Specificația Tehnică Completată

Model: OP-S8, PN:68243114, DM: DM000568831 User Manual OP-S8 Chair , Producător:OPTOMIC ESPANA S.A. , Țara:Spania .

Specificarea tehnică deplină solicitată de către	Specificarea tehnică deplină propusă de către
autoritatea contractantă	autoritatea ofertantă
Denumire Fotoliu ORL	Denumire Fotoliu ORL - DA
Descriere Fotoliu ORL este un fotoliu utilizat în timpul	Descriere Fotoliu ORL este un fotoliu utilizat în timpul
intervențiilor otorinolaringologice	intervențiilor otorinolaringologice DA
Descriere generală	Descriere generală
Număr de segmente 3, picioare, șezut, spate	Număr de segmente 3, picioare, șezut, spate DA din brosura OP-S8.
Ajustare pozitie electrică	Ajustare pozitie electrică DA pag. 4 din brosura OP-S8
Cotiere ajustabil	Cotiere ajustabil DA pag. 13 din User Manual OP-S8
	Chair.
Suport pentru cap ajustabil	Suport pentru cap ajustabil DA pag. 8 din User Manual OP-S8 Chair.
Suport pentru tălpi	Suport pentru tălpi DA pag. 4 din brosura OP-S8
Tipuri de mișcări Trendelinburg, antitrendelinburg, sus-	Tipuri de mișcări Trendelinburg, antitrendelinburg, sus-
jos, ajustare unghi spate și suport picioare	jos, ajustare unghi spate și suport picioare DA din brosura OP-S8.
Greutate susținută maximă Minim 180 kg	Greutate susținută maximă 200 kg DA pag. 4 din brosura OP-S8.
Suprafață lavabilă rezistentă la dezinfectanți	Suprafață lavabilă rezistentă la dezinfectanți DA pag. 4 din User Manual OP-S8 Chair.
Grosimea tapițeriei Minim 5 cm de densitate înaltă.	Grosimea tapițeriei Minim 5 cm de densitate înaltă. DA
Cerință către furnizor	Cerință către furnizor
Garanție Minim 2 ani	Garanție DA 2 ani.
Livrare la locul solicitat Instalare și dare în exploatare	Livrare la locul solicitat Instalare și dare în exploatare DA
Training pentru utilizatori și ingineri	Training pentru utilizatori și ingineri DA
	Adăugător:
	- Este prezete 6 programe
	- Manevrile se face cu ajutorul unei pedale de
	tip jostick ce permite ajustarea fotoliu conform
	necesităților utilizatorlui
	- Rotirea in jurul axei a fotoliului 300°.
	- Structura din metal vopsit rezistent la factori
	externi.



producing quality

USER MANUAL

OP-S8 CHAIR

Rev 2.0. - 28/02/2014



OP-S8 CHAIR

Chair Model:	
Serial No:	



0. SYMBOLS

SAFETY SYMBOLS AND INDICATORS



Warning, consult the attached documents. All paragraphs with this symbol should be observed with special attention.



Type B Equipment



Warning: Very hot surface

OPTOMIC ESPAÑA S.A. reserves the right to change, without prior notice, the design and specifications included in this manual.



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2. WARNINGS AND PRECAUTIONS

THE FOLLOWING INFORMATION IS VERY IMPORTANT FOR SECURITY REASONS AND SHOULD BE TAKEN INTO CONSIDERATION WHEN USING THIS EQUIPMENT.

OPTOMIC ESPAÑA S.A., MANUFACTURER OF THIS EQUIPMENT, ASSUMES NO RESPONSIBILITY FOR PERSONAL OR MATERIAL DAMAGES SUSTAINED BY THIRD PARTIES RESULTING FROM WRONGFUL OR INADEQUATE USE OF THIS EQUIPMENT, POOR EQUIPMENT MAINTENANCE OR CARE, INCORRECT INSTALLATION, DISREGARD FOR THE INSTRUCTIONS PROVIDED IN THIS MANUAL, REPAIRS CARRIED OUT BY UNQUALIFIED OR UNAUTHORISED PERSONNEL.

