# User Manual

# InVacMed

## Vacuum massage unit


CE 0197

| Manufacturer: | Distribution and service in Poland: |
|---|---|
| **Meden-Inmed Sp. z o.o.**<br>ul. Wenedów 2<br>75-847 Koszalin<br>Poland | Service: +48 94 344 90 48<br>Website: **www.en.meden.com.pl/service**<br>E-mail: **service@meden.com.pl** |

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# 1 Introduction

We would like to congratulate you on the excellent choice of InVacMed vacuum massage unit of our design and manufacture.

The user's compliance with the recommendations contained in this user manual and the use of the information contained therein enables safe, long-term and trouble-free use of the InVacMed vacuum massage unit.

General notes:

1. The product should be operated by qualified and trained personnel, who has read through this user manual.
2. Using, operating and servicing of the product inconsistently with this user manual is prohibited and may lead to damage which is incriminating for the user and for which the manufacturer is not responsible.
3. The manufacturer prohibits performing any modifications in the used device.
4. If the operation and parameters of the product are inconsistent with the description in this user manual, the product must not be used. Please report this fact to the manufacturer or supplier immediately.
5. The warranty covers all material and manufacturing defects.
6. Every repair of the product must be conducted by the manufacturer or an authorized service and recorded in the repair list added to the warranty card. Failure to comply with this requirement will void the warranty on the product.
7. Technical description of the device with a list of spare parts and methods of their replacement is available from the manufacturer on request.
8. Any serious InVacMed vacuum massage unit incident shall immediately be reported to the manufacturer and to the competent authority of the Member State where the user or patient is resident.

The warranty conditions shall become invalid if the device is used for the purpose other than the purpose for which it was designed or if it is not operated in accordance with the instructions provided in this User Manual.

The manufacturer shall not be liable for the consequences of improper (inconsistent with the conditions set out in this User Manual) use of InVacMed vacuum massage unit.

## 1.1 Symbols

| | CAUTION! |
|---|---|
|  | This indicates actions which, if not carried out in compliance with the contents of this User Manual, may result in impairment of conditions or safety hazards for the user and/or operating personnel. Similar markings are provided on the unit where it is essential to read and follow the User Manual when using the device. |
|  | Follow the instructions in the User Manual.<br>The marking is located on the casing of the device. |
|  | Applied part type BF |
|  | Electrical safety class II device |
| MD | Medical device |
| UDI | Unique Device Identification |
| REF | Catalogue number |
| SN | Serial number |
| LOT | Lot ID (applies to accessories) |
|  | Do not disassemble |
| IP20 | Protection level against solid objects and water provided by the casing |
|  20YY | Manufacturer and year of production |
|  | According to the provisions of the Act on used equipment, it is prohibited to dispose of used equipment marked with the crossed-out garbage can symbol with other waste. Used electrical and electronic equipment should be handed over to a collection point. The above statutory obligations were introduced to limit the quantity of waste electrical and electronic equipment and to ensure an appropriate level of collection, recovery and recycling of waste equipment. Proper implementation of these duties is particularly important when waste equipment contains hazardous components that have a particularly negative impact on the environment and human health. |

# 2 Intended use

The InVacMed device is designed for vacuum massage and electrode attachment during electrotherapy treatments.

The InVacMed device allows you to carry out combined electrotherapy and vacuum massage treatments in continuous mode with a constant negative pressure value prevailing in the space under the suction electrodes cups and in pulsation mode with a variable negative pressure value in the range of 60 to 400 mbar.

The device has the possibility of cooperation with electrotherapy units manufactured by „Elektronika i ElektroMedycyna" from Otwock.

It is possible to connect the InVacMed device to electrotherapy units from other manufacturers using additional transition cables.

## 2.1 Indications

- burns,
- traumatic scars,
- burn scars,
- cellulite,
- improvement of the tissue elasticity,
- venous and lymphatic stasis
- inflammation and edema in muscles,
- skin graft with (at least 3 months of postoperative healing (0.2 mm thick)),
- non-specific neck and nape pain.

## 2.2 Contraindications

CAUTION!

There is a risk of significant subcutaneous hemorrhages as a result of the treatment in the part of the body where the suction electrodes would be attached.

- third trimester of pregnancy,
- skin sensitive to irritation,
- central neurological conditions,
- peripheral paralysis,
- diabetes,
- taking medications i.e. Aspirin, Warfarin, Marcumar, Methrotrexate and Cyclosporin,
- infection (fever in the last 24 h),
- limitation of upper limb movements (if the treatment is performed on the upper limbs).

## 2.3 Intended target group

Patients over the age of 18 are referred for vacuum massage treatments with the InVacMed device by their attending physician, who evaluates their condition for suitability for the treatment. The physician and/or qualified personnel, who perform the vacuum massage treatment, determine the initial parameters, such as: the duration of the treatment, its intensity and repetition frequency.

## 2.4 Users

Users of the InVacMed vacuum massage unit are qualified personnel who have read the information contained in the user manual for this device.
The device is intended for use in professional medical care environments such as hospitals, clinics, outpatient clinics, etc.

