GLOBUS

ITALIAN EXCELLENCE

ULTRASOUND THERAPY

User Manual

MEDISOUND 3000

CE
0476

DEAR CUSTOMER

THANK YOU FOR CHOOSING A GLOBUS PRODUCT. WE REMAIN AT YOUR ENTIRE DISPOSAL FOR ANY ASSISTENCE OR ADVICE YOU MAY NEED

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TECHNICAL FEATURES

Device

Case:	ABS food grade
Protection level of the case:	IP 20
Dimensions:	170x220x60
Weight: about 1000 g.	
Certifications	CE MDD certificate

Transducer

Transducer:	Head Ø 4.2 cm.
Transducer emission:	continuous, pulsed.
Emission frequency:	1- 3 MHz
Duty Cycle:	10%-100%
Maximum power:	3 W/cm^2 (± 20%)
Protection level of the handpiece:	IP 67

Power supply

XP Power
Type AC/DC
Model: AFM60US18C2
PRI: 100-240Vac 1.5A 50-60Hz
SEC: 18Vdc 3.34A

Battery (optional)

Battery pack:	Ni-MH 12V 4Ah

Use and storage conditions

Temperature:	from 0°C to 35°C
Max. relative humidity:	from 15% to 93%
Atmospheric pressure:	from 700 hPa to 1060 hPa
Storage and transportation temperature:	from -10°C to 45°C
Max. relative humidity:	from 30% to 75%

INTENDED USE OF THE DEVICE

Medisound 3000 is not intended for domestic use, and it has been conceived to be used in the following operating environments:

- clinics;
- physiotherapy centers;
- rehabilitation in general;
- general pain treatments (medical sector).

The use of the device is permitted only to qualified personnel (doctors and physiotherapists).

DEVICE CLASSIFICATION

The device has been manufactured in compliance with applicable technical standards, and it has been certified in compliance with Directive 93/42/EEC as amended by directive 2007/47/CE on medical devices, by the Notified Body Kiwa Cermet Italia, Via Cadriano 23, 40057 Granarolo Dell'Emilia (BO) Italy (n° 0476), in order to ensure product safety.

Medisound 3000 is classified as:

- Class IIa device (Directive 93/42/EEC, Annex IX, rule 9, as amended).
- Class II with BF type applied part (Classif. CEI EN 60601-1);
- device with casing not protected against the penetration of water;
- device and accessories not subject to sterilization;
- device not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide;
- device for continuous operation;
- device not suitable for outdoor use.

SAFETY PRECAUTIONS

To ensure maximum safety, the device must be used respecting the rules and the limitations indicated by the user manual.

The manufacturer declines all responsibility for all use differing from what is indicated in this manual.

The full or partial reproduction in any form and by any electronic or mechanical means of the texts and/or pictures contained in this manual without the written authorization of the manufacturer is forbidden.

If the package, the cable or the connector of the power supply show signs of wear or damage, replace it instantly.

The device should be connected to the mains with its power supply; before doing so, make sure that the power system complies with the directives in force in your country. Make sure that the power supply will be easily unplugged.

It is strictly forbidden to modify the device.

Warnings before the use

We advise against the use of the device in conjunction with other electronic devices, especially with those used to maintain vital functions, make reference to the tables attached, for a correct use of the electromedical device. If you have to use the device near or upon other devices, pay attention to how it is working.

Read carefully the entire operating manual before using the device; keep this manual with care.

The unit must be used only with the diffusers provided with the original equipment (or Globus brand) and according to the therapeutic methods described.

Before every use, always check the integrity of the device. This is a fundamental requirement for carrying out the therapy; do not use the device if the buttons or the cables are defective or malfunctioning.

The device:

- as you turn the device on, make sure that the software version and the model of the device appear on the screen, which means that the device is working and ready to be used.

If it does not show that information or it does not show all the segments, turn it off and on again. If the problem persists, contact the service center and do not use the device.

- Shutdown right after turning on indicates that the battery is low. Recharge as indicated in the section HOW TO CHARGE THE BATTERIES (if Medisound 3000 works with the rechargeable battery pack purchased as an optional accessory).

Warnings during the use

Medisound 3000 has been designed for a continuous use.

If the cables are damaged, replace them with original spare parts and do not use them anymore.

The device must be kept out of the reach of pets that may damage it and contaminate it with parasites.

The cable of the diffuser and of the power supply must never be wound up around the neck to avoid all risk of strangulation and suffocation.

Mobile and fixed radio communication devices might affect the operation of the electromedical device: see the tables attached to this manual.

Side effects

With high power intensity, the ultrasound head in contact with the skin may reach temperatures above 41°C, which may redden or cause light burns to the skin. In these cases it is advisable to replace the gel often or do the therapy in immersion. If, at the end of the treatment, skin redness or light burns are observed, it is advisable to refresh the part with cold running water. If the problem persists, it is possible to treat the part with a medication by using medicated gauzes (with connectivine, fitostimoline), which accelerate the skin regeneration process, or use specific creams, available on the market, containing the same substances.

Isolated cases of skin irritation may occur in subjects with high skin sensitivity.

In case of allergic reaction to the gel, suspend the treatment and contact a specialist.

