



# **BTL-VAC II**

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 customers' needs.

Your suggestions and comments are always welcome since we believe an ongoing relationship with our customers is critically important to our future product line.

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.btl.net.com> for the latest information on BTL products and services.

Again, thank you for being a BTL customer.

BTL Industries, Ltd.

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# 1 BASIC CHARACTERISTICS OF THE DEVICE

## 1.1 INTENDED USE

The **BTL-Vac II** vacuum unit is intended for easy attachment of vacuum electrodes of electrotherapy devices to patient's body to perform electrotherapy.

Electrotherapy is a non-invasive therapeutic method based on electrical current flow through the human tissues. The electric current is applied with the use of electrodes directly through the patient's skin. The use of electrotherapy is accepted in the field of rehabilitation for acute and chronic pain management, treatment of neuromuscular dysfunctions, range of joint mobility improvement, acute and chronic oedema reduction and peripheral blood flow increase.

## 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 the 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 electrotherapy is suitable for the patient.

## 1.5 CHARACTERISTICS OF THE DEVICE

For the **BTL-Vac II** vacuum unit it is easy to set the vacuum degree, which ensures careful as well as reliable attachment of the electrodes on various types of patients and on various places of the body. Vacuum unit works both in continuous and pulse modes, which supports the overall effect of the performed therapy. The pulse modes perform mechanical massage together with electrotherapy, which improves metabolism and blood circulation in the tissue.

The vacuum unit can be used both for one-channel and two-channel electrotherapy. On the control panel it can be easily switched between the use of the vacuum electrodes and of the plate electrodes without the need to reconnect the cables.

Three sizes of vacuum electrodes for all types of applications can be supplied with the device, including sponges that provide optimum passage of the electric current into the tissue.

The device is distinguished by very quiet running and easy operation. It automatically checks the quantity of fluid that accumulates in the reservoir during the operation (as a result of the suction of moistened sponges) and signals the necessity of its emptying. The reservoir is placed inside the device and can be emptied easily and quickly using the draining hose with a tap.

The vacuum unit can be installed in trolley designed for *BTL-4000 Smart/Premium* and *BTL-5000 Series* devices.

## 2 SAFETY PRECAUTIONS



- Read the User's Manual carefully and become familiar with all its safety requirements, operating procedures and maintenance instructions prior to use of the device. It is prohibited to use the device and its accessory in any manner that is not in accordance with the User's Manual.
- The device is intended solely for professional use. Medically educated and trained personnel (physician, physiotherapist) may use the device for therapy. Protect the device against unauthorized use.
- As the source of the electrotherapeutic signal use only a *BTL-4000 Smart/Premium* or *BTL-5000 Series* electrotherapy device. The use of any other than the mentioned source of signal may endanger the health of the patient and/or the operator(s) seriously!
- Check whether the parameters of the main power supply correspond to the requirements of the device according to the Chapter **Technical Parameters**.
- The mains to which the device will be connected must be installed and revised according to the existing valid standards for electrical installations in medical locations. 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, following the instructions included in the Chapter **Connection to the Mains**. Do not use extension cords with multiple sockets or multi-socket adaptors. Plug in the device into a directly accessible mains socket to ensure immediate device unplug in emergency cases.
- The device must be transported, stored and operated in the environment defined in the Chapter **Technical Parameters**. **The device is designed for indoor use only.**
- It is prohibited to use the device in a location where explosion or water intrusion risk are present and in dusty or humid environment. It is prohibited to use the device in spaces where flammable anaesthetics oxidizing gases ( $O_2$ ,  $N_2O$ ) and other flammable gases or vapours are present.
- The vicinity of the device must be free of any metallic surfaces and things that could theoretically cause any conductive contact with the connector or the vacuum or plate electrodes of the device. Do not place any other electrical equipment behind the device.
- 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 does not use or emit any toxic substances during its operation, storage or transport under the stated conditions.
- Place the device out of direct sunlight and electromagnetic fields of surrounding devices (even cell phones and other portable radio-frequency communications equipment) to prevent unwanted interference. If unwanted interference occurs, place the device further from the source of interference or contact the BTL authorized service.
- The device heats up during operation and therefore must not be located near devices that heat up or produce heat. The device is cooled by forced air circulation. The cooling vents are located on the side edges on the rear of the device and they must not be covered.
- It is prohibited to place any objects that produce heat or objects that contain water or other liquid on the device. Before the device is handled the reservoir must be emptied! It is forbidden to move the device during the operation.
- 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 (at least 2 hours).
- Prior to any use, check the device and its accessories carefully for any mechanical, functional or other damage (loose cables, damaged cable insulation, connectors, electrodes, controls etc.). In case of any damage or deviation from the normal function (appearance) is found (e.g. non-standard behaviour of the controls and indicators during the device start), stop using the device immediately and contact the authorised BTL service. If the device is further used in spite of the presence of discrepancies and/or defects, the user is solely responsible for any damage caused by the device.
- **WARNING: No modification of this equipment is allowed!**

- Do not try to open or remove protective covers or dismantle the device for any reason. There is a danger of electric shock and serious injury. All service actions must be done by an authorized BTL service only; otherwise BTL bear no responsibility for further operation of the device.
- Never connect accessories connectors or any other connectors to plugs in other device than those specified in the User's Manual. There is a serious risk of electric shock and serious damage to the device! The device is equipped with a protective system against connecting other accessories than those supplied by the manufacturer. Never touch the patient and the connectors on the rear panel of the device at the same time. Also, never connect the cables supplied with the device to other device than BTL-Vac II, otherwise there is the danger of electric shock!
- The vacuum cables with vacuum electrodes, electrotherapy cables with plate electrodes or interconnection cables shall always be dis/connected from/to the device only after the device is switched off and unplugged from the mains. Never disconnect the cables during therapy! The electrotherapy cables with plate electrodes shall always be connected to the device only after putting on the plate electrodes.



