User's Guide

PROMOTAL®

KOMPACT

Model Shown : 235-10 + accessories

Examination table
235-10 / 235-15

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

22, rue de Saint-Denis de Gastines
B.P. 26 - 53500 ERNÉE Cedex

FRANCE

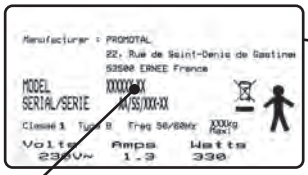
Tél. : +33 (0)2 43 05 12 70
Fax : +33 (0)2 43 05 68 99
internet : www.promotal.com

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



Year(YY)/Week(WW) of manufacture

Summary

Summary

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
CE marking	Fuse rating	Protective earth
Dangerous voltage / risk of electrocution	To be disposed off separately from household waste	Equipotential terminal
Refer to the instruction manual / brochure	General safety sign	Housing protection classification
Catalog reference	serial number	For indoor use 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.

Do not sit on the back rest

Do not sit on the leg rest

You must not use the medical device for transfers

Do not sit on the armrests

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
- Leg rest
- Gynecological examination stirrups (accessories)

Electrical power supply

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

Equipped with the optional electrical outlets, 240-01xx, this medical device is electrical class 1. It must be connected to a grounded power supply system only.

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.

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.

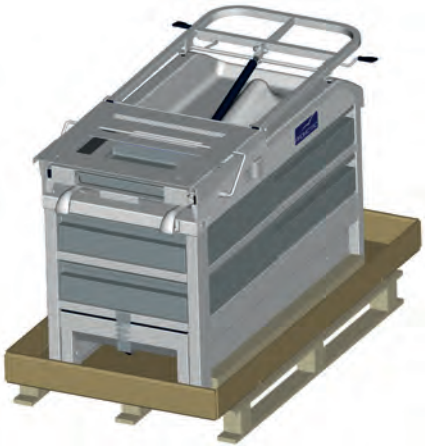
2) If possible, transport the medical device on its pallet up to the final place of use.

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 Optionss, 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:

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

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 purpose

This medical device is designed for use in professional premises only:

- Medical office
- Health establishment

This medical device must not be installed in domestic premises.

This medical device is intended for general or specialist medical examinations and acts. Only health professionals (doctors, caregivers) and/or qualified members of the technical staff can handle or use the device.

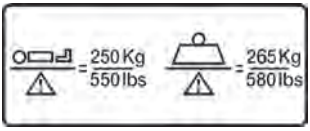
Patients and companions must not intervene directly on the device. They must not have access to the device's controls.

During the consultation, supervision of children is the responsibility of the parents or of the practitioner.

This medical device must never be used as a healthcare bed.

This medical device must not be used in the presence of anaesthetics flammable in contact with air or nitrous oxide to avoid all risks of explosions.

Patient weight capacity



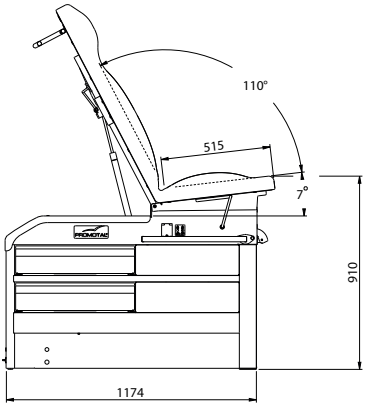
Protection against penetration of liquids

- **IP X1**

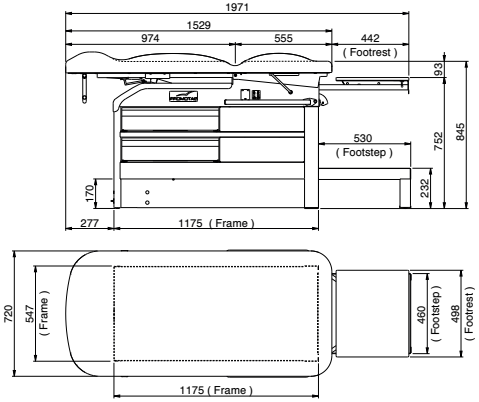
Characteristics

Height 84 cm
Steel frame with white epoxy finish
Headrest adjustable by means of a gas lift
Manual seat tilt (7°)
Removable leg rest
Upholstery Width 72 cm
Seamless removable upholstery
Upholstery with M1 fireproof coating
Paper roll holder,
Maximum length 50 cm – ø 20 cm (head end)
Pull-out stirrups
Removable plastic tray

