INSTALLATION AND OPERATION MANUAL

AQUAMOBIL

Underwater massage device

CE 0197

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1. INTRODUCTION

The user's compliance with the recommendations from this instruction manual and use of the information contained enables safe, long-term and failure-free use of the underwater massage device. All comments and observations regarding making of the device and contents of his manual should be sent to our address:

Meden-Inmed Sp. z o.o.
ul. Wenedów 2
75-847 KOSZALIN
tel: +48 94 347-10-40
fax: +48 94 347-10-41
e-mail: *meden@meden.com.pl*

GENERAL NOTES

1. The product should be operated by a qualified and trained personnel who have read the contents of these operating instructions.
2. The use, operation and servicing of the product in a manner inconsistent with this manual is not permitted and may lead to damage that are responsibility of the user and for which the manufacturer is not responsible.
3. The device manufacturer prohibits any modifications to the used device.
4. If the operation and parameters of the product are inconsistent with the description in this instruction manual, the product may not be used. Please immediately report this fact to the manufacturer or supplier.
5. Every repair of the product must be made by a manufactory or authorized service center and registered in the list of repairs attached to the guarantee card. Failure to comply with this requirement will void the guarantee on the product.
6. Any serious portable underwater massage device AQUAMOBIL incident shall immediately be reported to the manufacturer and to the competent authority of the Member State where the user or patient is resident.
7. The guarantee conditions will not be respected if the user will use the product contrary to the intended purpose or will not follow the rules of use in these operating instructions.
8. Technical description of the device together with a list of spare parts and the instructions of their replacement (including the non-detachable power cord) is available from the manufacturer on demand.

2. INTENDED USE

The AQUAMOBIL underwater massage device is meant for bathtubs that are not equipped with installation dedicated for such treatment. In order to choose the right type of water stream during the treatment, it is required to select a nozzle with the appropriate diameter and set the pressure of the water jet by using the shut-off and pressure control valve.

The effect of the underwater massage performed with a water jet is comparable to a classic massage, causing an increase blood and lymph flow. However, the positive impact of the underwater massage is stronger than the classic massage because it is additionally accompanied with thermal and hydrostatic effect of the bath. These factors substantially modify the mechanical force effect generated by water jet being directed onto the patient's body. The advantages of the underwater massage with a water jet include the uniformity of the impact on the tissues with an individually determined and constant dose of mechanical energy (thanks to a proper selection of water pressure, nozzle diameter, its distance from the body and the incidence angle of the water jet) and a maximum possible relaxation of the muscles is obtained due to the water bath conditions. This massage technique allows better access to the tendons, ligaments, and periarticular tissue of many important bones and ossicles more efficiently than when applying classic massage*.*

The underwater massage with a water jet is performed during a full or half bath in water with a temperature of 34-35-36ºC, and in case of people sensitive to heat, in water with a temperature of 30-34ºC. The duration of the procedure should be selected individually in the range from 5 to 20 minutes. You should start with a short period of time and gradually increase it as the adaptation to the treatment develops*.*

The product is intended for use in professional medical care facilities equipped with a dedicated power supply system, such as hospitals, clinics, etc.

2.1 Indications

- osteoarthritis,
- chronic low back pain.

2.2 Contraindications

- infections,
- untreated hypertension,
- decompensated cardiopathy,
- progressive cancer,
- progressive inflammatory disease,
- decompensated psychiatric disorder,

- immune deficiency,
- progressive heart disease,
- progressive neoplasia,
- chronic bronchitis,
- foreseeable intolerance to thermal care,
- (intolerance to heat, baths, swimming pool, etc.).

2.3 Patient target group

The attending physician refers patients to underwater massage treatments and evaluates their health to determine the advisability of treatment. Underwater massage treatments are carried out under the supervision of personnel. The target group of patients receiving underwater massage therapy is between 18 and 80 years of age.

2.4 Users

The AQUAMOBIL underwater massage device can be used only by qualified personnel familiarized with the information contained in the user manual supplied with the device.

2.5 CE mark

CE 0197

The AQUAMOBIL underwater massage device is manufactured in accordance with Medical Device Regulation 2017/745 (class IIa, rule 9) and has a CE marking, according to the manufacturer declaration.

