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INSTRUCTIONS FOR USE

OP-G7+ CHAIR

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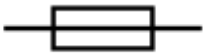
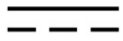
www.optomic.com

OP-G7+ CHAIR

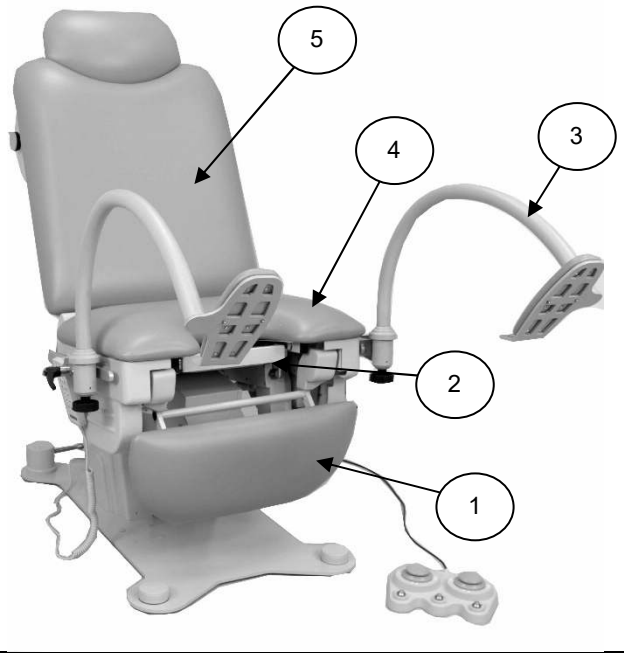
1. Table of contents

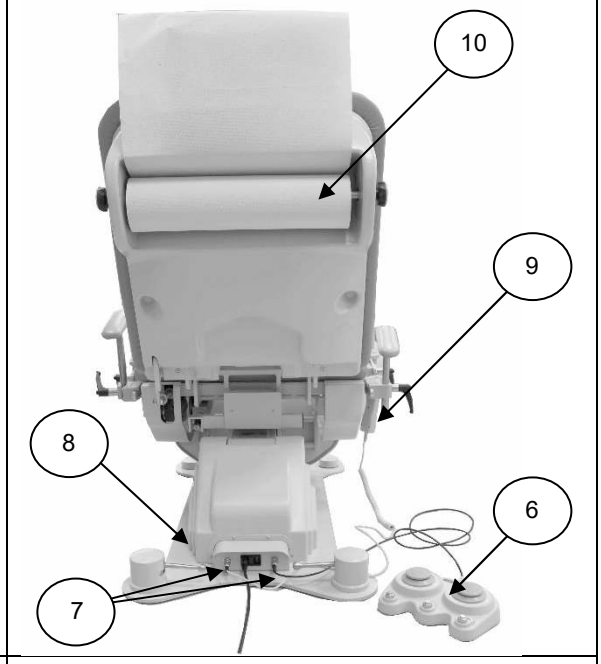
2. Symbols and safety instructions

	Warning The term Warning draws attention to a dangerous situation for the patient or the doctor. Failure to observe this notice could lead to injury to the patient or the doctor.
	Caution The term Caution draws attention to certain maintenance or safety measures that must be carried out in order to prevent deterioration of the equipment.
NOTE	Note Paragraphs preceded by the term Note contain special information for the handling of the equipment.
	Recycling symbol
	Type B device
	Manufacturer
	Serial number
	Fuses
	Waste from electrical and electronic equipment
	Instructions for use
	AC power
	Medical Device
	CE certificate

	DC power
	Earth
	Off
	On
YYYY	Identifying date of manufacture in SN XX YYYY ZZZZ – YYYY being the year of manufacture.

3. Product description





1. Leg rest	6 Foot pedal
2. Slide-out secretion tray	7 Foot pedal / Hand control connection
3. Leg supports as chosen (with foot supports or Goepel type)	8 Base
4. Seat	9 Hand control
5. Back and headrest	10 Paper roll holder

4. Intended use

The OP-G7+ chair allows all examination techniques in gynaecology, obstetrics, and urology.

The equipment must only be used by specialized personnel, with the relevant training and qualification.

Residual risks: There are no residual risks directly associated to the product.

Contraindications: There are no contraindications directly relating to the product.

Side effects: There are no side effects directly associated to the product.

5. User´s qualification

The OP-G7+ chair must only be used by personnel with the relevant medical qualifications.

The indications contained in the Instructions for use are only useful for the handling, cleaning, and maintenance of the equipment.

6. Warning indications

Please read these Instructions for use as carefully as possible and strictly observe the recommendations. The terms Warning, Caution, and Note have special meanings. They text must be read carefully as they appear in the Instructions for use.

	Read the Instructions for use carefully before using the equipment.
	Check operation and cleaning before use.
	Check the correct condition of the equipment and accessories used in combination. Damaged equipment or accessories must no longer be used.
	Accessories can only be combined as indicated in the Instructions for use. Please observe the Instructions for use and the specifications of the medical equipment used in combination.
	The device must not be used in places where there is a danger of explosion.
	The equipment must not be used with dangerous gases or together with equipment that could generate dangerous gases.
	To avoid the risk of electric shock, this equipment must be connected to a power supply with protection.
	Portable and mobile RF equipment can affect the correct operation of the equipment. In the hypothetical case of electromagnetic interference, you can eliminate them by modifying the orientation or location of the equipment, increasing the distance between pieces of equipment or connecting the different devices to independent electrical circuits.

	The use of a power supply cable other than the one supplied - except for those sold by OPTOMIC - may cause an increase in emissions or a decrease in the insusceptibility of the equipment.
	Check that there are no obstacles around the chair that could prevent operation. To ensure that the backrest can be fully reclined without any danger, we recommend keeping a distance of 2 meters from the seat to the nearest wall. To prevent accidents, please verify no person or element can be trapped by the movements of the chair. Danger of crushing/trapping. Do not place objects or elements on the internal and/or motorized parts.
	According to the legal provisions, the manufacturer is only liable for the safety specifications of the device if the maintenance, repair, and modification work is carried out by himself or by another person authorized by him. Otherwise, the manufacturer will not assume any responsibility, making NULL AND VOID the right of warranty and/or claim. The manufacturer shall also decline any liability for improper use of the equipment or if it has been used for purposes other than that for which it was MANUFACTURED. Safety-related components must only be replaced with original parts. After each modification or repair, a safety test must be carried out to ensure that the equipment complies with the technical safety specifications of current regulations.
	Repair of the device, regardless of importance, must only be carried out by qualified personnel who have passed the training course provided by OPTOMIC ESPAÑA, S.A. to authorized technicians. The user, or authorized distributor, is fully responsible for verifying that said technical personnel are qualified and authorized.

