

User Manual



APOLIUM®



Model presented: 2800-10



Model presented: 2800-15



PODIATRY chair
2800-10 / 2800-20 / 2800-30

Identification of product and owner

Model name:

Serial number:

Acquisition date:

Owner name / Organization:

Supplier name:

Supplier telephone number:

Promotal approved After Sales service Company:

Legal information

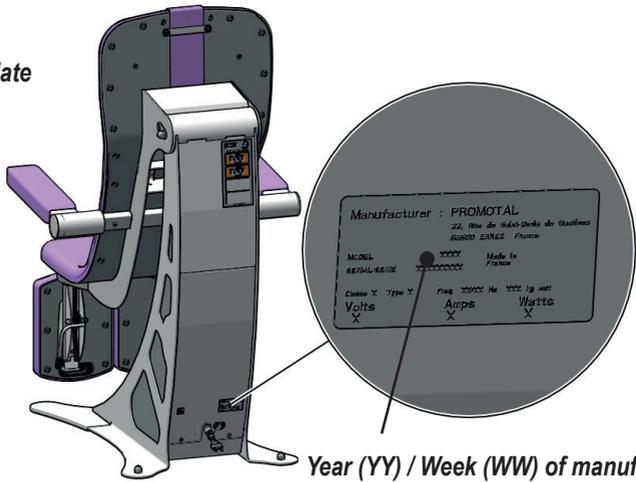
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The descriptions and specifications contained in the present User Manual are considered to be correct at the time of printing.

Promotal reserves the right to modify or declare obsolete its models and procedures without notice.

Before ordering, we recommend that you contact a local sales manager.

Identification plate



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



Do not use sharp objects



Manufacturer



Type B applied part



Double insulation



To be disposed off separately from household waste



Dangerous voltage / risk of electrocution



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



General safety sign



Refer to the instruction manual / brochure



CE marking



Housing protection classification



It is forbidden to sit on the leg rest



It is forbidden to sit on the arm rests



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:

- PVC upholstery
- Arm rest
- Leg rest
- Headrest (accessory)

Electrical power supply



Class 2 type products do not have an earth connection due to the use of double-insulated electrical boxes supplied by a bipolar cable

Electromagnetic interference

This Promotal medical device was designed and built to minimise electromagnetic interference with other equipment. If interference is, however, observed, 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:

-15 °C to +60 °C (+5 °F to 140 °F)

Relative humidity :

10 % to 90 % (without condensation)

Atmospheric pressure :

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 chair to the pallet..

4) Next, take the chair 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:

Authorised EC Representative

Within the European Union, all problems, complaints or questions should be addressed to the Authorised EC Representative of Promotal indicated below:

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 is designed for use in professional premises only:

- Podiatry or Pedicure Medical Practice.
- Healthcare establishments

This appliance must not be installed in domestic premises.

This Medical Device is intended for podiatry and pedicure medical examinations and acts. Only health professionals (podiatrist-pedicurist, doctors, caregivers) and/or qualified members of the Technical staff can handle or use this device.

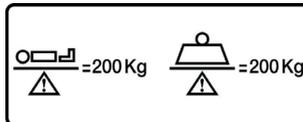
Patients and companions may not intervene directly on the device. They must not have access to the device's controls.

Parents or the practitioner are responsible for supervising children during the visit.



To avoid all risks of explosion, this medical device must not be used in the presence of flammable anaesthetics in contact with air, or with oxidizing gases such as oxygen or nitrous oxide.

Patient weight capacity



Characteristics

Electrically powered adjustable height combined with Trendelenburg (1 motor) from 51 to 154 cm.

Wireless pedal control

Steel structure, grey RAL7035; white trim RAL9016

Anatomical, seamless upholstery with fire-retardant covering M1.

Foam thickness: 4 cm dual density

- top: visco-elastic foam 50 kg/m³,

thickness : 2 cm.

- bottom: foam 40 kg/m³ 8Kpa,

thickness : 2cm.

Two flip-up arm rests.

Two adjustment levellers under the base.



Electrical connection

This medical device must be connected to the mains supply.

