BTL EMSCULPT

USER’S MANUAL

CONTENTS

1 GENERAL INFORMATION

1.1 INTENDED PURPOSE

BTL EMSCULPT is intended for treatment of obesity by fat reduction through neuromuscular stimulation and increase of the blood flow.

When BTL EMSCULPT is connected with the optional accessory EMSELLA Chair Applicator, the intended purpose is extended as follows: to provide pelvic floor muscle strengthening for treatment of urinary incontinence in male and female patients.

1.2 OPERATING ENVIRONMENT

The device is intended to be used primarily in the professional healthcare facility environment. The device is designed for indoor use only, not for use in a location where explosion, water intrusion hazards, extremely corrosive environment, and rich oxygen environment are present, not for use in a dusty or humid climate, and not to be exposed to direct sunshine. The device is not intended for home use.

1.3 PATIENT PROFILE

The device is intended for adult patients only seeking the treatment conditions specified in intended purpose. The patient must not show any signs of the contraindications. Before application of the therapy it is necessary to take into account patient's medical history and examine the patient thoroughly to determine whether or not the application of therapy is suitable for the patient.

1.4 USER PROFILE

The device shall be operated by a healthcare professional.

The user shall be familiar with all safety precautions and warnings, operating procedures and maintenance instructions given in the manual. The device must not be operated by pregnant women.

1.5 DESCRIPTION OF THE DEVICE

BTL EMSCULPT consists of the main unit and the applicator(s). The main unit is equipped with a colour touch screen with a wide view angle that makes the device easy to use. The on-screen information guides the user through the entire therapy procedure. The therapeutic parameters are easily set using the touch screen and buttons on the device. During therapy, the screen displays information about the remaining therapy time and other therapy parameters. The therapy can be applied through clothes.

1.5.1 PULSE QUALITY MONITOR

Pulse parameters are being continuously monitored during therapy, In the event of any mismatch with expected values, the therapy is stopped to protect the device. Unwanted changes in pulse parameters may typically be caused by the presence of major metallic or ferromagnetic objects in the application field.

Pulse Quality Monitor is not intended to protect the operator and/or a patient. You must follow all device operation and safety instructions stated in this Manual; otherwise the device can be damaged and the operator or a patient can be seriously injured.

1.6 CONTRAINDICATIONS

- cardiac pacemakers
- implanted defibrillators, implanted neurostimulators
- electronic implants
- pulmonary insufficiency
- metal implants
- drug pumps
- application in the head area
- application in the heart area
- malignant tumour
- injured or otherwise impaired muscles
- fever
- pregnancy

For Contraidications related to EMSELLA Chair Applicator refer to User's manual of the applicator (supplied together with the applicator)

1.7 POSSIBLE SIDE EFFECTS

The side effects may include, but are not limited to:

- muscular pain
- temporary muscle spasm
- temporary joint or tendon pain
- local erythema or skin redness

For Possible side effects related to EMSELLA Chair Applicator refer to User's manual of the applicator (supplied together with the applicator)

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

2 SAFETY PRECAUTIONS AND WARNINGS

	Read the User's Manual carefully and become familiar with all its safety requirements, operating procedures and maintenance instructions before using the device. Use the device and its accessories only in accordance with the User's Manual.
	Therapy is strictly prohibited for persons with electronic implants.
	Ensure that persons with pacemakers are not present in the vicinity of the device while the device is in operation.
	Do not deliver therapy to patients with metal implants.
	Do not apply therapy over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
	Do not apply therapy over the neck and/or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contraction may be strong enough to close the airway or cause difficulty breathing.
	Do not apply therapy transcerebrally.
	Do not apply over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
	Do not apply over, or in proximity to, cancerous lesions.
	Caution should be used with patients with: suspected or diagnosed heart problems; suspected or diagnosed epilepsy; tendency to haemorrhage following acute trauma or fracture; following recent surgical procedures when muscle contraction may disrupt the healing process; over the menstruating or pregnant uterus, and over areas of the skin which lack normal sensation.
	Long-term effects of chronic magnetic stimulation are unknown.
	Always keep verbal contact with the patient during therapy. Never leave the patient unattended.
	Before starting therapy, always check the device and its accessories (such as cable, applicators, connectors, touch screen) for mechanical, functional or other damage. In case of a defect or deviation from normal function, stop using the device immediately and contact a BTL authorized service centre. Do not use the device should any defects be presented.
	During therapy and applicator calibration, do not place any electronic equipment (medical devices, mobile phones, tablets, watches, PCs, credit or debit cards, USB flash drives and any other data carriers, wires, cables, etc.) in the vicinity less than 1 m of the applicator(s) and applicator cable(s).

	During applicator calibration, do not place any ferromagnetic or metallic materials in the vicinity less than 1 m of the applicator(s). Do not leave the applicator(s) in the applicator holder(s) during applicator calibration. The applicator holders are metallic.
	Incorrect position of applicators can cause high voltage risk to the operator and the device can be damaged. See Chapter 4.2.1. for applicator positions.
	Always fix the applicator(s) by fixation belts. Do not hold applicators in hand during therapy. Always fix the applicator(s) cable(s) in the cable holder during therapy.
	Do not connect any cables or devices into the USB ports. These are for service purposes only! Only devices approved by the manufacturer can be connected to these ports.
	Modifications to the device and its accessories are prohibited. Do not try to open or remove the device protective covers or disassemble the device for any reason. There is a danger of electric shock and serious injury. All servicing must be carried out by an authorized BTL service centre; otherwise BTL bears no responsibility for further operation of the device.
	Never use the accessories' ports or other ports to plug in anything else but what the ports have been designed for. There is a serious risk of electric shock and serious damage to the device! The device is equipped with a protective system against connecting accessories other than those supplied by the manufacturer. The device does not function with accessories from other manufacturers.
	Do not place the applicator(s) close to any part of the device during therapy.
	Protect the device against unauthorized use.
	The applicator(s) can only be plugged in and unplugged when the device is turned off.
	To unplug applicator(s), release safety locks and pull out the connector(s). Never pull the applicator(s) cable(s). Never disconnect the applicator(s) during therapy.
	Use of accessories other than those specified in this manual may result in increased electromagnetic emissions or a decreased resistance of the device. This does not apply to any parts provided by BTL as part of an authorized service.
	The device should not be used adjacent to or stacked with other equipment.
	Do not push the device.
	Prior to starting therapy, make sure all parameters set match your requirements. Review therapy contraindications.
	The mains to which the device will be connected must be installed and revised according to the current standards for electrical installations in healthcare facilities. Make sure voltage parameters of the power supply grid and device requirements match.

