BTL-5000 Shockwave Series

USER'S MANUAL



BEFORE YOU START

Thank you for showing your interest and buying our device the BTL- 5000 SWT Series. We hope you will be satisfied and thanks to you, this device will help many patients.

All of us at BTL wish you every success with your BTL- 5000 SWT Series. 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. Please call or email us your suggestions.

While we would like you to start using your equipment right away, we encourage you to thoroughly read this manual in order to fully understand the operational features of the BTL-5000 SWT system.

Again, thank you for being a BTL customer. In the event of any problem, or if you require service, please make an initial call to your local distributor, who will decide whether to refer the problem to our office.



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1 GENERAL CHARACTERISTICS OF THE DEVICE

The **BTL -5000 SWT Series** is a modern device enabling the application of therapies by using no invasive shockwaves. Shockwaves are one of the most effective ways of treatment of pain connected to the musculoskeletal system. Today, this is the second most frequent reason of absence from work.

The **devices** are equipped with a colour touch screen on the **main unit**, and considerably simplifies the use of the device. The touch screen is equipped with a touch pen for easy operation of the device. A vertically positioned device enables you to see the information on the screen clearly from different servicing positions. In addition, the brightness of the display can be adjusted to suit the light conditions in the office or the health centre. The information displayed on the screen will guide you throughout the whole therapy, simply adjust the parameters by pressing the touch screen buttons and turning the knobs on the device.

Selecting a diagnosis from a list of alphabetically organized treatment protocols, or selecting a program, will make an easy and efficient start to the therapy. You can adjust any treatment parameter manually by the simple use of the touch screen buttons. Throughout the whole therapy, the device informs you about the therapeutical method used, type of treatment, number of applied shocks, total and remaining shocks, frequency used, intensity and other necessary data.

Save your time by using the predefined programs of the **main unit**. Based on detailed research and practical use of the device, the well-organized predefined protocols will present recommendations for treatment of various conditions.

The **BTL- 5000 SWT** allows you to insert the names of your clients and other relevant information into the internal memory of the device and connect the client data with predefined or your own protocols. When your clients call again, simply recall their name and apply the pre-set therapy.

With every BTL-5000 SWT you can purchase a trolley specially designed for the BTL products. Its design offers maximum comfort of storage and use of the device. Four steady wheels provide simple movement of the device in the office or the health care centre.

The trolley includes a range of accessory containers and baskets.

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



1.1 BTL - 5000 SWT SYSTEM SERIES

The device consists of three units: the main unit, the compressor unit and the applicator.

- Main system BTL- 5000 unit, which includes the main microcomputer and software for control of the whole equipment, including user encyclopaedia and the therapy guide.
- Compressor apart from the compressor there is also the complete electronics attached for the regulation of the ballistic pressure.
- Applicator ergonomical applicator simplifies the "course of" the therapy, following the instructions of the main unit.

The system enables the connection of two applicators. Each applicator can contain a different transmission element, differing in its size and characteristic. Thereby the system features an advantage of service abilities for two different therapies, with no need to change the transmission elements. However, only one applicator can be active at a time. It is not possible to use two applicators together, at the same time.

1.2 SHOCKWAVE AND ITS CHARACTER

The shockwave is defined as a wave with a rapid increase of pressure in a very short time and gradual decline with a phase of small negative pressure.

Shockwaves are aimed at the affected areas that are the cause of chronic pain. The influence of shockwaves leads to for example dissolution of calcic deposits and better vascularisation, and in its final effect it causes relief of pain.

Outside the client's body (extracorporeally), a pressure pulse with a high amplitude is generated, and its energy is concentrated into the target area in the body. The pressure pulse without major losses travels through a water medium to the client and penetrates soft tissue.

The pressure course of the shockwave in time expressively differs from the pressure course of the harmonic sound wave. The shockwave is compared to the ultrasonic waves particularly characterized by a pressure jump change, higher amplitude and non-periodicity.

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

A substantial part of the shockwave energy penetrates into 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 inhomogeneities.

The shockwave is defined as a pressure pulse with these characteristics:

- High positive pressure amplitude 10 to 1000 MPa = 100 to 1000 Bar (100x atmospheric pressure)
- Low negative pressure amplitude 1 to 10 MPa
- Short time duration 1 μs to 20 μs
- Rapid pressure increase < 100 ns
- Broad frequency spectrum 1 Hz to 1 MHz



For therapeutical application, these values are lower, especially the maximum pressure amplitude, which is about 15 MPa, pulse length is 10 to 20 μ s, and frequency of the applied shockwave is 1 to 25Hz. The treatment is generally carried out without local anaesthetic and lasts about 15 to 30 minutes. During the first week after the treatment, the client should avoid all activities that could excessively strain the treated area.

1.3 SHOCKWAVE GENERATION

Several types of generators were developed for the shockwave therapy, providing shockwaves with varied characteristics. Shockwaves in their time span and spatial arrangement carry the imprint of the generation method.

The BTL 5000 SWT uses the ballistic principle of the shockwave generation.

1.3.1 BALLISTIC PRINCIPLE OF THE SHOCKWAVE GENERATION

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

1.4 BIOLOGICAL EFFECTS OF THE SHOCKWAVE

The shockwave effects mainly occur at sites, where there is a change in impedance, such as the bone-soft tissue interface.

There is an improvement of regeneration and repair of tissues in the following areas and achievement of the following effects:

- **cellular effect** increase in transmittance of a cell membrane (improvement of ionic channels activity), stimulation of cell division, stimulation of cellular cytokines production,
- **reproduction of vessels in the area of tendons and muscles**, improvement of blood circulation and MTB-increase in concentration of growth factor beta 1 chemotactic and mitogenic effect on osteoblasts,
- effect on nitrogen oxide system (bone healing and re-modelling),
- improvement of micro circulation and metabolism,
- · dissolution of calcic fibroblasts,
- support of collagen production,
- · reduction of tissue tension,
- analgetic effect:
 - destruction of afferent nerves and nerve receptors,
 - CNS stimulants, sensed as pain; are also inflammation transmitter substances,
 - regression of pain caused by local ischemia,
 - gate control theory of pain.



1.5 ADVANTAGES OF THE SHOCKWAVE TREATMENT

- by targeted operation of the shockwave, strain of surrounding tissues is quite insignificant
- the body is not strained by pharmaceuticals (except a short term effect of local anaesthesia)
- · possibility to prevent from necessity of surgical intervention and relevant hazard
- thanks to ambulatory treatment the absence from work reduces to a minimum, as well as the absence from training routine of sportsmen
- for some indications (e.g. tennis elbow) there is basically no other effective treatment

1.6 POSSIBLE SIDE EFFECTS AFTER THE 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
- momentary increase of pain can appear immediately after the treatment
- haematoma
- petechia
- · skin damage after previous corticoid therapy
- · shockwave application can cause undesirable heart activity

1.7 INDICATIONS FOR THE SHOCKWAVE TREATMENT

- · plantar fasciitis
- achillodynia achillobursitis
- inflammations and calcification of shoulder joint tendons
- pain in the groin area
- · epicondylitis (tennis and golf elbow)
- the apex patellae syndrome and tibial stress syndrome
- · pain in the area of the hip and the iliotibial tract
- · jumper's knee / patellar tendinitis
- · pain in the hamstring insertions
- pain on the palmar side of the wrist
- · exostoses of small hand joints in case of grade 1 arthrosis
- acupuncture
- pain trigger points painful points in muscles



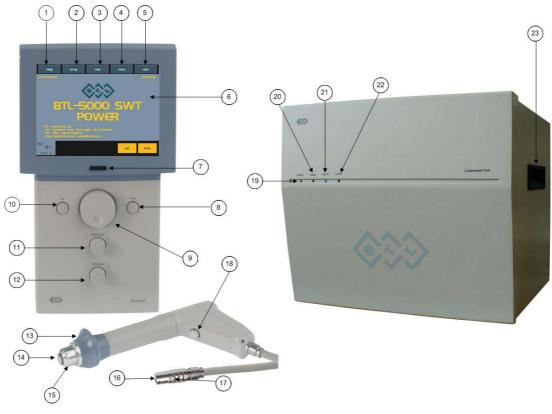
1.8 CONTRAINDICATIONS TO THE SHOCKWAVE TREATMENT