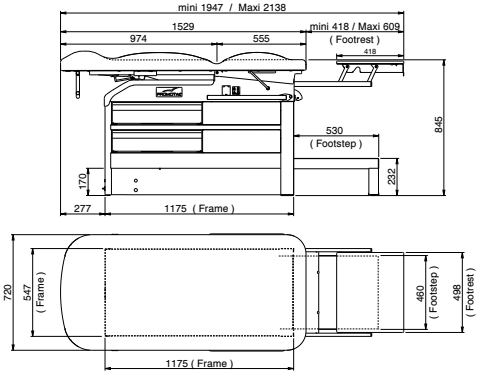
Dimensions / Installation precautions



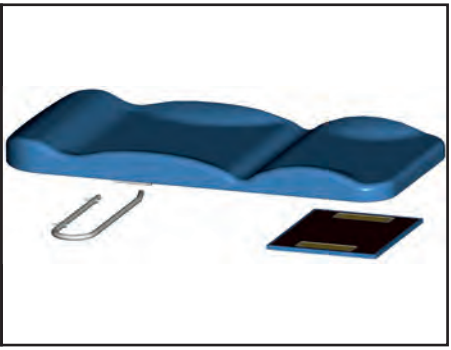
235-10 / 235-15



235-10 / 235-15 + Option 272-01

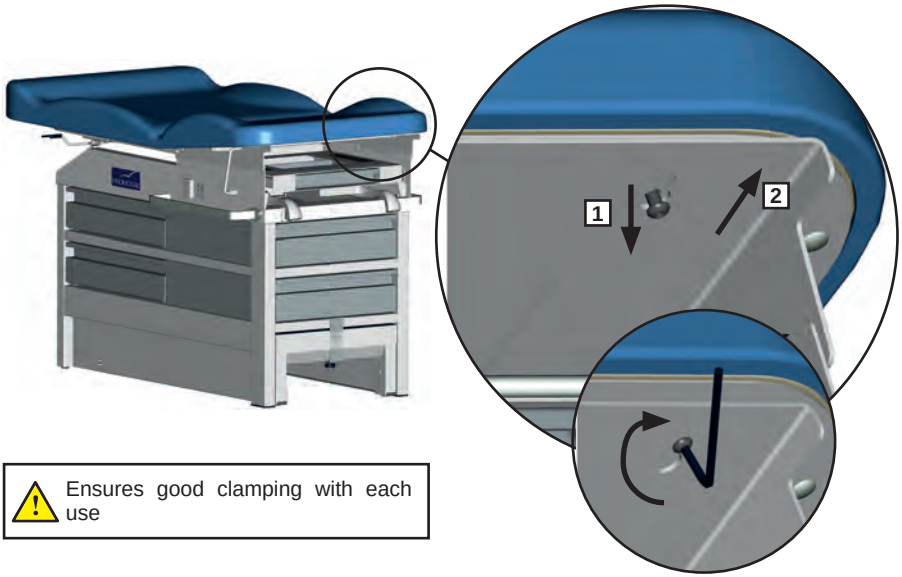


The table is delivered dismounted.
The packaging contains 2 boxes :
the frame the upholstery, the paper roll holder.



