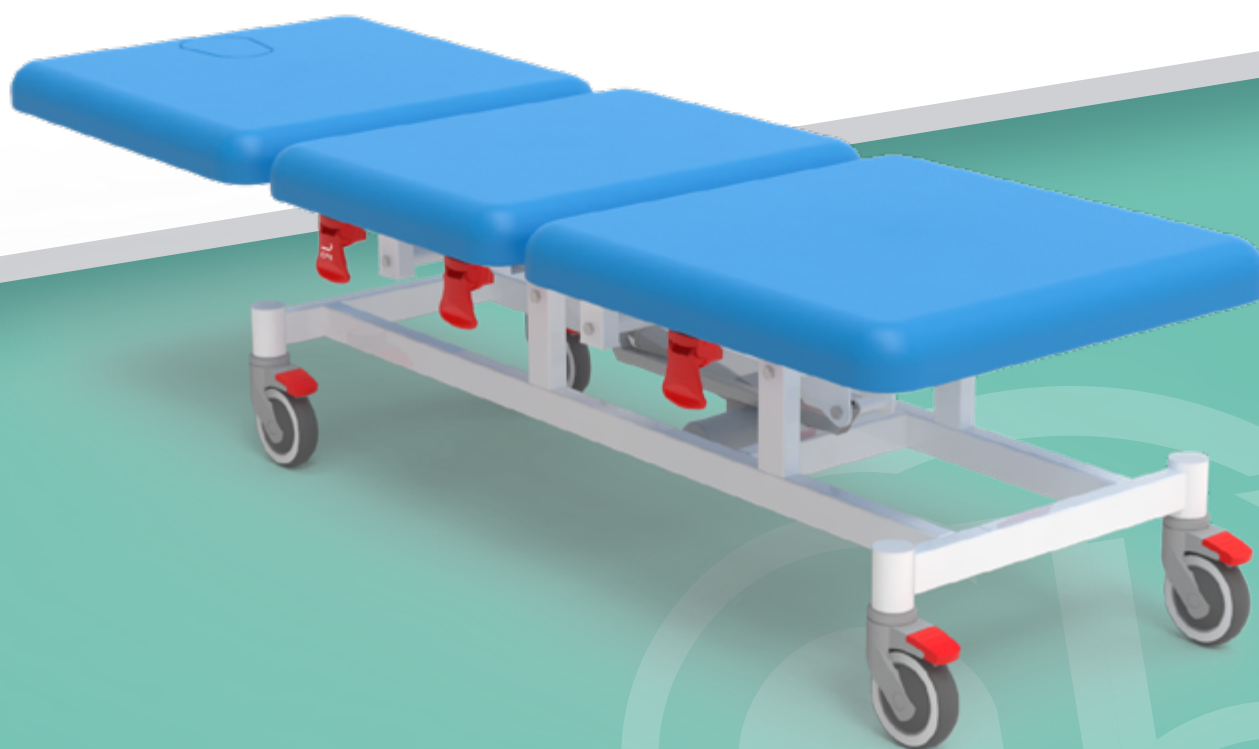




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MANUAL STRUCTURE

Generality

The rights of translation, electronic storage, reproduction and total or partial adaptation by any means (including microfilm and photocopies) are reserved for all countries. This user manual has been written to provide instructions on the correct functioning of the device in all its parts, including compatible accessories. If discrepancies are found, it is possible to report them to one of the addresses indicated in the document.

After consulting this document, the end user will be able to:

- take the precautions to use the device in safe conditions;
- effectively use all the functions of the device.

The user manual consists of the following dedicated sections:

- **Structure of the manual:** information on the structure of the manual.
- **Normative requirements:** list of regulations applicable to the device.
- **Method of transport and installation:** describes the suitable methods of transporting the device and the correct installation procedure.
- **Device description:** contains information about: the type of device, the intended use, the life cycle and operation, functionality, instructions for use, information about safety and performance and finally the procedures for training in use .
- **Usage:** describes the activities for the correct functioning of the device.
- **Compatible accessories:** indicates the accessories available for the device and provides the list of incompatibilities connected to it.
- **Scale display operation (if provided):** describes the correct functioning of the scale display in all its parts.
- **Device malfunctions:** describes the problems encountered when using the device and proposes any solutions.
- **Maintenance and assistance:** the ordinary maintenance procedures necessary to keep the device in perfect working order are described. The contacts of the technical assistance service are also indicated. The detailed list of the most frequent faults and the relative necessary remedial actions is shown in the service manual as these actions must necessarily be carried out by competent and adequately trained personnel.
- **End of life and disposal:** the methods of disposal and end of life of the device and the references to the RoHS directive are described.
- **Contacts and certifications:** company contacts and certifications are reported.

