BTL-6000 LYMPHASTIM EASY

USER'S MANUAL

CONTENTS

1 BASIC CHARACTERISTICS OF THE DEVICE

1.1 DEVICE DESCRIPTION

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. The sleeve consists of a series of mutually independent air chambers that are inflated in a predefined cycle according to the needs of the client.

1.2 INTENDED PURPOSE

BTL-6000 Lymphastim is a non-invasive therapeutic device used to improve lymphatic and blood flow in the lower and upper extremities. The device can be used to treat disorders of peripheral blood and lymphatic circulation such as lymphoedema, post-traumatic and post-surgical swelling and heavy-legs syndrome.

1.3 USER PROFILE

The device shall be used by medically educated personnel. The user shall be familiar with all safety precautions, operating procedures and maintenance instructions given in this User's manual.

1.4 OPERATING ENVIRONMENT

The device is intended solely for professional use in medical facilities. The device is designed for indoor use only, not for use in a location where explosion or water intrusion hazards are present, not for use in dusty or humid environment and not to be exposed to direct sunshine. The device is not intended for home-use.

1.5 PATIENT PROFILE

The use of the device is not limited by gender, age or weight of the patient.

The patient must not show any signs of contraindications determined for the device. The user should take into account a detailed patient's medical history and examine the patient thoroughly to determine whether or not the application of therapy is suitable for the patient

1.6 CONTRAINDICATIONS

- 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

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

1.8 PRE-SET PROGRAMS

Nr.	Name	Recommended Pressure	Recommended Time	Characteristics and Effects of the Program
01	Massage	40 – 80 mmHg	30 min	The chambers are inflated and deflated in succession. The effect is similar to that of a superficial massage.
02	Physiological	30 – 70 mmHg	30 min	Removes stasis and encourages re-education of the vascular system. Mainly used for regeneration and sport medicine.
03	Preparation	30 – 70 mmHg	20 min	Preparative program to be used to stimulate the body's tissues before further lymphatic treatment.
04	Lymph Drainage	30 – 70 mmHg	45 min	Similar to manual lymphatic drainage massage. Starts by unblocking the groin or axillar ganglion. This is the most suitable program for aesthetic medicine.
05	Elephantiasis	30 – 80 mmHg	45 min	The chambers are inflated in succession and then remain inflated. This program is suitable for marked lymphostasis and significant retention of lymphatic fluid.
06	Venopress	20 – 50 mmHg	30 min	The program for support and increase of blood flow in peripheries. Helps to prevent vascular problems like varices or phlebedemas.
07	Embrocation	30 – 70 mmHg	45 min	Sequential inflating of single chambers in order to ensure careful removing of lymphatic fluid.
08	Reversed Combi	30 – 70 mmHg	45 min	Combined program where chambers are inflated in preset pattern. Starts by releasing the stasis, continues by successively pushing the lymphatic mass proximally.

Important Notes:

Pressure should always be set with regard to the comfort of the patient.

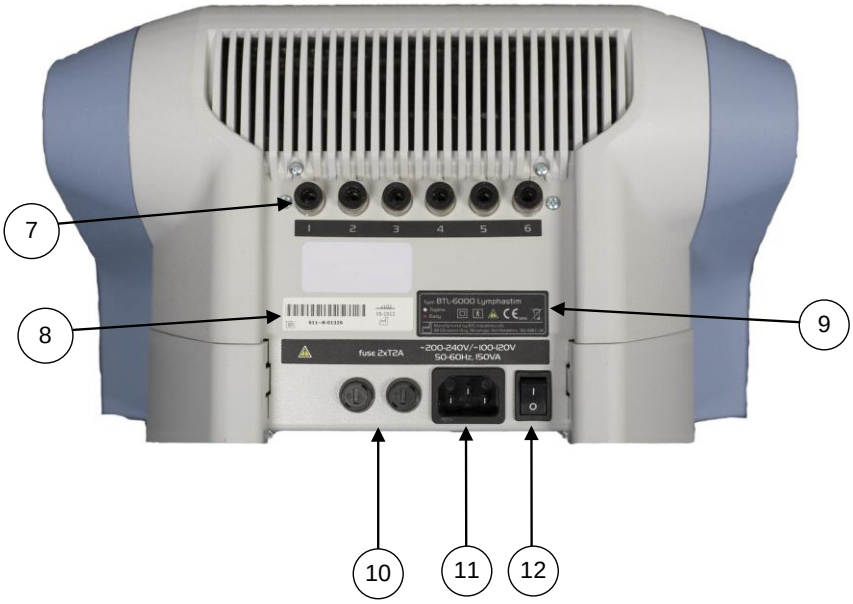
- The sensitivity to pressure can change during the course of treatment sessions. It is recommended to repeatedly ask the patient about their comfort and sensations during therapy.
- In programs designed for treating lymphatic problems (Numbers 04, 05, 07 and 08), pressure exceeding 70 mmHg is not recommended.
- For programs designed for stimulation of the vascular system (Numbers 02 and 06), lower pressure and a faster inflation speed is recommended.
- The patient should not have any contra-indications listed in this manual!
- Always check the health condition of the patient who has to undergo the treatment with Lymphastim device.
- It is possible to combine the programs according to the needs of the patient and/or to produce the desired results.

