INSTALLATION AND OPERATION MANUAL

WKD

Whirl Massage Device

for Lower Limbs

CE 0197

Manufacturer:

MEDEN - INMED, Spółka z o.o.
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Dear Customer!

We would like to congratulate you on the right choice and wish you satisfaction with our product. Please read this manual carefully as it contains important information and the manufacturer's notes on proper installation, use and maintenance of the product.

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 WKD whirl massage device. Please send any comments and remarks concerning the manufacture of the WKD whirl massage device and the contents of this Manual to our address:

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ul. Wenedów 2
75-847 KOSZALIN
tel: +48 94 347-10-40
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GENERAL NOTES:

1. The product should be operated by qualified personnel familiar with the contents of this Manual.
2. Using, operating and servicing the product inconsistently with this Manual is prohibited and may result in damage incurred by the user, for which the manufacturer is not accountable.
3. The manufacturer of the device prohibits any modifications to the device.
4. Do not use the device if its performance and parameters do not answer the description in this Manual. Immediately notify the manufacturer or supplier of this fact.
5. Any repair of the device must be performed by the factory service staff or an authorized service center and registered in the repair list attached to the warranty card. Failure to observe this requirement will void the product warranty.
6. The warranty will void if the user uses the product in a manner not intended for it or fails to observe the operating instructions given in this Instruction Manual.
7. The technical specification of the WKD whirl massage device with a list of spare parts and the replacement procedure (including the inseparable power cord) is available from the manufacturer upon request.
8. Any serious the WKD whirl massage device incident shall immediately be reported to the manufacturer and to the competent authority of the Member State where the user or patient reside.

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.

1. INTENDED USE OF THE DEVICE

The WKD whirl massage device for lower limbs is designed for hydrotherapy treatments with a pump-induced water stream. The whirl massage causes hyperemia, reduces swelling and venous blood stasis, while having an analgesic and muscle relaxing effect.

1.1. Indications

CAUTION!

The personnel should pay special attention to patients' safety while they are taking a seat in the device basin and while they are leaving it. Using an assistive step that facilitates these activities is permitted only in the presence of a staff member, who should assist the patient during these activities. Wipe the step surface dry after each use.

The whirl bath takes 20-30 minutes in water at a temperature of 35-40°C (depending on recommendations).

Recommendations for hydrotherapy treatments:

- post-traumatic rehabilitation of lower limbs, neurological disorders, fatigue of the musculoskeletal system;
- various forms of rheumatic diseases;
- some forms of peripheral circulation disorders, conditions after venous thrombosis, early stages of arterial stenosis, Raynaud's disease, conditions after frostbite and after surgical treatment of varicose veins;
- Complex Regional Pain Syndrome;
- osteoarthritis.

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

1.2. Contraindications to using a whirl massage

CAUTION!

The attending physician refers patients to whirl massage treatments and evaluates their health to determine the advisability of treatment.

Venous inflammation and thrombosis and trophic skin lesions constitute absolute contraindications.

1.3. Patient target group

The attending physician refers patients to whirl massage treatments and evaluates their health to determine the advisability of treatment. The whirl massage treatments are carried out under the supervision of service personnel.

The target group are patients over 18 years of age.

2. TECHNICAL SPECIFICATIONS

The basin of the WKD whirl massage device is made of high-quality gelcoat reinforced with glass fibre.

The outer casing of the device is also made of gelcoat reinforced with glass fiber. The use of such materials assures long-term and failure-free operation of the device.

