

User's Guide



POLY+CARE



Model Shown : 48010-01 + 47126-01
47750-01 + 11679-01



Ambulatory medicine chair
48010-01

Product Identification

Model Number :

Serial Number :

Date of Purchase :

Name of Owner / Facility :

Name of Dealer :

Dealer's Phone Number :

Promotal Authorized Service Company :

Legal Notice

PROMOTAL

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The descriptions and specifications contained in this

Operating Manual are deemed correct at the time of printing.

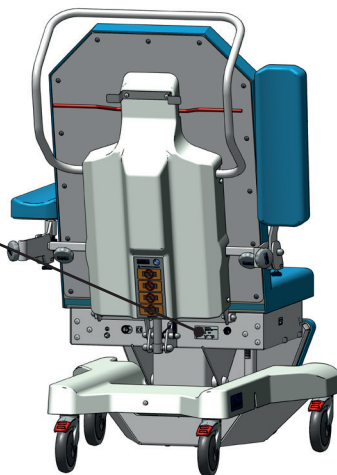
Promotal, however, reserves the right to modify its models and its procedures or render them obsolete without notice.

Before any order, we recommend that our customers consult a local sales manager.

TYPE PLATE

Manufacturer : PROMOTAL			
22, Rue de Saint-Denis de Gastines			
53500 ERNÉE France			
MODEL	XXXXXX		
SERIAL/SERIE	AA/SS/XXX-XX		
Classe I	Type B	Freq 50/60Hz	XXXX
			Maxi
Volts	Amps	Watts	
230V~	1.3	330	

Year(YY)/Week(WW) of manufacture



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Important information

Safety symbols



Warning sign

Information marked with this symbol must be read and strictly complied with!

Remark Draws your attention to a procedure, practice or situation.



Humidity limitation



Maximum number of stacked pallets



Correct orientation for transportation



Atmospheric pressure limitation



Temperature limitation



Fragile



Keep in a dry place



Not to use sharp objects



Manufacturer



Type B applied part



Fuse rating



Protective earth



Dangerous voltage / risk of electrocution



To be disposed off separately from household waste



Equipotential terminal



Life cycle (motor cycle)
1 minute working / 9 minutes stopped



General safety sign



Housing protection classification



Catalog reference



serial number



For indoor use only



Refer to the instruction manual / brochure



CE marking

Remark

the equipotential terminal allows the connection of an equipotential conductor to bring all the different elements of an electro-medical system to the same potential.



do not sit on the back rest



you must not use the foot rest as a foot step



do not sit on the leg rest



do not push against the seat



you must not sit on the arm rests

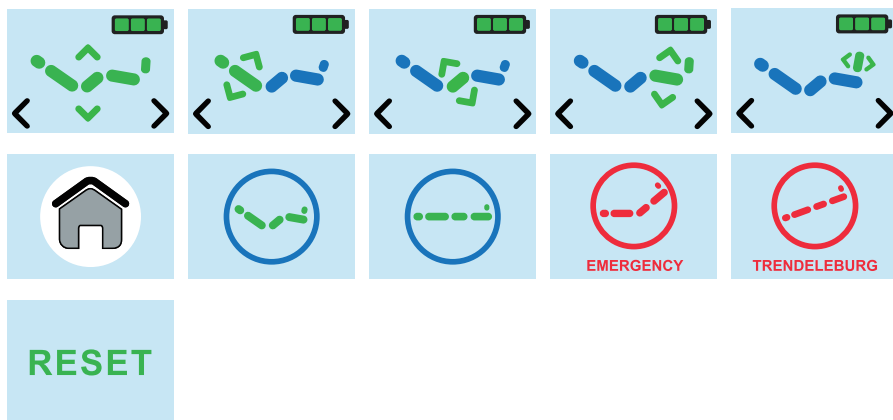


you must lower the seat before moving



Warning

You must not remove the pictograms and warning signs provided by the manufacturer! The manufacturer disclaims all responsibility in case of removal of these signs.



Applied parts

The applied parts according to standard EN 60601-1 are:

- Mattress
- Foot rests
- Dialysis arm support
- Head rest (accessories)

Electrical power supply



The equipotential terminal must not be used as a protective earth connection under any circumstances.



This medical device has electrical classification 1, it must only be connected to a power supply equipped with a protective earth.

Electromagnetic interference

This Promotal medical device was designed and built to minimize electromagnetic interference with other equipment. If interference is, however, observed, you must remove the apparatus causing the interference from the room and/or plug it into an isolated circuit.

Unpacking precautions

Medical device delivered on a wooden pallet

The medical device positioned on a wooden pallet may be easily moved using a forklift truck, as long as this is used correctly. Before transportation,

ensure that the forklift truck is correctly positioned in relation to the pallet, and that the unit is stable.

Storage conditions

Room temperature:

Relative humidity :

Atmospheric pressure :

-15 °C to +60 °C (+5 °F to 140 °F)

10 % to 90 % (without condensation)

0.5 bar to 1.05 bar (500 hPa to 1050 hPa)

All storage must be carried out in accordance with the following recommendations:

- Clean, aired and temperate area.
- Medical device stored in an area sheltered from bad weather and direct sunlight.
- Dry room.
- Medical device protected from shocks.

– Do not store in an area subject to frequent passage.

– Do not stack material.

– Keep in its original packaging until the final destination.

Conditions of use

- Dry and temperate area.
- Maximum altitude : 2000 m

– Temperature 10 to 40 °C

– Relative humidity 75% maxi.

Unpacking and Installation


Step by step

1) During unpacking, remove all staples and remove the cardboard packaging carefully.

Caution : be careful with cutting tools, as fragile parts of the medical device (*covering, plastic housing, etc.*) may be near them.

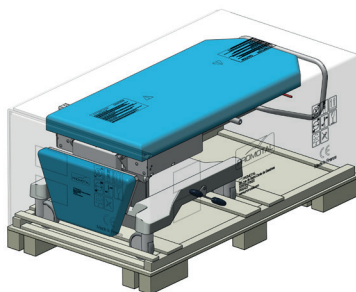
2) If possible, transport the medical device on its pallet up to the final place of use.

The medical device is adjusted to a resistant position for transportation.

see: as indicated in the diagram 

3) Cut the two green bands that fix the DM to the pallet..

4) Next, take the DM off the pallet.



Caution

Four people are required to remove the medical device from the pallet.

Check

Having unpacked the medical device, follow these steps:

- 1) Check the delivery documents to ensure that the delivery is complete.
- 2) Check the external components for any damage during transportation.

3) Check that the packaging contains the medical device, accessories and Options, the supply cable (*if electrical MD*) and the User Guide.

