User manual

BALMED ECO, STANDARD

Bathtub for balneological baths

CE 0197

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1 Introduction

The user's compliance with the recommendations contained in the instruction manual and the use of the information contained therein enables safe, long-term and trouble-free use of the BALMED bathtub for balneological baths.

General remarks:

1. The product should be operated by qualified and trained personnel acquainted with the context of this operation manual.
2. Using, operating and servicing the product in a manner inconsistent with this manual is not allowed and may lead to damage which is incriminating for the user and for which the manufacturer is not responsible.
3. The device manufacturer prohibits any modifications to the device being used.
4. If the operation and parameters of the product are inconsistent with the description in this instruction manual, the product may not be used. Please report this fact to the manufacturer or supplier immediately.
5. Every repair of the product must be made by a factory or authorized service and registered in the list of repairs attached to the warranty card. Failure to comply with this requirement will void the warranty on the product.
6. Any serious BALMED bathtub for balneological baths 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. Technical description of the bathtub with a list of spare elements and methods of their replacement is available at the manufacturer's request.

The warranty conditions shall became invalid if the device is used for the purpose other than the purpose for which it was designed or if it is not operated in accordance to the instructions provided in this manual.

The manufacturer shall not be liable for the consequences of improper (inconsistent with the conditions set out in this User Manual) use of BALMED bathtub for balneological baths.

1.1 Symbols

	Hot water control valve (coloured red)
	Cold water control valve (coloured blue)
	CO_2 saturated water control valve - option
	Cold brine control valve (coloured blue) - option
	Hot brine control valve (coloured red) - option
	Cold sulfur water valve (coloured blue) - option
	Hot sulfur water valve (coloured red) - option
	Shower head control valve
	LED lighting control button – CHROMO option
	Direction of closing the shut-off and control valves
	WARNING!
	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.

	Follow the instructions for use
	Manufacturer, YYYY – year of production
	Type B applied part
MD	Medical device
SN	Serial number
MAX 6 bar	Maximum nominal inlet water pressure
"CO_2"	CO_2 saturated water supply – option
IPX5	Protection against water spray from all sides of the housing
REF ECO	Capacity up to the overflow equals 240 l, and the minimum capacity for the treatment is 140 l.
REF STANDARD	Capacity up to the overflow equals 300 l or 270 l, and the minimum capacity for the treatment is 150 l and 160 l respectively
	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.
UDI	Unique Device Identification

2 Intended use

2.1 Balneological treatments

BALMED is a bathtub, specially designed and intended for balneological treatments - carbonic or brine baths and pearl therapeutic baths (AIR option) and/or baths with water illumination (CHROMO option). The BALMED bathtub has a quick filling system from the bottom of the basin, which minimizes the release of CO_2 saturated water during the preparation of a carbonic acid bath. The bathtub is made of materials resistant to the influence of aggressive chemical and physical factors, which allows for reliable and long-term use in conditions necessary for balneological baths using brines and other therapeutic mineral waters.

2.1.1 Indications for the use of balneological baths

- subacute supraspinatus tendinopathy,
- osteoarthritis,
- chronic low back pain,
- ankylosing spondylitis,
- rheumatoid arthritis,
- cervical syndrome,
- chronic venous insufficiency,
- fibromyalgia,
- obesity,
- depression,
- stress.

2.1.2 Contraindications of the use of balneological baths

- angina pectoris,
- cardiovascular disorders,
- thrombosis,
- organ failure (cardiac, renal, pulmonary, hepatic),
- diabetes,
- incontinence,
- active infectious diseases,
- stroke,

- severe osteoporosis,
- immunodeficiency,
- nervous system disorders,
- severe difficulty walking,
- epilepsy,
- multiple sclerosis,
- open wounds,
- heat urticaria,
- inflammatory bowel disease,
- febrile conditions.

2.1.3 Patient target group

The attending physician refers patients to balneological baths and evaluates their health to determine the advisability of treatment.

2.2 Carbonic acid baths

WARNING!

For the carbonic acid baths are directed patients with the order of the attending physician, who assesses their condition in terms of suitability for the procedure.

CO_2 contained in water is released on the skin in the form of bubbles that micromassage the receptors of touch and pressure. In addition, CO_2 absorbed through the skin causes the expansion of capillaries, arterial and venous. Thanks to this, blood pressure is reduced and its shift from other parts of the body to the skin. It influences the increase of oxygen, nutrient and functional nutrients supply as well as acceleration of the process of removing waste metabolic products.
The recommended bath temperature range is 33ºC -34ºC and the bath time is from 6 (20) to 12 (30) minutes and depends on the general condition of the patient. The full course of treatment includes a series of 12 to 15 baths, no more than 3-4 carbonic acid baths per week.

2.2.1 Indications for the use of carbonic acid baths

- functional circulatory disorders,
- first and second-degree hypertension,
- capillary blood circulation disorder in the skin,
- narrowing of the lower limbs vessels on the atherosclerotic background,
- conditions after myocarditis, degeneration of the myocardium,
- neurovegetative and psychosomatic diseases,

- rheumatic diseases in the non-serious period with simultaneous occurrence of heart disease,
- obesity.

2.2.2 Contraindications of the use of carbonic acid baths

- acute heart disease,
- insufficiency of the circulatory-respiratory system,
- hypotension,
- thermoregulatory disorders,
- skin disorders,
- hard to heal wounds.

2.3 Brine baths

The effect of brine bath is based on the irritating effect of salt penetrating into the epidermis and into the sweat glands. Salt also causes softening and loosening of the epidermis.
Warm baths (bath temperature 34ºC-37ºC) are performed in lower concentration brine (from 0.5% to 1.0%). Hot baths (bath temperature 37ºC-40ºC) are made in brine with a higher concentration (from 2.0% to 3.0%). The treatment cycle starts in low concentration brine (treatments every other day), and then increases in subsequent baths, increasing their frequency to 4-5 baths a week.

2.3.1 Indications for the use of brine baths

Warm baths:

- chronic arthritis, rheumatism of soft tissues, neuralgia,
- multiple sclerosis,
- neurosis, psychoneurosis, insomnia and nervous exhaustion.

Hot baths:

- degenerative diseases of the spine,
- reproductive organs diseases.

2.3.2 Contraindications of the use of brine baths

Brine baths must not be used in Sudeck's disease, conditions with bone decalcification, chronic rheumatoid rheumatism and in states of general cachexia.

2.4 Pearl baths – AIR option

The pearl bath has a positive effect on the cardiovascular system, musculature, respiratory system and digestion. The wide therapeutic possibilities of the pearl bath are the result of a positive massage effect on the human body.

2.4.1 Impact factors

MOISTURIZATION – by the contact of water with the skin, the regulation of heat in the blood vessels is trained and metabolism is facilitated.

