INSTALLATION AND OPERATION MANUAL

WKR

Whirl Massage Device

for Lower Limbs and Spine

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

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GENERAL REMARKS:

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 WKR 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 WKR 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 WKR whirl massage device for lower limbs and spine 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

WARNING!

The operating staff 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

WARNING!

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 WKR whirl massage device is built of premium quality glass fiber reinforced gelcoat.

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.

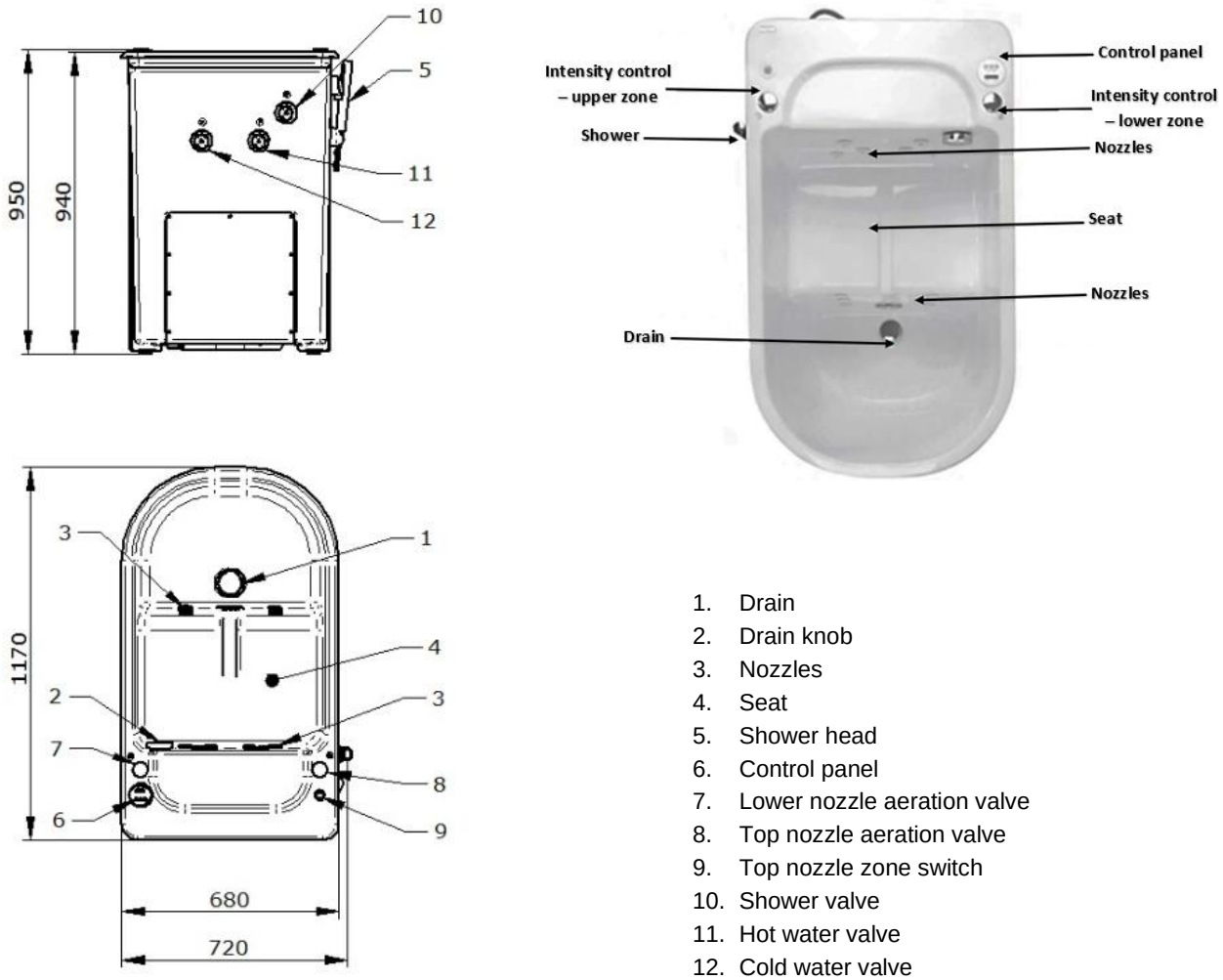
The entire water system, except for the connections, is made of PVC, which ensures its high reliability and cost-effective water consumption during treatment (75-210 liters).