Remark:

Within the European Union, all problems, complaints or questions should be addressed to:

Promotal
22, rue de Saint-Denis de Gastines
53500 Ernée,
FRANCE
Telephone : + 33 (0)2 430 517 76
Fax : + 33 (0)2 430 572 00

Cleaning protocol

Warning

It is vital to read the user's manual thoroughly before manipulating this Medical Device. The equipment should only be used for its intended purpose as described in our documentation. Installation and connection must only be carried out by qualified personnel. The electrical components (cylinder, box, control handle, battery, adapter, etc.) must not be

opened under any circumstances. PROMOTAL shall not be held liable for any damage resulting from non-compliance with these instructions.



Any modification to the medical device without written authorization from the manufacturer is forbidden.



Caution

Only accessories designed and provided by Promotal for this medical device are authorised for use.



Caution

This medical device is not intended to be cleaned in a washing tunnel.

Cleaning/Disinfecting

This medical device must be regularly cleaned using the appropriate detergent products and disinfected using bactericidal, virucidal and fungicidal disinfectants.

A mild detergent such as soapy water can be used for routine cleaning of upholstery, stainless steel, aluminium or painted surfaces, plastic parts and control components, followed by effective rinsing and thorough drying.

Detergents and disinfectants designed for use with medical appliances, such as those containing quaternary ammonium compounds, hydrogen peroxide, ethanol, chlorine compounds, etc. can be used on our medical devices provided that:

- The concentration prescribed by the suppliers of such products are complied with;
- The application conditions (contact time, quantity used, temperature, rinsing, etc.) are complied with;
- The supplier's instructions state that the detergent-disinfectant used is suitable for use with:
 - PVC, ABS, Polyamide, Polyurethane, Polypropylene
 - Epoxy-coated metal surfaces
 - Stainless steel or aluminium metallic surfaces.

Warning:

- Solvents are strictly prohibited.
- The use of abrasive powders or any other abrasive product should be avoided.
- High-pressure cleaning is forbidden.



Under no circumstances shall Promotal be held liable under warranty for any damage caused by non-compliance with the use instructions for a detergent-disinfectant.



Intended use

This Medical Device (DM) is designed for outpatient treatment in healthcare institutions; this articulated chair can be used to transport patients either sitting up or lying down, in addition to in the reception, awakening, recovery and Tredelenburg* positions.

This appliance must not be installed in domestic premises.



This chair is not an OPERATING TABLE

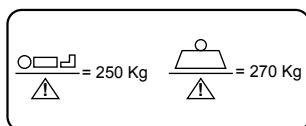
Authorisation to use

Health professionals (doctors, caregivers) and/or qualified members of the technical staff can handle or use the table.

The patient and attendants can intervene on the table in order to allow the patient to re-adjust his position only under the condition that he has been informed about the operation of the table by the medical personnel.

The appliance must not be used in the presence of anaesthetic mixtures that are inflammable with air, oxygen or nitrous oxide.

Patient weight capacity



Electrical connection

This device must be connected to the mains supply.

• Connection to the mains supply:

100 V or 240 V (depending on the country)

• Frequency:

50/60 Hz

• Electric shock protection class/protection degree:

Class 1/B device

• Absorbed power:

575 W

• Intermittent operating mode:

1 min / 9 min



In the event of prolonged non-use, it is recommended to switch the couch off.

¹ This equipment is a chair designed for minor outpatient operations such as defined by the CREDES (Centre de Recherche, d'Etude et de Documentation en Economie de la Santé) and the IAAS (International Association for Ambulatory Surgery); based on the recommendations of the SFAR (Société Française d'Anesthésie et de Réanimation) concerning procedures that are eligible for outpatient surgery.

Characteristics

Steel structure with white epoxy finish

Electrically adjusted height ranging from 57 to 92 cm

Electrically adjusted backrest

Electrically adjusted leg rest (incline and extension)

15° reverse Trendelenburg position

Upholstery, thickness: 80 mm, including 1 x 35HR foam layer, thickness: 50 mm and 1 viscoelastic (memory) foam layer, thickness: 30 mm

4 independent 150-mm Ø wheels, including 1 steering castor at the head end

4 x 150-mm Ø wheels with centralised braking, and a 5th wheel (optional)

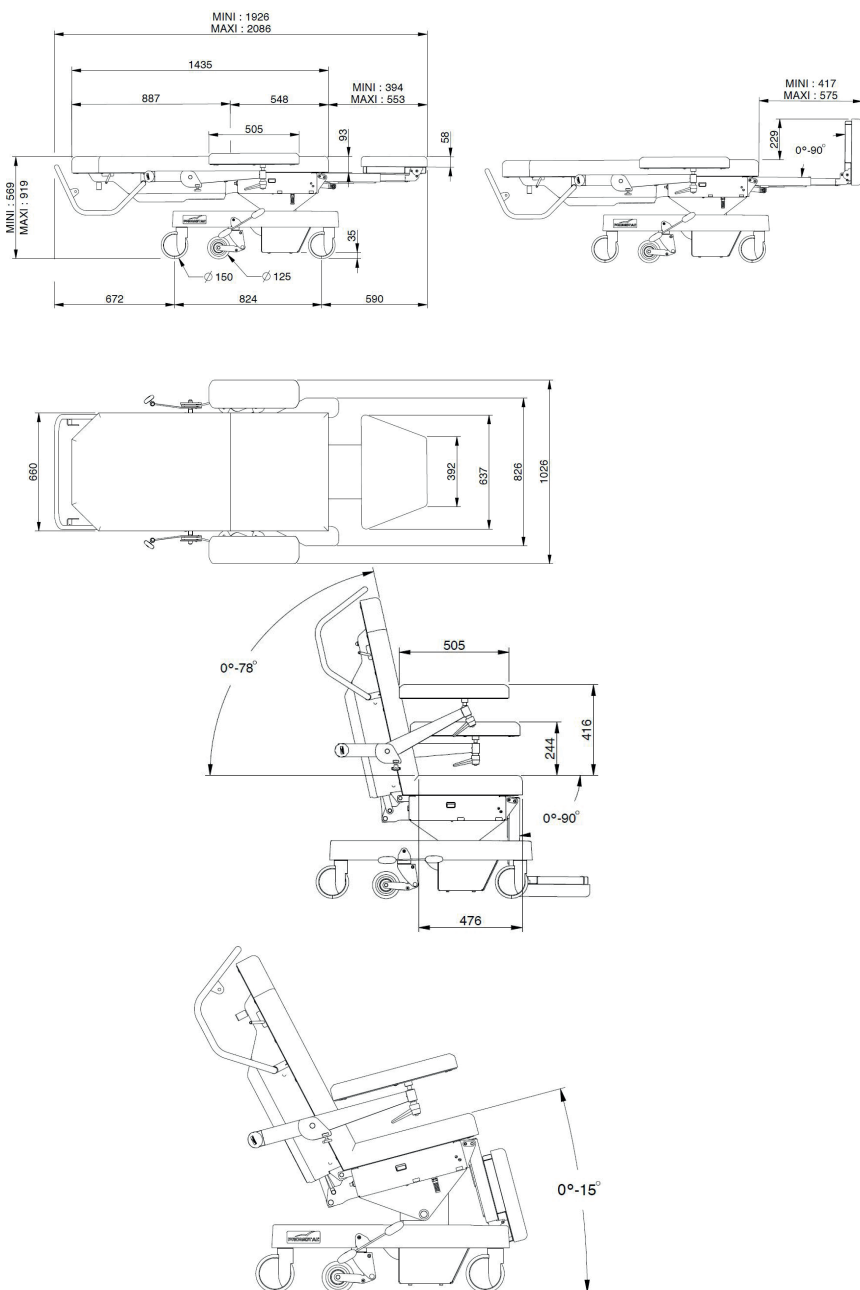
Battery for emergency positioning (50 cycles depending on use)

