USER MANUAL

WKG

Whirl Massage Device

for Upper Limbs

CE 0197

Manufacturer:

MEDEN - INMED, Spółka z o.o.

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Dear Customer!

Congratulations on your right choice! We wish you a lot of success and full satisfaction from using our product. Please read this Installation and User's Manual carefully, as it contains important information and manufacturer's notes on the proper installation, use and maintenance of the device.

Introduction

The User's compliance with the recommendations in the Instruction Manual and the application of its information enable safe, long-term and failure-free use of the WKG whirl massage device. Please send any comments and remarks concerning the manufacture of the WKG whirl massage device and the contents of this Manual to our address:

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ul. Wenedów 2
75-847 KOSZALIN
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GENERAL INFORMATION:

1. This medical device that should be operated by qualified and trained personnel who have read this Installation and User's Manual.
2. The use, operation and servicing of the device in a manner inconsistent with this manual are not permitted and may result in damage which the manufacturer is not liable for. Full liability for such damage lies with the user.
3. Making any modifications to the device is forbidden by the manufacturer.
4. If the operation of the device and its parameters are not in accordance with the description in this manual, the device must not be operated. The user must report this fact to the manufacturer or supplier immediately.
5. Each repair of the device must be performed by the manufacturer service or a service authorized by the manufacturer. Each such repair must be recorded in the repair list attached to the warranty card. Failure to comply with the requirement will void the warranty for the device.
6. Warranty terms will not be respected if the device is used not as intended or if the usage guidelines given in this Installation and User's Manual are not followed.
7. A technical description of the WKG whirl massage device for upper limbs, a list of replacement parts and instructions on their replacement are available from the manufacturer upon request.
8. Any serious WKG whirl massage device for upper limbs 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 manufacturer reserves the right to introduce changes in the design of the device, which do not affect the basic requirements of functionality and safety. The illustrations in this manual serve merely as a visual guide. Variations result from the order specifications.

SYMBOLS

	Shower
	Cold water regulation valve (content in blue)
	Warm water regulation valve (content in red)
	Water drain is opened
	Water drain is closed
	Direction of closing the control valves
	Aeration
	Alternating current
	Follow the user's manual
	Warning sign. This symbol identifies actions which performed not in accordance with the contents of the Installation and User's Manual may result in deterioration of the conditions or threat to the safety of the user and/or the personnel operating the WKG whirl massage device for upper limbs. A similar marking has been placed on the device where the Installation and User's Manual must be read, and its instructions must be observed when using the device.
	Applied part type B
MD	Medical device
	In accordance with the provisions of the Act on Waste Electrical and Electronic Equipment, disposal of used equipment marked with a crossed-out wheeled bin symbol with other household waste is prohibited. Waste electrical and electronic equipment should be returned to the appropriate collection point. These statutory obligations have been introduced to limit waste from waste electrical and electronic equipment and to ensure an adequate level of collection and recycling of used equipment. The correct implementation of these obligations is particularly important in the case of waste equipment containing dangerous components that have a particularly negative impact on the environment and human health. Dispose of non-electrical equipment in accordance with local regulations.
UDI	Unique Device Identification
SN	Serial number
YYYY	Manufacturer, YYYY – year of manufacture
IPX5	Protection against water spray from all sides of the housing
MAX 6 bar	Maximum nominal pressure of the water supply

1. INTENDED USE OF THE DEVICE

The WKG whirl massage device for upper limbs is designed for hydrotherapy performed by means of a stream of water generated by a pump.

Whirl massage results in increased blood perfusion, decreased oedema, reduced venous congestion, accompanied by analgesic effect and muscles relaxation.

1.1 Indications

WARNING!

The personnel should pay special attention to the safety of the patient when taking a seat in the device basin and when leaving the basin. The use of the step facilitating these operations is allowed only when personnel are present and shall assist the patient during these operations. The step surfaces should be wiped dry after each use.

The whirl bath is carried out for 20-30 minutes in water at a temperature of indications 35-40°C. Indications for hydrotherapy treatments:

- upper limbs rehabilitation in post-injury conditions, nervous disorders, fatigue of the muscular - nervous system,
- various forms of rheumatic diseases,
- some forms of peripheral circulation disorders, conditions after venous thrombosis, early stages of constricting arteritis, Raynaud's syndrome, post frostbite and post varices surgery conditions,
- complex syndrome of regional pain,
- degenerative joint disease.

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

1.2 Contraindications

WARNING!

Whirl massage sessions are performed only on a leading physician's order, who evaluates patients' condition in terms of potential benefits of whirl massage.