The user is advised to scrupulously follow the instructions contained in this manual, especially those concerning the safety standards and routine maintenance operations. By user we mean qualified personnel. The correct and safe

The functioning of this appliance depends on its use, installation (carried out by specialized personnel), operation and maintenance.

Consulting the manual

This manual accompanies the device of which it is an integral part. The indications contained therein are addressed to the user of the equipment, who will find in these pages the suggestions for correct use in safe conditions. Current legislation requires the owner of the equipment to make sure that the operator is aware of the contents of the manual.

Preservation of the manual

In order to keep this manual correctly, it must be:

- Placed in an accessible place;
- Safeguarded from deterioration (dust, humidity, liquids or carelessness);
- Available for consultation by the operator until disposal of the device;
- Consulted for equipment setup and operation before start-up.

Definitions and symbols

Below are all the pictograms with their descriptions and references.

SYMBOL	DESCRIPTION	REFERENCE
	The manual contains instructions that must be read before using the device or accessory	ISO 7010-M002
	General warning sign	ISO 7010-W001
	Warning: dangerous voltage	IEC 60878 ISO 3864
	Forbidden to sit	ISO 7010-P018
	Forbidden to go up	ISO 7010-P019
	Type B Applied Part	IEC 60417-5840
	Equipotentiality	IEC 60417-5021
	AC	IEC 60417-5032

In case of loss of the manual in paper version, there is the possibility of being able to download a copy of the same in digital version, in the dedicated section of the site www.gardenbalance.it

NORMATIVE REQUIREMENTS

This introductory chapter contains all the useful information for:

- device identification;
- the regulations followed in the construction of the device and the indications relating to safety in the use of the device;
- the warranty and assistance conditions and how to contact the manufacturer (especially in cases of controversial interpretation of the manual or extraordinary maintenance).

Classification

Class I compliant with the requirements of REGULATION (EU) 2017/745 on medical devices. Class I applied part type B compliant with the prescriptions of the standard CEI EN 60601-1 (CEI 62-5).

Equipment identification

The device described in this manual is intended for sanitary use.

References

In order to equip the machinery with safety devices that can avoid any form of risk to the operators during the normal phases of use of the same, the construction criteria contained in the following legislative and regulatory references have been followed and applied. **Legislative references:**

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 relating to medical devices, which amends directive 2001/83/EC, regulation (EC) n. 178/2002 and the regulation (CE) n. 1223/2009 and repealing Council directives 90/385/EEC and 93/42/EEC.

Normative requirements:

- EN 60601-1: electromedical equipment: general safety standards;
- EN 60601-1-2: electromagnetic compatibility;
- CEI EN 62304: software for medical devices - software life cycle processes;
- CEI EN 62366: medical devices - Engineering application of the usability characteristics of medical devices;
- CEI EN 60601-1-6: electromedical equipment - General requirements for basic safety and essential performance - Collateral standard: usability;
- Technical file and Quality manual.

The device must therefore be considered safe equipment in relation to the construction methods.

Provisions envisaged by the consolidated text 81/2008

The medical device complies with REGULATION (EU) 2017/745 concerning medical devices. The affixing of the CE marking confirms compliance with the essential requirements of the aforementioned directive also by virtue of the application of the harmonized standards to the manufacturing of the device listed in the previous paragraph. In these conditions, the device is manufactured in a workmanlike manner as required by art. 81 of the consolidated text 81/2008.

Marking

The device was designed and built in compliance with the provisions of the REGULATION (EU) 2017/745 directive called Medical Devices, and therefore has the requirements to be equipped with the CE marking.

