BTL-6000 LYMPHASTIM TOPLINE

USER’S MANUAL

BEFORE YOU START

Dear Customer,

Thank you for purchasing BTL technology. All of us at BTL wish you every success with your system. We pride ourselves on being as responsive as possible to our customer's needs. Your suggestions and comments are always welcome since we believe an ongoing relationship with our customers is critically important to our future product line.

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

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

Again, thank you for being a BTL customer.

BTL Industries, Ltd.

CONTENTS

1 BASIC CHARACTERISTICS AND INTENDED USE

1.1 INTENDED USE

The BTL-6000 Lymphastim is a state-of-the-art device which is primarily used for the therapeutic treatment of lymphoedema of the extremities as well as to generally improve blood flow to the extremities.

1.2 USER PROFILE

The device shall be operated by medically educated personnel (physician, physiotherapist). The users shall be familiar with all safety requirements, operating procedures and maintenance instructions.

1.3 OPERATING ENVIRONMENT

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

1.4 PATIENT PROFILE

The use of the device is not limited by age or weight of the patient. The patient must not show any signs of the conditions defined in chapter **Contraindications**. Before the application it is necessary to take the patient's medical history and make a thorough examination to determine whether or not the application of this therapy is suitable for the patient.

1.5 GENERAL CHARACTERISTICS OF THE DEVICE

The device works according to the principle of intermittent pneumatic compression, also known as pressotherapy. The extremity to be treated is inserted into an inflatable sleeve which then massages the extremity when the sleeve is filled with compressed air, regulated by the control unit, via a system of hoses. Each of sleeves consists of a series of mutually independent air chambers that are inflated in a predefined cycle according to the needs of the client.

1.6 CONTRAINDICATIONS OF LYMPHATIC DRAINAGE THERAPY

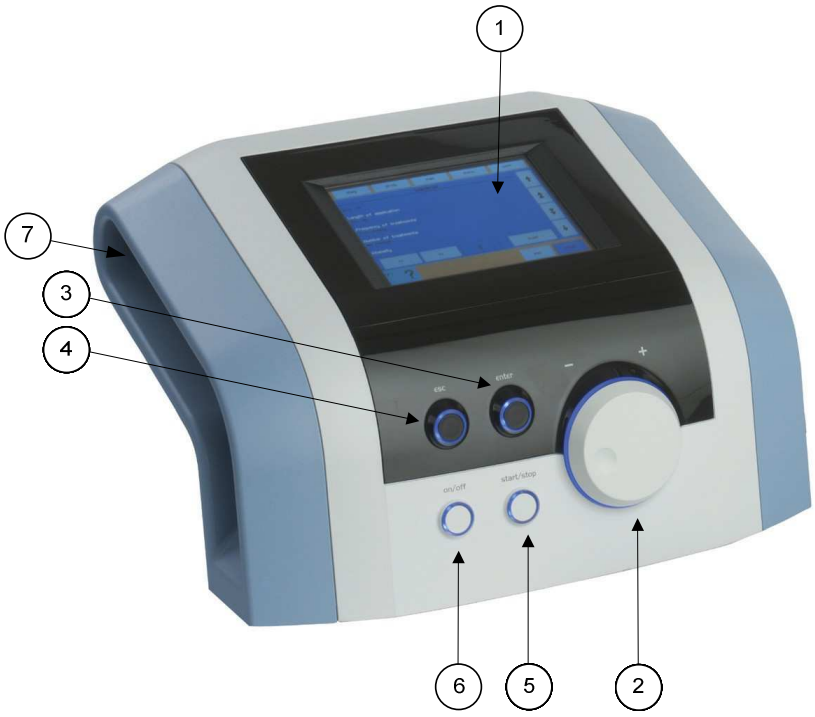
- Acute neuropathy and plexopathy
- Acute pulmonary oedema
- Acute soft-tissue trauma
- Circulatory problems: acute thrombophlebitis, known (or suspected) deep vein thrombosis
- Decompensated cardiovascular diseases
- Epilepsy
- Febrile conditions
- Glaucoma
- Hepatic or renal insufficiency
- Thyroid gland malfunction
- Infectious diseases
- Lymphangitis
- Occlusive processes in lymphatic paths
- Osteosynthesis or joint replacement in treated area
- Pacemaker
- Malignant hypertension
- Obscure pain in abdominal area
- Pathological pregnancy
- Tumorous diseases

1.7 POSSIBLE SIDE EFFECTS OF LYMPHATIC THERAPY

- Temporary increase of pain
- Petechiae
- Capillary rupture – if pressure exceeds the recommended level
- Hematoma
- Vegetative reaction – in clients with a sensitive vegetative system
- Lymphatic congestion – in untreated areas

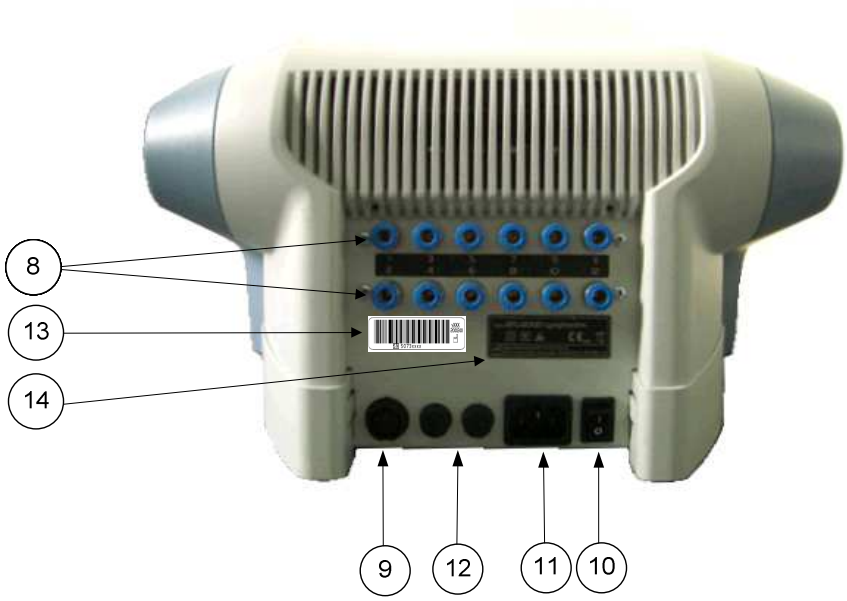
2 OPERATING INSTRUCTIONS

2.1 FRONT PANEL



1. touch screen
2. **select** knob (to select and/or set individual parameters)
3. **enter** key (to confirm the selection or setting)
4. **esc** key (to reject the selection or setting and to return to the previous screen)
5. **start/stop** key (to start and interrupt therapy)
6. **on/off** switch (back lit, in blue, when the control unit is ‘’ON’’.
7. USB port in the space of the handle of the device. The USB port serves only for service purposes such as upload of firmware; it is not designed for therapy use!