Absolute contraindications: phlebitis, venous thrombosis and trophic skin lesions.

1.3 Target patient group

Patients are referred to the whirl massage treatments on the recommendation of the attending physician, who evaluates their condition in terms of suitability for the treatment. The whirl massage procedures are conducted under the control of operating personnel. The group of patients benefiting from the whirl massage are patients over 18 years of age.

1.4 Users

WKG whirl massage device for upper limbs can be used only by qualified personnel who have read the information contained in the user manual for this device.

2. TECHNICAL SPECIFICATIONS

WARNING!

Do not modify the device without the written authorization of the Manufacturer.

The manufacturer reserves the right to make changes to the design of the device that do not compromise the basic requirements of functionality and safety. The illustrations in this manual are for guidance only and variations are based on order specifications.

2.1 Technical characteristics

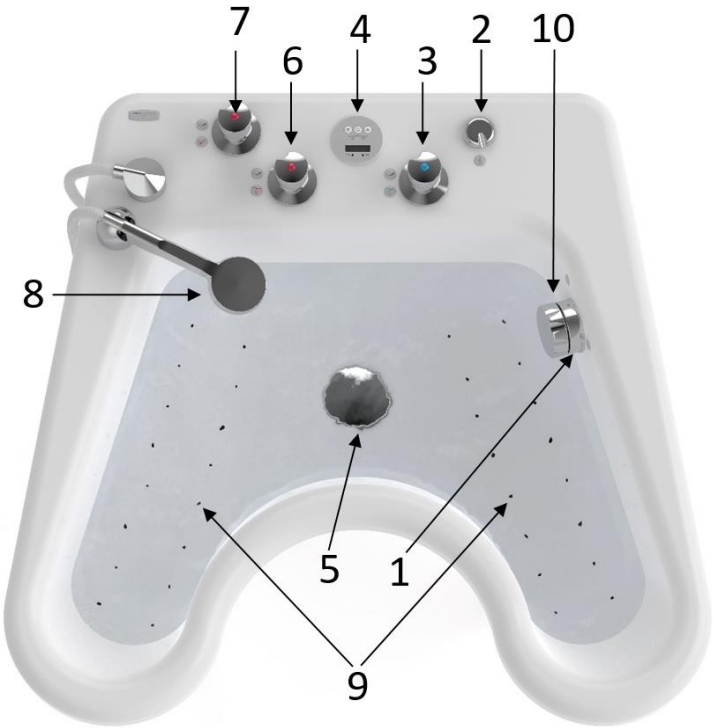
The WKG whirlpool basin is made of high-quality fiberglass-reinforced acrylic, and the housing is made of fiberglass-reinforced gelcoat. The use of such materials provides many years of trouble-free operation of the device.

The entire water system, except for the connections, is made of PVC, which provides high reliability. The device has an economical consumption of water during treatment (30-45 liters).

Filling the basin with water is carried out by manually opening the hot/cold water valves (fig.1 item 3 and 6) or by an automatic filling system (option).

During treatment, the water temperature is maintained by a specially developed water system.

The whirlpool massage system is realised by an electronically driven water pump, which pumps water under pressure through 44 nozzles (fig.1 item 9) located in the device basin.



1. *"DRAINAGE" valve*

2. *"AERATION" valve*

3. *"COLD WATER" valve*

4. *Control panel*

5. *Water drain with suction*

6. *"WARM WATER" valve*

7. *"SHOWER" valve*

8. *Shower handle*

9. *Hydromassage jets*

10. *Overflow*

Figure 1 - WKG whirl massage device for upper limbs view

2.2 Technical parameters

Parametrs	WKG
Capacity	
– to overflow [l]	47
– minimum level for bathing [l]	37
Dimensions	
Height [mm]	920
Width [mm]	940
Lenght [mm]	880
Weight of device [kg]	60
Housing	
Number of covers	1
Colour of covers	biały
Niecka wanny	
Overflow	+
Colour	white or green „calypso”
Operating parameters	
Power supply conditions	230 V ~ 50 Hz
Maximum power consumption [A]	5
Housing class	IPX5
Protection class	I
Applied part (basin filled with water)	typ B
Maximum patient weight [kg]	135
Maximum safe load of the chair (SWL) [kg]	180
Ambient temperature [°C]	10 – 40
Maximum hot water pressure in the supply system [bar/MPa]	6 / 0,6
Maximum cold water pressure in the supply system [bar/MPa]	6 / 0,6
Maximum hot water temperature in the supply [°C]	60
Maximum time of	
– filling to overflow [sec]	~50
– emptying [sec]	~60

2.3 CE mark

CE 0197

The WKG whirl massage device for upper limbs is manufactured in accordance with Medical Devices Regulation 2017/745 (class IIa, rule 9) and has CE marking, according to the manufacturer declaration.