- This equipment should never be used where there is a risk of explosion or near inflammable liquids.
- Disinfectant and sterilizing liquids are agents which violently attack plastic and rubber, and eventually make them lose their physical properties, therefore please use these liquids as little as possible.
- The unpacking of the chair by anyone unauthorised by OPTOMIC ESPAÑA, S.A. permanently cancels the equipment's warranty.
- This equipment includes electronic components which may be harmful to the environment if
 they are not handled correctly. Therefore, once the life cycle of the chair is over, the
 applicable national and local regulations related to the management of environmental waste
 must be observed, or the product can be returned to OPTOMIC ESPAÑA S.A. for the
 management of dangerous components.



According to legal regulations, the manufacturer only accepts liability for the device's safety specifications if maintenance, repair and modification procedures are carried out by the manufacturer or a person authorized by the manufacturer.

Otherwise, the manufacturer will not assume any responsibility, and the warranty will be cancelled automatically.

The manufacturer will not accept responsibility for the inappropriate use of the equipment or if it is used for purposes other than those for which it was manufactured.

Components relevant to safety will only be replaced with original parts.

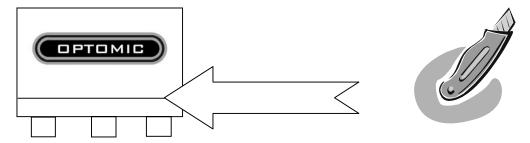
After any modification or repair, a safety test will be carried out, to confirm the equipment meets all technical specifications related to safety in accordance with current regulations.

All modifications, repairs and tests should be registered on the MAINTENANCE CHART.



3. UNPACKING AND INSTALLATION

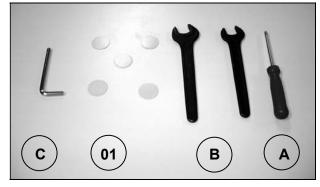
For its transport, the OP-S8 chair is attached by its base to a wooden pallet. The unpacking is done from the bottom of the box where it rests on the transport pallet; cut the adhesive tape there to release the cardboard cover or the wooden box, depending on the packaging.



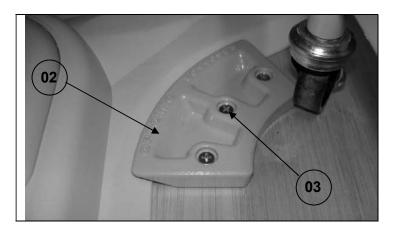
The tools supplied to set up the equipment are in a plastic bag which contains the following items:

- 1 Philips screwdriver (A)
- 1 17mm spanner (B)
- 1 5mm Allen wrench (C)
- 8 Self-adhesive base end trims [01].





With the Philips screwdriver [A] remove the screws [03] which anchor the rounded plastic supports [02], releasing the chair from the wooden pallet.



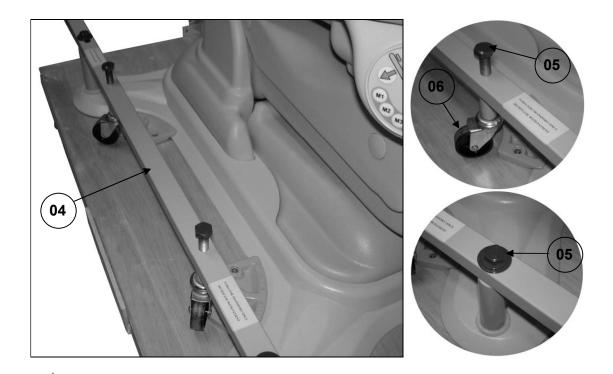


NOTE: The OP-S8 chair optionally comes with transport bars with wheels [04] (to use exclusively for easier handling and transport of the equipment), which can be moved using the ends of these bars as handles to roll it on the floor or lift it to overcome obstacles such as kerbs, steps, barriers, etc.

When the chair is free proceed to move it from the wooden pallet to the floor.

<u>WARNING</u>: to carry out this operation at least two people will be needed, <u>do</u> <u>not try to move the chair from the pallet alone</u>, even rolling it on its wheels.

Proceed to lift the chair seizing it by the transport bars [04], **do not seize the chair anywhere else**, and place it on the floor beside the wooden pallet.



WARNING: due to the weight of the equipment, move it VERY CAREFULLY helped by people used to moving heavy objects. To carry out these operations, protect legs and feet and constantly make sure that there are no objects, animals or children in the path of transport or where you wish to place the chair. When possible move the chair using its transport bars with wheels.

Once on the floor, lift the chair acting on the screws [05], connected to the transport wheels [06] located on the bar. Tighten the hexagonal screws gradually and simultaneously with the help of the 17mm spanner until the chair is not touching the floor.

