

Theia 1.0

Surgery chair

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User Manual



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STRUCTURE OF THE MANUAL

Generalities

Rights of translation, electronic storage, reproduction and adaptation in whole or in part by any means (including microfilm and photostatic copies) are reserved for all countries. This user manual has been prepared to provide instructions on the proper operation of the device in all its parts, including compatible optional components. If any discrepancies are found, you may report them to one of the contact details given within the document.

Upon completion of the consultation of this document, the end user will be able to:

- take precautions to use the device safely;
- effectively use all functions of the device.

The user manual consists of the following dedicated sections:

- **Structure of the manual:** guidance on the structure of the manual.
- **Regulatory references:** list of regulations applicable to the device.
- **Methods of transportation and installation:** describes the proper ways to transport the device and the correct installation procedure.
- **Device description:** contains information about: device type, intended use, life cycle and operation, functionality, instructions for use, information about safety and performance, and finally procedures for training in use.
- **Usage:** describes activities for proper operation of the device.
- **Device malfunctions:** describes the inconveniences encountered while using the device and proposes possible resolutions.
- **Maintenance and service:** routine maintenance procedures necessary to keep the device in perfect working order are described. Technical service contacts are also given. A detailed list of the most frequent faults and their necessary remedial actions is given in the service manual as these actions must necessarily be carried out by competent and properly trained personnel.
- **End-of-Life and Disposal:** disposal and end-of-life of the device and references to the RoHS directive are described.
- **Contacts and certifications:** company contacts and certifications are given.

It is recommended that the user strictly follow the requirements in this manual, especially those concerning safety regulations and routine maintenance. User means qualified personnel. The proper and safe operation of this equipment depends on its use, installation (by qualified personnel), operation and maintenance.

Consultation of the manual

This manual accompanies the device of which it is an integral part. The information contained in it is addressed to the user of the equipment, who will find in these pages suggestions for its proper use under safe conditions. Current regulations require the owner of the equipment to ensure that the operator is familiar with the contents of the manual.

Retention of the manual

In order to properly store this manual, it should be:

- Placed in an accessible location;
- Safeguarded from deterioration (dust, moisture, liquids or neglect);
- Available for operator consultation until the device is disposed of;
- Consulted on setting up and running the equipment before startup.

Definitions and symbols

Below are all the pictograms with their descriptions and references.

SYMBOL	DESCRIPTION	REFERENCE
	The manual contains instructions to be read before using the device or optional components	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
	Applied Part Type B	IEC 60417-5840
	Equipotentiality	IEC 60417-5021
	Alternating current	IEC 60417-5032

If you lose the hard copy of the manual, there is the possibility of being able to download a copy of it in digital version, in the dedicated section of the website **www.gardhenbilance.it**

REGULATORY REFERENCES

This introductory chapter reports all useful information for:

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

Classification

Class I complies with the requirements of REGULATION (EU) 2017/745 on medical devices.

Class I applied part type B complying with the requirements of IEC EN 60601-1 (IEC 62-5).

Equipment identification

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

References

In order to equip the machinery with the safety devices that can prevent operators from any form of risk during the normal phases of its use, 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 April 5, 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Certificate No. 126/MDR, issued by Notified Body No. 0051 IMQ S.p.A. with reference to Im class IIa devices).

Normative references:

- IEC EN 60601-1/A2:2022 electromedical equipment: general standards for safety;
- EN 60601-1-2:2020 electromagnetic compatibility;
- EN 62304/A1:2015-10 medical device software - software life cycle processes;
- IEC EN 62366:2014 medical devices - Engineering application of utilization characteristics of medical devices;
- IEC EN 60601-1-6:2016 electromedical equipment - General requirements for basic safety and essential performance - Collateral standard: usability;
- Technical File and Quality Manual.

Therefore, the device should be considered safe equipment in relation to the way it is constructed.

Provisions under the Consolidation Act 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 manufacture of the device listed in the previous paragraph. Under these conditions, the device is manufactured in a workmanlike manner as required by Article 81 of the Consolidated Text 81/2008.

Marking

The device was designed and manufactured in accordance with the requirements of the directive REGULATION (EU) 2017/745 called Medical Devices, and has, therefore, the requirements to be CE marked.

CND / EMDN	Z12011201
GMDN code	38447
No. progressive/R	2407286/R
UDI-DI di Base	805771740POOPKQ

 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		# Theia 1.0 SN aaDPnmm	
Main voltage V~ 230 Max power VA 1200 Frequency Hz 56/60 Ton/Toff min 2/18 Protection IP44	Patient max load  = kg 300 kg 		
Safety CI I 	Safe working load  = kg 335 kg 		
Medical device classification I MD	UDI (01)UDI-DI+SERIAL (11)ggmmaaaa (21)aaBPnmm (400)NNNNN/AA/OP		
		   	

Qualified personnel

The manufacturer considers only **experienced users to be authorized to use the device**, to be understood as **"persons who have been trained in the use of the device during the training carried out by gardhen balance personnel when commissioning the device and who have been recorded on the appropriate form, mod_04 - record of training in the use of devices"**.

It is also specified that, as stated in the relevant technical documentation, the Manufacturer considers as below the different types of Operators/Users:

- **Expert User:** Person who will use the device and is trained in its use (Hospital staff who have participated in training in the use of the device);
- **Lay User:** Person who will use the device without having received training (e.g., Patient, health care personnel who have not participated in user training, etc.).

A natural person properly trained and instructed in the use of the device and the possible risks and/or dangers caused by its misuse. **It is reiterated that the manufacturer considers only the Expert User to be authorized to use the medical device.**

PLEASE NOTE: Any use not covered in this manual is to be considered improper and exonerates Gardhen balance S.r.l. from any liability for any damage caused to property or persons resulting from such improper use. Diligence on the part of the operating personnel in the use of the equipment and compliance with the instructions in this manual are necessary factors in avoiding accidents and malfunctions.

Identification of the Manufacturer

Gardhen balance S.r.l. Via G. Luraghi - c/o Consorzio IL SOLE - Lotto S 80038

Pomigliano d'Arco (NA) - ITALY - P. IVA n°03281501217

Phone +39.081.8692160 | Fax +39.081.8692460

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

SNR: IT-MF-000013019

Equipment security

The equipment is equipped with protective devices to ensure the safety of the operator, provided he or she follows the instructions in this manual and 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 as follows:

- wheels equipped with a braking system;
- absence of protruding edges;
- fully sanitizable device;
- equipotential system between the sections.
- equipotential node located on the back of the backrest.

Safety Warnings

The medical device can be equipped with LED light alarms on hand control for safety alerts.

Orange LED for signaling the moving device:

- off: indicates that none of the device sections are moving;
- on: indicates that at least one of the device sections is moving.

Green LED for signaling the status of the hand control:

- off: indicates that the hand control is disabled;
- lit: indicates that the hand control is enabled.

Green LED for signaling the connection of the device to the power supply:

- off: indicates that the device is disconnected from the power supply;
- on: indicates that the device is connected to the power supply.

Emergency devices

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

- memory buttons;
- CPR;
- Trendelenburg.

Residual risks

Residual risk of electrical type

This device works under electrical voltage, opening the protective enclosures of electrical parts may expose you to the residual risk of electrocution. Should it be necessary to open the protective enclosures of the electrical parts, disconnect the device from the power supply beforehand. In any case, work on the protective enclosures of electrical parts must be carried out by Authorized Technical Personnel.

REGULATORY INFORMATION

Intended use device

Devices intended for patient accommodation during hospitalization and medical examinations and procedures in general.

Groups of Patients Intended

Patients who have to undergo ophthalmic or minor surgery.

Frequent directions for use

- Ophthalmic Surgery,
- Minor Surgery.

Contraindications

It is not recommended that the device be used for patients with medical conditions that necessitate the use of special and/or custom-made devices. Use of the device in environments where flammable gases are used is not recommended.

Warnings

The device should be used according to the requirements of the service manual and should be maintained considering the contents of the service manual.

MODES OF TRANSPORT AND INSTALLATION

Please read the instructions regarding installation and connection carefully, following the directions provided. The Manufacturer disclaims any liability relating to malfunctions or inconveniences due to incorrect installation or improper use of the instrument.

Transport

Transportation of the new device is carried out by the Manufacturer or qualified transportation companies. If the purchaser intends to move the device to a new location, he/she should arrange to contact the Manufacturer or distributor.

Imballo

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

Reception

Each device before departure is tested and certified as defect-free. Any damage found upon arrival of the equipment at the destination must be reported immediately to the Manufacturer so as not to incur immediate forfeiture of warranty conditions.