WATER PRESSURE – water pressure (hydrostatic) stimulates blood circulation towards the heart and transports metabolic products.

TEMPERATURE – the recommended temperature range for the pearl bath is from 20ºC to 40ºC. Bath temperature equal to 35°C, called neutral temperature, is felt as pleasant. The greater the deviations from this temperature down or up, the more intensively the stimul i act on the body and change its reactions. Water around the body during massage is in constant motion. This prevents the formation of an insulating buffer layer around the body, which in turn affects the acceleration of heat flow by 25% compared to a regular bath at the same temperature.

2.4.2 Mechanism of impact

The introduction of a stream of compressed air of regulated intensity into the water during the bath causes the skin's mechanoreceptors to massage. The pearl bath combines the effects of hydrostatic processes and intense irritation of the patient's body Surface.

2.4.3 Contraindications for the use of pearl baths

In the case of diseases such as: acute and severe infections, vascular clots, dilation of the artery, hyperthyroidism, inflammation and kidney disease, severe cardiovascular disease, bleeding, malignant tumors, epilepsy, as well as during pregnancy and all acute diseases it is necessary for the doctor to decide on the possibility of using and dosing the bath.

People with a weak heart or coronary disease should remember that in addition to consultation with a doctor, it is recommended to use a hemisphere or a bath in a sitting position. The duration of such bath should not exceed 20 minutes and the water temperature should not be higher than 38ºC.

In the event of an allergic reaction due to the use of bath additives, please consult with a doctor.

2.4.4 Patient target group

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

2.5 Users

Bathtub for balneological baths BALMED can be used only by qualified personnel familiarized with the information contained in the user manual supplied with the device.

2.6 CE mark

CE 0197

Bathtub for balneological baths BALMED is manufactured in accordance with Medical Device Regulation 2017/745 (class IIa, rule 9) and has a CE marking, according to the manufacturer declaration.

3 Technical characteristics

The basin is made of high acrylic glass and quality polyester resins reinforced with fiberglass. The outer housing of the bathtub is made of glass fiber reinforced polyester resin (ECO, STANDARD 300 basin) or gelcoat (270 basin). The use of such materials provides long-term and trouble-free operation of the bathtub. The entire water installation, except for the connections, valves, thermomixer was made of PVC, which ensures its high reliability.

Filling the bathtub with hot and cold water and mineral water (brine, sulfur water) takes place through manually controlled valves. Bath filler is placed at the top of the basin and supplementary nozzles filling with CO_2 saturated water, are located at the level close to the bottom of the bathtub. The shower is powered by a thermo-mixer with adjustable temperature ~38°C.

The pearl massage system (AIR option) is carried out by an electrically driven blower which draws in air under pressure and forces it through channels (ECO, STANDARD 300 l) into the bathtub. The air passing through the holes - placed in the bottom of the bathtub - is broken up into particles of various sizes, which are released into the water in the bathtub.

Bath with water illumination (CHROMO option) is carried out by illuminating the water in the tub from the LED light sources of the appropriate color located on the sides of the bathtub.

3.1 Technical parameters

The bathtub is made to orders and their specification is listed below:

Bathtub parameters		BALMED		
		ECO	STANDARD	
Capacity [l]	Up to the overflow	240	300	270
	Minimum necessary for operation	140	150	160
Dimensions [mm]	Depth	450		400
	Width	750		800
	Length	1950		1990
	Maximum height	755		810
Mass (full equipment) [kg]		75 ± 15		140

Handles		2 (steel)	2 (polymer)
Overflow		+	
Basin colour		green "calypso" - standard, white - standard, other to be agreed (option)	white
Bathtub housing	Colour	white	
Power supply and safety measures (only for AIR and/or CHROMO option)	Power conditions	230 V/50 Hz	n/a
	Power consumption	5 A	n/a
	Protection class	I	n/a
	Application part	type B, 	n/a
Housing class		IPX5	n/a
Operating parameters	Pressure of the power supply installations	0-6 bar (max 6 bar) 0 – 0,6 MPa (max 0,6 MPa)	
Maximum time	Filling (up to the overflow)	~4 minutes* (2x Ø ¾" DN20, 5 bar)	
	Emptying (from overflow)	~2 minutes 15 sekund*	
Permissible patient weight [kg]		135	

*+/- 15 seconds, time may vary depending on the capacity of the BALMED bathtub basin
n/a - not applicable

Table 1 - Technical parameters of the bathtub BALMED ECO, STANDARD

3.2 Bathtub options

option/BALMED bathtub	ECO	STANDARD 300 l	STANDARD 270 l
AIR – pearl bath (air channels with 64 openings)	option	option	not available
CHROMO – bath with lighting effects (12 or 24 led points)	option		not available

3.2.1 AIR option

The pearl massage system (AIR option) is carried out by an electrically driven blower which draws in air under pressure and forces it through channels into the bathtub. The air passing through the holes - placed in the bottom of the bathtub - is broken up into particles of various sizes, which are released into the water in the bathtub.

3.2.2 CHROMO option

On request, the bathtub is equipped with a lamp or LED light system that makes it possible to achieve effects of colored water while bathing. Depending on the order, the light control is carried out from the panel level or by means of a button.

Number of LED points	Light effects
12 or 24	1. selected color: red, green, blue, yellow, cyan, orange, purple, white
	2. cyclically switched colors mentioned above
	3. smooth slow transitions between basic colors
	4. "dance" of lights - flashing
	5. smooth, quick transitions between the colors of the rainbow

3.3 Completion

Standard equipment	
Bathtub for balneological baths BALMED (options depending on the order)	1 pc.
Bathtub step	1 pc.
User manual with warranty card and periodic technical inspection card	1 pc.
Foot rest - ECO, STANDARD 300 l	option
Foot rest - STANDARD 270 l	accessory

Any changes to the bathtub specifications may result from the order for its execution.
Check the components of the bathtub against the specification on reception.

3.4 Transport and storage

WARNING!

If the bathtub will not be used for more than 2 weeks or will be transported to another location, it is recommended to empty the bathtub water system from water.

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

Temperature of storage and transport [°C]	positive (max 60°C)
Air humidity during storage and transport [°C]	5% - 95% without condensation

4 Design and operation

WARNING!

It forbidden to modify the device without the written authorization of its manufacturer.

WARNING!

Use the shower head (pos. I fig. 1-2) only to rinse the bathtub.

The manufacturer reserves the right to make changes to the bathtub structure that do not violate basic functional and safety requirements. The illustrations in this manual are for reference only and the design variants result from the specifications of the order.