Built-in push bar

2 removable curved foam armrests on swivel adjustment system, and heat-formed M1 covering



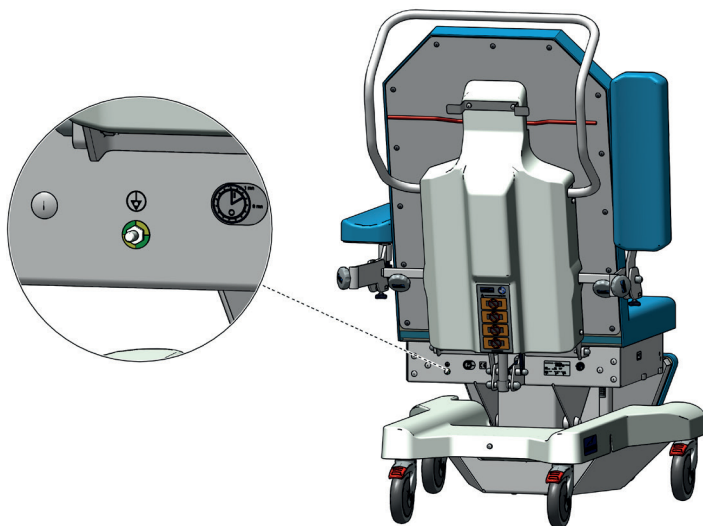
Dimensions 47000-01 + 47188-01



Equipotential terminal



this medical device is electrical class 1. It must be connected to a grounded power supply system only.



Remark

the equipotential terminal allows the connection of an equipotential conductor to bring all the different elements of an electro-medical system to the same potential.



The equipotential bonding conductor must never be used as the earth connection for protection.

**Safety note**

Before using the medical device lowering control, ensure that no objects or obstacles are between the moving parts and the ground.

**Safety note**

When applying preset positions (Home, Comfort, Bed, Trend and Emergency) do not leave the patient on the medical device without supervision

**Safety note**

Unplug the power supply cable before moving the MD.

**Caution**

the supply cable for this medical device may represent an obstacle and cause falls. Do not forget its presence when moving around the device once connected to the mains supply.

**Caution**

A power failure may prevent the patient support from being lowered. In such an event, the patient must be lowered under the best possible safety conditions.

**Caution**

For all types of installation, the mains power supply to which the medical device is connected must be accessible to allow disconnection in an emergency.

(Integrated with the chair power supply)

Accumulator

Note: the chair can operate in
“**ACCU. mode**” or
“**Sector mode**”.

Charging the accumulator

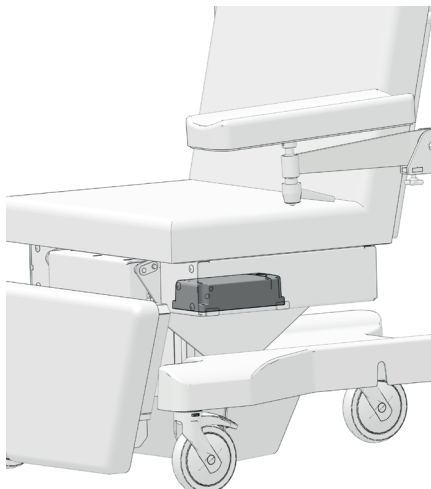
Before using the chair for the 1st time, it is recommended to leave it plugged into the mains for 24 hours to enable the accumulator to charge fully.

*Note: The chair will lose power after (approximately) 5 to 10 operating cycles in “**accu.mode**”.*

Visual charge indicator on the control

The control has a **LED**

- The **LED** indicates the accumulator's charge status.
- One flashing bar - the accumulator needs charging.
- Two bars - the chair is charging or in use
- Three bars - the chair is fully charged.



Accumulator safety symbols



Certification standard



Do not throw the product away with household waste

IP66

Protection rating



Recyclable



Use in dry conditions only

Pb

Contains pollutants Lead, etc.



Fuses

Technical characteristics of the accumulator

Voltage	25,6 V DC
Amperage	4 Ah
Accumulator type	Li-Ion
Voltage (maximum)	30 V DC
Charging time	Approx. 8 h (depending on the power supply unit)
Useful life	approx. 1000 cycles (depends on how the chair is used)
Discharge time	approx. 1 an (storage)

Using the individual control

Manual command

Presentation

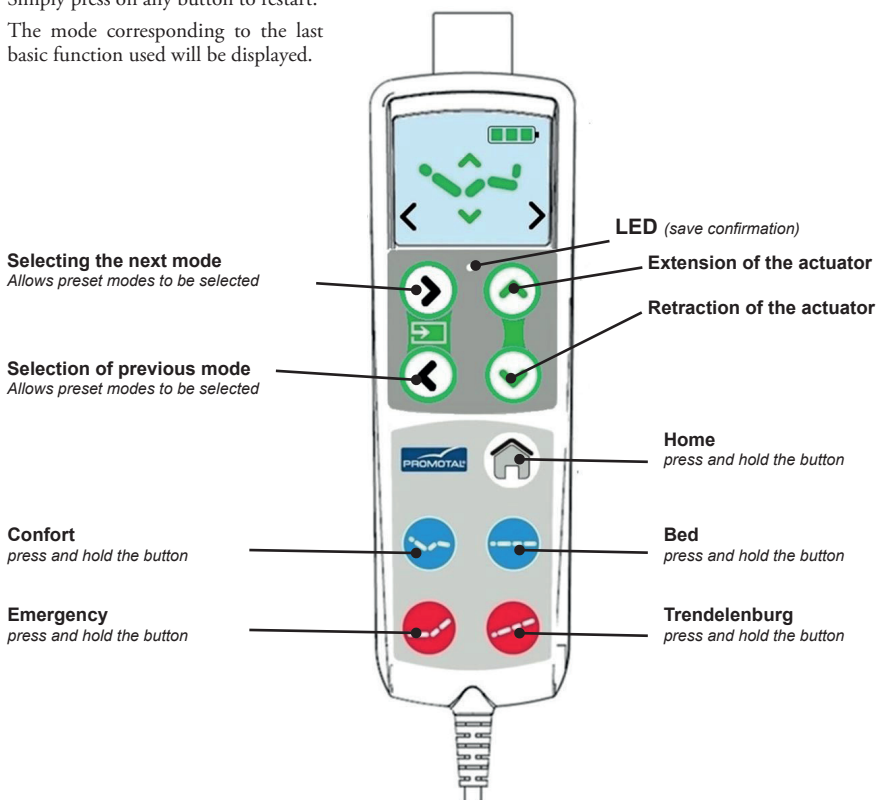


Safety note

When applying preset positions (Home, Comfort, Bed, Trend and Emergency) do not leave the patient on the medical device without supervision

The control goes into standby mode after not being used for 1 minute. Simply press on any button to restart.

