Installation and User's Manual

WKS

Whirl Massage Device for Feet and Shanks

CE 0197

Manufacturer:

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Dear Customer !

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

GENERAL INFORMATION:

1. This medical device that should be operated by qualified and trained personnel who have read this Installation and User's Manual.
2. The use, operation and servicing of the device in a manner inconsistent with this manual are not permitted and may result in damage which the manufacturer is not liable for. Full liability for such damage lies with the user.
3. Making any modifications to the device is forbidden by the manufacturer.
4. If the operation of the device and its parameters are not in accordance with the description in this manual, the device must not be operated. The user must report this fact to the manufacturer or supplier immediately.
5. Each repair of the device must be performed by the manufacturer service or a service authorized by the manufacturer. Each such repair must be recorded in the repair list attached to the warranty card. Failure to comply with the requirement will void the warranty for the product.
6. Any serious whirl massage device for feet and shanks WKS incident shall immediately be reported to the manufacturer and to the competent authority of the Member State where the user or patient is resident.
7. Warranty terms will not be respected if the device is used not as intended or if the usage guidelines given in this Installation and User's Manual are not followed.
8. A technical description of the whirl massage device for feet and shanks WKS, a list of replacement parts and instructions on their replacement are available from the manufacturer upon request.
9. Before starting any repair disconnect the power supply AC 230 V/ 50 HZ.

1. INTENDED USE

The whirl massage device for feet and shanks WKS is designed for hydrotherapy performed by means of a stream of water generated by the pump. Whirlpool massage results in increased blood perfusion, decreased oedema, reduced venous congestion, accompanied by analgesic effect and muscles relaxation.

1.1 Indications

WARNING!

Operating personnel should pay special attention to patient safety when seated in the equipment basin and when exiting the basin. The use of step is only permitted in the presence of staff who should assist the patient during these activities. The step surfaces should be wiped dry after each use.

The whirlpool bath is performed for 20-30 minutes in water at a temperature of 35-40°C, depending on the indications.

Indications for hydrotherapy treatments:

- rehabilitation of lower limbs in post-traumatic conditions, nervous disorders, muscular-nervous system fatigue;
- 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;
- degenerative joint disease.

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

1.2 Contraindications

WARNING!

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

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

1.3 Patients' target group

Patients are referred to the whirlpool massage treatments on the order of the attending physician, who evaluates their condition in terms of suitability for the treatment. The whirlpool massage procedures are conducted under the supervision of service personnel.

The group of patients benefiting from the whirlpool massage are patients over 18 years of age.