2.4 Device set

WKG whirl massage device	1 pc.
Patient chair	1 pc.
User manual with Warranty card and Periodic technical test card	1 pc.

2.5 Transport and storage

Transport and storage of the WKG upper limb whirling massage device should be carried out in the manufacturer's transport packaging at a temperature above 0°C, in a dry and covered room.

Storage and transport temperature [°C]	positive (max. 60°C)
Humidity during storage and transport [%]	5 - 95 non-condensing

If the user plans to stop operating the device for more than 2 weeks or expects to transport it, it is advisable to drain the water system of the device. The following steps should be carried out:

- empty the device water system,
- disconnect the connection hoses from the water system above the non-return valves (so that water drains from the whirlpool system),
- leave all valves in open position also the water discharge valve.

3. SAFETY MEASURES

3.1 Place of use

WARNING!

For sanitary reasons, it is not recommended to permanently connect the device's drainage system to the building's drainage system.

WARNING!

It is recommended that additional and easily accessible valves are placed in the room to shut off the hot and cold water supply to the device should be placed in the room so that personnel can quickly access the shut-off valves in the event of a system failure or uncontrolled water leakage from the device.

3.2 Notes for use

WARNING!

The requirement of carrying out treatments in the device for the WKR type whirl massage is water change after each patient.

WARNING!

Do not exceed the temperature of treatment water in the device above 40°C as this may result in patient burns or other hazards due to excessively high water temperatures.

WARNING!

When filling the device with water, remember to fill with cold water first and then add hot water to reach the desired temperature.

A diagram of the WKG whirl massage device installation, available from the manufacturer, contains detailed instructions on how to install the device. The whirl massage device should be placed in a room of dimensions that ensure its proper operation. After the whirl massage device has been installed, a passage of a minimum width of 80 cm should be available on each side of the device.

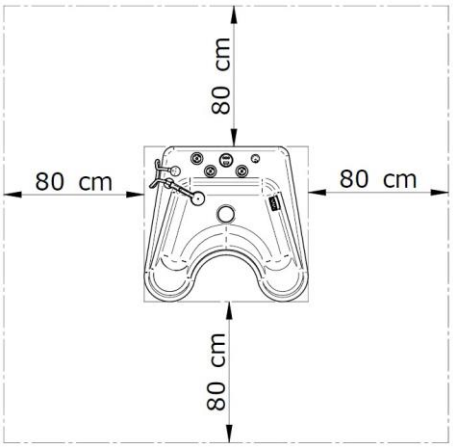


Figure 2 – Suggested placement of the WKG device in the room

4. PREPARATION FOR USE

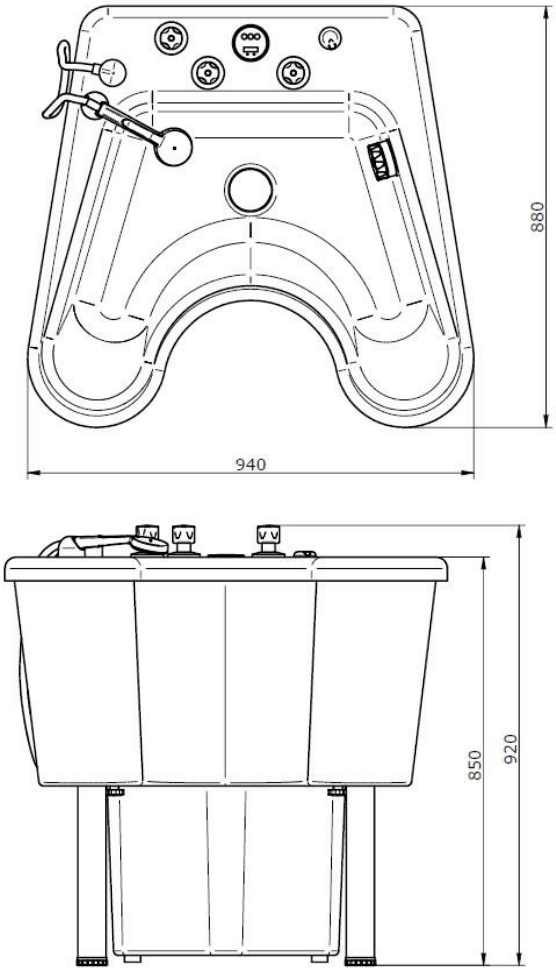


Figure 3 - The dimensions of the WKG device (dimensions in mm)