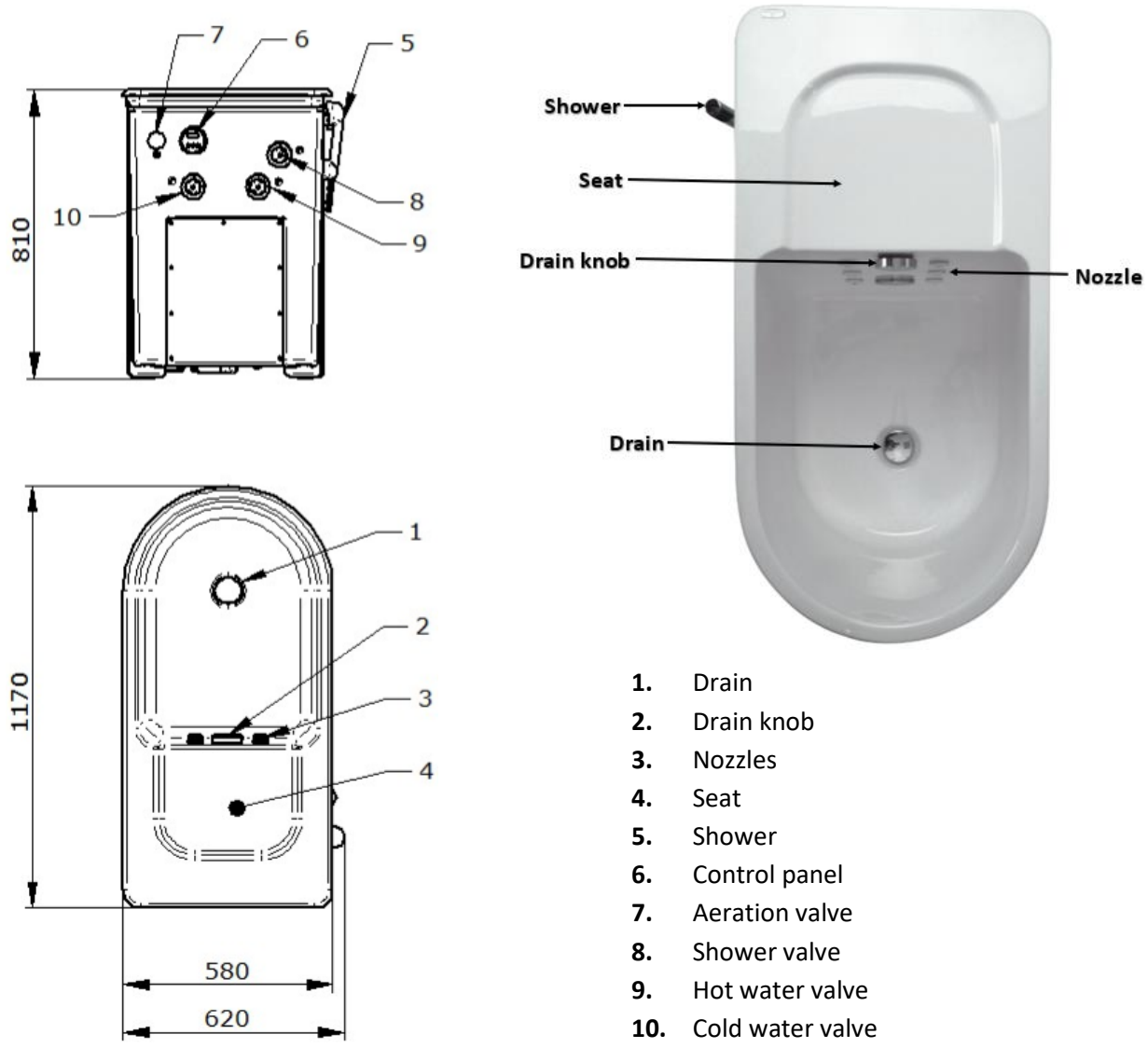
The entire water system, except for the connections, is made of PVC, which ensures its high reliability and cost-effective water consumption during treatment (120-160 liters).

ter filling the device with water by opening the hot/cold water valves (fig.1 item 9 and 10) and pushing the "ACTION" buton, the basin is filled to a capacity of approx. 120 liters.

The bath can be activated in manual control mode or in program control mode.

The water pump, switched on in an appropriate time sequence, pumps water through 6 nozzles (fig.1 item 3) located in the device basin.