2.2 REAR PANEL



8. connectors for the hoses of the basic tube
9. connector for accessory detection
10. main power switch
11. socket for connection of the main power cable 230 V (or 110 V) to the device
12. main fuses
13. production label with serial number and manufacturing date
14. type label – contains information: type of the device, manufacturer, safety and warning symbols

2.3 ASSEMBLY AND SET-UP

Inspect the box for damage and report any damage to the transport carrier and the distributor. Do not proceed with assembly and set-up if the box is damaged. After bringing the device from a cold environment into a warm one, allow it to adapt to room temperature for approximately 2 hours. Keep the original box and packaging to ensure safe future transport of the device.

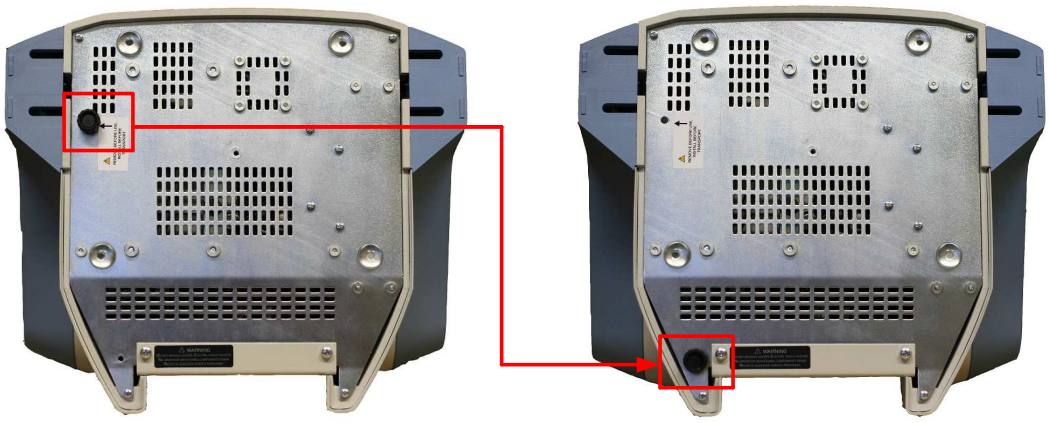
Unpack the device and place it on a stable horizontal surface which is suitable for its weight. We recommend using the BTL cart, which can be purchased separately. Always position the device out of direct sunlight. During operation, the control unit gets warm, so it must not be positioned near direct heat sources. The control unit is self-cooled by forced air circulation. The cooling vents are located on the rear panel and on the bottom of the control unit. Do not cover or block these vents. Allow a minimum of 4 inches (10 cm) clearance behind the rear panel. Do not place the device on a soft surface (such as a towel) which may obstruct air flow to the bottom cooling vents.

Do not put any heat-producing devices or 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.

Please contact an authorized BTL service with any questions you may have.

Set-up Procedure:

1. Unscrew the locking bolt on the bottom of the device. The bolt serves to prevent the vibration and jarring of the pump during transport. Keep the bolt for future use (screw it to the bottom of the device, see the picture below) or use it for secure the device the (optional) cart.



2. In order to connect the accessories of the BTL-6000 Lymphastim, the user must use the connector ports (**8**). Make sure that the hoses (in the hose bundle) are connected properly according to their labels (Hose 1 to Connector Port 1, etc.). Connect the detection cable of the accessory to the detection port (**9**). For important details about connection and disconnection see below **Special Operational Notes**.

   The connector includes small o-rings that can slide down during unauthorized manipulation.

   If you hear a sound of air leaking from the connector, please check the o-rings and change them if needed.

3. Connect the selected accessory to the basic tube. Lymphatic drainage is accomplished by using special accessory sleeves, which are designed for individual body parts: The arms, the legs and the waist. Each accessory is equipped with a simple connector for connecting to the main bundle of hoses. This means that it is not necessary to plug and unplug individual hoses from the control unit for various accessory replacement/attachment.

4. Connect the device to the power source by using the main cable which should be plugged in the power supply connection port (**11**) and to a 110 V or a 230 V electrical outlet. The device will recognize the voltage automatically. Plug the device directly into the power source. Do not use any extension cords, splitters or voltage adaptors.
5. To turn on the device, switch on the main power switch (**10**) to the "I" position.
6. After pressing the **on/off** switch (**6**) on the front panel of the device the welcome screen will appear. The device is ready for use when the buttons on the front panel are active.
7. The device will automatically detect the accessories/applicators, then it will specify the type of accessories/applicators and then it will display it on the screen in the appropriate tab. In case of improper accessories connection, a warning and a help tip will appear on the screen with instructions as to where to properly connect the appropriate accessories.
8. To turn off the device, press the **on/off** button (6) on the front panel AND THEN turn off the main power switch (**10**) on the rear panel. This will protect the device against electrical damage.

Special Operational Notes:

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

Connecting and disconnecting the hoses to the device:

To connect the hose, grip it and plug it into the respective connector and push.

To disconnect the hose, grip the blue ring of the connector with your fingers, push it and then pull the hose out with the other hand.

When disconnecting the connectors with hoses, it is necessary to remove each hose individually, one by one, not the entire connector at the same time.

Connection of the cable for accessories detection:

To connect the accessory detection cable, plug in the cable connector, push the indented lock ring in and turn it clockwise to lock it in place.

ATTENTION! To disconnect the connector, grip the indented lock ring, not the entire connector. Turn the indented lock ring counter-clockwise and only after the lock ring has been released, should the connector be pulled to disconnect it. Continue to grip the indented lock ring with your fingers while pulling.