2.6 Symbol definitions

	Device switch
	Direction of closing the shut-off and pressure control valve
	Jet control valve
	Disinfection water tank
	Follow the instruction manual

	Manufacturer
MD	Medical device
SN	Serial number
REF	Catalog number
IPX5	Protection against water spray
	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. Dispose of waste non-electrical equipment in accordance with applicable regulations.
	Warning sign. This indicates actions which, if not carried out in compliance with the instructions in this manual, may result in impairment of conditions or safety hazards for the user and/or operating personnel. A similar marking is attached to the device where it is essential to read and follow the Operating Manual when operating the device.
UDI	Unique Device Identification

3. TECHNICAL CHARACTERISTICS

WARNING!

The manufacturer reserves the right to make changes to the device structure that do not violate basic functional and safety requirements.

The control stand is made of glass fiber reinforced plastic. The water installation is made of copper pipes and hoses with braid made of acid resistant steel. External hoses (suction and delivery) are selected to meet the relevant performance requirements. At the inlet of the suction hose there is a filter to protect the pump from damage by contaminants present in the post-treatment water. The AQUAMOBIL device is also equipped with a pressure gauge, thermometer (information on the water temperature is displayed on the control panel during the treatment), disinfection system and transportation handles (fig. 2).

3.1 Technical parameters

Technical parameters of the underwater massage device are presented in the table below:

AQUAMOBIL	
Length [mm]	470
Width [mm]	740
Height [mm]	1070
Weight [kg]	55
Pressure of water jet [bar]	0 – 4 (depending on the nozzle applied and the valve setting)
Water temperature	equal to the temperature of water in the bathtub
Environment temperature [°C]	10- 40
Power conditions	230 V~ 50 Hz
Power consumption [A]	7
Protection class	I
Housing class	IPX5
Dry-running protection of the pump	YES

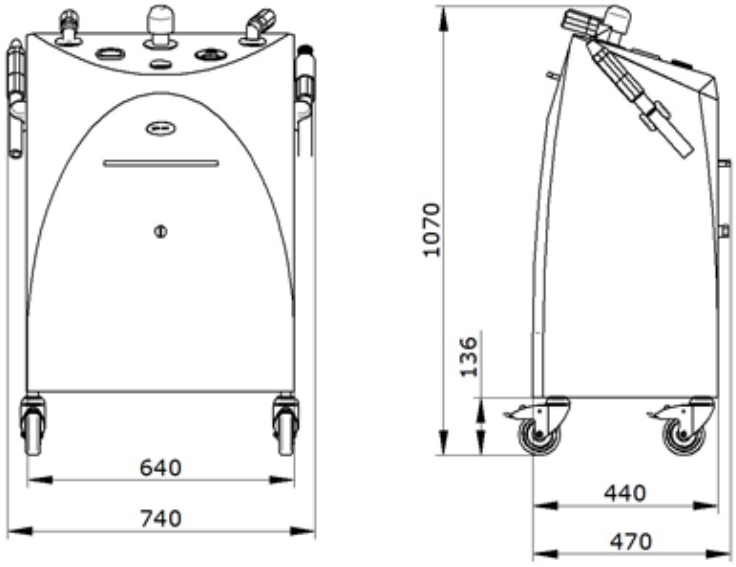


Figure 1 – AQUAMOBIL underwater massage device view with dimensions [mm]

3.2 Completion

Standard equipment	
The AQUAMOBIL underwater massage device	1 pc.
Interchangeable nozzles with diameter:	
Fi 4 – P/N 02-OBR-2571	1 pc.
Fi 5 – P/N 02-OBR-0005	1 pc.
Fi 6 – P/N 02-OBR-0391	1 pc.
User manual with warranty card and periodic technical inspection card	1 pc.

3.3 Transport and storage

Transport and storage of the AQUMOBIL device should be carried out in the manufacturer's transport packaging at a temperature higher than 0°C, in a dry and indoor room.

Temperature of storage and transport [°C]	positive (max 60°C)
Air humidity during storage and transport [°C]	5% - 95% without condensation

4. DESIGN AND OPERATION

The manufacturer reserves the right to introduce such changes to the design of the device, that do not impair its functionality or safety of operation. Drawings provided in this manual are informative only.