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



1. Drain
2. Drain knob
3. Nozzles
4. Seat
5. Shower
6. Control panel
7. Aeration valve
8. Shower valve
9. Hot water valve
10. Cold water valve

Figure 1 - View of the WKD whirl massage device for lower limbs

The WKD whirl massage device is made to order and its parameters are presented in the table below:

Specifications	WKD
Basin's working volume [l]	
- minimum (all nozzles immersed)	120
- maximum (up to overflow)	160
Maximum device dimensions [mm]	
Length	1170
Width	620
Height	810
Wight of device (without water) [kg]	55
Overflow	+
Color	white or calypso
Device casing	
Inspection cover	1
Color	white
Operating parameters	
Supply conditions	230 V ~ 50 Hz
Power consumption	5 A
Casing class	IP X5
Protection class	I
Applied part (basin filled with water)	type B
Patient weight [kg]	135
Maximum safe working load (SWL) [kg]	300
Ambient temperature	10°C ÷ 40°C
Maximum permissible water temperature at the start of treatment	37°C
Maximum time [min].	
- filling to the maximum bath level *	3
- emptying	2

* Depends on water pressure in connections, recommended flow ~70l/min

3. ACCESSORIES

The complete WKD device includes:

- WKD whirl massage device,
- Step for the patient.

At delivery, check the compliance of the device against the specifications.

3.1. Marking

CE 0197 The WKD whirl massage device for lower limbs is manufactured in accordance with Medical Device Regulation 2017/745 (class IIa, rule 9) and has a CE marking, according to the manufacturer declaration.

	Shower
	Cold water regulation valve (marked in blue)
	Hot water regulation valve (marked in red)
	Direction of closing of shut-off and control valves
	Aeration
	Closed water drop
	Opened water drop
	Follow the User Manual
	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.
	Applied part type B
	Maximum safe working load
	Maximum safe step load
	Manufacturer XXXX-XX – year and month of production
IP X5	Protection against water spray
MAX 6 bar	Maximum nominal pressure of the water supply
	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.

4. SAFETY MEASURES

4.1. Location of operation

CAUTION !

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

CAUTION !

It is recommended that additional, easily accessible valves be placed in the room to shut off the utility supply to the device.

4.2. Recomendations for use

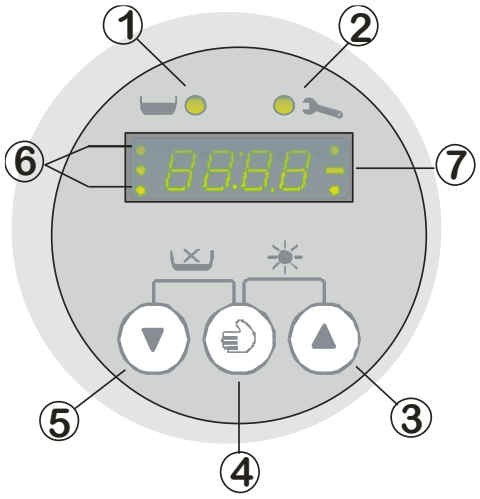
The requirement of carrying out treatments in the device for the WKD whirl massage is water change after each patient.

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

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.

5. OPERATION OF THE WKD DEVICE

5.1. Control panel



① „LEVEL" indicator

② „DESCALING" indicator

③ „INCREASE" button

④ „ACTION" button

⑤ „DECREASE" button

⑥ „REGULATION"

⑦ Display

Figure 2 – Control panel

5.2. Operating modes

The control panel and zone button enable operation of the following operating modes of the device:

5.2.1. „WAIT” modes

The device starts working in the “WAIT” mode after the power is turned on and returns to it from the "MASSAGE" mode and the "DESCALING" mode. The water pump is switched off and the display shows the moving Start message alternating with the water temperature in the basin [e.g. 23°C].

Briefly pressing the "DECREASE" or "INCREASE" button displays the set time of the treatment session and the subsequent presses change the set value. If the device basin is empty, briefly pressing the "ACTION" button activates the automatic filling mode. The display shows alternately the FILL message and the water temperature. The basin is filled to a minimum level of 120 l, which is controlled by the sensor, or till the filling is stopped by the user. Hold down the "ACTION" button to enter the manual fill mode, where water fills the basin for as long as the button is held.