	Observe the Instructions for use for cleaning and maintenance of the equipment.

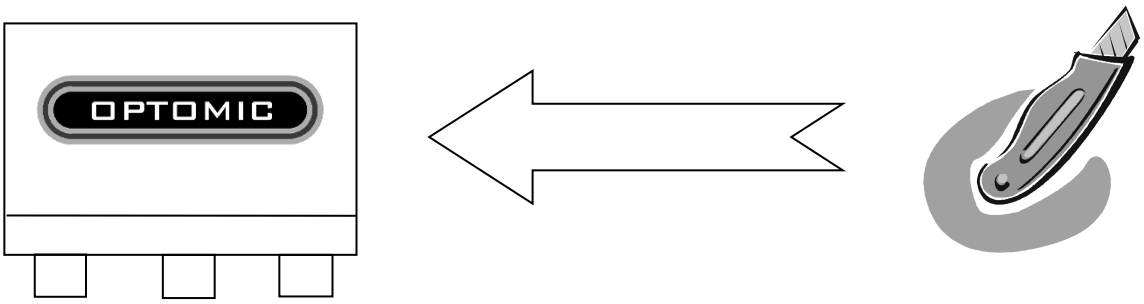
NOTE	Equipment deterioration arising from the incorrect handling of the equipment will not be recognized as guaranteed.
	 This equipment contains electronic components that can be harmful to the environment if not managed properly, so once the useful life of the equipment is over, the applicable national and local regulations on management of electrical and electronic waste, or the product must be followed. It may be returned to OPTOMIC for the recycling of hazardous components.
	Any serious incident regarding the product must be reported to the manufacturer and to the competent authority of the member state where user and/or patient are established.

7. Unpacking and list of contents

Verify the completeness of the device received and check for possible transport damages. In the event of complaints, please contact OPTOMIC immediately.

For transport, the OP-G7+ chair is fixed by its base to a wooden pallet.

To unpack the chair, cut the two tension straps and remove all the screws. Open the wooden cover and lift the wooden element carefully so as not to rub against the chair.

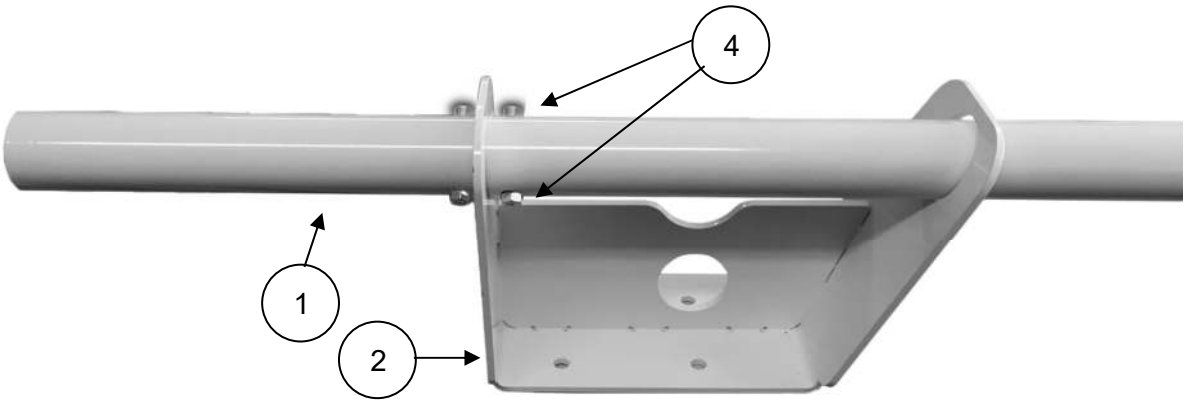


Next, find the two transport bars supplied with the chair.

Remove the four wooden pieces fixing the chair to the pallet.

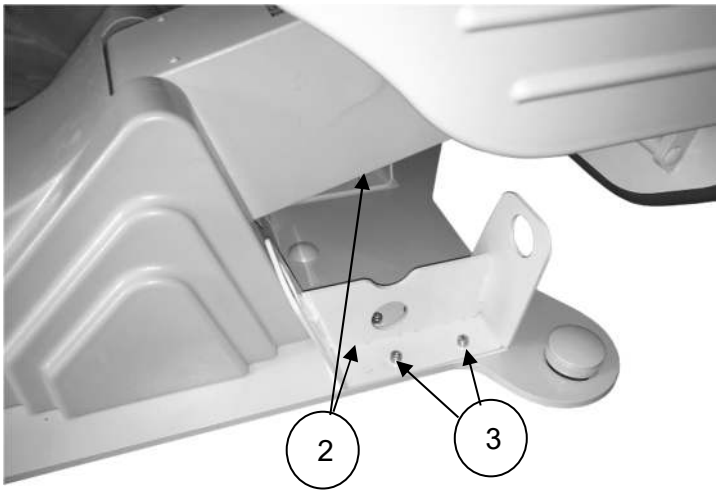
Connect the chair to the power supply (see paragraph 8.2, Connections) and raise the chair seat to insert the transport bars.

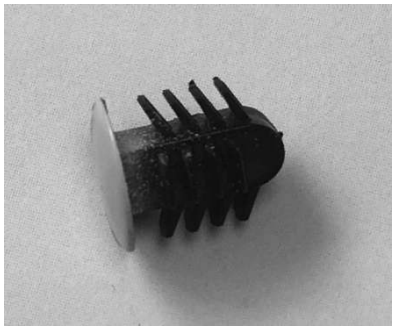
Insert the transport bar **[1]** through the holes in the transport support **[2].** Place the M6x45 screws **[4]** with their nut, to prevent the transport bar from slipping.



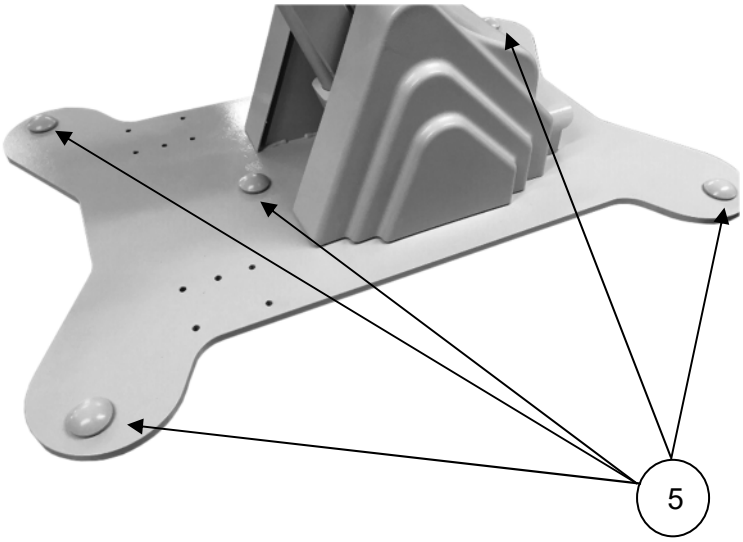
Bring the chair to the location where it will be installed.