- 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.



- In connectors marked with this symbol, the values of supply voltage may exceed safe values.
- Prior to start of the therapy make sure that all set parameters match your requirements. Never apply contact therapies on irritated or damaged skin.
- For the good transfer of electric current, always use well moistened sponges when applying the electrotherapy. For details see Chapter **Vacuum Electrodes**.
- The vacuum electrodes cannot be used when applying direct currents, where it is necessary to soak the electrodes with protective solutions. The product of electrolysis can seriously damage the electrodes.
- When the vacuum electrodes are not in use (or when the therapy is being applied by means of the plate electrodes), they have to be placed on a non-conductive surface out of the reach of metallic objects. When the plate electrodes are not in use, they have to be placed on a non-conductive surface out of the reach of metallic objects.
- It is not allowed to run HVT therapy with vacuum unit.
- Simultaneous connection of the patient to a high-frequency surgical device may cause burning in the place of the electrodes and possible damage to the vacuum unit and electrotherapy device.
- Simultaneous connection of the patient to an ECG monitor or ECG alarm system may cause temporary malfunction of the ECG systems or lead to unreliability of the data measured by these systems.
- The operation of the device in close vicinity (e.g. within 1 m) of a shortwave or microwave therapy device may cause the instability of the device output.
- The therapy by means of vacuum and plate electrodes requires uninterrupted contact (at least acoustic) with the patient.



- The device must be disposed in a way common for electric and electronic equipment. 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 must be placed out of the reach of children.

### 3 CONTRAINDICATIONS

The list of contraindications specifies the situations, in which the manufacturer does not recommend the application of electrotherapy by means of the vacuum unit.












For optimum treatment, the physician must first take a detailed patient medical history, including previous treatment modalities, examine the patient's general suitability for application and discuss the treatment regimen with the patient.



If contraindications are not respected, the physicians prescribing therapy and the centre or clinic where the procedure is performed are fully responsible for the treatment and the patient's safety. List of contraindications:

- Febrile conditions of any etiology
- Overall cachexia of any etiology (this does not apply to TENS in terminal stages of metastatic tumours)
- Applications in the area of the chest, heart, eyes, thyroid gland, gonads and large sympathetic plexuses
- Regions of known or suspected malignancy
- Tissues infected with tuberculosis or other forms of virulent bacteria
- Cardiovascular diseases, inflammations of veins and lymphatic vessels
- Bleeding conditions and haemorrhagic disorders
- Serious cardiac or respiratory insufficiency
- Metal objects in the place and path of the application – active implantable devices (e.g. pacemaker), endoprostheses, splints and bolts, piercing
- Pregnancy (this does not apply to electrotherapy outside the abdominal and pelvis area)
- Allergy to the protective solutions used for the impregnation of the electrode pads
- Irritated or in any way eroded skin (including needle punctures), trophic and inflammatory skin changes
- Sensation disorders in the area of electrode location (relative contraindication)
- Psychopathological syndromes
- Multiple cerebrospinal sclerosis
- Electroanalgesia without exact diagnose of pain etiology