The mode corresponding to the last basic function used will be displayed.



Description of functions


Home position

This is the standard entry and exit position, with:

Raised backrest

Retracted footrest


The seat is positioned 53 cm from the floor

To apply this position, press and hold 

NB: this position cannot be adjusted

Bed position

This position is at a height of 63 cm, with the leg rest, headrest and seat horizontal

To apply this position, press and hold 

NB: this position cannot be adjusted

Trendelenburg position (Trend)

This is a high Trendelenburg position with a 15° incline (head downwards) and the leg rest horizontal to hold the patient in place

To apply this position, press and hold 

NB: this position cannot be adjusted

Emergency position

This is an emergency position with a 15° incline, headrest and leg rest horizontal

To apply this position, press and hold 

NB: this position cannot be adjusted

Comfort position

This is a comfortable position with:

Slightly raised backrest

Leg rest at 47°

5° incline

To apply this position, press and hold 

NB: this position cannot be adjusted



Safety note

When moving to one of the programmed positions by sustained contact (*reception, supine position, emergency position*), do not leave the patient on the couch unattended.

Using the control panel

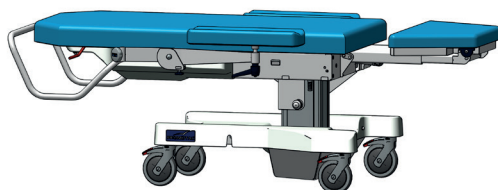
Reception position

The position below is obtained by a sustained press on the manual control .



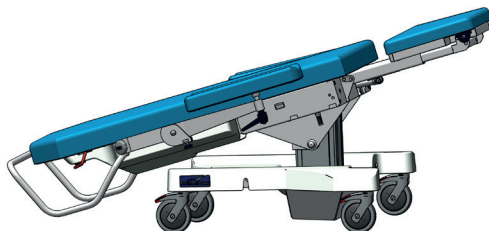
“Stretcher/Bed” Position

The position below is obtained by a sustained press on the manual control .



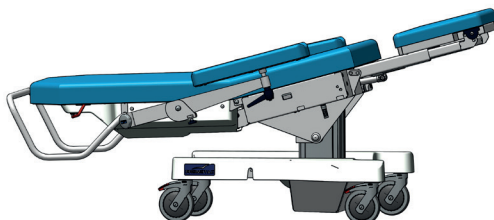
Trendelenburg position

The position below is obtained by a sustained press on the manual control .



Emergency position

The position below is obtained by a sustained press on the manual control .



Confort position

The position below is obtained by a sustained press on the manual control .



Using the control panel

To adjust the height

Use the control panel.



To adjust the back rest

Use the control panel.



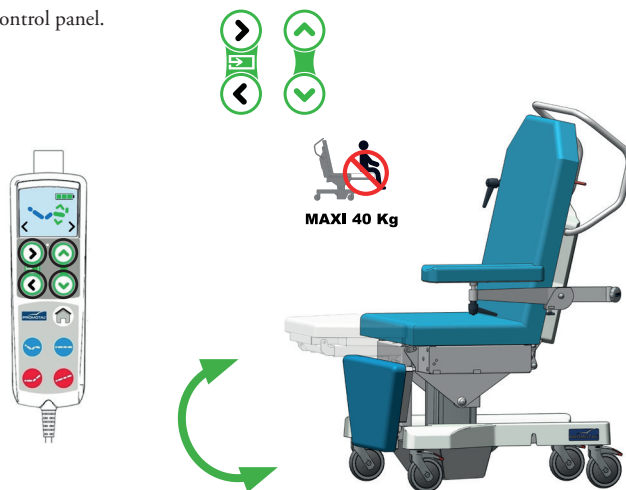
To adjust seat inclination

Use the control panel.



To adjust the foot cushion

Use the control panel.



Using the PolyCare

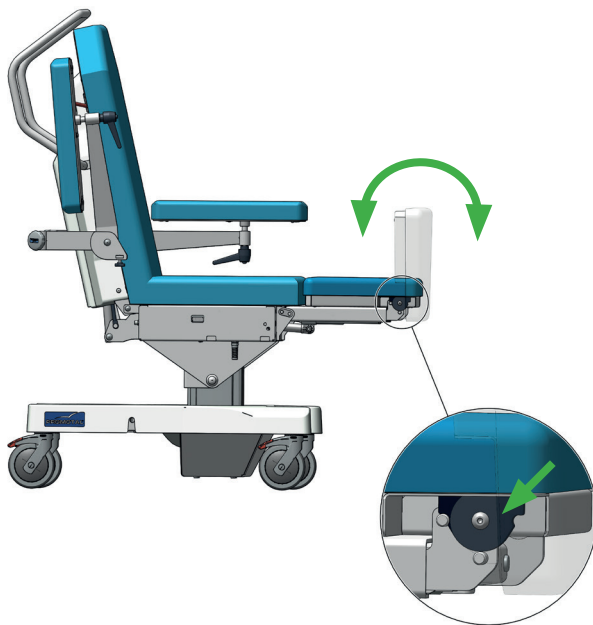
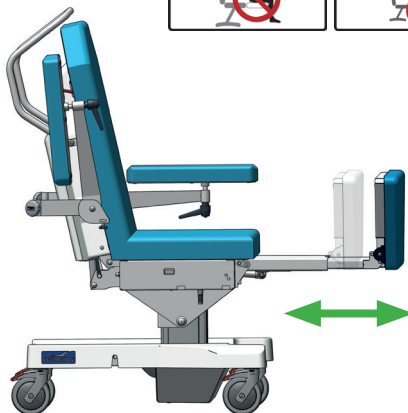
Adjustment of the electric foot-bar

(reference 47188-01)

Use the control panel.



MAXI 40 Kg



Mechanical braking on individual and steering wheels

Using the castors

The MD is equipped with 3 wheels with 2 functions (free or locked) and one wheel with 32 functions (directional, free), which is marked with a green ring.