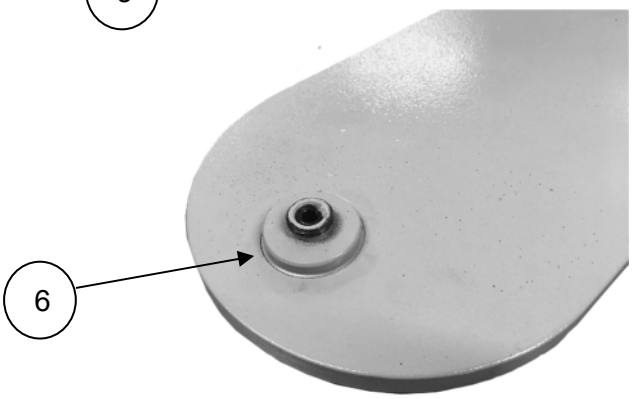
Using the 6mm Allen key, remove the transport supports **[2],** removing the M8 screws **[3]** fixing them to the equipment. Once the transport supports have been removed, the decorative caps **[7]** will be placed in the visible holes on the base.





Finally, remove the base decorative caps **[5]** to access the levellers **[6]**. With the 5mm Allen key, adjust the levellers until the chair is completely stable.





List of contents:

- Chair
- Pedal
- Hand control
- 2 fuses 10T
- Paper roll
- Transport bars
- Instructions for use
- Tools
  - 6mm Allen key
  - 5mm Allen key
  - 2 x M6x45 Screws
  - 2 x M6 Nuts
  - 10 x Decorative caps

8. Operation

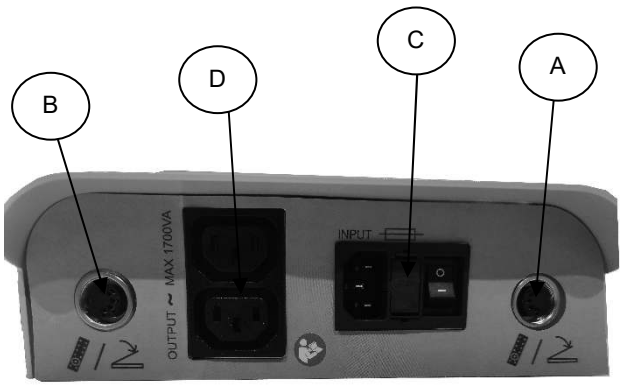
8.1. Placing of leg supports

Loosen the attachment handle until the mechanism is released.

Insert the leg support in the rail, sliding it to the desired position and re-tighten the handle.

The handle must be released so that the tightening system is loose.

8.2. Connections



Connect the pedal to the base of the seat, in either of the two positions indicated in the drawing. (A or B).

The connector has a determined position to ensure proper connection.

Connect the hand control to the base of the seat, in either of the two positions indicated in the drawing. (A or B).

The connector has a determined position to ensure proper connection.

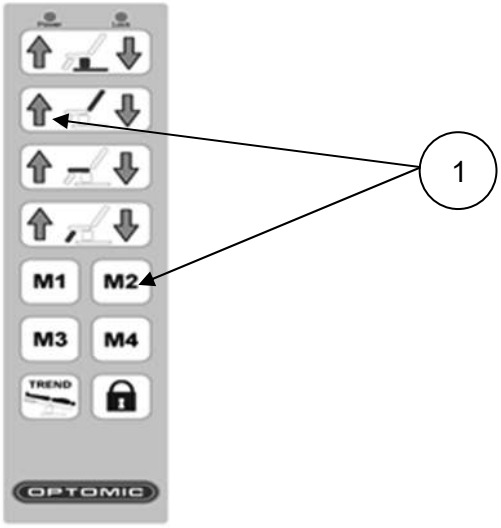
Connect the mains cable (C).
Switch on the equipment.
2 beeps will be heard indicating that the system is ready for use, and the green LED on the remote (power) will light up.

The equipment has two voltage outputs (D) for connecting other equipment.

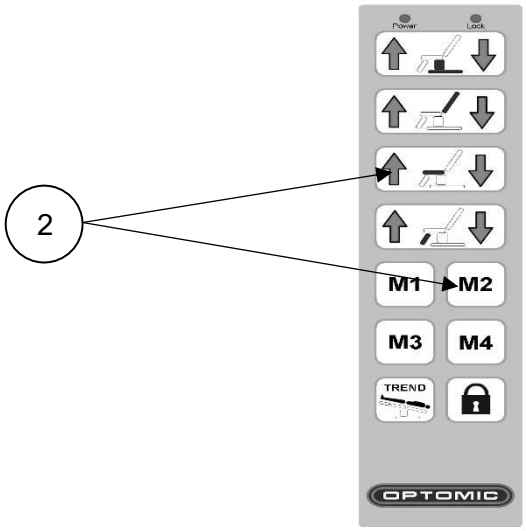
8.3. Sensor calibration

To the correct sensor calibration proceed as follows:

1. Turn off the OP-G7+
2. Press and hold “Backrest Up” and “M2” buttons at the same time.



3. While pressing switch on the device until you hear the confirmation beep (green and red leds start flashing). You are now in calibration mode.
4. Set he chair as follows:
   Press backrest up button to its maximum
   Press pelvic movement button to its maximum.
   Press leg rest movement down to its end
   Press chair lowering movement button to its end.
5. Press and hold “Pelvic movement up” and “M2” buttons at the same time until you hear the confirmation beep (green and red leds light fixed).



6. Turn off the device.
7. Switch on the device.

9. Operation of the equipment

NOTE: If an anti-Trendelenburg memory is required, you can record it up to 8º. This is done by manually bringing the backrest to 0º, and moving the seat up to those negative 8º, the desired height, about 6cm of safety, and then record as indicated in the section on Programming Memories.

 As a safety measure, the chair is programmed so that the leg rest will automatically retract when it is lowered to a given height,

 When the chair is in welcome position, or very close to it, if you want to make a movement or go to a memory, the chair will automatically go up 6 cm for safety and from there it will go to the chosen memory or to the movement required manually .