- application to certain tissues (eyes and their surroundings, myocardium, spinal cord, gonad, kidneys, liver)
- coagulation of blood disorders
- polypus in the area of treatment
- pregnancy
- coagulation of blood disorders and the use of anticoagulants
- thrombosis
- tumour disease
- polyneuropathy
- acute inflammation
- growing cartilage in children
- therapy using corticoids
- inapplicable in areas and organs with possible gas content
- inapplicable on areas in proximity to large nerves, vessels, spinal cord and head



2 INSTRUCTIONS FOR USE

2.1 FRONT PANEL OF THE BTL- 5000 SWT



- 1. diag button to select diagnosis
- 2. **prog** button to select therapy program
- 3. **man** button to set therapy parameters manually
- 4. **menu** button (to set date, time, language, display contrast, sounds, user options, etc.)
- 5. **user** button (lists of clients, user diagnoses, programs and sequences, recent therapies, etc.)
- 6. touch screen
- 7. **ON/OFF** power switch ("ON" status indicated by the blue backlight)
- 8. **enter** key (to confirm selection or setting)
- 9. **select** knob (to select and set individual parameters)
- 10. **esc** key (to cancel selection or setting and return to the previous status)
- 11. **time / stop** knob (to set therapy time, and to start and stop therapy)
- 12. **intensity** knob (to set intensity)
- 13. hand rest of the applicator
- 14. shock transmitter of the applicator
- 15. shock transmitter screw cap of the applicator
- 16. connector of the applicator
- 17. guide mark of the connector
- 18. applicator button for therapy start
- 19. power activation indicator of the compressor
- 20. indicator signalling ready to generate shockwaves ready
- 21. active tab indicator for the applicator output out A
- 22. active tab indicator for the applicator output out B
- 23. handles for easy transport of the compressor unit

2.2 REAR PANEL OF THE BTL- 5000 SWT



- 24. dummy plugs of the connectors
- 25. mains switch to switch the main unit on/off
- 26. socket for connection of the mains cable 230 V (or115 V) to the main unit
- 27. line fuse of the main unit
- 28. power switch 230V / 115V (bottom part of the main unit)
- 29. label with serial number and production date
- 30. com in communication link input for the main unit (for servicing purposes only)
- 31. com in / out communication link connector between the main unit and the compressor
- 32. type plate showing device type, manufacturer and safety precautions and warning signs
- 33. ventilation louver
- 34. communication link input / output for the compressor unit
- 35. ON / OFF power switch for the compressor unit
- 36. socket to connect the mains cable 230 V (or 115 V) to the compressor unit
- 37. line fuses of the compressor unit
- 38. power switch 230V / 115V of the compressor unit
- 39. connectors for the shockwave applicators
- 40. input for connection of foot pedal
- 41. communication connectors (for servicing only)
- 42. catchment container



2.3 ASSEMBLY AND PUTTING INTO OPERATION

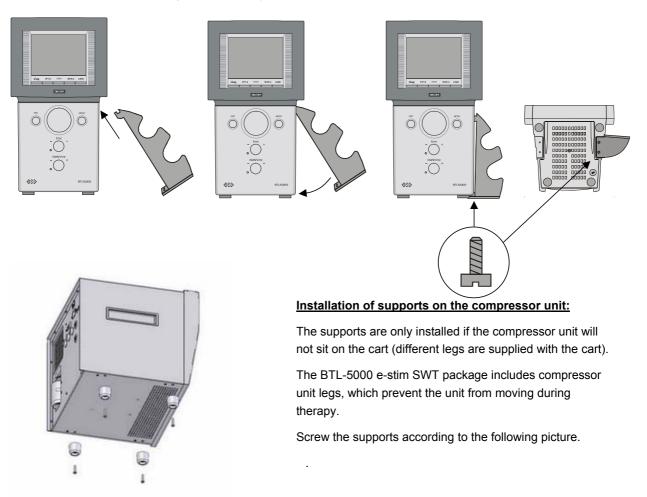
Inspect the package and in case of any damage report it to the delivery service or your distributor. Do not proceed with installation or assembly if the package is damaged.

Unpack the device and place it on a stable horizontal surface suitable for the weight of the device. Always position the unit out of direct sunlight. The device heats up therefore it must be placed away from a direct heat sources such as radiators or room heaters. Cooling of the equipment is provided for by forced air circulation. Cooling vents are located on the rear panel and at the bottom of the BTL-5000 SWT and must not be covered. Do not position the device on a soft surface as it may obstruct the air flow to the bottom cooling vents. Do not put any objects producing heat or containing water or other liquid on the top of the device. Do not place the device close to equipment producing strong electromagnetic, electric or magnetic field (diathermy, X-rays, etc.), as the electronic systems of the device could be undesirably influenced. In case of any questions please call your authorised BTL distributor.

Retain the original packaging to ensure the eventual safe transportation of the device.

Attaching the accessory holder:

Remove the protective caps from the holes on a side of the device. Use a screwdriver to gently slide the blade under the cap and take it out. Align the accessory holder and secure it with two screws from below.







- Connection of the BTL -5000 SWT main unit with the compressor is accomplished by connecting the communication cable to the input/output of the communication link on the relevant unit. Plug the communication cable into the link connector on the main unit (31) and into the link connector (34) on the unit of the compressor.
- 2. At first connect the shockwave compressor to the socket and then the main unit of the BTL -5000 SWT device.

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

Check the correct mains voltage - 230 V (or 115 V)

Before the first connection of the device to the mains, it is necessary to check if both the mains voltage switches (**26** and **28**) are in the position corresponding to local voltage standards, (either in the position 230V or 115V). For details, see the note <u>"Switching the device to different mains voltage"</u> in the chapter **MAINTENANCE AND SAFETY INSTRUCTIONS**. In case of any questions please call your BTL distributor.

3. Connect the supplied accessories step by step to the **output connectors** (**39**) on the rear panel of the shockwave compressor as follows (item No. 3 on the picture):

Turn the connector of the applicator so the red spot on its end is in direct line with the red spot on the output connector of the shockwave compressor and then plug the connector in.



WHEN DISCONNECTING THE CONNECTOR, hold the grooved end part of the applicator of the connector with your fingers, slowly pull the connector towards you and disconnect it carefully.

WARNING!!! DO NOT TURN THE WHOLE CONNECTED CONNECTOR BY FORCE, AS IT CAN DAMAGE THE DEVICE!!!

The device detects the accessories, specifies the type and displays it on the screen in the appropriate tab. In the case of connecting improper accessories by mistake, a warning and help will display on the screen with instructions where to connect the appropriate accessories.



- 4. Activate the ON / OFF power switch of the compressor unit (35).
- 5. Then turn the power supply switch to switch the main unit ON/ OFF (25)
- 6. Press the ON /OFF switch placed on the front panel of the main unit (7)

Note:

After switching on, the device will test all its internal circuits and functions (about 10 - 15 secs) and in the case of any fault the system will signalize it and 'lock' itself into a secure mode. If this situation occurs, please call your authorised BTL distributor.

2.4 OPERATING THE DEVICE

2.4.1 TOUCH SCREEN

The touch screen can display several graphic items, some of them are only informative, some can be pressed and thereby activated. See the following basic items:

- soft buttons (can be pressed to change the indicated values)
- · informative text
- channels tabs (switching between the channels and selection)

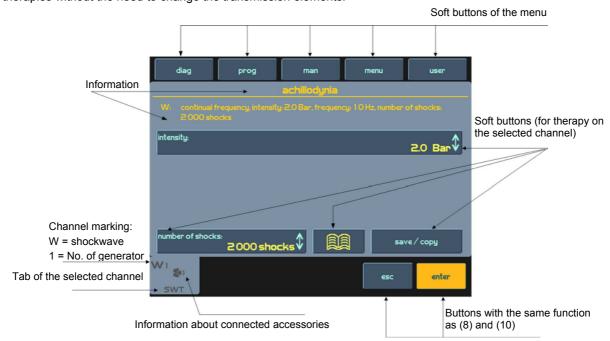
The items on the touch screen can be pressed by a finger or by using a special pointer with a soft tip, so - called touch- pen, which is included in the accessories of the device. The touch screen must not come in contact with any sharp objects, ball pens etc.