Should the delivered product have 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. Thereafter, the consignee shall immediately report what has happened to the Manufacturer, providing material or evidence giving objective evidence of the damage. finally, the package shall not be opened upon written authorization issued by the shipper or Gardhen bilance.

Moving

Before moving a device, it is mandatory that:

- brakes have been turned off;
- the power cord has been removed from the power outlet;
- any optional components of the device have been disconnected.

Lifting

To lift the equipment, use a hoist that can support its weight (at least 200 kg). The safe zones and anchor points for lifting are marked in the lower part of the basement. It is forbidden to lift the device in areas other than those previously described or from the net floor. It is forbidden to overturn the device.

Positioning

Placing the equipment at the work site involves performing the following steps:

- place the device in its final location, making sure that in any of its reachable positions it does not interfere with any obstacles, in order to avoid accidental damage and hazards;
- activate the parking brakes;
- the unit should not be installed near heat sources, in humid or dusty places. The ideal operating temperature is from 10°C to 40°C;
- must be placed on the device the kit, if any.

Installation

The work area must have the following characteristics:

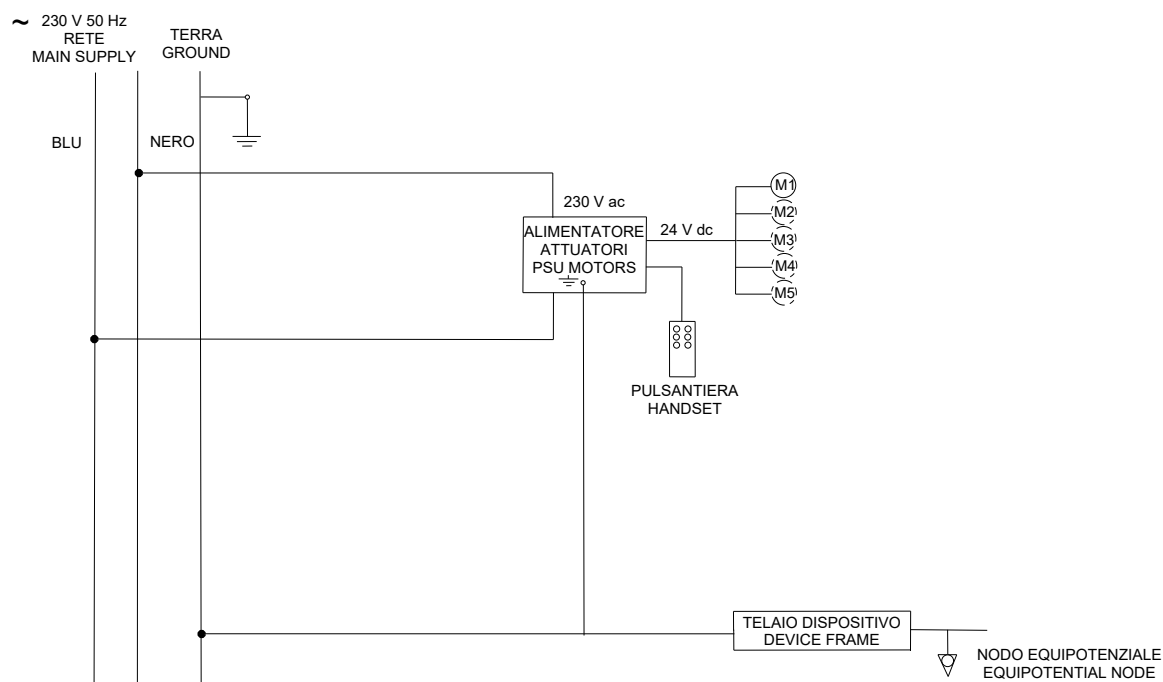
- electrical installation complying with the standard on electrical installations in premises used for medical purposes standard IEC 64/8 sec. 710 or IEC 60364-7-710.
- Supply voltage 110-230 Vac 50-60 Hz $\pm$ 10%;
- flat and level floor;
- environment with appropriate fire prevention measures.

WARNING | All connection operations should be performed with the power supply voltage off.

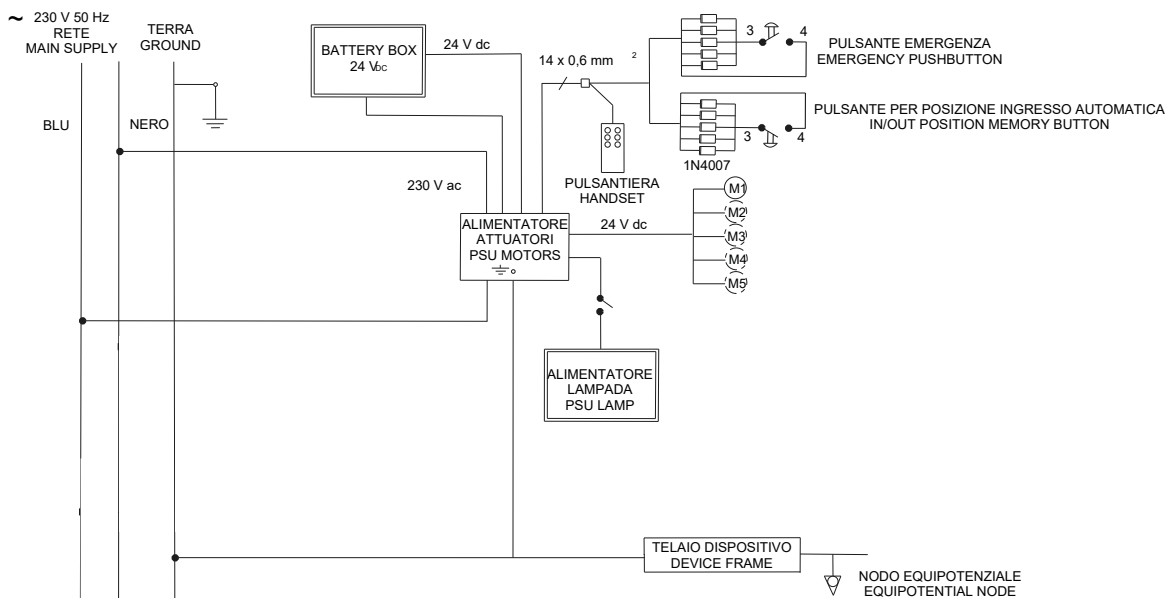
For connections, proceed as follows: network separation is routinely made by electrically connecting the instrument to the 110-230 Vac 50-60 Hz $\pm$ 10% single-phase power supply, plus ground using the cable with built-in socket provided.



WIRING DIAGRAM - STANDARD CONFIGURATION



WIRING DIAGRAM - CONFIGURATION WITH OPTIONAL COMPONENTS



DEVICE DESCRIPTION

The device has a frame made of reinforced steel protected by ABS cover. Equipped with low-voltage electric motors of the anti-crushing type, controlled by special control panel. The armrests have the possibility of manual adjustment by means of special mechanism. The chair is equipped with casters to facilitate movement from place to place even with patient on board, a foot pedal locking system is provided to give the device additional stability when stationary.