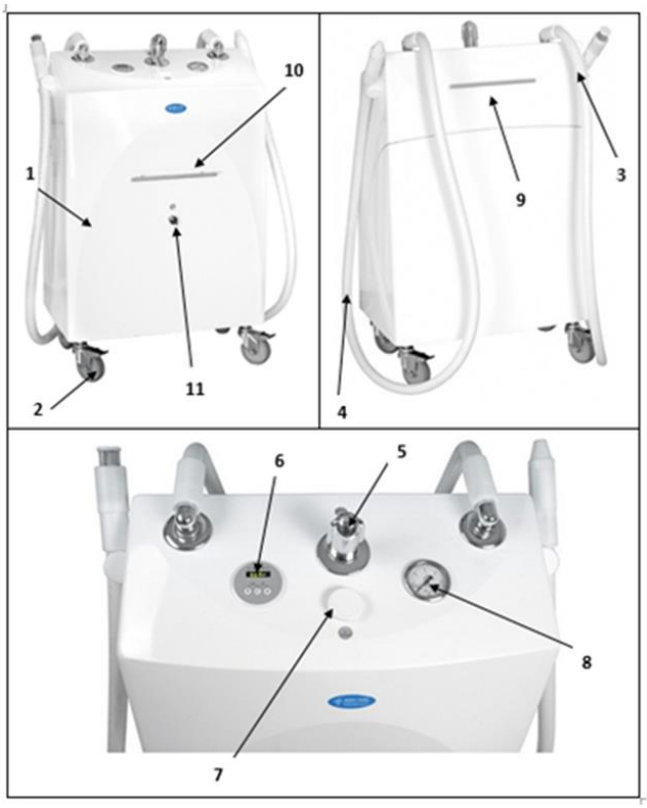


Figure 2 - AQUAMOBIL underwater massage device view with operating and adjustment elements

1 *– control stand*	***6*** *– control panel*
2 *– casters with a locking mechanism*	***7*** *– disinfectant tank plug*
3 *– water suction hose (with a filter)*	***8*** *– pressure gauge*
4 *– water delivery hose*	***9,10*** *– handles for relocation of the device*
5 *– shut-off and pressure control valve*	***11*** *– device switch*

5. SAFETY MEANS

5.1 Place of use

WARNING!

The AQUAMOBIL device is designed for use with clean running water.

For an underwater massage, a basin (bathtub) or other therapeutic tank is required from which the AQUAMOBIL pump will draw water in a closed circuit.

The assembly and the first activation of the device is carried out by the service of the contractor or an entity authorized by the contractor.

6. PREPARE THE DEVICE FOR USE

6.1 Connecting to the 230 V~50 Hz mains electricity

WARNING!

Connection of the electrical system of the AQUAMOBIL device to the 230V/50Hz supply network should be performed by a licensed electrician. Confirmation of the proper electrical connection of the device by a licensed electrician is one of the warranty conditions.

WARNING!

The AQUAMOBIL device must be connected to the electrical installation permanently.

WARNING!

To avoid risk of electrical shock, the device must be connected only to a supply network with protective earth.

WARNING!

For reliable and complete disconnection of the power supply from the mains power supply, there is an external power switch installed in the switchgear from which the mains power is provided to the device.

The power circuit must be allocated only to power this device (it must not power any other devices) and must include:

- residual current device (RCD) with a rated tripping current not exceeding 30 mA,
- all-pole disconnect switch with a minimum contact gap of 3 mm, placed in the room where the appliance is operated, at a location allowing easy and fast access for personnel in the case of an emergency. If the switch is not visible from the position of normal use by the operator or service personnel, additional means must be provided to lock in the off position.
- cross-section of power supply cable 3x1,5 mm^2.

Determine the exact length of the free end of the cable to allow for free operation of the device at the dedicated bath.

The enclosure of mains terminal device is equipped with a cable gland ensuring tight clamping on a round cable with a diameter of a 5-10 mm.

When using a cable of different size, appropriate technical measures must be taken to ensure that the mains terminal device is protected against water ingress to a minimum of IPX5.

The electrical installation to which the device is connected must conform to the applicable legal regulations (e.g. PN-HD 60364-7-701, PN-HD 60364-7-710).

6.2 First start-up

WARNING!

The manufacturer's product has been completely drained of water. After refilling the product with water, the user assumes responsibility if the water freezes.

In the AQUAMOBIL device, the pump has been flooded with antifreeze (to -25°C) for the time of transport. The fluid is glycerol-based, environmentally friendly, non-freezing and certified by PZH.