Selected channel

The BTL -5000 SWT Series allows the connection of up to two applicators, but only one can be active. Only one so-called "selected channel" can be operated at a time. The selected channel has a light tab. All information on the screen and all control elements relate to this channel. The most important information about therapies on the other channels can be viewed on their tabs.

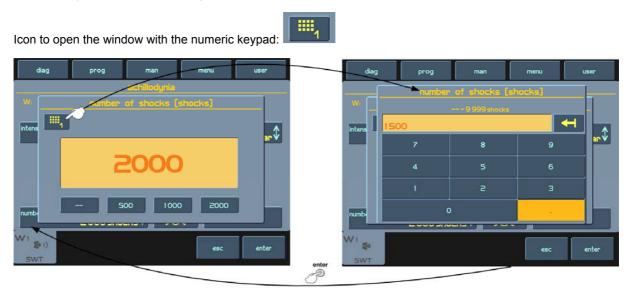


The BTL 5000 SWT does not allow the use of two applicators at the same time. Each applicator can contain a different transmission item, differing in its size. This brings the advantage of applicability for two different therapies without the need to change the transmission elements.



2.4.2 NUMERIC KEYPAD

In addition to setting the numerical values with the **select** knob (**9**) on all the screens, you can also use the "numeric keypad" for quicker setting.



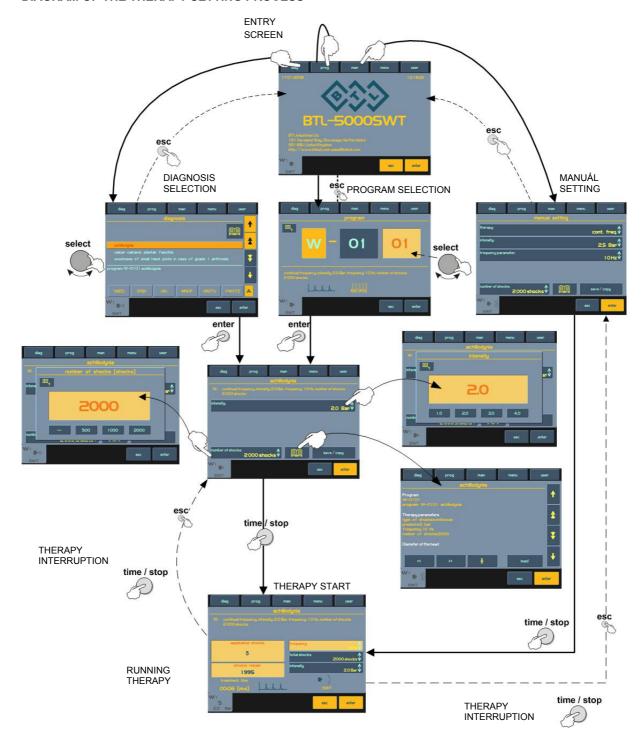
Press the numeric keypad button to display the window with the numeric keypad for the parameter with the light button (on the picture: the button - number of shocks - 2000). Set the required values and return to the previous screen by pressing the **enter** (8) button. If you do not want to enter any values or change the selected parameter, leave the window with the numeric keypad by pressing the **esc** (10) button.

If you enter a value out of the allowed range of values (stated above the entering box) or the device cannot set it, then the value is rounded to the nearest lower allowed value.



2.5 THERAPY (SETTING PRINCIPLE)

2.5.1 DIAGRAM OF THE THERAPY SETTING PROCESS



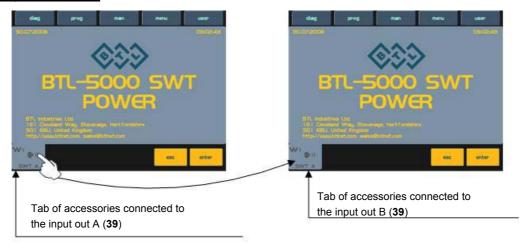


2.5.2 WELCOME SCREEN AND SELECTION OF CHANNELS, TABS AND ACCESSORIES

After switching the device ON, the entry screen includes information on the channel tabs with icons of connected accessories. The number of channels - tabs dependents on the required configuration of the device. By pressing the tab, information of the actual channel displays. Information adjusted on the "invisible channels" will definitely remain saved. Almost the full screen is available for the "selected channel" - see the picture.



Switching the channels:



To switch between the connected accessories, press the W1 tab, see the picture. If both shockwave accessories are connected, then the channel W1 displays the tab of accessories connected to the input **out A** (39), and by pressing it, information on accessories connected to the input **out B** (39) will display.

Examples of information on the tabs:



Tab of channel W1 with no connected accessories



Tab of a selected channel W1, where the **shockwave therapy** can be applied with the connected accessories BTL- 214-1 (**SWT A**)



Tab of a selected channel W1, where the **shockwave therapy** can be applied with the connected accessories BTL- 214-1 (**SWT B**)

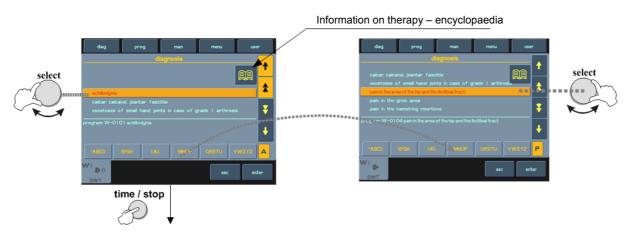


2.5.3 SETTING THERAPY PARAMETERS VIA THE 'DIAG' BUTTON

A list of diagnosis will display after pressing the **diag** (1) button. Each tab – channel – has its own assigned list of diagnosis.

A fast search for diagnosis can be done by pressing the buttons with initial letters. For example, press the **MNOP** button once and all diagnosis beginning with the letter M will display. According to of the number of presses, other letters will display e.g. 2 presses of **MNOP** = N, 3 presses = O and 4 presses = P. The actual selected letter is displayed in the box on the right, next to the buttons.

After finding the required diagnosis, select it by pressing the enter (8) button.

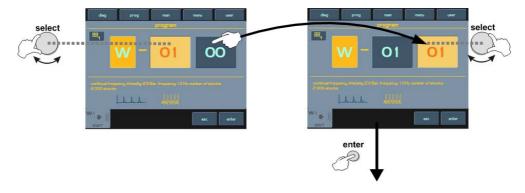


2.5.4 SETTING THERAPY PARAMETERS VIA THE 'PROG' BUTTON

After pressing the **prog** (2) button, a screen will display, where a number of the required therapy program can be entered. Numbers of the particular programs include prefix – a letter matching the selected therapy:

W - Shockwave therapy.

Switching between the two parts of the program number



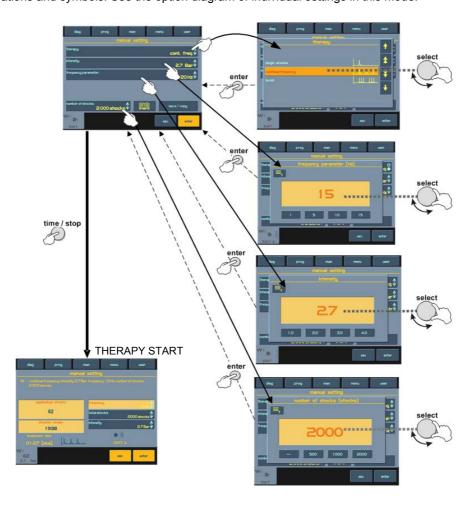
For faster entry of the program number, you can also use the numeric keypad – for more details see the chapter **Numeric keypad**.



2.5.5 SETTING THERAPY PARAMETERS MANUALLY (USER SETUP) VIA THE 'MAN' BUTTON

The screen of the therapy parameters for the user (manual) setting will display by pressing the **man (3)** button. All specifications of the therapy can be adjusted and possibly saved as the user program or the diagnosis.

By pressing the particular soft buttons, the actual menus and setup dialogs will appear. The majority of dialogs include illustrations and symbols. See the option diagram of individual settings in this mode:





2.5.6 THERAPY PARAMETERS SCREEN – ERGONOMIC, STANDARD AND EXPERT MODE

This screen always opens before the start of therapy, by pressing the **diag (1)** or **prog (2)** buttons (see **Diagram of the therapy setting process**). The screen either shows the most important parameters of the therapy – you have selected the ergonomic operation mode, or is shows all information on the therapy – you have selected the expert or standard operation mode. In addition, the expert mode can modify all the parameters.