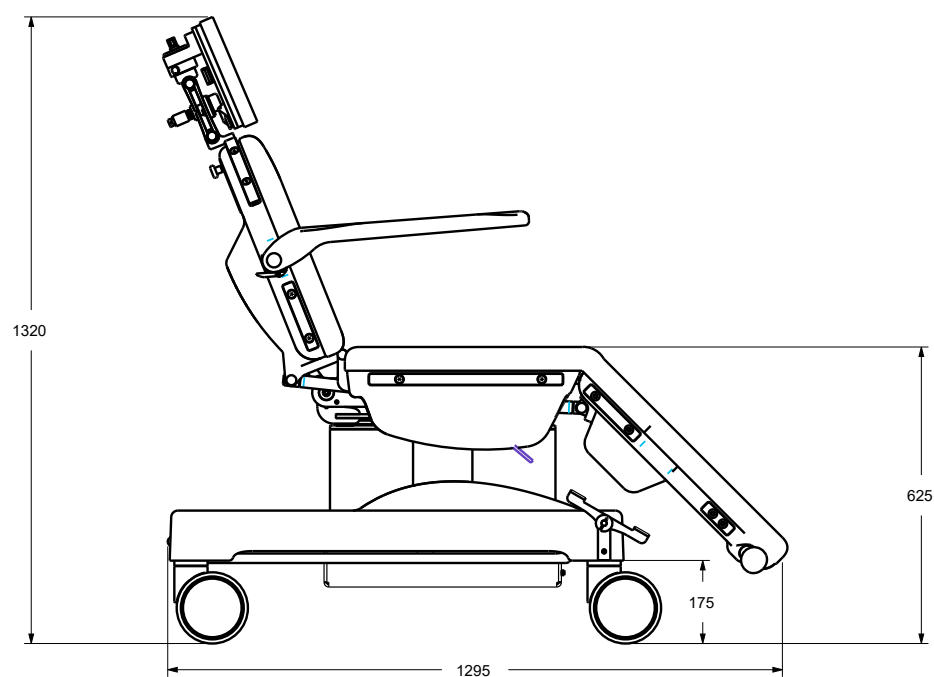
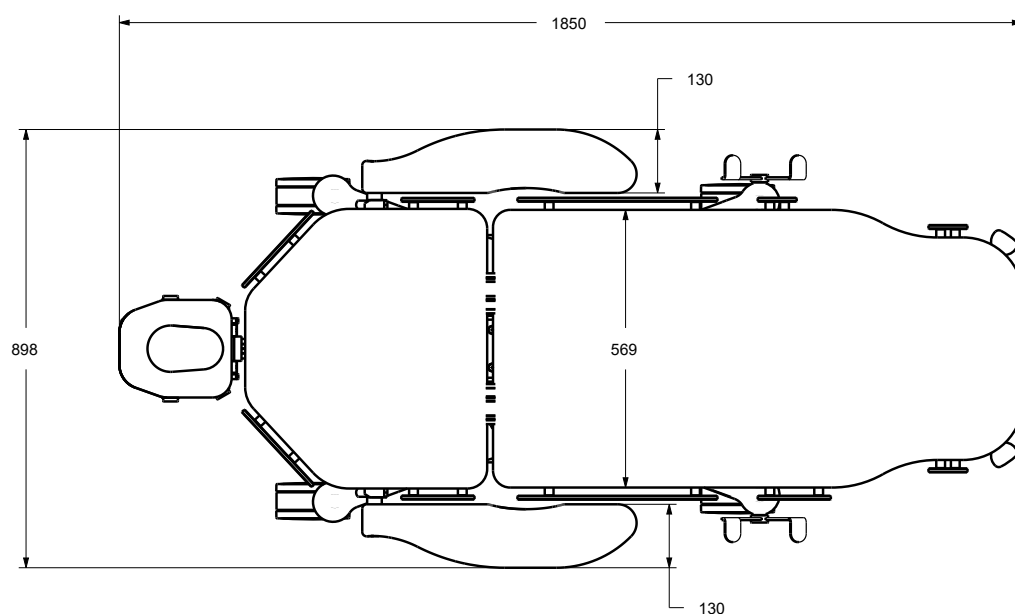
TOGETHER



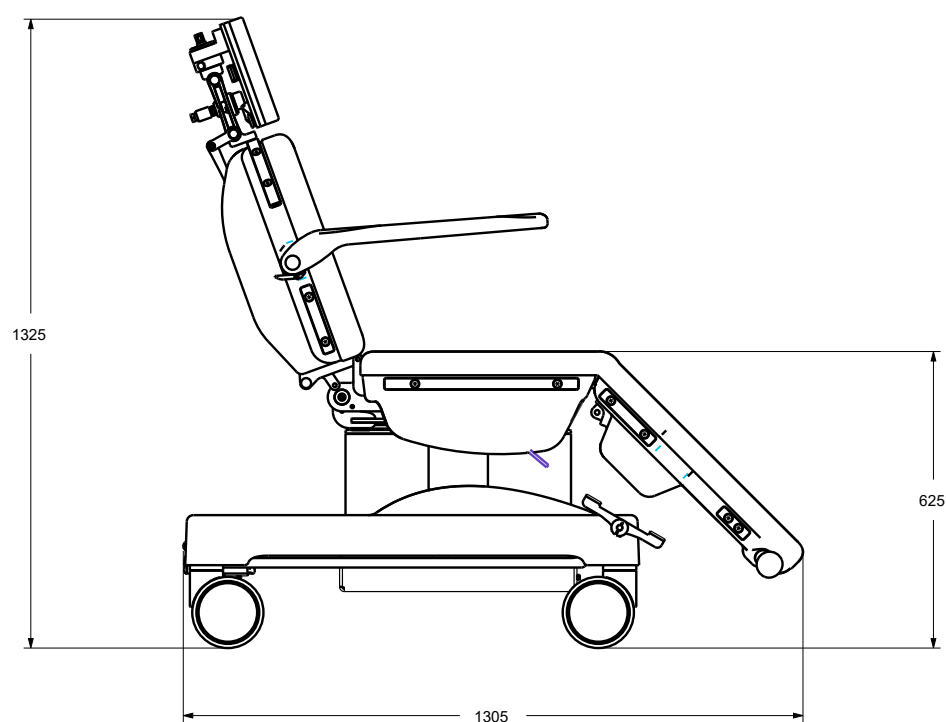
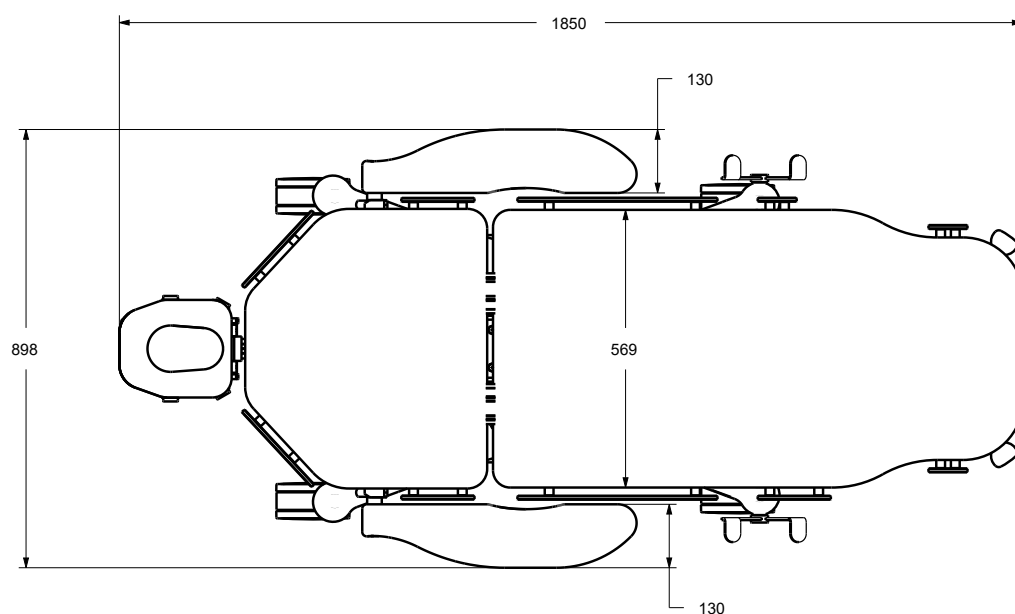
- 1. Headrest
- 2. Backrest section
- 3. Seating section
- 4. Leg section
- 5. Wheels
- 6. Braking system
- 7. Armrests
- 8. DIN bar
- 9. Carrying knob

TECHNICAL DATA - THEIA 1.0	
Device weight	70 kg
Power	50/60 Hz ± 10% (internal fuses cannot be inspected)
Absorption	4 A max / 480 VA
Surface treatment	Thermosetting epoxy powder coating
Wheels	Ø 100 mm swivel with braking system
Safe Workload	335 kg
Max dynamic load	300 kg
Environmental conditions	10 and +40°C 30 and 75% RH 645 and 795 Hg
Maximum backrest angle	~ 76°
Maximum femoral angle	~ 45°
TRENDELENBURG	~ 17°
Trendelenburg inverso	~ 17°

DIMENSIONAL - THEIA 1.0



DIMENSIONAL - THEIA 1.0 VERSION WITH MOTORIZED HEADREST



USE

Power the device by connecting the cable to the electrical outlet. Vary the angle of the sections and variable height of the device using the supplied hand control or the operator panel if optional components are available. Remember that whenever the device is powered up, the patient hand control must be enabled with the appropriate inhibit key. Use caution when sections of the device are moved in order not to run into any interference with objects placed in the surroundings.

It is only possible to transfer patients from one department to another if the route allows it and is not rough (e.g., steps, depressions); handling is only and exclusively allowed by the device's special carrying handles. The device should not be used to transport and/or weigh goods (if the device is equipped with a weighing system) in order to prevent damage to the device.

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

Starting equipment

Plug the power plug into the electrical outlet and, if the device has one, turn on the display using the ON/OFF button on the display.

Patient accommodation

Use the following precautions when accommodating the patient on the device:

- make sure the brake system is in the stationary condition;
- make sure the device is in its lowest position in order to reduce the risk of injury from falls;
- make sure must be arranged in the entry/exit position to facilitate patient accommodation.

WARNING | The device's armrests serve only a support function for the upper limbs. Any other use beyond that stated above is not permitted.