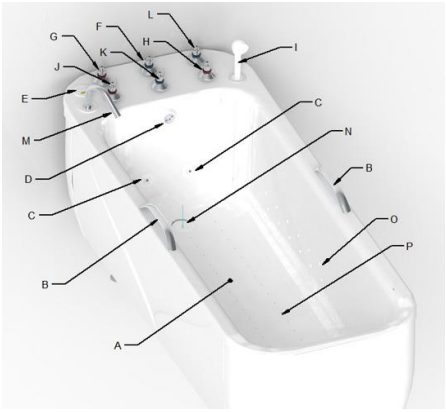


Figure 1 - Basin view of ECO and STANDARD 300 l bathtub with operating and adjustment elements

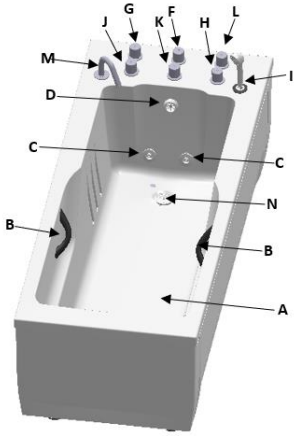


Figure 2 - Basin view of STANDARD 270 l bathtub with operating and adjustment elements

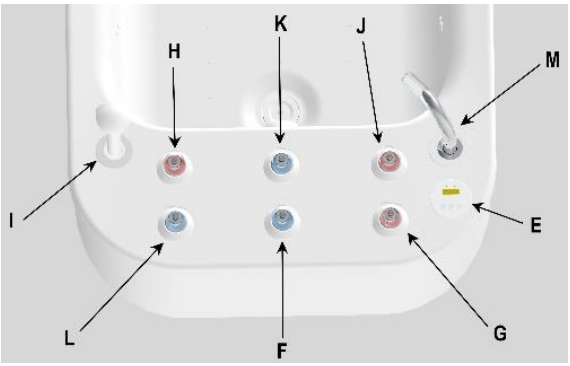
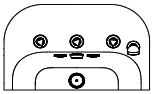
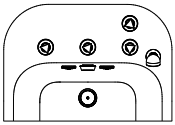
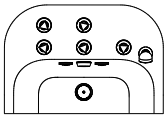
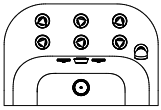


Figure 3 - View of the BALMED bathtub base crown

A	Bathtub basin	I	Shower head
B	Handles	J	Hot water valve
C	Additional two nozzles filling the bathtub	K	Cold water valve
D	Overflow hole	L	CO_2 saturated water valve
E	Control panel (AIR option) or a button (CHROMO option)	M	Bath filler (n.a. CO_2)
F	Cold brine or sulfur water valve	N	Water drain plug
G	Hot brine or sulfur water valve	O	LED spots (CHROMO option)
H	Shower head valve	P	Pearl massage channels (AIR option)

Figures 1 and 2 show a top view of the BALMED bathtub basin with adjustment and operating elements. In the lower part the anatomically shaped basin **(A)** there are two additional nozzles for filling **(C)** water saturated with CO_2. On the upper edge of the bathtub there are filling valves: hot water **(J)** and cold water **(K)**, hot brine (or sulfur water) **(G)**, cold brine (or sulfur water) **(F)**, water saturated with CO_2 **(L)**, shower head **(I)** for rinsing with a shower head valve **(H)** and bath filler **(M)**. The temperature of the water flowing out of the shower head is set to 38°C by means of a thermostatic valve. Valves: **(G)**, **(F)**, **(L)** occur depending on the order option. On the line of maximum water level in the basin there is an overflow hole **(D)** with a water drain plug **(N)** attached. The bathtub is equipped with a larger diameter drain, allowing water to be drained after bathing with suspensions. On the crown of the basin handles **(B)** are mounted to facilitate taking a position in the tub. The control panel or a button **(E)** - depending on the order - is installed in the AIR and CHROMO options.

View of the valve arrangement in the BALMED bathtub depending on the version	
BALMED 3	
Cold water **(K)**	
Hot water **(J)**	
Shower head valve **(H)**	
BALMED 4	
Cold water **(K)**	
Hot water **(J)**	
Shower head valve **(H)**	
CO_2 saturated water, brine or sulfur water **(L)**	
BALMED 5	
Cold water **(K)**	
Hot water **(J)**	
Shower head valve **(H)**	
CO_2 saturated water, cold brine or sulfur water **(F)**	
Hot brine or sulfur water **(G)**	
BALMED 6	
Cold water **(K)**	
Hot water **(J)**	
Shower head valve **(H)**	
CO_2 saturated water, cold brine or sulfur water **(F)**	
Hot brine or sulfur water **(G)**	
CO_2 saturated water **(L)**	

Versions of the bathtub for balneological baths BALMED ECO, STANDARD are described in the table below:

Version 3	Three valves – filling valve for cold and hot water, shower head valve
Version 4	Four valves – filling valve for cold and hot water, shower head valve, filling valve for CO_2 saturated water, brine or sulfur water
Version 5	Five valves – filling valve for cold and hot water, shower head valve, filling valve for cold brine or sulfur water and CO_2 saturated water
Version 6	Six valves – filling valve for cold and hot water, shower head valve, filling valve for cold brine or sulfur water, hot brine or sulfur water and saturated water CO_2

5 Safety means

5.1 Place of use

WARNING!

For sanitary reasons it is not allowed to install a permanent (closed) connection between the bathtub drain and a drain system of the building.

WARNING!

The rooms in which balneological treatments are carried out should be equipped with bottom gas overflows and mechanical supply and exhaust ventilation with bottom exhaust to ensure increased air exchange exceeding two times per hour.

WARNING!

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

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

5.2 Notes for use

WARNING!

A condition for carrying out treatments in the BALMED bathtub is to change the water after each patient.

WARNING!

When filling the bathtub with water, remember to first fill the basin with cold water and then add warm water to the desired temperature.

WARNING!

Do not exceed the temperature of the treatment water in the bathtub above 40ºC as it may cause patient burns or other dangers resulting from too high-water temperature.