Contraindications

Do not use ultrasounds in the following cases:

- patients with cancer diseases, because ultrasound can favor the proliferation of tumor cells;
- on hematomas;
- conditions such as thrombophlebitis, in which the administration of ultrasounds can cause the rupture of emboli;
- areas affected by acute sepsis, because the infection can spread;
- radiotherapy produces the opposite effect on tissues, so ultrasound should not be used on areas exposed to radiations for at least six months after the last irradiation;
- osteoporosis, because ultrasound can promote decalcification. This is not an absolute contraindication, consult your physician;
- articulations with epiphysis during the bone growth phase.
- on the ocular area and near it;
- during pregnancy and menstrual periods in the abdominal and lumbar areas;
- near glands and the heart.

EQUIPMENT

- Carrying case
- Ultrasound gel (REF G0869)
- Power supply (REF 5216)
- Device
- Transducer (G5374)

The device comes fully equipped with ultrasound gel, transducer, carriage case, power supply. Opening the package, it is necessary to check that the basic equipment is complete. If some elements should be missing, contact immediately the authorized retailer where you purchased the product.
Control carefully the integrity of the device and its accessories.
All the supplied information can be modified without previous notice.
The device can be combined with some optional accessories (see the features on our website www.globuscorporation.com). To purchase these accessories, please contact your dealer.

Accessories not included:

- Ref. G1120 rechargeable battery (Ni-MH 12 V 4Ah)
- Ref. G5516 Handpiece 16 mm for Medisound 3000

DEVICE OPERATION

In order to start the device, the following elements must be connected. **Pay particular attention to avoid damage to the connections.**

Device

Power supply by electricity mains. Medisound 3000 works connected to the mains (the rechargeable battery is not supplied with the device but can be requested as an optional accessory). To connect the power supply to the connector, plug it as shown in the figure (see arrow below).

Handpiece

To connect the handpiece to the device, plug the connector in the intended inlet on the back of the unit (see picture). The part of the connector with the word Globus must be kept upwards.

Accessories (rechargeable battery)

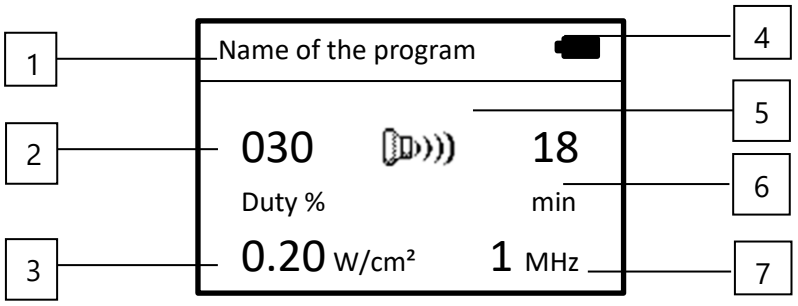
The device can be powered with a set of rechargeable nickel-metal hydride batteries (12Vdc 4000mAh) with high performances and without memory effect (the rechargeable batteries are optional).

It is advisable to recharge the batteries when the battery indicator on the display indicates ¼. Turn the device off and disconnect the diffuser, then connect it to the included power supply by inserting the plug in the appropriate inlet.

Do not use a power supply different from the one provided with the device. Contact the customer service to replace the battery pack.

DEVICE DESCRIPTION

The execution screen on the device display will be explained below.



1 - Indicates the name of the selected program

2 - Indicates the duty cycle used in the selected program

3 - Power in Watts per cm²

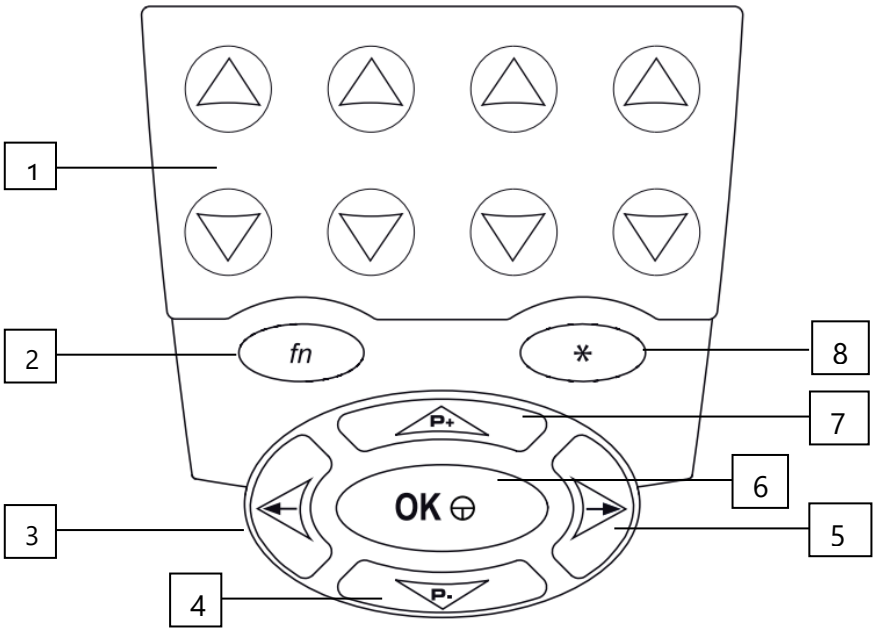
4 - Indicates the type of power supply used

5 - Indicates the status of the handpiece (in operation, paused, disconnected ...)