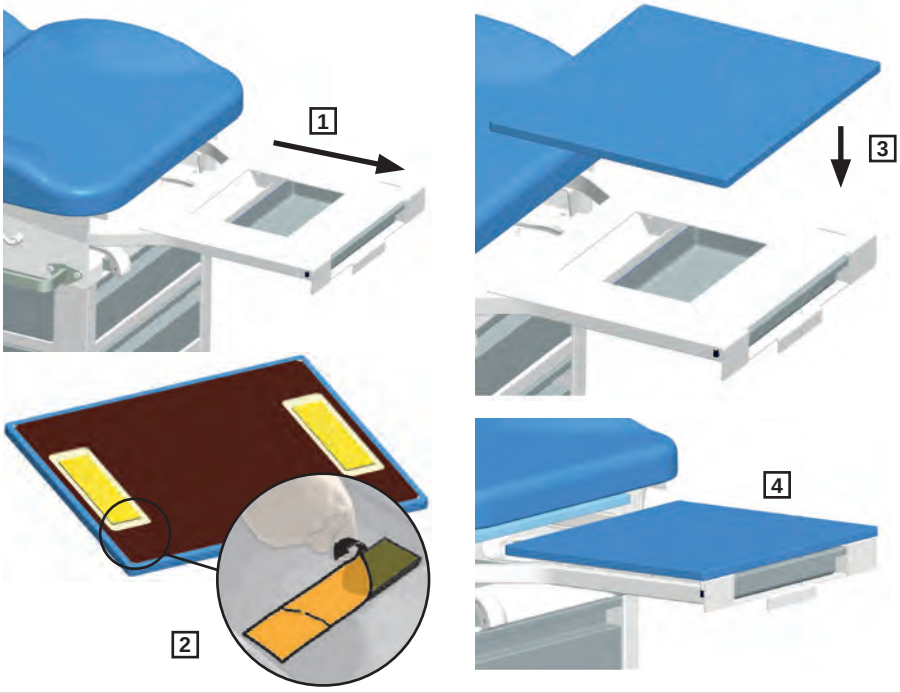
Laying out the sleeping surface

One piece upholstery



Ensures good clamping with each use

Legrest upholstery



Caution
When this medical device is equipped with option 240-01xx, the power supply cable may represent a fall risk. Be aware of the cable when walking around the device once it is connected to the mains.

Safety note
Unplug the power cord before moving the medical device.

Warning
Connecting equipment to the multiple socket outlet effectively leads to creating a Medical Electrical System and the result can be a reduced level of safety.

Safety note
Table must be positioned in normal use such that the power cords can be easily accessed to unplug.

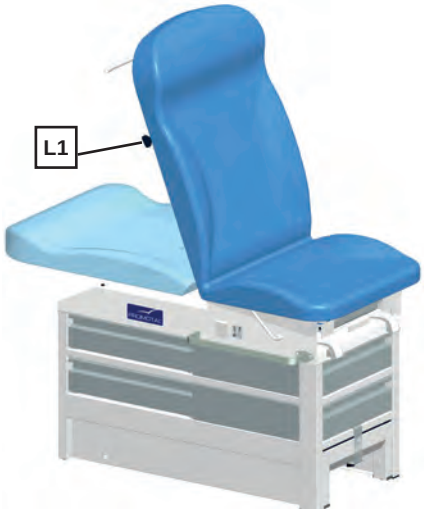
Warning
No modification of this equipment is allowed.

Caution
To completely isolate the table from electrical mains supply, both power cords must be unplugged.
When using high frequency surgical devices or endocardial catheters:
• Use non-conductive material to insulate patient from metal portions of the table.
• Consult operating instructions for the device before using in conjunction with drawer or upholstery heater.
Failure to comply may result in electric shock or burns to patient.

Backrest tilt adjustment

With one hand, operate the lever (L1), and with the other hand, lower or raise the backrest according to the desired inclination.

> ⚠ The patient should not lean on the backrest during adjustment.

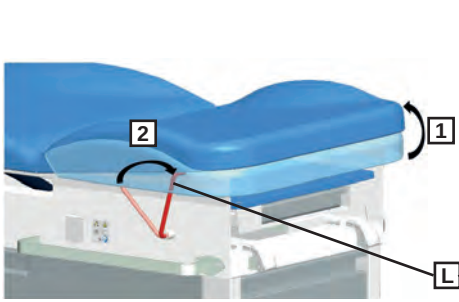


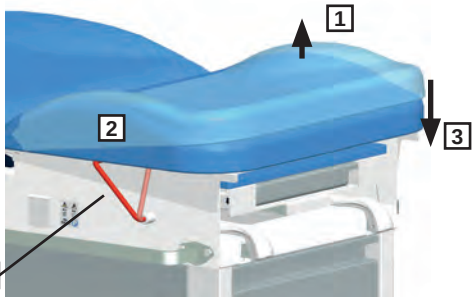
Trendelenburg position

Principle

A. Lift the seat until it clicks into place.

B. With one hand hold the seat and with the other bring the lever (L) backwards. Replace the seat on the base.





> ⚠ **Caution**
> Make sure the device is locked before the patient gets on the table.