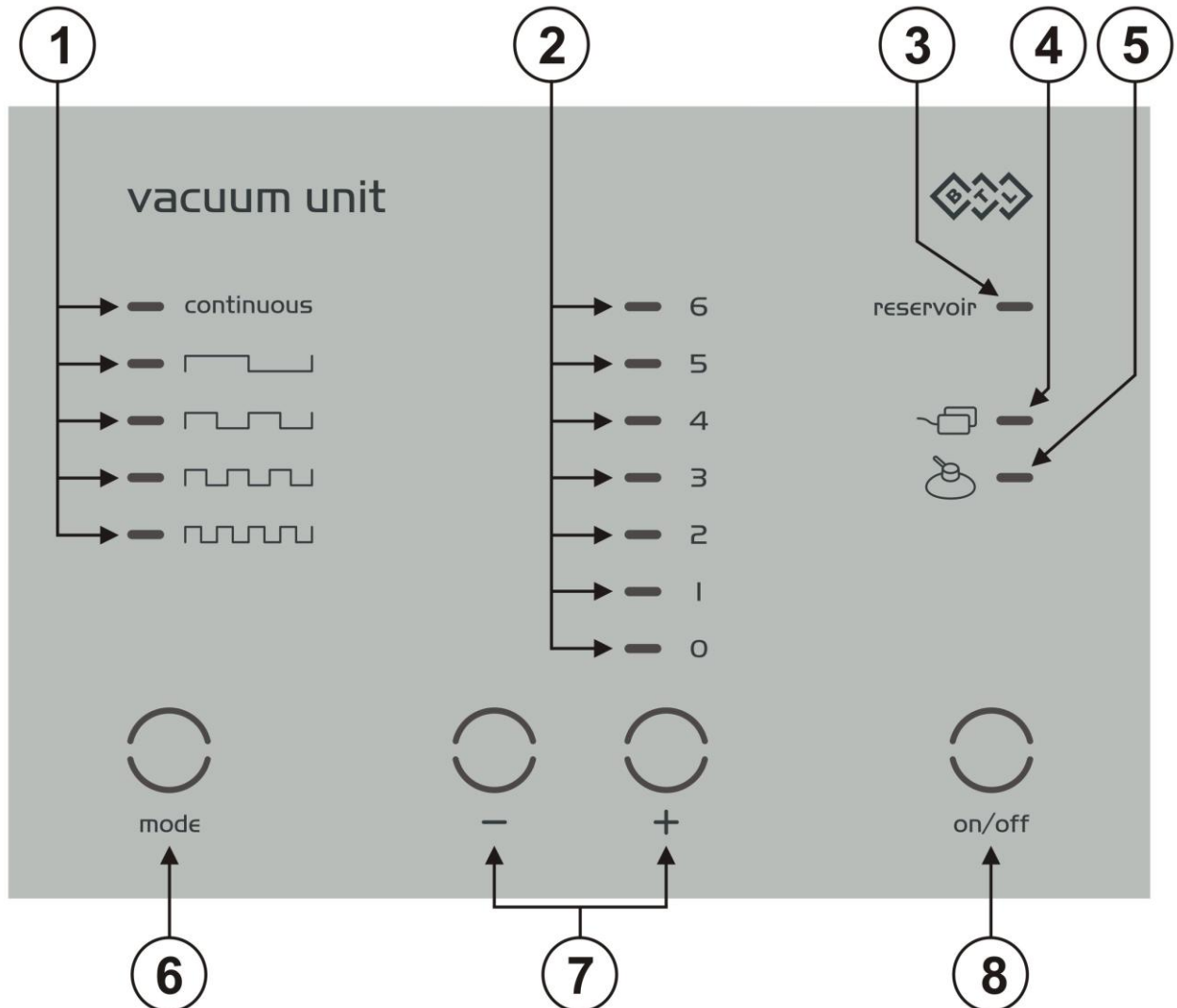
## 4 SYMBOLS AND MARKINGS

	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
	Catalogue number
	Batch code
	Class II equipment
	Caution



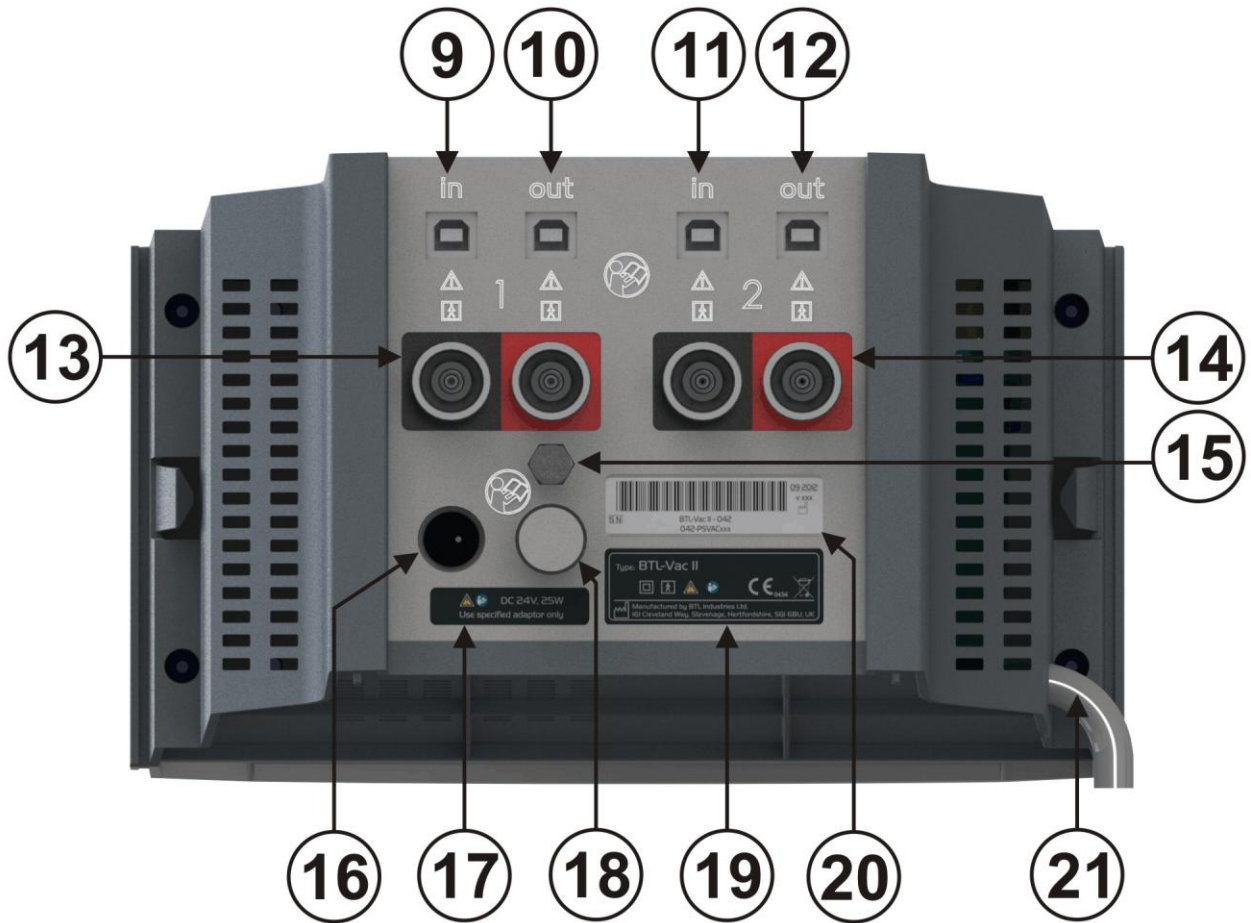
## 5 OPERATING INSTRUCTIONS

### 5.1 FRONT CONTROL PANEL



- 1 Indicators of continuous or pulse modes
- 2 Indicators marked by 0 – 6 indicating set vacuum level
- 3 Indicator **reservoir** indicating the necessity to empty the reservoir
- 4 Indicator signalling output to the plate electrodes (at the vacuum level 0)
- 5 Indicator signalling the output to the vacuum electrodes (at the vacuum levels 1 – 6)
- 6 Button **mode** for the selection of the continuous or pulse modes
- 7 Buttons (+) and (–) for change of the vacuum level
- 8 Button **on/off** for switch the device on/off (signalled by the blue backlight)

