

## Installation and User's Manual

# WKG

## Whirl Massage Device for Upper Limbs



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 WKG whirl massage device for upper limbs incident shall immediately be reported to the manufacturer and to the competent authority of the Member State where the user or patient is resident.
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 WKG whirl massage device for upper limbs, a list of replacement parts and instructions on their replacement are available from the manufacturer upon request.
9. Before starting any repairs disconnect the power supply AC 230 V / 50 Hz.

# 1. INTENDED USE OF THE DEVICE

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

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

## 1.1 Indications



### WARNING !

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

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

Indications for hydrotherapy treatments:

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

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

## 1.2 Contraindications



### WARNING!

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

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

## 1.3 Target patient group

Patients are referred to the whirl massage treatments on the recommendation of the attending physician, who evaluates their condition in terms of suitability for the treatment. The whirl massage procedures are conducted under the control of operating personnel.














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

## 2. TECHNICAL DATA

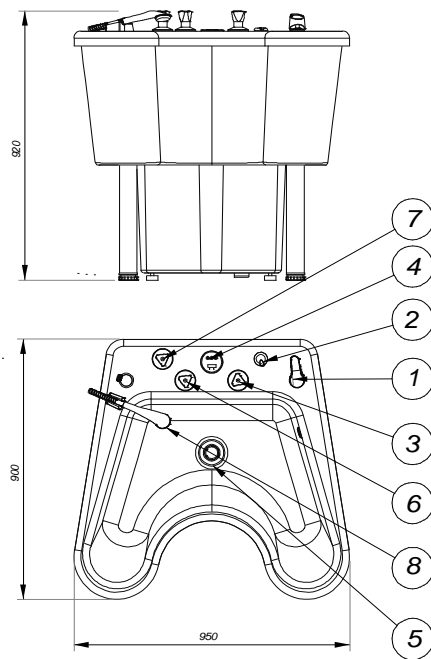
### 2.1 Marking



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

|   |   |
|---|---|
|    | Shower  |
|    | Cold water regulation valve (content in blue)   |
|    | Warm water regulation valve (content in red)  |
|    | Water drain is opened   |
|    | Water drain is closed   |
|   | Direction of closing the control valves   |
|  | Aeration  |
|  | Alternating current   |
|  | Follow the user's manual  |
|  | Warning sign This symbol identifies actions which performed not in accordance with the contents of the Installation and User's Manual may result in deterioration of the conditions or threat to the safety of the user and/or the personnel operating the WKG whirl massage device for upper limbs. A similar marking has been placed on the device where the Installation and User's Manual must be read and its instructions must be observed when using the device.   |
|  | 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. Control panel
5. Water drain with suction
6. "WARM WATER" valve
7. "Shower" valve
8. Shower handle

**Fig. 1 - WKG whirl massage device for upper limbs view**

## 2.3 Technical parameters

|  |        |
|--|--------|
| Basin working capacity:                            |        |
| maximum (up to overflow) [l]                       | 45     |
| minimum (all nozzles immersed) [l]                 | 30     |
| Maximum temperature of water supply:               |        |
| - in continuous cycle [°C]                         | 45     |
| - short duration(< 1 minute) [°C]                  | 65     |
| Time:  |        |
| to fill the basin (up to overflow) [s]             | 76     |
| to empty the basin (after a treatment session) [s] | 42     |
| Height [mm]  | 920    |
| Width [mm]   | 950    |
| Length [mm]  | 900    |
| Weight (empty) [kg]                                | 60     |
| Power supply [VAC/Hz]                              | 230/50 |
| Current consumption (max.) [A]                     | 5      |
| Class protection and type                          | I, B   |
| Protection degree IP                               | IPX5   |

## 2.4 Delivered set

|   |         |
|---|---------|
| Complete WKG whirl massage device for upper limbs | 1 piece |
| Patient chair                                     | 1 piece |

### 3. INSTALLATION OF THE DEVICE

#### 3.1 Preparing the room



**WARNING !**

The WKG whirl massage device for upper limbs is a device permanently connected to the power supply.