 If you wish to manually lower the chair to the lowest position, while it is lowering and when it reaches the area of those 6cm, it will automatically set the seat to 0º, the leg rest will be fully retracted (safety measure in case it had not been fully retracted), and the backrest will rise at least 15º if it is below 180º.

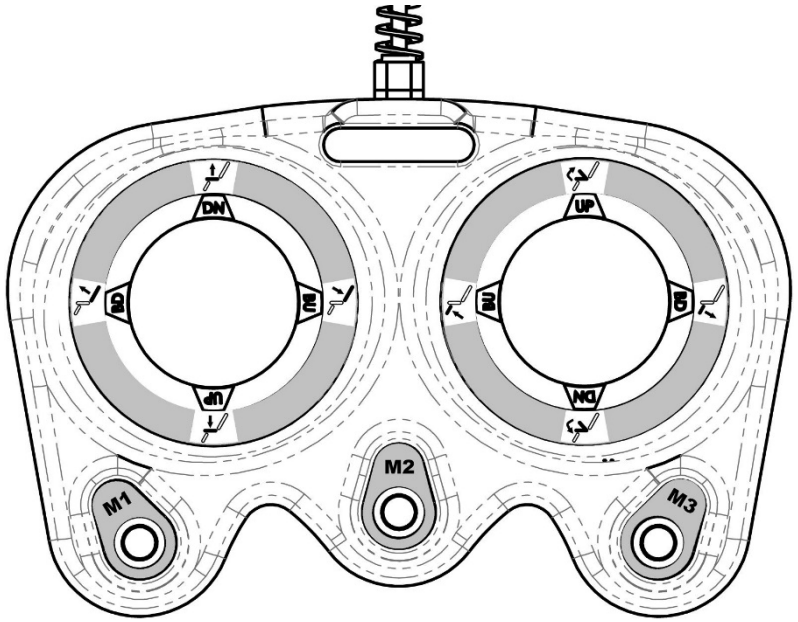
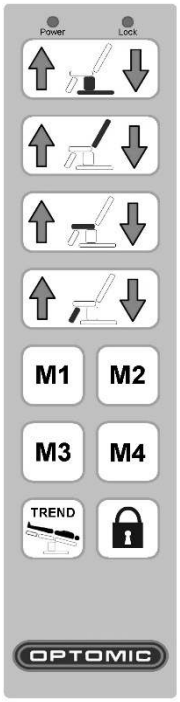
 As a safety measure, the chair is programmed to perform some movements from a determined minimum height. If the chair detects it is not at that safety height, it will lift until reaching it, and only then will it proceed with the movement indicated by the user.

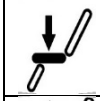
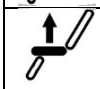
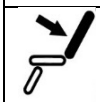
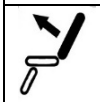
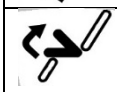
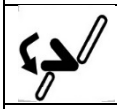
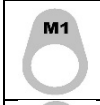
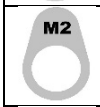
9.1. Movements

THE 4 MAIN MOVEMENTS

The OP-G7+ chair has the motorized fundamental movements required for patient positioning in gynaecological, obstetric and urology practices.

Using the pedal or hand control, the chair can be moved to any desired position.

	
PEDAL	HAND CONTROL

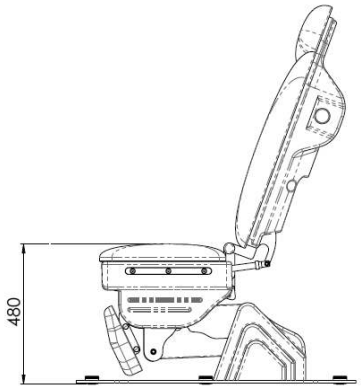
SYMBOLS			
PEDAL		**HAND CONTROL**	
	Lowering the chair		Chair raising and lowering movement
	Raising the chair		
	Backrest decline		Backrest movement
	Backrest up		
	Leg rest down		Leg rest movement
	Leg rest up		
	Pelvic movement -		Pelvic movement
	Pelvic movement +		
	Programmable memory 1		Programmable memory 1
	Programmable memory 2		Programmable memory 2
	Programmable memory 3		Programmable memory 3
			Programmable memory 4
			Trendelenburg position (programmable by user)
			Movement blocking. The red LED “lock” lights up when the function is activated. To unlock it, press again.

As a safety measure, the chair is programmed to perform some movements from a determined minimum height. If the chair detects it is not at that safety height, it will raise until reaching it, and only then will it proceed with the movement indicated by the user.

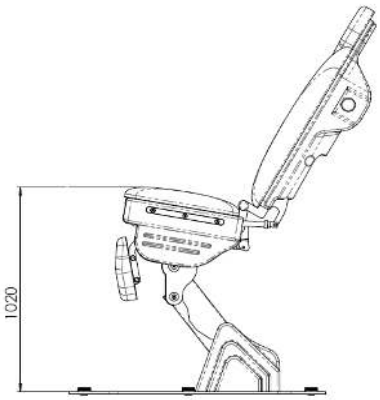
9.2. Range of movements

MOTORIZED RAISING AND LOWERING MOVEMENT

Minimum: **480 mm**
Maximum **1.020 mm**



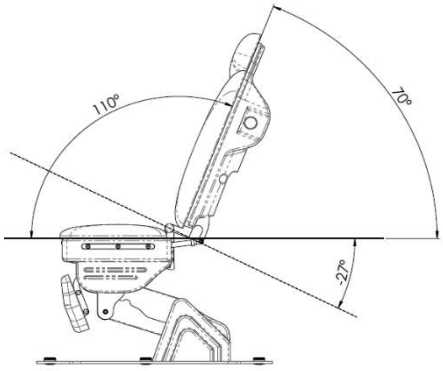
LOWEST



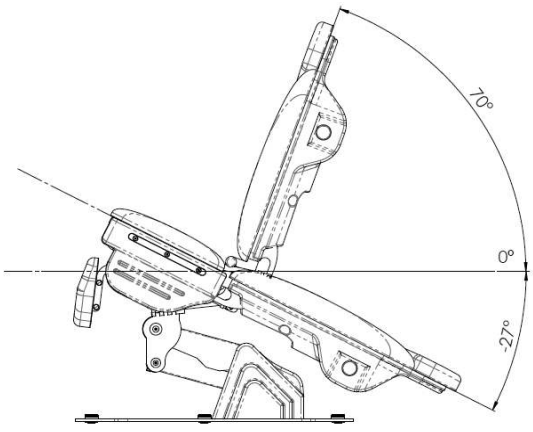
HIGHEST

MOTORIZED BACKREST MOVEMENT:

Maximum: **+70º**
Minimum: **-30º**



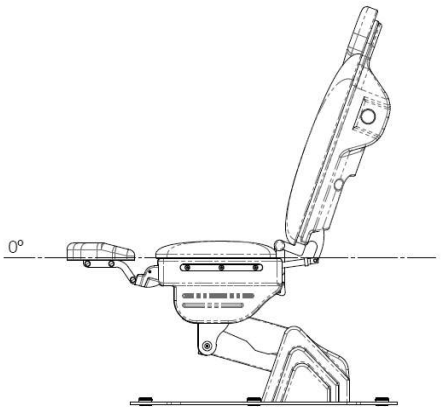
MAXIMUM



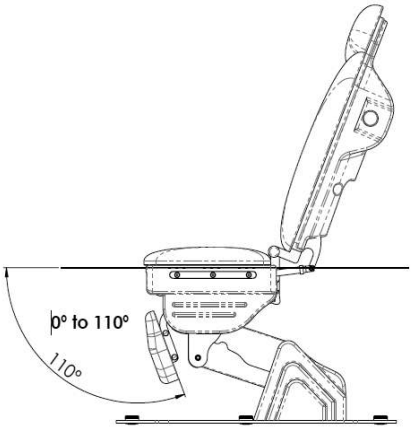
MINIMUM

MOTORIZED LEG REST SECTION PLATE MOVEMENT:

Maximum: **0º** horizontal - laid out
Minimum: **-110º** fold up - hidden



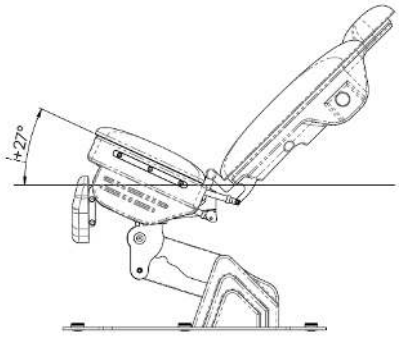
MAXIMUM



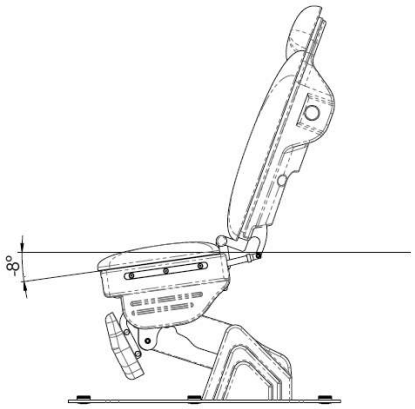
MINIMUM

MOTORIZED PELVIC ANGLE MOVEMENT:

Maximum: **+27º** positive examination angle
Minimum: **-8º** negative examination angle



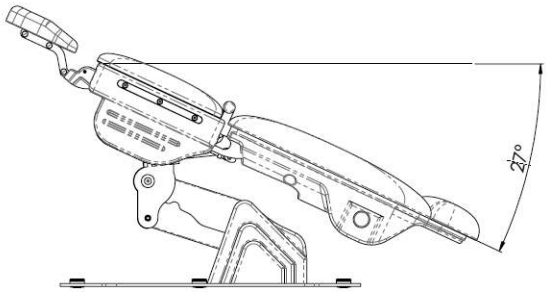
MAXIMUM

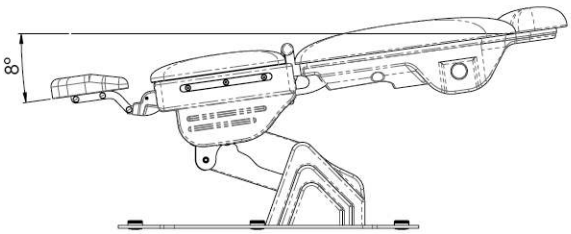


MINIMUM

TRENDELENBURG AND ANTI-TRENDELENBURG POSITIONS:

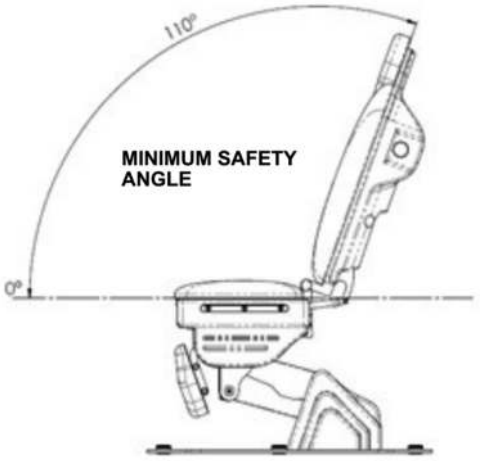
Trendelenburg: **-30º**
Anti-Trendelenburg: **8º**





MINIMUM SAFETY ANGLE:

Minimum 110º Safety System



9.3. Programmed memories

The OP-G7+ chair has 8 programmable memories; two of them programmed at the factory (with the possibility of reprogramming), Trendelenburg, as well as M1 (welcome).

- Trendelenburg: Memory located in the hand control.

  By pressing this memory, the chair will action backrest, seat and lifting-up to -12º, automatically and working together. The user can reprogram this memory from -5º to -30º.

- M1 (Welcome): Memory located both on the pedal and hand control.

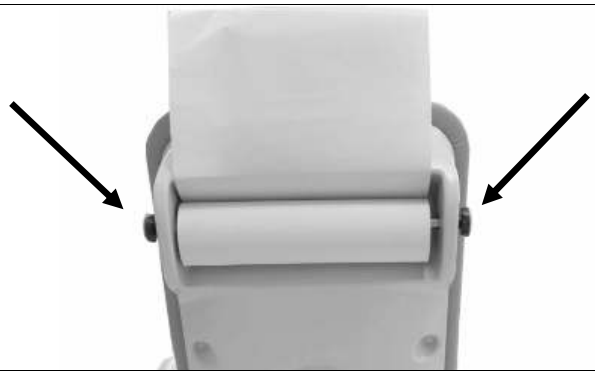
  This is the welcome position, making it easier to sit in the chair. By pressing M1, the chair will automatically lower the seat to 0º position, the backrest to 110º position, the leg rest will be fully retracted, and height will be positioned at the lowest point. This memory can be reprogrammed in both controls, but it is advisable to keep it at least in one of them.

Memory programming:

1. Set the desired position.
2. Choose the memory (foot or hand control) and press the button for 6 seconds to have it saved. A confirmation beep will be heard.