If the water level is high enough for the procedure, briefly pressing the "ACTION" button activates the "MASSAGE" mode. A short beep sound and 3 blinks of the "LEVEL" indicator signal an inadequate water level in the basin.

Simultaneous holding down the "DECREASE" and "ACTION" buttons will activate the "DESCALING" mode, provided that the water level is sufficient. A short beep sound and a 3-fold "LEVEL" indicator blink signal indicate an inadequate water level in the basin.

5.2.2. „MASSAGE” mode

A sufficiently high level of water in the basin for the selected massage zone is required to activate the "MASSAGE" mode. Completion of the "MASSAGE" mode and return to the "STANDBY" mode happens automatically after the preset treatment time, which is a maximum of 30 minutes, or when the water level in the basin drops below that required for the safe operation of the water pump. The display shows the time remaining to the end of the massage [e.g. 0:12], the water temperature in the basin is displayed interchangeably with the time [e.g. 23°C]. A short press of the "ACTION" button will interrupt the "MASSAGE" mode and return to the "WAIT" mode, regardless of the status of treatment time counter.

5.2.3. „DESCALING” mode

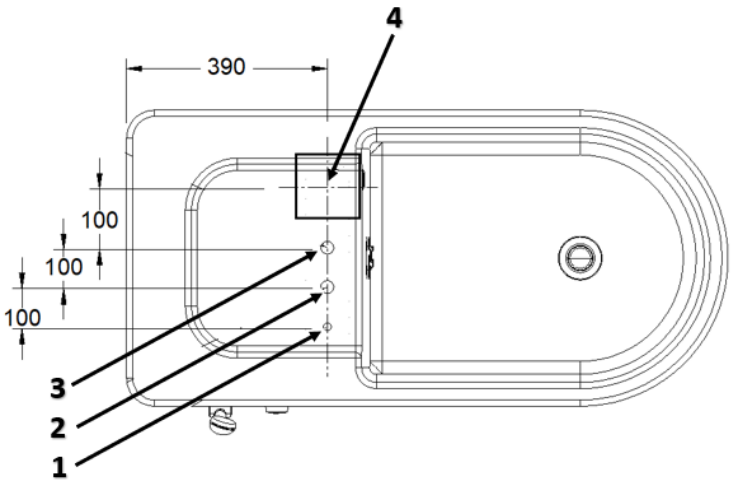
The method of descaling is described in section 5.5 of this Manual. To run the "DESCALING" mode, a sufficient water level in the basin is required. Ending the "DESCALING" mode and returning to the "WAIT" mode is automatic after the preset time has elapsed or when the water level falls below the level required for the pump safe operation. The display shows the time that remains until the end of descaling [e.g. 0:25] alternating with the message 0--0. The descaling time set by the factory is 60 minutes and can be changed to 30 or 15 minutes by service (depending on the hardness of the water used for the treatment) during installation or inspection of the device. Setting the descaling time to 0 minutes means resigning from notification of the necessity of descaling. The necessity of descaling is signalled by the "DESCALING" indicator which blinks until the "DESCALING" mode is started and completed. Failure to perform descaling will result in delay, signalled by sound and the message ---- on the display, every time the "MASSAGE" mode is activated. The message }~ means that pressing the "ACTION" button again will start the pump.

6. PREPARATION FOR USE

CAUTION !

Do not move the device after it has been assembled as this may lead to a leak in the water system and impair the electrical system supplying the device.

Device assembly diagram, available from the manufacturer, provides a detailed device mounting technique. The device should be placed in a room of sufficient size to ensure proper functioning of the hydromassage device. After placing the device in its final position, a passage of at least 80 cm wide should be left on either side.