2 OPERATING INSTRUCTIONS

2.1 FRONT PANEL

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

2.2 REAR PANEL



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

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 trolley, which can be purchased separately. Always position the device out of direct sunlight. During operation, the device gets warm, so it must not be positioned near direct heat sources. The device is self-cooled by forced air circulation. The cooling vents are located on the rear panel and on the bottom of the device. 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.

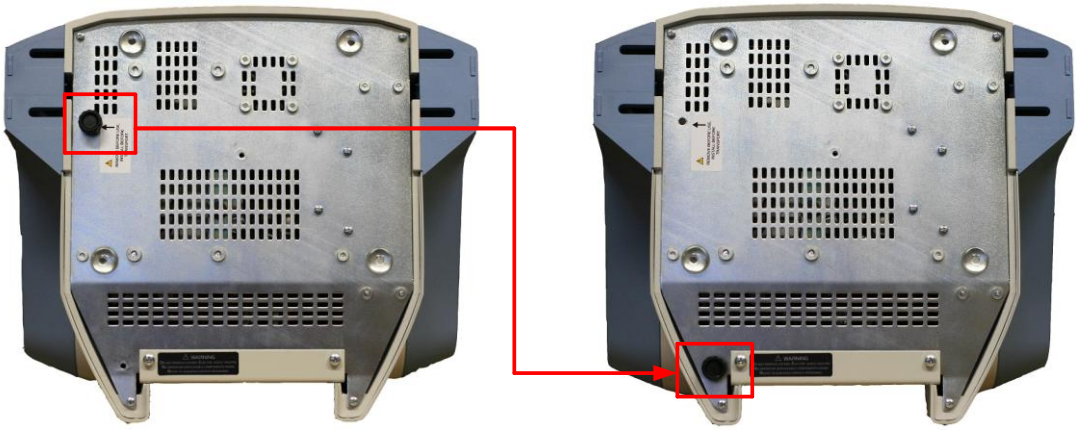
Do not put any heat-producing devices or objects containing water or other liquid on the device.

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 securing the device to the (optional) trolley.



2. In order to connect the accessories of the BTL-6000 Lymphastim, the user must use the connector ports (**7**). Make sure that the hoses (in the hose bundle) are connected properly according to their labels (Hose 1 to Connector Port 1, etc.). For important details about connection and disconnection see below **Special Operational Note**.

   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 applicator sleeve(s) to the basic tube. Lymphatic drainage is accomplished by using special applicator sleeves, which are designed for individual body parts: The arms, the legs and the waist. Each applicator 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 (**12**) to the "**I**" position.
6. After pressing the **on/off** button (**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. 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 Note:

Connecting and disconnecting the hoses to the device:

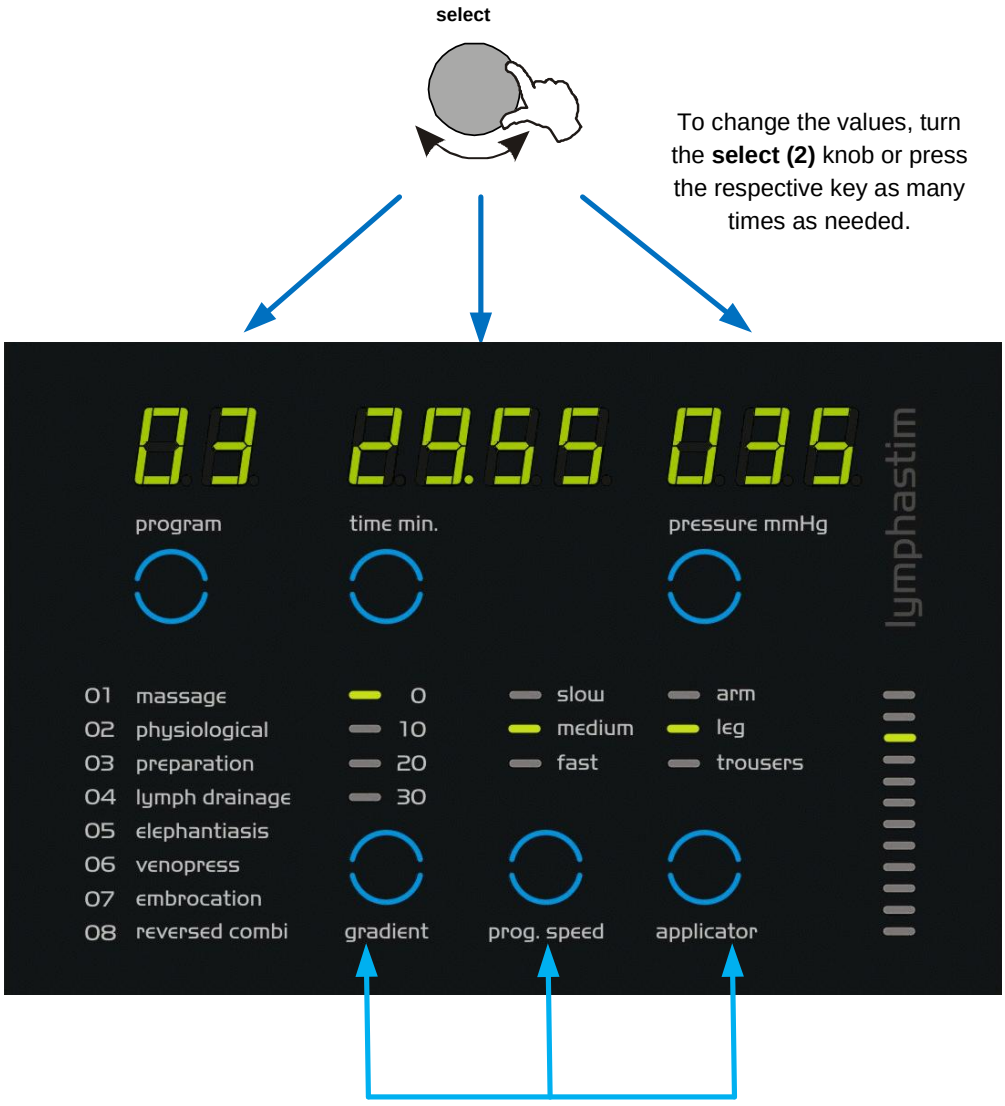
To connect the hose, grip it, plug it into the respective connector and push.

To disconnect the hose, grip the ring of the connector, 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.

2.4 BASIC OPERATION

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



2.4.1 CONTROLS FOR SETTING PROGRAM, TIME AND PRESSURE

Program, **time** and **pressure** can be set in two ways.

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

1. Use the **select** knob: Turn it to the right to increase the value and to the left to decrease the value. Or:
2. Press the respective button again to change the set value as follows:
    - Program: The number of the next program will appear.
    - Time: The duration will increase by 10 minutes.
    - Pressure: The pressure will increase by 10 mmHg.

After the changes have been made, the function is active (keeps blinking) for 5 seconds. When the blinking stops, the changes are entered.

In order to set the therapy parameters, the user should first select the required therapy program number. Only then it will be possible to change the values of **time**, **pressure** and **pressure gradient**. The changed values can be saved in the device's temporary memory by quickly pressing the **ente**r button or by clicking on the button of another function. These values are only saved for the therapy session currently being prepared by the user. Unless the user saves the changes to the parameters, see Chapter 2.5.8, the changes will be lost when the device is turned off. After turning the device on again, the values saved in the permanent memory will be restored.