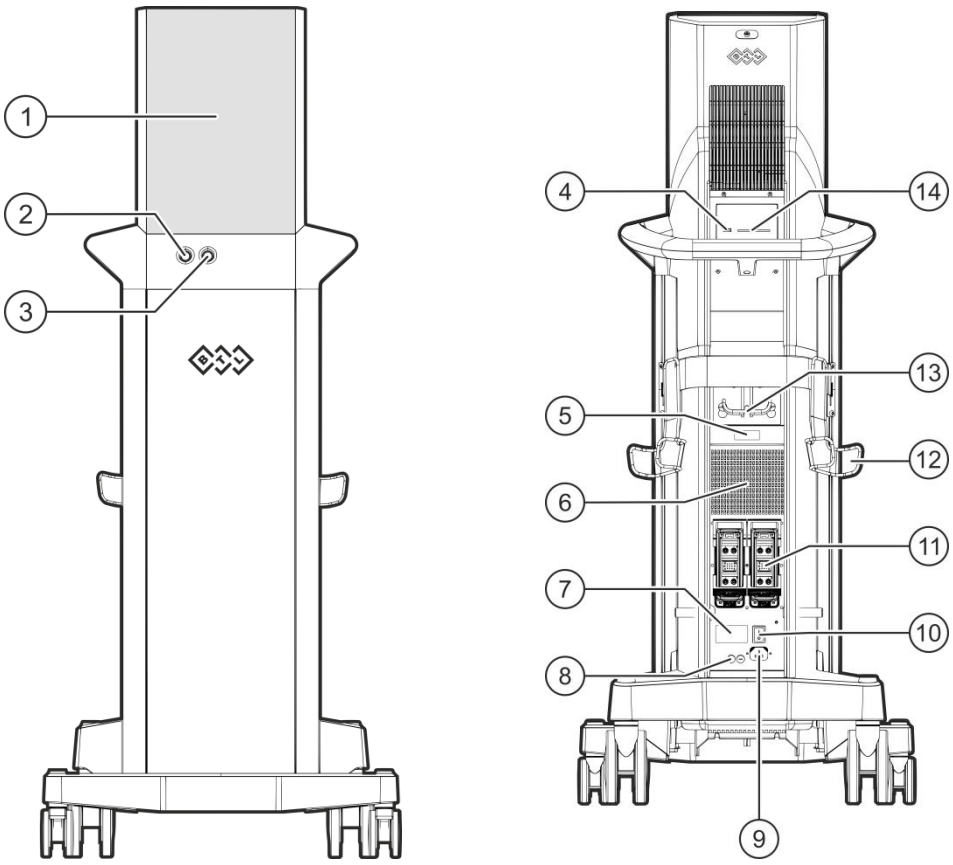
	Transport, store and operate the device in the environment defined in Chapter 10. Do not operate the device if there is any danger of explosion or water intrusion into the device. The device cannot be in contact with flammable anaesthetics or oxidizing gasses (O2, N2O, etc.). The device is not intended for exterior use!
	Do not place the device near other devices that produce strong electromagnetic fields (such as diathermy, X-ray, cell phones, and radiofrequency) in order to prevent mutual functionality influence. If this happens, move the device further away from the source of interference or contact an authorized BTL service centre.
	Do not place the device in direct sunlight or near heat sources. It might lead to an excessive temperature increase and possible risk for the patient and the device. The device heats up during operation and therefore must not be located near direct heat sources. The device is cooled by forced air circulation. The cooling vents are located on the rear panel of the main unit and on the applicators' sides. The vents must not be covered. When placing the device, leave at least 10 cm of free space behind the rear panel.
	Do not place any objects that produce heat or objects containing water or other liquids on the device.
	After moving the device from a cold to a warm environment, wait until the temperature equalizes before its connection to the mains (at least 2 hours).
	Applicators' and cables' surfaces might be hot when in operation or during the cooling process after therapy. Never turn the device off before the cooling process is finished.
	The device displays messages concerning deviations or defects of the device and its accessories. If you are not sure what a message means, stop using the device and contact a BTL authorized service centre.
	Keep the device out of reach of children.
	During transport, always disconnect applicators from the device.
	The device has applied parts of the BF (Body Floating) type – i.e. parts which come into direct physical contact with the patient during normal device use.
	The output voltage values of ports marked with this symbol can exceed safe values.
	Dissipate static electricity by touching a grounded metal object before connecting or handling the device connected to the USB port.
	The device must be disposed in a way common for electric and electronic equipment. The lithium battery must be removed and disposed of separately according to local hazardous waste disposal requirements. Do not place the device in municipal waste containers! The device does not contain any toxic materials, which could harm the environment in case of proper way of disposal.