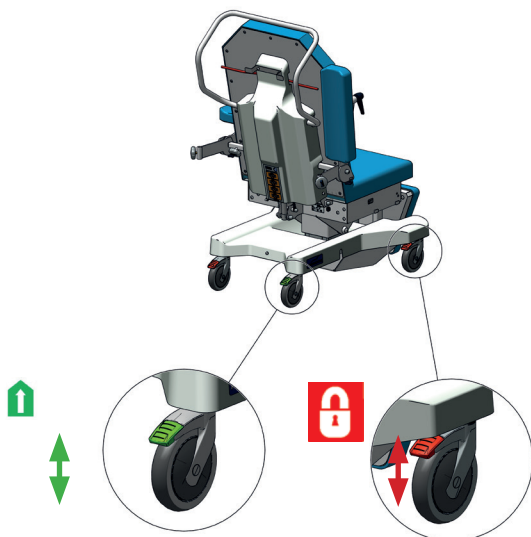
This wheel is located at the head end of the MD.

1: The wheels move freely.

2: (Brake position): The wheels are completely locked.

3: Directional position:

The wheel (head end) is directionally locked. This wheel controls the swivel direction of the MD.



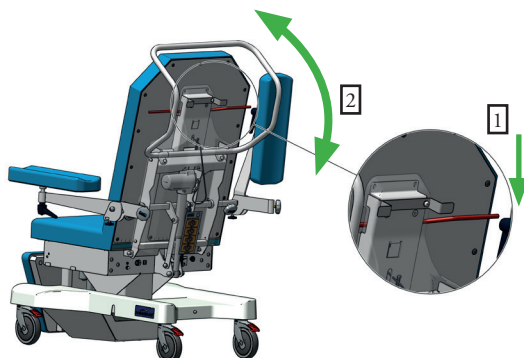
Caution

Ensure brakes are fully engaged before installing a patient.

Emergency mechanical disengaging

Using the disengaging

- Grasp the handle on one side of the headrest and raise it by leaning on the frame.
- Simultaneously, manually support the lowering of the headrest up to the desired position.
- Release the handle.



Using the PolyCare

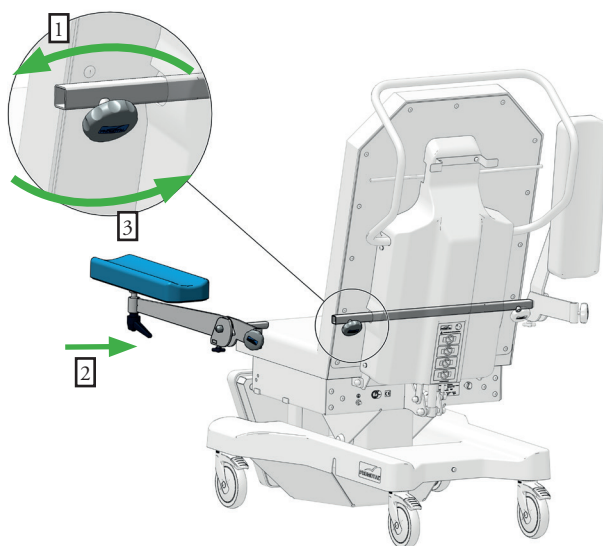
Dialysis arm rest

The armrests follow the movement of the backrest



Dialysis armrest assembly

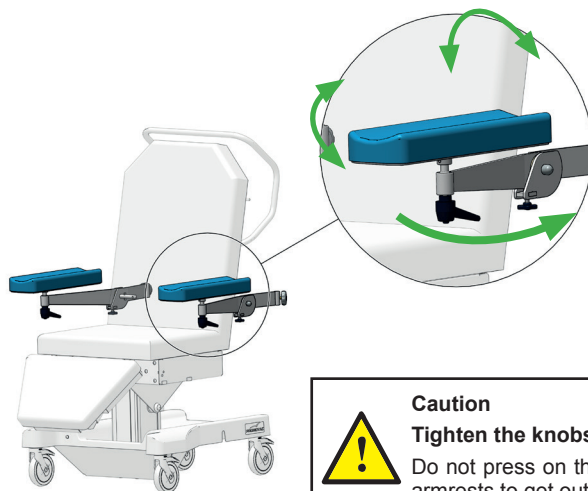
Please note that the armrests are supplied dismantled at the time of delivery.



Check that the parts are securely tightened before each use

To adjust dialysis arm rests

The armrests can be swivelled in all directions thanks to a ball joint located under the armrest. To adjust them, unscrew the knob (VS) then set them to the required angle



Caution

Tighten the knobs before use.

Do not press on the ends of the armrests to get out of the chair.

Retracting the arm rests

(during patient transfer only or if the doctor needs access the patient)

- Pivot the arm rest around its axis until it reaches the raised position.

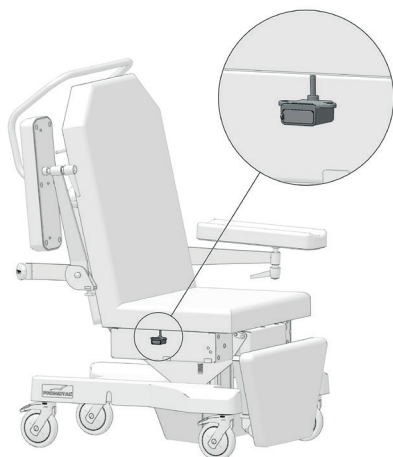


Options

USB socket

(Input 24 VDC / Output 5V 2A)

Connect one USB device to the socket located to the right of the seat.



The centralized brakes

(reference 47126-01)

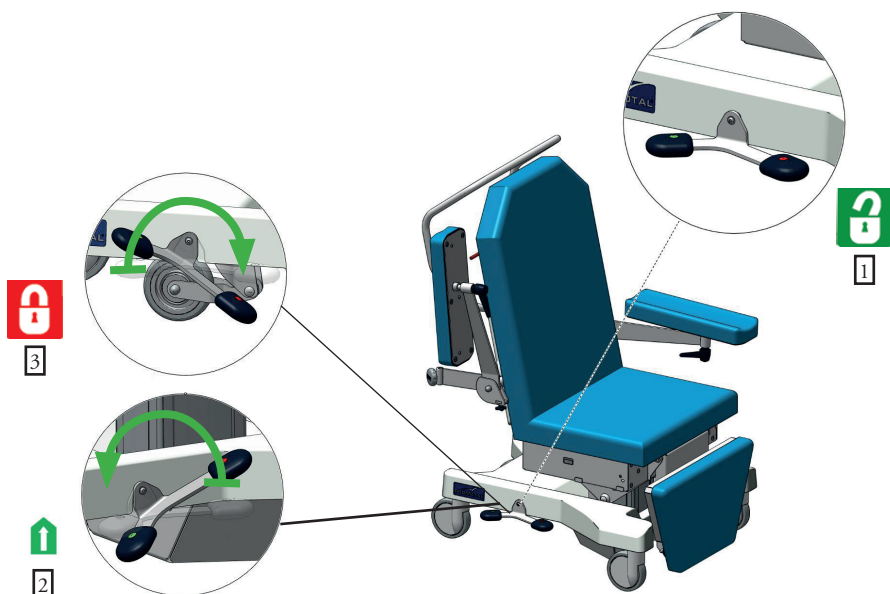
Using the centralized brakes

3 pedal positions

- 1 : Pedal in horizontal position : The 5 wheels are free.
- 2 : Pressing the green pedal (Directional position): The wheel of Ø 125 will get directionally locked when the stretcher will be moving. The stretcher can rotate easily with respect to this wheel.
- 3 : Pressing on the red pedal (Braking position): The 4 wheels of Ø 150 are completely blocked. 4 castors are locked.