The differences between the modes are apparent from the following pictures:







Ergonomic mode

Standard mode

Expert mode

The operation mode can be set in the menu of the device by pressing **menu** (4) – for more details see the chapter **Operation mode**. The expert operation mode can be entered from any mode by the quick selection – press the **man** (3) button.

2.5.7 SETTING NUMBER OF SHOCKS

The total number of shocks for the therapy can be adjusted on screen of the therapy parameters, even during the therapy course. The number is set either by pressing the button - number of shocks, or quick selection – by turning the **select (9)** knob.

With the button number of shocks you can select "endless therapy" - see the picture

The endless therapy includes an infinite number of shocks, that can be applied at the start of the therapy (end of therapy is not limited by marginal number of shocks).

2.5.8 SETTING THERAPY INTENSITY

The intensity (power) of the shockwave therapy can be only adjusted on the screen of the therapy parameters, even during the therapy course. The intensity is adjusted either by pressing the **intensity** button or quick selection – by turning the **intensity** (12) knob.

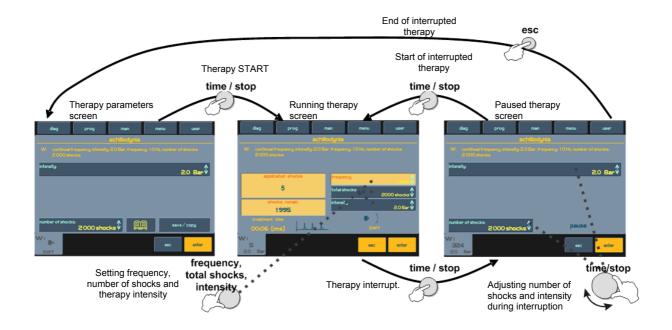
To enter the quick mode of intensity setting, press the intensity knob and turn it at the same time – the adjusted intensity changes much faster.

2.6 COURSE OF THERAPY

2.6.1 START - INTERRUPTION - END OF THERAPY

Start the therapy by pressing **time / stop** (11). The therapy can start only, if the channel screen displays the therapy parameters and all the parameters are adjusted correctly. The device will signalize possible discrepancies.

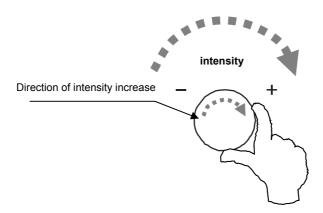




Interrupted therapy – paused therapy – can be restarted by pressing the **time / stop** key and can be finished by pressing **esc** (10).

In pause – interrupted therapy – the parameters of intensity and total number of applied shocks can be modified by turning the **time / stop (11)** knob.

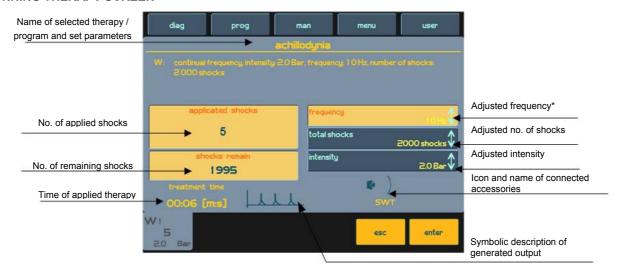
The intensity can be also changed during the therapy by turning the **intensity** (12) knob to the right – to increase the intensity, or to the left – to decrease the intensity. For a quicker intensity setting, press the **intensity** (12) knob while turning. The intensity setting will be much faster when pressing the knob.



The shockwaves therapy can also be started / interrupted by the **button**, located on the shockwave **applicator** (18), or by the foot pedal (40). The initial setup of the button or the pedal is adjusted to AUTO. The device automatically recognizes the holdoff time of the button on the applicator, or the foot pedal and the selected method of control. If you hold the button or the foot pedal for more than 1sec, then after its subsequent release the therapy will stop (as in the **continual** mode, see the chapter **APPLICATOR BUTTON MODE** / **FOOT PEDAL MODE**). During the time of pressing the button or the foot pedal, generation of shockwaves will be in progress. If the button of the applicator or the foot pedal is pressed for less than 1sec, then after its release the device will be set to the option **ON/OFF** (see the chapter **APPLICATOR BUTTON MODE** / **FOOT PEDAL MODE**).



2.6.2 RUNNING THERAPY SCREEN



Pressing the **time / stop** (11) key can also start and interrupt the therapy – see the chapter **Start - interruption - end of therapy**.

*the maximum frequency value according to the relevant configuration of the device is 15 Hz or 22 Hz (see more in the table in the chapter **Device configuration**).

2.7 THERAPY PARAMETERS

Each therapy can have different parameters. For each therapy, only the parameters that describe that therapy will be displayed and these parameters can be adjusted in the manual mode, after pressing the **man** button. An exact description of the parameters for individual therapies can be found in the relevant **User's manual**.

2.8 ENCYCLOPAEDIA

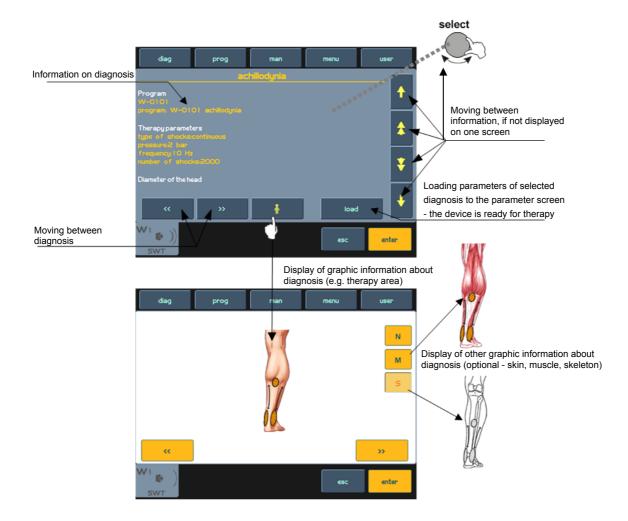
The encyclopaedia includes information on possible therapies and examples of areas for the shockwave application. The device is always supplied with a hard copy of encyclopaedia. Its electronic format is included in the device, and is available from most screens and menus.

Icon to open the encyclopaedia:



If you open the encyclopaedia after a selection of a particular diagnosis, the existent information to the selected diagnosis will be displayed. Otherwise you will enter the contents of the encyclopaedia – the list of particular diagnosis. You can browse through the encyclopaedia by turning **select** (9). After the selection of the required diagnosis, you will enter the particular information about the diagnosis by pressing **enter** (8):





2.9 THERAPY SAVING

The user can select a particular operation after pressing the **save** button. Depending on a selected operation, a form with the appropriate data will be revealed. An example of the procedure is displayed on the following screens.

You can save the therapy always after setting the therapy parameters – i. e. from the **screen of therapy parameters** – see the chapter **Therapy parameters screen** - ergonomic, standard and expert mode. The following information is saved for each shockwave therapy:

- Frequency
- · Number of shocks
- Intensity

When saving the therapy, enter:

- Name of the diagnosis (therapy) will be displayed in list of diagnosis under the diag (1) button
- Program number will be displayed between programs under the prog (2) button
- Description, additional information it is displayed in both lists "below the line"



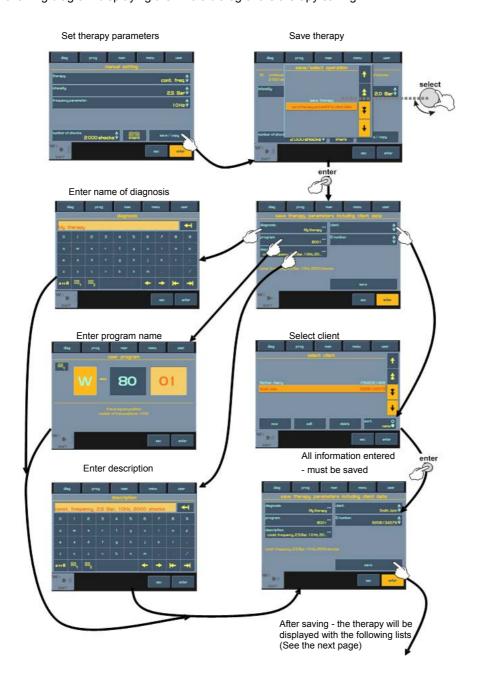
You can choose the number of the saved program from the numbers 8000 to 8999. The device offers you the lowest available number. And during saving it adds a letter of the corresponding compressor belonging to the program. So the resulting number can be e.g.: W- 8001 for the shockwave therapy.