WARNING: the transport bars are exclusively to move the OP-S8 chair. For safety reasons, **NEVER** use the chair or sit a patient down on it with these transport bars on.

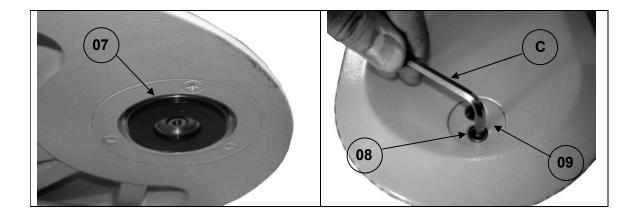


4. LEVELLING OF THE CHAIR

Once the exact location of the OP-S8 chair is decided on, lower it trying to raise simultaneously the four wheels. With the same 17mm spanner loosen the screws [05] and remove the transport bars (these must be put away with the screws, for future transport of the chair).

Now proceed to level the chair following these steps:

- 1. The levellers [07] must be embedded in the base ends. Use the 5mm Allen wrench (C) on the bore farthest from the base centre [08], turning it anti-clockwise without forcing it.
- 2. Lower the levellers carefully until they are touching the floor (do not force them to avoid lifting the central part of the chair).
- 3. If one of the base ends is on a very different level from the rest, higher than the leveller [07], wedge it using an appropriate block.



- Confirm the levelling has been correctly carried out by sitting on the chair to see if any of the levellers do not make contact with the floor. Do not force a leveller until it lifts the base end.
- **5.** Once the levelling is finished, place the self-adhesive base end trims [01] in their place [09]. You will find them in the same bag as the installation tools. There are some extra ones [01], in case the original ones get damaged. **Store them in a safe place.**

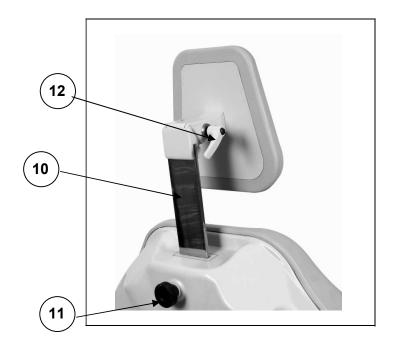


5. ASSEMBLY / ADJUSTMENT OF THE HEADREST

Remove the protective packaging from the headrest. Be careful so as not to damage its upholstery or paint.

Follow these steps for assembly:

- 1. Introduce the headrest shaft [10] in its socket in the backrest and block with the control knob [11].
- 2. To adjust the position depending on the height of the patient, loosen the control knob [11], put the headrest at the required height, and tighten it again (without forcing it).
- 3. To adjust the inclination use the handle on the back of the headrest [12].



6. START UP

To start up the OP-S8 chair follow these steps:

1. Connect the power supply cable to the mains.

<u>WARNING</u>: the motors can only operate in working cycles of 10% maximum. This means approximately, in practical terms, rising and lowering the chair completely and waiting 3 minutes to do the same again. Cycle: 2 minutes use, 18 minutes rest.



7. MOVEMENTS AND MEMORIES

7.1 MOVEMENTS

4 MAIN MOVEMENTS

The OP-S8 chair has the main movements required for the correct placing of the patient in ENT practices motorized.

Using the foot pedal control (Joystick type) the chair can be moved to any desired position.

Moving the pedal forwards the chair will rise. Moving it backwards it will come down.

Moving the pedal to the right, the backrest will move backwards, the legrest up and the footrest down. Moving it to the left, the backrest will move forwards, and the legrest and footrest will go back to their earlier positions.

Frontal examination position

The patient's back is placed at an angle of 95° with respect to the base. The headrest area comes forward, providing a very comfortable position for the doctor to carry out the examination sitting on a stool in front of the chair.

Trendelenburg position:

Reclines the backrest to an angle of -10° below the horizontal of the headrest, relieving quickly any dizziness.





7.2 MEMORIES

Apart from the 4 keypad memories, the OP-S8 chair has 2 more memories on the pedal buttons, and all of them can be programmed by the user.