CAUTION!!! TURNING THE CONNECTOR BY FORCE COULD RESULT IN SERIOUS DAMAGE TO THE DEVICE!

2.4 BASIC OPERATION

2.4.1 WELCOME SCREEN AND TABS OF ACCESSORIES

The welcome screen displays information about the connected accessories and the therapy setting tabs. Data regarding connected accessories is indicated by a series of icons, which are explained below.

Displaying of the type of accessory:

Tab of Channel Y1: Indicates that no accessories are connected.

Tab of Channel Y1: Indicates that an accessory is connected but it is not detected.

Tab of Channel Y1: Indicates that the arm-accessory is connected.

Tab of Channel Y1: Indicates that the leg-accessory is connected.

Tab of Channel Y1: Indicates that the trouser-accessory is connected.

Tab of Channel Y1: Indicates that the accessories adaptor for 2 legs or for 2 arms is connected.

2.4.2 TOUCH SCREEN

The touch screen contains several graphic elements. Some are only for informative purposes and the others can be pressed and activated. These basic elements include:

- 3D buttons (by pressing, the user can change their values)
- Information texts

The touch screen can be operated by touch or by using the special soft-tip stylus that is supplied with the control unit. Do not touch the screen with any sharp objects (such as a writing instrument, such as a pen or pencil).

BTL-6000 Lymphastim allows the connection of accessories for various therapies; the basic ones are designed for lower and upper extremities.

2.4.3 NUMERIC KEYBOARD

The user can enter numerical values by using the numeric keyboard for faster setting of values (instead of using the **select** knob).

The icon for the opening of the numeric keyboard window: 

By pressing the numeric keyboard icon button, the user can open the numeric keyboard window. After entering the applicable value(s) and pressing **enter** the user is returned to the previous screen. If you do not want to change the selected parameter press **esc** to exit the numeric keyboard window. If the user enters a value outside of the allowed value range (the allowed value range is stated above the enter field) or if the unit cannot set the required value, the value will be rounded down to the closest allowed value.

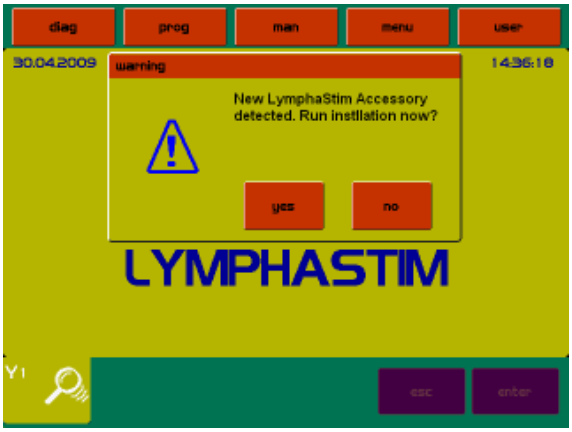
2.4.4 ALPHANUMERIC KEYBOARD

For functions requiring entering text, the alphanumeric keyboard pops-up after clicking on the respective field.

2.5 THERAPY SETTINGS

2.5.1 CONNECTING ACCESSORIES

When a new accessory is connected to the device for the first time, installation is required:



Select the right accessory from the menu:

To confirm the installation of a new accessory, press the **yes** button. Then, select the correct accessory and press the **install** button or **enter**. The data will be stored in the control unit and the device will automatically remember the appropriate accessory.

Notes:

To connect the interface for either both arms and/or both legs, the user needs to respectively select legs or arms accessory.

If the device will be always used with the interface for either 2 arms or 2 legs, then the user can identify the adaptor as the respective accessory (arm or leg). In this way, the user does not have to identify the accessory each time.

2.5.2 SETTING THERAPY PARAMETERS VIA SELECTION OF DIAGNOSIS: THE “DIAG” BUTTON

A list of diagnoses will appear after pressing the **diag** button. The diagnoses are divided into two basic groups:

- Beauty / Aesthetic
- Medical

If the user has diagnoses or sequences added to clients, the menu will contain the following additional items:

- User diagnoses / programs
- User sequences

To find a diagnosis quickly, press the button for the first letter of the therapy. For example, after pressing the **MNOP** button once, there are listed diagnoses starting with the first letter, in this case "M". Other letters are searched depending on how many times the button is pressed. The selected letter will be displayed in the box to the right of the buttons.

The therapy number is written in the footnote for each diagnosis. For details about the therapy program, click the encyclopaedia icon.

After finding the required diagnoses press **enter** to select. Then the screen will appear where the user can select the accessory (arm, leg, trousers) to be used. The user can only select the accessory which is currently connected to the control unit.

For each therapy session, the duration and pressure is already preset. Both can be changed at the user's discretion. The duration of therapy can be altered before the start of therapy or during therapy (while paused). The pressure in the accessory chambers can be altered changed before the start of therapy or during therapy in order to prevent discomfort of the client. To change the values of these the functions, click on the selected icon and change the setting. Then, press **enter** to confirm the selection.

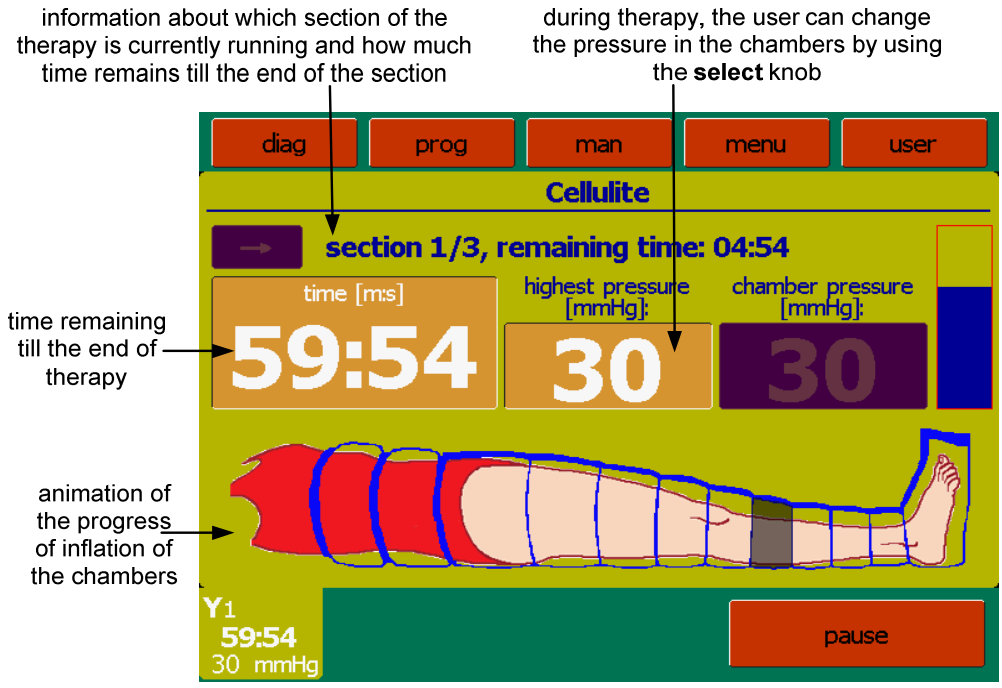
2.5.3 START, INTERRUPTION AND END OF THERAPY