2.9.1 SAVE THERAPY AND ADD IT TO THE CLIENT DATA

All therapy parameters that are saved in this item of the menu are the same as the previous item included in the therapy saving menu. The saved therapy will also appear in both lists – the list of diagnosis and the list of programs.

In addition it will also display in the list of therapies assigned to the entered client.

See the following diagram displaying the whole dialog of the therapy saving.





The saved therapy can be found in these lists on the relevant channel:



2.9.2 END OF THERAPY / SHOCK GENERATION

On a regular basis the therapy ends after the application of the adjusted number of shocks. If, for whatever reason, you want to end or interrupt the therapy before finishing the adjusted number of shocks, it is possible to interrupt the therapy by pressing the **time / stop** key or the button on the applicator. To end the therapy press **esc**.

The generation of shocks will finish by expiry of the adjusted number of shocks applied, or it is possible to finish their generation by releasing (in a state of continual mode) / and pressing again the button of the applicator (in a state of ON /OFF mode) see the chapter **Shockwave setting - applicator button mode**.



3 DEVICE MENU

After pressing menu (4) it is possible to browse the following offers by using the select knob:

- Accessories
- Encyclopaedia see the chapter Encyclopaedia
- Unit settings
- · Specific settings

3.1 ACCESSORIES

In this submenu you can select:

- · Installation of accessories
- Information about connected accessories
- Information about the number of clients and connection of connectors on the rear panel of the device

3.1.1 INSTALLATION OF ACCESSORIES

Each connected accessory has the memory that includes identification data of the actual accessory. According to this data, the device recognizes which accessory is connected, if it is compatible or not, and if the device can work with the connected accessory or not. The memory also contains a serial number of the accessory.

As the memory contains a lot of information and its downloading lasts from 30 seconds to 2 minutes, there is an installation of accessories provided for faster work of the device. After the installation, only the serial number of the accessory is downloaded from the accessory memory and the other information is read from the device memory.

During the installation process, follow the instructions on the screen. In particular:

- During the installation switch off therapies on all the compressors of the device
- Do not have other accessories connected than the one that is being installed (and connect it directly, not via interface cables)

These guides are necessary for decrease of electromagnetic interference that could cause improper downloading of the memory data.

3.1.2 INFORMATION ABOUT ACCESSORIES

This item of the menu displays the information about connected accessories such as Name of the accessory, its serial number etc. And mainly it displays for which generator – output / input – the accessory has been intended and the number of already applied shocks.

dag prog man menu user Accessories W1 A Name SWT Production name / Serial number 21 < 25 - 75 - 75 (100 / 21 45 500000) Production date Designed for device 3 Accessory total applicated shocks 0 Tube total applicated shocks 0 Tube total applicated shocks 1 Tube total applicated shocks 0 Tube total applicated shocks

3.1.3 INFORMATION ABOUT CONNECTORS

In the BTL - 5000 SWT, this item of the menu only includes the specification of blind / connected connectors on the rear panel of the main unit.



3.2 UNIT SETTINGS

This submenu offers the options of setting and displaying these parameters:

- · Password setting
- · Sound setting
- · Screen saver and auto switch-off
- Colour setting
- Setting of display contrast
- · Date and time setting
- Language setting
- · Operation mode
- Touch panel calibration
- · User options
- · Style of operation
- · Setting of HW key
- Unit information
- Unlocking code
- · Service functions

3.2.1 PASSWORD SETTING

This menu can change the code - password demanded by the device when it is switched on. There is no further work with the device possible, without entering this password. As standard, the device is supplied "unlocked" – with the password switched off.



3.2.2 SOUND SETTING

This includes acoustic signalling of the pressed buttons, touch panel, etc. and accomplishment of certain operations (therapy start, therapy interruption, end of therapy etc.). The device includes **standard sounding** as set from the manufacturer, i.e. signalling the therapy operations. All audio tones can be switched off (**without tones**) or modified as required.

This item can edit individual audio schemes, create new ones and modify audio tones for each operation separately.



The sound volume can be sets in the menu item **User options**.



3.2.3 SCREEN SAVER AND AUTO SWITCH-OFF

This includes the setup of the screen saver type, activation time of the screen saver, period of time during which the screen should be switched off and idle time of the whole device.

3.2.4 COLOUR SETTING

The user can set colours of all elements displayed on the screen. There are 50 preset colour schemes available to choose from, or, if not satisfied with any of them, the user can create and save his/her own colour schemes. In the custom colour scheme, the user can step by step select individual elements.

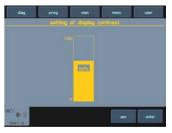
3.2.5 SETTING OF DISPLAY CONTRAST

After selecting this offer, the optimum contrast (readability) of the display can be set by turning the **select (9)** knob.

As the contrast of the screen depends on various factors, (such as temperature), there is a fast and direct setting of the screen contrast, by using the **select (9)** knob while simultaneously holding the **enter (8)** and **esc (10)** keys.







3.2.6 DATE AND TIME SETTING

This allows the user to set the date and time in the device.

3.2.7 LANGUAGE SETTING

Preferred language of the texts displayed in the device. As standard, English is preset by the manufacturer.

3.2.8 OPERATION MODE

Select one of the three modes, see the chapter **Therapy Parameters Screen – Ergonomic, Standard and Expert Mode**. The ergonomic mode is preset by the manufacturer as standard.

3.2.9 TOUCH PANEL CALIBRATION

If the buttons on the touch screen do not react when pressed, the touch screen needs calibration. The calibration procedure is apparent from the screen of the device. It is advisable to use the touch- pen during calibration and follow the instructions, displayed on the screen of the device.

Unsuccessful calibration can always be interrupted by pressing the **esc** button.

To verify the touch screen adjustments, use the "touch panel function test" feature.

3.2.10 USER OPTIONS

Here, you can set:

- Direction of movement in the menu when turning the select (9) knob
- Alphabetical order of diagnosis and certain menus (from A to Z / from Z to A)
- Position of the tab bar (up / down)
- Sound volume



3.2.11 STYLE OF OPERATION

NEW STYLE OF OPERATION

Use this option for main units of the first series (manufactured in 2001 and start of 2002). These devices have the knobs (11) and (12) marked as time (11) and start / stop (12). It is necessary for these devices to select the option new style of operation = no after download of the new version of firmware.

New units are preset by the manufacturer to a new operation mode (new style of operation = yes).

• END OF THERAPY - SETTING ZERO INTENSITY / TIME

After the end of the therapy you can choose, if you want to leave the adjusted data of time and intensity on the screen in zero values, or display the values of the last performed therapy.

• REPEAT SOUND FOR END

This item can switch on / off the function of repeated warning tone of the therapy end.

3.2.12 SETTING OF HW KEY

The device can be remotely configured. For example, if you later decide to purchase the upgrade, the manufacturer (distributor) will send you 64 -digit code (so - called **HW key**) that you will enter and the device will reconfigure its hardware according to the entered key. For the actual HW configuration see the chapter **Unit information.**

3.2.13 UNIT INFORMATION

This item shows certain information about the device – serial number, device type, firmware version, etc. It also contains the information up to when the device will operate – so called "device validity". If the operation of the device is time limited, this item indicates until which date the device stays fully functional.

3.2.14 UNLOCK CODE

If the operation of the device is time limited, then in this item you can enter the so-called "unlocking code" for cancellation of the operational time limitation of the device.

3.2.15 SERVICE FUNCTIONS

REPAIR OF FILES

This checks the file system in the device - system of saved information and repairs possible errors - deletes empty files, etc. We recommend using this feature in the case of lack of memory, if the device rejects to save any data, or if you are in doubt that some data may have been lost, etc.