- Connection to the mains supply: 120 V or 230 V (depending on the country)
- Frequency: 50/60 Hz
- Protection classification: Class 2/ type B device
- Absorbed power: 575 W
- Intermittent operating mode: 1 min / 9 min
- Maximum operating altitude: 2000 m



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

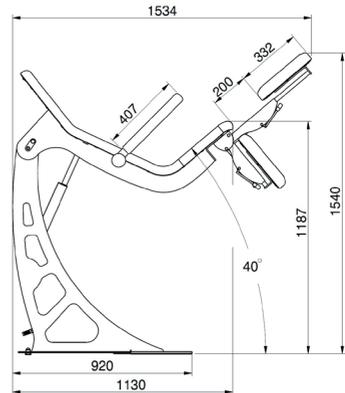
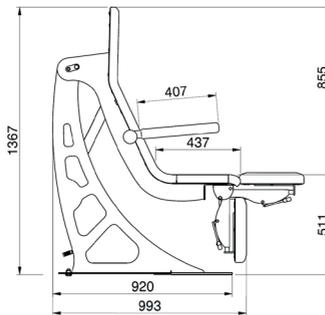
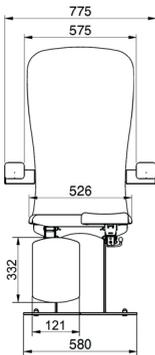


Caution

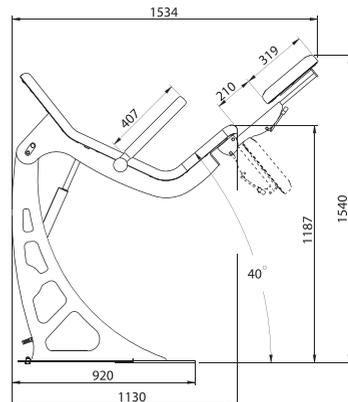
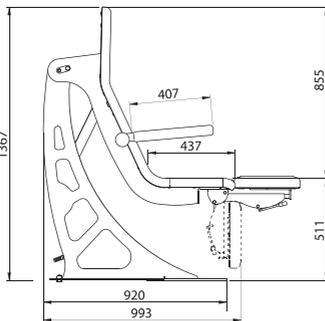
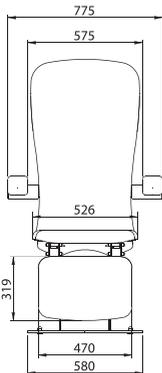
A power cut could prevent the patient support from being lowered to the low position. The patient would then have to be helped off while ensuring their safety in the best possible conditions.

Dimensions

2800-10 / 2800-20 / 2800-30



2800-15



**Caution**

To avoid malfunctions and for safety reasons, no objects must be left under the chair's seat or between its moving frames.

**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.

Connection to the mains



Perimeter protection for the user

To avoid risks of pinching between the upper structure and the base of the medical device, the housing is equipped with sensors that cut-off movements in the event of pressure on the central part of the housing.



**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 using pre-programmed positions (*reception, QE1* and *QE2 for the 2800-30 model*), all movements can be stopped by simply pressing the buttons on the foot pedal or, as a last resort, by disconnecting the mains plug.

**Safety note**

When using pre-programmed positions (*reception, QE1* and *QE2 for the 2800-30 model*), do not leave the patient on the chair unattended.

**Safety note**

Unplug the power supply cable before moving the MD.

Using the individual control

The programmed functions are grouped on manual command and the foot pedal.

Manual command

(for model 2800-30)

Presentation



Safety note

When using pre-programmed positions (reception, QE1, QE2), do not leave the patient on the chair unattended.

QE = Quick Exam

Setting the height (Up)

Setting the height using press-and-hold



Setting the height (Down)

Setting the height using press-and-hold

Setting the leg plate tilt LEFT (Extended)

Setting the tilt using press-and-hold



Setting the leg plate tilt RIGHT (Extended)

Setting the tilt using press-and-hold

Programming the controls
Memorisation button by press-and-hold

QE1 position
Position fully configurable by the user

Setting the leg plate tilt LEFT (Retracted)

Setting the leg plate tilt LEFT (Retracted)

Setting the tilt using press-and-hold



Setting the leg plate tilt RIGHT (Retracted)

Setting the tilt using press-and-hold

Welcome Position

Standard position for getting on and off the chair (H: 55cm)
One press (impulse).