 Gardhen Balance S.r.l. Via G. Luraghi c/o Consorzio Il Sole lotto S 80038 Pomigliano d'Arco (NA) - Italia mm/aaaa Tel. +39.081.8692160 Fax +39.081.8692460 E-mail: info@gardhenbalance.it www.gardhenbalance.it		REF Physio SN aaDLnnn Intended use: Multifunctional couch	
Nominal voltage V 230 Absorbed power VA 460 Frequency Hz 56/60 Ton/Toff min 2/18 Protection grade IP44	Protection class I Class I	Safety working load  = kg 215 kg Max. patient load  = kg 180 kg	UDI  (01)UDI-DI+SERIAL (11)ggmmaaaa (21)aaBPnnn (400)NNNNN/AA/OP
 		 -10°C / +40°C  30% / 75%  	

Repertoire registration number:2293758/R

National Classification of Medical Devices (CND):V080603

Qualified personnel

Physical person adequately trained and instructed in the use and/or maintenance of the device and in the eventual risks and/or dangers caused by its improper use. Qualified personnel assigned to maintenance and repair activities must be specifically competent and qualified to carry out the aforementioned tasks. The equipment can only be used by qualified personnel.

PLEASE NOTE:Any use not contemplated in this manual is to be considered incorrect and exonerates Gardhen Balance Srl from any liability for any damage caused to things or people deriving from such improper use. The diligence of the operating personnel in the use of the equipment and the observance of the indications given in this manual are necessary factors to avoid accidents and malfunctions.

Identification of the Manufacturer

Garden balance Srl Via G. Luraghi - c/o Consorzio IL SOLE – Lot S 80038

Pomigliano d'Arco (NA) – ITALY - VAT No. 03281501217

Telephone +39.081.8692160 | Fax +39.081.8692460

E-mail info@gardhenbalance.it | PEC gardhenbalance@pec.it | WEB www.gardhenbalance.it

Equipment safety

The equipment is equipped with protective devices which guarantee the safety of the operator, provided he complies with the instructions in this manual and with the purpose for which the device is intended.

Safety devices

The device is equipped with safety systems for the user who will be protected from potentially dangerous conditions. The safety devices installed are the following:

- wheels equipped with braking system;
- absence of protruding edges;
- headboard with safety system;
- perimeter bumpers;
- fully sanitizable device;
- equipotential system between sections.

Safety Warnings

Luminous alarms: LED on the pushbutton panel for power signaling on the engine control unit.

Emergency devices

The device is equipped with systems for managing emergency conditions such as:

- bilateral CPR leverage;

Residual risks

Residual electrical risk

This device works under electric voltage, opening the protective casings of the electrical parts can expose you to the residual risk of electrocution. If it should be necessary to open the protective casings of the electrical parts, first disconnect the device from the mains power supply. In any case, interventions on the protective enclosures of the electrical parts must be carried out by authorized technical personnel.

METHOD OF TRANSPORTATION AND INSTALLATION

We invite you to carefully read the installation and connection instructions, respecting the indications provided. The Manufacturer declines all responsibility for malfunctions or inconveniences due to incorrect installation or improper use of the instrument.

Transport

The transport operations of the new device are carried out by the Manufacturer or by qualified transport companies. If the buyer intends to transfer the device to a new location, he must contact the manufacturer or distributor.

packing

The device is shipped in a single package containing the device with its accessories. The specially sealed packaging is made of shockproof material (triple wave cardboard) arranged on a wooden platform. To open the package, carefully cut the straps used to fix the cardboard to the platform. Then manually remove the adhesive tape and/or the protective plastic. Do not use sharp objects or knives to open the packaging, as they could damage the device or parts of it.

Receipt

Before departure, each device is tested and certified as free from defects. Any damage found upon arrival of the equipment at the destination must be immediately communicated to the Manufacturer in order not to incur the immediate decay of the warranty conditions.

If the delivered product has damaged packaging, the recipient must mark it in writing on the document provided at the time of delivery. Any claim must describe in detail the damage found. The delivery document will be duly signed by both the recipient and the courier. Subsequently, the recipient will immediately notify the Manufacturer of what happened, providing material or evidence that provides objective evidence of the damage. finally, the packaging must not be opened without previous written authorization issued by the shipper or by Gardhen Balance.

Shift

Before moving a device, it is mandatory that:

- the brakes have been released;
- the power cord has been removed from the socket;
- any device accessories have been disconnected.

Lift

To lift the equipment, use a lifter capable of withstanding its weight (at least 200 kg). The safe areas and the anchoring points for lifting are marked in the lower part of the base. It is forbidden to lift the device in areas other than those previously described or from the mattress level. It is forbidden to turn the device upside down.