After the device is turned off and then on again, the control panel will display the last therapy with the values saved in permanent memory. For example, last time the therapy program number 5 was used. Settings of the program (stored in permanent memory) are: time duration of 30 minutes, a pressure of 45 mmHg and pressure gradient of zero. During the last therapy session, the user changed the pressure value to 60 mmHg, the pressure gradient to 10, selected a faster program speed and used a leg applicator sleeve. After the device is turned off and then on again, the values for time, pressure and pressure gradient will be restored to the permanent settings, but the program speed and applicator will remain same as last entered.

2.4.2 CONTROLS FOR SETTING PRESSURE, GRADIENT, PROG. SPEED AND APPLICATOR FUNCTIONS

The settings for **pressure gradient**, **prog. speed** and **applicator** can be changed by pressing the respective button until the desired indicator lights up. The user set values for **prog. speed** and **applicator** will be retained after changing the therapy program.

2.5 THERAPY SETTINGS

2.5.1 PROGRAM

The device contains eight pre-set therapies:

01 massage

02 physiological

03 preparation

04 lymph drainage

05 elephantiasis

06 venopress

07 embrocation

08 reversed combi

2.5.2 TIME

Displays the therapy time (duration of therapy). The default setting is 30 minutes for each therapy session. The user can change the therapy time, even while a session is running. The duration can be set in increments of whole minutes, but the countdown of the duration will be displayed in both minutes and seconds. The maximum duration possible for one session is 99 minutes.

2.5.3 PRESSURE

Displays the value of pressure in the chambers of the applicators sleeves in mmHg (10 mmHg = 1.33 kPa). The various pre-set programs have different pre-set pressures. The maximum possible pressure is 160 mmHg.

The pressure should be set according to the physician's recommendations and the patient's comfort. The therapy should not be unpleasant or uncomfortable for the patient. In the event of patient discomfort, it is also possible to adjust the pressure during a therapy session.

2.5.4 GRADIENT

Allows the setting of the pressure gradient in the applicator sleeves in  percent (%):

- 0 - The pressure is the same in all chambers of the applicator sleeve.
- 10 - The pressure decreases with a gradient of 10 %. For example, if pressure is set to 40 mmHg, then the pressure in the first chamber would be 40 mmHg and the pressure in the last chamber would be 36 mmHg. (40 mmHg - 10 % (4 mmHg) = 36 mmHg).
- 20 - The pressure decreases with a gradient of 20 %.
- 30 - The pressure decreases with a gradient of 30 %.

2.5.5 PROG. SPEED

Allows the setting of the speed of inflation of the applicator sleeves:

- **slow:** Slow sleeve inflation
- **medium:** Medium sleeve inflation
- **fast:** Fast sleeve inflation

2.5.6 APPLICATOR

List of applicator sleeves that can be connected to the device:

- **arm:** Sleeve for the arm(s)
- **leg:** Sleeve for the leg(s)
- **trousers:** Compact sleeve for both legs

Before starting therapy, check that the connected applicator corresponds to the settings. It is not possible to change applicator sleeves during the course of a therapy session!

To treat either two arms or two legs simultaneously, use the Interface for 2 arms or 2 legs.

2.5.7 START, PROGRESS AND END OF THERAPY

After setting therapy parameters according to the physician's recommendations and/or patient's needs and comfort, start the therapy session by pressing the **start/stop** button **(5)**. By default, the therapy will stop when the set time elapses. To stop therapy, press **start/stop (5).** A therapy session cannot be paused.

After the therapy session has ended, the applicator sleeves will automatically deflate. To stop the deflation of sleeves, press the **esc** button **(4)**.

During the therapy session, the user can modify the length of its duration (**time**), the pressure in the chambers (**pressure**), the pressure gradient (**gradient**) and speed of sleeve inflation (**prog. speed**). See chapters 2.4.1 and 2.4.2.

Before the start of each therapy session, check that the correct applicator is connected for the selected therapy program.

2.5.8 SAVING THERAPY

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

For each therapy program, the user can permanently preset the following parameters: Time, Pressure and Pressure Gradient.

The user can set and then save the new parameters for therapy time, pressure and pressure gradient by pressing the "**enter**" button (5) and holding it until the backlighting of the buttons blink. The selected settings are saved in the device's permanent memory and will be loaded as presets when the device is turned on the next time.