If you stop pressing manually, all automatic movements will stop, leaving the chair in the position set and ready for manual or memory movements.

9.4. Paper roll placing

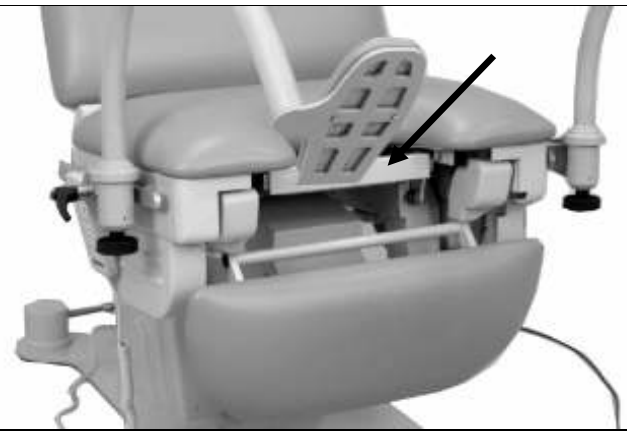


To place the new paper roll, unscrew the knobs indicated in the drawing. Both knobs will come out of their housing with a shaft.

Hold the roll in its position, insert the knob and fix it. Repeat the operation with the other one.

If there is a roll of paper already placed, hold it with one hand, preventing it from falling. To insert the new roll of paper, keep holding it until the two knobs are secure.

9.5. Secretion tray



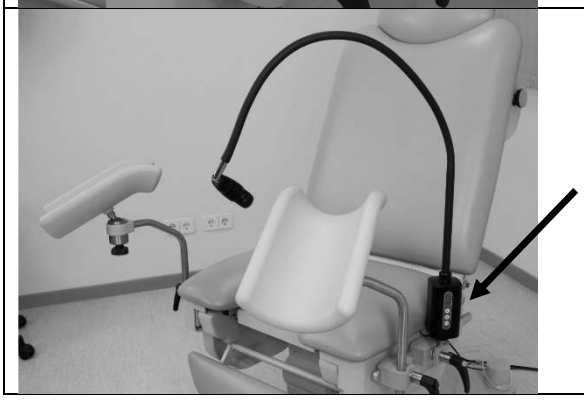
The secretion tray has a manual opening and closing system with a brake.

To remove the secretion tray, the leg rest must be folded down.

10. Accessories

10.1. LED examination lamp

Positioning the examination lamp

	Loosen the attachment handle until the mechanism is released. Insert the examination lamp in the rail, sliding it to the desired position and re-tighten the handle.
	Connect the plug of the lamp to the auxiliary power socket of the chair, located on the left side under the rail.

The lamp is designed for partial illumination of the area to be examined.

- Small lamp holder of only 35mm in diameter, not blocking the sight line of doctor and nurse.
- 100cm flexible cross arm.
- Electronic transformer to control brightness.

Technical specifications of the examination lamp

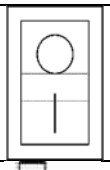
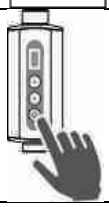
Power	3W
LED number	1 LED
Light intensity	5.000 lx - 68.000lx D=30cm
	1.200lx – 52.000lx D=40cm
Lamp field diameter	Max. 200mm Min. 50mm D=30cm Max. 250mm Min. 55mm D=40cm
Colour temperature	4.800 - 5.500K
Control system	Brightness graduation adjustment
Voltage	5V

Settings of the examination lamp

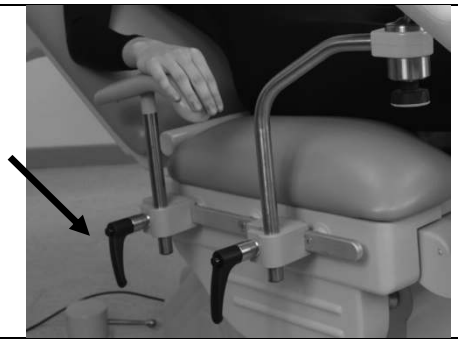
Setting the position of the lamp:

Hold the flexible arm and gently pull the lamp head to adjust the position.

Brightness settings:

	Put the rear switch in position "I" (On)
	Gently touch on control panel to increase○,▲ or decrease○,▼ light intensity. The setting range has 5 levels.

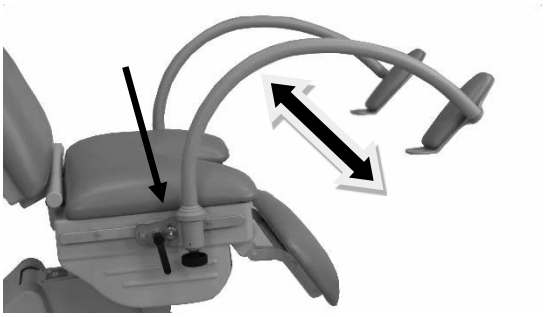
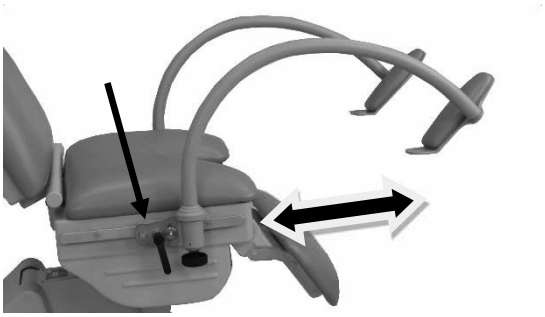
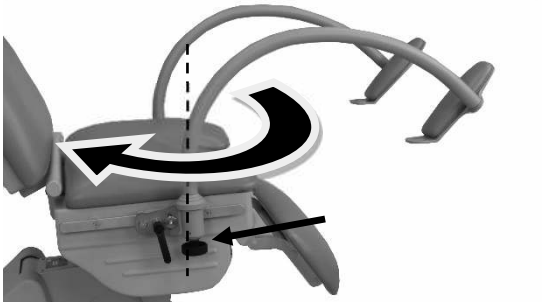
10.2. Armrest

	Loosen the attachment handle until the mechanism is released. Insert the armrest in the rail, sliding it to the desired position and re-tighten the handle.