# 3 Technical characteristic

## 3.1 Technical parameters

Table 1 - Technical parameters of the InVacMed device

| Technical parameters | | InVacMed |
|---|---|---|
| Power supply | | 230 V/50-60 Hz |
| Power consumption [A] | | max. 0,1 A |
| Fuse | | 125 mA T/250 V |
| Vacuum in the pneumatic system [mbar] | | max. 400 (relative) |
| Reservoir-dehydrator capacity [ml] | | min. 80 |
| „$H_2O$" optical alarm level [ml] | | no more than 50 |
| Pulsation frequency [impulses/min] | | 15-90 |
| Device operation mode | | continuous running duty |
| Mode of operation (vacuum in the pneumatics system) | | continuous, pulsation |
| Vacuum range [mbar] | continuous mode | 60-400 |
| | pulsation mode | 100-400 |
| Dimensions (WxHxD) [mm] | without accessories | 335x135x285 |
| | with the drain tube | 335x135x325 |
| Device weight (without accessories and packaging) [kg] | | ok. 3,4 |
| Electrical safety class | | II |
| Applied parts | | type BF (suction electrodes) |
| Protection level | | IP20 |
| Environmental conditions (temperature, humidity, pressure) | operation | 15 °C – 40 °C, 30 % – 75 % non-condensing, 700 – 1060 hPa |
| | storage | 5 °C – 45 °C, <75 % non-condensing, 700 – 1060 hPa |
| | transport | -10 °C – 45 °C, 20 % – 95 % non-condensing, 700 – 1060 hPa |

## 3.2 Classification

CE 0197 InVacMed vacuum massage unit is manufactured in accordance with Medical Device Regulation 2017/745 (class IIa, 9 rule) and has a CE marking, according to the manufacturer declaration.

## 3.3 Transport and storage

Device should be transported in covered means of transport in accordance with applicable law with packaging protected against opening. The device should be stored indoors in dry conditions. Environmental conditions for transport and storage are shown in Table 1.

# 4 General warnings and safety measures

CAUTION!

The InVacMed device may only be used in such rooms where the electrical installation is carried out in accordance with generally applicable standards.

CAUTION!

Connecting the InVacMed device to a 230 V power grid shall be in accordance with the general provisions for fire protection for medical premises.

CAUTION!

The InVacMed device must be plugged into a 230 V wall outlet so that the power cord plug can be easily removed from the outlet.

CAUTION!

To reliably disconnect the InVacMed device power system, unplug the power cord of the device from the 230 V power outlet.

CAUTION!

The InVacMed device is not prepared and cannot operate in rooms where flammable gases or vapors are present.

CAUTION!

The InVacMed device is not designed for use in humid areas. Install the InVacMed device in a dry location so that it is protected from water or other liquids leaking into the device.

CAUTION!

The InVacMed device should not be exposed to high temperatures (radiator, sun, etc.).

CAUTION!

Before connecting or disconnecting the power supply to the InVacMed device it is absolutely essential to disconnect it from the patient circuit.

CAUTION!

The InVacMed device should be unplugged from the 230 V power grid before disinfecting the room where the device is installed.

CAUTION!

Damaged connection cables and electrodes should be immediately replaced with working ones.

CAUTION!

Emptying of the reservoir-dehydrator should be carried out immediately after the treatment, during which the optical alarm "$H_2O$" occurred. Emptying of the reservoir-dehydrator should be carried out with the 230 V power cord of the device disconnected from the power grid.

CAUTION!

Before changing the place of use of the InVacMed device, it is necessary to completely empty the reservoir-dehydrator beforehand, regardless of the status of the "$H_2O$" indicator.

CAUTION!

The InVacMed device is designed to work with electrotherapy units produced by the „Elektronika i ElektroMedycyna" from Otwock.

CAUTION!

The cooperation of the InVacMed device with electrotherapy units, whose construction and design must comply with the requirements of the current version of the EN 60601-1 standard, is possible after obtaining an appropriate connection cable from the manufacturer of the InVacMed device.

CAUTION!

When the InVacMed device is used with a connected electrotherapy unit, it is important to follow the safety instructions provided by the electrotherapy device manufacturer.

CAUTION!

The InVacMed device must not be placed above another device if water leakage from the reservoir-dehydrator could cause a flood hazard to the device below.

CAUTION!

The user is obliged to have a technical inspection of the InVacMed device carried out once a year by the manufacturer or a technical service authorized by the manufacturer. The technical inspection should include the program of activities, presented in the table (see section 12 of this User Manual), in which its results should also be documented.

CAUTION!

Any repair following an InVacMed device failure must be completed with a safety test and confirmed by a test report.

CAUTION!

The InVacMed device has a non-removable mains power cord that cannot be replaced by service personnel.

CAUTION!

Viscose pads should be stored in dry conditions. Viscose pads should not be stored in a closed container without air access.