QE2 position
Position fully configurable by the user

Saving programmed positions

The QE1 and QE2 buttons are factory default settings, and can be modified. To save a New position on the QE1 or QE2 button, just move the chair to the desired position, then Press the M and QE1 (or QE2) buttons simultaneously for 10 seconds.

Remark: This foot control operates with two (2) LR03 - AAA Alkaline 1.5V batteries.

In the event of malfunction, these batteries will have to be replaced.

(See page 29: **REPLACING USED BATTERIES IN THE FOOT PEDAL**)

The programmed functions are grouped on the foot pedal.

Foot pedal

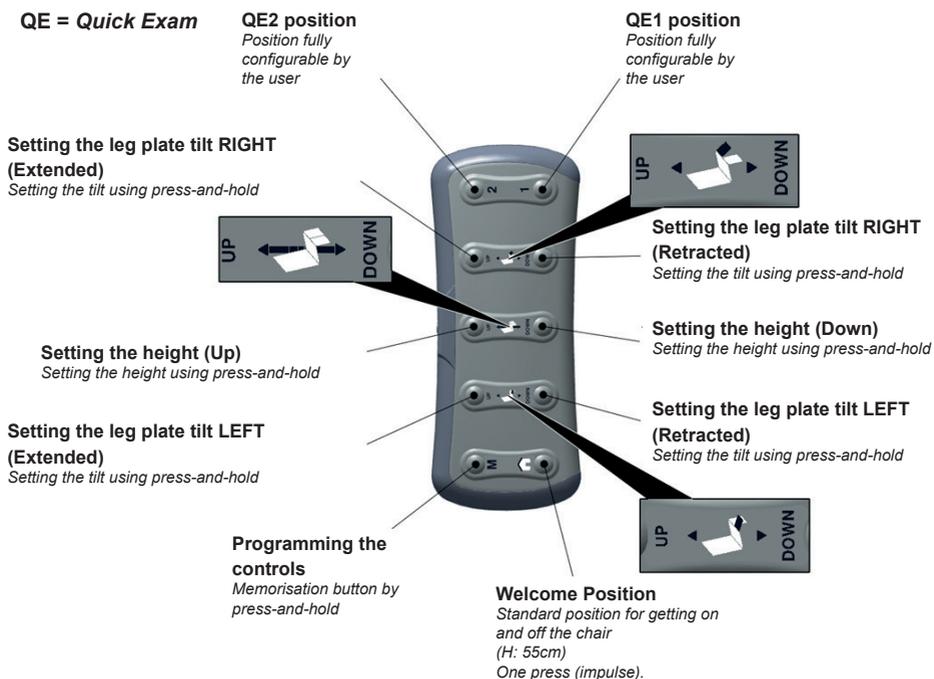
(for model 2800-30)

Presentation



Safety note

When using pre-programmed positions (reception, QE1, QE2), do not leave the patient on the chair unattended.



Saving programmed positions

The QE1 and QE2 buttons are factory default settings, and can be modified. To save a New position on the QE1 or QE2 button, just move the chair to the desired position, then Press the M and QE1 (or QE2) buttons simultaneously for 10 seconds.

Remark: This foot control operates with two (2) LR03 - AAA Alkaline 1.5V batteries.

In the event of malfunction, these batteries will have to be replaced.

(See page 29: **REPLACING USED BATTERIES IN THE FOOT PEDAL**)

Using the individual control

The programmed functions are grouped on the manual command and the foot pedal.

Manual command

(for models 2800-10, 2800-15, 2800-20)

Presentation



Nota sécurité

Lors du rappel de positions programmées (*accueil et examen*), ne pas laisser le patient installé sans surveillance sur le fauteuil.

Using the foot pedal

Just press and hold the foot pedal's push button to activate the desired movement. The movement stops as soon as you take your foot off the pedal. The chair is fitted with an internal system that limits the upper and lower positions.



Use the foot pedal to return to pre-programmed positions:

Note: These positions are factory default settings and cannot be changed by the user.

Double press on the **Left** side of the manual command to return to the examination position.

Double press on the **Right** side of the manual command to return to the reception position.



The programmed functions are grouped on the foot pedal.

Foot pedal

(for models 2800-10, 2800-15, 2800-20)

Presentation



Safety note

When using pre-programmed positions (reception and examination), do not leave the patient on the chair unattended.