2. TECHNICAL DATA

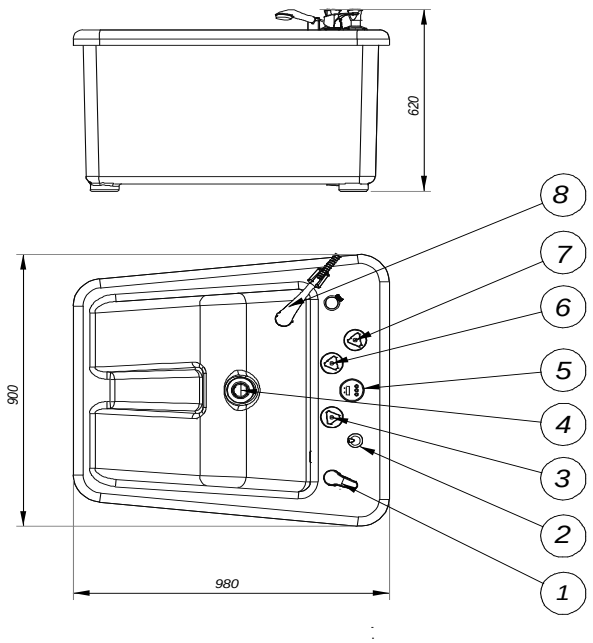
2.1 Marking

CE 0197

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

	Shower
	Cold water regulation valve (content in blue)
	Warm water regulation valve (content in red)
	Water drain is opened
	Water drain is closed
	Direction of closing the control valves
	Aeration
	Alternating current
	Follow the user's manual
	Warning sign This symbol identifies actions which performed not in accordance with the contents of the Installation and User's Manual may result in deterioration of the conditions or threat to the safety of the user and/or the personnel operating the whirl massage device for feet and shanks WKS. A similar marking has been placed on the device where the Installation and User's Manual must be read and its instructions must be observed when using the device.
	Type B applied part
	Medical device
	In accordance with the provisions of the Act on Waste Electrical and Electronic Equipment, disposal of used equipment marked with a crossed-out wheeled bin symbol with other household waste is prohibited. Waste electrical and electronic equipment should be returned to the appropriate collection point. These statutory obligations have been introduced to limit waste from waste electrical and electronic equipment and to ensure an adequate level of collection and recycling of used equipment. The correct implementation of these obligations is particularly important in the case of waste equipment containing dangerous components that have a particularly negative impact on the environment and human health. Dispose of non-electrical equipment in accordance with local regulations.

2.2 Technical Features



1. "*DRAINAGE*" *valve*
2. "*AERATION*" *valve*
3. "*COLD WATER*" *valve*
4. *Water drain with suction*
5. *Control panel*
6. "*WARM WATER*" *valve*
7. "*Shower*" *valve*
8. *Shower handle*

Figure 1 - Whirl massage device for feet and shanks WKS top view

2.3 Technical parameters

Basin working capacity:	
maximum (up to overflow) [l] minimum (all nozzles immersed) [l]	45 65
Height [mm]	620
Width [mm]	900
Length [mm]	980
Weight (empty) [kg]	45
Power supply [VAC/Hz]	230/50
Current consumption (max) [A]	5
Class protection	I, type B
Protection degree IP	IPX5

2.4 Delivered set

Complete whirl massage device for feet and shanks WKS	1 pc.
Patient chair	1 pc.

3. INSTALLATION

3.1 Preparing the room

WARNING !

The whirl massage device for feet and shanks WKS is a device permanently connected to the power supply.

WARNING !

It is recommended to place additional, easily accessible valves in the room to cut off the supply of media to the device.

WARNING !

The whirl massage device must be connected to a 230 VAC/50 Hz power supply by an authorised person.

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

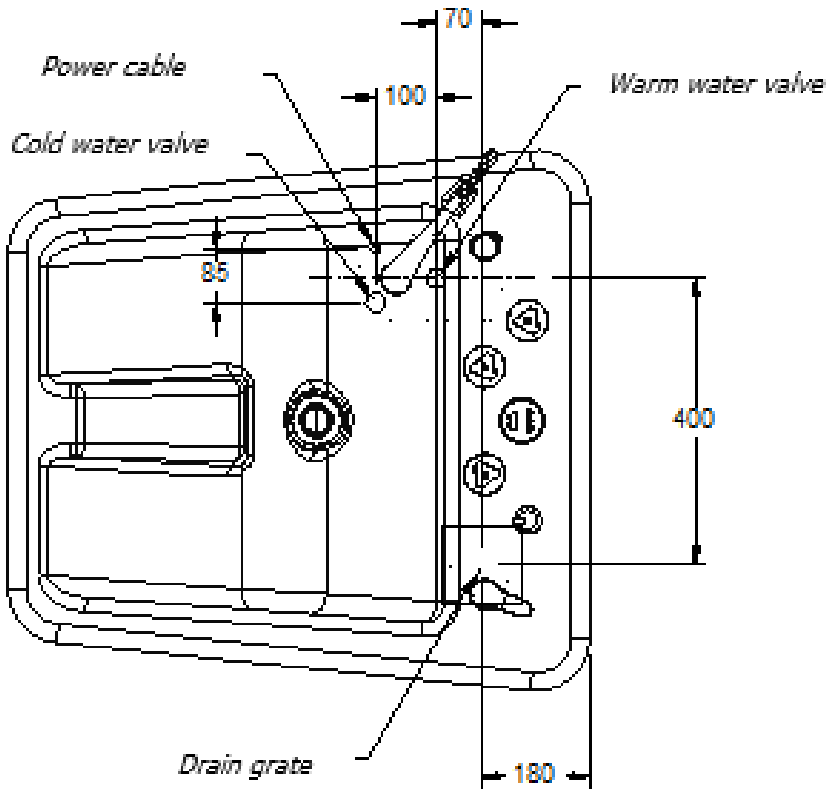


Figure 2 - Distribution of utilities inlets/outlets in the floor

At the site of installing the whirl massage device the following utilities inlets/outlets should be available:

- hot water supply terminated with an external thread 3/4", secured with a shut-off valve installed in the room wall;
- cold water supply terminated with an external thread 3/4", secured with a shut-off valve installed in the room wall;
- waste water outlet to a drain (grille) with an outlet pipe Ø min. 100 cm along the whole length of the pipe to the riser;
- electricity supply 230 VAC/10 A 50 Hz with a 1 m cable.