Positioning

Placing the equipment on the job site involves performing the following operations:

- place the device in its final location;
- activate the parking brakes;
- the appliance must not be installed near heat sources, in damp or dusty places. The ideal operating temperature ranges from 10°C to 40°C;
- any equipment must be positioned on the device.

Installation

The work area must have the following characteristics:

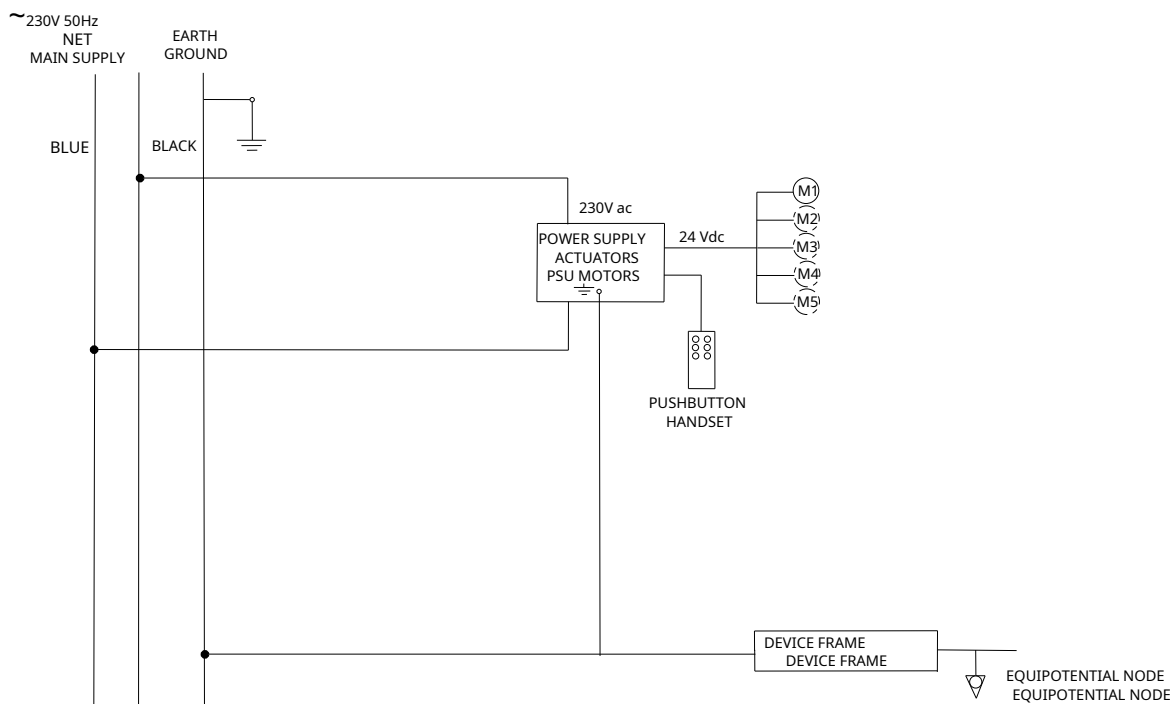
- electrical system compliant with the standard on electrical systems in rooms used for medical use, standard CEI 64/8 sect. 710 or IEC 60364-7-710.
- Supply voltage 110-230 Vac 50-60 Hz $\pm$ 10%;
- flat and leveled floor;
- environment with adequate fire prevention measures.

ATTENTION | All connection operations must be carried out with the supply voltage disconnected.



For the connections, proceed as follows: the mains is separated by regularly connecting the instrument to the 110-230 Vac 50-60 Hz $\pm$ 10% single-phase mains, plus earth via the cable with integrated socket supplied.

WIRING DIAGRAM - STANDARD CONFIGURATION



DEVICE DESCRIPTION

The device is equipped with a reinforced frame, made of steel through pre-treatment and thermosetting epoxy paint.

The minimum height of the top equal to 502 mm, allows easy accommodation for all patients. However, it is possible to adjust the device up to a maximum height of 977 mm, obtaining 475 mm of total excursion. The sections are moved by gas springs actuated by levers placed on the sides of the sections themselves.

The cot is equipped with swivel castors with brake (Ø 120 mm), non-marking, low rolling resistance, very silent, sliding on bearings and with high capacity. Each is equipped with a special brake that can be operated by means of a pedal lever.