Using the foot pedal

Just press and hold the foot pedal's push button to activate the desired movement. The movement stops as soon as you take your foot off the pedal. The chair is fitted with an internal system that limits the upper and lower positions.



Use the foot pedal to return to pre-programmed positions:

Note: These positions are factory default settings and cannot be changed by the user.

Double press on the **Left** side of the raising pedal to return to the examination position.

Double press on the **Right** side of the raising pedal to return to the reception position.



Remark: This foot control operates with two (2) LR03 - AAA Alkaline 1.5V batteries.

In the event of malfunction, these batteries will have to be replaced.

(See page **29: REPLACING USED BATTERIES IN THE FOOT PEDAL**)

Using the chair

Adjusting the height

Using the foot pedal

Caution
 Make sure there are no objects under the chair before lowering it.



Height safety mechanism

When returning to the reception position  the chair stops at 55cm. Release the pedal, then press on the button used to lower the chair to continue lowering it down to 50cm. (press-and-hold)

Setting the arm rests



Safety
 To avoid malfunctions and for safety reasons, no objects must be left between the moving frame of the arm rest and the chair backrest.



Setting the tilt angle of the leg rest (for model 2800-10)

This equipment is fitted with a mechanism that locks the leg rest permanently.

To change the tilt upwards, grip the lower part of the leg rest and raise it to the required tilt.

To change the tilt downwards, hold the leg rest with one hand and push the control lever (L2) of the locking system downwards with the other. The mechanism is now unlocked and the leg rest can be lowered.

Releasing the control lever locks the control mechanism.



Caution

Always hold the patient's leg when changing the tilt of the leg rest. (risk of malfunction or sudden release).



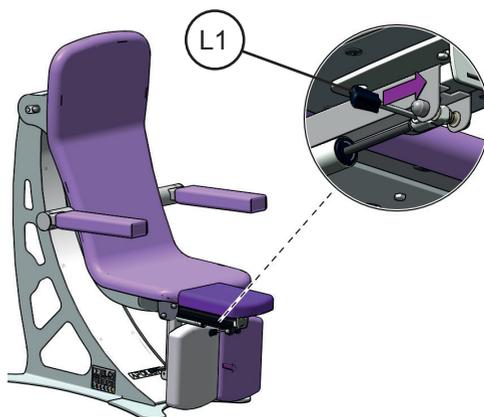
Setting the tilt angle of the leg rest (for model 2800-20)

Actuate the lever (L1) with one hand, and lower or raise the leg rest to the required tilt with the other.



Caution

Always hold the patient's leg when changing the tilt of the leg rest. (risk of malfunction or sudden release).



Using the chair

Setting the tilt angle of the leg rest (for model 2800-30)



*All the individual controls are used by pressing and holding.
(releasing the control interrupts the corresponding movement).*



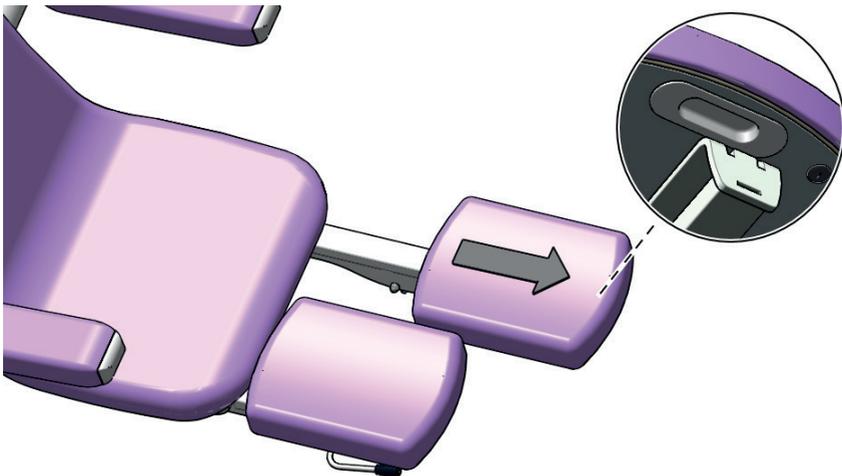
Safety

To avoid malfunctions and for safety reasons, no objects must be left under the leg rest or between the chair's moving frames.