6 - Treatment duration

7 - Emission frequency

Keyboard



1- UP/DOWN buttons: to increase and decrease the power.

2- Fn button: changes the power display indicating the total power and not the power per cm²

3- ON/OFF/OK button: turn on, turn off, confirm treatment

4- * Time button: modification of the treatment duration

5- Left/Right button: to navigate/return to the main menu

6- P+/P- button: to select the menu, the area and the program

DEVICE USE

Automatic calibration of the handpieces

Each time the machine is switched on, it automatically carries out the head calibration procedure. Note: at start-up, the head must be clean, dry and free in the air (not in contact with any object or surface).

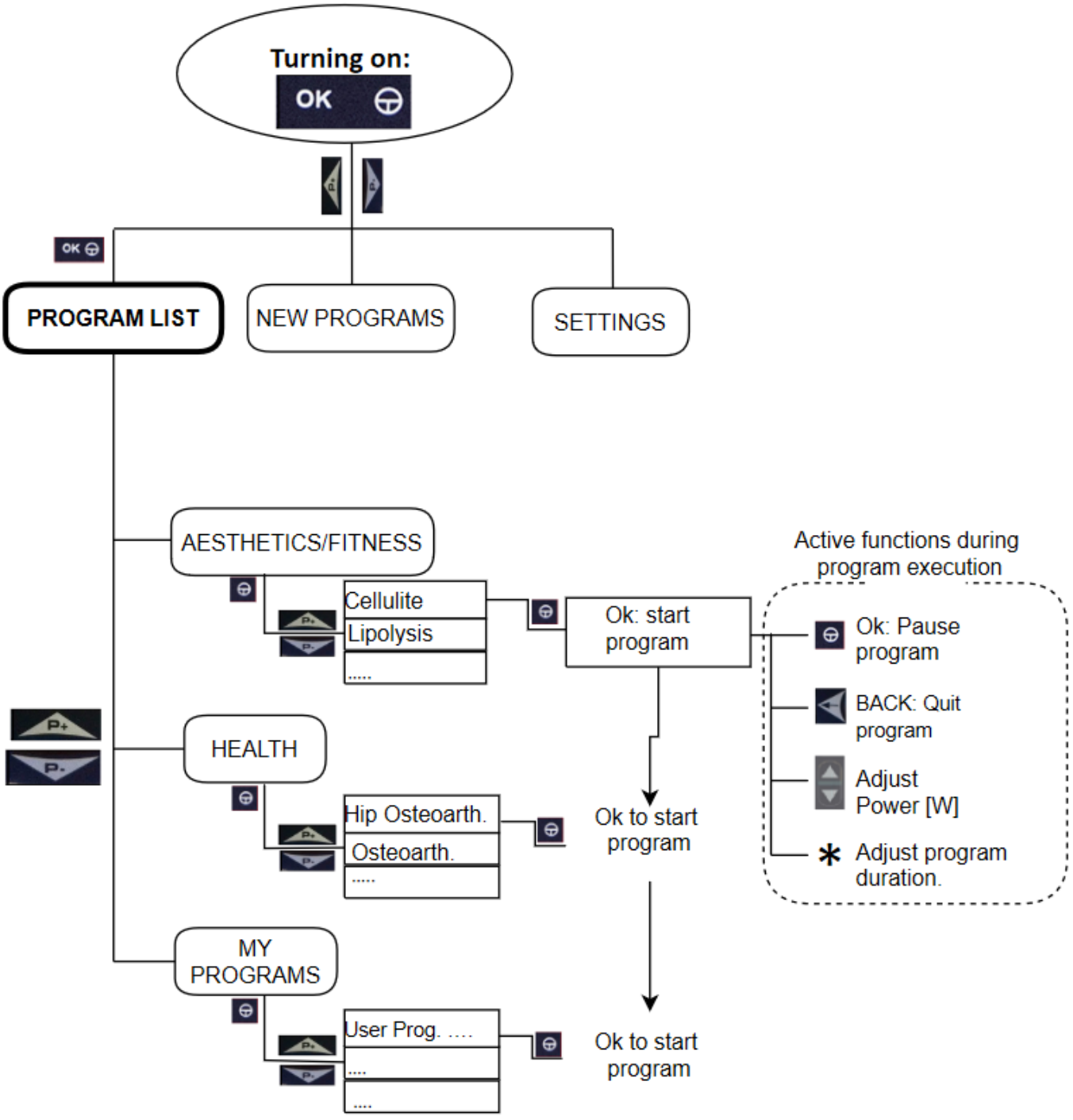
Turning the device on/off

Connect the device to the mains.

To turn on or off, press and hold the On/Off (OK) button until an acoustic signal is heard.