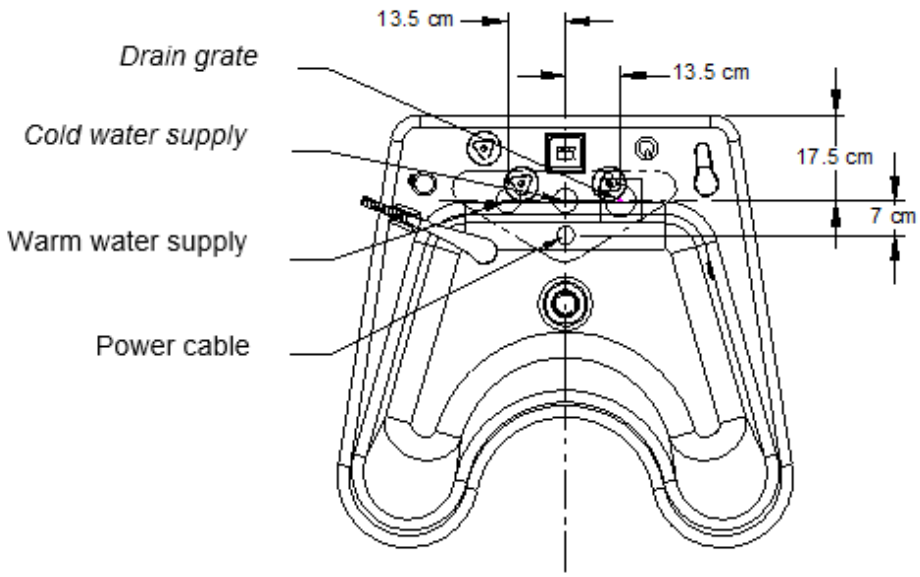


Figure 4 - Distribution of media outlets in the floor

In the place where the device is located, the following should be carried out from the floor (fig.4):

- hot water supply terminated with an external thread 3/4", secured with a shut-off valve,
- cold water supply terminated with a 3/4" external thread, secured with a shut-off valve,
- discharge of used water into a drain (grating) with an outlet pipe Ø min. 100 mm with a flow capacity of min. 3.5 l/s along the entire length of the outlet section to the riser,
- power supply connection – see section 4.2 “Connection to the 230 V~50 Hz mains electricity” below.

Recommendations:

- the internal diameter of the media supply system is min. DN 20 over the entire length,
- the maximum pressure of the supply media - 6 bar (0,6 mPa),
- maximum hot water temperature - 60°C,
- install easily accessible valves (e.g. on the wall) in the room to shut off the medium supply to the device, so that personnel can quickly access the shut-off valves in the event of installation failure or uncontrolled water leakage from the device installation.

4.1 Connection to the water supply and drainage systems

WARNING!

The device was properly levelled during the manufacturing process. If the area where the device is located has uneven flooring, it needs to be leveled so that each of its four legs has a firm grip on the ground.

WARNING!

Bath water should be free of mechanical impurities (e.g., by using adequate filters) that could harm the valve system permanently. The warranty does not cover the device repair if such a cause of failure is discovered.

WARNING!

After the installation of the device is completed, do not move it, as the water system may become unsealed and the electrical system supplying the device may be damaged.

WARNING!

The temperature of the hot water must not exceed 60°C due to the properties of materials used for the manufacture of the device. Exceeding the inlet hot water temperature of 60°C may lead to a malfunction of the device in a short time. Such defects will not be covered by the warranty.

The WKG device is manufactured to meet the location and assembly conditions specified by the user. 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.

The outflow of water after treatment should be done with a pipe with a diameter of at least 100 mm ending with a floor drain with a siphon installed in the surface of the floor.

The floor within the floor drain shall slope in its direction.

4.2 Connection to the 230V ~ 50 Hz mains electricity

WARNING!

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

WARNING!

Connection of the electrical system of the 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 WKG device must be connected to the electrical installation permanently.

WARNING!

To disconnect the device reliably and completely from the mains supply, there is an external power switch installed in the switchboard from which the mains supply is fed to the device.

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

- cross-section of power supply cable 3 x 1.5 mm^2,
- an overcurrent circuit breaker 10 A with a type C characteristic curve,
- residual current device (RCD) with a rated tripping current ≤ 30 mA,
- all-pole disconnect switch with a minimum contact gap of 3 mm, located in a place that allows easy and quick access for personnel in case of emergency.
  If the switch is not visible by the operator or service personnel from the position of normal use, additional means must be provided to lock in the off position.