Setting the tilt angle of the leg rest (except 2800-15)



Setting the length of the leg rest (except 2800-15)



Caution

When adjusting the leg rest, lift the patient's leg up slightly to take the weight off the leg rest.

Using the chair

Setting the tilt angle of the leg rest (for model 2800-15)

This equipment is fitted with a mechanism that locks the leg rest permanently.

To change the tilt upwards, grip the lower part of the leg rest and raise it to the required tilt.

To change the tilt downwards, hold the leg rest with one hand and push the control lever (L2) of the locking system downwards with the other. The mechanism is now unlocked and the leg rest can be lowered.

Releasing the control lever locks the control mechanism.

Caution
Always hold the patient's leg when changing the tilt of the leg rest. (risk of malfunction or sudden release).



Setting the length of the leg rest (for model 2800-15)



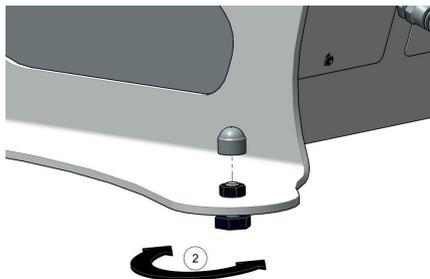
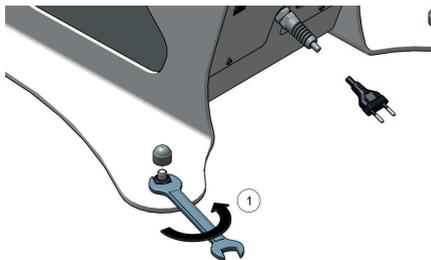
Caution
When adjusting the leg rest, lift the patient's leg up slightly to take the weight off the leg rest.



The levellers

Adjusting the levellers

Screw or unscrew the leveller (P) to the required height.



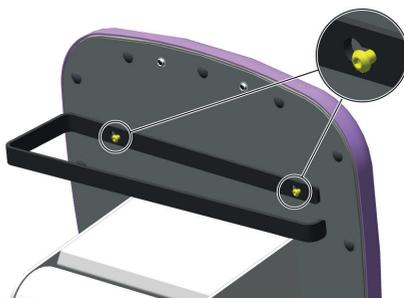
Paper roll

(reference 167-10)

Installing the roll holder



Allen key n°4



Accessories



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

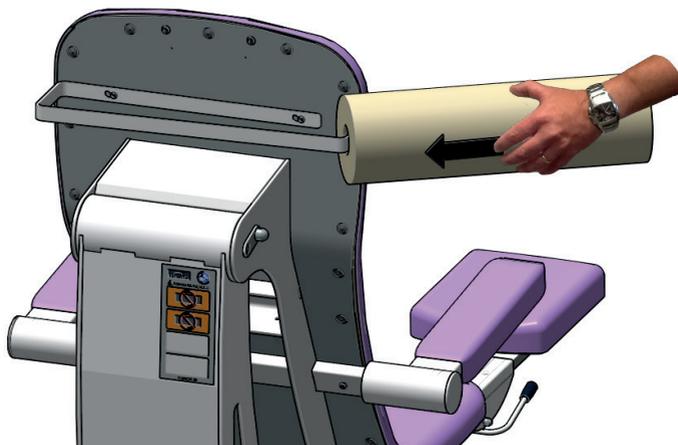
Installing the paper roll

Unroll the paper onto the upholstery before the patient gets onto the chair.



Caution

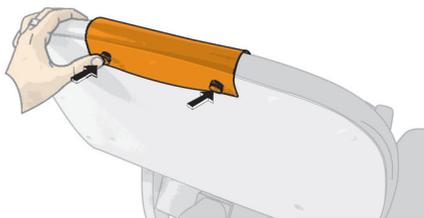
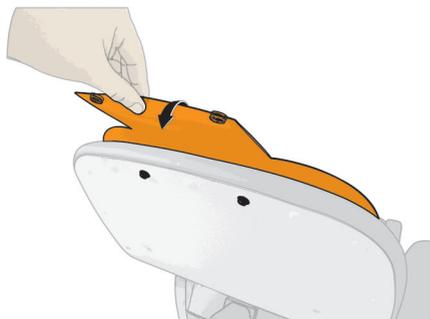
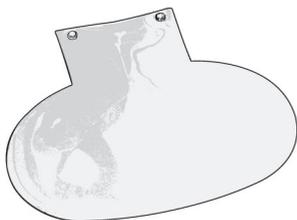
Take care to follow the instructions in order to maximise the equipment's lifetime.