6 Preparing for use

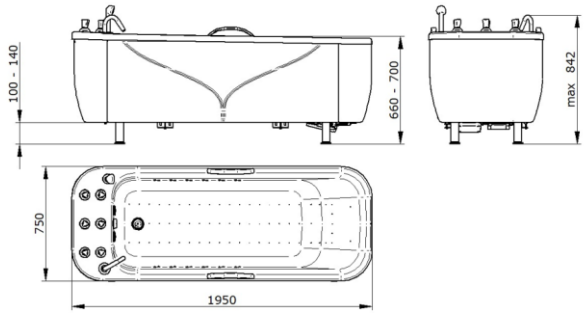


Figure 4 - Bathtub BALMED ECO and STANDARD 300 l (dimensions in mm)

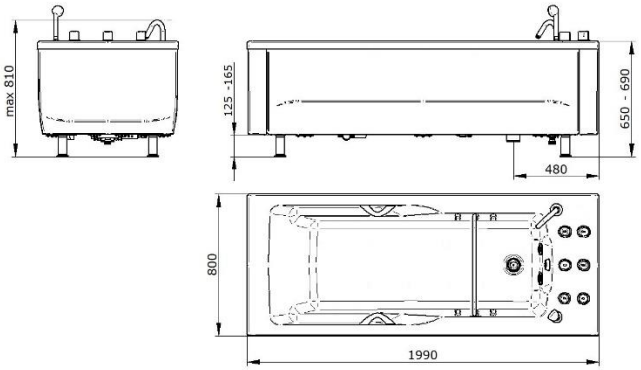


Figure 5 – Bathtub BALMED STANDARD 270 l (dimensions in mm)

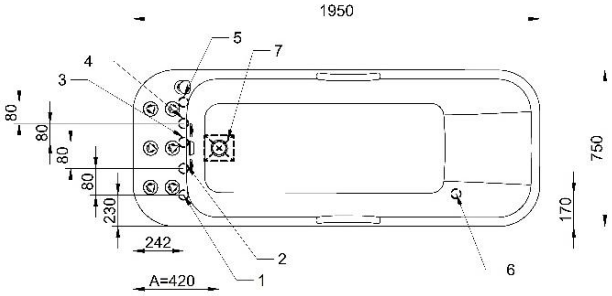


Figure 6 - BALMED bathtub dimensions and layout of media outlets in the floor (dimensions in mm)
Dimension A = 420 mm ensures the position of the grille directly under the drain opening

In the place where the bathtub is installed, it should be led out of the floor to a maximum height of 150 mm:

(1) Hot brine connection, terminated with a check valve with a G3/4" nipple;

(2) Cold brine connection, terminated with a check valve with a G3/4'' nipple;

(3) CO_2 saturated water connection, terminated with a check valve with a G3/4'' nipple;

(4) Cold water connection, terminated with a check valve with a G3/4'' nipple;

(5) Hot water connection, terminated with a check valve with a G3/4'' nipple.

In the place where the bathtub is installed, it should be led out of the floor:

(6) Power supply connection – see section 6.1;

(7) Drain tube of a diameter not less than DN100 (it is recommended to use a floor drain grate with an air trap and a drain tube of min. 100 mm in diameter, ensuring the minimum flow rate of 3.5 l/s).

Recommendations:

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

6.1 Connecting to 230 V/50 Hz mains electricity – AIR, CHROMO options

WARNING!

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

WARNING!

The bathtub for balneological baths BALMED must be connected to the electrical installation permanently.

WARNING!

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

WARNING!

The bipolar disconnect 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.

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

- residual current device (RCD) with a rated tripping current not exceeding 30 mA;
- an overcurrent circuit breaker 6 A with a type C characteristic curve;
- all-pole disconnect switch with a minimum contact gap of 3 mm, placed in the room where the appliance is operated, at a location allowing easy and fast access for personnel in the case of an 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 in the off position.
- cross-section of power supply cable 3x1,5 mm^2.

The enclosure of mains terminal device is equipped with a gland ensuring tight clamping on a round cable with a diameter of a 6-10 mm. When using a cable of different size, appropriate technical measures must be taken to ensure that the mains terminal device is protected against water ingress to a minimum of IPX5.

The electrical installation to which the device is connected must conform to the applicable legal regulations (e. g. EN 60364-7-710).

6.2 Connecting to the water supply and drainage systems

WARNING!

The bathtub water must be free from solid impurities that may cause irreversible damage to the valve system, this can be ensured e.g. by applying appropriate filtering units. If such a reason for the bathtub's malfunction is found, the warranty does not cover its repair.

WARNING!

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

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 bathtub is made according to the location and installation conditions indicated by the user. Water flow should be directed through a drainpipe having a diameter not smaller than 100 mm and a floor drain grate installed flush with the floor surface. The floor in the vicinity of the floor drain should be graded towards the drain.

6.2.1 Marking of bathtub connection hoses

Each of the connection hoses in the BALMED bathtub is appropriately colour-coded to differ which medium should be connected to it:

- hose with 1 blue strip – cold water supply
- hose with 1 red strip – hot water supply
- hose with 2 blue strips – cold brine or sulfer water supply
- hose with 2 blue strips – hot brine or sulfer water supply
- hose with 2 blue strips and mark "CO_2" – cold brine or sulfer water or CO_2 saturated water supply

6.2.2 Connecting CO_2 saturated water supply to the bathtub

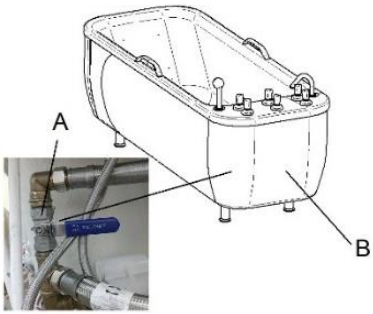
WARNING!

The maximum temperature of CO_2 saturated water must not exceed 40°C as patient burns or other hazards may result from too high-water temperature.

To connect CO_2 saturated water supply to the BALMED bathtub use a hose with two blue strips and mark "CO_2". Next step is to close the bath filler ball valve (pos.A fig.7). In order to execute this step, remove the bathtub front cover (pos.B fig.7) and move the lever of the bath filler ball valve to the closed position.

The BALMED bathtub is delivered with bath filler ball valve set by default in the open position.

Closing bath filler ball valve will cause CO_2 saturated water to fill the bathtub only through the filling nozzles located at the bottom of device (pos.C fig.1).



A – Bath filler ball valve
(in fig.7 shown in closed position)
B – Bathtub front cover

Figure 7 – Bathtub filler ball valve

6.3 Assembly/disassembly bathtub covers

Housing of the BALMED bathtub consist of four covers: front, rear and two side covers.

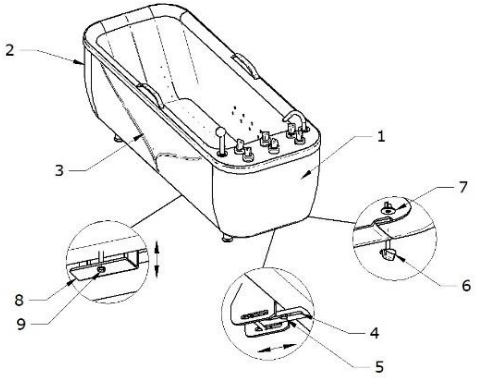


Figure 8 – BALMED ECO and STANDARD 300 I bathtub view with cover elements

1.	Front cover	6.	Plastic wing screw
2.	Rear cover	7.	Plastic wing nut
3.	Side cover	8.	Side cover holder
4.	Front cover holder	9.	Screw
5.	Screw		

To disassembly the BALMED ECO, STANDARD 300 I bathtub covers, first remove the front cover:

1. Loosen the screw (pos.5 fig.8) and slide out the front cover holder (pos.4 fig.8).
2. Remove the plastic wing screw (pos.6 fig.8) and plastic wing nut (pos.7 fig.8).