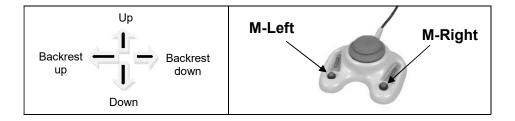
Key	Action	
M-Left	Programmable memory M5	
M-Right	Programmable memory M6	

7.3 PROGRAMMING A MEMORY ON THE JOYSTICK

First place the chair in the position you wish to memorize with the foot pedal (button **M-Left** corresponds to memory **M5** and button **M-Right** to memory **M6**).

Then press the button corresponding to the memory that will be programmed (M-Left, M-Right) for 3 seconds. You will hear one confirmation beep.

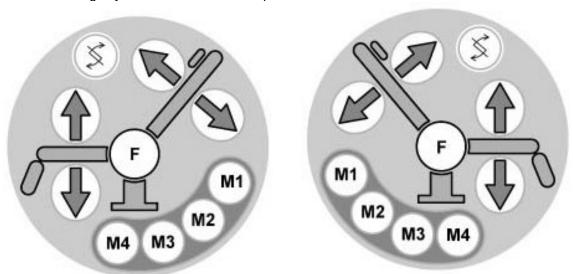
Once programmed, just pressing the buttons will take the chair to the memorized position.





8. MOVEMENT CONTROL

The following keyboards are located on top of the backrest.



NOTE: with these keypads, as with the joystick pedal, the OP-S8 chair can be moved manually in all its movement range.

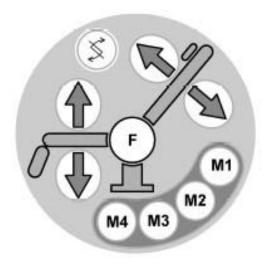
The movement keys respond to constant pressure. In other words, there is movement while the key is pressed down. Two keys can be pressed simultaneously, as long as they do not have opposite functions, this way a patient can be raised and reclined at the same time.

<u>WARNING</u>: the motors can only operate in working cycles of 10% maximum. This means approximately, in practical terms, rising and lowering the chair completely and waiting 3 minutes to do the same again. Cycle: 2 minutes use, 18 minutes rest.

Key	Action
	Bring the backrest up
	Recline the backrest
	Raise the seat
1	Lower the seat



9. PROGRAMMABLE MEMORIES



The OP-S8 chair, apart from the pedal memories, has 4 memories which are located on the lower right hand side of the keypads and marked as **M1**, **M2**, **M3** y **M4**. These can be programmed by the user:

Key	Action
M1	Programmable memory 1
M2	Programmable memory 2
M3	Programmable memory 3
M4	Programmable memory 4

To program a memory first take the chair to the desired position. Then press the memory you wish to program for 3 seconds, until you hear a confirmation beep.



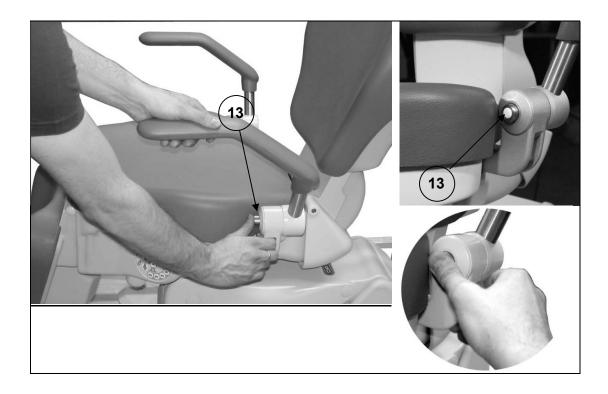
10. ARMRESTS

The armrests have an anchorage mechanism at the bottom which allows them to be folded down and out of the way.

To fold the armrests down, press down on the button [13] while you rotate the armrest to the bottom of the chair.

Use both hands to fold down the armrests.

For safety reasons, grip the armrests only by the upholstered area.



The armrests only have two positions:

<u>Up:</u> in this position the patient can rest his/her arms. When the patient first sits down this position is recommended. One of the armrests can be folded down to make access to the chair easier, for people with certain problems or for tests which require the patient to sit at right angles to the backrest.

<u>Down:</u> in this position the patient cannot rest his/her arms. When it is necessary to get close to the patient for examination this position is recommended. Also when a person with great overweight has to sit down and is not comfortable with the armrests up.

In any other position the armrests are free of any blocking and can be dangerous.