3 USED SYMBOLS AND MARKINGS

	Warning
	Caution
	Type BF applied part
	Warning, magnetic field
	Follow instructions for use
	No access for persons with pacemakers
	No pushing
	Name and address of the manufacturer
	Date of manufacture
	Class II equipment
	Dangerous voltage
	Marking a connector sensitive to electrostatic discharge
	Fuse
SN	Serial number
LOT	Batch code
REF	Catalogue number
	Stand-by (**on/off**)
	Stop (Stop therapy)
	Separate collection for electrical and electronic equipment
CE 0051	CE mark demonstrating compliance with the Regulation (EU) 2017/745 as amended (0051 is an identification of Notified Body)
MD	Medical device
EC REP	Authorized representative in the European Community

4 DEVICE AND ACCESSORIES

4.1 FRONT AND REAR PANEL OF THE MAIN UNIT

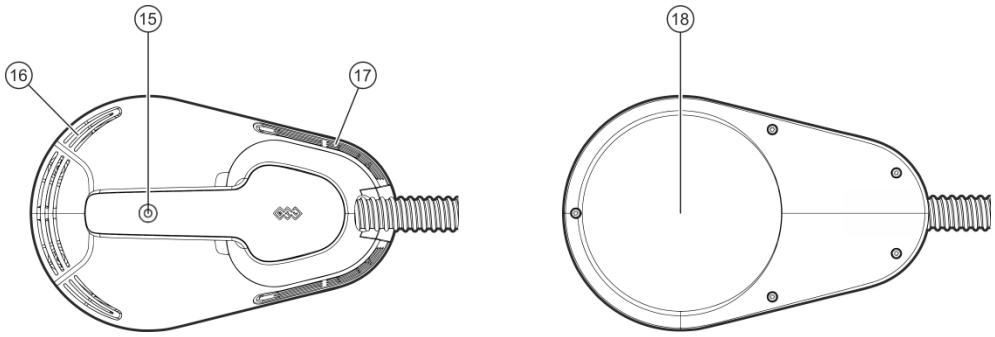


1. touch screen
2. button (switch device from/to standby mode)
3. button (stop therapy)
4. USB port located in the grip space of the device. The port is for use only in accordance with IEC 60950-1; it is intended ONLY for technical servicing purposes, e.g. loading firmware; it is not intended for therapeutic use.
5. production label (with serial number)
6. ventilation grid
7. type label
8. two fuses
9. mains cable connector
10. mains power switch
11. applicator connectors (A and B channel)
12. applicator holder
13. cable holder
14. service card slot

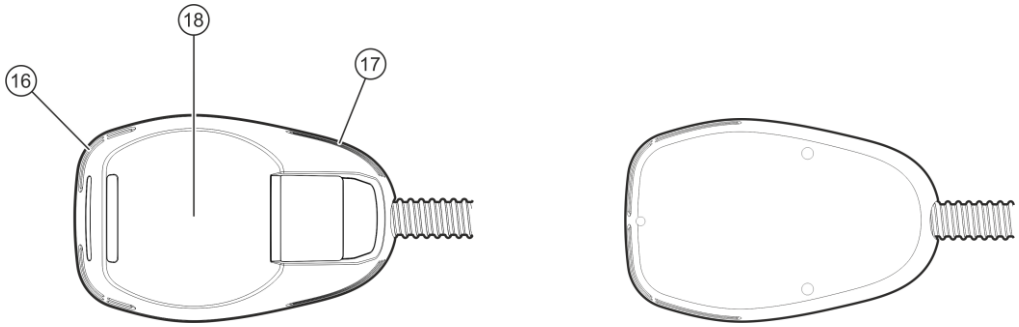
4.2 APPLICATOR

Large applicator BTL-299-6 and Small applicator BTL-299-7 (hereinafter also referred to as the “BTL-299-6” and “BTL-299-7”) can be connected to the device. The applicator has a marked spot showing the coil center (15, 18), air vents (16, 17) and therapy application area (18). Applicators are always supplied with a service card. Applicators are only functional when a matching service card is inserted in the service card slot. The applicator may be in contact with the patient’s skin. The warmest part (up to 43 °C) of the device with potential contact is the applicator hose. The applicators should be in defined positions. See the applicators’ position below.

BTL-299-6



BTL-299-7



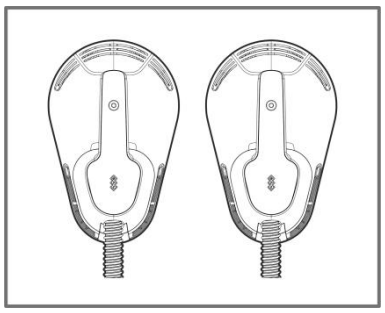
The applicators must always be fixed by the fixation belt and must not be held in hand during therapy. The applicator cable must always be fixed in the cable holder during the therapy.

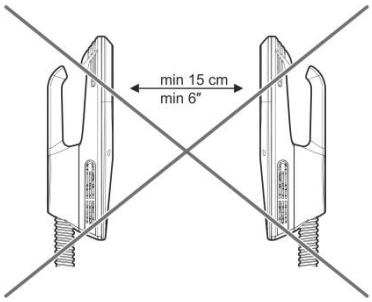
BTL-299-3 EMSELLA Chair Applicator

For detailed information regarding EMSELLA Chair Applicator BTL-299-3 please refer to User’s manual of the applicator (supplied together with the applicator). The information substitutes or supplements information mentioned in this main manual.

4.2.1 APPLICATORS' POSITION

When both applicators are in use, do not position them less than 15 cm facing or overlapping each other, as shown in the picture below.





The picture is for demonstrative purposes only. The same applicators position allowance applies to the BTL-299-7 applicators.

When only a single applicator is in use do not place it within a 15 cm proximity of any other applicator.

Incorrect position of applicators can cause high voltage risk to the operator and the device can be damaged.

4.3 LIST OF ACCESSORIES AND COMPONENTS

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

Available accessories and other components:

- Large applicator BTL-299-6
- Small applicator BTL-299-7 – optional
- EMSELLA Chair Applicator BTL-299-3 – optional
- Fixation belt
- Service card
- Power cord
- Mains fuses
- Display cover

5 DEVICE INSTALLATION

Always inspect the packaging for damage. If the packaging is damaged, do not proceed with assembly and set-up and return the device to the distributor. Keep the original packaging to ensure safe future transport of the device.