To start therapy, press the **start/stop** key. Therapy can only be started when the therapy parameters are set correctly and displayed on the screen. The device will warn you of any discrepancies.

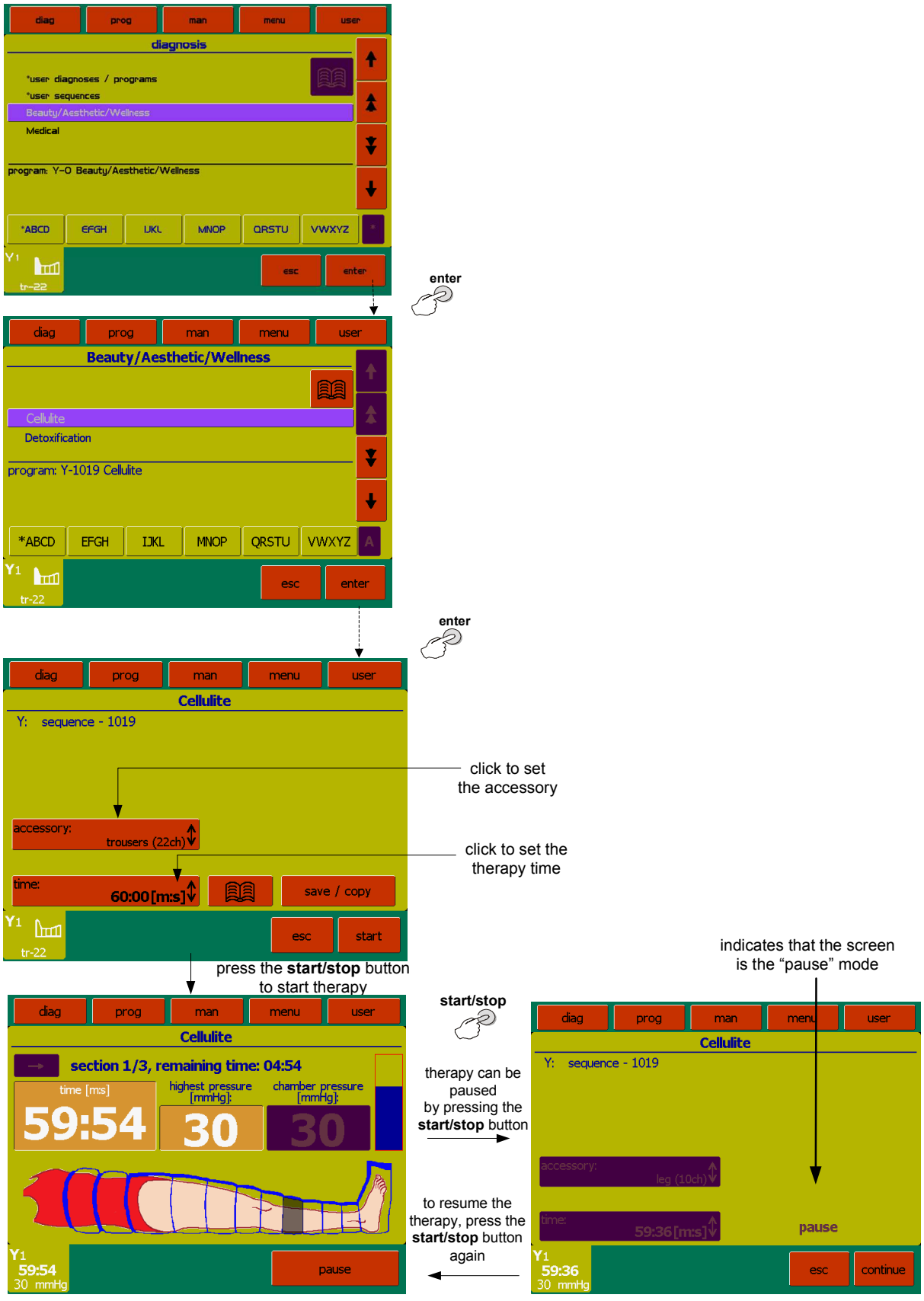
To interrupt/pause therapy, press the **start/stop** key. While paused, it is possible to modify the duration and the pressure. To resume therapy, press **continue** key on the screen. During therapy, the user can still modify the pressure by using the **select** knob.

Therapy ends after the set time has elapsed. If the set time elapses in the middle of a running therapy cycle, the device will complete the therapy cycle. This default setting can be changed by using of the end mode function. For more information, see chapter **End-mode of Therapy**. To end therapy, press **esc** (in pause).

Running therapy screen:



Setting, starting and interruption of therapy:



2.5.4 SAVING THERAPY

The user can save a therapy sequence after inputting a set of therapy parameters from the manual therapy parameters screen. After pressing the **save / copy** button, two options are offered:

- Save therapy

  The user can save the therapy under their user name and assign a new program number to it. A total of 495 therapy programs can be stored.

- Save therapy and add it to the client data

  The user can save the therapy program for a particular client, either by name or by client identification number. Click on **client** or **ID** option. After selecting the client, press **enter** to save the therapy.