## 5.2 REAR PANEL



- 9 Input connector **in** for the connection of channel 1 of the electrotherapy device
- 10 Output connector **out** for the connection of the plate electrodes of channel 1
- 11 Input connector **in** for the connection of channel 2 of the electrotherapy device
- 12 Output connector **out** for the connection of the plate electrodes of channel 2
- 13 Output connectors for the connection of the vacuum electrodes of channel 1 (black cathode (-), red anode (+))
- 14 Output connectors for the connection of the vacuum electrodes of channel 2 (black cathode (-), red anode (+))
- 15 Aeration filter
- 16 Connector of the power supply (only for the use of the adaptor according to **Technical Parameters**)
- 17 Power supply label
- 18 Outlet filter
- 19 Type label of the device
- 20 Manufacturing label of the device containing the serial number
- 21 Reservoir draining hose

### 5.3 INSTALLATION OF THE DEVICE

The vacuum unit comes in a separate package – at the receipt of the device check the packaging for damage. In case of serious damage do not install the device and return it to the distributor. We recommend keeping the packaging for possible further transport of the device.

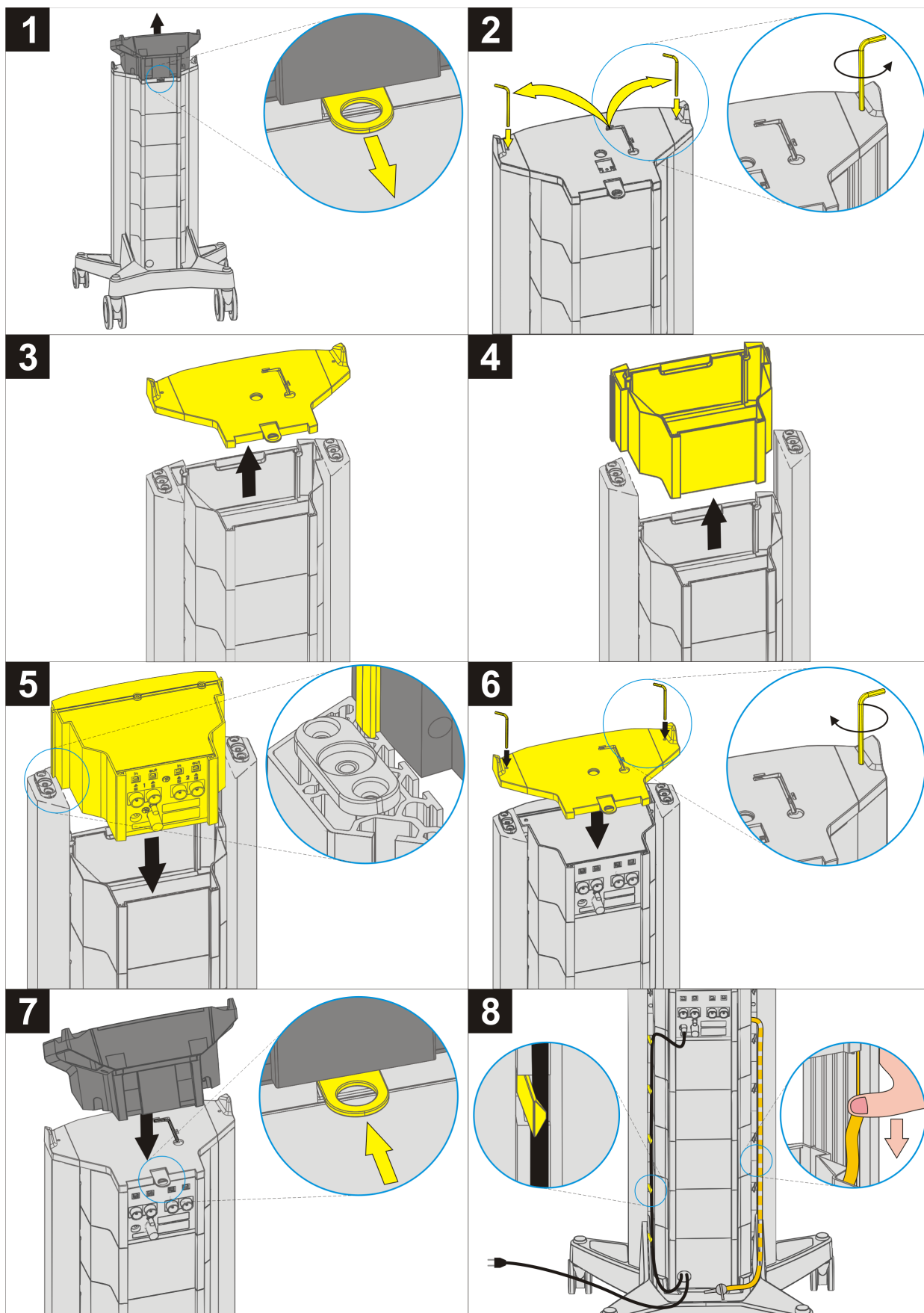
The vacuum unit can be installed in the trolley designed for the *BTL-4000 Smart/Premium* and *BTL-5000 Series* devices. For more detailed information on the assembly of the trolley see the User's Manual supplied together with the trolley.