Plastic cover (head end)

(reference 2806-01)

Installing the protective cover

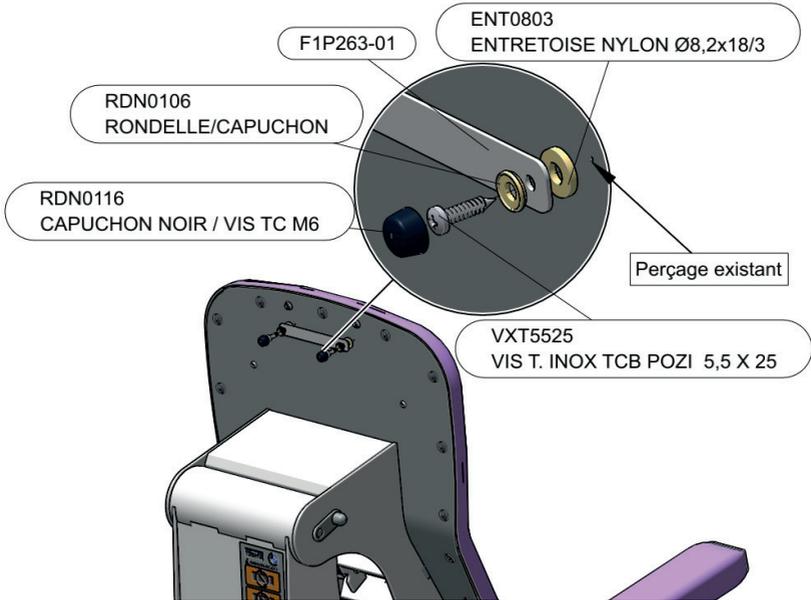


 Only accessories designed and provided by Promotal for this medical device are authorised for use.

Head rest

(reference 2802-01)

Installing the head rest

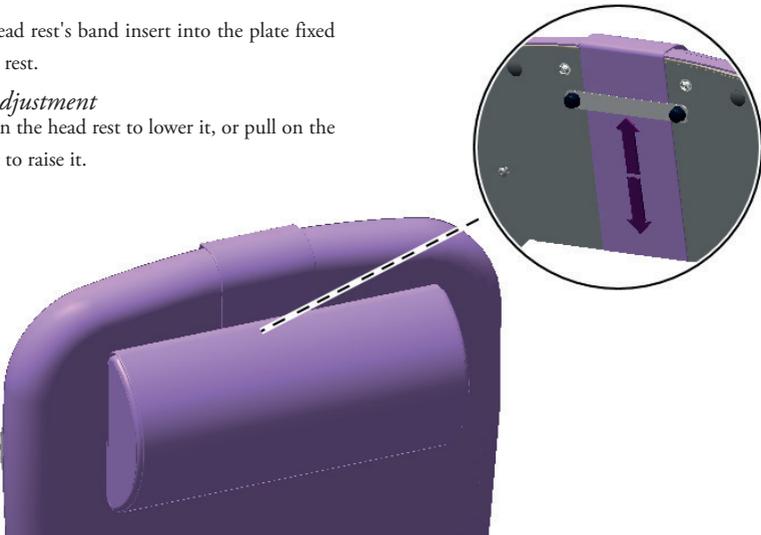


Positioning

Push the head rest's band insert into the plate fixed to the back rest.

Adjustment

Just press on the head rest to lower it, or pull on the band insert to raise it.





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

Rectangular pan

(reference 2864-01)



Positioning

“Kidney dish” pan

(reference 2864-10)



Positioning

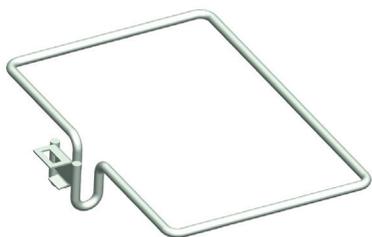
Accessories



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

Pan for plastic bag

(reference 2874-01)



Positioning



Plastic bag

(reference 962)

Delivered in rolls of 20 bags.





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

Disposable cover / leg rest

(reference 2804-01) (except 2800-15)

Delivered in boxes of 100 items.