The power supply circuit should be equipped with:

- independent protection with a 10 A overcurrent circuit breaker with C-type characteristics;
- a residual current circuit breaker with a rated residual current of ≤ 30 mA;
- a bipolar power switch to switch off all phases (between the device and the residual current device in the room where the device is installed with a minimum contact opening of 3 mm, in a position allowing easy and fast access for personnel in case of emergency.

  If the switch is not visible from the position of normal use by the operator or service personnel, additional means must be provided to lock it in the off position

3.2 Connecting the whirl massage device

WARNING!

Due to sanitary reasons, a permanent connection of the device drainage system with the building sewage system is not recommended.

WARNING!

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

The sequence of activities:

1. The electric cable coming from the floor should be connected to the junction box of the device (Fig. 3 – A).
2. Unscrew the four screws securing the rear cover of the massage device.
3. Once the whirl massage device is set in the designated position, it must be levelled by means of adjustable feet screwed into each of the four legs of the device.
4. To connect the whirl massage device to the water supply system, connect appropriately the hoses (the red hose with warm water and the blue one with cold water) with ball valves in the floor (seal the joints with 3/4" seals).
5. Check the correctness and tightness of the hydraulic hoses connections. Insert the plug of the electrical cable led out from the water pump into the socket installed on the electrical cable led out from the floor.
6. Hang the electrical cable on the hanger located on the right inner wall of the devise housing.
7. Screw the rear cover of the whirl massage device to complete its installation. Check correctness of functioning.

The regulations for the electrical installation of the room, it must respond to the requirements of the applicable legislation (PN-HD 60364-7-710, PN-HD 60364-7-701).

Figure 3 – Junction box

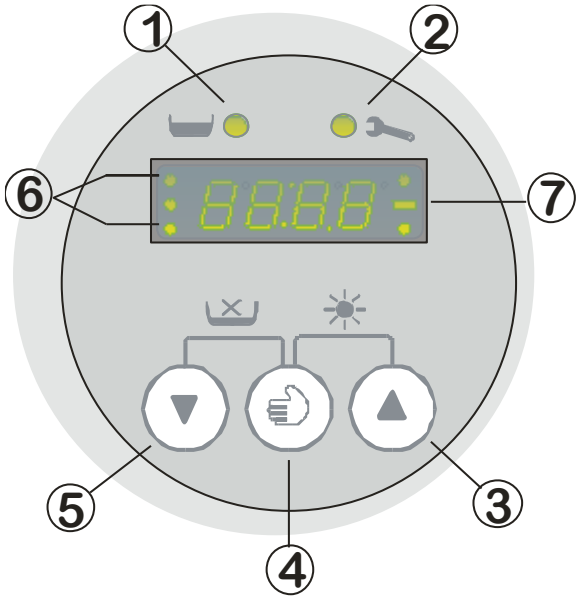
A – Cable connection point

4. OPERATION

WARNING !

Do not exceed the temperature of the treatment water in the device above 41ºC as it may cause patient burns or other dangers resulting from too high water temperature.

4.1 Control panel



① "LEVEL" indicator

② "DESCALING" indicator

③ "INCREASE" button

④ "ACTION" button

⑤ "DECREASE" button

⑥ "REGULATION" indicator

⑦ Display

Figure 4 - Control panel

4.2 Operating modes

The control panel provides the following operating modes.

4.2.1 “WAIT” MODE

The device starts working in the “WAIT” mode after the power is turned on and returns to it from the "MASSAGE" mode and the "DISCONNECTION" mode. The water pump is switched off and the display shows the moving **Start** message. In models equipped with a temperature sensor the **Start** message alternates 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.

Briefly pressing the "ACTION" button activates the "MASSAGE" 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.

Simultaneous holding down the "DECREASE" and "ACTION" buttons will activate the "DISCALING" 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.