1. Power cable
2. Hot water valve
3. Cold water valve
4. Floor drain

Figure 3 – Layout of media inlets / outlets in the floor

At the location where the equipment is to be placed, it is necessary to lead out from the floor:

- hot water supply led out of the floor at the height of 10 cm, finished with an external thread 3/4", secured with a shut-off valve installed in the wall of the room;
- cold water supply led out of the floor at the height of 10 cm, finished with an external thread 3/4", secured with a cut-off valve installed in the wall of the room;
- discharge of used water to a sewer, floor drain with an outlet pipe Ø min. 100 mm with the capacity of min 3.5 l/s, across the entire length of the drain vertically;
- power supply ~230 V/10 A/ 50 Hz with 1 m cable (see section 6.1.).

6.1. Electricity supply connection 230V ~ 50 Hz

CAUTION !

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

CAUTION !

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

CAUTION !

The WKD whirl massage device for lower limbs must be connected to the electrical installation permanently.

CAUTION !

The bipolar spinner cut-off switch is used for effective disconnection of the device from the supply network. It is located in the room where the device is operating, where it can be easily and quickly accessed by personnel in case of emergency.

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

The power supply circuit for the device should be equipped with:

- cross-section of power supply cable 3x1.5mm^2;
- independent protection with a C-type 10 A circuit breaker;
- a differential switch with a rated residual current of 30 mA;
- a bipolar power switch to cut off all phases (between the device and the differential switch in the room where the device is used) with a minimum access of 3 mm contact, in a location that allows easy and quick access by personnel in case of emergency.

  If the switch is not visible from the position of regular usage by the operator or service personnel, additional measures should be taken to allow the switch to be locked in the off position.

The casing of the mains terminal block is equipped with a gland ensuring tight clamping on round cable with the diameter of 5-9mm. When using a cable of a different size, appropriate technical measures must be taken to ensure that the mains terminal block is protected against water ingress to a minimum of IPx5.

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

6.2. Water and sewage line supply

CAUTION !

The WKD device was properly leveled during the manufacturing process.
In case of an uneven floor in the bathtub siting location, the bathtub levelling shoul be done with the outer levelling feet, so **the central foots stand firmly on the floor**.

CAUTION !

The water used in the bath should be deprived (for example through proper filtering) of solid pollutants that may cause irreversible damage of the valve system. In case of declaring of such cause of the failure, the warranty does not entail its repair.

CAUTION !

The temperature of the incoming hot water should be lower than 60ºC because of the type of construction materials used. Exceeding of the hot water temperature above 60ºC, may cause a bath instalation failure in a short time, and the warranty does not entail its repair.

The WKD device is manufactured according to the location and installation conditions indicated by the user. Installation and initial start-up of the device is carried out by the service of the manufacturer or a unit authorized by the manufacturer.

The outflow of water after the treatment should be carried out with a pipe with a diameter of at least 100 mm ending with a grating and trap mounted on the floor.

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

6.3. Installation of the device

Installation sequence:

1. Connect the power cord lead from the floor to the junction box of the device (fig. 4 - A).
2. Unscrew the four mounting screws on the rear cover of the device.
3. Once the device has been placed in its designated location, it should be leveled using the adjustable feet screwed into each of the device's four legs.
4. In order to connect the device to the water mains, connect the hoses (red colour is for hot water, blue colour is for cold water) to the connections in the floor (use 3/4" gaskets to seal the connection).

After screwing on the back cover of the device and inspecting for proper operation, the assembly is finished.

Figure 4 – Junction box
A – Cable connection point

7. MAINTENANCE AND SERVICE

7.1. Activities schedule

CAUTION !

When leaving the device unattended overnight or for extended periods of time, close the valves supplying utilities to the device to avoid accidental unsealing of the pressurized water system.

CAUTION !

The WKD whirl massage device for lower limbs has been completely emptied of water by the manufacturer. After refilling the device with water, the user assumes responsibility in case of damage to the device caused by freezing water.