After moving the device from a cold to a warm environment, wait until the unit temperature equalizes to the ambient room temperature before connecting it to the mains (at least 2 hours).

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

Always place the device out of direct sunlight. The device gets warm during operation, so it must not be positioned near direct heat sources. The device is cooled by forced-air circulation. The cooling vents are located on the rear panel of the device and on the applicator(s) and must not be covered. Do not place any heat-producing devices or any containers with water or other liquids on the device. Do not place the device close to appliances emitting strong electric, electromagnetic or magnetic fields or X-rays; otherwise the device could be undesirably influenced.

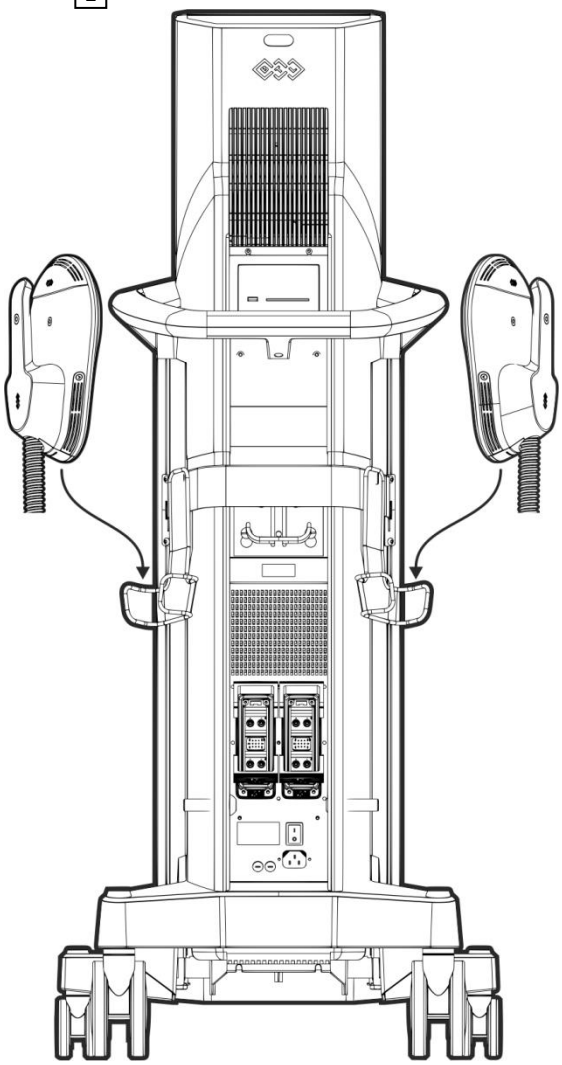
For any questions, contact an authorized BTL service centre.

5.1 INSTALLATION OF THE APPLICATOR(S)

Installation Procedure:

1. Insert applicator(s) to the applicator holder(s).
2. Connect the applicator(s) to the main unit. Use safety locks to fix the connector(s).
3. Place the applicator(s) cable(s) into the cable holder.
4. Calibrate the applicator(s) (follow instructions in Chapter 6.4.4)

1



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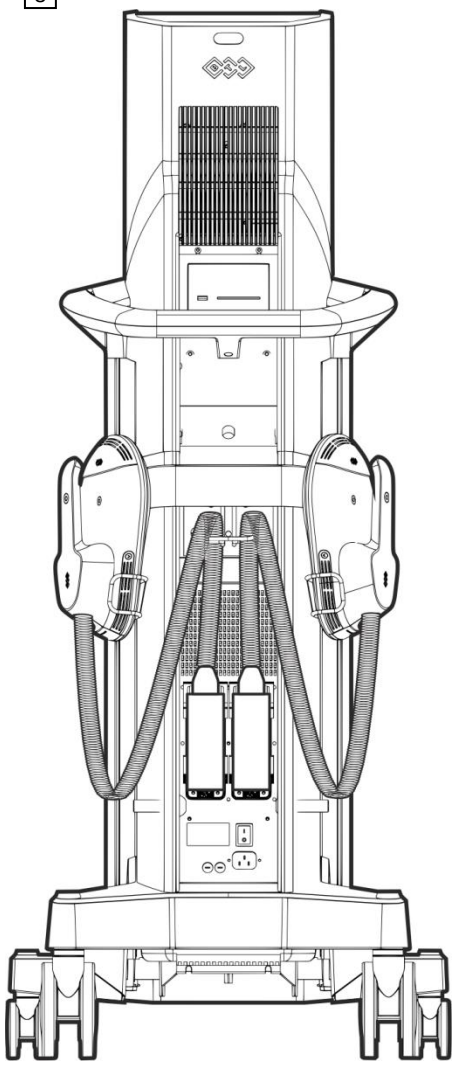

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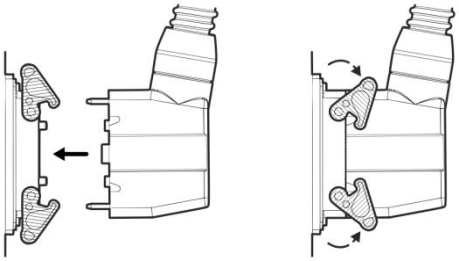


The safety locks must be appropriately locked to connect the connector(s) correctly.

6 BASIC DEVICE OPERATION

The device comes with preinstalled software and the necessary hardware to run this software. There is no need from the user perspective to change either the hardware or software. If there are any new versions of the software released in the future then BTL service personnel will handle the upgrading of the software if required.

6.1 APPLICATOR EXCHANGE

You must calibrate the applicator after every installation or exchange.

The applicator can only be unplugged when the device is turned off. Never turn the device on when the applicator is disconnected.