4.2.2 “WAIT” MODE (AUTOMATIC FILLING OPTION)

The device starts working in the “WAIT” mode after the power is turned on and returns to it from all other modes (the "MASSAGE" mode, the “DESCALING” mode and the "AUTOMATIC FILLING" mode). If the basin was empty and then filled up, a beep will sound (a sequence of three short beeps followed by 1 second break.) Pressing any button stops the sound generation. The water pump is switched off and the display shows the moving **Start** message. In models equipped with a temperature sensor the **Start** message alternates 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.

Briefly pressing the ACTION” button activates the “AUTOMATIC FILLING” mode. The basin is filled up to the level determined by the massage zone sensor, or till the filling is stopped by the user. The display shows the FILL message alternating with the water temperature. Pressing and holding down the "ACTION" button activates the manual filling mode.

Simultaneous holding down the "DECREASE" and "ACTION" buttons will activate the "DISCALING" 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.

4.2.3 “MASSAGE” MODE

To run the "MASSAGE" mode, a sufficient water level in the basin is required. Ending the "MASSAGE" mode and returning to the "WAIT" mode is automatic after the preset time (which is a maximum of 30 minutes) has elapsed or when the water level falls below the level required for the pump safe operation. The display shows time remaining till the end of the massage session [e.g. **00:12**]. In whirl massage devices equipped with a water temperature sensor, the display shows the time alternating with the water temperature in the basin [e.g. **23°C**]. If the device requires descaling, switching on the massage will be delayed and possibly only after pressing again the massage button. During the delay a sound signal will be generated.

Briefly pressing the "ACTION" button causes interruption of the "MASSAGE" mode and return to the "WAIT" mode regardless of the time counter.

4.2.4 “DESCALING” MODE

The method of descaling is described in section 5.5 of this Installation and User’s 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. **00:25**] alternating with the message **0oo0**.

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 another pressing the "ACTION" button will start the water pump.

4.3 Water filling

WARNING!

Mechanical damage to the valve heads due to improper handling (over tightened with excessive force, too high water temperature during filling, water with mechanical impurities - gravel, sand, mortar) and seals as wear parts are not subject to manufacturer's warranty conditions.

Before water filling check whether the “DRAINAGE” valve is in the “WORK” position.

So as to fill the basin with water set the “Aeration” valve knob in the **H** position and unscrew the “WARM WATER” and “COLD WATER” valves on the panel of the whirl massage device.

The temperature of water can be controlled by adjusting the flow rate of warm and cold water. The treatment water temperature in the basin should not exceed 41^0C due to the danger of patient burns or other hazards caused by excessive water temperature.

4.4 Water filling (automatic filling option)

WARNING!

For proper operation of the whirl bath, the required water level should be above the upper jet nozzles. A water level sensor in the basin of the whirl bath automatically detects an insufficient water level in the basin and does not allow the water pump to run. Operating the whirl bath with a water level below the lower jet nozzles may cause irreversible damage to the water pump.

Before water filling check whether the “DRAINAGE” valve is in the “WORK” position. So as to fill the basin with water set the “AERATION” valve knob in the H position and unscrew the “WARM WATER” and “COLD WATER” valves on the panel of the whirl massage device and press the “ACTION” button.

The water temperature can be controlled by adjusting the flow rate of warm and cold water.

4.5 Adjusting the massage intensity

The massage intensity is adjusted using the "**AERATION**" knob that has three positions: H, M and L. They correspond to the intensity steps:

- **H** - the smallest aeration, the highest intensity of water jet,
- **M** - medium aeration, medium intensity of water jet,
- **L** - the biggest aeration, the lowest intensity of water jet.

4.6 Draining the whirl bath

To empty the whirl massage device, set the "DRAINAGE" valve to the position "OUTLET".

5. MAINTENANCE

5.1 Schedule of procedures

WARNING!

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

WARNING!

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

Procedure	Repetition period
Cleaning and disinfection of the basin	after each treatment session
Disinfection of the water system	every day after the last treatment session
Descaling of the water system	according to the indication on the control panel
Electrical safety testing	once a year and after each breakdown / repair

5.2 Cleaning the device after a treatment session

WARNING!

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

WARNING!