> ⚠ **Caution**
> of pinching when lowering the seat.

Leg rest

Using the leg rest

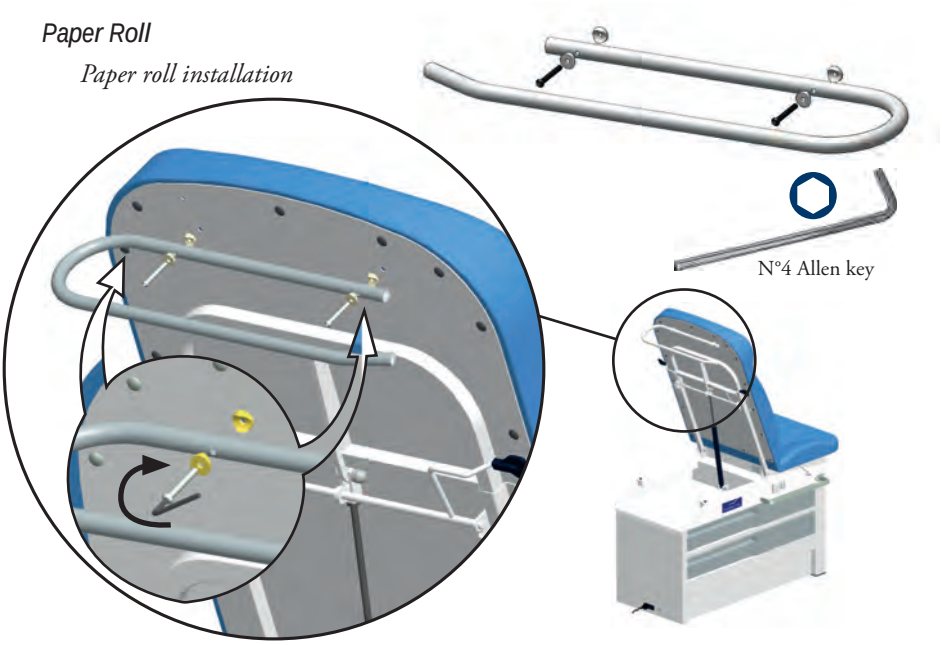
Caution
Maximum permissible load : 25 kg

Footstep

Using the footstep

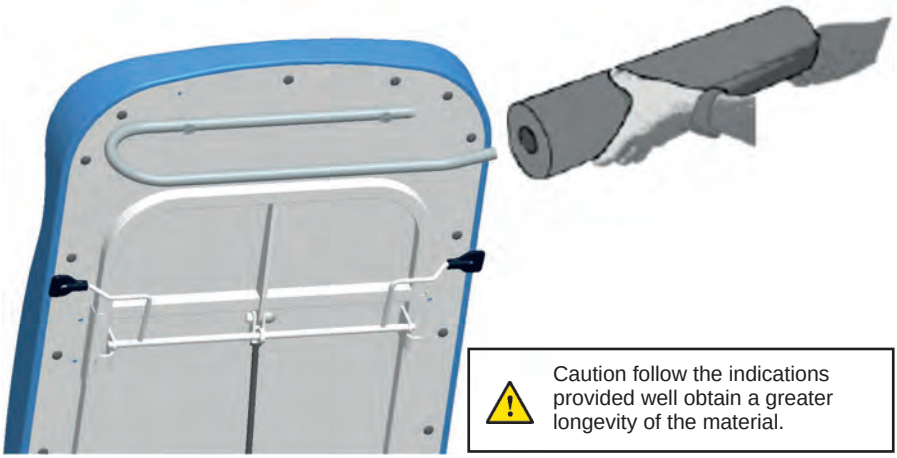
Paper Roll

Paper roll installation



Using the paper roll

Cover the upholstery with paper before use.