# 5 Device description

## 5.1 Front control panel

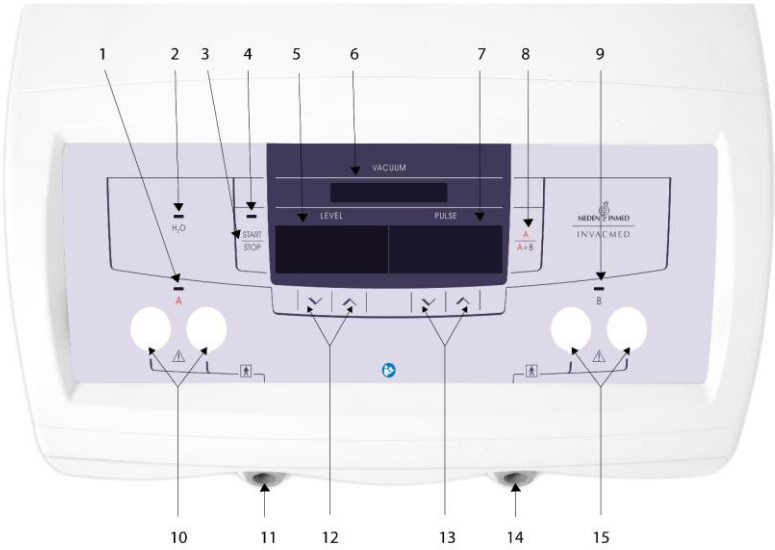


Figure 1 - View of the front control panel of the InVacMed device

The individual elements of the front control panel (Fig. 1) function as follows:

(1) - „Circuit A" indicator lights up to signal the presence of the signal from the connected electrotherapy unit on the "Circuit A" connection (10) (the signal is present only during running treatment - the treatment indicator (4) lights up).

(2) - „$H_2O$" indicator – lights up to signal the need to empty the reservoir-dehydrator.

(3) - START / STOP button – starts and stops the treatment.

(4) - Treatment indicator – lights up to signal that the treatment is running.

(5) - „LEVEL" display – displays the set vacuum level.

(6) - „VACUUM" display – displays real-time vacuum level in suction electrodes; display dimmed – no vacuum.

(7) - „PULSE" display – displays the set pulsation frequency (number of pulses per minute).

(8) - A / A+B button – is used to select connection on which the signal from the electrotherapy unit is present.

(9) - „Circuit B" indicator lights up to signal the presence of the signal from the connected electrotherapy unit on the "Circuit B" connection (15) (the signal is present only during running treatment - the treatment indicator (4) lights up).

(10) - „Circuit A" connection is used to connect the electro-pneumatic cables with suction electrodes in the patient's circuit A.

(11) - "Electrodes – circuit A" connection is used to connect conventional electrodes for electrotherapy and conduct treatment without suction electrodes in the patient's circuit A.

(12) - Buttons used to set the vacuum level:

button – level reduction, button – level increase.

(13) - Buttons used to set the pulsation frequency:

button – frequency reduction, button – frequency increase.

(14) - "Electrodes – circuit B" connection is used to connect conventional electrodes for electrotherapy and conduct treatment without suction electrodes in the patient's circuit B.

(15) - „Circuit B" connection is used to connect the electro-pneumatic cables with suction electrodes in the patient's circuit B.

## 5.2 Rear panel

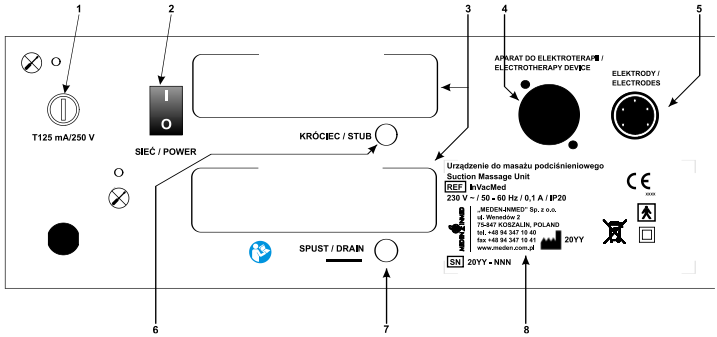


Figure 2 - View of rear panel of the InVacMed device

The individual elements of the rear panel (Fig. 2) function as follows:

(1) - Fuse socket T125 mA (T-slow), 250 V.

(2) - Power switch (**1** – ON, **0** - OFF), 230 V power supply.

(3) - Information on how to empty the reservoir-dehydrator.

(4) - „Electrotherapy device" connection allows you to connect the electrotherapy unit.

(5) - „Electrodes" connection is used to connect conventional electrodes for electrotherapy and conduct treatment without suction electrodes.

(6) - Stub, used to attach the drain tube after draining the reservoir-dehydrator.

(7) - Drain outlet that allows you to drain the reservoir-dehydrator.

(8) - Device nameplate.

## 5.3 Accessories

CAUTION!

Use accessories specified by the device manufacturer.