Electrical Handling

Included batteries and functionality

The surgical chair is equipped with two external batteries that are rechargeable and interchangeable with each other, with special desktop battery charger. Replacing the batteries allows continuous use of the device ensuring its permanent autonomy.

To remove the discharged battery, located on board under the leg rest, press the red button and pull it out (as shown in the figure). To reinsert it, slide it into the slot, a "CLACK" will then be heard to confirm proper insertion. During normal use of the device, make sure the other external rechargeable battery is placed on charge.



There is a buffer battery, not visible integrated to the device that only intervenes exclusively in the time it takes to exchange the discharged battery with the charged one

If the device is not used for a period greater than or equal to 3 days, repeat the "First Commissioning" cycle.

Device control: the device is equipped with control panel with clear silk-screen printing on each individual button, which allow total handling of the device.

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

Preset Memories:

- Input memory location.
- Operator-assisted exit memory position.
- Trendelenburg memory position.
- CPR (cardiopulmonary resuscitation CPR) memory position.

Moving Sections:

- Backrest.
- Legs.
- Variable height.
- Seating.



WARNING | Avoid pulling and/or extending the control panel wire beyond its capacity. It is forbidden to simultaneously and repeatedly press several keys at a time in order to cause damage to the control unit.



User-settable memory locations

In addition to the memory positions pre-set by the manufacturer, the device has three other memory positions available: "1 SET," "2 SET," and "3 SET," which can be set by the user according to his or her needs.



Choose the desired configuration by adjusting one of the sections: backrest, seat and legs, according to your needs using the appropriate adjustment buttons from the control panel.



Once you have chosen the desired configuration, press the "SAVE" key and then select one of the three keys "1 SET," "2 SET," and "3 SET" in relation to where you want to store the position. The control unit will send an audible "BEEP" signal which will confirm that the memory has been saved.

INPUT MEMORY LOCATION AND TRANSPORT



You can reach that position by operating the memory button



OUTPUT MEMORY POSITION



You can reach that position by operating the memory button



TRENDELENBURG MEMORY POSITION



This position can be reached by operating the memory button. This position is useful in case of hypotensive events.



CPR (CARDIOPULMONARY RESUSCITATION CPR) MEMORY POSITION



You can reach that position by operating the related memory button. In that position, you can practice Cardiopulmonary resuscitation (CPR / CPR) is an essential first aid technique in emergency situations, when we are faced with cardiac arrest



BACKREST MOVEMENT



To move the backrest section, press the indicated button plus one of the two arrows for angular adjustment of the back section at the same time.



LEGREST MOVEMENT



To move the legrest section, press the indicated button plus one of the two arrows for angular adjustment of the leg section at the same time.



SEAT HEIGHT MOVEMENT



To adjust the height of the seat section, press the indicated button plus one of the two arrows at the same time.



SEAT ANGLE MOVEMENT



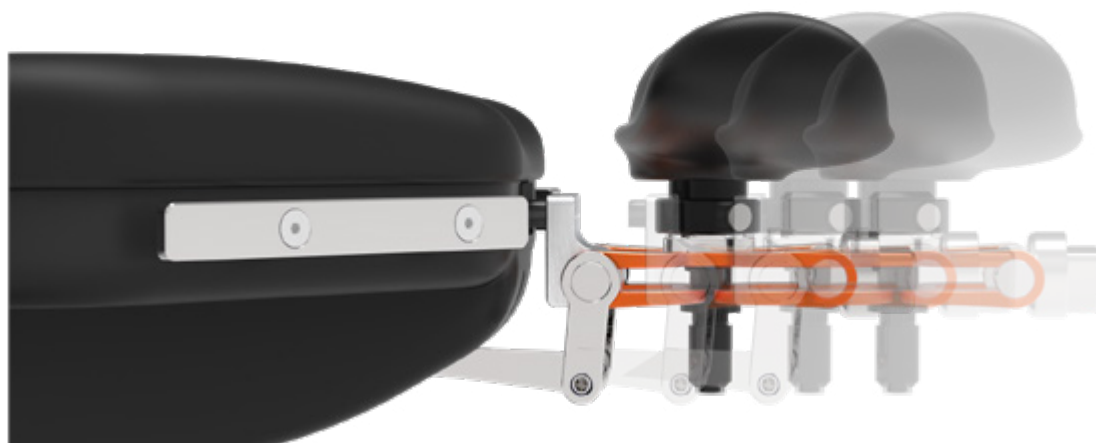
To adjust the seat section tilt, press the indicated button plus one of the two arrows at the same time.



HEADREST HEIGHT ADJUSTMENT (VERSION WITH MOTORIZED HEADREST)



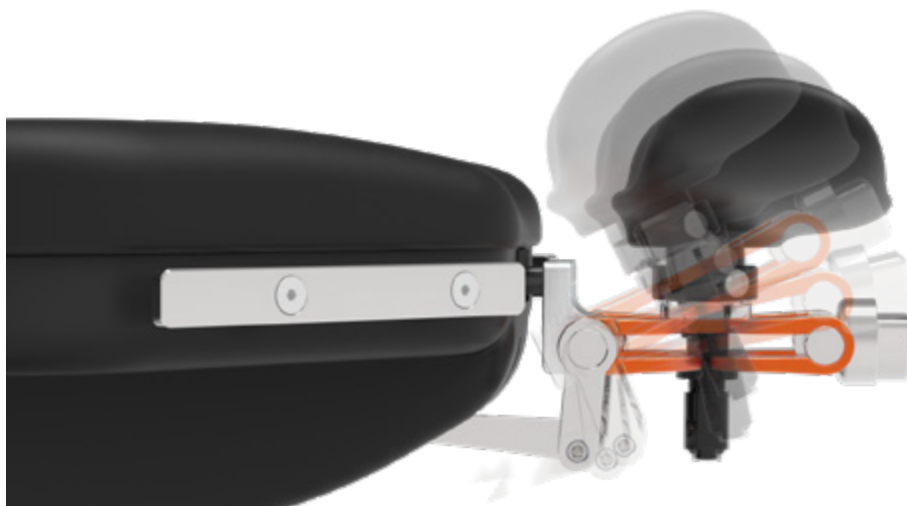
To adjust the height of the headrest, press one of the two buttons on the control panel.



HEADREST TILT ADJUSTMENT (MOTORIZED HEADREST VERSION)



For headrest tilt adjustment, press one of the two buttons on the control panel.



Manual handling

Use of armrests

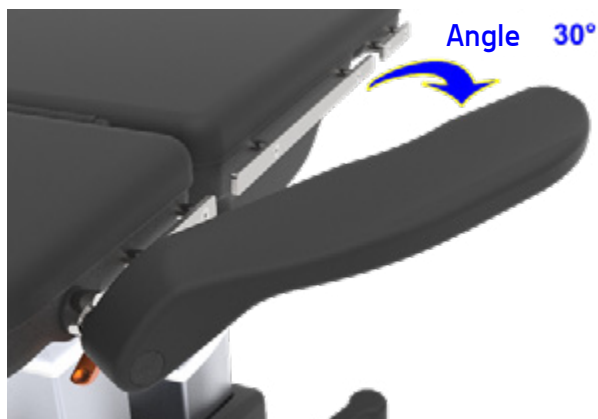
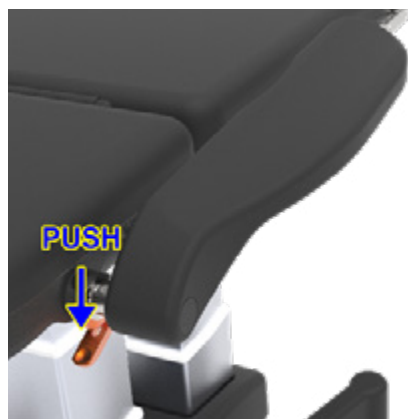
The armrests follow the movement of the backrest and are fully foldable and removable. The armrest, in a position parallel to the seat, can be pulled out by making a rotation of about $2^{\circ}/3^{\circ}$ and then pulling outward until it is fully extended.



When inserting the armrest, make sure the position indicators (indicated by arrows) on the chair and armrest match.



You can orient the armrest at an angle of up to 30° by operating the orange lever at the end of the armrest and rotating it outward, as shown in the figure.



To reposition the armrest, rotate inward until a "CLACK" is heard.