After cleaning the basin, close the "SHOWER" valve carefully and turn the water discharge knob to the extreme left position.

After each treatment, drain all the water out of the basin, clean the strainer and clear the water drain.

Avoid leaving the basin filled with water for a long time after the treatment session, as this will make it difficult to remove impurities from the basin.

The best way to care about the device is to clean the surface of the basin and fittings using a damp cloth and soap. Cleaned surfaces rinse with water and wipe dry with a soft cloth to prevent the buildup of calcium deposits. Do not use abrasive sponges or scouring agents (containing abrasives) to clean the fittings

or the basin, as this will cause scratches or dulling of their surface. Also do not clean fittings with cleaning agents containing solvents or mineral acids, do not use calcium/magnesium deposits removal agents, fluids containing acetic acid, nor agents intended only for sanitary ceramics. Such chemicals cause dulling or dimming of the protective coating and, with prolonged contact without thorough rinsing, can lead to local or complete etching. To rinse the basin, open the "SHOWER" valve on the right side of the valves panel. From the shower flows the water rinsing the basin.

5.3 Basin disinfection after a treatment session

WARNING!

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

After clearing the strainer and cleaning the basin, the basin should be disinfected with a surface disinfectant that does not damage acrylic coatings. For this purpose the agent available in Poland under the trade name Incidin-Foam can be used. Other agents for disinfection of hydromassage baths water systems, for example those available under the trade name TOP or FORTE, may also be used. When disinfecting, observe the instructions for use provided by the disinfectant manufacturer and, in particular, keep the recommended concentration of the solution and the exposure time. Following disinfection, use the shower to thoroughly rinse the basin surface of the disinfectant. Then wipe dry the basin with a soft cloth.

5.4 Disinfection of the water system

WARNING!

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

Periodic disinfections of the water system of the device should be carried out using agents available in Poland under the trade name TOP or FORTE which contain the active substance CAS 27083-27-8. Other agents intended for disinfection of hydromassage baths water systems may also be used. When disinfecting, observe the instructions for use provided by the disinfectant manufacturer and, in particular, keep the recommended concentration of the solution and the exposure time.

Fill the basin with water to the treatment level (all nozzles must be covered). Add the disinfectant in the amount needed to get its proper concentration (follow the manufacturer's instructions). Then turn on the massage for 3 minutes and leave the device filled with disinfectant solution for the period indicated in the disinfectant instructions.

After this time, drain the basin and fill it with clean water to the treatment level. Then turn on the massage for 10 minutes to flush the water system of the device. After the flushing has been completed, drain the basin and rinse it with warm water from the shower. Wipe dry the basin with a soft cloth.

5.5 Descaling of the water system

WARNING!

Depending on the hardness of the water used for the treatment sessions, the descaling of the whirl massage should be performed once every 14 to 28 days. Too large accumulation of deposits on the nozzlesand in the water pump may damage the whirl massage device.

Descaling is intended and designed to prevent precipitation of impurities and chemicals from water used to perform treatment sessions. Such deposits and scale may impede the pump operation and reduce the treatment intensity and failure-free running time of the device.

Please note that approximately 45 litres of water are consumed for one 15-minute treatment session, which means that during 8 hours (3 treatments per hour) total water consumption from the water-pipe network is about 1.08 m3 (24x0.045). During one 15-minute treatment session the pump pours 5.18 m3 (345x15) of water through the nozzles and into the basin, which produces a flow of over 120 m3 (3x5,18x8) of water over 8 hours of operation. For descaling you can use "KAMIX" (purchased e.g. from Meden-Inmed), following the manufacturer's instructions. We recommend the 0.5% - 1% concentration of the ready to use solution, which guarantees proper descaling of our devices (if 1% ready to use solution is used, the demand for "KAMIX" is 0.4 kg per 45 litres of water). At the same time, we allow the concentration of the ready to use solution to be reduced, depending on the amount of scale in the water system. The correct concentration of descaling solution should be experimentally determined by observing the degree of purity, eg of nozzles after the procedure. Reduction of the solution concentration should be discontinued when the descaling procedure fails to produce satisfactory results.

The basin should be filled with water above the minimum level, then pour the appropriate amount of descaling agent. Simultaneous holding down the "DECREASE" and "ACTION" buttons will activate the "DISCALING" 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. 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. 00:25] alternating with the message 0--0. Once the descaling has finished, drain the water with the descaling agent, wash the basin thoroughly, and then fill it with clean water to perform one complete massage cycle with a duration of 5 minutes.