For both options of saving a therapy, the user will have to enter the following data:

- Name of diagnosis (therapy), which will be displayed on the list of diagnoses under the **diag** button
- Program number, which will be displayed on the list of programs under the **prog** button
- Description or additional information to be displayed

The following information is saved for each therapy:

- Pressure parameters
- Method of inflation
- Timing parameters
- Time
- Accessory

2.5.5 SETTING THERAPY PARAMETERS VIA SELECTION OF PROGRAM: THE “PROG” BUTTON

After pressing the **prog** button, a screen will appear where the number of the required therapy program can be entered. All programs will be prefixed with the letter “Y” (lymphatic drainage).

After entering the selected program number press **enter** to confirm the selected diagnosis. The details about the selected program of therapy will then be shown; the user can select the **accessory** for the therapy as well as the **time** (duration) of the therapy.

2.5.6 USER SETTING OF THERAPY PARAMETERS: THE “MAN” BUTTON

The therapy parameter screen for user (manual) settings will appear after pressing the **man** button. All therapy parameters can be set and saved as **user diagnoses / programs**.

Pressing of individual buttons will open an individual menu and pop-up boxes for the settings. Most of the pop-ups are accompanied with illustrative pictures and/or symbols.

To run only one therapy program, choose the setting **therapy: Lymphastim.**

To run several therapy programs consecutively, choose the setting **therapy: sequence**.

2.5.6.1 Manual Setting of Therapy: Lymphastim

Manual setting allows the user to set one program of therapy. After setting the items, the user can save the therapy as a separate program by using of the **save / copy** button (see chapter **Saving therapy**). The user can save up to 999 new programs. The initial digit of program number is always "**8**" (i.e. 8001-8999).

In the mode **Therapy: Lymphastim** you can save the following:

- **Pressure parameters**
  - Basic: Setting the pressure gradient direction and value (in %) and the pressure value. The pressure will be the same in all chambers of the accessory.
  - Advanced: Setting the pressure separately for each chamber and the possibility to disconnect selected chambers by clicking on the desired chamber in the picture and then clicking the "disable chamber" button. The disconnected chambers will then be coloured a darker shade.
- **Method of inflation**

  This function allows the user to select one of the 15 pre-programmed methods of inflation. The inflation process is animation on the screen.
- **Accessory**

  Select the current accessory (leg, trousers, or arm).
- **Timing parameters**

  The user can set the timing parameters (in seconds) for the following functions:
  - Inflation speed
  - Hold time
  - Cycle pause

2.5.6.2 Manual Setting of Therapy: Sequence

Therapy sequence means a therapeutic session which consists of several programs running successively.

The user can select either to modify sequences of an existing therapy or to set a new therapeutic sequence. If the user decides to modify the sequence of an existing therapy, he/she must find it using the program number or the diagnosis name. After clicking on the sequence parameters, the user can add, modify or delete programs, included in the given therapy sequence. Once the user changes the parameters of an existing therapy sequence, the device will automatically prompt the user to save the sequence as a new one.

In the mode **Therapy: sequence** you can select/save the following:

- **Name of diagnoses**

  The user can enter the name of the new sequence or modify that of a previously saved one.
- **No.**

  A new sequence number which will start with 9 will be automatically selected by the device. It is possible to store up to 499 new numbers (9500-9999). The user can choose their own number, however it is not possible to change the first number (9). If the user does not set a number, the device will automatically choose the first available number in its memory.
- **Pressure**

2.6 USER SETTINGS: THE “USER” BUTTON

Pressing the "**user"** button will display the menu with items related to the data saved by the user:

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

2.6.1 CLIENTS

This selection allows the user to enter, edit and delete information about clients. The performed therapies can be assigned to each client.

The following information can be saved with each client:

- Name (surname first)
- ID Number
- Comment
- Therapies

After opening a field, the alphanumeric keyboard appears for entering the data (see chapter **Alphanumeric keyboard**).

The user can sort the clients alphabetically by name or numerically by identification number.

2.6.2 USER SEQUENCES

List of custom sequences set by the user.

2.6.3 USER DIAGNOSES / PROGRAMS

It is possible to start, delete or sort the therapy programs and the edit parameters, names and descriptions by using the buttons and options on the screen.

2.6.4 RECENT THERAPIES

This feature allows the user to select one of the recently performed therapies and after pressing the **load** button; the user can restart it and view its parameters.

2.7 UNIT SETTINGS: THE “MENU” BUTTON

After pressing the **menu** button you can scroll in the following menus by means of the **select** knob.

- Accessories
- Encyclopaedia
- Unit settings
- Specific settings

2.7.1 ACCESSORIES

2.7.1.1 Information

This item of the menu displays the information about any connected accessories such as name of the accessory, its serial number, etc.

2.7.2 ENCYCLOPAEDIA

The encyclopaedia provides information about diagnoses, possible therapies and examples of how to use the device. The electronic version in the device is accessible from most screens and from the device menu.

Icon for opening of **encyclopaedia**: 

If you open the encyclopaedia only after selection of a specific diagnosis, the information on the selected diagnosis will be displayed. Otherwise you will enter the encyclopaedia contents – the list of individual diagnoses. Here you can scroll by means of the **select** knob. After selecting the required diagnosis press the **enter** key to get to the specific information on the diagnosis:

2.7.3 UNIT SETTINGS

This submenu allows the setting and displaying of the following parameters:

- Password setting
- Sound setting
- Screen saver and auto switch-off
- Colour setting
- Setting of display contrast
- LED brightness settings
- Date and time setting
- Language setting
- Operation mode
- Touch panel calibration
- User options
- Style of operation
- Setting of hw key
- Unit information
- Unlock code
- User accounts
- Firmware upgrade
- Service functions
- Dialog history

2.7.3.1 Password Setting

This option allows the user to set or to change the device's password which is required by the device after the switch-on. Without entering the password, further work with the device is impossible. The device standard comes with this function disabled.

2.7.3.2 Sound Setting

The function sets audio signalling of pressing buttons / touch panel and of performance of various processes (start / interruption / end of therapy). The factory pre-sets are set to **standard**, which means that there will be audio signalling of therapy processes. The user can mute the sounds (**no sound**) or select another audio profile. The user can edit sound schemes, insert new ones or modify sound for each event separately. The user own setting will always be displayed at the end of the list of sound schemes.

Volume can be set in the **User Options** menu item.