Headrest

It is interchangeable with others available and included in the Gardhen balance product range. Removal is simple and is done by simply loosening the two knobs (fig.1 - 2)

FIG. 1

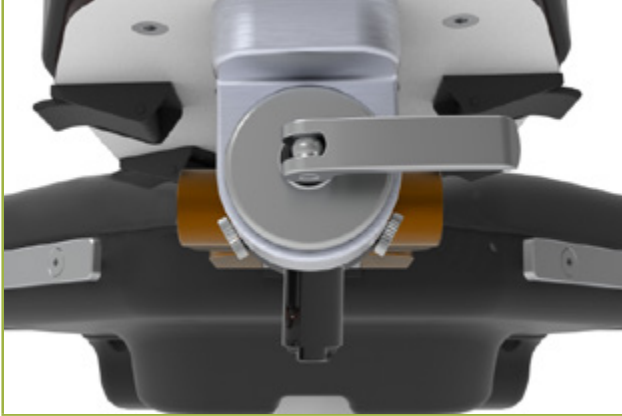


FIG. 2



and pulling out the headrest (fig. 3 - 4) as the attachment is a magnetic type. Once the headrest is reinserted, tighten the two knobs (fig.1 - 2).

FIG. 3

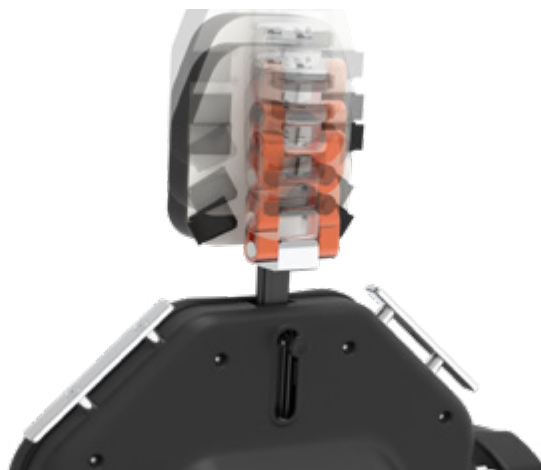


FIG. 4

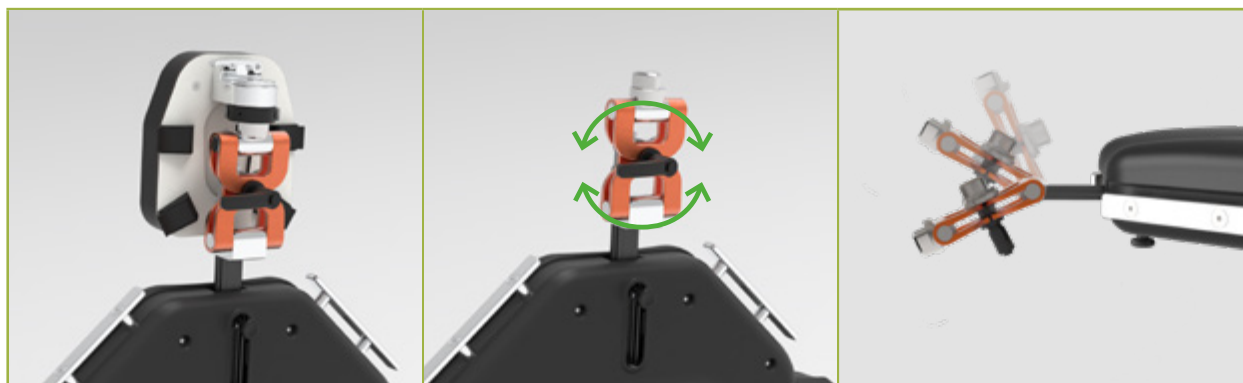


Headrest height adjustment (fig.5) is done by operating the spring plunger, pulling it (1) and simultaneously adjusting the height of the headrest (2).

Once the desired height is reached, release the spring plunger, which will automatically intercept one of the 6 positioning holes. To further secure the desired position, you will need to push the plunger back into the hole, or repeat the operation until the desired position is reached.



You can adjust the tilt of the headrest using the knob behind the butterfly mechanism. Once the tilt is adjusted tighten again to secure the position.



In addition to the above adjustments, the headrest (ACS4) is equipped with tilt adjustment from 0° to $\pm 15^{\circ}$ (fig.8). To adjust the angle $\pm 15^{\circ}$ operate the cam lever, once the desired angle is reached tighten the cam lever again.



The headrest is equipped with a face hole with the special closure cap that can be easily removed without any tools but with the simple use of hands.



The synchronous movement between the backrest and headrest ensures in all angular positions of the backrest the nuchal support of the patient, avoiding crushing and/or traction of the cervical area.



WARNING | The correct maneuver to ensure nuchal support of the patient in any angular position of the backrest is achieved by having the patient sit on the device when the device is in the "input memory position."



Carrying handles

The device is equipped with handles to facilitate small movements within the work environment.



ACCESSORIES

Please note that during consultation, you will need to take into account the allocation mentioned within the commercial document generated as a result of the order.

ACS5



On-board foot pedal controls for seat height and tilt adjustment. To be placed on the base of the device in the rear or side position (pair).

ACS6



On-board foot pedal controls for adjusting back section tilt and leg section tilt. To be placed on the base in the rear or side position (pair).

ACS43/1



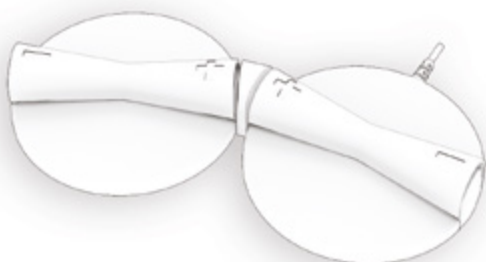
Foot pedal controls for headrest height and tilt adjustment. To be placed on the base of the device in the rear position (pair).

ACS5/4



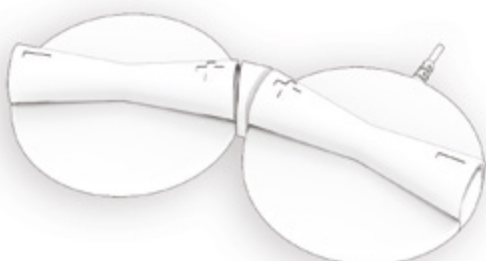
Foot controls for height adjustment and of the back section. To be placed on the base of the device in the rear position (pair).

ACS5/1



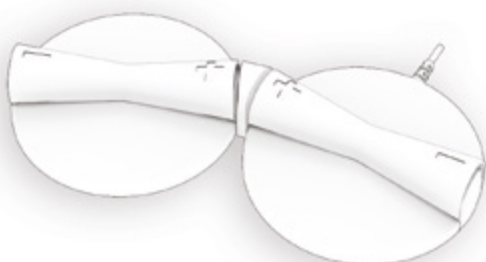
Foot pedal floor control for height adjustment and seat tilt (pair).

ACS5/2



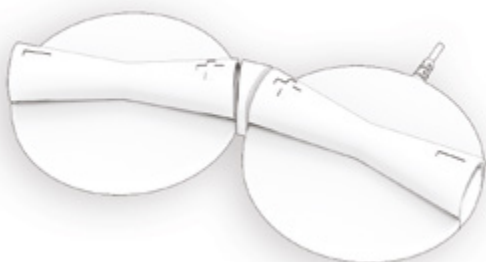
Foot pedal floor control for seat height adjustment and backrest tilt (pair).

ACS6/1



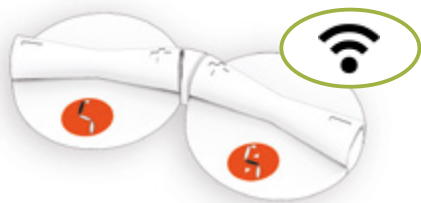
Foot pedal floor control to adjust the inclination of the back section and the inclination of the leg section (pair).

ACS43/2



Foot pedal floor control for headrest height and tilt adjustment (pair).

ACS5/3



Floor-mounted wireless foot control positioned according to surgeon's needs for: adjusting height and tilt of back section (pair).

ACS1



Synchronous occipital wrap-around headrest. Allows support of the head and prevents posterior or lateral falls. Also available in the pediatric version ACS1P.