TOGETHER



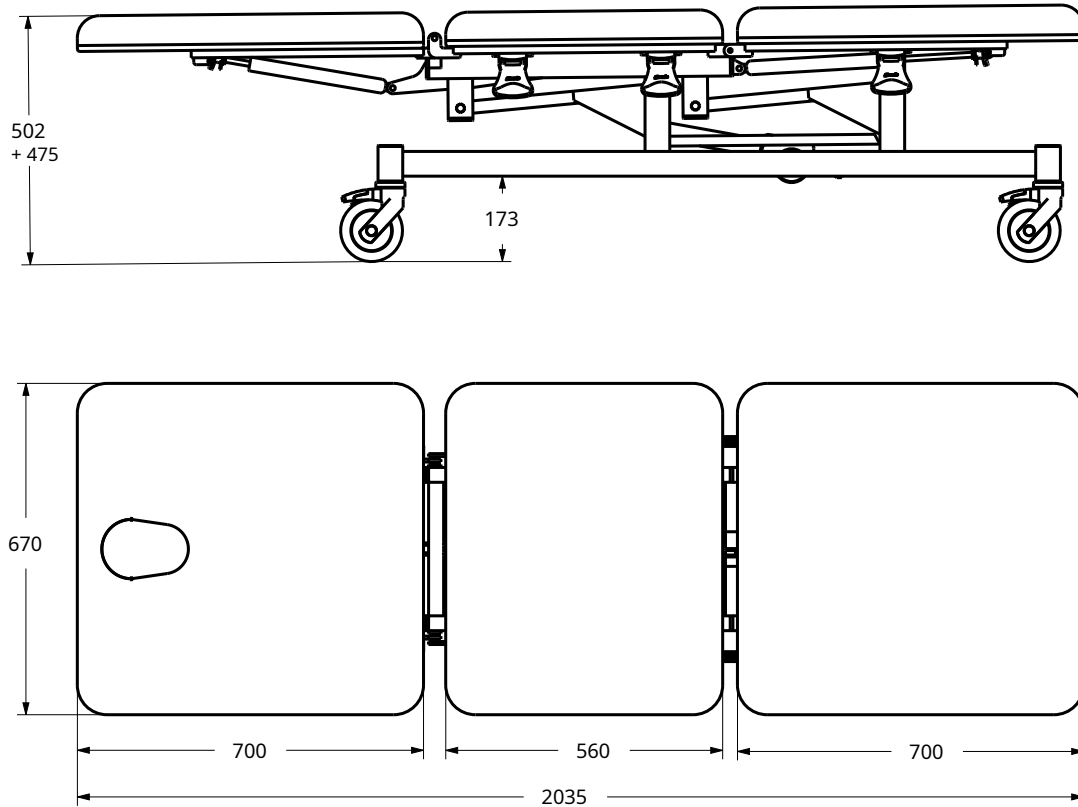
Together

1. Back section
2. Seated section
3. Leg section
4. Wheels
5. Brake pedals

TECHNICAL DATA

Device weight	70kg
Diet	50/60 Hz ± 10% (non-inspectable internal fuses)
Absorption	4A max
Surface treatment	Painting with thermosetting epoxy powders
Wheels	Ø 120 mm, stainless swivel with brake system
Safe workload	215kg
dynamic load max	180kg
Environmental conditions	10 to +40°C 30 to 75% RH 645 to 795Hg

DIMENSIONAL



USE

Power the device by plugging the cord into the electrical outlet. Vary the angle of the sections and the variable height of the device using the hand control supplied or the operator panel if the accessory is available. Remember that every time the device is powered up, the patient push-button panel must be enabled with the appropriate magnetic key. Pay attention when the sections of the device are moved, in order not to run into any interference with objects arranged in the surrounding environment.

It is possible to transfer patients from one ward to another only if the path permits it and is not bumpy (e.g. steps, depressions). The device must not be used to transport and/or weigh goods (if the device is equipped with a weighing system) in order to avoid damage.

The device should be left in its lowest position when the patient is unattended to reduce the risk of injury from falls. To avoid dangers related to improper use of the power cord, for example: kinking, cutting or other mechanical damage, you must make sure that the cord is lifted off the floor before handling the device.

Equipment startup

Insert the plug into the electrical outlet and, if the device is equipped with one, turn on the display using the ON/OFF button located on the display itself.

Patient accommodation

When proceeding to accommodate the patient on the device, use the following precautions:

- must be placed in a horizontal position;
- must be left in its lowest position to reduce the risk of injury from falls.