Standard equipment of the InVacMed device includes:

| | |
|---|---|
| Suction electrode, diameter 60 mm, 04-R0101-0010 (Fig. 3 item 1) | 4 pieces |
| Electro-pneumatic connection cable (black with black jack),04-R0101-0001 (Fig. 3 item 2) | 1 piece |
| Electro-pneumatic connection cable (black with red jack),<br>04-R0101-0004 (Fig. 3 item 3) | 1 piece |
| Electro-pneumatic connection cable (red with red jack),<br>04-R0101-0003 (Fig. 3 item 4) | 1 piece |
| Electro-pneumatic connection cable (red with black jack),<br>04-R0101-0002 (Fig. 3 item 5) | 1 piece |
| Disposable viscose pads, diameter 60 mm, 04-R0101-0005 (Fig. 3 item 6) | 8 pieces |
| Pneumatic connection cap (red), 04-R0101-0008 (Fig. 3 item 7) | 1 piece |
| Pneumatic connection cap (black), 04-R0101-0009 (Fig. 3 item 8) | 1 piece |
| User manual with warranty card and periodic technical inspection card | 1 piece |

In addition, the manufacturer of the InVacMed device offers:

| | |
|---|---|
| Connection cable for electrotherapy unit | acc. to the order |
| Suction electrode, diameter 30 mm, 04-R0101-0012 | acc. to the order |
| Suction electrode, diameter 90 mm, 04-R0101-0011 | acc. to the order |
| Disposable viscose pads, diameter 30 mm, 04-R0101-00014 | acc. to the order |
| Disposable viscose pads, diameter 90 mm, 04-R0101-00013 | acc. to the order |


Figure 3 - Standard InVacMed device accessories

# 6 Operation of the InVacMed device

## 6.1 Activating InVacMed

1. Plug the power cord into a 230 V power outlet.
2. Turn on the device using power switch on the rear panel. The "LEVEL" and "PULSE" displays light up.

## 6.2 Connecting InVacMed with an electrotherapy device

Connect the electrotherapy unit to the "Electrotherapy device" input jack on the rear panel of the InVacMed device, using the connection cable supplied with the InVacMed device.

## 6.3 Electrode suction cup preparation

Viscose pads are disposable. Before use, rinse them under running water and then squeeze out excess water. Place thus prepared pads in the cups of the suction electrodes.

Figure 4 - Suction electrode with a viscose pad

## 6.4 Connection selection

Subsequent pressing of the 

(Fig. 1 item 8) changes the connections on which the current from the electrotherapy unit appears. The "Circuit A" (Fig. 1 item 1) and "Circuit B" (Fig. 1 item 9) indicators are used to signal this change.

Depending on the status of the "Circuit A", "Circuit B" and treatment indicator (Fig. 1 item 4) (see section 12 below), the current from the electrotherapy unit will be present on the connections:

| treatment indicator | "Circuit A" indicator | "Circuit B" indicator | presence of power at the connections | type of electrodes used and place of connection |
|---|---|---|---|---|
| doesn't light up | unaffected | unaffected | „Electrodes - Circuit A" (Fig. 1 item 11) „Electrodes - Circuit B" (Fig. 1 item 14) „Electrodes" (Fig. 2 item 5) | conventional electrodes only – connect to the „Electrodes – Circuit A", „Electrodes - Circuit B" or „Electrodes" connections |
| lights up | lights up | doesn't light up | „Circuit A" (Fig. 1 item 10) „Electrodes - Circuit B" (Fig. 1 item 14) „Electrodes" (Fig. 2 item 5) – Circuit B only | suction electrodes – connect to the „Circuit A" connection conventional electrodes – connect to the „Electrodes – circuit B" or „Electrodes" connections |
| lights up | lights up | lights up | „Circuit A" (Fig. 1 item 10) „Circuit B" (Fig. 1 item 15) | suction electrodes – connect to the „Circuit A" and „Circuit B" connections |

## 6.5 Connecting electrodes

### 6.5.1 Patient circuits and suction cup electrode polarity

The patient's circuit A should be connected by the red electro-pneumatic cables.

The patient's circuit B should be connected by the black electro-pneumatic cables.

The polarity of the electrodes in each circuit is coded by the color of the cable plug (red and black) according to the color of the border around the connection socket and should correspond to the polarity that is set on the electrotherapy unit.

Before starting the treatment, check that the black and red cables are connected to the corresponding red and black connection sockets of the "Circuit A" and "Circuit B" connections of the InVacMed device (Fig.5).

### 6.5.2 Using only standard electrodes

Connect the cable with conventional electrodes to the "Electrodes" connection on the rear panel or to the "Electrodes - circuit A" and "Electrodes - circuit B" connections on the front of the device. Place the electrodes on the patient's body according to the instructions of the electrotherapy unit.