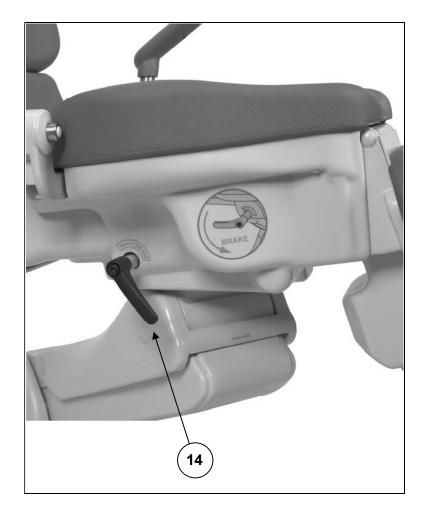


11. ROTATION AND BRAKING OF THE SEAT

The seat of the chair rotates approximately 300°.

To brake the seat, turn the brake handle **[14]** following the drawing indications. To release it, turn the handle in the opposite direction.

There is a brake handle on either side of the chair. Keep in mind that on one side the handle must be turned clockwise to brake, and on the other side anti-clockwise.









12. MAINTENANCE

WARNING:

TO CARRY OUT ANY CLEANING OR MAINTENANCE WORK DISCONNECT THE EQUIPMENT FROM THE POWER SUPPLY.

To clean and disinfect the external surface of the equipment, use a clean cloth, dabbed in a disinfectant soap solution (dissolution as indicated by the manufacturer), and then rinse with another cloth dabbed in water. Be very careful not to get any water or humidity into the equipment.

To carry out revision and maintenance tasks, please contact the OFFICIAL TECHNICAL SERVICE.

All REVISION, REPAIR, MAINTENANCE AND MODIFICATION tasks must be registered, with date and signature of the authorized company or person that carries them out, in the **MAINTENANCE CHART** attached to this manual.

Maintenance and Annual Inspection

Manufacturer recommendations:

OPTOMIC ESPAÑA S.A. recommends that an expert carries out an annual performance and safety inspection of the equipment.

The regular inspections can help foresee and prevent eventual breakdowns and alterations and, this way, increase the product's safety and life span.

Safety Test

- Carry out a visual control. Take into consideration that:
 - The device's indications and labels must be clearly readable.
 - The mechanical state must allow for a safe performance.
 - There must not be any dirt that can affect the device.
- Measure the leakage current according to EN 60601-1 and EN 60601-1-1.



13. TROUBLESHOOTING CHART

When the equipment presents a problem, consult the following chart:

PROBLEM	POSSIBLE CAUSE	ACTION
The seat does not turn	The brake is activated	Turn the handle following the drawing instructions
The chair does not respond to the raising and lowering controls	Broken pedal	Replace it
The backrest does not move forwards or backwards with the corresponding controls	Broken pedal	Replace it
The controls do not respond properly	Temperature and humidity conditions do not match those specified Damaged components	Verify Call the Technical Service
The chair does not move in any way	Failure in the supply	Verify electrical installation Verify the correct condition of the chair cable.
The chair goes to a position different from the one memorized	The chair has lost the motors position The memory has been incorrectly programmed	Reset origin (1) Memorize again

(1) Process to reset origin

When this process is carried out, the chair loses its memories.

- With the foot pedal, lower the chair completely, until you hear 3 beeps.
- Then take it to the Trendelenburg position, until once again you hear 3 beeps.
- This way the origin is reset.
- · Now proceed to program the memories again.

If the problem is not solved following these indications, call the Technical Service.

RETURN OF PRODUCT

If it is necessary to return the product, it must be done with the original packaging. We accept no responsibility for damages or flaws occurred during transport derived from defective packaging. Please attach the following information to the product:

- Name of owner
- Address of owner
- Type of equipment
- Equipment number (see type identifying plate)
- Description of flaw



14. TECHNICAL SPECIFICATIONS

ELECTRICAL

Input voltage Maximum power required for the chair Motors Motors – work cycle Protection type (UNE EN 60601/IEC 601) Classification Medical equipment group Interference suppression	
MATERIALS MaterialFlexible polyurethane, no latex, washable, hygienic, non-infla UpholsteryCompreh Colours	ensive upholstery without seams
MECHANICAL Maximum height of the seat support	900 mm
Minimum height of the seat support	
Seat rotation	
Minimum inclination of the backrest	
Dimensions of the folded equipment (mm)	
Weight	



15. MAINTENANCE CHART

All maintenance, repair or modification tasks must be registered in the following maintenance chart, with date and signature of the company or person who carried them out.