Electric movement

The device is equipped with a mobile button panel with clear silk-screen printing on each single button, which allows the device to be moved. This movement is allowed by motorized columns equipped with an automatic leveling system. Finally, the push-button panel is equipped with an integrated rear hook for its support and can be disabled using a special magnetic key.

The patient will have the possibility to operate the following movements.

- Variable height.



ATTENTION | Avoid pulling and/or extending the hand control wire beyond its capacity.

It is forbidden to press several keys simultaneously and repeatedly at a time in order to cause damage to the control unit.



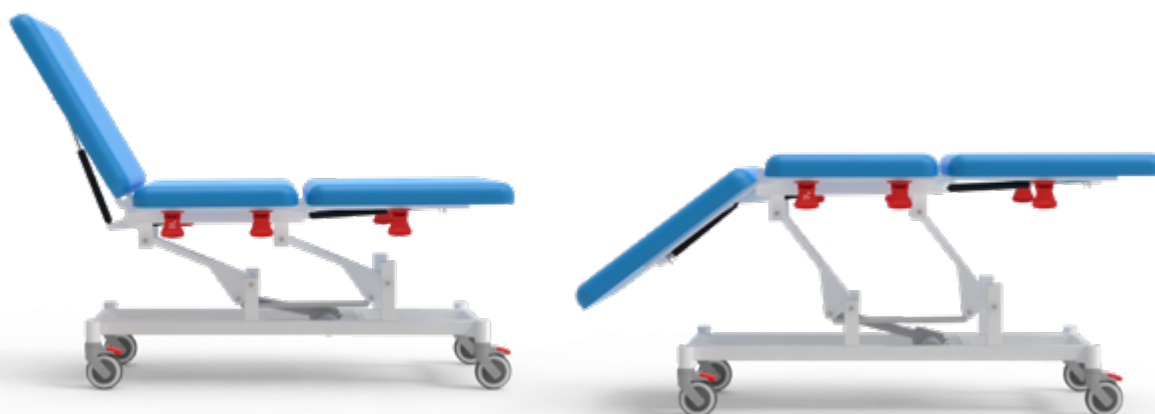
Manual handling

The backrest, seat section and leg section are manually operated by gas springs. After having pulled the lever located on both sides of the aforementioned sections, it is possible to manually move the device by adjusting it to the desired position. To bring the device back to its rest condition it will be necessary to repeat the reverse operation.

BACKREST SECTION MOVEMENT



To activate movement of the backrest section, manually pull the relative lever



HANDLING IN TRENDLENBURG LOCATION



To activate movement, manually pull the appropriate lever



MOVEMENT OF THE BACK AND LEG SECTION



To activate the movements of the sections, manually pull the appropriate lever



MOVEMENT OF THE FEMORAL AND LEG SECTION



To activate the movements of the sections, manually pull the appropriate lever



VARIABLE HEIGHT HANDLING



To activate the movement of the variable height, press the corresponding buttons on the control panel supplied.



COMPATIBLE ACCESSORIES

Below are all the accessories compatible with your device and their functions. Please note that in the consultation phase, it will be necessary to take into account the equipment mentioned in the commercial document generated following the order.

AC11



Roll holder positioned on the back of the backrest.

! ATTENTION

- Do not use the accessory to hold objects other than those for which it was designed.

AC4L



Infusion stand in stainless steel adjustable in height with 2/4 hooks.

! ATTENTION

- Do not move the device by the IV pole.
- Do not use the IV pole to hold objects other than those for which it was designed.

DEVICE MALFUNCTION

The following problems may occur while using the device.

Drawbacks	Resolution
The POWER ON light on the hand control does not light up	Check the power cord connections.
The POWER ON light on the push-button panel comes on but the sections do not move	Enable the hand control using the magnetic key. If the problem persists, contact support.
The control unit emits an acoustic signal (BEEP)	Make sure the cot is powered.
The display shows a series of dashes at the bottom	Make sure that no object hits the table top. Turn the display off and on again. If the problem persists, contact support.
The display shows a series of dashes at the top	The maximum capacity has been exceeded, unload part of the weight. If the problem persists, contact support.
The display shows a weight value (from 5 to 25 kg)	Turn the display off and on again.
The display shows a weight value > 25kg	Unload the weight from the table or contact assistance
Flashing display battery icon	Check that the device is connected to the 230V electrical outlet. Check that the LED on the push-button panel is on, otherwise contact assistance.
Service/maintenance	If shown on the display, contact assistance.