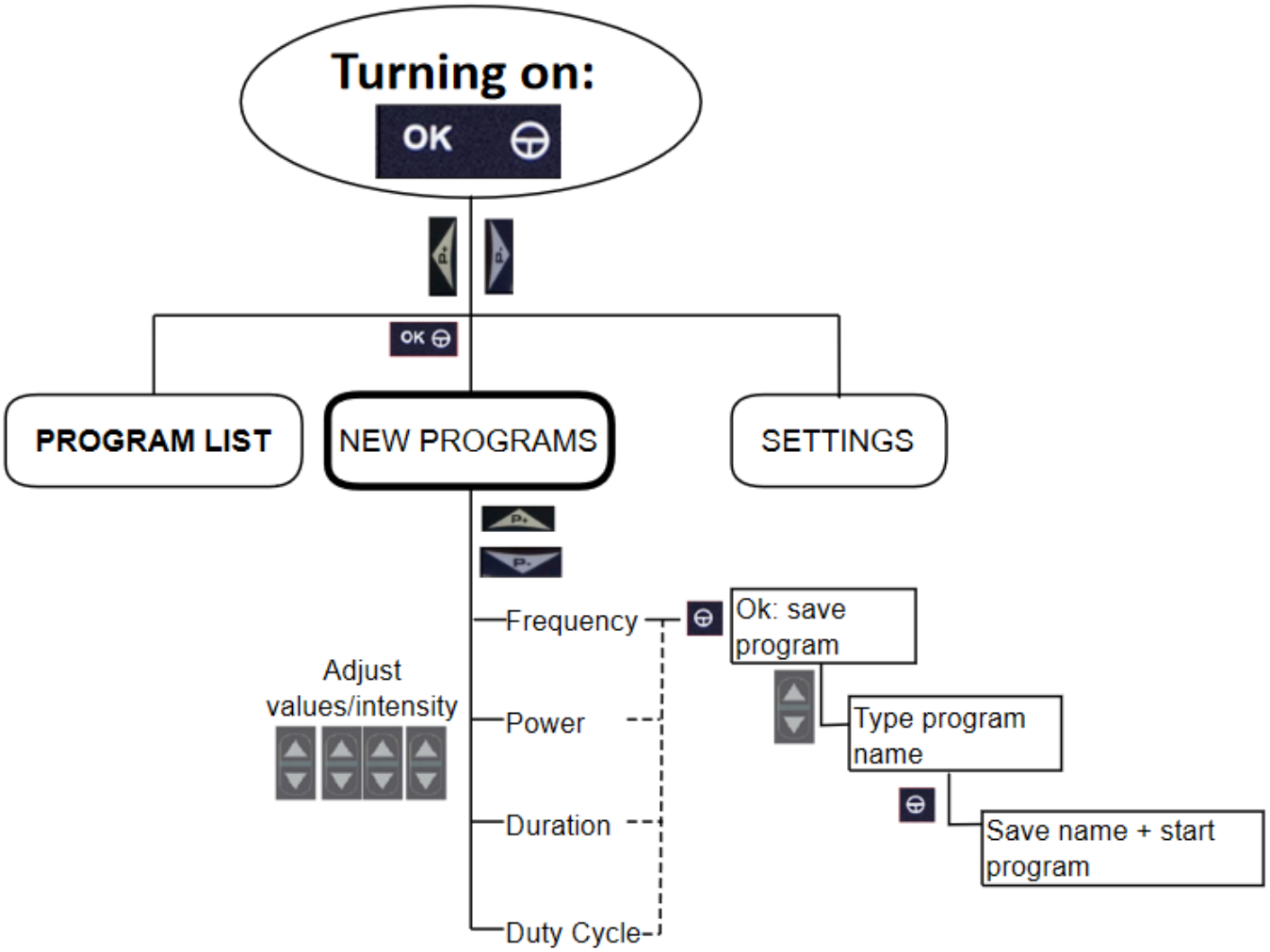
Choosing and starting an existing program

Follow the flow chart:



Creating a new program

Follow the flow chart:



Nota:

Note: BACK button to go back to the previous level

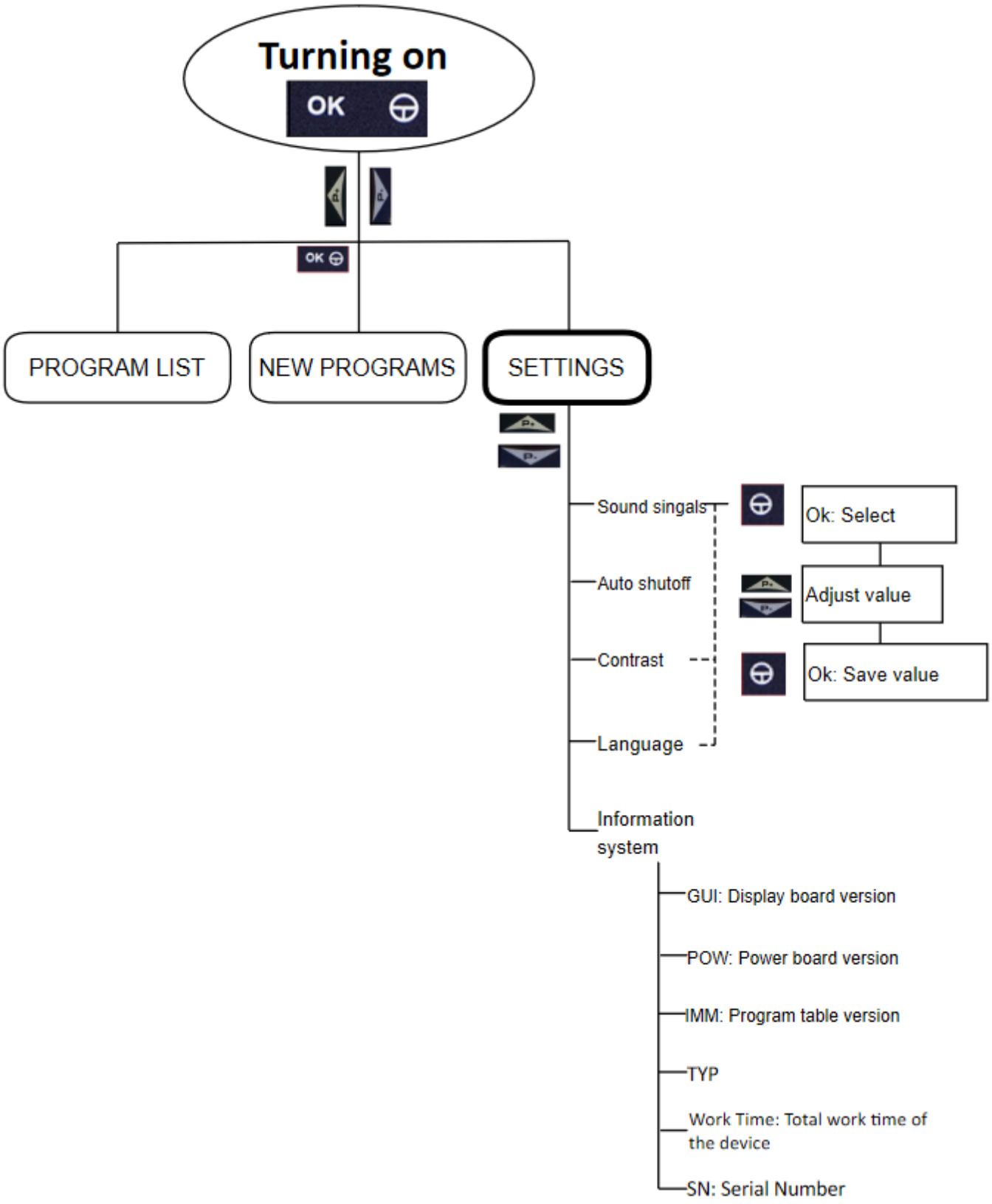
The saved programs will be stored in My Programs.
Press fn to delete a saved program.

Settings

By selecting Settings you access the menus to adjust the following functions:

- Acoustic signals
- Auto shut-off timer
- Contrast
- Language

Follow the flow chart:



Acoustic signals

If the acoustic signal function is on (ON) the device emits a tone when buttons are pressed.

Automatic shutdown

It allows to set the time after which, if not used, the machine switches off. It is possible to select a value between 1 and 20 minutes.

Use P+ and P- to select and confirm with the Ok button.

Contrast

Use the arrows to improve the contrast of the display and better read the information displayed.

Language

It is possible to select the interface language.

System information

It shows information about the hardware and software configuration of the device as well as the total time of use of the device.

PROGRAM LIST

List of the **Medical programs** contained in the HEALTH – REHAB area

Name of the program	Recommended power
Hip osteoarthritis	1 W/cm²
Knee osteoarthritis	1 W/cm²
Shoulder osteoarthritis	0.8 W/cm²
Spinal osteoarthritis	1 W/cm²
Ankle osteoarthritis	1 W/cm²
Osteoarthritis	1 W/cm²
Pseudoarthritis	1 W/cm²
Wrist Fracture	0.3 W/cm²
Fatigue Fracture of Tibia	0.2 W/cm²
Fracture	0.3 W/cm²
Carpal Tunnel	1 W/cm²
Epicondilytis	1.5 W/cm²
Back pain	1.2 W/cm²
Calcified shoulder tendinitis	1.5 W/cm²
Muscle Pain	0.5 W/cm²
Cervical Pain	1.5 W/cm²
Trapezius pain	1.2 W/cm²
Spinal stenosis	1.5 W/cm²

Because of the presence of clinical programs, this product is a medical device. Therefore, it is certified by the Kiwa Cermet Italia Body n. 0476 according to the 93/42/EEC EU directive for medical devices. The certification covers clinical applications.

List of **Aesthetic programs** (non-medical treatments)

Name of the program	**Recommended power**
Edematous cellulite	1 - 2 Watt/cm2
Fibrous cellulite	1 - 2 Watt/cm2
Lipolysis	1 - 2 Watt/cm2
Hypotonie	1 - 2 Watt/cm2
Stretch marks	1 - 2 Watt/cm2
Orange peel skin	1 - 2 Watt /cm2
Skin smoothing	1 - 2 Watt/cm2
Arms lymphatic drainage	1 - 1.5 Watt/cm2
Massage	1 - 1.5 Watt/cm2
Skin restructure	0.5 - 1 Watt/cm2
Face lifting	0.5 - 1 Watt/cm2
Photoaging treatment	0.5 - 1 Watt/cm2
Abdomen relaxation	1 - 2 Watt/cm2
Abdomen adiposity	1 - 2 Watt/cm2
Flabby thighs	1 - 2 Watt/cm2
Thigh/hip drainage	1 - 2 Watt/cm2
Thigh/hip massage	1 - 2 Watt/cm2
Gluteus/hips adiposity	1 - 2 Watt/cm2
Relaxation	0.5 - 1 Watt/cm2
Arm lymphatic drainage	0.5 - 1 Watt/cm2
Breast stretch marks	0.5 - 1 Watt/cm2
Breast relaxation	0.5 - 1 Watt/cm2
Wrinkle treatment	0.5 - 1 Watt/cm2
Scar treatment	0.5 - 1 Watt/cm2
Rosacea	0.5 - 1 Watt/cm2
Telangiectasias	0.5 - 1 Watt/cm2
Body pimples	0.5 - 1 Watt/cm2
Face pimples	0.5 - 1 Watt/cm2
Face acne	0.5 - 1 Watt/cm2
Keloid treatment	0.5 - 1 Watt/cm2
Active principle application	0.5 - 1 Watt/cm2

CE0476 does not refer to non-medical treatments.