   The screw and nut will be on both sides of the cover.

3. Carefully remove the front cover.
4. Repeat the above steps for the rear cover.

In order to remove the side covers of the BALMED ECO, STANDARD 300 l bathtub:

1. Loosen the screw (pos.9 fig.8) and slide down the side cover holder (pos.8 fig.8).

   Perform this step for the other side cover holder.
2. Carefully remove the side cover.
3. Repeat the above steps for the second side cover.

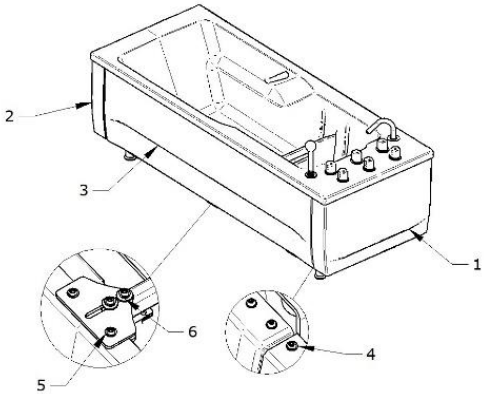


Figure 9 – BALMED STANDARD 270 l bathtub view with cover elements

1.	Front cover	3.	Side cover
2.	Rear cover	4-6.	Allen socket screw

To disassembly the BALMED STANDARD 270 l bathtub covers, first remove the front cover:

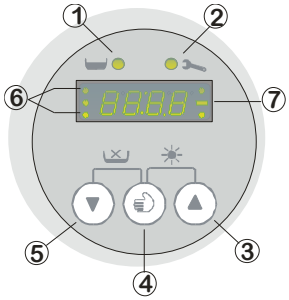
1. Using an allen key (not supplied), unscrew the allen socket screw in item 4 in figure 9. There are 2 such screws on each side of the bathtub.
2. Carefully remove the front cover.
3. Repeat the above steps for the rear cover.

In order to remove the side covers of the BALMED STANDARD 270 l bathtub:

1. Using an allen key, unscrew the 6 screws in item 5 fig.9 in the three brackets.
2. Using an allen key, loosen the screws in item 6 fig.9.
3. Carefully remove the side cover.
4. Repeat the above steps for the second side cover.

7 Control of the bathtub

7.1 Control panel – AIR, CHROMO options – only applies to the ECO, STANDARD 300 basin



1. "LEVEL" indicator
2. "SERVICE" indicator
3. "INCREASE" button
4. "ACTION" button
5. "DECREASE" button
6. "ADJUST" indicator
7. Display

Figure 10 – Control panel

7.2 Operating modes

The control panel allows operation of the following modes of operation of the device:

7.2.1 Stand-by

This is the mode in which the device starts operation after being powered on, and to which it returns from all other modes. The blower is switched off and the display shows a moving message "StaRt" alternately with water temperature indication (e.g. 23°C). Briefly pressing the "DECREASE" or "INCREASE" button, the set treatment time is displayed, and subsequent presses change the set value. Briefly pressing the "ACTION" button activate "MASSAGE" mode.

7.2.2 Massage

To activate the "MASSAGE" mode, a sufficiently high-water level in the basin is required (all channels must be under the water). In the "MASSAGE" mode, the display of the operating panel shows time remaining until the end of the massage [e.g. 0:12] alternating with the temperature of the water in the basin [e.g. 23°C]. During the "MASSAGE" mode it is possible to adjust the intensity of the treatment. Holding the "DECREASE" button decreases the power of the air pump and holding down the "INCREASE" button increases the power of the air pump. At any time during the "MASSAGE" mode, briefly pressing the "ACTION" button interrupts the "MASSAGE" mode and returns to "WAIT" mode (regardless of the treatment time counter). The automatic termination of the "MASSAGE" mode and return to the "STANDBY" mode takes place after the end of the set procedure time.

7.2.3 Blow-through air channels – AIR option

Operation in this mode requires that the bathtub to be empty. In order to start this mode, press the "INCREASE" and "DECREASE" buttons simultaneously. The channels are being dried by air being blown through them. The device remains in this mode until being stopped by the user. The blow-through starts with automatic increase of the air pump power. After being stopped by the user the pump power decreases, after which the device enters the "STAND-BY" mode.

7.2.4 Water illumination – CHROMO option

Simultaneous pressing on the "ACTION" and "INCREASE" buttons turns on or off the water illumination by means of LED elements, built into the basin of the bathtub. A short simultaneous pressing of the "ACTION" and "INCREASE" buttons causes cyclic switching of active colors (sequence of changes) of water illumination in the basin. Colour switching (sequence of changes) only works when the water illumination function is switched on.

7.3 CHROMO option without AIR option

CHROMO option is switched on by pressing the button marked - 
The change of color and switching to the program of automatic color change is done by pressing this button twice.

8 Sequence of operations

WARNING!

The bathtub at the manufacturer has been completely emptied of water. After refilling with water, user takes responsibility if there is a damage to the tub due to freezing water.

WARNING!

Personnel should pay special attention to patient safety when taking a seat in the tub and when exiting the bathtub. Facilitating use of the step is permitted only in the presence of personnel who should assist the patient during these activities. Wipe the step surfaces dry after each use.

WARNING!

Each time before the patient enters the bathtub, check the water temperature to prevent burns when the water is too hot (higher than 40ºC).

WARNING!

Do not use shampoos or other highly foaming agents during the bath.

WARNING!

Personnel should pay special attention to the patient's safety during adding hot water.

WARNING!

Periodically, once a day, check the condition of the step surface if it is not dirty or cracked. In case of dirt wipe with a damp cloth, in case of a crack the use of the step is forbidden. In case of abrasion/damage of the structural step surface the use of the step is forbidden.

WARNING!

It is recommended that during balneological baths, once the patient is positioned in the bathtub basin, the water level line should not go higher than the heart line.

8.1 Carbonic acid bath

WARNING!

In case a carbonic acid bath is being performed, the pearl massage must not be used. Applying the pearl massage function causes fast degassing of water (separation of carbon dioxide from water), due to which it loses its therapeutic qualities.

WARNING!

Methods of preparation and performing of the carbonic acid bath treatments should be defined by the organization which uses the equipment, in the form of obligatory instructions. This manual contains only the minimum necessary information relating to this subject.

WARNING!