After filling the device with water by opening the hot/cold water valves (fig.1 pos. 11 and 12) and pushing the "ACTION" button to level one (75 liters) for lower limb massage or level two (165 liters), electronically controlled for spine and lower limb massage.

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

The water pump, switched on in an appropriate time sequence, p[umps water through 12 nozzles (fig.1, item 3) located in the device basin.

During treatment the temperature of the water is maintained by a custom-made water system.



1. Drain
2. Drain knob
3. Nozzles
4. Seat
5. Shower head
6. Control panel
7. Lower nozzle aeration valve
8. Top nozzle aeration valve
9. Top nozzle zone switch
10. Shower valve
11. Hot water valve
12. Cold water valve

Figure 1 - Overview of the WKR whirl massage device

The WKR whirl massage device is custom-made and the manufacturing specifications are shown in the table below:

Specifications	WKR
Basin's working volume [l]	
- lower limb massage zone	75
- spine massage zone	165
- overflow	210
Maximum device dimensions [mm]	
Length	1170
Width	680
Height	950
Weight (with a step, without water) [kg]	< 75
Overflow	+
Colour	white or calypso
Device casing	
Inspection cover	1
Colour	white
Operating specifications	
Power supply conditions	230 V ~ 50 Hz
Power consumption	7 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
Room temperature	10°C ÷ 40°C
Maximum permissible water temperature at the start of treatment [°C]	37°C
Maximum time [min].	
- filling to the maximum bath level*	2,5
- emptying	4

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

3. ACCESSORIES

The complete WKR device includes:

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

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

3.1. Marking

CE 0197

The WKR lower limb and spine whirl massage device is made in compliance with Regulation (EU) 2017/745 of the European Parliament and of the Council (Class IIa, Rule 9) on medical devices and is certified with the CE mark, by the manufacturer's 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
	Spine massage zone switch
	Closed water drop
	Opened water drop
	Follow the Instruction 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.
	Type B applied part
	Maximum safe device 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. Place of use

WARNING!

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

WARNING!

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

4.2. Recommendations for use

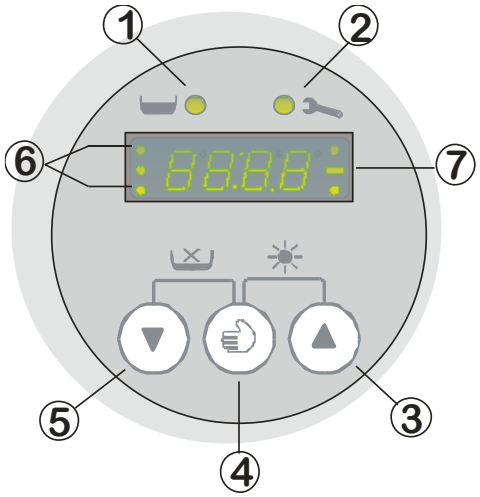
The requirement of carrying out treatments in the device for the WKR type whirl massage is water change after each patient.

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 WKR DEVICE

5.1. Control panel



① Sign "LEVEL"

② Sign "DESCALING"

③ Sign "INCREASE"

④ Sign "ACTION"

⑤ Sign "REDUCE"

⑥ Sign "REGULATION"

⑦ Display

Figure 2 - View of the 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. Standby

In this mode, the device starts working when the power is turned on and returns to it from the "MASSAGE" and the "DESCALING" mode. If the basin was empty and later filled, an audio signal is activated (three short signals repeated every 1 second). Pressing any key stops the signal. The water pump is turned off and there is a sliding Start message on the display interchangeably with the temperature of the water in the basin [e.g. 23°C]).