2.7.3.3 Screen Saver and Auto Switch-off

Selects the design of the screen saver and sets the time for its activation. The function also sets the idle time for auto power-off of the screen and for auto power-off of the entire device. To cancel the screensaver mode, press the **esc** key on the device. Do not forget to save the settings by pressing the **enter** key.

2.7.3.4 Colour Setting

The user can set the colours of all elements displayed on the screen. 50 pre-set colour schemes are available, which the user can select from. If the user is not satisfied with any of them, then it is possible to create and save custom colour schemes. In the custom colour scheme, the user can successively select individual elements.

2.7.3.5 Setting of Display Contrast

Selection of this option by means of the **select** knob enables to set the optimum contrast (readability) of the display.

As the display contrast depends on many factors (e.g. the temperature of the display), it is possible to quickly change the contrast by pressing the **enter** (**3**) and **esc** (**4**) keys simultaneously and turn the **select** knob (**2**) (with both keys still pressed).

2.7.3.6 LED brightness Settings

This function allows the user to set the brightness of the LED backlighting of the buttons and the select knob.

2.7.3.7 Date and Time Setting

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

2.7.3.8 Language Setting

This function allows the user to select the language of the text displayed. English is the factory pre-set.

2.7.3.9 Operation Mode

This function allows the user to select one of the three modes of operation of the device: ergonomic, standard and expert. The factory-preset is the ergonomic mode.

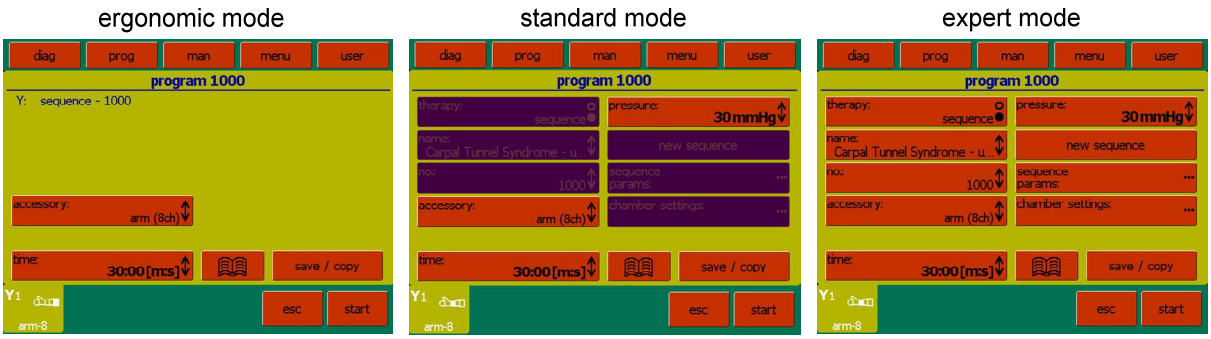
The differences between the operation modes consist of the possibilities of modification of therapy settings on the screen, which always appears before starting therapy by using of the **diag** or **prog** button. The expert mode of operation can be entered anytime by pressing the **man** button.

Ergonomic mode: The user only sees the most important parameters and can change accessories and therapy time.

Standard mode: The user sees all information about therapy and can change accessories, pressure and therapy time.

Expert mode: The user will see and can change all therapy parameters.

The differences between the modes can be best seen on the therapy settings screen, which always appears before starting of therapy.



2.7.3.10 Touch Panel Calibration

If the buttons on the touch screen do not react when pressed, the touch screen needs calibration. The process of calibration is shown on the screen. During calibration, use the touch-pen (stylus) and follow the on-screen instructions.

Calibration, if not successful, can be interrupted at any time by pressing the **esc** button.

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

2.7.3.11 User Options

This submenu allows the setting and displaying of the following parameters:

- movement direction within menu (standard / reverse)
- sorting diagnoses (in ascending order / in descending order)
- tab position (top / bottom)
- sound volume

2.7.3.12 Style of Operation

This submenu allows the setting and displaying of the following parameters:

- **Set zero intensity**

  Here the user can select whether after the end of therapy, the intensity values on the screen shall remain zero, or whether the values of the last performed therapy will be displayed.

- **Set zero time**

  Here the user can select whether after the end of therapy, the time values on the screen shall remain zero, or whether the values of the last performed therapy will be displayed.

- **Zero intensity for sequences**

  Here the user can select whether after the end of therapy, the sequence intensity value on the screen shall remain zero, or whether the values of the last performed therapy will be displayed.

- **Repeat sound for end**

  The user can switch on/off the function of the repeating audio signal which indicates the end of therapy.

2.7.3.13 Setting of HW Key

Function designed for future upgrade of the device**.**

2.7.3.14 Unit Information

This option displays some info about the unit (serial number, type of the device, firmware version, etc.). It also contains the information about "device validity", i.e. till when the device will be fully functional.

2.7.3.15 Unlock Code

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

2.7.3.16 User Accounts

You can create an account for every user who operates the device.

2.7.3.17 Firmware upgrade

The function allows upgrading the firmware.

2.7.3.18 Service Functions

- **Repair of files**
  Checks the file system in the unit and repairs possible errors – deletes files with no link etc. Recommended for use in case of a lack of memory, if the unit refuses to save data, or if the user think that some data have been lost, etc.
- **File system formatting**
  Clears all data and programs created by the user. The user may select this function if the “repair of files” function did not help. Unfortunately, all user data and user settings of the device will be lost.
- **Delete accessories**
  Deletes all installed accessories. Use only in case of improper installation – corrupted accessory image on the channel tab, connected accessories are not detected (the “**?**” symbol is displayed), etc.
- **Default setting without loss of user data**
  All factory settings are restored. User data, such as clients, therapies, etc. are preserved.

2.7.4 SPECIFIC SETTINGS

- Accessory installation
- Pressure unit settings
- End-mode of the therapy
- Sleeve emptying after the treatment

2.7.4.1 Accessory Installation

Each connected accessory has a memory that includes identification data of this accessory. According to these data the unit recognizes which accessory is connected, whether it is compatible, whether the unit can work with it, and decides accordingly, how it will work with the accessory. The memory also contains the unique serial number of the accessory.
The memory contains a lot of information and reading it takes from 30 seconds to 2 minutes. The “installation of accessories” function serves for faster functioning of the unit. After the installation, under normal operation of the device only the serial number of the accessory is read from the accessory’s memory and the other information is read from the unit’s memory.