**WARNING !**

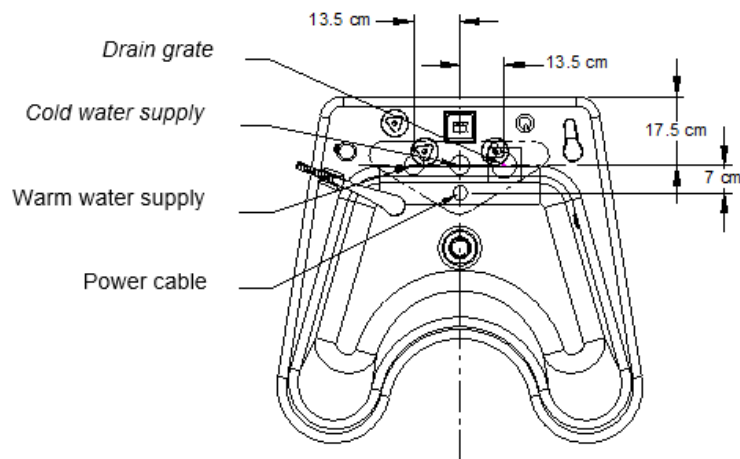
It is recommended to place additional, easily accessible valves in the room to cut off the supply of media to the device.



**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.



**Fig. 2 - Distribution of utilities inlets/outlets in the floor**

In the place where the unit is located, the following should be carried out from the floor:

- hot water supply terminated with an external thread 3/4", secured with a shut-off valve installed in the room wall and a check valve preventing water from entering the installation;
- cold water supply terminated with a 3/4" external thread, secured with a shut-off valve installed in the room wall and a check valve preventing water from entering the installation;
- waste water discharge into waste water outlet (floor drain) with an outlet pipe Ø min. 100 mm with a flow capacity of min. 3.5 l/s along the entire length of the outlet section to the riser;
- power supply 230 VAC/10 A 50 Hz with a 1 m cable.

The unit's 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 whirl massage device.
3. Connect both hoses appropriately to the pipes led out from the floor (the red hose with warm water and the blue hose with cold water).
4. Set the cover on the floor at the location of the whirl massage device.
5. Place the whirl massage device inside the cover so that its feet are placed in the appropriate openings of the cover.
6. Insert the water supply hoses and the power cable into the rear leg of the whirl massage device and pull their free ends into the device.
7. Connect the hoses with the valves located under the upper top of the device.
8. Connect the 230 V socket with the plug led out from the housing of the water pump engine.
9. Having checked the correctness of the connections, the whirl massage device may be filled with water. Check tightness of the hydraulic connections.
10. Lift the cover up and screw it with four screws to the bottom of the whirl massage device.

After checking correctness of the device operation, its installation is completed.

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.



**Fig. 3 – Junction box**  
**A – Cable connection point**



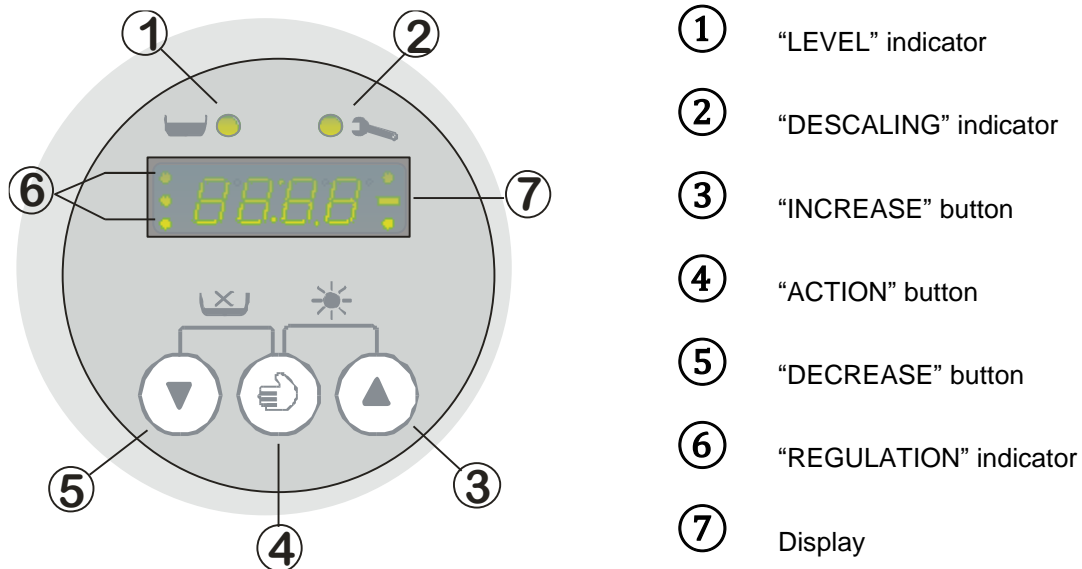
## 4. OPERATING THE DEVICE



### WARNING !

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

### 4.1 Control panel



**Fig. 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 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 "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" (AUTOMATIC FILLING OPTION)