MAINTENANCE AND ASSISTANCE

Maintenance activities must be carried out in compliance with the standard CEI EN 62353 Electro-medical equipment - Periodic checks and tests to be carried out after repairs on electro-medical equipment by qualified personnel authorized by the Manufacturer.

Preventive maintenance

Device functionality and safety: to maintain the original characteristics of this medical device in terms of operation and safety, it is mandatory to carry out preventive maintenance on an annual basis by personnel authorized by the manufacturer, also in compliance with national decrees or international laws on safety in the workplace.

Metrological verification (valid only for devices with integrated scale): to ensure the metrological fidelity of this medical device over time, the manufacturer suggests a six-monthly metrological verification of the weighing system. The activity must be entrusted to personnel authorized by the manufacturer and performed in compliance with the requirements of the EN 45501 standard.

Extraordinary maintenance

Extraordinary maintenance interventions must be carried out exclusively by qualified personnel authorized by the manufacturer. These interventions are mandatory, in particular, when:

- the device has been subjected to unusual external mechanical stresses;

- the device has been subjected to dripping liquids;
- the device has been subjected to strong overheating;
- if the functionality of the device seems impaired;
- if any connectors, cables or other parts show signs of deterioration.

Electrical safety checks

The verifications are to be carried out annually by qualified personnel registered in the professional register of verification technicians.

Periodic checks: in case of preventive maintenance

Extraordinary checks: to be carried out after each repair/replacement of electrical equipment components.

The checks to be carried out are:

- visual inspection of all cables, insulation, casings etc. designed to prevent access to live parts;
- measurement of the resistance of the protective conductor;
- measurement of earth leakage currents;
- measurement of leakage currents for applied parts;
- functional test of the device;

Storage

If the device is not used for long periods, it must be kept in a place free from humidity and covered with cellophane. The environmental conditions to be respected are the following: $-10^{\circ} \div +40^{\circ}\text{C}$ 90% Ur non condensing. It is advisable to carry out a functional and electrical safety check after a long period of inactivity.

Cleaning

The lower part of the columns is protected by easy-to-sanitize thermoformed ABS covers. The reinforced frame is made of anti-rust S235JR steel, made stainless by pre-treatment and thermosetting epoxy paint enriched with antimicrobial.

The entire structure of the device, being ergonomic and free from accumulation points, is entirely and easily washable with all commonly used detergents. Furthermore, the load cells (present only in devices with integrated scales) are made of AISI 304 STAINLESS STEEL. The electrical parts of the device have a high degree of protection.

Before proceeding with any cleaning operation, disconnect the power supply of the device by disconnecting it from the power supply.

To obtain disinfection of the treated parts, it is recommended, if necessary and in accordance with the provisions of medical-health procedures, to clean the device according to the following methods: 1% sodium hypochlorite-based solutions; spray and use a cloth, then dry the treated parts immediately to avoid halos, stains and discolorations.

ATTENTION | DO NOT use corrosive and abrasive products. Don't use alcohol. Do not use abrasives on painted parts.



If it should prove necessary, in order to give new shine to the stainless steel parts, it is recommended to treat the device according to the following methods:

- polishing with Scotch Brite abrasive cloth or similar fine grain;
- lightly rub the cloth indicated above over the entire stainless steel surface.

ATTENTION | The polishing treatment is reserved for stainless steel parts. Then carry out a disinfection cycle as described above.



Spare parts

Spare parts for the product in question can be requested directly from the Manufacturer specifying the device model and serial number. The company declines all responsibility or damage caused to people or things due to the use of non-original spare parts.

Recommendations

Do not use the device in case of malfunctions and contact the technical service. In the event of any points of corrosion on the metal sheets, contact the assistance and maintenance service to restore them.

- It is forbidden to remove or open all the electrical parts of the device.
- The observance of the above indications determines the correct use of the equipment and a longer life of the same.
- Any unusual event must be promptly reported to the technical assistance service by fax.
- Any anomaly resulting from incorrect use of the equipment will invalidate the guarantee.
- Any tampering performed by unauthorized personnel irrevocably invalidates the guarantee and releases Gardhen Balance from any responsibility relating to the occurrence of anomalies.