The housing of the power supply cable is equipped with a gland to ensure tight clamping on a round cable with a diameter of 5 – 9 mm. If a cable of a different size is used, appropriate technical measures must be taken to ensure that the power mains cable is protected from water ingress by a minimum of IPX5.
The electrical installation to which the WKG device is connected must meet the requirements corresponding to current regulations (e. g. EN 60364-7-710).

4.3 Assembly of the device

The sequence of activities:

1. Set up the device in the designated location according to the installation instructions.
2. Open the inspection door at the rear of the device.
3. Insert the supply hoses and power cable into the rear leg of the device.
4. Connect the power cable from the floor to the device's junction box (fig.5 item A).
5. Screw the two supply hoses onto the corresponding hoses from the floor (red indicates hot water, blue indicates cold water).
6. After verifying the connections, fill the whirlpool massage device with water and check for any leaks.

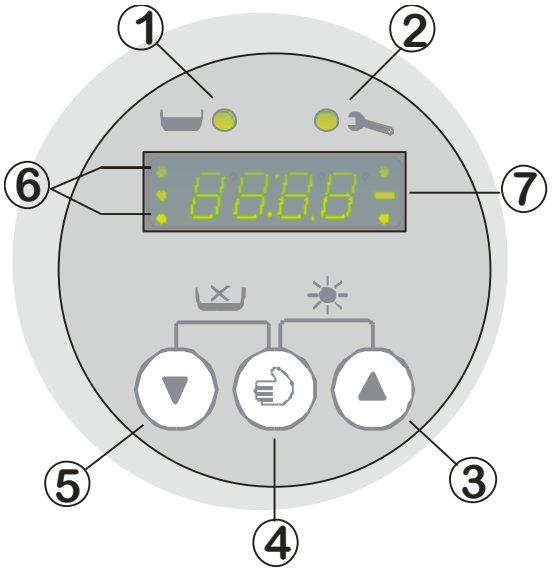
Once the device's operation has been confirmed, the installation is complete.

Figure 5 – Junction box

A – Cable connection point

5. OPERATING THE DEVICE

5.1 Control panel



1. “LEVEL” indicator
2. “DESCALING” indicator
3. “INCREASE” button
4. “ACTION” button
5. “DECREASE” button
6. “REGULATION” indicator
7. Display

Figure 6 - Control panel

5.2 Operating modes

5.2.1 Standby

Standby mode starts automatically when the power is turned on or when other modes are completed. The control panel shows “StaRt” and displays alternately with the value of the water temperature in the basin (e.g. 23°). This mode continues uninterrupted until the power is turned off or until another mode is selected.

5.2.2 Massage

The main mode of operation of the device, in which the hydromassage treatment is performed. Its activation is possible only after the basin is filled with water to the appropriate level (see section 6.1). Otherwise, when activating the mode, a single beep will be generated and the “LEVEL” LED will blink three times. Activation of this mode is performed in the “STANDBY” mode by pressing the “ACTION” button. While the whirlpool is operating in this mode, the display shows the time remaining until the end of the massage (e.g. 0:12) alternating with the value of the water temperature in the basin (e.g. 23°). Termination of this mode occurs automatically after the expiration of the set treatment time, which is a maximum of 30 minutes. This mode can also be stopped manually during the treatment by briefly pressing the “ACTION” button.

5.2.3 Descaling

A mode of operation designed to prevent the formation of sludge, resulting from the precipitation of impurities and chemical compounds from the water used for treatment, which obstruct the operation of the device pump. A description of the operation of this function is described in more detail in the maintenance in section 7 below.

6. SEQUENCE OF OPERATIONS

WARNING!

Before the patient enters the device with water, check the temperature on the main screen of the control panel to ensure that it does not exceed 40°C and additionally check with an additional thermometer.

WARNING!

Do not turn on the pump without water in the device.

WARNING!

When bathing, do not use shampoo or other strong foaming agents.

WARNING!

When bathing a patient in the device, it is forbidden to add water to it.

6.1 Water filling

WARNING!

Fill the device with hot water at a maximum temperature of 60°C. Be sure to pour cold water first and then add hot water.

WARNING!

Personnel should pay attention to the water level in the basin during filling. If the water reaches the overflow level, turn off the water supply immediately.

WARNING!