Briefly pressing the "LOWER" or "INCREASE" button displays the pre-set treatment time, and further presses change the pre-set value.

Briefly pressing the "ACTION" button activates automatic filling mode. The basin is filled to the level determined by the massage zone sensor or until the filling is interrupted by the user. The display shows "FILL". The water temperature is displayed interchangeably with the message. Pressing the spine massage zone selection switch and the "ACTION" button will fill the basin with approx. 165 liters of water. Pressing and holding the "ACTION" button will enter manual fill mode, in which water fills the basin as long as the button is held down.

Simultaneously pressing and holding the "REDUCE" and "ACTION" buttons activates the "DESCALING" mode, as long as there is sufficient water level in the basin. A short audio signal and three flashes of the "LEVEL" diode or the diode on the spine massage zone switch indicate insufficient water level in the basin.

5.2.2. Massage

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]. If the device requests descaling, the massage will be delayed and will require re-confirmation with the massage start key. An audio signal will be generated during the delay.

A short press of the "ACTION" button will interrupt the "MASSAGE" mode and return to the "STANDBY" mode, regardless of the status of treatment time counter.

5.2.3. Descaling

The procedure for descaling is explained in section 10.5 of this Manual. A sufficiently high level of water in the basin is required for the "DESCALING" mode to be activated. The water level should be sufficient to cover all nozzles. If the water level stops below the nozzles during automatic refilling, add water manually so that all nozzles are covered by water. Simultaneously holding down the "REDUCE" and "ACTION" buttons activates the "DESCALING" mode, provided there is sufficient water level in the basin. A short audio signal and 3 flashes of the "LEVEL" diode or the diode on the spine massage zone switch indicate insufficient water level in the basin. Completion of the "DESCALING" mode and return to the "STANDBY" mode occurs automatically after the pre-set time has elapsed or when the water in the basin drops below the level required for safe operation of the water pump. The display shows the time remaining until the descaling is completed [e.g. 0:25], interchangeably with the O--O message.

The display shows the time remaining until the descaling is completed [e.g. 0:25], interchangeably with the O--O message. Setting it to 0 minutes deactivates notification about the necessity of descaling.

The need for decalcification is indicated by the "DECALCIFICATION" indicator flashing as long as the "DECALCIFICATION" mode has not been activated and fully executed.

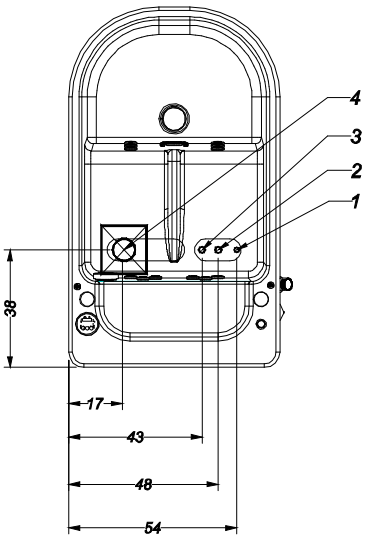
Failure to decalcify will result in a delay each time the "MASSAGE" mode is activated, indicated by a sound and a message on the display. The message }~ means that pressing the "ACTION" button again will activate the water pump.

6. PREPARATION FOR USE

WARNING!

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 cord
2. Hot water valve
3. Cold water valve
4. Floor drain

Figure 3 - Layout of utilities connections 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.

6.1. Connection to the electrical network 230V ~ 50 Hz

WARNING!

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

WARNING!

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

WARNING!

The WKR type device for spine and lower limbs whirl massage must be connected to the electrical installation permanently.

WARNING!

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. Connection to water and sewage system

WARNING!

The WKR device was properly leveled during the manufacturing process.
If the floor is uneven at the device location, level it with the outermost feet so that **all four legs are securely resting on the floor when finished.**

WARNING!