After preparing the device to work according to the instruction manual, empty the pump by unscrewing the drain plug (fig.3 pos.B) and after the liquid is drained, screw the plug on again.

The first start-up of the pump should be done without a patient to flush the water system in the device.

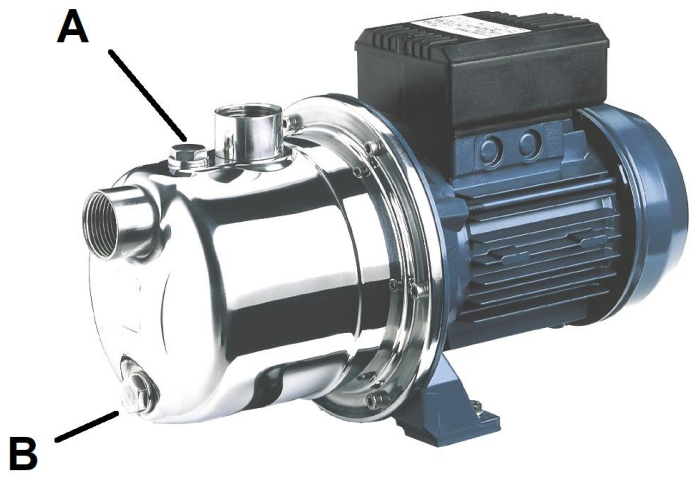


Figure 3 - Location of the plugs in the pump

A - Filling plug **B** - Drain plug

If the user plans to stop using the device for more than 2 weeks or plans to transport, it is recommended that the device's water system be emptied of water and the pump be flooded with a glycerol-based antifreeze (available from the Meden-Inmed).

To prepare the pump for downtime, perform the following steps:

1. Unscrew the drain plug (fig.3 pos.B) and remove the water from the pump, then screw the plug back on.
2. Leave all pump valves in the open position.
3. Unscrew the filling plug (fig.3 pos.A) and pour 1l of antifreeze into the pump through the opening of the filling plug (e.g. using a funnel - not supplied with the product).
4. After pouring the antifreeze into the pump, close the filling plug (fig.3 pos.A).

Performing the above procedure prepares the device for safe storage or transport.

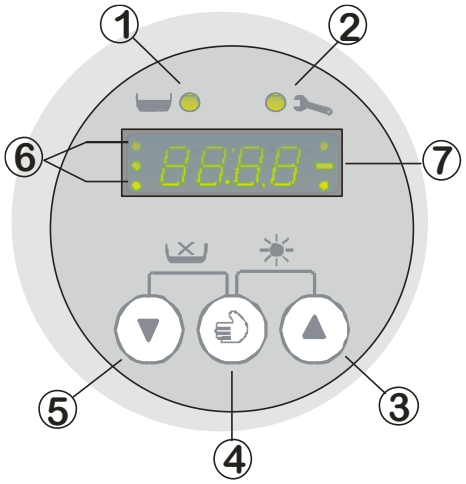
6.3 Protection against dry-running of the pump

The AQUAMOBIL device is equipped with a system protecting the pump against damage resulting from the dry-running. The system is activated within 5 seconds from the moment the pump is started. This delay is necessary to allow stabilization of the water flow through the hydraulic system. If the water suction hose with filter (fig. 2 pos. 3) remains outside the water tank, the pump will run dry throughout this time. During the treatment session, if a no-water condition is detected by the system, the pump will be switched off after ca. 2 seconds.

In case the pump has been switched off by the protection system, after its subsequent start-up, it may be switched off again after ca. 7 seconds. It results from the physical phenomena occurring on the rotor, after the air has filled a part of the pump. The next start up should be performed correctly. Switching off the pump by the system is signaled by lighting up of the “NO WATER” indicator (fig.4 pos.1). The indicator remains lit up until the water flow through the device stabilizes.

7. CONTROL OF THE DEVICE

7.1 Control panel



1 “NO WATER” indicator

2 “DISINFECTION LIQUID LEVEL” indicator

3 "INCREASE" button (inactive)

4 "START" button

5 "DECREASE" button

6 Not used

7 Display

Figure 4 - Control panel

After turning the power on and setting the device switch (fig.2 pos.11) in the "I" position, on the display (fig.4 pos.7) you will see moving "**START**" message.