In this mode, the device starts working when the power is turned on and returns to this mode from all other modes (MASSAGE mode, DISINFECT mode, Auto Fill mode). If the basin was empty and then filled,

a sound signal will be activated (three short sounds) repeated every 1 second. Pressing any key stops the sound. The water pump is turned off and the display shows a sliding StaRt message (in the version with a temperature sensor alternating with the value of the water temperature in the basin [e.g. 23°C]).

A short press on the " DECREASE" or " INCREASE" button displays the set treatment time, and subsequent presses change the set value.

Briefly pressing the "ACTION" button activates the Automatic Inflation mode. The basin is filled to the level determined by the sensor or until the filling is stopped by the user. The display shows FILL.

The water temperature is displayed alternately with the word FILL. Holding down the "ACTION" button will switch to manual filling mode.

Simultaneously holding down the " DECREASE" and "ACTION" buttons will activate the "DESCALING" mode provided there is sufficient water level in the basin. Short sound signal and LED "LEVEL" blinking 3 times indicates insufficient water level in the basin.

The procedure for the descaling is described in section 5.5 of this manual.

A sufficiently high level of water in the basin is required to start the "DESCALING" mode. The "DESCALING" mode is terminated and the "WAITING" mode is restored automatically after the set time has elapsed or when the water level in the basin is lower than that required for safe operation of the water pump. The time remaining until the decalcification is completed [e.g. 0:25] alternates with the message OooO on the display.

The factory-preset descaling time is 60 minutes and can be changed to 30 or 15 minutes by the service technician (depending on the hardness of the treatment water) during installation or maintenance of the appliance. Setting to 0 minutes means that no notification no longer be notified of the need to descale. The need for decalcification is indicated by the " DESCALING" indicator which blinks until the "DESCALING" mode is started and carried out The appliance is switched on and the "DESCALING" mode is completed.

#### **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].

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 5.4 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 **OooO**.

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



**WARNING!**

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

| Procedure                              | Repetition period                                |
|--|--|
| Cleaning and disinfection of the basin | after each treatment session                     |
| Disinfection of the water system       | every day after the last treatment session       |
| Descaling of the water system          | according to the indication on the control panel |
| 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 the nozzles must be covered). Add the disinfectant in the amount needed to get its proper concentration (follow the manufacturer's instructions). Then turn on the massage for 3 minutes and leave the device filled with disinfectant solution for the period indicated in the disinfectant instructions. After this time, drain the basin and fill it with clean water to the treatment level. Then turn on a 10 minutes massage cycle to flush the water system of the device. After the flushing has been completed, drain the basin and rinse it with warm water from the shower. Wipe dry the basin with a soft cloth.

## 5.5 Descaling 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 nozzles and 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 30 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 0.72 m<sup>3</sup> (24x0.03). During one 15-minute treatment session the pump pours 5.18 m<sup>3</sup> (345x15) of water through the nozzles and into the basin, which produces a flow of over 120 m<sup>3</sup> (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 30 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 "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. 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 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   |

### 6.3 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](mailto: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.

## 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.

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



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

\* WKG whirl massage device for upper limbs

| <b>Guidance and manufacturer's declaration – electromagnetic emissions</b>  |                   |  |
|---|-------------------|--|
| 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. |                   |  |
| <b>Emissions test</b>   | <b>Compliance</b> | <b>Electromagnetic environment – guidance</b>  |
| RF emissions<br>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<br>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<br>IEC 61000-3-2   | Class A           |  |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3   | Complies          |  |