Before the installation of the vacuum unit it is necessary to remove the upper drawer from the trolley, which will be replaced by the vacuum unit.

For the vacuum unit installation proceed the following steps (see Fig. 1 – 8 on the next page):

- 1) If the electrotherapy device is installed on the trolley, release the lock on the rear of the upper shelf of the trolley (see Fig. 1) and remove the device. **ATTENTION! Before any handling always switch the device off and unplug it from mains!**
- 2) Unscrew the screws from the holes on both sides of the upper shelf using the hexagonal wrench (attached on the top of the shelf) (see Fig. 2). Make sure that the screw is completely released to prevent breaking or excessive mechanical stress of the shelf when removing it. After releasing, the screws remain inside the desk to prevent their loss.
- 3) Remove the shelf by moving it upwards (see Fig. 3).
- 4) Pull the top drawer out from the trolley by the upward movement (the drawer moves in the guide rails of the metal sideboards – see Fig. 4). The drawer consists of two parts which can be split apart after being taken out. Keep the drawer (parts) for its possible mounting back into the trolley.
- 5) After the vacuum unit is unpacked, install it in the place left by the upper drawer by inserting it in the front guide rails of the metal sideboards (see Fig. 5). Leave the draining hose hanging freely along the sideboards of the trolley.
- 6) Cover the vacuum unit with the shelf and screw it carefully with screws in the holes on both sides (see Fig. 6).
- 7) Put the electrotherapy device on the shelf and secure it by the lock in the rear part of the shelf (see Fig. 7).
- 8) Place the power supply adaptors of the vacuum unit and electrotherapy device (*BTL-4000 Smart/Premium*) in the lower drawer (adaptors must not be placed on the stacker plate in the bottom part of the trolley to prevent the potential injury). Connect the output cable of the power pack and the mains cable through the hole on the rear of the bottom drawer. Connect the output cable of the adaptor in the connector of the power supply on the rear panel of the vacuum unit (**16**). For the cable fixation use the clamps on the sides of the drawers, the draining hose shall be fixed into the guide rail of the trolley metal sideboard by pressing it inside of the rail (see Fig. 8).

Place the trolley with the vacuum unit and the electrotherapy device on a place matching the operating conditions defined in the Chapters **Technical Parameters** and **Safety Precautions**.



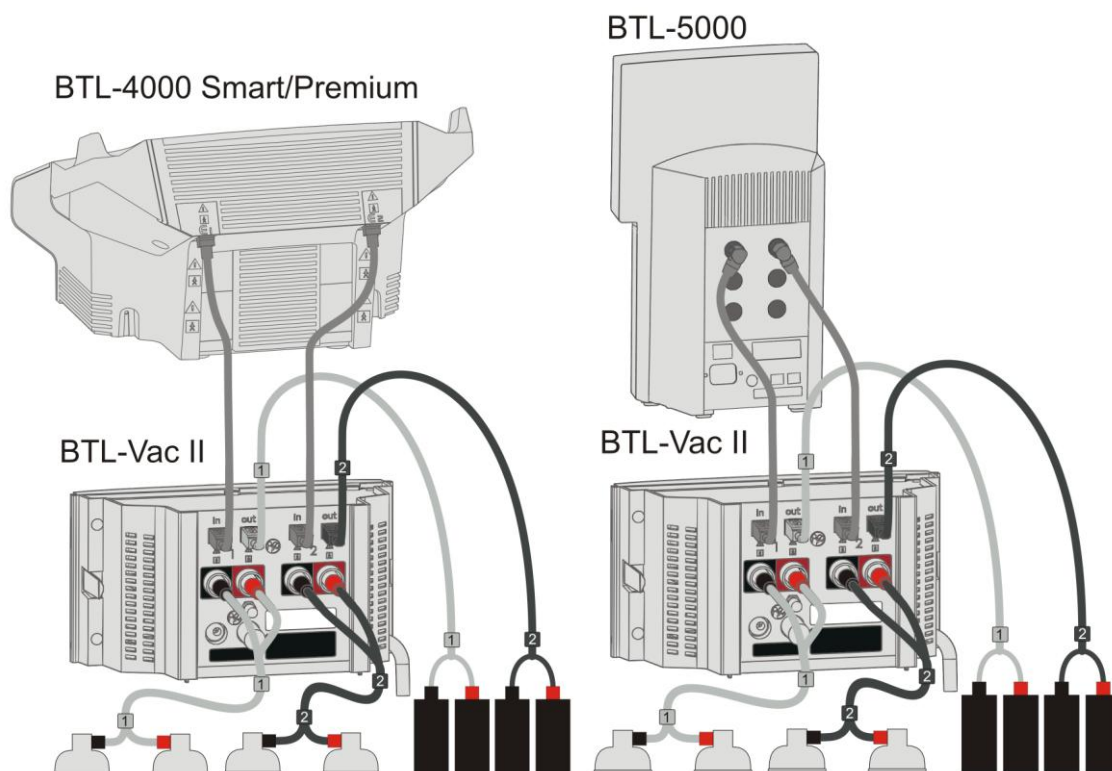
## 5.4 INTERCONNECTION WITH ELECTROTHERAPY DEVICES



As the source of the electrotherapeutic signal use only a *BTL-4000 Smart/Premium* or *BTL-5000 Series* electrotherapy device. The use of any other than the stated source of signal may lead to a serious injury to the health of the operator(s) and/or patient!