Single short pressing “START” button (fig.4 pos.4) will start the pump. The display will show the temperature of water flowing through the device. Press the "START" button again to stop the pump.

Pressing the “DECREASE” (fig.4 pos.5) and “START” (fig.4 pos.4) buttons simultaneously during operation of the device causes switching the device over to the “DISINFECTION” mode.

When the “NO WATER” indicator (fig.4 pos.1) is lit on it means that the device has been switched off by the system protecting the pump against dry-running. The indicator remains lit up until the water flow stabilizes after the next start-up (see section 6.3 for details).

7.2 Operation of the device

WARNING!

The method of preparing and performing an underwater massage procedure should be determined by internal instructions of conduct in the treatment device. Description in this instruction contains the necessary minimum information only.

WARNING!

It is forbidden to direct the water jet outside the basin (bathtub).

WARNING!

Pay attention to the way you hold the water whip to prevent it from slipping/falling out of your hands.

WARNING!

Do not use shampoos or other strongly foaming agents when operating the device.

WARNING!

Do not place objects, e.g. towels or clothes on the bathtub, which could fall into the water and clog the suction hose with filter (fig.2, pos.3) of the AQUAMOBIL device.

WARNING!

Organs and areas of the body such as the female breasts, abdomen, external genitalia, protruding parts of bones and areas with varicose veins, bone growths or other disease conditions should be excluded from the procedure.

WARNING!

Before starting the treatment, personnel should check the pressure of the water stream from the delivery hose (fig.2 pos.4) in order to adjust the optimal intensity of the underwater massage.

The order of operations when carrying out an underwater massage:

1. Fill the basin of the bathtub/tank from which the water will be drawn and prevent the water from draining out of it (e.g. with a plug).
2. Locate the underwater massage device close to the bathtub and stabilise its position by blocking the casters with a locking mechanism (fig.2 pos.2).
3. Insert the suction hose with filter (fig.2 pos.3) into the bathtub so that the end of the hose with filter is permanently submerged at least 10 cm under the water level and at the same time so that the filter does not touch the patient in the bathtub
4. Set the device switch (fig.2 pos.11) to the “I” position.
5. Unscrew the shut-off and pressure control valve (fig.2 pos.5), which allows you to adjust the water pressure in the jet.
6. Start the device by pressing the “START” button located on the control panel. During the first seconds of operation, the water jet may be unstable, which results from the presence of air in the pump.
7. During the underwater massage procedure, control the water pressure by reading the values displayed by the built-in pressure gauge (fig.2 pos.8).
8. When the procedure is finished, turn off the device using the "START" button (fig.4 pos.4) on the control panel and turn off the pressure control valve (fig.2 pos.5).
9. Set the device switch (rys.2 pos.11) to the “0” position.

8. MAINTENANCE

WARNING!

The filter on the suction hose (fig. 2 pos.3) must be checked and cleaned each time after treatment. Failure to do so may result in clogging of the filter and improper activity of the AQUAMOBIL and damage to the pump.

8.1 Activities schedule

Activity	Frequency
Cleaning the filter (suction hose)	after each treatment
Cleaning the device	after each treatment
Disinfection of the water system	after each treatment
Functionality check of the residua current device (RCD)	periodically, in a manner and frequency specified in the technical documentation of the disconnect switch
Electrical safety test	once a year and each time after a failure or repair

8.2 Cleaning the device

WARNING!

Do not clean the control stand with highly aggressive preparations or with rough cloths containing abrasive materials, which may cause irreversible tarnishing or damage to the surface of the AQUAMOBIL device.

The best method for everyday care is cleaning the surfaces of the AQUAMOBIL device with the use of wet cloth with addition of soap. The cleaned surface should be then rinsed with water and cleaned dry - such procedure prevents build up of scale. If, however, these deposits continue to build up on the surface, we suggest using a product called “GrohClean”(available from “Meden-Inmed”), whose carefully composed formula ensures proper care of the fittings.

Do not use rough sponges or scouring agents (containing abrasives) to clean the fixture, as it may tarnish or scratch the surface of the fixture. It is also forbidden to use:

- cleaning preparations containing solvents or mineral acids,
- preparations meant for removal of calcium-magnesium deposits,
- vinegar,
- liquids containing acetic acid or preparations meant for cleaning sanitary ceramics only.