TASKS CARRIED OUT Equipment No	REPAIRED BY	DATE	SIGNATURE

EVERY REPAIR OR MODIFICATION WAS CARRIED OUT BY AN EXPERT, OBSERVING SAFETY STANDARDS AS PER UNE EN 60601/IEC 601.



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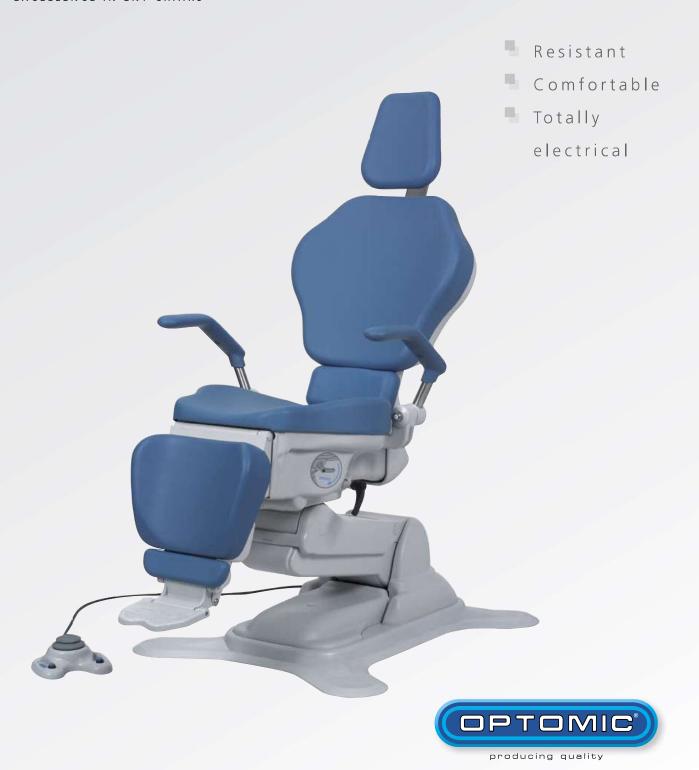
OPTOMIC ESPAÑA S.A.

C/ Madroño, 4 • 28770 Colmenar Viejo, Madrid. (Spain)
Tel: +34 902 22 11 77 · Fax: +34 902 22 11 78
mail@optomic.com · www.optomic.com



CHAIR OP-S8

EXCELLENCE IN ENT CHAIRS





[OP-S8]

FOLDING ARMRESTS

They are composed of a stainless steel axle padded with washable polyurethane. They fold down completely to provide more comfort for patients with reduced mobility and for lateral observations and practices.



STRONG HEADREST

There are two models available, both of them perfectly designed to keep the head of the patient in the required position during the examination.

Adjustable in height, it incorporates a quick removal system which facilitates the execution of positional tests and routine practices.



COMFORTABLE FOR DOCTOR AND PATIENT

AN ERGONOMIC PRODUCT

The OPTOMIC chairs design is based on the search for the comfort of the patient and ergonomics during exploration. This is the reason the geometry of its structure adapts to achieve the optimum distance between patient and doctor in every step of examination and treatment.







ROTATION AND BRAKE

ACCESSIBLE SYSTEM

The patient can be turned with great safety, stability and smoothness due to its high resistance bearings of conical rollers.

It has a double lever braking system, placed on either side of the seat, to avoid the doctor wasting time moving around the patient.

The 300° turn facilitates the examination of both ears.







CHAIR OP-S8





< FOOTREST, LEGREST AND BACKREST >

MOTORIZED ELEVATION SYSTEM

A PRECISE SYSTEM

A pedal facilitates the perfect control of the chair. It activates the up /down and inclination movements. It has two memories for user personalization.









HIGH RESISTANCE AND SMALL SIZE

The OP-S8 chair has a completely electrica system for the movement of the footrest and legrest, which is synchronized.

The legrest is concave to hold the patients calves for greater comfort and relaxation.

The range of the backrest movement goes from 80° to the Trendelenburg position.





The OPTOMIC OP-S8 chair is designed and manufactured using the best materials and most modern technologies. OPTOMIC's philosophy is based on the idea that both patient and doctor must be able to find a comfortable and safe position, to avoid unnecessary fatigue during an examination or surgical treatment.

CHAIR OP-S8





















Optomic - Ref. C082IN14



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

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