The interconnection of **BTL-Vac II** and *BTL-4000 Smart/Premium* or *BTL-5000 Series* is depicted in the following picture.

**ATTENTION! During the interconnection the devices have to be turned off and unplugged from the power supply or mains!**



Interconnect the vacuum unit with the electrotherapy device as follows:

- 1) The interconnection cable of electrotherapy channel 1 shall be connected in connector **in 1** on the vacuum unit (**9**). The interconnection cable of electrotherapy channel 2 shall be connected in connector **in 2** on the vacuum unit (**11**).
- 2) Connect the vacuum cables with vacuum electrodes in the output connectors for vacuum electrodes (**13**, **14**). The light grey vacuum cable marked as 1 shall be connected in the connectors of channel 1 (**13**) and the dark grey vacuum cable marked as 2 in the connectors of channel 2 (**14**). It is necessary to respect the colour marking for the cathode (black connector) and anode (red connector).
- 3) Connect the electrotherapy cables with plate electrodes in the output connectors for plate electrodes **out** (**10**, **12**). The light grey electrotherapy cable marked as 1 shall be connected in connector **out** of channel 1 (**10**) and the dark grey electrotherapy cable marked as 2 shall be connected in connector **out** of channel 2 (**12**). **Connect the plate electrode cables only when electrodes are deployed.**

**ATTENTION!** When disconnecting, vacuum and electrotherapy cables out from the device, always hold them by the connector, never by the cable itself. At that time the device has to be off and unplugged from the mains.

## 5.5 CONNECTION TO THE MAINS



Connect the device to the mains only through adaptor stated in the Chapter **Technical Parameters** and supplied together with the device. The use of any other than the stated adaptor may lead to a serious damage to the device with possible subsequent injury to the health of the patient and the operator(s)!

Do not use multi-connection extension cables or adapters.

Plug in the device into a directly accessible mains socket to ensure immediate device unplug in emergency cases.

## 5.6 OPERATION OF THE DEVICE

After interconnecting **BTL-Vac II** with the electrotherapy device and connecting to the mains, switch it on by pressing **on/off (8)** on the front panel. After switching on, the device performs the test of internal functions. The readiness for operation is indicated by the blue backlighting of the **on/off (8)** button. At the moment the plate electrodes are ready to use, which is indicated by the lighting up of the indicator signalling the output to the plate electrodes **(4)** and by the lighting up of the vacuum zero degree indicator **(2)** at the same time.

To put the vacuum unit into operation, press the **(+)** button to set the vacuum degree **(7)**. After the first pressing the device automatically sets the vacuum, suitable for the attachment of the electrodes (level 3). This is indicated by the lighting up of the respective vacuum degree indicator **(2)** and by the simultaneous lighting up of the indicator signalling the switched output to the vacuum electrodes **(5)**.

Put the moistened sponges in the vacuum electrodes and use slight deformation of the electrodes to stick them to the patient's body. If higher or lower vacuum degree is needed for the optimal attachment of the electrodes, modify it simply by pressing of the **(-)** and **(+)** buttons **(7)**; when increasing the vacuum, always follow patient's reactions. Do not attach the electrodes to the patient unless the vacuum cables are connected to the vacuum unit.

After switching the output to the vacuum electrodes the device always works in the continuous suction mode. This is indicated by the lighting up of the continuous mode indicator **(continuous) (1)**. Application of the vacuum electrodes to the patient's body is recommended in this mode.

The mode of therapy is changed by pressing **mode** button **(6)**. The selected mode is then indicated by the display of the mode waveform symbol **(1)**.

For sensitive patients, or on the body parts with thin and fine skin, set the vacuum to the lowest degrees. This will prevent excessive stress and possible damage to the skin and subcutis. For sensitive patient it is not recommended to use the pulse suction mode either.

When all parameters are set on the **BTL-Vac II** vacuum unit, start therapy on the electrotherapy device.

At the end of therapy, first finish the therapy on the electrotherapy device, then decrease the vacuum in the vacuum unit system to the zero degree by pressing of the **(-)** button **(7)**.

If the vacuum is decreased to level 0, the vacuum unit stops generating vacuum and switches the output automatically to the plate electrodes; the vacuum electrodes will be released. This is indicated by the level 0 of vacuum **(2)** and the indicator signalling the switching of the output to the plate electrodes **(4)**.

To switch off the device, press the **on/off** button **(8)**. After the complete switch-off the **on/off** button **(8)** goes out.



### 5.6.1 Vacuum Electrodes

The vacuum electrodes are available in three sizes – Ø 30 mm, Ø 60 mm and Ø 90 mm.

When applying electrotherapy, the correct passage of electric current is always provided by well moistened sponges, supplied with the vacuum electrodes. Sponges are supplied in the dried state (after first moistening they increase in size and become soft).

Always moisten the sponges with clean water.

For the moistening do not use protective solutions; for this reason the vacuum electrodes are not suitable for the application of direct currents and longer application of currents with DC component.

Before the first use it is necessary to wash the sponges carefully in tepid water! The sponges are from the factory impregnated with special substance preventing mould. After the washing and drying sponges become hard, what is not a defect – after the moistening they become soft again. After every therapy it is necessary to wash the sponges as described in the Chapter **Maintenance**.