MAINTENANCE AND CLEANING

Maintenance and cleaning of the device

In case of actual or alleged malfunctioning, do not tamper with the device do not try to repair it by yourself.

Do not try to repair the device and do not open it. Only specialized and authorized centers can repair it.

Avoid violent impacts, which may damage the device and lead to malfunctioning even if not immediately detectable.

Use this device in a dry, open-space environment (not wrapped in any materials).

Clean the device and the accessories only with disinfectant with sodium hypochlorite or quaternary ammonium salt (percentage: 0.2-0.3%) diluted with distilled water. After cleaning/disinfecting the device and its accessories, dry them perfectly with a clean cloth.

Always use the device and the accessories with clean hands.

It is recommended to use the device and the accessories in a clean environment to avoid contamination with dust and dirt.

It is recommended to use the device in a ventilated, well-aired space.

The parts should be cleaned/disinfected after every use, unless otherwise indicated.

After cleaning and/or disinfecting the head of the device and after each treatment, ensure that the head has no cracks or fissures whereby the conductive liquid may leak.

If the treatment head has cracks or fissures, replace it immediately.

Handle the treatment head with care. Inaccurate handling can modify its features.

The maintenance of the device should be made every 24 months. Contact the manufacturer for information about the maintenance process.

Usable life of the device

The product has an estimated usable life of 5 years. It is advisable to return the device to the producer or an authorized center to perform security and maintenance checks every two years.

The device can be used continuously when connected to the mains. The numbers of treatments depends on the battery charge. The estimated duration of the battery is of 6 months. Thereafter, it is advisable to replace it.

Disposal of the device

Do not throw the device or parts of it into the fire; dispose of the product in the specialized centers and respecting the regulations in force in your country. When the product has to be disposed of, the user can give it back to the retailer when purchasing a new device.

Correct waste separation or following the above-mentioned procedure contribute to avoiding possible negative effects on environment and health and promote the reuse and/or recycle of the materials that compose the device. The illegal disposal of the product entails the application of administrative fines in accordance with applicable regulations.

APPLICATION METHOD

Specific health applications

The therapeutic effects of ultrasound are partly due to the increase in temperature. They include analgesia, the fibrolytic effect and the trophic effect.

a) Analgesia

The analgesic effect is due to the heat and probably also to a direct action of the ultrasound on the sensitive nervous terminations.

b) Fibrolytic action

The oscillations of tissue particles produced by ultrasound determine the disruption of the collagen fibers of the fibrous tissues.

c) Trophic effect

Vasodilation, induced by temperature increase, facilitates the removal of catabolites and supplies the tissues with nutritive substances and oxygen; thus, ultrasounds improve the tissue trophism, facilitate the repair of the damaged tissues and accelerate the resolution of the inflammatory processes.

FITNESS and BEAUTY specific applications

- Applications for the absorption of active substances on the face and the body. The program is used for the application of cosmetic agents.

Ultrasound facilitates the absorption of oils, fat-soluble vitamins, products with liposome, emulsions and water-soluble agents.

The effect is to increase the permeability of the cells, decrease the skin functional barrier and increase the active ingredient channel activity.

- Treatment for surface wrinkles and sensitive skins.

The treatment is used to flatten-smooth wrinkles (expression wrinkles). Ultrasound, thanks to its thermal effects, warms the tissues and promotes the biochemical and metabolic processes.

- Treatment for acne, pimples on face and body.

In addition to an anti-inflammatory effect, the ultrasound activates the fibroblasts, which have an important role in the process of post-inflammatory regeneration. The collagen and elastic fibers produced after the ultrasound treatment, increase tissue elasticity, reducing the possible formation of post-acne scars. It is also possible to facilitate the absorption of anti-acne products and increase their effectiveness.

- Anti-cellulite treatments.

Ideal for cellulite problems. The thermal effect entails the mobilization of fat on the treated area. This way, fat metabolism and removal are enhanced.

Ultrasound action mechanism

Mechanical effects: the mechanical action is induced by the particle movement in the tissues crossed by the ultrasonic wave.

Although the movement of the single particles is small, the pressure variations that it produces are

considerable and generate important mechanical effects inside the tissues.
The mechanical modifications induced by ultrasounds determine:
a) Acceleration of the processes of diffusion through cellular membranes.
b) Scission of complex molecules (proteins, polysaccharides, etc).
c) Tissue micromassage
Thermal effects: the passage of ultrasounds through "the soft" tissues creates an increase in temperature with:
- the absorption linked to viscosity,
- the absorption induced by thermal conductivity and chemical absorption.
Ultrasounds produce heat through the vibrations, the collision and the friction of the cellular and intercellular structures that compose the tissues crossed by the sound waves. The thermal increase generates, as secondary effects, an increase in the cellular metabolism and the vasodilatation.
Chemical effects: the chemical action, with the modification of the local ph and of the permeability of cellular membranes and with molecular changes, is caused by the remarkable accelerating forces to which tissue particles are subjected at the passage of the ultrasonic wave.