FILE SYSTEM FORMATTING

If the feature **repair of damaged files** did not help you, select this function. Unfortunately, together with this formatting you will loose all the user data and user setup of the device.

• DELETE ACCESSORIES

This item will delete all the installed accessories – use it, when you install the accessories incorrectly – e.g. bad "scattered" picture on the tab, the connected accessories cannot be detected (permanently displayed **question mark**) etc.

• DEFAULT SETTING WITHOUT LOSS OF USER DATA

Restoration of all functions of the device the way they were preset by the manufacturer. User data – clients, therapies etc. will stay saved.



3.3 SPECIFIC SETTINGS

3.3.1 SHOCKWAVE SETTING

COMPRESSOR MODE

It adjusts two different types of the mode of pressure control in the system: - quick start

- silent mode



When using **quick start**, the pressure control in the system is activated during switching the device on, therefore the therapy start is instantaneous. We recommend using this setting especially during frequent operations. The disadvantage of this mode is a higher noise level of the device.

In **silent mode** the pressure control in the system is activated only immediately before the start of therapy - during entry to the manual screen of the main unit and after leaving, the pressure stops being kept in the system. That eliminates the noise of the device, if not in use. The disadvantage can be the prolonged start of the therapy – according to pressure in the system the start can be extended for about 10 to 15 seconds. We recommend using this setting for quieter operations.

• THERAPY CONTROL

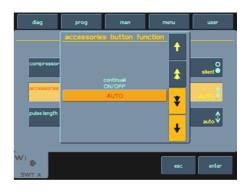
Here, you can set whether you want the therapy to be controlled by the button on the applicator (18) or using the foot pedal connected to the unit of the compressor (40). After selecting the type of therapy control, you can continue by setting the options of the applicator button mode, or the foot pedal mode (see the following chapter).

• APPLICATOR BUTON MODE / FOOT PEDAL MODE

This enables setting of the three different types of modes for the applicator button, or the foot pedal (according to setting in the previous chapter). You can choose from:

- AUTO mode
- Continual mode
- ON/OFF mode

When setting the **AUTO mode** the device automatically recognizes the holdoff time of the button on the applicator (18), or pressing the foot pedal (40) and the selected way of control. If you hold the button or the foot pedal for more than 1sec, then after its subsequent release the therapy will stop (as in the **continual mode**, see below). During the time of pressing the button, or the foot pedal, generation of shockwaves will be in progress.



If the button of the applicator, or the foot pedal is pressed for less than 1sec, then after its release the device will be set to the option **ON/OFF** (see below).

By selecting the **continual mode** you will set the generation of the adjusted shockwaves by only one press of the button on the shockwave applicator (18), or the foot pedal (40), to end the generation of shockwaves, another touch of the button on the applicator is necessary, or pressing the pedal.

During activated option of the **ON/OFF mode** it is necessary to hold the button of the applicator (**18**), or the foot pedal (**40**) pressed throughout the time of the application of shockwaves. Releasing the button or the pedal stops the generation of the shockwaves.

The setting is saved separately for the button of the applicator and for the foot pedal.



3.3.2 APPLICATOR KIT REPLACEMENT WIZARD

If, after a certain time, the applicator stops generating shockwaves correctly, it is possible to change the applicator kit, following the chapter **Procedure of worn-out tube and roller replacement**. Install this replaced kit according to the displayed instructions.

Procedure of the applicator kit replacement on the device:

- 1. Connect the original applicator to the compressor.
- 2. Start the applicator kit replacement guide.
- 3. Now, disconnect the original applicator from the compressor and complete the replacement of the kit (see the chapter **Procedure of worn-out tube and roller replacement)**
- 4. After completion of the kit replacement connect the applicator back to the same channel of the compressor unit.
- 5. Finish the guide.
- 6. The device has successfully installed the replaced kit.



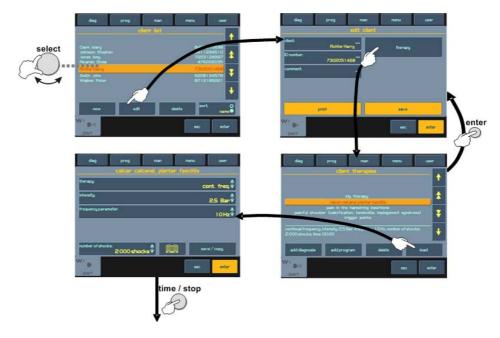
4 USER OPTIONS

Pressing the **user** (5) button will display the menu with items referring to the data saved by the user or referring to certain "special" functions of the shockwave generator:

- Clients
- · User sequences
- User diagnoses / programs
- · Recent therapies

4.1 CLIENTS

This item allows you to enter, edit and delete information about the clients. A particular therapy can be assigned to each client.



4.2 USER SEQUENCES

This feature - user sequences - is not active for the BTL- 5000 SWT Series.



4.3 USER DIAGNOSES/PROGRAMS

It is possible to start the user therapies, adjust their parameters, names and descriptions, delete them and sort them by using the buttons and offers on the screen. It is very similar to the creation of a new diagnosis / program – see the chapter **Therapy saving.** On the tab of the compressor you can only see those therapies that were created and belong to this tab.



4.4 LIST OF RECENT THERAPIES

This feature allows you to choose one of the recent accomplished therapies on the selected tab and after pressing the **load** button you can restart it and view its parameters.





5 **APPLICATION OF SHOCKWAVES**

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

- Provides proper and exactly specified contact of the applicator with the treated tissue during the therapy
- Minimizes transmission of reverse shocks to the hand of the therapist thanks to an inbuilt air damper

The component part of the applicator is an ergonomic hand rest (13) used for a comfortable grip of the applicator and prevents unwanted slipping of the hand from the holder of the applicator during the therapy. The ergonomic hand rest spins and can be any time adjusted into the desired position.

The anatomical shape of the handle allows the therapist to grip the holder of the applicator comfortably in different positions, exactly according to the type of the applied therapy and personal preferences of the therapist (left-handed person, right-handed person, man, woman).

The ergonomic shape of the handle offers the therapist sufficient support during the application, thereby preventing from the development of tiredness of the hand during the therapy.

Examples of holding the shockwave applicator

Examples illustrate the application of shockwaves in different places and various of ways of holding the applicator.

Trigger points

Painful shoulder



Tibial edge syndrome



Calcar calcanei (plantar fasciitis)







Epicondylitis



Achyllodinia



Patellar tendinopathy (jumper's knee)



Trigger points





6 ACCESSORIES

The device is not designed for use in connection with different accessories and other medical equipment except those stated in this manual.

The following list includes a summary of all accessories that can be supplied with the device.

For detailed information on individual accessories see the enclosed leaflet.

Standard BTL accessories:

- 1x trolley for the BTL- 5000 SWT
- 1x shockwave applicator with multi-focus shock transmitter Ø 15mm
- 1x replaceable multi-focus shock transmitter Ø 9m
- 1x replaceable focusing shock transmitter Ø 15mm
- 1x exchangeable kit (includes a spare set of O-rings)
- 1x applicator holder
- 1x gel 1000 ml
- 1x power cord
- 1x communication cable
- 4x silent blocks for compressor unit
- 1x spare fuse T1.6A/250V for the main unit
- 2x spare fuse T6.3A/250V for the compressor unit
- 1x pen for the for touch screen
- 1x CD with the user's manual
- 2x dust cover of the main unit
- · _ markers for output cables

Optional BTL accessories:

- transport case for the BTL- 5000 SWT
- · additional shockwave applicator with focusing shock transmitter
- foot pedal
- gel 300 ml







7 MAINTENANCE AND SAFETY INSTRUCTIONS

Service inspection and measuring of all parameters of the device and relevant recalibration must be executed at intervals shorter than 30 calendar months. The inspection is carried out by authorised BTL customer service on the basis user's order. The manufacturer does not guarantee for the technical parameters and safe operation of the product, if the inspection is not executed on the defined schedule.

Keep the device clean, do not store or use it for a long time in extremely dusty environments and do not spill any liquid onto the surface. Before using check the device and its accessories (especially cables) for mechanical or other damages. Do not use the device if damaged!