### 5.6.2 Liquid Reservoir

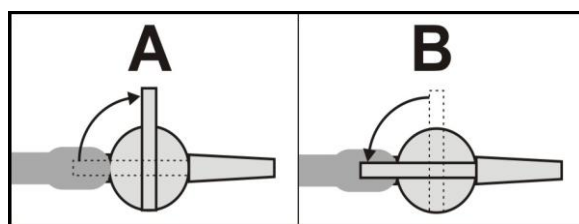
The suction of the moistened sponges during the operation of the vacuum unit causes the accumulation of liquid in the reservoir inside the device. The level in the tank is monitored by the electronics of the device and if exceeds the set limit, the reservoir has to be emptied. This is indicated by the flashing of the orange indicator **reservoir (3)** on the front panel of the device.

If the device starts signalling the necessity to empty the reservoir during the therapy, actual therapy may be completed without interruption. After the therapy is finished the reservoir has to be emptied, otherwise the device will not start the new therapy.

**ATTENTION! During the reservoir draining the device must always be turned off and the adaptor unplugged from the mains!**

The reservoir can be emptied easily using the draining hose. Place the hose with tap in a suitable vessel of a minimum volume of 650 ml and turn the tap to position B (according to the picture) to open it. When the draining is finished, close the tap on the draining hose by turning it to position A. Connect the device to the mains again and switch it on by pressing the **on/off** button **(8)**. If the tank draining was successful, the indicator **reservoir (3)** is not flashing and the device is ready for operation.

**ATTENTION!** The tap must always be closed during the therapy, i.e. in position A!



We recommend draining of the reservoir at the end of every operating day.

The reservoir should be disinfected in regular intervals (approx. 1 month) in the way described in the Chapter **Maintenance**.

### 5.6.3 Vacuum Modes

The device works both in continuous and pulse mode. The pulse modes perform mechanical stimulation together with electrotherapy, which improves the blood circulation in the tissue and supports the metabolism.

### 5.6.3.1 Continuous Mode

The vacuum in the system is kept constantly on the set value. The continuous mode is set by switching of the device to output to the vacuum electrodes (setting vacuum level above 0). If a pulse mode is set on the device, you can select the continuous mode by repeated pressing of the **mode** button **(6)** until the indicator **(continuous) (1)** signalling the continuous mode lights up.

The continuous mode is recommended when sticking the vacuum electrodes to the patient's body.

The operation in the continuous mode significantly extends the service life of the vacuum unit.

### 5.6.3.2 Pulse Modes

The vacuum in the system changes in regular pulses with a frequency of 5, 10, 15 or 20 pulses per minute. The change of the vacuum intensity in one period is within the range +30 hPa and -40 hPa from the selected vacuum degree. The values of each vacuum degree are listed in the Chapter **Technical Parameters**.

To switch between individual pulse modes, press the **mode** button **(6)**. The selected mode is indicated by the indicator with the symbolic representation of the mode waveform **(1)**.

## 5.7 ACCESSORIES OF THE DEVICE

### 5.7.1 Standard Accessories

- 1x mains adaptor (see Chapter **Technical Parameters**)
- 2x cables for the interconnection between BTL-Vac II and BTL-5000 Series
- 2x cables for the interconnection between BTL-Vac II and BTL-4000 Smart/Premium
- 2x patient vacuum cables – light grey for channel 1, dark grey for channel 2
- 2x patient cables for plate electrodes – light grey for channel 1, dark grey for channel 2
- 4x vacuum electrodes Ø 60 mm
- 4x sponges for electrodes Ø 60 mm
- 1x cleaning needle (for vacuum connectors)
- 1x fixation straps for the cables
- 1x user's manual

### 5.7.2 Optional Accessories

- vacuum electrodes Ø 30 mm
- sponges for electrodes Ø 30 mm
- vacuum electrodes Ø 90 mm
- sponges for electrodes Ø 90 mm



## 5.8 MAINTENANCE



**Before any maintenance switch off the device and unplug it from the mains!**

Follow all safety principles listed in the Chapter **Safety Precautions**.

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.

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

If you want to contact the authorized BTL service (because of finding any defect of the device or deviation from the normal function), please prepare the information about the device model, serial number and firmware version of the device. The firmware version number is indicated by the lighting up of one or more of the vacuum indicators **0 – 6 (2)** always after the start of the device when holding the **on/off (8)**; all mode indicators **(1)** are shining when the firmware version is displayed.

### 5.8.1 Cleaning of the Surface of the Device and its Parts

For cleaning of the device, its parts and accessories use a dry or slightly moistened soft cloth. For moistening use water or 2 % detergent solution. Never use agents containing alcohol, ammonia, acetone, benzene, thinners etc.

Never use abrasive materials for the cleaning of the device and its parts.

No part of the device needs to be sterilized.

### 5.8.2 Cleaning of the Accessories Coming into Contact with the Patient

The accessories that come into direct contact with the patient's body (electrodes and sponges) shall be cleaned after each use by means of disinfectants approved for the use in health service. After the disinfection it is necessary to rinse them with clean water to prevent undesirable allergic reaction! If you do not want to use the sponges immediately for the next therapy, let them dry completely on a dry and airy place.

At the end of every operating day disconnect the vacuum electrodes from the vacuum cables, unplug the cables from the output connectors of the device, hang them out and let them dry on a dry and airy place. When disconnecting the vacuum cables out from the device, always hold them by the connector, never by the cable itself.

### 5.8.3 Disinfection of the Reservoir

The disinfection of the reservoir is recommended to be done in regular intervals (at least once a month).