Caution
Ensure brakes are fully engaged
before installing a patient.



Accessories

IV pole

(reference 2985-01)

Installing the IV pole

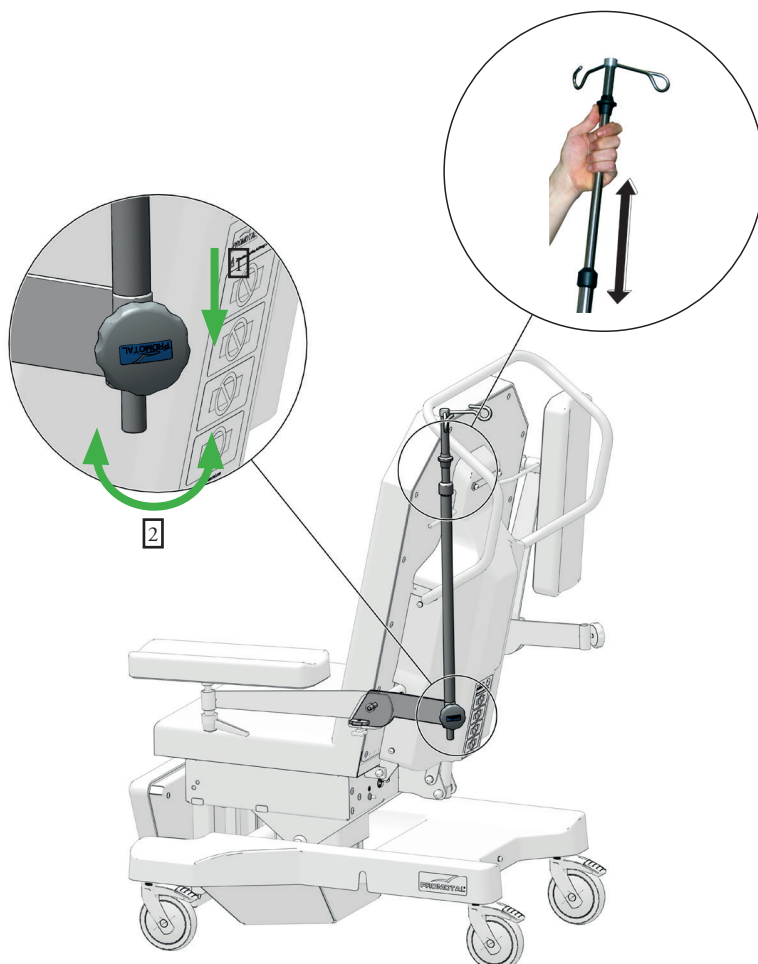
Unscrew the screw handle.

Insert the I.V. pole and rescrew.

Adjusting the height of the IV pole

The IV pole has 1 sliding stem.

Use the screw to adjust the height of the lower stem and the bolt to adjust the upper stem.



Check that the parts are securely tightened before each use

Adjustable head rest

(reference 11679-01)

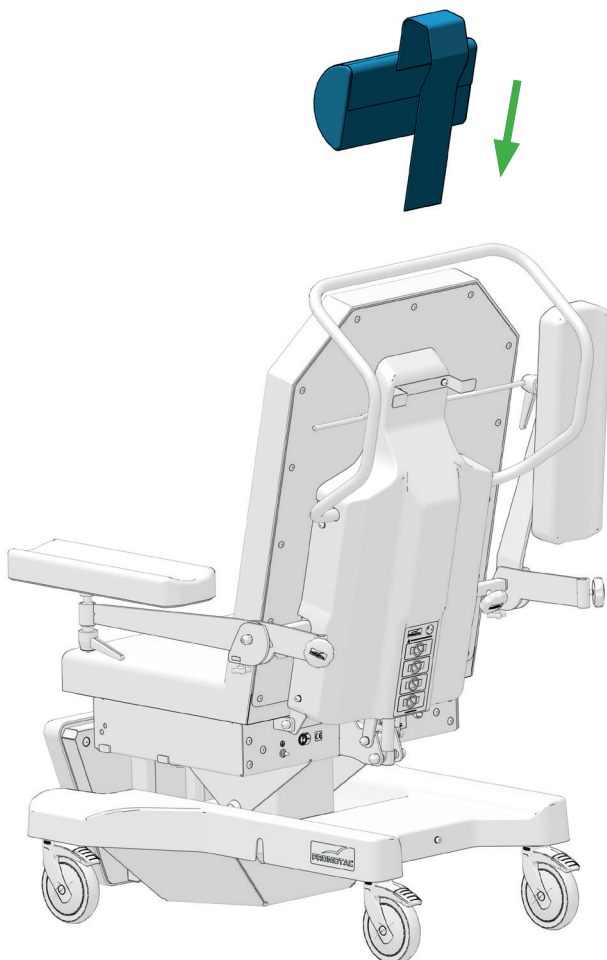
Using the head rest

Positioning:

- Push the head rest's band insert into the back rest frame.

Adjustment:

- The head rest can be adjusted simply by pressing on it to lower it, or by pulling on the band insert to raise it.