5.6 Electrical safety testing

The user's technical service should carry out or commission periodically (at least once a year and every time after the breakdown / repair of the device) electrical safety tests of the whirl massage device in the following areas:

- earth leakage current of the whirl massage device;
- patient leakage current (in the basin filled with water);
- earth path resistance (water pump motor fixing screw).

Tests should always be documented with a protocol of their results.

Independently check the operation of the residual current circuit breaker in the manner and in the time specified in the technical documentation of the circuit breaker.

6. CONDITIONS OF MAINTENANCE

6.1 Manufacturer's liability

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

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

6.2 Contact with the manufacturer's service

Meden-Inmed, Spółka z o.o., 75-847, Koszalin, ul. Wenedów 2

serwis: tel. +48 (94) 344 – 90 – 48

e-mail: service@meden.com.pl

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

6.3 Troubleshooting

Symptoms	Probable cause - Proceedings
No information on the display	Check the status of the overcurrent protection, residual current circuit breaker, main power switch and power cord of the whirl bath – switch off the power supply of the device and contact the service
After drainage some water remains in the basin	Level the whirl bath
While draining the basin, water is poured under the whirl bath	The drain grate does not "catch up" with the amount of water to be drained – clean the grate, or replace it with a grate DN 100
The drainage valve puts a lot of resistance	Hard water causes deposits on the valve surfaces – perform descaling, in the absence of improvement, contact the service
"Loose" valve knobs	Remove the coloured caps from the knobs and tighten the retaining screw
Water leaking from the shower connection	Check the seal and replace it if necessary, tighten the connection

7. STORAGE AND TRANSPORT

If the operator plans a break in the device's operation longer than 2 weeks or anticipates transporting it, it is recommended to empty the device's water system of water.

In this case follow the steps below:

- empty the water system of the device,
- disconnect the connection hoses from the water installation above the non-return valves (so that water flows out of the centrifuge system),
- leave all the valves in the open position, including the water discharge valve.

Transport and storage of the whirl massage device for feet and shanks WKS should be carried out in the manufacturer's transport packaging at temperatures above 0° C, and in a dry and under-roof space.

8. ELECTROMAGNETIC COMPATIBILITY

WARNING !

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

WARNING!

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

WARNING!

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment**.**

WARNING!

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

WARNING!

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

WARNING!

Do not use the unit in an environment where other equipment is operated whose energy emissions result from their normal operation (purpose). During normal operation, the control system of this equipment, like any other electronic device, generates, uses and can radiate radio frequency energy. If not installed and used in accordance with the instructions, this equipment may cause harmful interference to other devices in the vicinity. The manufacturer of this equipment does not warrant that interference will not occur in a particular location. To determine whether the device is causing interference to other products, you must change its location or disconnect it from the mains. You can try to correct the interference by the following measures: Reorient or relocate the device, increase the separation between the device and the interfering product, connect the device to a power outlet on a circuit different from that to which the other product is connected. Consult the Service.

Essential Performance - The risk assessment indicates that there are no risks to the functioning of this product.

** WKS Whirl massage device for feet and shanks*

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV (contact) ± 2/4/8/15 kV (air)	± 8 kV (contact) ± 2/4/8/15 kV (air)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines 100 kHz	±2 kV for power supply lines 100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % U_T; 250/300 cycles (50/60Hz)	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % U_T; 250/300 cycles (50/60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment* requires continued operation during power mains interruptions, it is recommended that the equipment* be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment*, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Radiated RF IEC 61000-4-3	3 V/m 80MHz do 2,7GHz	3 V/m 80MHz do 2,7GHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	EN 60601-1-2:2015, Table 9 *(see below)*	Complies	
	☒ *Professional healthcare facility environment*	☒ *Professional healthcare facility environment*	

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

9. WARRANTY CARD

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

Whirl massage device for feet and shanks: ***WKS***

serial number:

Seal , date and signature of the Warrantor:

Repairs Register	User's Comments
Electrical safety testing	**Date and signature of the inspector**
Protocol no:	
Inspection result:	
The next inspection within 12 months	