10.3. Leg supports with foot supports

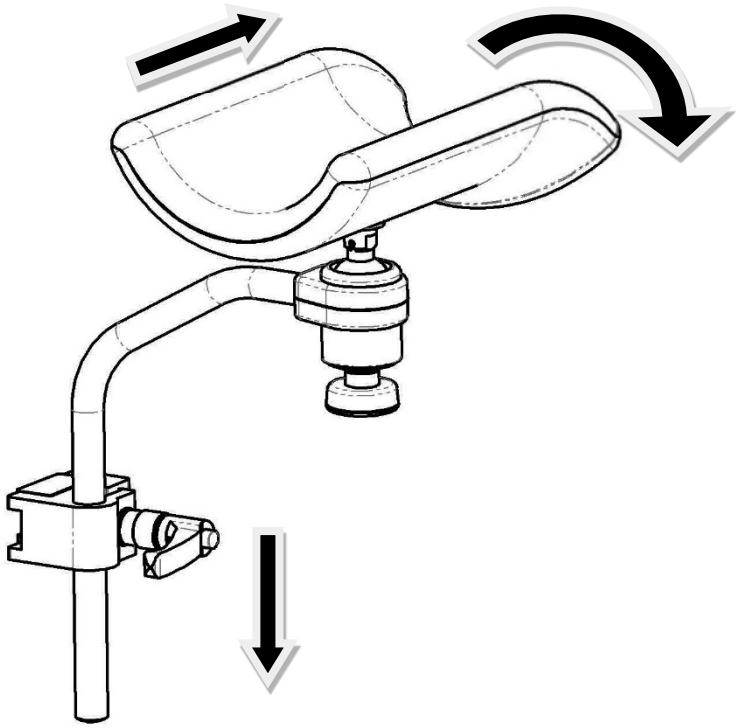
The OP-G7+ chair is provided with 2 rails located on each side of the seat. The leg supports are placed on these rails. The rails have standard size, so any accessory compatible with said standard - which does not affect normal operation - can be used. Size: 25 x 10mm.

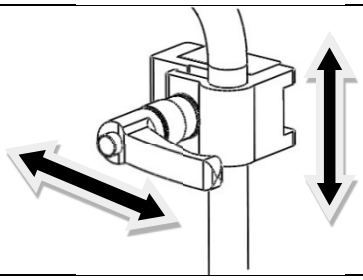
The leg supports with foot supports come with a cushioned support to use when the patient is barefoot. The cushioned support is magnetically attached, making it very easy to remove for patients wearing shoes.

	Leg support reclining movement. ⚠ The leg support needs to be held while changing position. It has 3 positions. To change inclination, release and pull out the bolt and fixing shaft, find the desired position, insert and tighten the control.
	Leg support movement on the rail. ⚠ The leg support needs to be held while changing position. Loosen the handle and slide the leg support along the rail to the desired position. Fix the handle again.
	Regulating leg support opening. ⚠ The leg support needs to be held while changing position. Using the control, you can modify the position of the bar, allowing it to open to the outside.

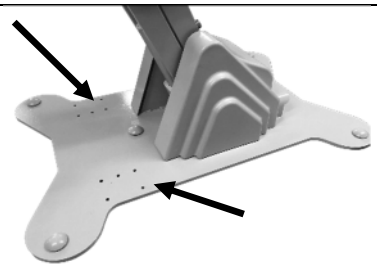
10.4. Goepel leg supports

The OP-G7+ chair is provided with 2 rails located on each side of the seat. The leg supports are placed on these rails. The rails have standard size, so any accessory compatible with said standard - which does not affect normal operation - can be used. Size: 25 x 10mm.



	Leg support cushion angle settings. This is a pre-set movement, so the control is used as a locking device once the patient is comfortably sitting.
	Leg support cushion position settings. The handle is used to fix the position once height and lateral position are reached.

10.5. Colposcope support

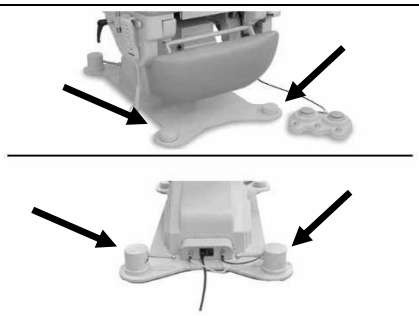


Remove the caps.

Place the colposcope support and fix it to the chair with the bolts.

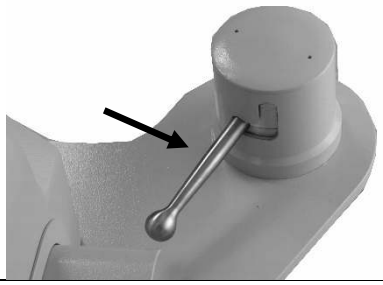
The colposcope support can be attached to both sides.

10.6. Hidden wheel system



The chair has four built-in wheels: Two of them located in the front and two in the rear.

To move the chair, it is necessary to release the rear wheels.



To release the rear wheels, looking at the back of the chair:

1. Step on the right lever and move backwards.
2. Step on the left lever and move backwards.

Once the chair is in place, re-lock the rear wheels, following the instructions inversely.

11. Cleaning and maintenance

<table>
<tr><td rowspan="4">  </td><td>To carry out any cleaning or maintenance work, disconnect the equipment from power supply.</td></tr>
<tr><td>During the preparation and application of solutions, strictly observe the instructions of the chemical product manufacturer regarding concentration and application time.</td></tr>
<tr><td>Disinfectant liquids are compounds that violently attack materials, and over time they lose their physical properties, so the use of these liquids should be as limited as possible.</td></tr>
<tr><td>To clean and disinfect outer surfaces of the equipment, use a clean cloth, slightly moistened, with a disinfectant solution (solution according to use instructions from the manufacturer).

<table><tr><th>Disinfectant</th><th>Manufacturer</th></tr><tr><td>Dismozon Plus</td><td>Bode Chemie, Germany</td></tr><tr><td>Green & Clean SK</td><td>Metasys, Austria</td></tr><tr><td>Sani-Cloth Active</td><td>Ecolab, Germany</td></tr></table></td></tr>
<tr><td>  </td><td>During each cleaning, check the perfect state of conservation of all the equipment parts.</td></tr>
</table>

Periodic inspection: A professional expert must periodically carry out a functional and safety inspection.

11.1. Fuse replacement

- Disconnect power cable from the mains.
- Disconnect chair power cable from power base.
- The fuse box is next to the switch, where the two fuses are located. The box has a small gap on the side to open it using a screwdriver.
- Replace the blown fuses and insert mentioned box as far as it will go.
- Connect the power cable to the chair and then to the mains.

12. Troubleshooting

ISSUE	POSSIBLE CAUSE	ACTION
Chair will not respond	Power cable is not connected	Plug in power cable
	Blown fuses	Replace fuses (Point 10)
	Electronic issue	Contact Technical Service
Chair will not respond to the pedal or hand controls	Controls in bad condition	Contact Technical Service
	It is not receiving power	Verify that it is properly connected
Leg rest falls down	Attachment system handle is released	Adjust attachment system handle
Chair movements not working properly	Loss of coordinate origins	

RETURN OF THE EQUIPMENT

If the device needs to be returned to factory, it must be shipped with the original packaging.