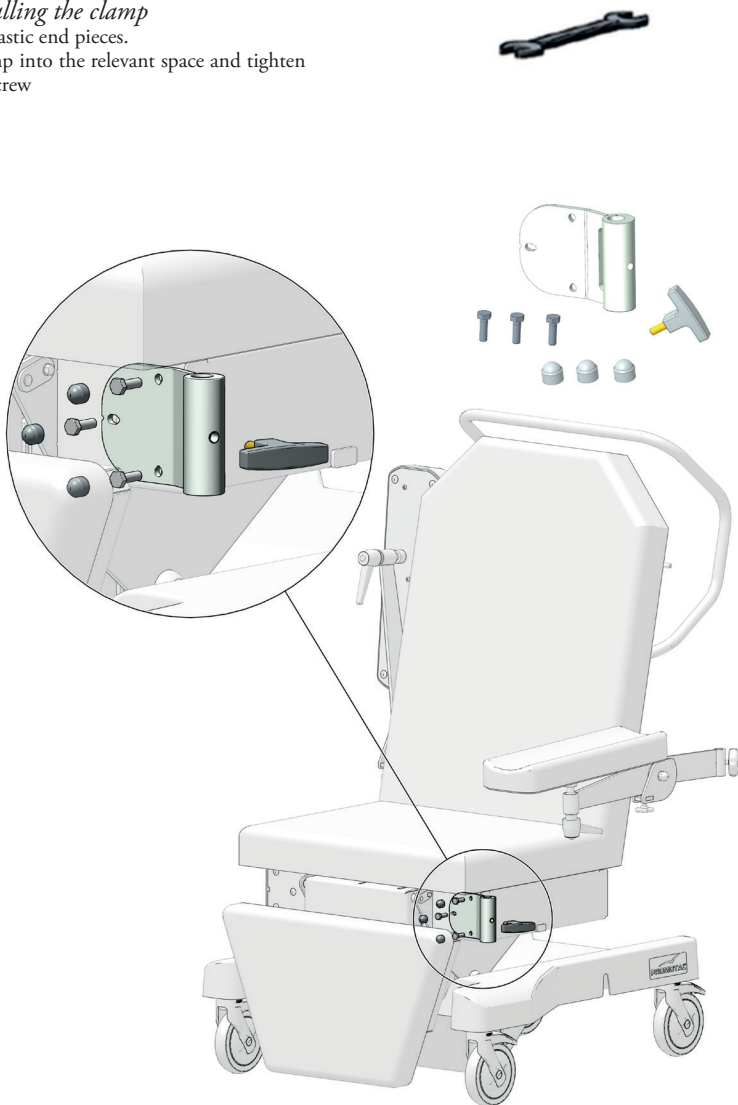
Accessories

Clamp

(reference 47351-01)

Installing the clamp

Remove the plastic end pieces.
Insert the clamp into the relevant space and tighten
the blocking screw



Check that the parts are securely
tightened before each use

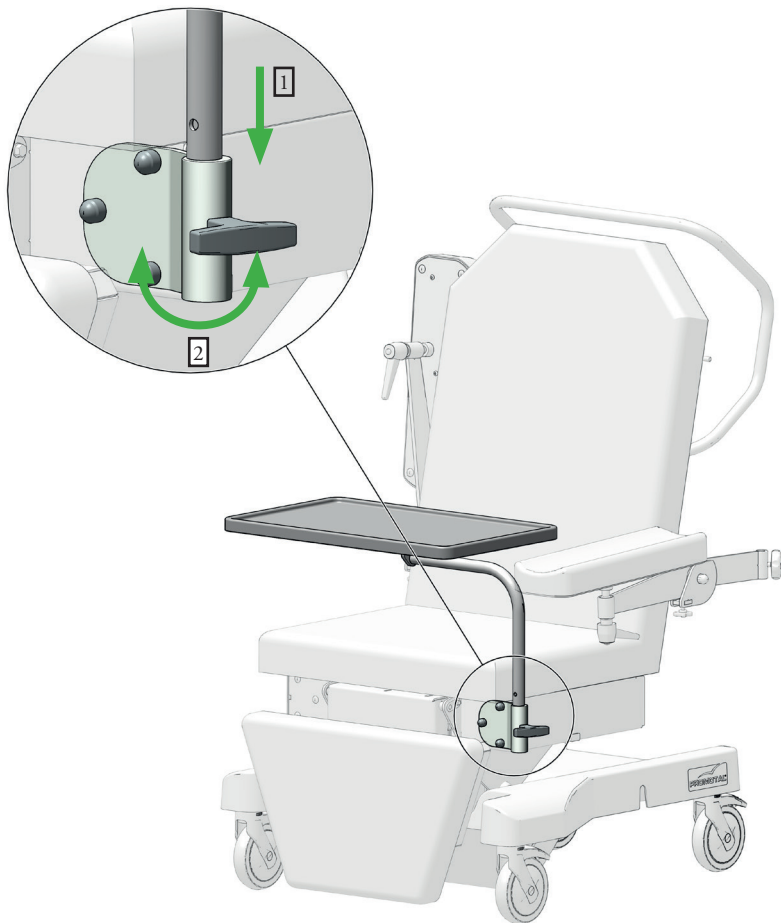
Reading table

(reference 47350-01)

- Loosen the clamp's tightening wheel
- Place the table shaft in the clamp provided for this purpose.

- Retighten the wheel.

Once the table has been fixed, you can adjust its orientation using the tightening wheel on the table shaft.



Check that the parts are securely tightened before each use



Caution
Clamps 47351-01 are required to install the accessories.

Panel support

(reference 47731-01)

- Loosen the clamp's tightening wheel
- Place the flexible shaft in the clamp provided for this purpose.
- Retighten the wheel.



Check that the parts are securely tightened before each use



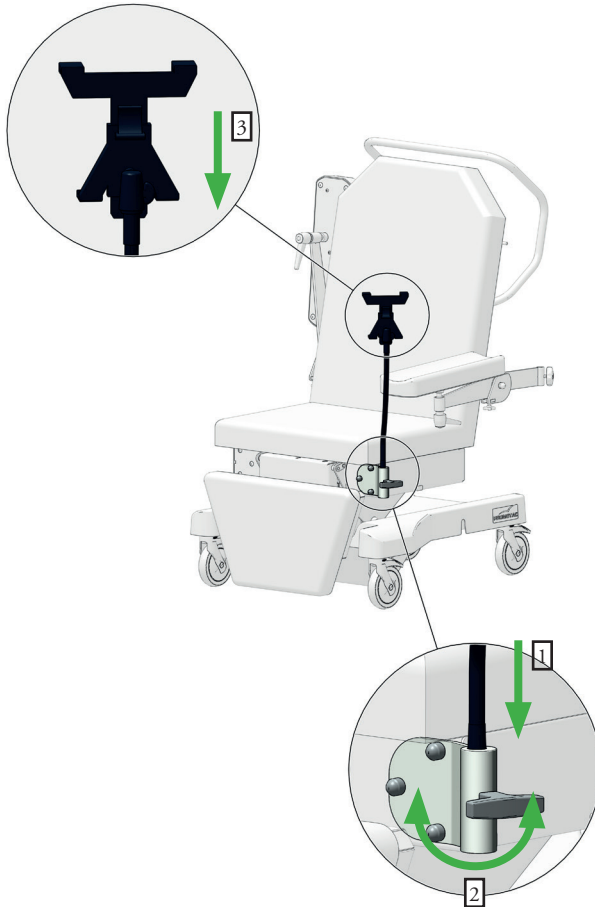
Caution
Clamps are required to install the accessories.

PDA support

(reference 47780-01)

Installing the support

- Loosen the tightening wheel of the vice.
- Place the flexible rod in the vice provided for this purpose.
- Retighten the handwheel.
- Fix the PDA on the support.



Check that the parts are securely tightened before each use



Caution
Clamps are required to install the accessories.