Cleaning the surface of the device and its parts:

Clean the BTL - 5000 SWT and its parts only with a lightly damp soft cloth. Use water or a 2 % detergent solution. Never use agents containing alcohol, ammonia, petrol, thinners, etc. To clean the device, do not use abrasive materials as they could damage the surface of the device and e.g. deteriorate metal parts of the applicator. There are no aseptic parts of the device and there is no need to sterilize them.

Cleaning accessories getting in contact with the client (e.g. shock transmitters):

Cleanse after each client using agents approved by the competent health officer. You can use e.g. Sekusept, Bacilol and other. For the cables of the accessories you can use e.g. Incidur spray etc. Surface of the shock transmitter with the cap can be washed with warm water, however for the complete removal of gel from the shock transmitter it is necessary to unscrew the shock transmitter and clean it.

Fuse replacement

The fuse of the main unit is set on the rear panel in a round black box (27). Fuses of the shockwave compressor are placed on the rear panel of the unit in a round black box (37). Check the accuracy of the inserted fuses during their replacement. The main unit (25) and the shockwave compressor (35) both use different types of fuses!

Before replacement, first make sure that the mains switches of the main unit (25) and the shockwave compressor (35) are in "0" position and disconnect the power cords from both units. Use a suitable screwdriver or a coin to turn the segment of the fuse case to the left and remove the fuse. Insert a new fuse and finish the replacement similar way, but turn it to the right. It is prohibited to insert a fuse with different indication, than mentioned on the sign above the fuse box.

This operation can be accomplished only by a person familiarized with this procedure!

Switching the device to different mains voltage

The witch of the main unit (28) is placed under the device in a round black box. The switch of the shockwave compressor (38) is placed on the rear panel of the unit. Before switching over, firstly make sure that the power switches (25, 35) are in the "0" position and disconnect the power cords from the device. Use a suitable screwdriver or a coin to turn the segment of the switches so sign on the switch with the arrow pointing to, correspond to the voltage of the local mains distribution system.



This operation can be accomplished only by person familiarized with this procedure!

If in doubt contact the authorised BTL customer service. The manufacturer is not responsible for any damage incurred by incorrect switchover.

Transport and storage

We recommend retaining the original packaging of the device to ensure its maximum protection during transportation. Disconnect the mains cables and the accessories cables. Avoid heavy shocks. The device must be stored or transported under the conditions defined in the chapter **Technical parameters**.

7.1.1 SHOCK TRANSMITTER REPLACEMENT PROCEDURE

The shock transmitter (14) can be replaced by another one as necessary; three shock transmitters are the part of the BTL - 5000 SWT standard accessories:

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

Replacement procedure:

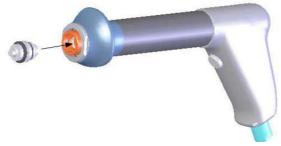
1. Unscrew the screw cap of the shock transmitter by hand (15).



2. Remove the shock transmitter from the applicator (14) (including both O - rings).



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



4. Put the shock transmitter's screw cap of the applicator back on and screw it tightly by hand (15).



7.1.2 PROCEDURE OF WORN-OUT TUBE AND PROJECTILE REPLACEMENT

If the applicator stops working correctly after a certain time, it is possible to change the worn-out system of tube and projectile by using the exchangeable kit that is part of the BTL - 5000 SWT package.

Do not use damaged applicators; otherwise you may cause risk of injury to the operating staff or the client.

The packaging of the spare kit includes:

- 1x exchangeable kit
- 1x key to unscrew / screw the cartridge screw cap
- 1x plastic covering of the exchangeable kit
- 1x set of spare O-rings

Replacement procedure:

1. Firstly, according to the chapter **Applicator kit replacement wizard** start guide of the kit replacement.



2. Unscrew the screw cap of the shock transmitter by hand (15).

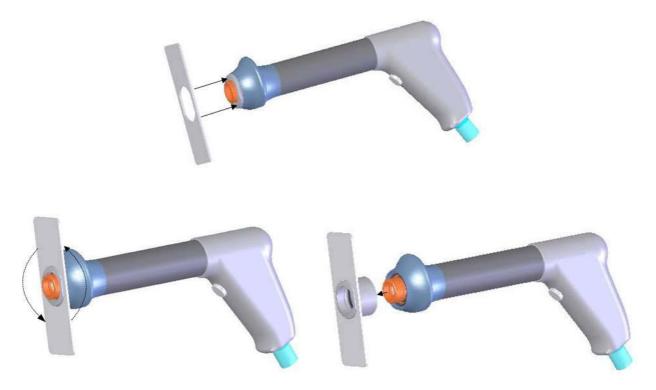


3. Remove the shock transmitter from the applicator (14) (including both O - rings).





4. Using the key (part of the packaging) unscrew the screw cap of the cartridge, follow the pictures.



5. Remove the worn-out kit from the cartridge of the applicator.

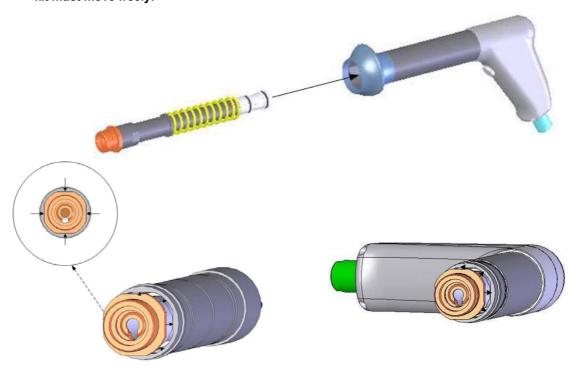


6. Take out a new replaceable kit from the plastic cover.



7. Carefully insert the kit "as it is" into the cartridge of the applicator in the direction shown in the picture (do not touch the rear cover behind the spring, as it is coated with a thin layer of lubricant from production!).

The front cover of the kit must be adjusted in position shown in the picture and inserted in one level with the edge of the outer case of the applicator (push the kit a tiny bit inside the case of the applicator). **The replaced kit must move freely!**



- 8. After the insertion of the kit, firmly screw the screw cap of the cartridge back using the key.
- 9. When replacing the applicator kit we recommend replacing the O-rings on the applicator attachment too. Spare O-rings are included in the accessories. Then put the applicator attachment (14) with both O-rings replaced back in.
- 10. Insert the shock transmitter back to the applicator (14) (including both O rings).
- 11. Put the screw cap of the shock transmitter back on and screw it tightly by hand (15).
- 12. Connect the applicator back to the BTL 5000 SWT device and finish the installation of the new kit according to the chapter **Applicator kit replacement wizard**.



7.2 SAFETY OF THE DEVICE

ATTENTION!





Only accessories connected to the connectors marked as follows can be applied to the client. The client's part is of BF type. Attention, the values of power, electric current or voltage can exceed the safe values of the power, current and voltage.

The device is equipped with a protective system against the connection of different equipment other than supplied by the manufacturer; consequently it does not allow for operation with equipment from other manufacturers.

Do not apply the shockwave to the areas with the body organs containing gases, or close to big nerves, vessels, spinal cord or the head!

The device does not use any pharmaceuticals or matters, which would be applied or were an integral part of the device.





The connectors marked with these signs can be connected with the foot pedal for initiation of the therapy. The foot pedal is placed under the bottom part of the shockwave compressor.



General safety precautions:

- Carefully read the service instructions before the first activation of the device.
- The device should only be used under the control of a physician who determined the indication.
- All personnel, using this device must be knowledgeable in the servicing technique, maintenance and verification of the device and about the principles of safe work with the device.
- Electrical mains connected to the device must be performed according to the existing valid standards (IEC 364) and must be certificated according to these standards. If you are not sure, that the power mains supply is in perfect order, carry out a technical revision by an engineering inspector.
- Crosscheck, whether the parameters of the power mains supply correspond with the requirements of the
 device according to the chapter Technical parameters and if the mains voltage switch on both units of the
 device is switched to the correct voltage according to the parameters of the power mains.
- The device is designed to work in an environment defined in the chapter **Technical parameters**. It must not be used in an environment with threats of e.g. explosion hazard, or water penetration. The device must not be used in connection with flammable anaesthetics, or oxidative gases (O2, N2O etc.).
- Place the device out of direct sunlight and out of reach of strong electromagnetic fields, to avoid undesirable
 interactions. In case of undesirable interactions place the device away from source of disturbance, or contact
 the authorised BTL service centre.
- Before every use, examine the device properly (loose cables, damaged cable insulation, the surface of
 accessories, functions of the display, operating elements etc.) and in case of any discrepancy stop using the
 device and contact the authorised BTL service centre. If the behaviour of the device shows any divergences
 from the function procedure described in the instruction manual, stop using the device and contact the
 authorised BTL service centre.