Chemical compounds listed above will cause dulling or darkening of the chromium protective coating and after prolonged contact or without proper rinsing, may lead to local or complete dissolution of the coating. As the formulas of commercial cleaning preparations are subject to frequent changes, we cannot guarantee that they can ensure proper care of the fittings surface. In case of doubt, test a preparation by applying it on a fitting area that is hidden from the view.

8.3 Disinfection system

WARNING!

Blinking “DISINFECTION LIQUID LEVEL” indicator (fig.4 pos.2) means that the disinfectant liquid has been used up. Starting the disinfection system is impossible under this condition. Top-up the liquid by unplugging the disinfectant tank (fig.2 pos.7) and pour in approx. 1l of the disinfection liquid.

To disinfect the water system of AQUAMOBIL device press the “DECREASE” and “START” buttons simultaneously to switch over to the “DISINFECTION” mode. The system automatically feeds disinfectant into the water system in an amount of approx. 125 ml. In order to obtain the correct concentration of the FORTE solution (100 ml of disinfectant per 200 l of water), estimate the capacity of the basin (bathtub) and fill it to 250 l of water for the specified disinfectant. To activate this mode, it is necessary to start AQUAMOBIL in advance (using the "START" button), and to place the suction hose with the filter (fig.2 pos.3) and the delivery hose (fig.2 pos.4) in a bathtub with clean water. Use the disinfection time as recommended by the manufacturer of the particular agent.

Once the disinfection process is complete, the bathtub should be emptied and filled with clean water up to bath level, after which the underwater massage should be run for 10 minutes to flush the device's water system of disinfectant residues.

9. CONDITIONS OF MAINTENANCE

WARNING!

Operating personnel should follow the recommendations in this manual. The device does not require any special supervision procedure during its use.

Upon request, the manufacturer shall provide circuit diagrams, lists of parts, as well as descriptions containing information that can facilitate repair of parts approved for repair by the manufacturer.

9.1 Periodic electrical safety test

WARNING!

During tests do not disconnect the permanently connected protective earth connection (according to EN62353, repeated disconnection and reconnection of the protective earth connection may result in deterioration of its mechanical and electrical properties).

Periodic electrical safety test should be carried out by qualified service personnel.

Check regularly correct functioning of the residual current device (RCD) in the device's power supply circuit and perform periodic electrical safety test of the AQUAMOBIL device as specified in the schedule of activities in section 8.1 above.

Periodic electrical safety test must be carried out according to the requirements of the current version of EN 62353.

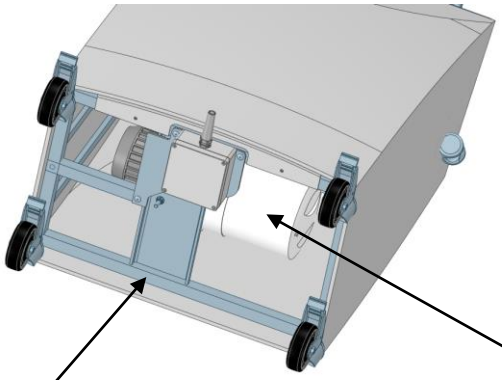
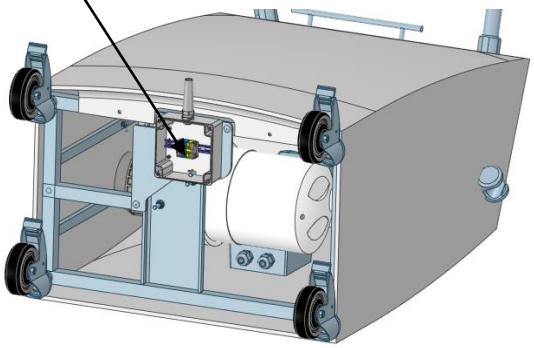
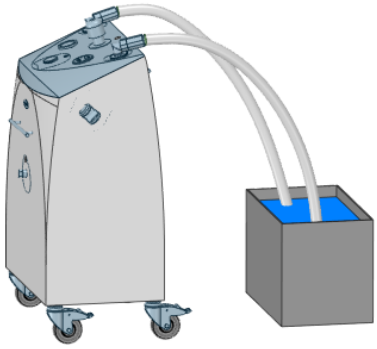
Ensure that the connection to the mains supply is established by a permanent connection that can be disconnected only with a tool (must meet the requirements for "permanently installed" device according to EN 62353).