6.2 DEVICE STARTUP / SHUTDOWN

1. Plug the main unit to the mains using the power cord. Plug the main unit directly into the mains; do not use extension cords with multiple sockets or multi-socket adaptors.
2. Switch the mains switch on the rear panel to the "**I**" position.
3. Press the **on/off** button on the front panel.
4. Turn the device off by pressing the **on/off** button**.** Thermal energy may be accumulated in the applicator at the end of the therapy; the automatic cooling process of the applicators has to be completed before the device shuts off. To interrupt the cooling process, press the **cancel** button. The unit turns off automatically after the cooling process is completed (when ambient and applicators' temperatures are equal).

Always let the automatic cooling process finish before turning the device off. Not respecting the required cooling time could cause the device damage and the operator or a patient injury.

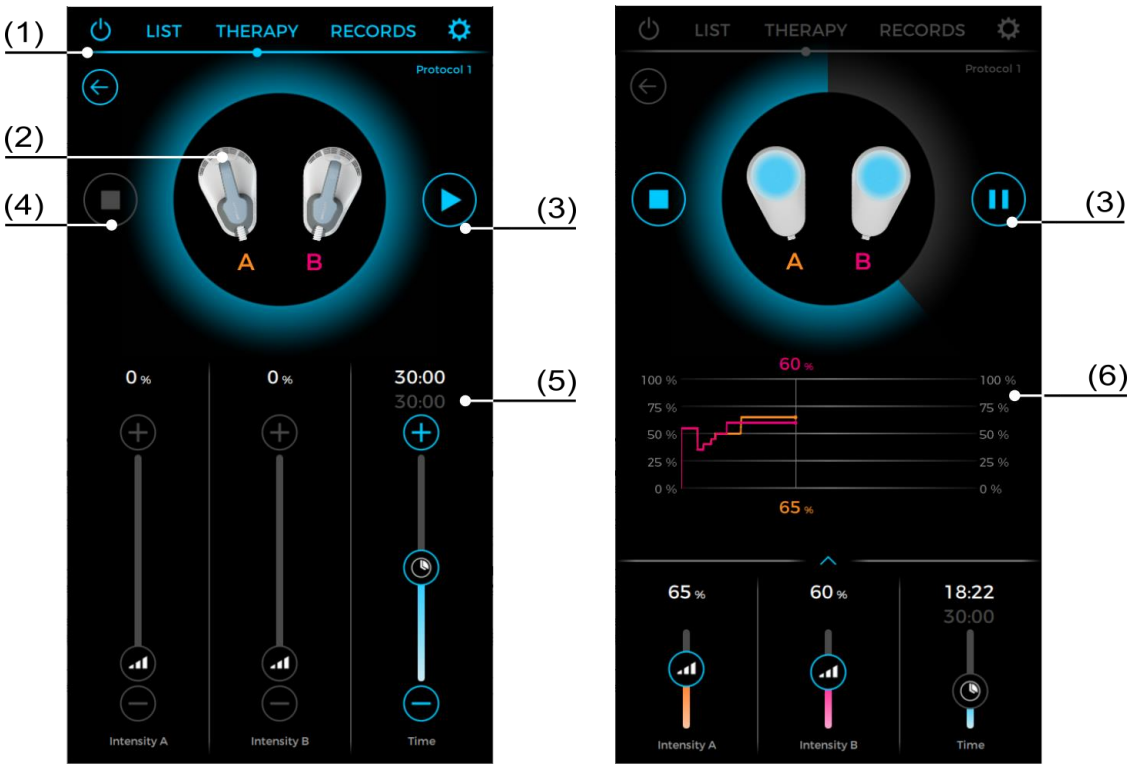
6.3 NAVIGATION CONTROLS

6.3.1 SETTING THE THERAPY BY CONTROLS

Preset therapy can be modified by controls placed on the therapy screen.

The following items and functions are displayed on the therapy screen:

(1) Navigation controls
(2) Channels selector
(3) Start/Pause therapy
(4) Stop therapy
(5) Setting up therapy parameters
(6) Therapy chart



6.3.1.1 Navigation controls

LIST	Displays list of preset protocols
THERAPY	Displays main therapy parameters
RECORDS	Displays list of therapy records
UNIT SETTING 	Sets the device functions

6.3.1.2 Channel selector

Press the channel selector to select active channel(s). Select between channel A, channel B or select both channels A and B.

	Channel A selected
	Channel B selected
	Both channels A and B selected

6.3.1.3 Therapy chart

Therapy chart indicates intensity settings during treatment.

6.3.1.4 Setting therapy time

Therapy time can be set up to 60 minutes using the time slider control (30 minutes when BTL-299-7 applicator in use). This function is available only before therapy is started.

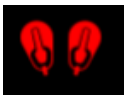
6.3.1.5 Setting Intensity

Intensity can be set using the intensity slider control on the touch screen. This function is available only when therapy has started.

The maximum intensity setting may be limited when higher frequencies or a longer therapy time are set.

6.3.1.6 Indications and warnings

The following symbols may appear on the screen to inform the user about the therapy and the state of the device:

	Selected stimulation frequency is too high or too low for the required intensity value (current output amplitude of electromagnetic pulses does not match the required value).
	The temperature symbol appears when the applicator(s) temperature or the internal device heat is approaching the limit for safe operation.
	The inserted service card is loading. Please wait.
	The inserted service card is invalid or the card reader is in an invalid state.
	General warning symbol indicates one or more of the following conditions: • An applicator is not connected or no supported applicator (excluding plug connectors) is connected (i.e. only plug connectors are connected). • Internal software warning.
	The applicators are reaching their service lifetime. See Chapter 9.

6.4 UNIT SETTINGS

Press the **unit setting** button on the touch screen to browse through the following menus of function settings and information screens:

Set the following parameters:

- Sound
- Date & Time
- Unit
- Applicators

6.4.1 SOUND

Use this option to change sound volume.

6.4.2 DATE & TIME

Use this function to set the time and date.

6.4.3 UNIT

In the unit submenu, view information and/or change settings for the following parameters:

- Software
- Hardware
- Network settings
- Keys
- Last events
- Operation mode
- Service functions
- Service
- Language

6.4.3.1 Software

Displays software packages and version number.