During the carbonic acid bath there is a possibility that, despite absorbing the carbon dioxide by patient's skin, it could be inhaled through his lungs. Breathing with air containing increased amount of carbon dioxide may be dangerous. The patient may feel sleepy and weary, therefore, during the carbonic acid bath his wellbeing should be periodically monitored.

Preparing the carbonic acid bath consists of mixing hot water at maximum temperature of 60°C with cold water saturated with CO_2 in such proportion that the resulting temperature of water in the tub passes within the range of 30°C to 35°C. First fill the clean basin with cold water (until the bottom of the tub is covered), next with hot water and then through supplementary nozzles add the CO_2 saturated water until the desired acidity and temperature are reached. Temperature and acidity of the resulting mix may be adjusted by adding cold water. The moment when the patient is positioned in the bathtub shall be considered a starting point of the bath (it is recommended that the water level line does not run above the patient's heart). After the patient leaves the tub, drain the water from the basin.

In case there is doubt whether the water prepared for bath is properly saturated with carbon dioxide, a measurement of free carbon dioxide in water should be performed (done e.g. with a KARAT meter – not included with the device). Carbon dioxide saturation in water is dependent on temperature and should pass within the range from 250 to 990 mg CO_2/dm^3 for carbonic acid water and not less than 1 g CO_2/dm^3 for oxalacetic water at room temperature. Water containing more than 400 mg CO_2/dm^3 is biologically active. Optimum conditions for carbonic acid bath are present at water temperature of 31 - 34°C and carbonic acid content in the range of 1,2 to 1,4 g CO_2/dm^3.

8.2 Prowadzenie kąpieli solankowej

WARNING!

Methods of preparation and performing of brine bath treatments should be defined by the organization which uses the equipment, in the form of obligatory instructions. This manual contains only the minimum necessary information relating to this subject.

Preparation of brine bath consists of mixing hot water with a maximum temperature of 60ºC with a brine of a certain concentration in such proportions that the water temperature in the basin tube is from 34ºC to 37ºC for a warm bath and 37ºC to 40ºC for a hot bath.

First fill the clean basin with cold water (until the bottom of the tub is covered), next with hot water and then add the brine until the desired brine concentration and temperature are reached. Temperature and brine content of the resulting mix may be adjusted by adding cold water. The moment when the patient is positioned in the tub shall be considered a starting point of the bath. After the patient leaves the bathtub, drain the water from the basin.

Method for calculating the salinity level of the bath:

To prepare a brine bath of a defined salinity level, mix the brine whose concentration is R with water in proportion as defined in the table below:

Concentration of the well brine R=4.00 %				
For a bath on salinity	100 liters		200 liters	
	Water [l]	Brine [l]	Water	Brine [l]
0.5 %	87.50	12.50	175.00	25.00
1.0 %	75.00	25.00	150.00	50.00
1.5 %	62.50	37.50	125.00	75.00
2.0 %	50.00	50.00	100.00	100.00
2.5 %	37.50	62.50	75.00	125.00
3.0 %	25.00	75.00	50.00	150.00
Concentration of the well brine R=4.50 %				
For a bath on salinity	100 liters		200 liters	
	Water [l]	Brine [l]	Water [l]	Brine [l]
0.5 %	88.89	11.11	177.78	22.22
1.0 %	77.78	22.22	155.56	44.44
1.5 %	66.67	33.33	133.34	66.66
2.0 %	55.56	44.44	111.12	88.88
2.5 %	44.45	55.55	88.90	111.10
3.0 %	33.34	66.66	66.68	132.32

Concentration of the well brine R=5.00 %				
For a bath on salinity	100 liters		200 liters	
	Water [l]	Brine [l]	Water [l]	Brine [l]
0.5 %	90.00	10.00	180.00	20.00
1.0 %	80.00	20.00	160.00	40.00
1.5 %	70.00	30.00	140.00	60.00
2.0 %	60.00	40.00	120.00	80.00
2.5 %	50.00	50.00	100.00	100.00
3.0 %	40.00	60.00	80.00	120.00
Concentration of the well brine R=5.50 %				
For a bath on salinity	100 liters		200 liters	
	Water [l]	Brine [l]	Water [l]	Brine [l]
0.5 %	90.91	9.09	181.82	18.18
1.0 %	81.82	18.18	163.64	36.36
1.5 %	72.73	27.27	155.46	54.54
2.0 %	63.64	36.36	127.28	72.72
2.5 %	54.55	45.45	109.10	90.90
3.0 %	45.46	54.54	90.92	109.08
Concentration of the well brine R=6.00 %				
For a bath on salinity	100 liters		200 liters	
	Water [l]	Brine [l]	Water [l]	Brine [l]
0.5 %	91.67	8.33	183.34	16.66
1.0 %	83.34	16.66	166.68	33.32
1.5 %	75.01	24.99	150.02	49.98
2.0 %	66.68	33.32	133.36	66.64
2.5 %	58.35	41.65	116.70	83.30
3.0 %	50.02	49.98	100.04	99.96
Concentration of the well brine R=6.50 %				
For a bath on salinity	100 liters		200 liters	
	Water [l]	Brine [l]	Water [l]	Brine [l]
0.5 %	92.31	7.69	184.62	15.38
1.0 %	84.62	15.38	169.24	30.76
1.5 %	76.93	23.07	153.86	46.14
2.0 %	69.24	30.76	138.48	61.52
2.5 %	61.55	38.45	123.10	76.90
3.0 %	53.86	46.14	107.72	92.28

Concentration of the well brine R=7.00 %				
For a bath on salinity	100 liters		200 liters	
	Water [l]	Brine [l]	Water [l]	Brine [l]
0.5 %	92.86	7.14	185.72	14.28
1.0 %	85.72	14.28	171.44	28.56
1.5 %	78.58	21.42	157.16	42.84
2.0 %	71.44	28.56	142.88	57.12
2.5 %	64.30	35.70	128.60	71.40
3.0 %	57.16	42.84	114.32	85.68
Concentration of the well brine R=7.50 %				
For a bath on salinity	100 liters		200 liters	
	Water [l]	Brine [l]	Water [l]	Brine [l]
0.5 %	93.33	6.67	186.66	13.34
1.0 %	86.66	13.34	173.32	26.68
1.5 %	79.99	20.01	159.98	40.02
2.0 %	73.32	26.68	146.64	53.36
2.5 %	66.65	33.35	133.30	66.70
3.0 %	59.98	40.02	119.96	80.04
Concentration of the well brine R=8.00 %				
For a bath on salinity	100 liters		200 liters	
	Water [l]	Brine [l]	Water [l]	Brine [l]
0.5 %	93.75	6.25	187.50	12.50
1.0 %	87.50	12.50	175.00	25.00
1.5 %	81.25	18.75	162.50	37.50
2.0 %	75.00	25.00	150.00	50.00
2.5 %	68.75	31.25	137.50	62.50
3.0 %	62.50	37.50	100.00	100.00

The values calculated in the tables above result from the following formulas:

$$S=Z/R*V$$

$$W=(1-Z/R)*V$$

$$V=S+W$$

where:

R - percentage concentration of brine used for preparing the bath;

S - volume of brine used for preparing the bath;

W - volume of water used for preparing the bath;

Z - bath salinity.