ACS2



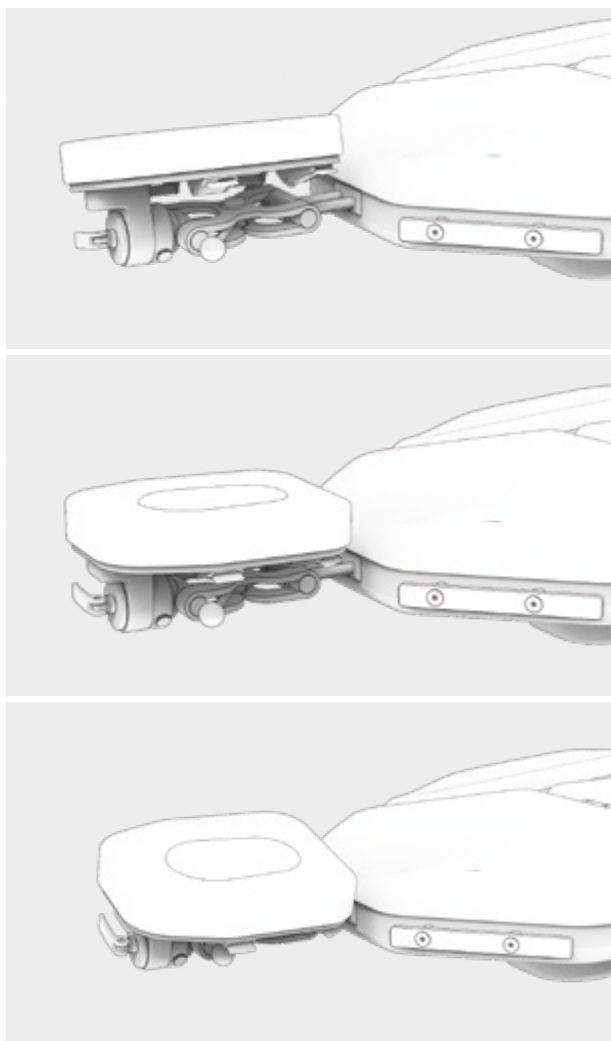
Wrapping nuchal headrest. Also available in the pediatric version ACS2P.

ACS3



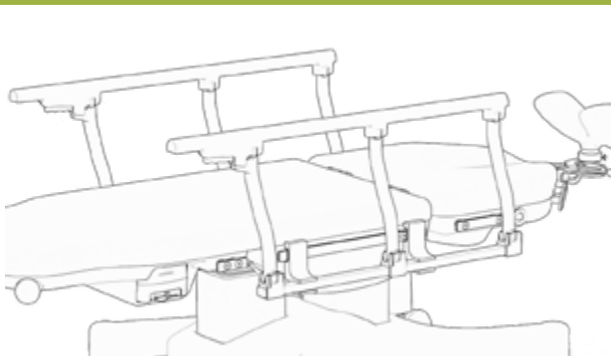
"X" headrest. Also available in the pediatric version ACS3P.

ACS4/1



Synchronous head section with face hole, bilateral adjustment from -15° to $+15^{\circ}$. Prepared for headband fastening (optional component ACS37) and chin strap (optional component ACS38).

ACS7



Pair of side rails on DIN rail. Lightweight, adjustable, washable flip-up and easily removable side rails in Stainless Steel on DIN rail.

ACS8



DIN rail mount/arm for hand surgery. Available with two attachment clamps for DIN rail mounting. Durable, lightweight radiolucent and easy to use. Coating made of water-repellent, non-toxic, antibacterial, ultra liquid-resistant technological material.

ACS8/1



DIN rail stand for hand surgery with stand, equipped with clamp and vertical adjustment so as to be stabilized at any height of the operating surface. Covered with water-repellent, non-toxic, antibacterial, ultra liquid-resistant technological material.

ACS8/2



DIN rail stand for humerus surgery with stand. For use with patient in prone position. Applies to the backrest for humerus surgery.

ACS9



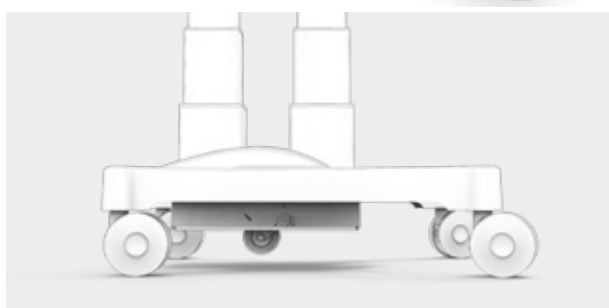
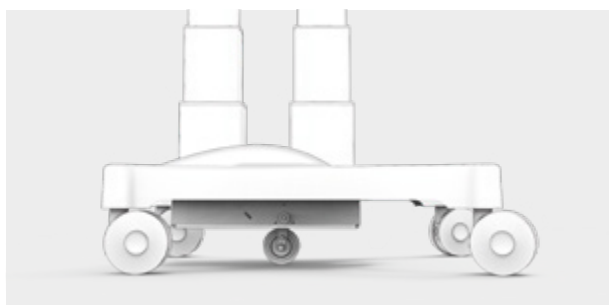
Support with band for upper limb immobilization on DIN rail.

ACS10



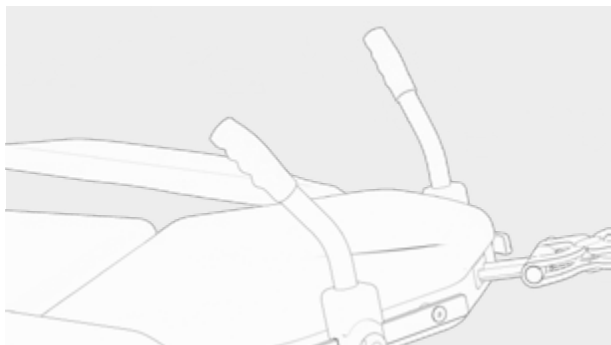
Pair of surgical forearm supports.

ACS12



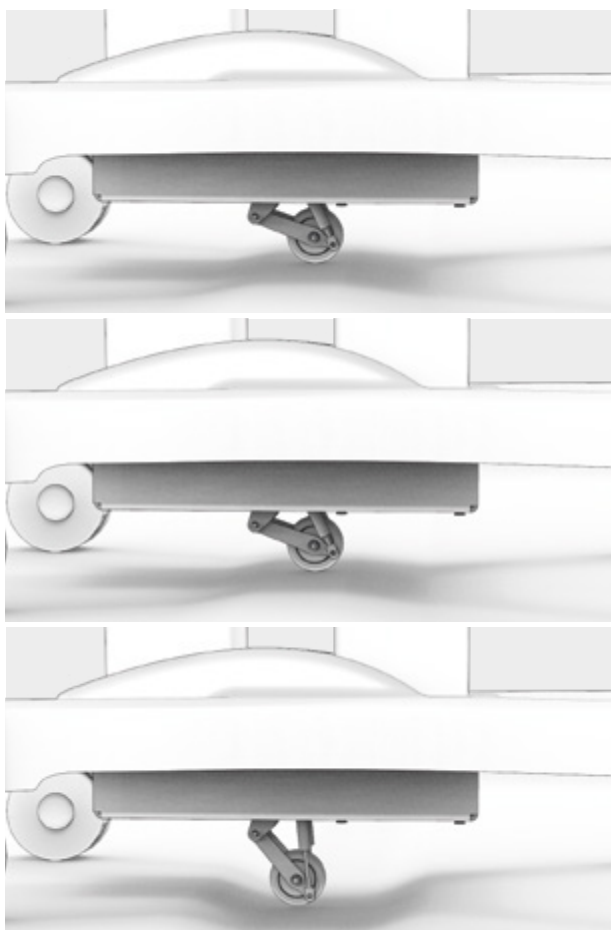
Fifth directional wheel with mechanical foot pedal engagement. It gives more stability and directionality to the device when transporting the patient from one ward to another. Makes it easier to push and steer, reducing the effort required for movement.

ACS11



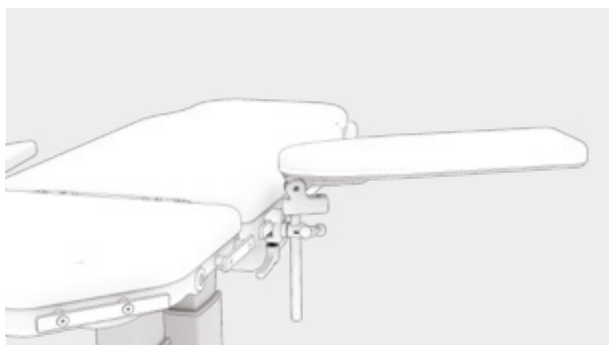
Easily removable DIN rail carrying handle. Compatible with low backrest, facilitates patient transport in both chair and crib configurations.

ACS13



Fifth swivel wheel without pedal, not retractable (fixed on the floor). Gives more stability and directionality to the device during patient transport from ward to ward.

ACS14



Multifunctional armrest on DIN rail. Height-adjustable, swiveling, tilting and easily removable. Alternative to the armrest supplied as standard.

ACS15



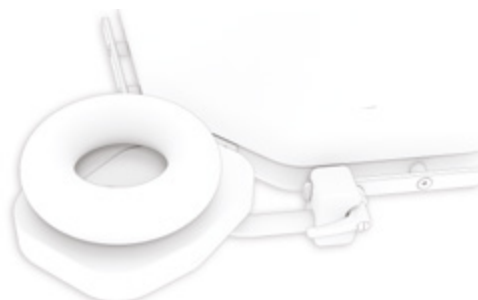
Support arm for hand control, bilaterally positionable on DIN rail. Flexible and adjustable according to the needs of the surgeon/operator.