Water for the bath should be free from mechanical impurities (e.g. by use of proper filters), which can cause irreversible damage to the valve system. If this is found to be the cause of the device's failure, the warranty does not cover its repair.

WARNING!

The temperature of incoming hot water should be below 60ºC because of the kind of materials used in the device manufacturing. Exceeding the temperature of 60ºC in incoming water, may cause a failure of the device installation in a short period of time; its repair is not covered by the warranty.

The WKR 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.

6.3. Assembly of the device

Assembly 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).
5. After verifying that the hydraulic hoses are properly connected and that the connections are sealed, insert the plug of the electrical cord leading from the water pump into the socket on the cord leading from the floor.
6. The electrical cord should be hooked up to the hanger located on the inside right wall of the device.

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

WARNING!

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.

WARNING!

The WKR whirl massage device for lower limb and spine 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

WARNING!

Use shower to clean the device. To do so, unscrew the valve pos.13 fig.1, and adjust the water temperature with the valves pos.12 fig.1 (hot water valve) and pos.11 fig.1 (cold water valve).
Turn off all valves after cleaning.

WARNING!

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

WARNING!

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 (fig.1, item 13) 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

WARNING!

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

WARNING!

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. Decalcification of the water system

WARNING!

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. 145 l of water is consumed, which during 8 hours of operation (3 treatments per hour) amounts to a total water consumption of 3.4 m^3 (24x0.145) from water mains. During one 15-minute treatment, the pump presses into the basin 3.75 m^3 (250x15) of water through the nozzles. It amounts to over 80 m^3 (3x3,75x8) 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 1.1 kg of Kamix agent for 145 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.

Fill the basin with water above the minimum level and then add the right amount of descaling agent for decalcification. Simultaneously holding down the "REDUCE" 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 WKR device measurements, the correct operation of the residual current device (RCD) in the power circuit of the WKR 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

WARNING!

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.

WARNING!

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

WARNING!

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.

WARNING!

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

WARNING!

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

8.1. Filling with water

WARNING!

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.

WARNING!

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.

WARNING!

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.

When the spine massage zone is selected, the basin of the device is automatically filled to a capacity of approx. 165 liters.

When the patient takes a sitting position in the basin, the water level in the device should rise so that all nozzles are covered. Depending on the patient's weight, this level may exceed the overflow, which will collect the excess water. The diode on the spine massage zone switch should continuously emit blue light when the back nozzle zone is switched on. When this function is disabled, the diode does not light up.

8.2. Bath – massage

WARNING!

Attention should be paid to patient safety while taking a seat in the device basin and during leaving the device. Using a step to facilitate these activities is permitted only in the presence of staff who should assist the patient during these activities. Wipe step surfaces dry after each use.

WARNING!

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.

WARNING!

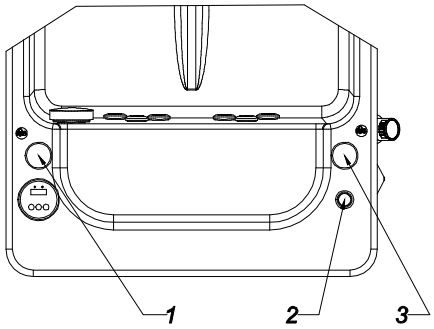
To reduce the intensity of the massage (aeration), turn the knob clockwise!

WARNING!

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 above.

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.



1. Intensity control for lower limb zone massage
2. Spine massage zone switch
3. Intensity controller for spine massages zone

Figure 5 - Massage intensity controller

8.3. Emptying the WKR device

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

9. CONDITIONS FOR TECHNICAL OPERATION OF THE DEVICE

WARNING!

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 fixtures), 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 deposits on the valve surfaces - decalcify, contact customer service if there is no improvement
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 with the service center

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 0ºC, 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.

WARNING!

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 Instruction Manual.

** The WKR 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.

WKR

Whirl massage device for lower limbs and spine:

Serial number: _____

Stamp, date and 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:		