6.4.3.2 Hardware

Displays device hardware and serial numbers.

6.4.3.3 Network settings

Displays information about network setup and its parameters.

6.4.3.4 Keys

Displays connection key required to work with the device (for servicing purposes only).

6.4.3.5 Last events

Displays list of the device's last events.

6.4.3.6 Operation mode

Use this function to switch between the device's basic and expert modes. Expert mode opens further possibilities for setting therapy parameters. Each protocol consists of three sections.

Expert mode therapy parameters on the therapy screen:

Intensity	Setting up intensity for channel A and/or B when therapy is on.
F1	Stimulation frequency setting for first section.
F2	Stimulation frequency setting for second section.
F3	Stimulation frequency setting for third section.
Time	Therapy time setting.

6.4.3.7 Service functions

This item is intended for servicing the device.

- Restore default settings
- Factory reset
- Export logs
- Enter unlock code

6.4.3.8 Servicing

Use this function to access servicing mode. It can only be used by an authorized service centre.

6.4.4 APPLICATORS

Use this menu to calibrate the applicators.

After every installation or exchange of an applicator, you should calibrate the applicator for optimal therapy performance and Pulse Quality Monitor function.

The applicator must be cooled down and removed from the applicator holder before calibration is started. All metallic or ferromagnetic objects have to be removed from the applicator area min. 1 m before calibration is started.

7 THERAPY

Suggested therapy time is 20 to 30 minutes per session, with sessions separated by at least 2 days.

7.1 PREPARING THE THERAPY

Prior to the treatment, the patient should remove all jewellery and electronic devices. For easy application it is recommended to remove clothes from the treated area and to position the patient lying down on the bed.

7.2 PLACING THE APPLICATOR

Place the applicator(s) on the area to be treated and fix the applicator(s) using the fixation belt supplied with the device or applicators. The fixation belt should be tightened over the centre of the coil(s) to minimize movements of the applicator(s) during the therapy.

Do not place the applicator(s) over bones or joint areas as this can result in a painful treatment.

7.3 SETTING THE THERAPY BY A PRESET

Select a preset in the navigation controls LIST by touching the button of the desired protocol on the screen.

After the selected preset is loaded the device displays the Therapy screen. Select the applicator(s) to be used for the treatment by pressing the channel selector on the screen.

7.4 SETTING THE TIME

The treatment time can be adjusted using the time slider control on the Therapy screen. This function is available only before start of the therapy. The default duration of a treatment is 30 minutes.

Therapy time cannot be modified when therapy has started.

7.5 THERAPY START

Press the **start** button on the touch screen and fill in the basic patient demographic information fields. Press the **start** button on the bottom of the screen again to start therapy.

Adjust the stimulation intensity until comfortable motor response of the treated area is achieved. The stimulation intensity has to be adjusted according to the patient's feedback.

7.6 COURSE OF THERAPY

During therapy the screen shows sliders with the main therapy parameters. The remaining time is highlighted to provide an instant overview of the course of the ongoing therapy.

Presence of an electromagnetic field during the ongoing therapy is indicated on the device by a non-zero intensity value on the **intensity** slider on the screen.

The intensity can be modified during therapy using the intensity slider control on the touch screen. Adjust the intensity according to patient's condition and feedback.

The maximum intensity may be limited when higher frequencies or a longer therapy time are set.

During therapy, check the applicator(s) regularly and make sure they stay positioned over the treated area throughout.

Do not turn off or unplug the device during therapy or the cooling process.

7.7 THERAPY INTERRUPTION - END

Terminate the therapy at any point by pressing the **stop** button on the touch screen or the **stop** button on the front panel.

If patient reports uncomfortable pain at the site of application during therapy, stop therapy immediately.

When the therapy time expires, therapy is stopped automatically. Remove the fixation belt and the applicator(s) from the patient. The fixation belt is reusable; do not discard.

8 TROUBLESHOOTING

The device is designed with operator and patient safety in mind. During each start-up, the device carries out self-diagnostics of the internal circuits and functions. If there is any unacceptable deviation, the device therapy tab is blocked. If the problem persists after device restart (turn the device off and on using the main switch), follow instructions on the screen and/or call an authorized BTL service centre.

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

Problem	**Possible reason and solution**
Device does not start.	Check the power cord and the power cord connector. Switch the main switch to ON position ("**I**").
Therapy tab is not available or therapy start is blocked after device start.	The device did not pass self-diagnostics. Check that the applicators are connected properly and restart the unit. If problem persists, follow the on screen instructions or call a BTL service centre.
Pulse Quality Monitor stopped the therapy.	Remove all metal objects in the proximity of applicators. Calibrate the applicators. Problems can persist if environment where the device is operated is strongly electromagnetically polluted.
Therapy stopped unexpectedly due to applicator or main unit overheating.	Ensure that all air vents of the applicators are free. Ensure that the recommended parameters of the therapy and device operating conditions are not exceeded.
Error during applicator calibration.	Check that the applicators are properly connected. Remove the calibrated applicator from its holder. Remove all metallic or ferromagnetic objects in proximity of the applicator. Restart the device and repeat calibration.
Applicators were disconnected from the main unit while in operation.	Switch the device off and reconnect applicators.
Applicators were connected to the main unit while in operation.	Restart the device.
Therapy cannot start and the temperature symbol on the screen is shining.	The applicators or the main unit are overheated. Wait until the temperature symbol stops shining and start again.
Therapy cannot start and the temperature and device's heat symbols on the screen do not shine. Warning message about exceeded allowed temperature appears.	The device can be overheated due to not respecting the maximum recommended therapy parameters or operating conditions, or another internal problem occurred. Switch the unit off and let it cool down for at least 30 minutes. If the problem persists after the device restart, follow the instructions and call your BTL service centre.
It is not possible to reach the same intensity values in consecutive therapies.	Maximum intensity values may differ in consecutive therapies due to change of ambient temperature and accumulated heat in the applicator(s).
The service card is inserted and the status of the device is  .	Inserted card is invalid or the card reader is in an invalid state. Reinsert the service card and wait for approximately 10 seconds. If the problem persists call your BTL service centre.
The service card is inserted and the status of the device is  .	Check the applicators connection. Reinsert the service card and restart the unit.
Therapy cannot be started and no warning symbols are shining.	Check that valid service card has been inserted. If the problem persists after the device restart, follow the instructions and call your BTL service centre.
The service card is inserted and the picture of applicators is in gray scale on the Therapy screen. Therapy cannot be started	Check that identical types of applicators are connected properly and the service card is relevant for the set of applicators. If the problem persists after the device restart, call your BTL service centre.