V - bath volume.

8.3 Pearl bath – AIR option

WARNING!

Do not perform the pearl massage treatment if sulfur water is used for preparing the bath.

WARNING!

It is forbidden to use a bath with pearl massage for mud baths due to the blockage of the pearl air channels in the basin.

WARNING!

Do not use preparations applied in the form of coarse suspensions, sols or mixtures of grinded solids, as they may block the pearl air channels in the basin.

WARNING!

Do not use suspension forming additives for bathing e.g., liquid mud, milk, chocolate, beer or additives in the form of powders, as this may block the air channels of the pearl massage system.

The preparation of the pearl bath consists of mixing warm water with cold water in such proportions that the water temperature in the bathtub is from 20ºC to 37ºC.

First fill the clean basin with cold water (until the bottom of the tub is covered), next with hot water. Temperature of the resulting mix may be adjusted by adding cold water. The moment when the patient is positioned in the tub shall be considered a starting point of the bath.

On the control panel, set the treatment time and press the "ACTION" button.

The power of the pearl massage can be changed by pressing and holding the "DECREASE" button to reduce the intensity of the massage (reducing the number of bubbles) or "INCREASE" to increase.

After the set time has elapsed, the pearl bath switches off automatically.

Bath with pearl massage can be switched off at any time with the "ACTION" button.

During the massage, it is advisable to change the position of the body. After switching off the massage, stay in the water for a while. Leaving the bathtub should be done slowly. It is also recommended to rest after a bath.

In order to increase the effectiveness of the treatment process, you can use plant additives for bathing.

List of the bath add-in preparations:

Type of preparation	Dosing	Pharmacological effect	Typical indications
Arnica (Arnica Montana)	full bath (250 l) ~2-4 spoonfuls of the extract	Facilitates absorbtion, soothes pain	Wounds, hematoma's, subcutaneous forms of rheumatism, overstrain-related pain of limbs
Waleriana (Waleriana officinalis)	according to the producer of the extract	Calms down	Insomnia, hyperfunction of thyroid gland, restlessness.
Oak bark (Cortex quecus)	as per instructions provided by the extract manufacturer	Contains tannin, produces a contracting effect.	Soothing rashes, anal ulcers, burns, vulvitis, skin mycosis

Pine needles (Pinus silvestris)	full bath (250 l) ~ 150 g pine needle extract	It contains essential oils, among others turpentine, calming effect, stimulates secretion, deodorizes	Disturbances in nervous balance, discomfort associated with climacteric, hyperthyroidism, upper respiratory tract catarrh
"Flower" hay (grass seeds) (Semina graminis)	according to the producer of the extract	Contains essential oils, causes hyperemia, spasmolytic action	Soft tissue rheumatism, arthritis, chronic bronchitis, pyogenic inflammation
Sweet flag (Acorus calamus)	according to the producer of the extract	It contains essential oils, bitterness, tannins, turpentine, and has a strong anti-aging effect	Rickets, constitutional malformation, festering wounds
Chestnut (Aesculus hippocastanum)	according to the producer of the extract	High content of saponins, bitter substances and tannins, increases resistance of capillaries, prevents the formation of blood clots	Rheumatism of soft tissues and joints, neuralgia, itching, peripheral blood supply disorders
lavender (Lavendula officinalis)	bath full (250 l) ~ 1-2 tablespoons bath extract	Sedative, slightly irritating to the skin, deodorizing	Ailments associated with climacterium, neuromuscular dystonia
Tannin-tan bath (oak and pine bark)	according to the producer of the extract	It contains large amounts of tannins	Rheumatism of soft tissues, neuralgias, chronic skin diseases
Rosemary (Rozmarinus officinalis)	bath full (250 l) ~ 1-2 tablespoons of rosemary extract	It contains large amounts of essential oils, improves blood supply to the skin and pelvic organs	Spastic circulatory disorders, climacteric complaints, rheumatism of soft tissues, crushing
Sage (Salvia officinalis)	according to the producer of the extract	It contains essential oils, resins, bitterness, tannins	Itchy eczema of the anus
Horsetail (Equisetum arvense)	according to the producer of the extract	It contains silicic acid, oxalic acid, bitter substances, stimulates tissue proliferation	Eczema sipping, calf ulcers and other difficult to heal wounds, chronic myelitis

9 Maintenance

WARNING!

Immediately after emptying the basin, water may still leak out of the filling nozzle openings for another 1 minute under the influence of gravity. Do not prevent such leakage by tightening the valves as it is not caused by incomplete closing of the valves. Closing the valves "by force" causes faster wear and tear and can lead to failure of the filling system.

WARNING!

When leaving the device without supervision overnight or for an extended period of time, close the valves that supply the media to the bathtub to avoid accidental leakage of the pressurized water system.

9.1 Activities schedule

Activity	Frequency
Basin cleaning and disinfection	after each treatment
Blow-through channels (AIR option)	each time after the treatment and after each emptying the basin from the water
Disinfection of the bathtub water system	daily, after the last treatment or once a week*
Checking the bathtub step surface condition	periodically, once a day, as described in the warning in section 9
Checking the condition of the ventilation system in the room where the balneological are carried out	periodically, at least once a week
Functionality check of the residual current device (RCD)	periodically, in a manner and frequency specified in the technical documentation of the disconnect switch
Descaling	periodically, not less than once every 3 months
Electrical safety testing (option: AIR, CHROMO)	once a year and each time after a failure or repair

* depending on the number of treatments

9.2 Cleaning the basin after use

WARNING!

It is recommended to drain the bathtub immediately after each bath session. Avoid leaving the basin filled with water for long periods of time after treatment, as this will make it more difficult to remove contaminants after emptying the basin.

Each time after completing the procedure, the basin should be emptied of the water used for the treatment, cleaned and the water drain should be cleared from any contaminants.

Avoid leaving the basin filled with water for a longer time after the treatment, as it will make it difficult to remove contamination after emptying the bathtub.

The best method for everyday care is cleaning the basin and its fittings with the use of damp cloth with addition of the soap. The cleaned surface should then be rinsed with water and cleaned dry with a soft cloth. Such procedure prevents buildup of scale. Never clean the bathtub with a coarse sponge or use preparations containing abrasives as this may lead to dulling or scratching of the cleaned surface. To rinse the tub, use the shower head (pos. I fig. 1-2) located at the top of the basin.