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

2.6 DEVICE SETTINGS

2.6.1 USER SETTINGS

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

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

Always before starting the therapy check that the device settings (*4 Arm*, *5 Leg*, *6 trou*) correspond with the connected applicator and the number of chambers.

2.6.1.1 End-Mode of Therapy

Displayed on the control panel: ***1 StoP***

- **On:** Immediate end of therapy. The therapy will stop when the time limit is passed, regardless of whether or not all cycles of the program have finished.
- **Off:** Completion of therapy cycle. The therapy will stop only after completion of all cycles included in the therapy program regardless of the selected duration of therapy.

2.6.1.2 Deflation of Sleeves after Therapy

Allows the selection of whether or not the applicator sleeves will deflate at the end of therapy.

Displayed on the control panel: ***2 EMPt***

- **On**: The applicator sleeve(s) will automatically deflate at the end of therapy.
- **Off**: The applicator sleeve(s) will remain full and will not deflate.

2.6.1.3 Sound Volume

Displayed on the control panel: ***3 Snd***

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

2.6.1.4 Setting of the Number of Chambers for the Arm Applicator

Displaying on the control panel: ***4 ArM***

Set the number of chambers of your connected applicator. For the *BTL-6000 Lymphastim 12 Easy* device there are following options: 8, 10 or 12. For *BTL-6000 Lymphastim 6 Easy* the options are: 5 or 6. Factory settings are: 6 chambers for *BTL-6000 Lymphastim 6 Easy* device, 8 chambers for *BTL-6000 Lymphastim 12 Easy*.

2.6.1.5 Setting of the Number of Chambers for the Leg Applicator

Displaying on the control panel: ***5 Leg***

Set the number of chambers of your connected applicator. For *BTL-6000 Lymphastim 12 Easy* device there are following options: 8, 10 or 12. For *BTL-6000 Lymphastim 6 Easy* the options are: 5 or 6. Factory settings are: 6 chambers for *BTL-6000 Lymphastim 6 Easy* device, 10 chambers for *BTL-6000 Lymphastim 12 Easy*.

2.6.1.6 Setting of the Number of Chambers for the Trousers Applicator

Displaying on the control panel: ***6 trou***

Set the number of chambers of your connected applicator. For the *BTL-6000 Lymphastim 12 Easy* device the options are: 16, 20, 22 or 24. For *BTL-6000 Lymphastim 6 Easy* the options are: 10, 11 or 12. Factory settings are: 12 chambers for *BTL-6000 Lymphastim 6 Easy* device, 24 chambers for *BTL-6000 Lymphastim 12 Easy*.

2.6.2 ADDITIONAL SETTINGS

2.6.2.1 Brightness Setting

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

2.6.2.2 Firmware Version Display

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

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 Easy.

Standard accessories:

- 1x Power supply cord (length 3 m)
- 2x Spare fuses T2AH / 250 V
- 1x User's Manual
- 1x Basic tube with connector
- 24x O-rings

Optional accessories:

For the BTL-6000 Lymphastim 12 Easy:

- 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 trousers 24 chambers with zipper

For BTL-6000 Lymphastim 6 Easy:

- Arm 6 chambers
- Arm 6 chambers – size S
- Leg 6 chambers – size L
- Leg 6 chambers – size M
- Leg 6 chambers – size S
- Trousers 12 chambers

For both models:

- Extension strip for trousers applicators
- Extension strip for leg applicator size L
- Extension strip for leg applicator size M and size S
- Interface for 2 arms or 2 legs
- Trolley

4 MAINTENANCE

Before any maintenance switch off the device and unplug it from the mains! Observe all safety principles listed in the Chapter **Safety Precautions**. Never dismantle the device and its accessories during cleaning!

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

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 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.The control panel shall be cleaned very gently using a dry soft cloth. The cloth may be slightly moistened with a commercially available screen cleaner. Never apply the agent cleaner directly onto the control panel!

Cleaning and maintenance of accessories which come into contact with the patient: These parts must be cleaned after each use. The accessory has to be worn over the patient's clothes, thus it is not necessary to disinfect the accessory after each use. If needed, the accessory can be cleaned and disinfected using cleaning agents which have been approved for medical devices. DO NOT USE cleaning agents containing CHLORINE, PERACETIC ACID, HYDROGEN PEROXIDE (e.g. Persteril, Chloramine, Savo, Incidin, Sekusept) as well as SOLVENTS or BLEACHES. Accessories have to be completely dry before the application.