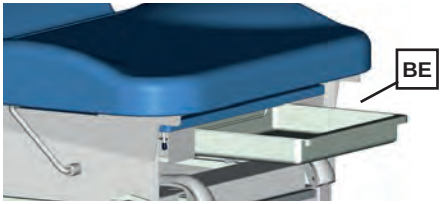


Caution follow the indications provided well obtain a greater longevity of the material.

Gynaecology debris tray

The tray is removable for easy cleaning, and can be pulled out or pushed back under the seat.

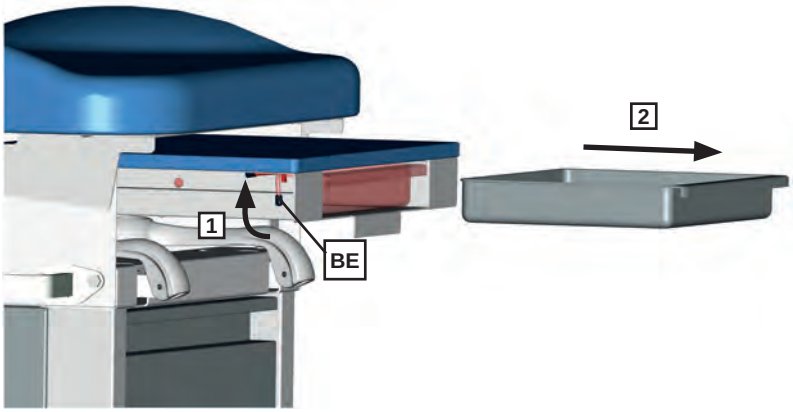
In order to prevent the tray from falling out, the table is equipped with a retractable stop.



Using the gynaecology debris tray

A: Pull out

Push back on the retractable stop. Hold it down while pulling out the tray:



B: Push back in

Simply push the tray back into place.

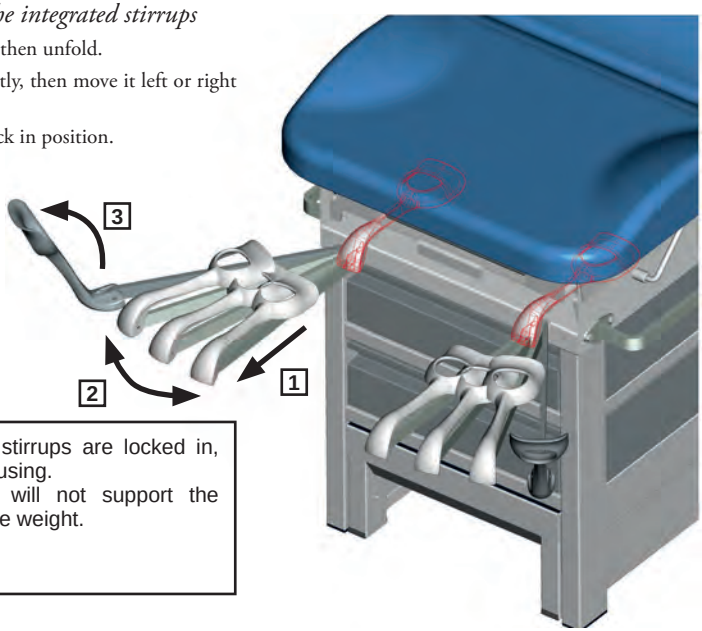
Integrated stirrups

Installing the integrated stirrups

1) Pull the stirrup out, then unfold.

2) Lift the stirrup slightly, then move it left or right as desired.

3) Release stirrup to lock in position.