### 6.5.3 Using only suction cup electrodes

1. Connect the suction electrodes with electro-pneumatic cables to the "Circuit A" and "Circuit B" connection sockets (Fig. 5 item a). If the treatment is to be carried out using two suction electrodes, insert the pneumatic connection caps into the "Circuit B" connections sockets (Fig. 5 item b).

a b

Figure 5 - Connecting the electro-pneumatic cables to the InVacMed device using 4 (a) or 2 (b) suction electrodes

2. Turn on the pump of the device with the START / STOP button.
3. When the pump is turned on, the signal from the electrotherapy unit is applied to the selected connections. The signal to the "Circuit B" connection can be switched on and off by successively pressing the A / A+B button. The "Circuit A" and "Circuit B" indicators light up to indicate on which connections the signal from the electrotherapy unit is present.
4. Place the suction electrodes on the patient's body at the required locations, and then suction them to the patient's skin by setting the appropriate vacuum value. Be careful not to set the vacuum too high, as this may be uncomfortable for the patient.

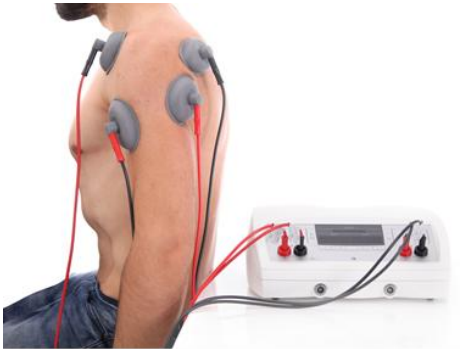

Figure 6 - Example of suction electrode placement on a patient

If the pulsation mode is indicated (which is definitely more pleasant for the patient), it can be activated by setting the desired pulsation frequency. The "VACUUM" bar indicator pulsates to the rhythm of the vacuum level fluctuations.

5. Check that the suction cups are sufficiently attached to the patient's skin.

### 6.5.4 Using standard electrodes in combination with suction cups

1. Connect two suction electrodes to the "Circuit A" connection and two conventional electrodes to the "Electrodes" connection socket on the rear panel or to the "Electrodes - Circuit B" connection socket on the front panel.
2. Set the desired vacuum level.
3. Check that "Circuit B" is disconnected - the "Circuit B" indicator does not light. If it is not disconnected, press the 

button to disconnect the signal from the electrotherapy unit in circuit B of the suction cups - the "Circuit B" indicator will go off.
4. Close the connection sockets of the "Circuit B" with the pneumatic connection caps, supplied with the device (Fig. 5 item b). In this connection arrangement, the signal from the electrotherapy unit is applied to the "Circuit A" connection sockets (suction electrodes) and to the circuit B of the conventional electrodes, connected to the "Electrodes" connection socket on the rear panel and to the "Electrodes – Circuit B" socket on the front panel.
5. Turn on the device pump with the 

button.
6. Place the suction electrodes and conventional electrodes on the patient's body in the required locations and then attach them to the patient's skin. Be careful not to set the vacuum too high, as this can be unpleasant for the patient. If the pulsation mode is indicated (which is definitely more pleasant for the patient), it can be activated by setting the desired pulsation frequency. The "VACUUM" bar indicator pulsates to the rhythm of the vacuum level fluctuations.
7. Check that the suction cups are sufficiently attached to the patient's skin.

## 6.6 Setting the vacuum level

The level is adjusted using the buttons for setting the vacuum level (Fig. 1 item 12). The „LEVEL" display (Fig. 1 item 5) shows the set vacuum level. In continuous mode, the pneumatics system of the InVacMed device enables a vacuum level in the suction cups in a range of 85 levels with a step of 1:

- from a minimum of 60 mbar (6 kPa) – a vacuum level set at 15,
- to a maximum of 400 mbar (40 kPa) – a vacuum level set at 99.

The minimum vacuum required to keep the suction cups on the patient's skin is approximately 60 mbar (6 kPa) – the vacuum level is set at 15. In pulsation mode, the pneumatics system of the InVacMed device allows the vacuum to be adjusted in a range of 75 levels with a step of 1:

- from a minimum level of 25, corresponding to a minimum vacuum of 100 mbar (the minimum necessary to keep the suction cups on the skin),
- to a maximum level of 99, corresponding to a maximum vacuum of 400 mbar.

## 6.7 Switching the pulsation mode on and off, setting the pulse frequency

The pulsation frequency can be adjusted using the buttons for setting the pulsation frequency (Fig. 1 item 13). The „PULSE" display (Fig. 1 item 7) shows the set pulsation frequency (number of pulses per minute).

Setting the value to 00 disables pulsation mode.

The pulsation can be adjusted from 15 to 90 pulses per minute with a step of 1.

The amplitude of the vacuum changes may decrease with increasing pulsation frequency.

## 6.8 Starting and stopping the treatment

CAUTION!

Reduce the current to zero in the electrotherapy unit before stopping the treatment.

Subsequent pressing the START / STOP button (Fig. 1 item 3) starts and stops the treatment.

A lit treatment indicator (Fig. 1 item 4) signals a running treatment. A turned off treatment indicator means the treatment has stopped.

## 6.9 Emptying the reservoir-dehydrator

CAUTION!