OPTOMIC ESPAÑA, S.A. is not to be held responsible for the damages or defects caused during transport due to deficient packing or incorrect handling.

When returning the device, please enclose the following information:

- Name of the owner
- Address of the owner
- Serial number of the device
- Description of the problem

13. Technical specifications

ELECTRICAL

Power connection ..... 110/230V - 50/60Hz
Maximum power demanded by the chair ..... 400 VA
Class ..... B
Medical device group ..... UNE EN 60601-1
Fuses ..... IEC 60127-2 - 2x 10A 250V~ T
Degree of protection IPX0

OTHER FEATURES

Max. allowable load ..... 310 kg
Upholstery ..... PUR-PVC washable and antibacterial polyester
..... Available in different colours
Fire regulations ..... Fireproof class M2 – B55852 1-2
Paper roll holder ..... 140mm diameter x 490mm length
Secretion tray ..... Stainless steel. Capacity of 2,5 l

ALLOWABLE ENVIRONMENTAL CONDITIONS

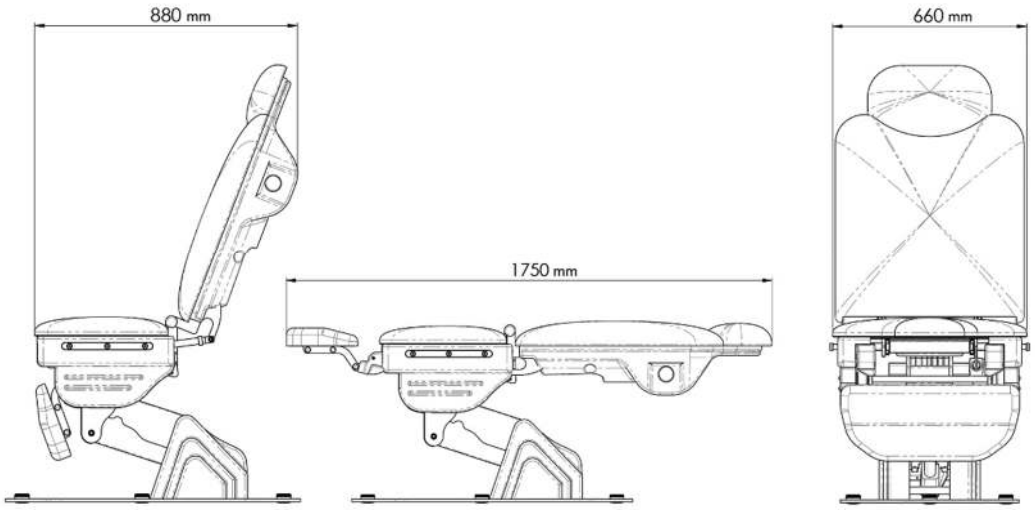
For use ..... 2~+45ºC, 20~90%RH, non-condensing
For transport ..... -10~+70ºC, 10~95%RH, non-condensing
For storage ..... -10~+70ºC, 10~95%RH, non-condensing
Air pressure ..... 700 – 1060 hPa

PRODUCT CLASSIFICATION

The OP-G7+ CHAIR is a **Class I** product according to Regulation (EU) 2017/745 on medical devices.

MECHANICS

Max. seat height ..... 1.020 mm
Min. seat height ..... 480 mm
Backrest max. inclination (Trendelenburg) ..... -30º
Pelvic movement ..... +27º - 8º
Leg rest movement ..... +0º -110º


880 mm
1750 mm
660 mm

14. Electromagnetic compatibility

Manufacturer's guide and declaration - electromagnetic emissions		
The equipment is intended for use in the electromagnetic environment specified below. The customer or user of the equipment must assure that it is used in the mentioned environment.		
Emissions test	**Compliance**	**Electromagnetic Environment - Guide**
RF CISPR11 emissions	Group 1	The equipment uses DR energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF CISPR11 emissions	Class B	The equipment is suitable for use in all establishments other than domestic establishments, and may be used in domestic establishments and those connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided that the following warning is considered: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. Mitigation measures may be required such as reorientation or relocation of the equipment or shielding the site.
IEC 61000-3-2 harmonic emissions	Class A	
Voltage fluctuations / IEC 61000-3-3 flicker emissions	Complies	

The equipment must not be used stacked or next to other equipment. If it is necessary to use it stacked or next to other equipment, it must be observed to verify normal operation in the configuration of use.

Manufacturer's guide and declaration - Electromagnetic immunity			
The equipment is intended for use in the electromagnetic environment specified below. The customer or user of the equipment must assure that it is used in the mentioned environment.			
Immunity test	**Test level of IEC 60601 Standard**	**Level of compliance**	**Electromagnetic Environment - Guide**
Electrostatic discharge IEC 61000-4-2	±8 kV by contact ±15kV by air	±8 kV by contact ±15kV by air	Floors should be wood, concrete, or ceramic tile. If the floor is covered with synthetic material, relative humidity should be at least 30%.
Fast Transients IEC 61000-4-4	±2 kV for mains supply. ±1kV for input/output lines 100 kHz	±2 kV for mains supply. ±1kV for input/output lines	Power supply quality should be that of a typical commercial or hospital environment.
Shock wave IEC 61000-4-5	±1 kV line ±2kV earth	±1 kV line ±2kV earth	Power supply quality should be that of a typical commercial or hospital environment.
Outages and interruptions IEC-61000-4-11	- 0% U_T; 0.5 cycle at 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º. - 0% U_T; 1 cycle. - 70% U_T; 25/30 cycles (at 0º). - 0% U_T; 250/300 cycles. NOTE: U_T = AC power supply voltage before application of test level.	- 0% U_T; 0.5 cycle at 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º. - 0% U_T; 1 cycle. - 70% U_T; 25/30 cycles (at 0º). - 0% U_T; 250/300 cycles.	Power supply quality should be that of a typical commercial or hospital environment. If the equipment user requires continued operation during power interruptions, it is recommended to have the equipment powered from an uninterrupted power supply or battery.
Magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Power frequency magnetic fields should be at levels typical of a commercial or hospital environment.
Conducted RF Immunity IEC 61000-4-6 Radiated Immunity IEC61000-4-3	3 V 150 kHz at 80 MHz 6 V ISM bands 3 V/m de 80 MHz at 2.7 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance at the transmitter frequency.

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