Mechanical damage to the heads of the filling valves, resulting from their improper operation (turning with excessive force, too high a temperature of water when filling, water with mechanical impurities - gravel, sand, mortar,) and gaskets as a consumable are not subject to the terms of the manufacturer's warranty.

WARNING!

The method of preparing and performing baths should be determined by the internal instructions of the operating device. The following description provides only the necessary minimum information on the subject.

Before filling the basin with water, check the position of the water discharge knob (fig. 7) - the knob should be in the “CLOSED” position.

Figure 7 - Closed water discharge knob

Adjust the temperature of the pouring water by adjusting the proportion of hot and cold water flow through the valves accordingly. The temperature of the treatment water in the basin should not exceed 40°C due to the fact that patient burns or other hazards resulting from too high water temperature may occur.

6.1.1 Manual filling

In order to fill the basin manually, the “COLD WATER” and “HOT WATER” valves located on the top of the device should be opened in the “STANDBY” mode. Reaching the required amount of water covering all jet nozzles allowing to turn off both valves will be signaled by an intermittent beep lasting about 10 seconds and turning off the “LEVEL” LED indicator. The beep can be interrupted by pressing any button on the control panel.

6.1.2 Automatic filling

For automatic filling of the basin, in the “STANDBY” mode, open the “COLD WATER” and “HOT WATER” valves located on the top of the device, then press the “ACTION” button, which will open the electrovalve and start filling water into the basin. During the filling of the basin, the display shows “FILL” alternately with the value of the temperature of the water in the basin. When the required amount of water covering all jet nozzles is reached, water pouring will stop automatically signaling the completion of water pouring by an intermittent beep lasting about 10 seconds and by turning off the “LEVEL” LED indicator on the control panel.

With automatic filling of the basin, there is no need to turn off the hot and cold water valves. Further operations will only require pressing the “ACTION” button for refilling. If you press and hold the “ACTION” button in the “STANDBY” mode, it will manually activate the filling of the basin until the button is released.

Automatic filling can be interrupted at any time of filling the basin with water by pressing the “ACTION” button on the control panel.

6.2 Setting the treatment time

The length of treatment to be carried out can be changed before each treatment. In the “STANDBY” mode, a short press of the “LOWER” or “INCREASE” button will display the set treatment time, and repeated presses will change this value.

During the ongoing “MASSAGE” mode, it is not possible to change the length of the treatment time.

6.3 Massage intensity adjustment

The intensity of the massage can be adjusted by decreasing or increasing the aeration with the knob “AERATION”. The knob is smoothly adjustable and has 3 levels of intensity (fig.8):

H - (HIGH) the lowest aeration - the highest intensity of the water flow,

M - (MEDIUM) medium aeration - medium intensity of the water flow,

L - (LOW) highest aeration - lowest intensity of water flow.

Figure 8 - Massage intensity adjustment, positions from left: H, M, L

6.4 Emptying the basin

To empty the device's basin of water, set the water discharge knob to the “OPEN” position (fig.9).

Figure 9 - Emptying the basin of water

6.5 Rinsing

In order to rinse the whirlpool when washing after the treatment (section 7.2), open the “SHOWER” valve by unscrewing the knob located on the right side of the device. The temperature of the shower water is regulated by the “COLD WATER” and “HOT WATER” valves.

7. MAINTENANCE

7.1 Schedule of procedures

WARNING!

If the unit is left unattended overnight or for a longer time, close the valves supplying the unit to avoid accidental unsealing of the pressurised water system.

WARNING!

The device has been completely drained of water at the manufacturer's premises. After refilling the device with water, the user assumes responsibility if damage to the device occurs due to water freezing.

Procedure	Repetition period
Cleaning and disinfection of the basin	after each treatment session
Disinfection of the water system	every day after the last treatment session
Descaling of the water system	according to the indication on the control panel
Functionality check of the residual current device (RCD)	periodically, in the manner and with the frequency specified in the technical documentation of the disconnect switch
Electrical safety testing	initially - before putting the device into service (after installation), periodically - not less than once a year and after each repair

7.2 Cleaning the device after a treatment

WARNING!

It is recommended to empty the basin immediately after each treatment session.

WARNING!control

Failure to disinfect or carry out disinfection not in accordance with the manufacturer's recommendations may result in deterioration of the hygienic condition of the device.

Each time after the completion of treatment, the basin should be emptied of the used water, the strainer should be cleaned and the drain cleared of any debris. Avoid leaving the basin filled with water for a long time after treatment, as this will make it difficult to remove debris after emptying.