During the treatment, water is extracted from the viscose pads and collects in a special reservoir inside the device. When the water level in this reservoir approaches its maximum, the "$H_2O$" indicator is activated, signalling the need to empty the reservoir. In this case, you can continue with the treatment you started. However, a new treatment cannot be started as long as the '$H_2O$' indicator is lit.

In order to drain the reservoir-dehydrator follow the instructions below:

- Turn off the device and disconnect the power cord plug from the 230 V power outlet.
- Disconnect the electro pneumatic cables and remove the pneumatic connection caps from the "Circuit A" and "Circuit B" connections.
- Prepare a vessel with a capacity of min. 150 ml and place it below the level marked "Drain".
- Pull off the end of the drain tube from the spigot (marked "STUB").
- Place the end of the drain tube in the prepared container, below the level marked "Drain", which will cause water to flow out through the drain and empty the reservoir. It may take up to 1 minute for water to flow out.
- Put the end of the drain tube back on the spigot.
- Connect the 230 V power cord and turn on the power using the switch on the rear panel of the device.

  The procedure for emptying the reservoir-dehydrator is also described on the rear panel of the device.

Figure 7 - Emptying the reservoir-dehydrator

### 6.10 Recommended operation area organization

CAUTION!

Do not place the InVacMed device above another device if water leakage from the reservoir-dehydrator could cause flood hazard to the device below.

Place the device on a stable and horizontal base at the place, where the treatment is performed, near the electrotherapy unit and power outlet. Ensure that the connection and power cords are placed in such a way that they cannot be accidentally pinched or broken and do not impede movement around the room.

# 7 Treatment

## 7.1 Test treatment

CAUTION!

Each time the vacuum value is selected, the impact of the previous treatment should be evaluated and taken into account in terms of the presence of traces of subcutaneous effusion.

For patients using vacuum massage for the first time, it is recommended to perform a test treatment with subsequent assessment of susceptibility to subcutaneous effusions.

For this purpose, the first treatment should be performed in no more than 10 minutes and at the minimum level at which the suction caps are still held on the patient's body (usually a level set at 15-20). The next massage is performed after inspecting patient's body in the treated areas and assessing the susceptibility to effusions:

- with no visible traces of subcutaneous effusion, the vacuum level can be increased,
- with traces of subcutaneous effusion, consider the advisability of continuing therapy.

## 7.2 Performing the treatment

CAUTION!

In order to remove or move the suction cups or electrodes during the treatment, first set the current value on the electrotherapy unit to 0.

1. Connect the InVacMed device to the electrotherapy unit (see section 6.2 above).
2. Turn on the InVacMed device (see section 6.1 above).
3. Turn on the power of the electrotherapy unit.
4. Check that the current of the electrotherapy unit is set to 0.
5. Set the desired vacuum level (see section 6.6 above) and pulsation frequency (see section 6.7 above).
6. Prepare the suction electrodes, if they are used during the treatment (see section 6.3 above).
7. Connect the suction electrodes and/or conventional electrodes. Then place them on the patient's body (see section 6.5 above).
8. Set the desired type and intensity of current and treatment duration on the electrotherapy unit.

## 7.3 Ending the treatment

1. Wait for the end of the treatment time set in the electrotherapy unit or set the current value in both patient's circuits to 0.
2. Stop the treatment (see section 6.8 above). After a few seconds, the suction electrodes can be easily removed from the patient's skin.

# 8 Maintenance

CAUTION!

Maintenance or repair activities of the InVacMed device must not be performed, when the device is being used by a patient.

CAUTION!

Before cleaning or repairing the InVacMed device, unplug it from the 230 V wall power outlet.

CAUTION!

Changing location and transporting of the InVacMed device should be carried out after emptying the reservoir-dehydrator.

## 8.1 General recommendation

For daily maintenance, it is not necessary to open the device casing. Only technical service personnel authorized by the manufacturer can open the device casing for repair purposes.

## 8.2 Keeping the device clean

### 8.2.1 Procedure of cleaning the device

Use a slightly damp, soft cloth to clean the front panel and casing of the device. If necessary, you can use a mild detergent. When cleaning, be careful not to let water or other liquid inside the device.

### 8.2.2 Procedure for cleaning the electrodes and the suction cup

CAUTION!

After each use, the electrodes and suction cups should be thoroughly cleaned in a lukewarm soap solution or a 70% ethanol solution. For better access to the suction cups, the metal electrodes can be removed from inside the cup. Then rinse the cups in running water and dry them with a clean cloth. After wiping dry, place the metal electrodes back into the cup.

### 8.2.3 Procedure for cleaning the reservoir-dehydrator

CAUTION!

Do not exceed the amount of 40 ml of alcohol and do not use foam-producing agents when cleaning the reservoir-dehydrator, as this may damage the device.

CAUTION!

Do not exceed the amount of 40 ml of water when cleaning the reservoir-dehydrator, as this may damage the device.