Check the condition and integrity of the power supply cord.

Perform measurements of protective earth resistance, isolation resistance and leakage current.

Each time a measurement is taken, the results must be documented in a protocol.

The type of performed measurements and acceptable limits defines a table below:

Measurement	Limit
Protective earth resistance	
 **A** - protective earth resistance of metal frame **B** - protective earth resistance of water pump frame If necessary, remove the layer of varnish, oxides, dirt, etc., that covers the subassembly.	300 mΩ
The isolation resistance between the mains part (L and N terminals) and the protective earth (PE terminal)	
	2 MΩ
Touch leakage current from accessible conductive parts	
 During the measurement, the water pump should be running, and the water tank must be electrically isolated from the earth potential and from leakage currents of other electrical devices in the vicinity that could interfere with the measurement.	100µA
Patient' s leakage current	
Perform the measurement in the measuring system analogous to the touch leakage current measuring system by immersing the measuring electrode in water filling the tank that closes the water circuit. The electrode should be made of stainless steel (in aqueous environments other materials may form an electrochemical cell, which distorts the results of measurements).	100µA

9.2 Responsibility of the manufacturer

The expected period of use is 7 years.

After 7 years from the date of manufacture of the device (and its equipment) the manufacturer is not responsible for the defects of the device, its equipment, and the resulting consequences. The manufacturer also does not bear any responsibility for the consequences to which the user or patient has been exposed, for example due to improper installation of the device, improper use of the device and its equipment, misinterpretation or non-compliance with the operating instructions and repairs by unauthorized persons.

9.3 Troubleshooting

Symptom	Possible cause	Procedure to be followed
The device does not work (control panel is not active)	The device is not connected to the power supply system	Connect the device to the power supply system
	The switch is in the “O” position	Set the switch to the “I” position
The control panel is active, the pump does not start after the button has been pressed	The suction hose remains outside of the water tank	Insert the hose in the water tank
	Clogged filter	Clean the filter
Too low water pressure or water does not flow from the suction hose	Pressure adjustment valve is closed	Open the valve
	Clogged filter on the inlet of the suction hose	Clean the filter
The pump switches off during the treatment session	The suction hose remains outside of the water tank	Insert the hose in the water tank
	Clogged filter on the inlet of the suction hose	Clean the filter

9.4 Contact with service

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

If the device has been purchased with an intermediary, please kindly provide information about the serial number and location of the device. These data will be stored in our service database, which enables us to apply terms of guarantee and service efficiently.

10. ELECTROMAGNETIC COMPATIBILITY

WARNING!

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

WARNING!

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

WARNING!

The 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.

WARNING!

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

WARNING!

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

Essential performance - the documentation of the risk management process shows the lack of essential performance characteristics for this product.

**The AQUAMOBIL underwater massage device*

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 power supply lines 100 kHz	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	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % U_T; 250/300 cycles (50/60Hz)	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % U_T; 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 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.
WARNING: U_T is the a.c. 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 IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 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. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Radiated RF IEC 61000-4-3	3 V/m 80MHz do 2,7GHz	3 V/m 80MHz do 2,7GHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	EN 60601-1-2:2015, Table 9 *(see below)*	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.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[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

1. The seller (authorised 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 (authorised 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 authorised service team of the seller (authorised representative, distributor) or other technical service authorised 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 device.
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 (authorised 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 (authorised 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 authorised 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.

The underwater massage device's serial number: _____

Date, signature and seal of the manufacturer or its representative: _____

The underwater massage device installed by: _____

Date, signature and seal of the installer: _____

<table>
<tr><th colspan="2">Repair registry</th><th>User’s notes</th></tr>
<tr><td colspan="2"></td><td></td></tr>
<tr><td colspan="2"></td><td></td></tr>
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<tr><td colspan="2"></td><td></td></tr>
<tr><td colspan="2"></td><td></td></tr>
<tr><td colspan="2">Electrical safety check</td><td>Date and signature of a person performing the check</td></tr>
<tr><td>Report No.</td><td></td><td rowspan="3"></td></tr>
<tr><td>Result of the check:</td><td></td></tr>
<tr><td colspan="2">Next check to be performed within 12 months</td></tr>
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