9 MAINTENANCE

Before any maintenance, switch the device off and unplug it from the mains! Observe all safety principles. 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.

Do not repair the device. All servicing must be carried out by an authorized BTL service centre. Only original parts can be used for repair; otherwise BTL bears no responsibility for further operation of the device.

Before contacting your authorized BTL service centre, please get ready the device model number, serial number and a detailed description of the issue you have encountered.

The applicators have limited service lifetime. After expiration, the applicators must be replaced before further operation of the device. To replace the applicators, call your BTL supplier or your service centre.

9.1 FUSE REPLACEMENT

Device fuses are located in the black fuse housing on the rear panel of the main unit. Ensure that the type and rating of the new and the replaced fuses match.

1. Turn off the device and disconnect the unit from the mains.
2. Remove the fuse housing by using a screwdriver.
3. Remove the burnt fuse.
4. Insert the new fuse. Make sure the fuse is properly seated within the fuse housing.
5. Connect the power cable to the unit and to the mains.
6. Turn on the device.

9.2 CLEANING OF THE SURFACE OF THE DEVICE

The device has to be always turned off by means of the mains switch when cleaning. The mains power switch has to be in **OFF** ("**0**") position.

To clean the device, use a soft cloth slightly moistened with water. Never use agents containing alcohol, chlorine, ammonia, acetone, benzine or thinners. Clean the touch screen gently by using a dry soft cloth. The cloth may be slightly moistened with a commercially available screen cleaner. Never apply the cleaner directly on the screen!

Never use abrasive materials, otherwise the surface of the device or accessories could get damaged.

9.3 CLEANING OF ACCESSORIES THAT COME INTO CONTACT WITH PATIENT

Always turn the device off before disinfecting applicators. Disinfectant must not reach the air vents.

Clean the applicators and the fixation belts after each use with disinfectants approved for use in medical environments. Do not use agents containing chlorine or those with a high alcohol content (more than 20 %). Use a soft cloth slightly moistened with disinfectant.

After disinfection, the accessories must be rinsed with a soft cloth slightly moistened with clean water so as to prevent an undesired allergic reaction!

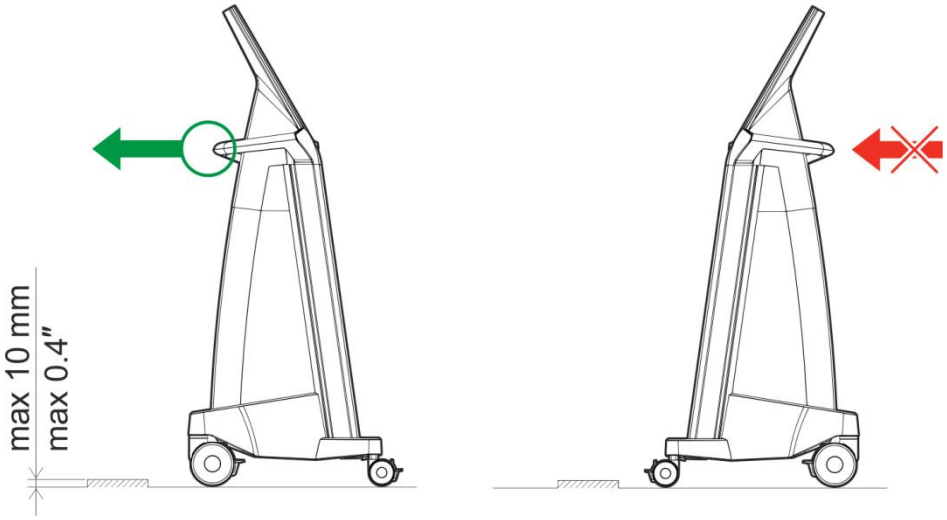
The device's accessories are designed for non-invasive use; therefore they do not need to be sterile and cannot be sterilized.

9.4 TRANSPORT AND STORAGE

Store the device packaging. Transport the unit and the applicators in the original packaging to ensure their maximum protection. Unplug the power supply cable and all accessory cables. Avoid strong shocks. The device should only be stored and transported under the defined conditions**.**

9.4.1 TRANSPORT OF DEVICE

Before moving the device, unplug the power supply cable and all accessories. Unblock all wheels of the device. Pull the device using the device holder; never push the device. See the picture below for the device permitted transport position.



9.5 USER DATA MANAGEMENT

The device incorporates a usage data management system for the purpose of running diagnostics and improving usability and performance of the system. Data collected does not contain any patient identification information.

The device is connected to the internet through a USB dongle. In case of any device misbehavior unplug the USB dongle.