Clean the reservoir-dehydrator once a week according to the following instructions:

- empty the reservoir-dehydrator (see section 6.9 above),
- connect all four electro-pneumatic cables without suction electrodes to the device (check that there is no water in the cables before connecting),
- prepare 40 ml of ethyl alcohol in a vessel,
- turn on the device, set the maximum vacuum level, turn off the pulsation mode and start the treatment,
- immerse the ends of the electro-pneumatic cables in a vessel with alcohol, so that all solution is sucked in,
- turn off the device and wait at least 15 minutes,
- empty the reservoir-dehydrator (see section 6.9 above),
- prepare 40 ml of water of at least potable quality in a vessel,
- turn on the device, set the maximum vacuum level, turn off the pulsation mode and start the treatment,
- immerse the ends of the electro-pneumatic cables in the vessel with water, so that all the water is sucked in,
- turn off the device,
- empty the reservoir-dehydrator (see section 6.9 above),
- disconnect the electro-pneumatic cables from the device and flush them with a water of at least potable quality.

## 8.3 Troubleshooting

### 8.3.1 „LEVEL" and „PULSE" displays do not light up

1. Make sure, that the device is turned on with the switch on the rear panel and that the power cord is securely connected to the power outlet.
2. Check with another working device, if there is voltage at the wall power outlet.
3. If the wall power outlet has power and displays still don't light up, replace the fuse in the device (see section 8.3.2 below).

### 8.3.2 Fuse replacement

CAUTION!

Always replace fuses with the ones that are identical in type, voltage and current values.

1. Disconnect the device from the 230 V power grid.
2. Insert a flat screwdriver into notch on the fuse socket.
3. Push the screwdriver in and turn it counterclockwise until it stops.
4. Remove the fuse with the holder.
5. Insert the holder with a new fuse into the fuse socket.
6. Insert a flat screwdriver into notch on the fuse socket.
7. Push the screwdriver in and turn it clockwise until it stops.

If the device still does not function properly, then contact the manufacturer or an authorized service representative.

## 8.4 Service contact

Meden-Inmed Sp. z o.o.
ul. Wenedów 2
75-847 Koszalin
tel. (94) 344 – 90 – 48
e-mail: service@meden.com.pl

If you purchased the device from a distributor, we kindly ask you to provide information about the serial number and place of use of the device by any means. This data will be placed in our service database, which will enable us to fulfill the warranty and service conditions efficiently.

# 9 Manufacturer's liability

The expected useful life is 5 years.

After 5 years from the date of manufacture of the device (and its equipment), the manufacturer is not responsible for defects in the device and its equipment and the resulting consequences. The manufacturer is also not responsible for any consequences that the user or the patient may suffer as a result of, for example, incorrect installation of the device, or as a result of a misdiagnosis, improper use of the device and its equipment, incorrect interpretation or failure to follow the user manual and repairs carried out by unauthorized persons.

# 10 Electromagnetic compatibility – guidance and manufacturer's declaration

CAUTION!

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.

CAUTION!

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.

CAUTION!

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.

CAUTION!

The device* may be susceptible to electromagnetic disturbances, but Basic Safety and Essential Performance are maintained.

Essential Performance – The risk assessment shows that there are no risks for functioning of this product.

*InVacMed – vacuum massage unit

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | The equipment* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | The equipment* is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* 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) ± 2/4/8/15 kV (air) | ± 8 kV (contact) ± 2/4/8/15 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 100 kHz | ±2 kV for supply lines 100 kHz | Mains power quality should be that of a typical commercial or hospital environment. |

| | | | |
|---|---|---|---|
| Surge<br>IEC 61000-4-5 | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | ± 1 kV line(s) to line(s)<br>± 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<br>IEC 61000-4-11 | 0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % UT; 1 cycle and 70 % UT; 25/30 cycles (50/60Hz)<br>1 phase: at 0°<br><br>0 % UT; 250/300 cycles (50/60Hz) | 0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % UT; 1 cycle and 70 % UT; 25/30 cycles (50/60Hz)<br>1 phase: at 0°<br><br>0 % UT; 250/300 cycles (50/60Hz) | Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment* requires continued operation during power mains interruptions, it is recommended that the equipment* be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>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. |
| Radiated fields in close proximity<br>IEC 61000-4-39 | 30kHz, CW, 8 A/m<br>134,2kHz, mod. 2,1kHz, 65 A/m<br>13,56MHz, mod. 50kHz, 7,5 A/m | 30kHz, CW, 8 A/m<br>134,2kHz, mod. 2,1kHz, 65 A/m<br>13,56MHz, mod. 50kHz, 7,5 A/m | |
| UWAGA: UT is the AC mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment. | | | |
| IMMUNITY test | IEC 60601 TEST LEVEL | Compliance level | Electromagnetic environment – guidance |
| Conducted RF<br>IEC 61000-4-6 | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands between 0,15 MHz and 80 MHz<br>80 % AM at 1 kHz | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands between 0,15 MHz and 80 MHz<br>80 % AM at 1 kHz | 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 equipment*, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.<br><br>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80MHz to 2,7GHz | 3 V/m<br>80MHz to 2,7GHz | |
| Proximity fields from RF wireless communications equipment<br>IEC 61000-4-3 | EN 60601-1-2:2015, Table 9 | Complies | |
| | · Professional healthcare facility environment | · Professional healthcare facility environment | |