Positioning



Back support

(reference 2880-01)



Adjustment

The back support cushion is inflated using a manual pump (pneumatic bulb).

The cushion is deflated by pressing on the valve (located close to the bulb) while pressing down with the lower back.

Accumulator

(reference 2892-01)



Accumulator - technical characteristics

Voltage	24 V DC
Amperage	2 Ah
Protection rating	IP66
Accumulator type	Lead gel
Voltage (maximum)	30 V DC
Charging time	Approx. 10 h (depending on the supply unit)
Lifetime	approx. 1000 cycles (depends on the chair's operating conditions)
Discharge time	approx. 1 year (storage)

Safety symbols on the accumulator

 CE marking

 Recyclable



To be disposed off
separately from
household waste

To be used in dry areas
only

IP66 Housing protection
classification



Safety:

To avoid malfunctions and for safety reasons, no objects must be left under the chair's seat or between the table's moving frames.

Medical device lifetime

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

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

For maintenance purposes, only components designed and supplied for this MD by Promotal are authorised.

Compulsory / specific maintenance

Once a year:

- Ensure that all screws are correctly tightened.
- Check the fixings of articulated parts.
- Ensure that the structure has not been deformed.
- 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 that the safety mechanisms are in proper working order (see page 12).

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

Torn upholstery no longer provides an effective anti-bacterial barrier and must be replaced immediately.



Material warning

DO NOT dismantle THE DEVICE

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

Replacing used batteries in the foot pedal

(battery reference (x2): LR03 - AAA Alkaline 1.5V)

To replace the batteries in this wireless foot pedal:

1. Turn the pedal over
2. Loosen the screw and remove the battery compartment cover
3. Remove the two used batteries and replace them with the two new batteries.
(make sure to place them with their polarities correctly positioned.)
4. Replace the cover and tighten the screw.

Wireless foot pedal for model 2800-30



Wireless foot pedal for models 2800-10, 2800-15 2800-20



Warranty information

Warranty

Promotal guarantees its equipment and associated components for a period of two (2) years¹ from the date of invoicing.

Commitments

Promotal undertakes to replace defective parts returned during the warranty period and which are found to be defective after examination by Promotal.

The distributor of Promotal is responsible for after sales service during and after the warranty period.

Exclusions

- This warranty does not apply to:

- (1) Wear parts and consumables.
- (2) Travel expenses and labour costs.
- (3) Failures resulting from improper use, obvious negligence or transportation of the device.
- (4) Equipment whose original characteristics have been modified by the user.
- (5) Control boxes, hydraulic and electric cylinders if they have been opened by the user (seals broken).
- (6) Damage, breakdown, failure or faults attributable to external causes (lightening, electrical power surges, floods, natural catastrophes, shocks, etc...) or the presence of foreign objects.
- (7) Damage due to incorrect connections or power supply, damage caused by corrosion or the gradual deterioration of the product.
- (8) Indirect damage linked to loss of use and penalties due to poor performance.
- (9) Aesthetic damage caused to external parts of the equipment which does not affect its functioning such as gouges, chips, scratches.
- (10) Devices whose serial number has been rendered illegible, modified or removed.

Exclusive obligation

The sole undertaking of Promotal during the warranty period is the replacement of defective parts. Promotal shall not be liable for direct, indirect, special or incidental damages, or loss resulting from the inability to use the equipment.

Absence of authorization

No person or company is authorised to enter into a commitment or obligation with regard to equipment in the name of Promotal.

THIS WARRANTY IS THE ONLY WARRANTY APPLICABLE TO PROMOTAL EXCLUDING ALL OTHER IMPLIED WARRANTIES.

¹ Upholstery is guaranteed for 1 year against manufacturing defects



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: Apolium 2800-10 / 2800-15 / 2800-20 / 2800-30

Description: Podiatry chair

Basic UDI-DI: 37014094APOLIUMHQ

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: 2016

Signed in Ernée,

On 26 May 2021

Rudolf MOURADIAN

Chairman

Promotal

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S.A.S.U [one-person simplified joint-stock company] with a capital of €4,290,660 - LAVAL Companies Register Siret [French business registration]
No.: 421 156 720 00011 - VAT No.: FR 67 421 156 720 - APE [business activity sector] Code: 3250 A



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