Reconditioning

For the reconditioning of the device, contact the supplier company at the following contact:
info@gardhenbalance.it

END OF LIFE AND DISPOSAL

In case of scrapping of the equipment it is advisable to:

- disassemble the device into its individual component parts (the main materials it is made of are as follows: iron, wood and plastic (various types);
- collect the parts by homogeneous categories;
- dispose of electronic components as industrial waste;
- deliver the mechanical and electrical devices to a center for the disposal of scrap metal (the material is recyclable).

Rohs and WEEE regulations (Legislative Decree 151 of 25 July 2005): This device was designed and assembled with high quality component materials, which can be recycled and reused. The wheelie bin symbol covered with an X means that the product meets the requirements of the Community Directive 2002/96/EC of 27 January 2003 on waste electrical and electronic equipment (WEEE). It also means that the product must not be disposed of together with normal household waste. Find out about the collection system for electrical and electronic products in force in the area where you wish to discard the product. When purchasing a new device of an equivalent type, the device to be dismantled can be returned to the distributor. Follow local waste disposal regulations and do not throw away old products with normal household waste.



CONTACTS AND CERTIFICATIONS

Garden balance Srl Via G. Luraghi - c/o Consorzio IL SOLE – Lot S 80038
Pomigliano d'Arco (NA) – ITALY - VAT No. 03281501217
Telephone +39.081.8692160 | Fax +39.081.8692460
E-mail info@gardhenbalance.it | PEC gardhenbalance@pec.it | WEB www.gardhenbalance.it

Certifications: for certifications consult our website www.gardenbalance.it

Warranty

The Gardhen Balance company undertakes exclusively to replace or repair free of charge the parts that are faulty due to material or workmanship defects starting from the date of delivery to the addressee, for a period of 12 months. The opening of the seals by unauthorized personnel immediately invalidates the Manufacturer's guarantee.

In the event that the guarantee service is carried out at the User's home, the latter is required to pay a fixed call fee, as per the ANIMA tariff in force. On the other hand, the intervention is free if it is carried out at an authorized Technical Assistance center to which the User will have the device delivered at his own expense.

Whenever a technical intervention is required, the User must show this certificate together with the tax receipt or purchase invoice. These documents will unequivocally certify the commencement of the warranty period, without which it will not be possible to apply the warranty conditions.

- In order for the guarantee to be effective, this certificate must be sent to the Gardhen Balance company completed in all its parts for acceptance of each of its clauses, within the real term of 10 (ten) days from the date of delivery of the product.
- Gardhen Balance will not validate certificates that have not been compiled, signed and sent in the manner and within the terms described in the previous point.
- The User loses the right to the guarantee if: he does not report the reported defects to Gardhen Balance or to one of its authorized technical assistance centres, within 8 (eight) days from the detection of the defect; repairs carried out by unauthorized persons or repairs carried out with non-original spare parts should be found; tampering should be found.
- The activities covered by the guarantee may take place both at the premises indicated by the User and at the authorized Technical Assistance Centers or at the headquarters of Gardhen Balance

according to the technical discretion of the Manufacturer. All costs of packing, removal and transport are to be paid and paid for by the User.

- Damages deriving from: improper use of the upholstery, wear of the device components, cleaning methods or use of chemical products not recommended by the Manufacturer, acts of vandalism, natural disasters, damage to any protective glass are excluded from the guarantee.
- The guarantee conditions will not be applied in the following cases: damages or breakages caused by transport; incorrect or bad installation of the product, insufficiency or abnormality of the electrical systems; carelessness, negligence or inability to use the product; the instructions for use are not followed; if the User is not the first purchaser; causes that do not depend on the Manufacturer; interventions for presumed defects or for convenience checks.
- Gardhen Balance is not responsible for damages deriving to the User from failure or imperfect functioning of the product or caused to things by defective functioning.
- Garden Balance will also not be liable for damage caused by a delay in carrying out the repairs or replacement of the parts covered by the guarantee.
- Installations and adjustments are not the responsibility of the Technical Assistance Service.
- These warranty conditions cannot be modified by any other verbal or written agreement.

For any dispute, the Judicial Forum of Naples is exclusively competent.

USER	
PRODUCT DESCRIPTION	
SERIAL NUMBER	
DELIVERY DDT NUMBER	
REFERENCE PERSON	
TELEPHONE NUMBER	
DATE	
SIGNATURE	



Garden scales Srl

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Learn more about

www.gardenbalance.it