The therapy with ultrasound can be carried out in two different modes: direct contact, with mobile head, and immersion.

Direct contact method

The direct contact mode consists in putting the emitting head in direct contact with the skin and interposing a substance (usually a special conductive gel) which favors the transmission between the head and the skin, the adherence and sliding and the elimination of possible air between the skin and the transducer, as the air, due to its reflecting capacity, would hinder the transmission of the ultrasonic wave.

Immersion method

It is useful when the surfaces to be treated are too small or irregular or when the area is so painful as to prevent direct contact. The part to be treated is immersed in a container with water together with the emitting head, placed at a maximum distance of 2-3 cm from the body surface to avoid an excessive dispersion of the ultrasonic beam with a decrease in therapeutic efficacy.
The water temperature has to be about 37°. The lower the water temperature, the greater the cutaneous heat loss and the lower the therapeutic effect.
The head can be moved in concentric circles holding the head surface parallel to the skin surface to reduce the refraction as much as possible. Common tap water has the problem that gas bubbles dissociate themselves from the water, they accumulate on the patient skin and on the treatment head, reflecting the ultrasound wave. If it is not possible to avoid the use of common water, it is necessary to frequently remove the gas bubbles from the surface and clean up the emission area of the head at the end of the treatment.

In a treatment with non-degassed water, the lowering of the ultrasound power is greater than in the direct contact treatment, so a higher dosage is required. When you use gas-free water, instead, the dosage has to be the same as in the contact treatment.

Recommended intensity

The device starts from a preset intensity of 0.0 Watt/cm2 and can reach a maximum power that depends on each protocol. The intensity shown in this manual is the one we suggest for this product line and is used in most of the known protocols. The physiotherapist is free to use the maximum recommended power or to adjust it according to the type of patient to treat.

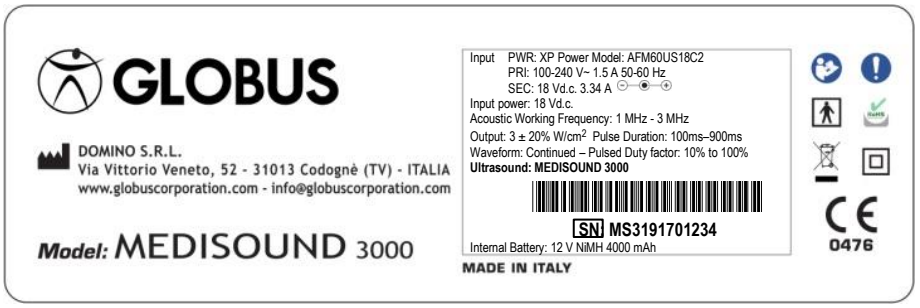
SYMBOLS AND LABELING

Annex 1: symbols and labeling on the device

	Warning
	This symbol on your device indicates that it complies with the directives on medical devices (93/42/CEE 47/2007CEE). The number of the notified unit is 0476.
	It indicates that this is a class II device.
	It indicates that this device has BF-type applied parts.
	WEEE symbol (Waste of Electrical and Electronic Equipment). Recycling symbol. The WEEE symbol used for this product indicates that the product cannot be treated as a household waste. The proper disposal of the product will contribute to protecting the environment. For further information on the recycling of this product, please contact the concerned office of your local body, the household waste management company or the store where the product was purchased.
	It indicates that the product has been produced in compliance with the directive 2011/65/EEC.
	It indicates the recommended temperature for the storage and transportation of the product.
	It informs the operator that s/he must read the manual before using the device.
	It informs the operator about a general compulsory behavior.
	It indicates the manufacturer.
	Alarms disabled.

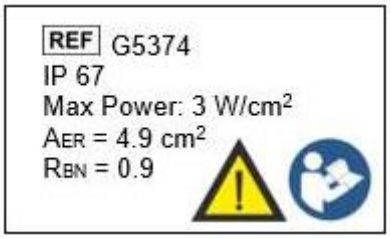
SN	It indicates the serial number of the device.
	Ionizing emissions
	It informs that the outputs of the device are sensitive to electrostatic discharges
IP	It indicates the protection against the ingress of water and dust.
PRI	Mains voltage
SEC	Power supply voltage
	It indicates the pressure of the environment in which the device and the accessories are transported and stored.
	It indicates the humidity of the environment where the device and its accessories are stored and transported
A_{ER}	Effective radiating area
R_{BN}	Beam nonuniformity ratio

Device



SN The first 4 digits of the serial number indicate the week and year of manufacture of the device you purchased (for example, if the code is *** 2319 *****, it means that the device was manufactured in week 23 of 2019).

Ultrasound head



SOUND AND LIGHT SIGNALS AND ALARMS

Annex 2: the sound signals comply with directive 60601-1-8 (CE MDD Certifications).

	Correct power emission	The treatment is carried out correctly
	Cable not connected	Check that the cable is connected to the right output
	Device in pause	Press OK to continue the treatment.
	No contact	Check that the gel is on the hand of the handpiece
	No contact disabled	It indicates that the contact control has been disabled
	On/off indicator	It turns on when the device is connected to the power supply and stays on during the emission
	PAUSE indicator (during the treatment)	It lights up when the emission is paused (also in the presence of a "hot" alarm)
	General error indicator	It lights up when the handpiece or the machine overheat.
	Power indicator	The LEDs light up progressively, increasing the power of the device

Cable not connected

If the non-connected cable symbol appears, verify that the device, the cables and the diffuser are intact and correctly used.