ACS16



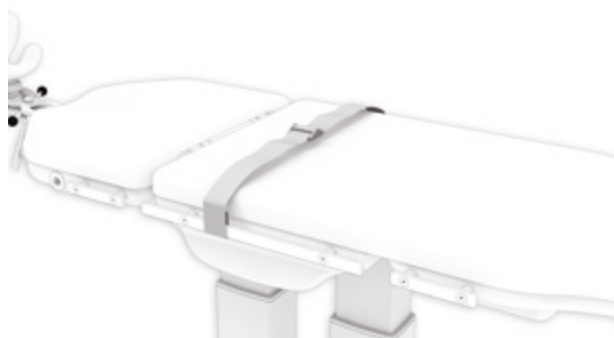
Flexible and adjustable DIN rail-mounted strapping. Available with two clamps. Used during surgery in the operating room for patient coverage and protection.

ACS18



Occipital pillow for head section.

ACS19



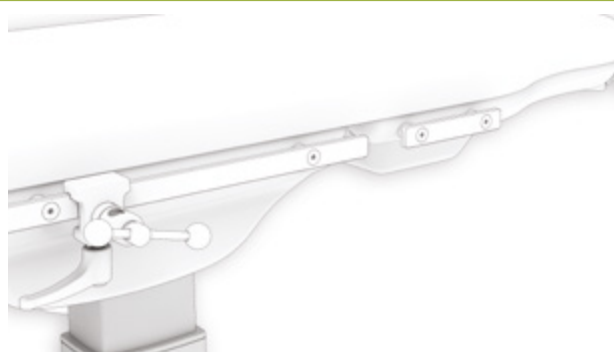
Safety belt on DIN rail. Adjustable body restraint system according to the patient's build.

ACS24



DIN rail-mounted instrument table. Available with clamp, intended to accommodate instruments needed for the completion of surgery.

ACS25



Stainless steel DIN clamp, universal, with radial joint useful for accommodating the optional components described in this section. It is operated by a single knob.

ACS26



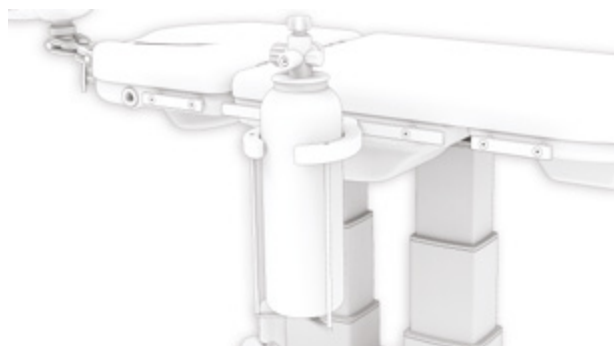
Arch ventilation face. Rapid supply of oxygen for ophthalmic surgery. Flexible rod that can be on DIN bar at the backrest to direct airflow to the patient's face.

ACS27



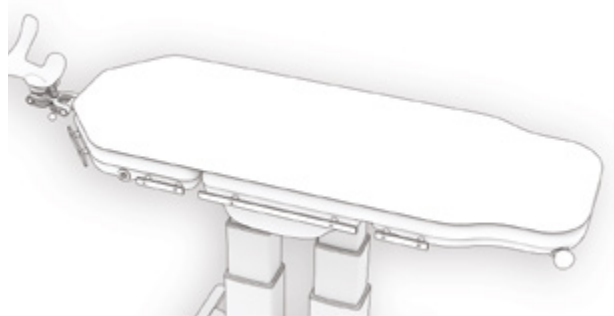
Single operating table cover. The surgical tabletop has a covering consisting of a single cushion, with no interruption.

ACS30



Tank holder on DIN rail. Can be placed on multiple points of the device thanks to quick coupling on DIN rail. Up to 7 kg.

ACS32



Additional radiolucent cushion. Allows, with the aid of X-ray plates, to perform X-rays on desired anatomical areas.

ACS33



STAINLESS STEEL, adjustable 2-hook or 4-hook DIN-rail holder rod.

ACS34



Trolley carrying optional headrest components.

ACS35



Optional component cart with DIN rail.

ACS37



Headband compatible with ACS4/1 headrest.

ACS38



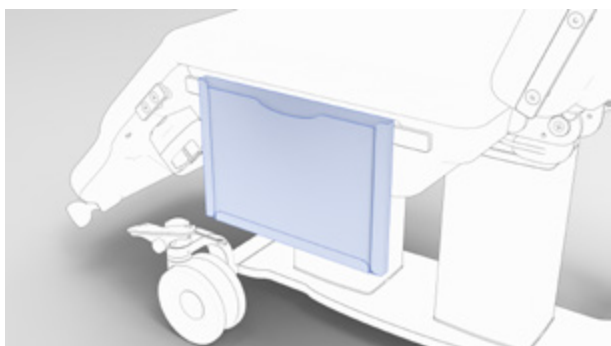
Chin rest compatible with ACS4/1 headrest.

ACS39/2



4x1 Mechanical centralized brake with anteroposterior control

ACS40



Folder holder on DIN rail.

ACS41



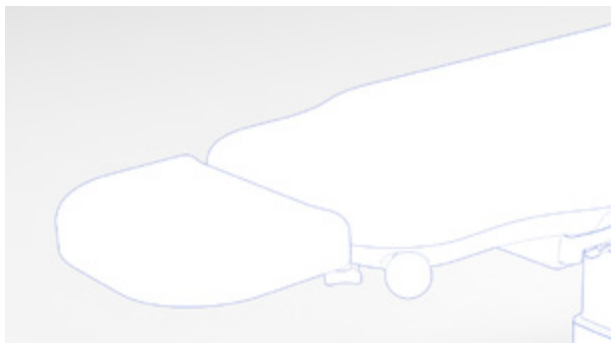
Removable monitor tray.

ACS42



Armrest with ball joint and straps on DIN rail.

ACS44



Removable leg rest extension.

ACS45



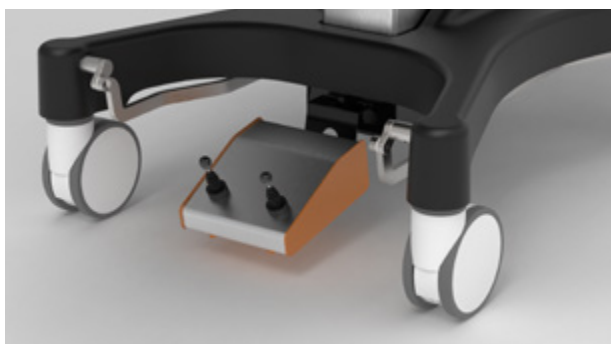
Pair of shoulder extensions on DIN rail.

ACS46



LED battery level indicator.

ACS47



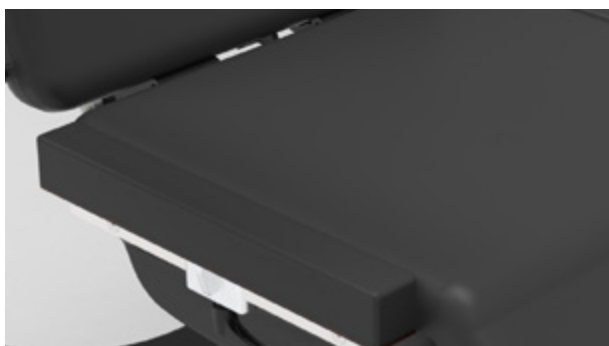
Control unit with joystick for surgeon adjustments.

ACS48



Safety system for the Trendelenburg position.

ACS49



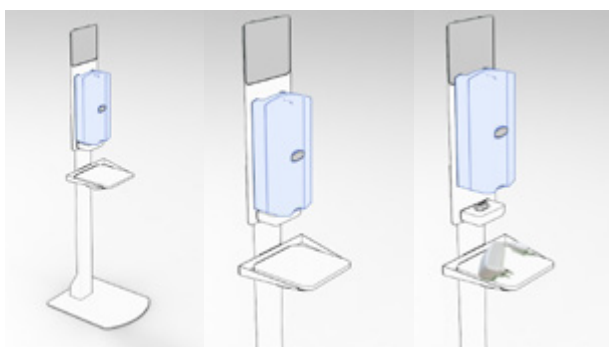
Additional elements on DIN rail for seat extension. Allows the surface area of the operating table to be extended.

ACS50



Armrests synchronous to the movement of the backrest, removable and adjustable in height

AC159



Painted steel column stand for battery charger with transformer support.