- If the device shows any signs of defects, or you are in doubt about its correct operation, stop the therapy immediately. If you cannot detect the source of doubts even after careful reading through the instruction manual, appeal to the authorised service department of the BTL device without delay. If the device is used contrary to this instruction manual, or it is used despite the device showing functional divergences from this instruction manual, then the user is responsible for any damage caused by the device!
- Do not disassemble the device in any case. Dismantling and unlocking the safety cover can cause danger of electric shock. Eventual replacement of the lithium battery and the air micro filter must by carried out by authorised BTL service centre.
- All materials and parts that come into direct contact with the client's body (detergents used for cleaning the shock transmitter ...), must meet the appropriate standards, relevant to irritation, allergization, toxicity genotoxicity, carcinogenity according to the standards ISO 10993 - 1, ISO 10993 - 3, ISO 10993 5. The user himself is responsible for all these materials and parts that were not supplied by the BTL device distributor.
- Do not connect the connectors used for the accessories and the other connectors with anything other than the equipment intended by the service instructions, as it can cause danger of electric shock and serious damage of the device!
- The device does not radiate or does not use any toxic materials during its operation, storage and transport under the given conditions.
- When transferring the device from a cold environment into warm, wait before plugging it into the power mains, until the temperature levels (2 hours minimum).
- Before starting the therapy, check whether all the adjusted parameters correspond to your requirements.
- The shock wave is used as the contact therapy Do not in any case apply on damaged skin!
- Do not terminate the application by switching off the mains switch, but by pressing the **time / stop** (11) key. When switching the device off and on, there is a time delay necessary of at least 3 seconds.
- When disposing of the device after years of operation, it is necessary to remove the lithium battery. Dispose
 of it in a proper way do not put the battery into the communal waste. The device can then be disposed of in
 the usual way. The device does not contain any toxic materials that could damage the environment when
 disposed of in the ecological way.
- It is not allowed to use the device and accessories other than according to the instruction manual.
- This device must be kept out of reach of the children.
- The device does not include any components to be reparable by the user, except the replacement kit. Do not remove any covers from the device. Repairs must always be provided by the authorised BTL service centre.
- Do not unplug the applicator during therapy.

7.3 WARRANTY CONDITIONS

The manufacturer provides a 24 months guarantee for the device from the date of purchase mentioned in the certificate of warranty, and 6 months for the accessories and the expendable supplies (guarantee does not apply to common wear of the parts).

Conditions of the guarantee determine, if the device is not used in compliance with this instruction manual, or unprofessional intervention to the device is carried out by third parties. In case of malfunction of the device always contact the authorized BTL service centre.



8 TECHNICAL PARAMETERS

Identification of the device BTL - 5000 SWT BASIC / BTL - 5000 SWT POWER

Operating conditions

Ambient temperature + 10 °C to+ 40 °C
Relative humidity 30 % to 75 %
Atmospheric pressure 700 hPa to 1060 hPa
Position vertical – on legs
Type of operation permanent

Transport and storage conditions

 $\begin{array}{lll} \mbox{Ambient temperature} & -10\ \mbox{°C to} + 55\ \mbox{°C} \\ \mbox{Relative humidity} & 25\ \mbox{\% to} \ 85\ \mbox{\%} \\ \mbox{Atmospheric pressure} & 650\ \mbox{hPa to} \ 1100\ \mbox{hPa} \\ \end{array}$

Position of the main unit any
Position of the compressor basic
Storage time max. 1 year

Additional conditions transport only in the supplied packing

Power supply

Main unit max. Input 80VA Compressor maximum input 550VA

Mains voltage (switched) ~ 99 V to 126 V (115 V nominal), AC

 \sim 198 V to 252 V (230 V nominal), AC

Frequency 50 Hz to 60 Hz

Equipment protection class II (according to IEC 536)

External exchangeable fuse 1xT1.6A / 250V, tube safety fuse 5 x 20 mm, according to IEC 127-2

(main unit)

2xT6.3A / 250V, tube safety fuse 5 x 20 mm, according to IEC 127-2

(compressor unit)

Power switch according to IEC 601 - 1 at the back of the device, position 0 and I

Design

Weight – main unit only max. 5.3 kg Weight – compressor unit max. 20 kg

 $\begin{tabular}{lll} Weight - applicator & max. 900 g including cable \\ Main unit dimensions (w x h x d) & 230 x 390 x 260 mm \\ Compressor unit dimensions (w x h x d) & 330 x 270 x 320 mm \\ Dimensions - applicator (w x h x d) & 40 x 280 x 140 mm \\ \end{tabular}$

IP code according to EN 60 529 IP 20

Display units

Graphic colour touch screen diag. 5.7" / 14.5 cm, resolution 320x240 pixels (BTL - 5000 SWT Basic)

diag. 8.4" / 21.5 cm, 640x480 pixels (BTL - 5000 SWT Power)

Indicators 1x blue for the main unit

1x green, 1x yellow, 2x blue for the compressor

Classification

Applied part type BF Class according to MDD 93/42/EEC IIb



Adjustable values

Shock intensity max. 3 / 5* Bar (maximum instantaneous value)

Shock frequency max. 15 Hz / 22 Hz* Therapy period 0 - 9999 shocks

*only for BTL- 5000 SWT POWER

Shockwave specifications

Maximum positive pressuremax. 15.8 MPaMaximum negative pressuremax. 0.9 MPaEnergy density0.25 mJ/mm²

Steps of adjustable values

Intensity 0.1 Bar Frequency 1 Hz

Total number of pulses per therapy dynamically - according to size from 1 to 50 shocks

8.1 APPLICABLE STANDARDS

Name	IEC, EN, ISO, MDD
Medical electric device. Part 1: General requirements for safety	IEC 601-1
Appendices to EN 601-1	A2, A11 a A12
Medical electric device. Part 1-1: Systems	IEC 60601-1-1
Medical electric device. Part 1: EMC - requirements and examinations	IEC 60601-1-2
ISM – radio interference characteristics	EN 55011
EMC – electrostatic discharge	IEC 61000-4-2
EMC – radiated electromagnetic field	IEC 61000-4-3
EMC – fast electric transient effects/pulse groups	IEC 61000-4-4
EMC – shock pulse	IEC 61000-4-5
Medical electric device. Part 4: Programmable electric medical systems	IEC 60601-1-4
Medical device - risk analysis	ISO 14971
Bio-compatibility of medical device	ISO 10 993-1
Statutory rules for determination of technical requirements to sanitary engineering assets	NV 181/2001 Col. MDD 93/42/EEC
Particular requirements for the safety of equipments for extracorporeally induced lithotripsy	IEC 60601-2-36
Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and	IEC 60601-2-10
muscle stimulators	
Clinical investigation of medical devices for human subjects	ISO 14155



8.2 MANUFACTURER

This product is manufactured in accordance with the EU Medical Devices Directive by:

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9 DEVICE CONFIGURATION

Type:	BTL-5000 SWT BASIC	BTL-5000 SWT POWER
Number of shockwave therapies	1	1
Display, diag.	colour touch screen diag. 5.7"	colour touch screen diag. 8.4"
Client's records	х	х
Encyclopaedia	х	х
Encyclopaedia with anatomical pictures	-	х
Predefined diagnosis	13	13
Preset programs	13	13
Language versions	х	х
Sound schemes	х	х
Colour schemes	х	х
Recent therapy	х	х
Electrotherapy upgrade	-	х
Laser therapy upgrade	-	х
Magnetic therapy upgrade	-	х
Ultrasound therapy upgrade	-	х
Additional applicator*	-	optional
Shockwave parameters :		
Pressure	1.5 - 3 Bar	1.5 - 5 Bar
Frequency	1 - 15 Hz	1 - 22 Hz
Individual shocks mode	х	х
Continual mode	х	х
Burst mode	-	x

^{*} Possible simultaneous connection of two applicators