| <b>Guidance and manufacturer's declaration – electromagnetic immunity</b>   |   |   |  |
|---|---|---|--|
| 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. |   |   |  |
| <b>IMMUNITY test</b>  | <b>IEC 60601 test level</b>   | <b>Compliance level</b>   | <b>Electromagnetic environment – guidance</b>  |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2  | ± 8 kV (contact)<br>± 2/4/8/15 kV (air)   | ± 8 kV (contact)<br>± 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<br>IEC 61000-4-4  | ±2 kV for power supply lines<br>100 kHz   | ±2 kV for power supply lines<br>100 kHz   | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surge<br>IEC 61000-4-5  | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth  | ± 1 kV line(s) to line(s)<br>± 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<br>IEC 61000-4-11  | 0 % U <sub>T</sub> ; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % U <sub>T</sub> ; 1 cycle and 70 % U <sub>T</sub> ; 25/30 cycles (50/60Hz)<br>1 phase: at 0°<br><br>0 % U <sub>T</sub> ; 250/300 cycles (50/60Hz) | 0 % U <sub>T</sub> ; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % U <sub>T</sub> ; 1 cycle and 70 % U <sub>T</sub> ; 25/30 cycles (50/60Hz)<br>1 phase: at 0°<br><br>0 % U <sub>T</sub> ; 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<br>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 <sub>T</sub> 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<br>IEC 61000-4-6   | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands<br>between 0,15 MHz<br>and 80 MHz<br>80 % AM at 1 kHz | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands<br>between 0,15 MHz<br>and 80 MHz<br>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.<br><br>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. |
| Radiated RF<br>IEC 61000-4-3  | 3 V/m<br>80MHz do 2,7GHz   | 3 V/m<br>80MHz do 2,7GHz   |   |
| Proximity fields from RF wireless communications equipment<br>IEC 61000-4-3 | EN 60601-1-2:2015, Table 9<br>wireless (see below)   | Complies<br><br><input checked="" type="checkbox"/> Professional healthcare environment <input checked="" type="checkbox"/> Professional facility healthcare environment |   |

| Proximity fields from RF wireless communications equipment  |                          |   |   |                   |              |                           |
|---|--------------------------|---|---|-------------------|--------------|---------------------------|
| Test frequency (MHz)  | Band <sup>a)</sup> (MHz) | Service <sup>a)</sup>   | Modulation <sup>b)</sup>                            | Maximum power (W) | Distance (m) | Immunity test level (V/m) |
| 385   | 380 – 390                | TETRA 400   | Pulse modulation <sup>b)</sup><br>18 Hz             | 1,8               | 0,3          | 27                        |
| 450   | 430 – 470                | GMRS 460,<br>FRS 460  | FM <sup>c)</sup><br>± 5 kHz deviation<br>1 kHz sine | 2                 | 0,3          | 28                        |
| 710<br>745<br>780   | 704 – 787                | LTE Band 13, 17   | Pulse modulation <sup>b)</sup><br>217 Hz            | 0,2               | 0,3          | 9                         |
| 810<br>870<br>930   | 800 – 960                | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5          | Pulse modulation <sup>b)</sup><br>18 Hz             | 2                 | 0,3          | 28                        |
| 1720<br>1845<br>1970  | 1700 – 1990              | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation <sup>b)</sup><br>217 Hz            | 2                 | 0,3          | 28                        |
| 2450  | 2400 – 2570              | Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7             | Pulse modulation <sup>b)</sup><br>217 Hz            | 2                 | 0,3          | 28                        |
| 5240<br>5500<br>5785  | 5100 – 5800              | WLAN 802.11 a/n   | Pulse modulation <sup>b)</sup><br>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. |                          |   |   |                   |              |                           |
| <sup>a)</sup> For some services, only the uplink frequencies are included.  |                          |   |   |                   |              |                           |
| <sup>b)</sup> The carrier shall be modulated using a 50 % duty cycle square wave signal.  |                          |   |   |                   |              |                           |
| <sup>c)</sup> 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 upper limbs:**

**WKG**

**serial number:**

**Seal , date and signature of the Warrantor:**

| <b>Repairs Register</b>                         |  | <b>User's Comments</b>                     |
|---|--|--|
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| <b>Electrical safety testing</b>                |  | <b>Date and signature of the inspector</b> |
| Protocol no:                                    |  |  |
| Inspection result:                              |  |  |
| The next inspection not later than in 12 months |  |  |
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