Oxygen bottle holder

(reference 47750-01)

Installing the bottle holder

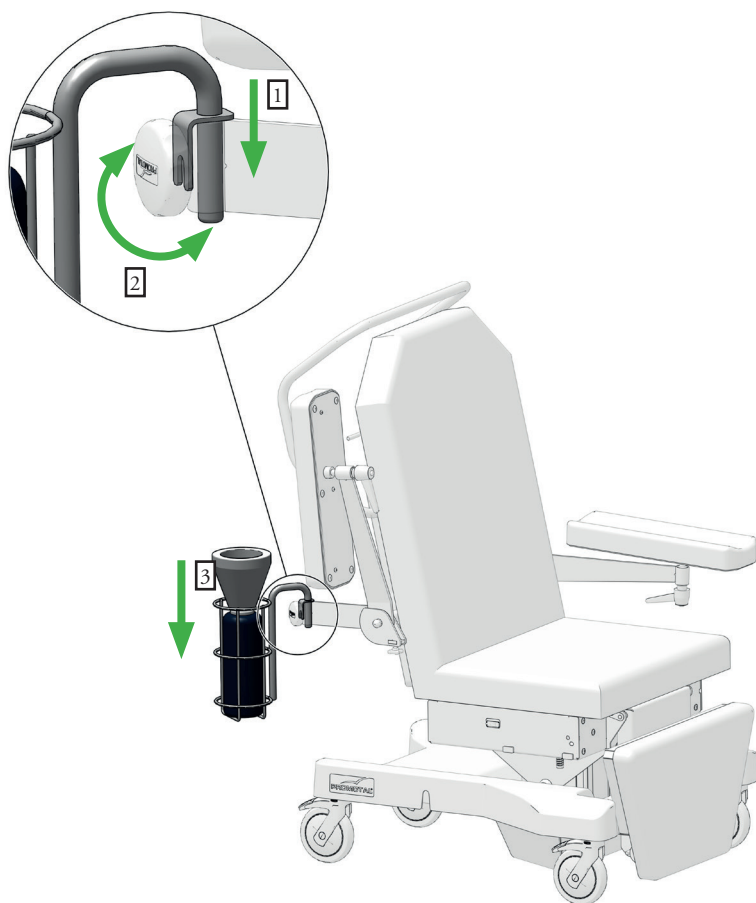
Insert the bottle holder into the location provided for this purpose.



Check that the parts are securely tightened before use



Ø maximum permitted: 120 mm





Lifespan of the Medical Device

This device is designed for a 10 year lifetime (except wear parts) under normal use conditions. This lifetime may vary according to frequency of use.

CHECK THE GENERAL CONDITION OF THE DEVICE AT LEAST ONCE A YEAR.

The wear parts are:

- The upholstery.
- The electric cylinders.
- The wheels and casters (*depending on the device model*)
- The tightening handles and wheels

Promotal recommends replacing the wear parts after 5 years use maximum.

For all interventions, contact your usual dealer, indicating the Serial number of the device.



Material warning

Within the framework of maintenance, only the installation of components designed and provided for this MD by Promotal is authorised.

Compulsory / specific maintenance

Once a year, ensure that the following checks are carried out by a qualified technician (contact your dealer):

- Ensure that all screws are correctly tightened.
- Check the fixings of articulated parts.
- Ensure that the structure has not been deformed.
- Ensure the fuses are in good condition.
- Check that the power cable has not been cut or damaged.
- Check the different connections (excessive play, noise...)
- Note this information and the control date in the maintenance record.

Once a month :

- Check the correct operation of the safety devices (cf page 16).

Medical device end of service life

Your dealer is responsible for the recovery and end of life treatment of this device.

If necessary, do not hesitate to contact Promotal. We can propose solutions to treat this equipment in the best conditions.



Material warning

Upholstery whose coating is torn no longer provides an effective anti-bacterial barrier and must be replaced without delay.



Material warning

DO NOT dismantle THE DEVICE



If a fault is detected, immediately contact your dealer or the dealer's technical department (cf. Warranty Chapter) for a complete diagnosis. If you have a doubt, do not use the device.

RESET procedure

If the medical device malfunctions, reset the motors.

Method

Press any button to activate the remote control

Press and hold buttons  and  until the LED starts to flash (about 30 seconds)





MAINTENANCE NOTEBOOK

Product Reference :
Serial number (cf. label) :
Manufacturing date (start date of warranty) :

.....
.../.../...

Date	Name of technician	Type of intervention - corrective action

If the product is returned to the retailer or manufacturer, please clean and disinfect the material.

Warranty Information

Warranty

Promotal warrants, to the original purchaser, products manufactured by Promotal and components to be free from defects in materials and workmanship for a period of two (2) years¹ from the date of purchase.

Obligations

Promotal will, at its discretion and expense, replace defective parts reported to Promotal within the applicable warranty period, and which, upon examination by Promotal, prove to be defective.

In accordance with CE regulation, Promotal's distributor is responsible for after sales service during and after the warranty period.

Exclusions

- This warranty does not extend to :

- (1) Spare parts and consumables.
- (2) Travel and labour expenses.
- (3) Breakdowns due to improper use, manifest neglect, or to moving the device.
- (4) Equipment whose original characteristics have been changed by the user.
- (5) Control units, hydraulic and electric jacks if opened by the user (seals broken).
- (6) Damage, breakdowns, failures, or defects attributable to outside causes (lightning, electric surges, floods, natural catastrophes, impacts, etc.) or to the presence of foreign objects.
- (7) Damage caused by improper hook-up or by the power supply, damage caused by corrosion or by gradual deterioration of the product.
- (8) Indirect damage related to loss of use and penalties generated by poor performance.
- (9) Aesthetic damage incurred by the outside parts of the equipment, which does not hinder proper operation, such as scratches, chips, and scrapes.
- (10) Devices whose serial number has been rendered illegible or has been changed or removed

Exclusive Remedy

Promotal's only obligation under this warranty is the replacement of defective parts. Promotal shall not be liable for any direct, indirect, special, incidental, exemplary, or consequential damages or delay, including, but not limited to, damages for loss of profits or loss of use.

No Authorization

No person or firm is authorized to create for Promotal any other obligation or liability in connection with the products.

THIS WARRANTY IS PROMOTAL'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED.

¹ Upholstery sets are warranted 1 year from manufacturing defaults.

EU Declaration of Conformity

We,

Promotal

22 rue de Saint Denis de Gastines

53500 Ernée – France

SRN: FR-MF-000001666

declare, under our sole responsibility, that the following electrical medical device:

Commercial name: PolyCare 48000-01 & 48010-01

Description: Ambulatory medicine chair

Basic UDI-DI: 37014094POLYM8

is a Class I medical device,

complies with the requirements of **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017,

complies with the following European directives:

- **Directive 2011/65/EU (RoHS 2)** of the European Parliament and of the Council of 8 June 2011
- **Delegated Directive (EU) 2015/863** of the Commission of 31 March 2015
- **Directive (EU) 2017/2102** of the European Parliament and of the Council of 15 November 2017

meets the applicable European standards,

bears, as such, the CE marking.

Year that the CE (Medical Devices) marking was initially affixed: 2024

Signed in Ernée,

On 1 April 2024



Rudolf MOURADIAN

Chairman

Promotal

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