AC74/3



Red emergency stop function button. The button, when operated, instantly cuts power to all motors

DEVICE MALFUNCTIONS

The following malfunctions may occur when using the device.

Inconveniences	Resolution
The POWER ON light on the hand control does not switch on	Check power cable connections.
The POWER ON light on the hand control comes on but the weight display does not light up	Contact service.
The POWER ON light on the hand control turns on but the sections do not move	Enable the hand control via the master key. If the problem persists, contact service.
The control unit emits an acoustic signal (BEEP)	Make sure that the bed is powered.
The display shows a series of dashes at the bottom	Check that the bed's mattress support is not impacted. Switch the display off and on again. If the problem continues, contact service.
The display shows a series of dashes at the top	The maximum load capacity has been exceeded, unload some of the weight. If the problem persists, contact service.
The display shows a weight value (5 to 25 kg)	Switch the display off and on again.
Display shows a weight value > 25kg	Unload weight from the bed or contact service
Display battery icon flashing	Check that the device is connected to the 230V electrical outlet. Check that the LED on the hand control is lit; if not, contact service.
Service/maintenance	If shown on display, contact service.

MAINTENANCE AND SERVICING

Maintenance activities shall be performed in accordance with CEI EN 62353 Medical electrical equipment - Periodic inspections and tests to be carried out after repairs of medical electrical equipment by qualified personnel authorised by the manufacturer.

Preventive maintenance

Functionality and safety of the device: in order to maintain the original characteristics of this medical device in terms of operation and safety, preventive maintenance must be performed annually by personnel authorised 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 scales): to ensure the metrological fidelity of this medical device over time, the manufacturer suggests a six-monthly metrological verification of the weighing system. This activity should be entrusted to personnel authorised by the manufacturer and performed in accordance with the requirements of EN 45501.

Extraordinary maintenance

Extraordinary maintenance work must only be carried out by qualified personnel authorised by the manufacturer. Such interventions are mandatory, in particular, when:

- the device has been subjected to unusual external mechanical stress;
- the device has been subjected to dripping liquids;

- the device has been subjected to severe overheating;
- if the functionality of the device appears to be impaired;
- if any connectors, cables or other parts show signs of deterioration.

Electrical safety checks

Verifications are to be carried out annually by authorised and registered members of the professional register of verification technicians.

Periodic verifications: in case of preventive maintenance

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

The checks to be carried out are:

- visual inspection of all cables, insulations, enclosures, 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 to applied parts;
- functional test of the device.

Storage

Should the device be out of use for long periods, it must be stored in a moisture-free place and covered with cellophane. The environmental conditions to be observed are as follows -10° ÷ +40°C 90% RH non-condensing. It is recommended to carry out a functional and electrical safety check after a long period of inactivity.

Cleaning

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

Risk of injury during cleaning operations

- Ensure that all manual adjustment functions are locked.
- Check that the device is disconnected from the mains.
- Check that the parts to be cleaned are properly accessible.
- Entrust cleaning operations to suitably trained personnel.

Risk of damage to the device due to the use of incorrect cleaning agents or procedures

- The device is not machine washable.
- The device is not designed for spray, shower, pressure or steam cleaning.
- The choice of detergents/disinfectants and their correct concentration is the responsibility of authorised cleaning/disinfection personnel who are adequately instructed in the use of the type and concentration of detergents. It is also advisable to let the detergent act on hidden parts before cleaning in order to avoid unwanted discolouration.
- Do not use germicides or other radiants for disinfection if they act directly on the device.
- Follow the instructions and dosage prescribed by the manufacturer of the cleaning agents.
- Failure to follow these procedures may result in damage to the device.

WARNING | In order to disinfect the treated parts, it is advisable, when necessary and in accordance with medical procedures, to clean the device as follows: use 1% sodium hypochlorite solutions; spray the solution on the parts to be treated and then use a cloth, drying the treated parts immediately to avoid halos, stains and discolouration.



WARNING | DO NOT use corrosive or abrasive products. Do not use alcohol. Do not use abrasives on painted parts.



Should it prove necessary, in order to give the stainless steel parts a new shine, we recommend treating the device as follows

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

WARNING | 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 by specifying the device model and serial number. The company disclaims any liability or damage caused to property or persons 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 corrosion of the plates, contact the service and maintenance department for repair.

- It is forbidden to remove or open all electrical parts of the device.
- Observance of the above instructions will lead to proper use of the equipment and a longer service life.
- Any unusual occurrence must be promptly reported to the technical assistance service by fax.
- Any anomaly resulting from the incorrect use of the equipment will lead to the forfeiture of the warranty.
- Any tampering carried out by unauthorised personnel irrevocably invalidates the warranty and relieves Gardhen balance of any responsibility for the occurrence of faults.

Reconditioning

For the reconditioning of the device, please contact the supplier company at **info@gardhenbalance.it**

END-OF-LIFE AND DISPOSAL

When scrapping the equipment, it is advisable to:

- break down the device into its individual component parts (the main materials of which it is composed are: iron, wood and plastic (various types);
- collect the parts by homogeneous categories;
- dispose of electronic components as industrial waste;
- deliver mechanical and electrical equipment to a scrap metal disposal centre (the material is recyclable).

Rohs and WEEE regulation (Legislative Decree 151 of 25 July 2005): This device has been designed and assembled with high quality component materials that can be recycled and reused. The symbol of a wheeled bin covered with an X means that the product meets the requirements of EU 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 with normal household waste. Find out how to collect electrical and electronic products in the area in which you wish to dispose of the product. When purchasing a new device of an equivalent type, you can return the device to be discarded to the distributor.

Follow local waste disposal regulations and do not dispose of old products in normal household waste. Proper disposal of products helps prevent environmental pollution and possible health damage as well as avoiding penalties for non-compliance.



CONTACTS AND CERTIFICATIONS

Gardhen balance S.r.l. Via G. Luraghi - c/o Consorzio IL SOLE - Lotto S 80038

Pomigliano d'Arco (NA) - ITALY - P.IVA n° 03281501217

Telefono +39.081.8692160 | Fax +39.081.8692460

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

Certifications: for certifications please consult our website **www.gardhenbalance.it**

Warranty

Gardhen balance undertakes only to replace or repair free of charge any parts found to be defective due to faulty material or workmanship starting from the date of delivery to the recipient, for a period of 24 months. The opening of seals by unauthorised personnel shall immediately invalidate the Manufacturer's warranty. In the event that the warranty service is carried out at the User's domicile, the User shall pay a fixed call-out fee, as per the current ANIMA price list. On the other hand, the service is free of charge if it is performed at an authorised Technical Assistance Centre where the User will have the device delivered at his own expense. Whenever a technical intervention is required, the User shall present this certificate together with the fiscal receipt or purchase invoice. These documents will unequivocally certify the commencement of the warranty period, without which the warranty conditions cannot be applied.

- For the guarantee to be effective, this certificate must be sent to Gardhen balance completed in its entirety for acceptance of each of its clauses, within the actual term of 10 (ten) days from the date of delivery of the product.
- Gardhen balance will not validate certificates which have not been completed, signed and sent in the manner and within the deadline described in the previous point.
- The User loses the right to the warranty if: he does not report the defects complained of to

Gardhen bilance or to its authorised technical assistance centre within 8 (eight) days of the defect being detected; repairs carried out by unauthorised persons or repairs using non-original spare parts are discovered; tampering is detected.

- The activities covered by the warranty may take place either at the premises indicated by the User or at authorised Technical Assistance centres or at the premises of Gardhen bilance according to the technical discretion of the Manufacturer. All packaging, removal and transport costs are the responsibility of the User.
- Excluded from the guarantee are damages resulting from: improper use of the upholstery, wear and tear of the device's components, cleaning methods or use of chemical products not recommended by the Manufacturer, acts of vandalism, natural disasters, damage to any protective glass.
- The warranty conditions will not be applied in the following cases: damage or breakage caused by transport; incorrect or improper installation of the product, insufficient or abnormal electrical installations; neglect, negligence or inability to use the product; failure to follow the instructions for use; if the user is not the first purchaser; causes not dependent on the Manufacturer; interventions for alleged defects or for convenience checks.
- Gardhen bilance is not liable for any damage caused to the User as a result of failure or malfunction of the product or caused to property as a result of faulty operation.
- Nor shall Gardhen bilance be liable for damage caused by a delay in carrying out repairs or replacements of parts covered by the warranty.
- Installations and adjustments are not the responsibility of the Technical Assistance Service.
- These warranty conditions may not be altered by any other verbal or written agreement.

The Court of Naples has exclusive jurisdiction for any dispute.

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

NOTE



Gardhen balance S.r.l.

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www.gardhenbalance.it