If the problem persists, please contact the customer care.

Contact control (no contact)

Hold the "fn" button down for about 3 seconds to disable the contact control (the symbol appears on the top-right of the screen) until the end of the ongoing treatment. To re-enable the control, press and hold the "fn" button again.

Overheating alarm (hot)

Red led on + "hot" text appearing + 3-sec. beep. It means that there is an overheating problem or the head or the device. The device pauses automatically and the orange led lights up.

Solution to head overheating

Add gel on the head or plunge it in the water to cool it down. When the red led turns off, it is possible to continue the treatment by pressing the OK button.

Solution to device overheating

Check that the fans turn on automatically and wait for the red led to turn off. It is possible to continue the treatment by pressing the OK button.

If, after trying both solutions, the red led has not turned off, switch the device off and wait a few minutes. Turn the device on.

Is the red led still on?
NO. The problem has been solved. Use the device as usual.
YES. Contact the service center.

WARRANTY CONDITIONS

The device is guaranteed to the first user for 12 months from the purchase date against defects in materials or manufacturing, provided that it is used properly and kept in normal conditions of efficiency.
Warranty coverage is limited in the following cases:
- six (6) months for included accessories subject to wear, e.g. power supplies, handpieces, cables.

In order to take advantage of the warranty service, the user must comply with the following warranty clauses:
1. The products have to be sent for repairs by and at the expenses of the Customer in their original packages and with their full original equipment.
2. The warranty of the product is subject to the exhibition of a fiscal document (sales receipt, receipt or sales invoice), that attests the purchase date of the product.
3. The repair work shall have no effect on the original expiry date of the warranty and shall neither renew nor extend it.
4. If no defects are found, during the repair work, the costs related to inspection times shall in any case be charged.
5. The warranty becomes void if the damage is caused by: impacts, falls, erroneous or improper use of the product, use of non-original external charger/power supply, accidental events, alteration, replacement/detachment of the warranty seals and/or tampering with the product. Moreover, the warranty does not cover damages caused during transportation due to unsuitable packages (see point 1).
6. The warranty does not cover the inability to use the product, other incidental or consequential costs or other expenses incurred by the purchaser.

N.B. Before returning the device for repairs, we suggest reading carefully the user manual and consulting the Globus website.
If you have to return the product for repair, please contact your dealer or the Globus customer service.

EMC accompanying documents

"WARNING: The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this equipment may
lead to increased electromagnetic emissions or a decrease in the electromagnetic immunity level of this device, resulting in incorrect operation. "

NOTE: The EMISSION characteristics of this device make it suitable for use in industrial and hospital environments (class A of CISPR 11).

If used in residential environments (for which class B of CISPR 11 is normally required) this equipment may not offer adequate protection for radio frequency communication services.

The user may need to apply disturbance mitigation measures, such as the relocation or reorientation of the device.

Essential performance

PERFORMANCE	CONDITION	RISK	ACCEPTED EVENT
Ultrasound energy emission.	External disturbance (Burst).	Display information no longer readable.	The machine must stop the stimulation.
			The machine must maintain the stimulation and accept the commands.
	Lack of internal power supply.	Interruption of the treatment.	The machine must signal the battery exhaustion and the interruption of the treatment.
	Lack of external power supply.	Interruption of the treatment.	The machine must continue the treatment, signaling that operation is carried out in battery mode.
	Detachment of an electrode.	Unpleasant stimulation or painful electric shock in case of reconnection of the electrode.	The machine must monitor the current constantly on each channel set beyond 9mA. In case the detected current is below a certain threshold, the machine must rest the current of the channel.
	Failure to detect microcurrent cable.	Dangerous stimulation.	The machine must report an error relating to the electrodes and prevent the program from starting.
	Too intense current setting in the case of microcurrents.	Dangerous stimulation.	The machine must downgrade the voltage boost stage to prevent the supply of current beyond the maximum value.
			The machine must not start the microcurrent treatment if it does not detect the hardware downgrading of the voltage boost converter stage.
Loading of the programs from the memory.	Error in the data from the memory.	Execution of an incorrect program.	The machine must check the correctness of the data of the programs. If an error is detected, the device must remove the program from the program list.

Loading machine settings.	Setting data memory error.	Impaired operation.	The machine must check the correctness of the setting data and, in the event of errors, it must load the default settings present in copy in the memory and indicate on the display that the reset has been carried out.
		Unreadable display.	The machine must check the value of the contrast setting. If it is out of range, the machine must reset the value to the default one.
Battery charge.	Battery overheating.	Damaging of the device, display information no longer readable, explosion, fire.	The device must monitor the temperature of the battery, if a certain threshold is exceeded, the battery charging must be interrupted.

In compliance with:

EN 60601-1: 2006 + A1: 2013
EN 60601-1-2: 2015
EN 60601-2-10: 2015

Warning: radiofrequency communication devices (including accessories like antennas or antenna cables) must be used at least 3 meters away from every part (including cables and accessories) of the device. Otherwise the performance of the device may be affected.

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