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

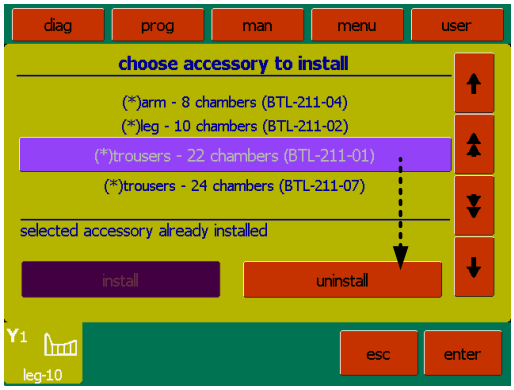
- All therapies must be completed/stopped during installation
- Only one accessory may be connected to the unit at a time.

Following these rules is necessary to reduce electromagnetic interference, which could cause improper reading of the memory data.

This submenu allows the setting and displaying of the following parameters:

- **Install new accessory**

  Select the accessory that will be installed after clicking the **install** button; at the same time the user can uninstall all accessories here. If there is an asterisk (*) next to the accessory, it means that the accessory is installed; in such case the box **uninstall** is active instead of **install**.



- **Select current accessory**

  The user can select an accessory from among the installed accessories; this can only be done if another accessory is currently being detected by the device.

- **Uninstall current accessory.**

  This function will only uninstall the current selected accessory.

- **Uninstall all**

  This function will uninstall all installed accessories.

2.7.4.2 Pressure Unit Settings

The menu allows choosing the unit of pressure - *mmHg* or *kPa*.

2.7.4.3 End-mode of Therapy

Allows the user to select the mode for the end of therapy by either:

- Time priority
  Therapy ends a pre-set time limit, regardless whether all therapeutic cycles completed or not.
- Treatment cycle priority
  The therapy ends only after completion of all cycles, which the therapy includes, regardless of the set time of therapy.

2.7.4.4 Deflation of Sleeves after Therapy

The function allows selecting whether or not the accessory will be deflated after the end of therapy.

3 ACCESSORIES

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

The following is a list of all accessories that can be used with the BTL-6000 Lymphastim Topline.

Standard accessories:

- 1x Main cable
- 2x Spare fuses T2AL / 250V
- 1x Stylus (touch-pen)
- 1x User's Manual
- 1x Basic tube with connector
- 24x O-rings

Optional accessories:

- Arm 8 chambers
- Arm 8 chambers – size S
- Leg 10 chambers – size L
- Leg 10 chambers – size M
- Leg 10 chambers – size S
- Trousers 24 chambers
- Trousers 24 chambers with Velcro
- Trousers 24 chambers with Velcro – size XL
- Trousers 24 chambers with zipper
- Extension strip for leg applicator size L
- Extension strip for leg applicator size M and size S
- Extension strip for trousers
- Extension strip for trousers 24 chambers with zipper
- Interface for 2 arms or 2 legs
- Trolley

4 MAINTENANCE

The service inspection including measuring of all parameters of the device and possible recalibration shall be performed at intervals shorter than 30 months, unless a shorter period of time is set by local regulations. The inspection shall be performed by an authorized BTL service. If the inspection is not performed in at least 30-month intervals, the manufacturer does not guarantee the technical parameters or safe operation of the product.

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

Exterior cleaning of the device: Use a soft cloth slightly moistened with water or with a 2 % detergent solution to clean the exterior of the BTL-6000 Lymphastim device and its parts. Never use cleaning agents containing alcohol, ammonia, benzine, thinners, etc.

Never use abrasive cleaning materials which will scratch the device's surfaces. No parts of the device require sterilization. Care should be given to prevent water or other liquids from getting inside the device.

Cleaning and maintenance of accessories which come into contact with the client: These parts must be cleaned after each use. The accessory has to be worn over the client's clothes, thus it is not necessary to disinfect the accessory after each use. If necessary, the accessory can be cleaned and disinfected using cleaning agents which have been approved by a competent health officer (e.g. Sekusept, Bacilol, and Incidur Spray). For the cables of device, the user can use Incidur Spray and the alike. DO NOT USE SOLVENTS!!!

After the end of therapy, the device removes the air from the accessories and sets it in the standby position. It is not necessary to disconnect the accessory manually. The accessories can be punctured by sharp object. Be careful when handling the accessories near sharp objects such as knives or shears. Do not bend the tubes too much.

Fuse replacement: The fuses are 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 power cable 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!

Plugging the device into electrical outlet: The device is equipped with automatic voltage detection. It can be used with both 110 V and 230 V electricity.

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.
- Tighten the arresting screw which is found on the bottom of the device. This screw locks the compressor pump in position for transport.
- 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**.

5 SAFETY PRECAUTIONS

- Before turning on the device for the first time, read this manual carefully.
- The applied parts are classified as Type BF. Inner surface of Lymphastim applicators is considered as applied part.
- The device is equipped with a protection system that prevents the connection of accessories other than those supplied by the manufacturer.
- The accessory has to be worn over the client's clothes or cloth specially designed for lymphatic drainage therapy.
- The device does not use any drugs, creams, gels or other substances which are an integral part or which are applied by its use.
- The device may only be used under the supervision of the physician prescribed the treatment.
- All staff members must be properly trained before using the device. This training should include operation, maintenance and safety precautions.
- The electrical wiring to which the device is to be connected must be installed and tested according to the existing valid standards. If the user is not sure that the main power supply is safe, it should be inspected by an inspection engineer.
- Check whether the parameters of the main power supply correspond to the requirements of the device according to chapter **Technical Parameters**. Also, verify that the voltage switch on the device is turn to the correct voltage according to the main power supply parameters.
- The device requires the environmental conditions that are stated in the chapter **Technical Parameters**. It must not be used in an environment where there is a danger of explosion or of water penetrating the device. The device cannot be in connection with flammable anaesthetics or oxidizing gasses (O_2, N_2O, etc.).
- Do not place the device in direct sunlight or near strong electromagnetic fields to prevent mutual functionality influence. If this happens, move the device further away from the source of interference or contact an authorized BTL service.
- Inspect the device thoroughly before each use. Look for loose cables, cracked cable insulation, functional behavioural difference in the displays or controls. If any anomalies or inconsistencies are found, stop using the device and contact an authorized BTL service.
- If the device shows any defect or if the user has any doubts concerning its correct and safe functioning, terminate therapy immediately. If the user does not determine the source of concern after a thorough study of the user's manual, then he/she should contact an authorized BTL service. 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, the user is responsible for any damage to the device.
- Do not try to open, remove protective covers, or dismantle the device for any reason. There is a danger of electrical shock and/or serious injury. Even the replacement of the control unit's lithium battery must be done an authorized BTL service only!
- No modification of the device is allowed!
- The connectors for accessories, as well as the other connectors, must not be used for connecting anything else other than what they are designed for; there is a danger of electrical shock and/or serious damage to the device.
- If a therapy sequence is interrupted due to power failure (such as a blackout), do not allow the accessory to stay under pressure. Carefully disconnect the accessory from the basic tube.