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 "**0**" 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 mains voltage.

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. The device must only be transported and stored under the conditions defined in the chapter **Technical Parameters**.

5 SAFETY PRECAUTIONS

The accessory has to be worn over the client's clothes or cloth specially designed for lymphatic drainage 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!

- 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 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 who prescribed the treatment.
- The electrical wiring to which the device is to be connected to 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.
- The device must be plugged in directly, do not use extension cords with multiple sockets or multi-socket adaptors. As an isolation means from mains supply is used appliance coupler. Do not position the device so that it is difficult to operate the disconnection of the device.
- Check whether the parameters of the main power supply correspond to the requirements of the device according to the 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 chapters **Technical Parameters** and **Operating Environment**.
- 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 department.
- 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 department. 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. Even the replacement of the control unit's lithium battery must be done an authorized BTL service only!
- No modification of this 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.
- 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 the device adapt to room 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** button.
- 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 department.
- Do not disconnect an accessory during therapy.

5.1 SYMBOLS AND MARKINGS

	Warning
	Type BF applied part
	Follow instructions for use (User's manual)
	Separate collection for electrical and electronic equipment
	Name and address of the manufacturer
	Date of manufacture
	Serial number
	Catalogue number
	Batch code
	Class II equipment
	Earth (ground)
	CE mark

6 TECHNICAL PARAMETERS

Name	**BTL-6000 Lymphastim Easy**
Models	BTL-6000 Lymphastim 12 Easy, BTL-6000 Lymphastim 6 Easy
Optimal 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	max 240 VA
Mains voltage	~ 200 V – 240 V / ~ 100 V – 120 V
Frequency	50/60 Hz
Electrical protection class	II 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	2x T2AH/250 V, 5 x 20 mm; in accordance with IEC 60127-2
Power switch according to IEC 60601-1	On the back of device, positions **0** (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	
Display	3x LED display
Buttons	6x on top panel / 4x on front panel
Indicator lights	1x orange, 10x blue, 22x yellow-green
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 – 160 mmHg (2.67 – 21.3 kPa)
Pressure adjustment accuracy	±20 % of max. pressure value
Methods of inflation	8 options

6.1 ESSENTIAL PERFORMANCE OF THE BTL-6000 LYMPHASTIM EASY

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

6.2 ELECTROMAGNETIC COMPATIBILITY (EMC)

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

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

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

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the the BTL-6000 Lymphastim Easy, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The BTL-6000 Lymphastim Easy is intended to be used in professional healthcare facility environment. Example of suitable environment are: Physician offices, clinics, multiple treatment facilities, hospitals (patient rooms, physiotherapy care) etc.

The BTL-6000 Lymphastim Easy 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 Easy.

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The BTL-6000 Lymphastim Easy is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 Lymphastim Easy should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The BTL-6000 Lymphastim Easy 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The BTL-6000 Lymphastim Easy is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Warning: The BTL-6000 Lymphastim Easy is designed for use by medical professional only.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Recommended separation distances between portable and mobile RF communication devices and BTL-6000 Lymphastim Easy

The BTL-6000 Lymphastim Easy is intended for use in an electromagnetic environment in which radiated RF disturbance is controlled. The customer or the user of the BTL-6000 Lymphastim Easy can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the BTL-6000 Lymphastim Easy as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter [W]	***Separation distance according to frequency of transmitter [m]***			
	150 kHz – 80MHz $d = [3.5/V_1]\sqrt{P}$	***150 kHz – 80 MHz*** $d = [3.5/V_1]\sqrt{P}$ ***– ISM bands***	***80 MHz – 800 MHz*** $d = [3.5/E_1]\sqrt{P}$	***800 MHz – 2.7 GHz*** $d = [7/E_1]\sqrt{P}$
0.01	0.12	0.06	0.12	0.23
0.1	0.38	0.18	0.38	0.73
1	1.2	0.58	1.2	2.3
10	3.8	1.88	3.8	7.3
100	12	5.83	12	23