10 TECHNICAL PARAMETERS

Name	BTL EMSCULPT
Operating conditions	
Ambient temperature	+10 °C to +30 °C
Relative humidity	30 % to 75 % (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa
Position	Vertical – on castors
Type of operation	Continuous
Transport and storage conditions	
Ambient temperature	-10 °C to +55 °C
Relative humidity	10 % to 85 % (non-condensing)
Atmospheric pressure	650 hPa to 1100 hPa
Position	Vertical / Horizontal in the packaging
Other conditions	Transport only in the supplied packaging
Power supply	
Maximum input	2800 W (peak)
Supply voltage	100 V to 240 V AC (mains impedance max. 0.20 Ω) It is recommended to supply the device from the separate power circuit. If the RCD is used, it shall also be separate and have time-delay
Frequency	50 to 60 Hz
Protection class	II (connection to protective earth for functional reasons only)
External fuse	2x T10 AH / 250 V, 5x20 mm
Switch	On the front panel, marked by symbol
Mains power switch	On the rear panel, positions **0** (off) and **I** (on)
Classification	
Applied parts type	BF / Single-patient
Number of channels	Two
Essential performance according to IEC 60601-1	No essential performance
Design	
Weight	44 kg / 86 kg including packaging and accessories
Dimensions (w x h x d)	580 x 1380 x 580 mm
Packaging dimensions (w x h x d)	700 x 770 x 1600 mm
Display	
Graphic colour touch screen	15.6" / 39.6 cm, 1920 x 1080 px.
Therapy	
Time settings (±5 %)	BTL-299-6: 0 to 60 min. BTL-299-7: 0 to 30 min.
Pulse type	Sine, biphasic
Magnetic field pulse width (±20 %)	BTL-299-6: 280 µs BTL-299-7: 190 µs
Settable intensity range (±20 %)	BTL-299-6: 0.5 to 1.8 T BTL-299-7: 0.7 to 2.0 T
Intensity settings unit	Relative 0–100 % (therapy pulses not generated at 0 %)
Pulse repetition rate (accuracy ±5 %)	1–150 Hz
Power Cord Specifications	
Rating	250 V, 10 A (125 V, 15 A)
Minimum requirements on hardware	The device comes with preinstalled software and the necessary hardware to run this software. There is no need from the user perspective to change either the hardware or software. If there are any new versions of the software released in the future, then BTL

Name	BTL EMSCULPT
	service personnel will handle the upgrading of the software if required.
Operating system (BTL-088 platform only)	Linux
BTL-088 platform	CPU: Freescale™ i.MX 6Quad (4x ARM® Cortex™-A9) RAM: 1GB DDR3
BTL-799 Generator FW	MCU: SH2 R5F71324AD80FPV (Renesas SH-2 at 80 MHz) RAM: 16 kB MCU: STM32F405RGT6 (ARM® 32-bit Cortex®-M4 CPU with FPU at 168 MHz) RAM: 128 + 64 kB
Network connection	
Purpose of connection	Network/data coupling is not necessary to achieve intended use. Network connection is an optional feature only. Network connection is intended for passive monitoring and reporting the device usage statistics. Connection is strictly unidirectional from device to manufacturer server. There is no possibility to control any function of device or perform device upgrade through network connection.
Characteristics, configuration and specification	A connection into IT-NETWORK is established via 3G/UMTS/4G/LTE mobile network operator. PEMS allows connecting only preselected GSM USB dongles in bridge-mode (DHCP, NAT, etc. are a part of GSM dongle itselft). An interface between PEMS and GSM dongle (ITNETWORK) is IPv4 ethernet interface protected by firewall.
Intended information flow	For the communication, a mobile network operator mobile IP (MIP) and the internet infrastructures are used. PEMS communicates with BTL servers using TCP/TLS protocols.
Hazardous situations associated with network connection	None (no impact on the therapy when connection lost)
Protection against unauthorized use	All applications are run under non-root user. This user does not have permission to access any operation system features which may corrupt the system or may change the system integrity.

10.1 ELECTROMAGNETIC COMPATIBILITY (EMC)

Medical electrical equipment should be used with precaution 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. The device is intended for use in a professional healthcare facility environment acc. to IEC 60601-1-2 standard.

The use of accessories, transducers and cables other than those specified, with the exception of the transducers and cables sold by the manufacturer as spare parts for the internal components, may increase the radiation or reduce the device durability.

The following accessories have been tested and proven to meet the requirements of the IEC 60601-1-2 standard: Applicator BTL-299-6, Power cord, length 3 m, 250 V, 10 A (125 V, 15 A), Mains fuses.

Guidance and manufacturer's declaration – electromagnetic emissions		
The BTL EMSCULPT device is intended for use in the electromagnetic environment specified below. The user of the BTL EMSCULPT device should ensure that it is used in such environment.		
Emissions test	***Compliance***	***Electromagnetic environment – guidance***
RF emissions CISPR 11	Group 1	BTL EMSCULPT device uses RF energy only for its internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	BTL EMSCULPT device 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**: BTL EMSCULPT device is designed for use by medical professionals only. BTL EMSCULPT may cause radio interference or disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the BTL EMSCULPT or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the device			
BTL EMSCULPT device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BTL EMSCULPT device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BTL EMSCULPT device 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 $d = 1.17\sqrt{P}$	***80 MHz to 800 MHz*** $d = 1.17\sqrt{P}$	***800 MHz to 2.5 GHz*** $d = 2.34\sqrt{P}$
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 meters (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 EMSCULPT device is intended for use in the electromagnetic environment specified below. The user of the BTL EMSCULPT device should assure that it is used in such an environment.			
Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment – guidance***
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply 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 % UT (>95 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <5 % UT (>95 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25 cycles at 0° <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <5 % UT (>95 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25 cycles at 0° <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BTL EMSCULPT device requires continued operation during power mains interruptions, it is recommended that the BTL EMSCULPT device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">BTL EMSCULPT device is intended for use in the electromagnetic environment specified below. The user of the BTL EMSCULPT device must ensure that the device is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 V</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the BTL EMSCULPT device, 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
$d = 2.34\sqrt{P}$ 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 meters (m).

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

Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">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 EMSCULPT is used exceeds the applicable RF compliance level above, the device 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 EMSCULPT.</td></tr>
<tr><td colspan="4">b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

11 MANUFACTURER

This product is manufactured by:

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CE 0051

Date of last revision: 21th August 2023

ID: 799-80MAN2166EN02106