Activity	**Frequency**
Cleaning and disinfecting the basin	after each treatment
Disinfection of the device's water system	every day after the last treatment
Descaling of the water system	as shown on the control panel
Electrical safety test	once a year and after every failure/repair

7.2. Cleaning and disinfecting the basin after each patient

CAUTION !

Use shower to clean the device. To do so, unscrew the valve item 8 fig.1, and adjust the water temperature with the hot water valve (item 9 fig.1) and the cold water valve (item 10 fig.1). After cleaning, turn off all valves.

CAUTION !

Omission of disinfection or its performance inconsistent with the manufacturer's recommendations may result in worsening the sanitary condition.

CAUTION !

It is recommended to empty the device basin immediately after treatment !

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.

In order to flush the basin, open the shower valve (item 8 fig.1) on the right side of the valve panel. Water to flush the basin will flow from the shower.

Once a quarter, the condition of the basin surface should be evaluated and any scratches or chips should be removed after consultation with the manufacturer's service center.

7.3. Disinfection of the basin after treatment

CAUTION !

Damage resulting from the use of inappropriate disinfectants or maintenance products are not covered by the manufacturer's warranty!

After cleaning the strainer and the basin, disinfect the basin with a surface disinfectant that does not damage gelcoat. A product available in Poland with the trade name Incidin-Foam 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

CAUTION !

The use of foaming agents for disinfection or washing and their insufficient rinsing may result in the formation of a large amount of foam after activating the whirl massage.

Periodic disinfection of the device water system should be carried out with special preparations containing the CAS 27083-27-8 active substance (available in Poland under the trade names TOP or FORTE). Other preparations for this purpose that are intended for disinfection of the water system of whirl baths can 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 up to treatment level (so that all nozzles are covered) and add disinfectant

(follow the manufacturer's instructions for use), then activate the massage for 3 minutes and leave the device filled with disinfectant solution for the period specified in the disinfectant instructions.

At the end of this time, empty the basin and fill with clean water to treatment level, then carry out one massage cycle lasting 10 minutes to flush the device water system. After flushing is complete, empty the basin, rinse with warm shower water and wipe dry with a soft cloth.

7.5. Descaling of the water system

CAUTION !

Depending on the hardness of the water used for treatment, the device should be descaled once every 14-28 days. Too much build-up on the nozzles and the pump can cause damage!

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.

Note that for one 15-minute treatment, approx. 120 l of water is consumed, which during 8 hours of operation (3 treatments per hour) amounts to a total water consumption of 2,9 m^3 (24x0,12) from water mains. During one 15-minute treatment, the pump presses into the basin 5,18 m^3 (345x15) of water through the nozzles. It amounts to over 120 m^3 (3x5,18x8) of water during 8 hours of operation.

Use "KAMIX" for descaling (available at Meden-Inmed). 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 0,9 kg of Kamix agent for 120 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 descaling solution by e.g. observing the degree of cleanliness of the nozzles after treatment. Stop reducing the concentration as soon as the descaling procedure has no visible effect.

Fill the basin with water above the minimum level and then add the right amount of descaling agent for decalcification. Simultaneously holding down the "DECREASE" and "ACTION" buttons activates the "DESCALING" mode, provided there is sufficient water level in the basin. A short acoustic signal and the "LEVEL" diode or the diode on the spine massage zone switch blinking 3 times indicates insufficient water level in the basin. Exit from "DESCALING" mode and return to "WAITING" mode occurs automatically after the set time has elapsed or when the water level in the basin drops below that required for safe operation of the water pump. The display shows the remaining time until the descaling is completed [e.g. 0:25], interchangeably with the O--O message. Select and activate the "DESCALING" mode. After the descaling is completed, drain the water with the preparation, rinse the basin thoroughly and after filling it with clean water, perform one massage cycle 5 minutes in duration.

7.6. Periodic testing for electrical safety

Operating staff should follow the instructions in this Manual.

The User's technical service should carry out or commission periodic (at least once a year and each time after failure/repair) tests of the product's electrical safety. Testing should be conducted in accordance with 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).