The best way of maintenance is to clean the basin surface and fittings with a damp cloth and soap. Cleaned surfaces should be rinsed with water and wiped dry with a soft cloth, which prevents lime build-up. Do not use coarse sponges or scouring agents (containing abradant) to clean the fittings, as this will tarnish or scratch its surface. It is also not recommended to use fittings cleaners that contain solvents or mineral acids, lime and magnesium buildup removers, liquids containing acetic acid, and products for sanitary ceramics only. Such chemicals cause tarnishing or dimming of the decorative coating, and after prolonged contact without thorough rinsing may lead to its partial or complete erosion. To rinse the basin, open the “SHOWER” valve. It is recommended to rinse the basin with water from the shower head not more than 1 minute.

7.3 Basin disinfection after a treatment

WARNING!

Damages resulting from the use of improper disinfectants or the basin care agents are not subject to manufacturer's warranty terms.

After cleaning the strainer and the basin, disinfect the basin with a surface disinfectant that does not damage acrylic coatings. A product available in Poland with the trade name Incidin OxyFoam S can be used for this purpose. Other products for disinfection of the water system of hydromassage bathtub, e.g. under the trade names TOP or FORTE may also be used. When disinfecting, follow the instructions for use provided by the manufacturer of the disinfectant, especially in regard to the recommended concentration of the solution and exposure time. After finishing disinfection, use the shower to thoroughly rinse off any remaining disinfectant. Then wipe the surface dry with a soft cloth.

7.4 Disinfection of the water system

WARNING!

The use of disinfecting or cleaning foaming agents and inaccurate flushing of them may cause a large amount of foam to form when the whirl massage is switched on.

Periodic disinfections of the water system of the device should be carried out using agents available in Poland under the trade name TOP or FORTE which contain the active substance CAS 27083-27-8. Other agents intended for disinfection of hydromassage baths water systems may also be used. When disinfecting, follow the instructions for use provided by the manufacturer of the disinfectant, especially regarding the recommended concentration of the solution and exposure time. Fill the basin with water to the treatment level (all the nozzles must be covered). Add the disinfectant in the amount needed to get its proper concentration (follow the manufacturer's instructions). Then turn on the massage for 3 minutes and leave the device filled with disinfectant solution for the period indicated in the disinfectant instructions. After this time, drain the basin and fill it with clean water to the treatment level. Then turn on a 10-minute massage cycle to flush the water system of the device.

After the flushing has been completed, drain the basin and rinse it with warm water from the shower. Wipe dry the basin with a soft cloth.

7.5 Descaling the water system

The purpose of descaling is to prevent lime build-up caused by the precipitation of impurities and chemical compounds from the water used for the procedures which hinder the functioning of the pump and reduce the intensity of the procedures thus reducing the time of failure-free operation of the device.

Its activation is possible only after the basin is filled with water to the appropriate level (see paragraph 6.1). Otherwise, when activating the mode, a single beep will be generated and the “LEVEL” LED will blink three times.

Activation of this mode is done in the “STANDBY” mode by pressing and holding the “DECREASE” and “ACTION” buttons simultaneously. While the device is operating in this mode, the display shows the time remaining until the end of descaling (e.g. 0:10) alternating with the message “OooO”. Termination of this mode occurs automatically after the expiration of the preset time, which is 60 minutes in the factory, or by briefly pressing the “ACTION” button.

Use "KAMIX" for descaling (available at Meden-Inmed) and follow the instructions of its manufacturer. We recommend using 0.5%-1% concentration of the pre-made solution, which provides sufficient strength of the agent to carry out the decalcification process in our equipment (e.g. 1% concentration of the pre-made solution equals the use of 0,4 kg of Kamix agent for 30 liters of water). At the same time, we allow reducing the percentage concentration of the ready solution, depending on the degree of scaling of the device water system. Experimentally determine the right concentration of the decalcification solution by e.g. observing the degree of cleanliness of the nozzles after treatment. Stop reducing the concentration as soon as the decalcification procedure has no visible effect.

After the descaling is completed, drain the water with the device, then thoroughly wash the basin (section 7.2) and after filling it again with clean water, perform one massage cycle with a duration of 10 minutes. After which, drain the water again and thoroughly wash the basin. Wipe dry the basin with a soft cloth.