| Proximity fields from RF wireless communications equipment | | | | | | |
|---|---|---|---|---|---|---|
| Test frequency (MHz) | Band a) (MHz) | Service a) | Modulation b) | Maximum power (W) | Distance (m)) | Immunity test level (V/m) |
| 385 | 380 –390 | TETRA 400 | Pulse modulation b) 18 Hz | 1,8 | 0,3 | 27 |
| 450 | 430 – 470 | GMRS 460, FRS 460 | FM c) ± 5 kHz deviation 1 kHz sine | 2 | 0,3 | 28 |
| 710 | 704 – 787 | LTE Band 13, 17 | Pulse modulation b) 217 Hz | 0,2 | 0,3 | 9 |
| 745 | | | | | | |
| 780 | | | | | | |
| 810 | 800 – 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation b) 18 Hz | 2 | 0,3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |
| 1720 | 1700 – 1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation b) 217 Hz | 2 | 0,3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400 – 2570 | Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation b) 217 Hz | 2 | 0,3 | 28 |
| 5240 | 5100 – 5800 | WLAN 802.11 a/n | Pulse modulation b) 217 Hz | 0,2 | 0,3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |
| NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3. | | | | | | |
| a) For some services, only the uplink frequencies are included.<br>b) The carrier shall be modulated using a 50 % duty cycle square wave signal.<br>c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. | | | | | | |

# 11 Warranty card

1. The seller (authorized representative, distributor) offers a 24 month warranty, starting from the date of purchase of the equipment, as indicated in a proof of purchase.
2. The seller (authorized representative, distributor) is responsible for any faults whether in quality or quantity occurring immediately after unpacking the product from its original shipment packaging only if they have been reported in a written form within 2 working days following the delivery.
3. The warranty will be fulfilled only by the authorized service team of the seller (authorized representative, distributor) or other technical service authorized by the manufacturer.
4. A repair time exceeding 3 days, shall result in the extension of the warranty period by a time equivalent to the total time during which the device was out of order.
5. In case a faulty subassembly has already been repaired three times, the manufacturer shall be obliged to replace a faulty subassembly with a new one.
6. The user must ensure all the maintenance service described in the manual in order to benefit from the warranty coverage.
7. In case the installation and operation instructions have not been observed, the manufacturer shall bear no responsibility for the safety of the user or patient during the use of the unit.
8. The warranty does not cover faults of parts and materials resulting from natural wear and tear, which means faults other than material or workmanship, as well as faults resulting from poor or no maintenance (e.g. valves, bearings, guides, fans etc.).
9. The seller (authorized representative, distributor) shall bear no responsibility for any loss, whether consequential or incidental, including loss of profits or costs incurred that result from a failure to follow the instructions set out in the installation and user manual.
10. The seller (authorized representative, distributor) shall bear no responsibility resulting from this warranty for any loss, whether consequential or incidental, including loss of profits or costs incurred by failure of the equipment.
11. Faults that occur within the warranty period and are not reported to the authorized service are not covered by the warranty.
12. Costs resulting from an unfounded claim shall be borne by the user.
13. The warranty shall not cover equipment:
    - damaged as a result of fire and lightning or force majeure,
    - with a name plate and/or serial number or factory seals removed or damaged,
    - damaged due to its use in a manner other than defined in the operation manual,
    - where repairs or modifications have been done by unauthorized personnel,
    - damaged mechanically due to improper handling or transportation.
14. In case the equipment covered by the warranty has been re-sold, no new warranty document will be issued.
15. The warrantor shall not issue a duplicate of the Warranty Card.
16. This warranty does not exclude, limit or suspend your consumer statutory rights.

| INVACMED | Vacuum massage unit | Date, signature and stamp of the Warrantor: |
|---|---|---|
| SN | - | |

| Repair registry | User's notes |
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# 12 Periodic technical tests report

| InVacMed device – serial number: | / | | | | | | |
|---|---|---|---|---|---|---|---|
| Test | Positive result (Yes/No) | | | | | | |
| | TO control | | | | | | |
| Date | | | | | | | |
| Functions of the device | | | | | | | |
| Patient leakage current | | | | | | | |
| Pneumatic system tightness | | | | | | | |
| Continuous vacuum | | | | | | | |
| The number of pulses in the pulsation mode | | | | | | | |
| Connections and circuits switch | | | | | | | |
| "$H_2O$" signaling and treatment lock | | | | | | | |
| Name and signature of the person checking | | | | | | | |

| Test | Positive result (Yes/No) | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| Date | | | | | | | |
| Functions of the device | | | | | | | |
| Patient leakage current | | | | | | | |
| Pneumatic system tightness | | | | | | | |
| Continuous vacuum | | | | | | | |
| The number of pulses in the pulsation mode | | | | | | | |
| Connections and circuits switch | | | | | | | |
| "$H_2O$" signaling and treatment lock | | | | | | | |
| Name and signature of the person checking | | | | | | | |