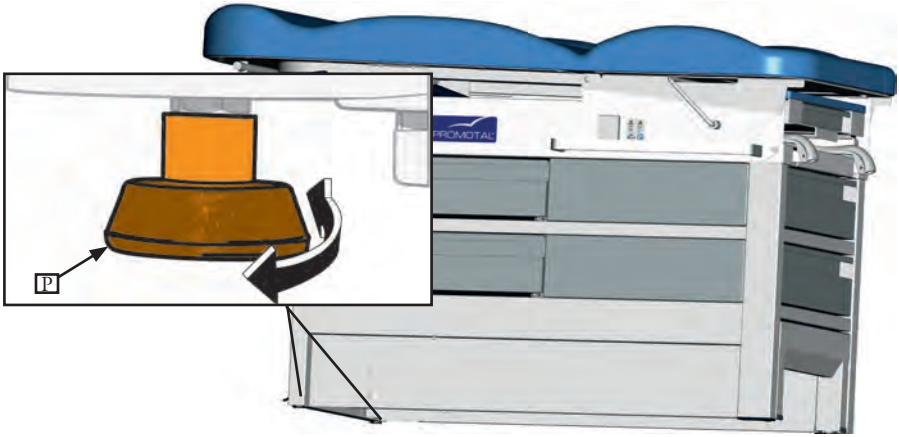
> ⚠ Be sure the stirrups are locked in, place before using.
> The stirrups will not support the patient's entire weight.

The levellers

Adjustment of the levellers

Only concerns the 2 rear levellers.

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



Drawers

The table is equipped with:

- 2 Pass through side drawers (accessible from both sides)
- 2 Front drawers with soft/self-close system

Caution
Maximum permissible load : 8 kg

Caution
Maximum permissible load : 5 kg

Braking

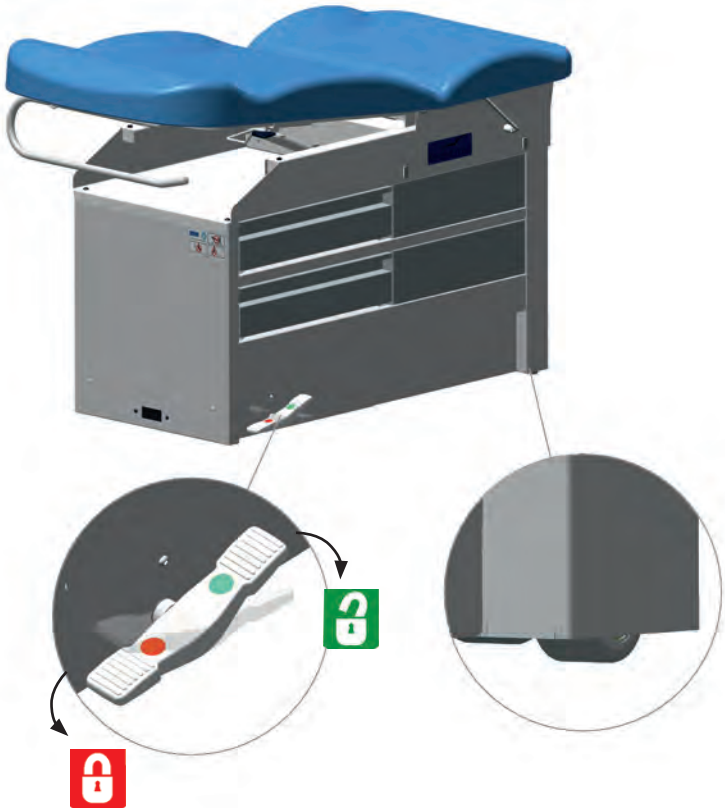
(only on models 235-15)

Using the brakes

2 pedal positions

1 : Press on the green foot pedal : All 2 castors are free.

2 : Press on the red foot pedal (brake position) : all 2 castors are locked.



Caution
Ensure brakes are fully engaged before installing a patient.

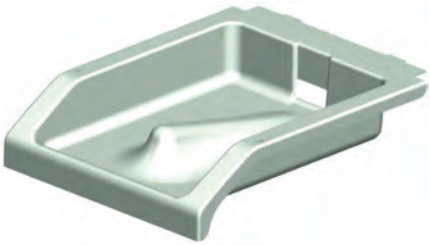
Only accessories designed and provided by Promotal for this medical device are authorised for use.

Rear tray for storing paper rolls

(239-10)

Set up

(Follow the instructions in the installation guide provided with this accessory).



2 removable plastic trays / Side drawers

(239-15)

Set up

Open the drawer all the way and insert the plastic tray.