- The device does not use or emit any toxic substances during its operation, storage or transport under the stated conditions.
- After bringing the device from a cold environment into a warm one, do not plug it into the power source immediately. Let it adapt to the new temperature for approximately 2 hours.
- Before the start of therapy, check to see whether all input parameters correspond to the user's intents.
- To terminate operation, do not use the main power switch! Instead, press the **esc** key.
- The time interval between turning off the main power switch and turning it back on must be at least 3 seconds.
- If it is necessary to discard the device, the lithium battery must be removed. The removed battery must be disposed according to local hazardous waste disposal requirements. Do not place the device in municipal waste containers. The device itself does not contain any toxic materials which could harm the environment.
- The device and accessories must be used in compliance with this manual.
- The device must be placed out of the reach of children.
- The device does not contain any components, except the fuses, which can be repaired / replaced by the user. Do not remove the cover from the control unit. All repairs must be done by an authorized BTL service.
- Do not disconnect an accessory during therapy.
- Do not place the device near running water. Do not spill water (or other liquids) on the device. There is a risk of electric shock!
- PC connected to the USB connector has to comply with standard EC-60950-1. USB max working voltage is 5 V. PC connected to the USB connector can’t be located in patient environment – approximately 1.5 m around the patient.

5.1 SYMBOLS AND MARKINGS

	General warning sign
	Type BF applied part
	Follow instructions for use
	Waste electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
	Serial number
	Class II equipment
	Batch code
	Catalogue number

6 TECHNICAL PARAMETERS

Name	**BTL-6000 Lymphastim Topline**
Model	BTL-6000 Lymphastim 12 Topline
Operating conditions	
Ambient temperature	+10 °C to +40 °C / 50 °F to 105 °F
Relative humidity	30 % to 75 %
Atmospheric pressure	700 hPa to 1060 hPa
Position	Horizontal
Type of operation	Continuous
Transport and storage conditions	
Ambient temperature	-10 °C to +55 °C / 15°F to 130°F
Relative humidity	10 % to 85 %
Atmospheric pressure	650 hPa to 1100 hPa
Position	Horizontal
Additional conditions	Transport only in the original container. Lock screw must be secured.
Power supply	
Maximum input	70 W / 240 VA
Mains voltage	~100 V to 120 V or ~200 V to 240 V
Frequency	50 Hz to 60 Hz
Electrical protection class	II (according to IEC 536) Note: The protective ground contact on the mains plug is used only for functional grounding. The device is not equipped with protective grounding.
External exchangeable fuse	2 tube fuses (T2AL / 250V / 5 x 20 mm); in accordance with IEC 127-2
Power switch according to IEC 60601-1	On the back of device; positions **O** (off) and **I** (on). To disconnect from the mains, unplug the male plug of the power supply cable from the mains socket outlet.
Design	
Weight	Max. 7.5 kg (16.5 lbs)
Weight of accessories	Varies according to type
Dimensions (w x h x d)	320 x 190 x 280 mm / 12.5" x 7.5" x 11"
Covering grade according to EN 60 529	IP 20
User interface	
Graphic colour touch screen	640 x 480 pixels / 5.7“ (14.5 cm) diagonally
Indicator lights	1x orange, 4x blue
Classification	
Applied parts type	BF
Class according to MDD 93/42/EEC	IIa
Adjustable values	
Therapy time	Up to 99 minutes
Pressure adjustment range	20 to 160 mmHg (2.67 to 21.3 kPa)
Pressure adjustment accuracy	±20 % of max. pressure value
Methods of inflation	15 options

6.1 ESSENTIAL PERFORMANCE OF THE BTL-6000 LYMPHASTIM TOPLINE

Switching the device off using the mains power switch.

6.2 ELECTROMAGNETIC COMPATIBILITY (EMC)

The BTL-6000 Lymphastim Topline needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document. Portable and mobile RF communications equipment can affect the BTL-6000 Lymphastim Topline.

Guidance and manufacturer's declaration – electromagnetic emissions		
The BTL-6000 Lymphastim Topline is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 Lymphastim Topline 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 Lymphastim Topline uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BTL-6000 Lymphastim Topline 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	

The BTL-6000 Lymphastim Topline should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BTL-6000 Lymphastim Topline should be observed to verify normal operation in such configuration.

Recommended separation distances between portable and mobile RF communications equipment and the BTL-6000 Lymphastim Topline			
The BTL-6000 Lymphastim Topline is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BTL-6000 Lymphastim Topline can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BTL-6000 Lymphastim Topline as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter [W]	***Separation distance according to frequency of transmitter [m]***		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	***80 MHz to 800 MHz*** $d = 1{,}2\sqrt{P}$	***800 MHz to 2.5 GHz*** $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in 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 BTL-6000 Lymphastim Topline is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 Lymphastim Topline should assure that it is used in such an environment.			
Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment – guidance***
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BTL-6000 Lymphastim Topline requires continued operation during power mains interruptions, it is recommended that the BTL-6000 Lymphastim Topline be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The BTL-6000 Lymphastim Topline is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 Lymphastim Topline should assure that it is used in such an environment.			
Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment – guidance***
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the BTL-6000 Lymphastim Topline, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}17\sqrt{P}$ $d = 1{,}17\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}33\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (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 
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.			
[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 Lymphastim Topline is used exceeds the applicable RF compliance level above, the BTL-6000 Lymphastim Topline 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 Lymphastim Topline. [b]) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

6.3 MANUFACTURER

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

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