 V/m
80 MHz to 2.7 GHz</td><td>Compliance in same levels as test levels</td></tr>
<tr><td colspan="4">Table 9 of IEC 60601-1-2:2014:</td><td></td></tr>
<tr><td>27 V/m</td><td>385 MHz</td><td>PM 18 Hz</td><td></td><td></td></tr>
<tr><td>28 V/m</td><td>450 MHz</td><td>FM 5 kHz</td><td></td><td></td></tr>
<tr><td rowspan="3">9 V/m</td><td>710 MHz</td><td rowspan="3">PM 217 Hz</td><td></td><td></td></tr>
<tr><td>745 MHz</td><td></td><td></td></tr>
<tr><td>780 MHz</td><td></td><td></td></tr>
<tr><td rowspan="3">28 V/m</td><td>810 MHz</td><td rowspan="3">PM 18 Hz</td><td></td><td></td></tr>
<tr><td>870 MHz</td><td></td><td></td></tr>
<tr><td>930 MHz</td><td></td><td></td></tr>
<tr><td rowspan="3">28 V/m</td><td>1720 MHz</td><td rowspan="3">PM 217 Hz</td><td></td><td></td></tr>
<tr><td>1845 MHz</td><td></td><td></td></tr>
<tr><td>1970 MHz</td><td></td><td></td></tr>
<tr><td>28 V/m</td><td>2450 MHz</td><td>PM 217 Hz</td><td></td><td></td></tr>
<tr><td rowspan="3">9 V/m</td><td>5240 MHz</td><td rowspan="3">PM 217 Hz</td><td></td><td></td></tr>
<tr><td>5500 MHz</td><td></td><td></td></tr>
<tr><td>5785 MHz</td><td></td><td></td></tr>
<tr><td colspan="6">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="6">a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BTL-6000 RSWT Easy is used exceeds the applicable RF compliance level above, the BTL-6000 RSWT Easy should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BTL-6000 RSWT Easy.</td></tr>
<tr><td colspan="6">b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

9.1 ESSENTIAL PERFORMANCE OF THE DEVICE

The BTL-6000 RSWT Easy has no essential performance according to IEC 60601-1.

9.2 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.

CE 0051

Date of last revision: 06th January 2021

ID: 844-80MANEEN02100