(x2)

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

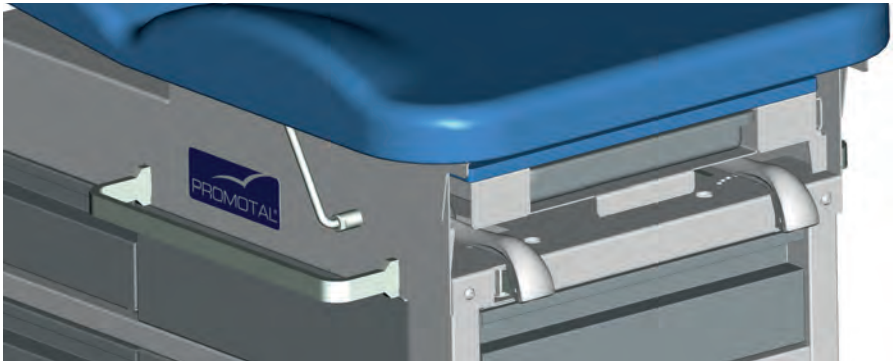
Pair of stainless steel rails 25x10
(278-01)

VXM59820 (x4)

Remove plastic end caps

install the pair of rails

(Follow the instructions in the installation guide provided with this accessory).

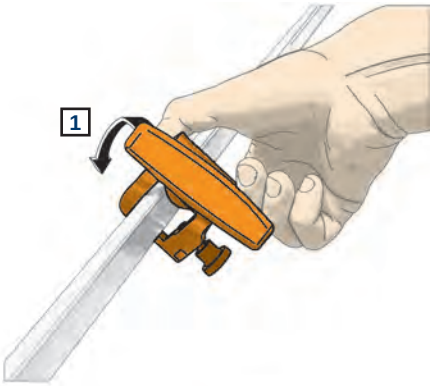


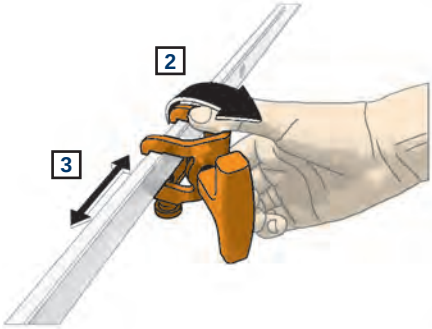
Sliding clamp for 25 x 10 rail

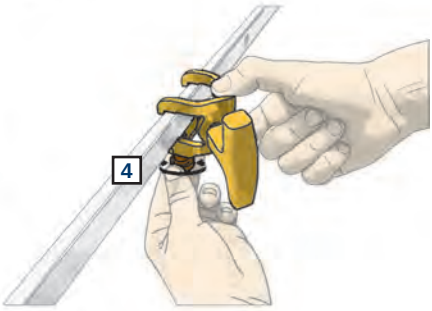
(reference 878-12)

Installing the clamp

878-12

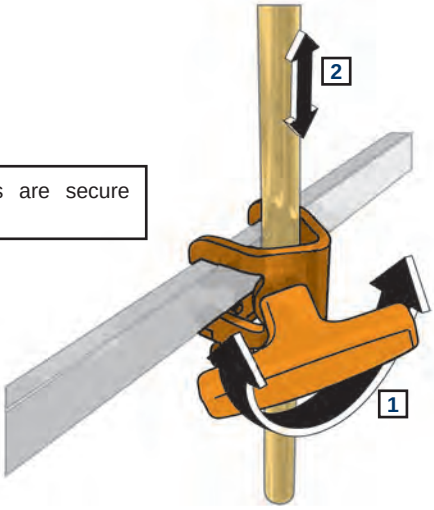






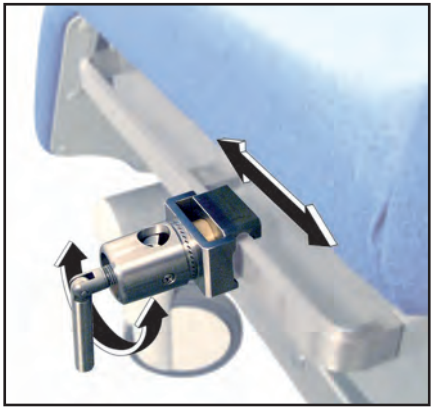
Using the clamp

> ⚠ Check that the parts are secure before use.