- 1) Immerse the connectors of the vacuum cables (after disconnecting the electrodes) in a vessel with a disinfectant (min. 450 ml, max. 550 ml) approved for the use in health service for the disinfection of plastic materials (agent not reacting with Polyoxymethylene). The agent must be non-frothing.
- 2) Press the **(+)** button **(7)** to start the suction of the device (leave the device in the continuous suction mode) and wait until the **reservoir** indicator **(3)** starts flashing. Immediately press the **(-)** button **(7)** to decrease the vacuum to 0. During the entire time it is necessary to stay near the device to prevent suction of more liquid than is total volume of the inner reservoir (the liquid could flow out and damage the device or its parts).
- 3) Take the vacuum cables out from the vessel with the disinfecting solution and rinse them in clean water. Switch the device off by pressing the **on/off (8)** button and disconnect the power pack from the mains.
- 4) Empty the reservoir completely into a suitable vessel in the way described in the Chapter 5.6.2.

- 5) If the solution flowing out from the device is significantly dirty, perform the disinfection repeatedly (always with new and clean disinfecting solution).
- 6) Connect the device in the mains again and switch it on by pressing the **on/off** button **(8)**. If the tank draining was successful, the indicator **reservoir (3)** is not flashing and the device is ready for use.

#### 5.8.4 Transport and Storage

Keep the original package. Transport the unit in the original box to ensure maximum protection. Unplug the main power cord and all accessory cables. Take care to avoid shocks or jarring movements to the device during transport. This device shall only be transported and stored under the conditions defined in the Chapter **Technical Parameters**. Do not store the device in dusty or humid environment.

## 6 TECHNICAL PARAMETERS


<b>Name</b>	<b>BTL-Vac II</b>
<b>Operating conditions</b>	<b>For indoor use only</b>
Ambient temperature	+10 °C to +40 °C
Relative humidity	30 % to 75 %
Atmospheric pressure	800 to 1,060 hPa
Position	Horizontal
Type of operation	Continuous
<b>Storage and transport conditions</b>	
Ambient temperature	-10 °C to +55 °C
Relative humidity	10 % to 85 %
Atmospheric pressure	650 to 1,100 hPa
Position	Any (the collection tank must always be empty)
Other conditions	Transport only in the supplied package
<b>Power supply</b>	
<b>Mains power supply</b>	<b>BTL-4000 Adaptor, model SA160D-24U-M</b>
Voltage / output current	Input mains voltage: AC 100 V to 240 V
Mains frequency	Output voltage: 24 V DC, max. 2.5A
	50 – 60 Hz.
	<b>The device may only be used with the stated adaptor!</b>
<b>Device</b>	
Supply voltage	24 V DC
Device input	Max. 25 VA
Device class according to IEC 536	II
Disconnection from mains acc. to IEC 60601-1	By the mains supply cable
Device switch	On the front panel, marked on/off
<b>Design</b>	
Weight	1.9 kg device, 4.2 kg including package
Dimensions (W x H x D)	250 x 130 x 209 mm
Degree of protection acc. to EN 60529	IP20
Functional volume of the reservoir	500 ml
<b>Set values</b>	
<b>Vacuum</b>	
Range	60 – 220 hPa (0.06 – 0.22 Bar)
Step of setting	7 stages (0, 60, 100, 140, 180, 200, 220 hPa)
<b>Number of pulses</b>	
Selection from values	5, 10, 15, 20 pulses/min.
<b>Inputs/outputs</b>	
Type of device by the patient connection	Single-patient, 2 independent electrotherapies
Applied part of the device	Plate electrodes (not included in the packaging) Vacuum electrodes – see Chapter 5.6.1 All applied parts in the function of one applied part
<b>Accuracy of the set values</b>	
Setting of vacuum	± 30 %
Pulse frequency	± 5 %
<b>Classification</b>	
Type of patient part according to IEC 60601-1	BF
Class according to MDD 93/42/EEC	IIB
<b>Interconnection</b>	
Possibility to interconnect with the devices	BTL-4000 Smart/Premium and BTL-5000 Series. <b>Other combinations are not allowed!</b>

## 6.1 EMC DECLARATION

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
BTL-Vac II is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-Vac II should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
RF emissions CISPR 11	Group 1	BTL-Vac II must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.  BTL-Vac II 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.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
BTL-Vac II is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of BTL-Vac II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and BTL-Vac II as recommended below, according to the maximum output power of the communications equipment.			
<b>Rated maximum output power of transmitter [W]</b>	<b>Separation distance according to frequency of transmitter (m)</b>		
	<b>150 kHz to 80 MHz <math>d=1,17\sqrt{P}</math></b>	<b>80 MHz to 800 MHz <math>d=1,17\sqrt{P}</math></b>	<b>800 MHz to 2,5 GHz <math>d=2,34\sqrt{P}</math></b>
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.			

<b>Directive and declaration of manufacturer – Electromagnetic immunity</b>			
BTL-Vac II is intended for use in the electromagnetic environment specified below. The customer or the user of BTL-Vac II should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
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 line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <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 BTL-Vac II requires continued operation during power mains interruptions, it is recommended that the BTL-Vac II 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: UT is the a.c. mains voltage prior to application of the test level.			

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
BTL-Vac II is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-Vac II should assure that it is used in such an environment.			
<b>IMMUNITY test</b>	<b>IEC 60601 TEST LEVEL</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of BTL-Vac II, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:  <math>d=1,17\sqrt{P}</math> 80 MHz to 800 MHz  <math>d=2,34\sqrt{P}</math> 800 MHz to 2,5 GHz</p> <p>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).</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	<p>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<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>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-Vac II is used exceeds the applicable RF compliance level above, the BTL-Vac II 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-Vac II.</p>			
<p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

## 7 MANUFACTURER

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