9.3 Disinfection of the basin after use

WARNING!

The damages resulting from the use of improper disinfection or surface care preparation are not covered by the manufacturer's warranty .

WARNING!

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

After having cleaned the drain and cleaning the bathtub it is necessary to disinfect the basin by using a soft sponge or cloth soaked in disinfectant, suitable for use on acrylic and gelcoated surfaces. For this purpose, preparation e.g. Septer, Cleanisept, Incidin Foam, San Clear Med (available from Meden – Inmed) can 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. It is important to ensure that agents and tools that could scratch or damage the surface of the basin are not used.

When disinfection is complete, use the shower head (pos.I fig.1-2) to rinse the remnants of the disinfection preparation from the basin then start the air channels blowing (AIR option) and then wipe the surfaces dry with a soft cloth. Do not clean the bathtub's basin and covers with highly aggressive cleaning agents as this may tarnish or damage the surface.

9.4 Disinfection of the water system – AIR option

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 pearl bath (AIR option).

Periodic disinfection of the devices water system should be carried out with special preparations available under the trade names TOP or FORTE, SEPTER, Whirlpool Disinfection. Other preparations for this purpose that are intended for disinfection of the water system of hydromassage bathtubs 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 up the basin with water to the treatment level (all channels must be covered) and add disinfectant to obtain the right concentration of preparation (follow the instructions of the manufacturer) and turn on the „MASSAGE" mode for 3 minutes and then leave the device filled with the disinfectant solution for the period of time indicated in the instructions for the disinfectant.

When disinfection is complete, drain the water, next fill basin with clean water up to the treatment level, turn on one massage cycle with a duration of 10 minutes to flush the device water system. After flushing is complete, empty the bathtub and rinse it with shower head (pos.I, fig.1-2). At the end, wipe the surfaces dry with a soft cloth.

9.5 Descaling of the water system – AIR option

WARNING!

Depending on the hardness of water used for the baths as well as the intensity of the device operation, the descaling procedure should be performed not less than once every 3 months. Too high build-up of mineral sediment on the channels may reduce the pearl bath effectiveness.

Descaling is meant to prevent settling of sediments formed by impurities and chemical compounds precipitating from water as sediments obstructing the blower operation, reduced effectiveness of the treatment and – in effect – shorten the fault-free operation time of the device. Descaling may be performed with the use of descaling preparation KAMIX (available from Meden-Inmed) by following the manufacturer's operating instructions of the preparation.

The bathtub should be filled with water to the treatment level. After that an appropriate amount of descaling preparation should be added and left for the time as provided in the preparation instructions for use. After the descaling is completed, thoroughly clean the basin and rinse it with shower head (pos.I, fig.1-2). At the end wipe the surfaces dry with a soft cloth.

10 Conditions of maintenance

WARNING!

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

10.1 Periodic electrical safety testing – AIR, CHROMO options

WARNING!

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

Periodic electrical safety tests should be carried out by qualified service personnel.

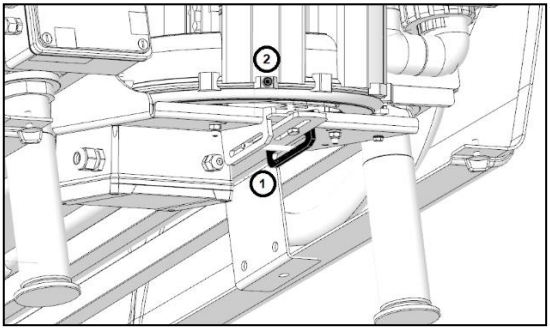
Perform a visual inspection and measurements according to the requirements of the current version of EN 62353. Ensure that the connection to the mains supply is established by a permanent connection that can be disconnected only with a tool (must meet the requirements for "permanently installed" device according to EN 62353).

Check regularly correct functioning of the residual current device (RCD) in the device's power supply circuit as specified in the schedule of activities in section 9.1 above.

Periodic electrical safety test is required after any failure or repair of the BALMED bathtub as specified in the schedule of activities in section 9.1 above.

Leakage current should be measured with the massage and lighting options turned on (if this feature is present in your model).

The type of performed measurements and acceptable limits defines a table below.

Measurement	Limit
Protective earth resistance: 1 – bathtub support frame 2 – blower motor case  Figure 11 - View of measuring points in the BALMED ECO, STANDARD 300 l bathtub If necessary, remove the layer of varnish, oxides, dirt, etc., that covers the subassembly.	300 mΩ
Touch leakage current from accessible conductive parts	100µA
Patient' s leakage current WARNING: Do not mistake with the applied part leakage current due to an external voltage on the applied part, which is not applicable in this case 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.

10.2 Responsibility of the manufacturer

The expected period of use is 7 years.

After 7 years from the date of manufacture of the device (and its accessories), the manufacturer shall assume no responsibility either for the faults of the device and its accessories or for any consequences that may have arisen from such faults. The manufacturer shall assume no responsibility for any consequences from which the user or patient may suffer, if such consequences result e.g. from improper installation, improper use of the device and/or its accessories, wrong interpretation of or not observing the manufacturer's instructions for use or from repairs performed by unauthorized persons.

10.3 Troubleshooting

Symptom of malfunction	Possible cause – Solution
No message in the display (option: AIR and CHROMO) or the illumination does not turn on after pressing the button	Check the condition of the: - an overcurrent circuit breaker, - residual current device, - main power cut-out switch of the device Check the power supply cable of the device. Switch the power off and contact the service.
After emptying the basin, some water remains in the bathtub	Level the bathtub foundation
Water spills under the bathtub during draining	The drain does not "keep up" with the collection of water - clean the outflow
Unpleasant odour is emitted from the bathtub	Regularly apply the disinfection procedure
Water is leaking from the shower head connection	Check the sealing - replace, when necessary, tighten the connection

10.4 Service contact

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

If you buy the device with an intermediary, please kindly provide information about the serial number and location of the device. These data will be placed in our service base, which will allow us to efficiently implement the terms of the warranty and service.

11 Electromagnetic compatibility – applies to AIR, CHROMO options

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.

Essential performance - the documentation of the risk management process shows the lack of essential performance characteristics for this product.

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.

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 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % UT; 250/300 cycles (50/60Hz)	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % UT; 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.
WARNING! UT is the AC 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 for the bathtub supplied and a 12-month warranty for the pearl bath blower. The warranty period runs from the date of sale shown in the sales document.
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 device.
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 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.

BALMED	ECO		STANDARD		Date, signature and stamp of the Warrantor:
SN			-		

Repair registry	User's notes
Electrical safety check	Date and signature of a person performing the check
Report No.	
Result of the check:	
Next check to be performed within 12 months	