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

The tested values must not exceed the limits specified in the following table:

Measurement	**Limit**
Earth resistance of water pump motor body *If necessary, remove layers of paint, oxides, etc., that cover the device.*	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.

Independently of the WKD device measurements, the correct operation of the residual current device (RCD) in the power circuit of the WKD device must also be checked in the manner and at the time specified in the technical documentation of the respective RCD.

8. SEQUENCE OF ACTIONS DURING OPERATION

CAUTION !

Two-pole power switch for the spinner is used for effective disconnection of the device from the mains. It is located in the room where the device is operating, in a place allowing easy and quick access of personnel in case of emergency.

CAUTION !

Do not use shampoo or other strong foaming agents during the bath.

CAUTION !

Before the patient enters the device filled with water, check the temperature on the main control panel screen to ensure it does not exceed 37°C. Check also with an additional thermometer.

CAUTION !

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

CAUTION !

It is forbidden to add water during the patient's bath.

8.1. Filling with water

CAUTION !

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

CAUTION !

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

CAUTION !

Mechanical damage to the filling valves bulbs resulting from improper handling (forceful manipulation, too high temperature of water during filling, water with mechanical impurities - gravel, sand, mortar) and seals as operating material are not subject to the manufacturer's warranty.

Before filling, make sure the water release knob is in the closed position. To pour water into the basin, open the "HOT WATER" and "COLD WATER" valves located on the control panel and press the "ACTION" button. The temperature of the poured water can be regulated by adjusting the flow ratio of hot and cold water.

the basin of the device is automatically filled to a capacity of 120 liters.

When the patient is in the correct position for treatment, the water level in the unit should rise to a level that covers all the nozzles, otherwise the water can be added by holding down the "ACTION" button.

8.2. Bath – massage

CAUTION !

The personnel should pay special attention to the safety of the patient while taking a seat in the device basin and while leaving the device. The use of the step to facilitate these activities is only allowed in the presence of personnel who should assist the patient during these activities. The step surfaces should be wiped dry after each use.

CAUTION !

Avoid using additives such as coarse suspensions, sols, and mixtures of crushed solids that may block the pearl nozzle openings in the bottom of the basin.

CAUTION !

To reduce the intensity of the massage (aeration), turn the knob clockwise!

CAUTION !

It is prohibited to place any parts of clothing, towels, etc. on the device's panel or other elements of the basin during the patient's bath, as these could fall into the basin during treatment and cause clogging of the pump's suction elements.

In order to carry out the bath - massage, it is necessary to set the bath parameters specified abovej.

Massage intensity adjustment by aerating the water stream is carried out for each zone individually by using the regulator knobs (fig. 5) - the bigger the air stream, the stronger the water jet from the nozzles.

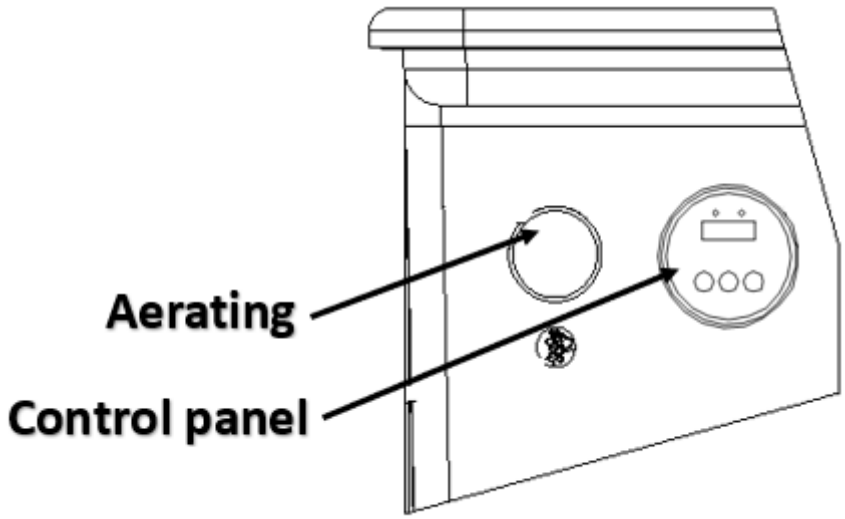


Figure 5 - Massage intensity controller

8.3. Emptying the WKD device

In order to empty the device, set the water discharge knob in the open position.