7.6 Electrical safety testing

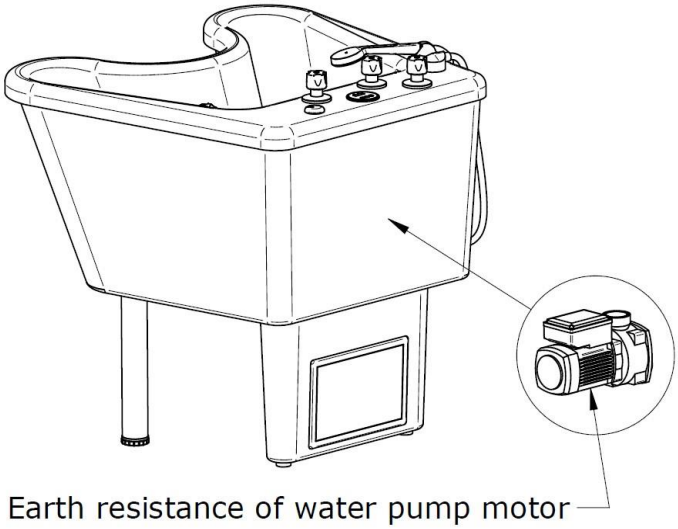
WARNING!

During tests do not disconnect the permanently connected protective earth connection (according to EN 62353, repeated disconnection and reconnection of the protective earth connection may result in deterioration of its mechanical and electrical properties).

Electrical safety tests should be carried out by authorized service personnel. Regularly check the correct operation of the residual current device (RCD) in the device's power supply circuit and perform periodic electrical safety test in accordance with the schedule of activities in section 7.1 above.

Electrical safety tests must be carried out in accordance with the requirements of the current version of EN 62353. When conducting a visual inspection 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), and whether there are no signs of damage to the power cord.

The results of electrical measurements must not exceed the limits specified in the following table:

Measurement	Limit
Earth resistance of water pump motor body.  *If necessary, remove the layer of varnish, oxides, dirt, etc. that covers the component.*	300 mΩ
The insulation resistance between the mains part (L and N terminals) and the equipment earth (PE terminal).	2 MΩ
Touch leakage current from accessible conductive parts.	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 device basin. 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

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

8. CONDITIONS OF MAINTENANCE

WARNING!

The manufacturer will make available upon request circuit diagrams, parts lists, descriptions to assist in the repair of those parts that are approved by the manufacturer for repair.

8.1 Manufacturer's liability

After 7 years from the date of manufacture of the device (and its equipment), the manufacturer is not responsible for defects of the device or its equipment and resulting consequences.

The manufacturer also assumes no responsibility for the consequences that the user or patient has been exposed to, resulting from, for example, improper installation of the device, or poor diagnosis, misuse of the device or its equipment, misinterpretation or failure to follow the instructions in the user's manual, and repairs by unauthorised persons.

8.2 Troubleshooting

Symptoms	Probable cause - Proceedings
No information on the display	Check the status of the: - overcurrent protection, - residual current circuit breaker, - main power switch Check power cable of the device. Switch off the power supply of the device and contact the service.
Water remains in the basin after the drain	Level the device foundation
Water spills under the device during draining	The drain grate does not “keep up” with the amount of water to be drained – clean the grate, or replace it with a grate DN 100
The drainage valve puts a lot of resistance	Hard water causes deposits on the valve surfaces – perform descaling, in the absence of improvement, contact the service
“Loose” valve knobs	Tighten the mounting screws after removing the colored caps from the knobs
Water leaking from the shower connection	Inspect (replace gasket if necessary), tighten connection

8.3 Contact with the manufacturer’s service

Meden-Inmed Sp. z o.o.

ul. Wenedów 2

75-847 Koszalin

service: tel. +48 (94) 344 – 90 – 48

e-mail: service@meden.com.pl

If you purchased your device from an intermediary, please kindly provide us with your serial number and location of use. These data will be placed in our service database, which will allow us to smoothly fulfill warranty and service conditions.

9. 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

WARNING !

Do not use the device in the environment where other devices that emit radio frequency energy are used. The device control system, like other electronic devices, generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. The device manufacturer cannot guarantee that interference will not occur even when the device is placed properly. To check if the device causes interference to other devices, change its position or disconnect its battery. An user is encouraged to try to eliminate interference by reorienting or relocating the device, increasing separation distance between devices or consulting a service technician.

Essential performance and safety - there are no essential performance characteristics according to the risk assessment.

* WKG whirl massage device for upper limbs

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.
NOTE 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.

10. WARRANTY CARD

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 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, shower handset with connection 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.

Whirl massage device for upper limbs: ***WKG***

Serial number of device: _____

Seal, date and signature of the Warrantor: _____

Repairs Register	User’s Comments

Electrical safety testing		Date and signature of the inspector
Protocol no:		
Inspection result:		
The next inspection not later than in 12 months		