For transmitters at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable for the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: In case of a frequency of 80 MHz or 800 MHz, the formula for higher frequency range is applicable.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity				
The BTL-6000 Lymphastim Easy is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 Lymphastim Easy should assure that it is used in such an environment.				
Immunity test	***IEC 60601:2007 test level***	***IEC 60601:2014 test level***	***Compliance level***	***Electromagnetic environment – guidance***
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 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 Repetition frequency 5 kHz	±2 kV for power supply lines ±1 kV for input/output lines Repetition frequency 100 kHz	±2 kV for power supply lines ±1 kV for input/output lines Both repetition frequencies	Mains power quality should be that of a typical hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical 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 at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <5 % U_T (>95 % dip in U_T) for 1 cycle at 0° 70 % U_T (30 % dip in U_T) for 25 cycles at 0° <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <5 % U_T (>95 % dip in U_T) for 1 cycle at 0° 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 hospital environment. If the user of the BTL-6000 Lymphastim Easy requires continued operation during power mains interruptions, it is recommended that the BTL-6000 Lymphastim Easy be powered from an uninterruptible power supply or a battery. Basic safety is not affected when the device turns off.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.
NOTE: U_T is the AC MAINS VOLTAGE before the application of the test level.				

Guidance and Manufacturer's Declaration – Electromagnetic Immunity				
The BTL-6000 Lymphastim Easy is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 Lymphastim Easy should assure that it is used in such an environment.				
Immunity test	***IEC 60601:2007 test level***	***IEC 60601:2014 test level***	***Compliance level***	***Electromagnetic environment – guidance***
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff} 150 kHz to 80 MHz 6 V_{eff} in ISM bands 150 kHz to 80 MHz	3 V_{eff} 150 kHz to 80 MHz 6 V_{eff} in ISM bands 150 kHz to 80 MHz	Portable and mobile RF communications equipment shall be used no closer to any part of the BTL-6000 Lymphastim Easy, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [3.5/V_1]\sqrt{P}$ 150 kHz to 80 MHz $d = [3.5/E_1]\sqrt{P}$ 80 MHz to 800 MHz $d = [7/E_1]\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). The intensities of the fields from fixed high-frequency transmitters, determined by the summary of the electromagnetic characteristics of the location [a)], shall be lower than the compliance level in every frequency band. Interference [b)] may occur in the vicinity of a device identified with the following mark: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.7 GHz including test level values for related frequencies listed in table below (*Table of values for immunity test according to IEC 60601-1-2 (IEC 61000-4-3)*	3 V/m 80 MHz to 2.7 GHz Compliance level values for related frequencies are listed in table below below (*Table of values for immunity test according to IEC 60601-1-2 (IEC 61000-4-3)*	
NOTE 1: In case of a frequency of 80 MHz or 800 MHz, the formula for higher frequency range is applicable. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				
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 for fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location, in which the BTL-6000 Lymphastim Easy is used, exceeds the applicable RF compliance level as stated above, the BTL-6000 Lymphastim Easy should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BTL-6000 Lymphastim Easy. b) Location of BTL-6000 Lymphastim Easy should complies distances from transmitters such as (mobile phones, routers, AM and FM radio broadcast) listed in the table below. Not respecting recommended distances could lead to interference which would be expressed to user as abnormal performance (interrupt therapy, loosing detection of applicator etc.). In case of any abnormal performance is observed additional measures may be necessary, such as reorienting or relocating the BTL-6000 Lymphastim Easy.				

Guidance and Manufacturer's Declaration – Electromagnetic Immunity						
Table of values for immunity test according to IEC 60601-1-2 (IEC 61000-4-3)						
Frequency (MHz)	***Band (MHZ)***	***Max power (W)***	***IEC 60601 distance (m)***	***Compliance level (m)***	***IEC 60601 Immunity test level (V/m)***	***Compliance level (V/m)***
385	380-390	1,8	0,3	0,3	27	27
450	430-470	2	0,3	0,3	28	28
710	704-787	0,2	0,3	0,3	9	9
745						
780						
810	800-960	2	0,3	0,3	28	28
870						
930						
1720	1700-1990	2	0,3	0,3	28	28
1845						
1970						
2450	2400-2570	2	0,3	0,3	28	28
5240	5100-5800	0,2	0,3	0,3	9	9
5500						
5785						

6.3 MANUFACTURER

BTL Industries Ltd.

161 Cleveland Way

Stevenage

Hertfordshire

SG1 6BU

United Kingdom

Email: sales@btlnet.com

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

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