9. CONDITIONS FOR TECHNICAL OPERATION OF THE DEVICE

CAUTION !

Upon request, the manufacturer will make available circuit diagrams, component lists, and specifications helpful in repairing parts that the manufacturer approves for repair.

9.1. Manufacturer's liability

The expected lifetime is 7 years.

After 7 years from the production date of the device (and its accessories), the manufacturer is not liable for any defects of the device and its equipment and their consequences. The manufacturer holds no liability for any consequences to which the user or patient may be exposed, resulting e.g. from the incorrect assembly of the device, or resulting from misdiagnosis, misuse of the device and its equipment, misinterpretation of or failure to follow the instruction manual, and repair carried out by unauthorized persons.

9.2. Troubleshooting

Symptoms of malfunction	Probable cause - Procedure
1. No information on display	Check the condition of the overcurrent protection, differential switch, main device power supply switch, check the power supply cable - turn off the device power supply and contact the service
2. "Flickering" of the characters on the display	If the temperature in the motor compartment of the pump exceeds 85 degrees, the power switch will automatically engage. Switch off the power supply and contact the service center
3. Water remains in the basin after the drain	Level the device foundation
4. Water spills under the device during draining	Floor drain does not "keep up" with water intake - clean the drain
5. Drain valve creates a lot of resistance	Hard water causes build-up of scale on the valve surfaces - carry out descaling; if no improvement, contact the service center
6. "Loose" valve knobs	Tighten the mounting screws after removing the colored caps from the knobs
7. Water leaks from the shower connection	Inspect (replace gasket if necessary), tighten connection

9.3. Contact z serwisem

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

When purchasing a device from an intermediary, we kindly ask you to provide, in any way of your choosing, information about the serial number and place of use of the device. The data will be placed in our service database, which will help us to fulfill the warranty and service conditions efficiently.

10. STORAGE AND TRANSPORT

If the user plans a 2-week or a longer break in the device's operation, or wants to transport it, it is recommended to drain the device's water system.

The following steps should be taken to address the above:

- drain the water system in the device;
- disconnect the connecting hoses from the water system above the check valves (so that water drains from the water system);
- leave all valves in the open position, including the water discharge valve.

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

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

11. ELECTROMAGNETIC COMPATIBILITY – GUIDANCE AND MANUFACTURER'S DECLARATION

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.

CAUTION !

Do not use the device in an environment where other devices are used whose energy emission results from their normal operation (purpose). The device's control system during normal operation, like any other electronic device, generates, uses, and can emit radio frequency energy. If this device is not assembled and used in accordance with the instructions, it may cause harmful interference to other devices nearby. The manufacturer of this device does not guarantee that interference will not occur even in its specific location. To determine whether the device is causing interference to other products, move it around or disconnect it from the mains. You may try to correct the interference by one of the following measures: reorient or relocate the device, increase its distance from the affected device, connect the device to a power outlet on a different circuit than the one supplying power to the affected device. Consult the service center.

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

Medical electrical equipment requires special safety measures regarding electromagnetic compatibility (EMC) and must be installed and activated as specified in the EMC information included in this User Manual.

** The WKD whirl 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.
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
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
1720 1845 1970	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
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 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
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.						

12. 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 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 lower limbs: **WKD**

Serial number: _____

Stamp, date, signature of the Warrantee: _____

Register of repairs		User's comments
Electrical safety test		**Date and signature of tester**
Protocol no.:		
Test result:		
Next test within 12 months		
Protocol no.:		
Test result:		
Protocol no.:		
Test result:		
Protocol no.:		
Test result:		
Protocol no.:		
Test result:		
Protocol no.:		
Test result:		