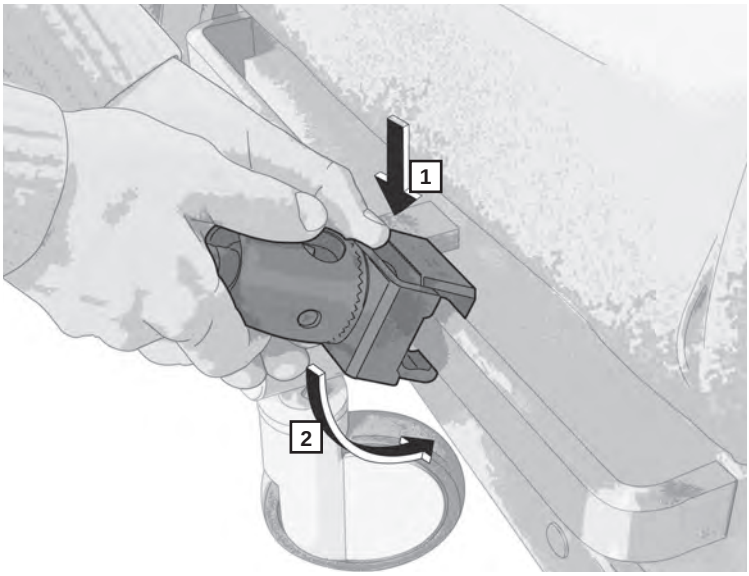
Only accessories designed and provided by Promotal for this medical device are authorised for use.

Rotating clamp for 25 x 10 rail
(reference 879-10)



Installing the clamps

Insert the clamp on the rail.



Tighten the screws before use.

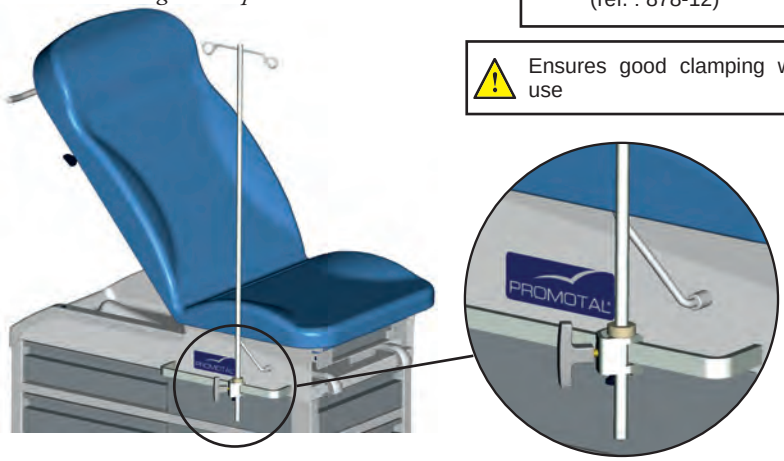
2 hook IV pole

(reference 985-01)

Installing the IV pole

Caution
Clamps are necessary to install these accessories.
(réf. : 878-12)

Ensures good clamping with each use



Auto-blocking I.V. pole

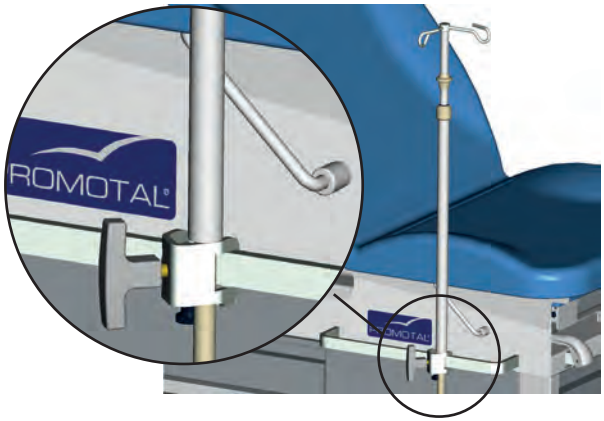
(reference 2985-01)

Installing the IV pole

Unscrew the screw handle.
Insert the I.V. pole and rescrew.

Caution
Clamps are necessary to install these accessories.
(réf. : 878-12)

Ensures good clamping with each use



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.

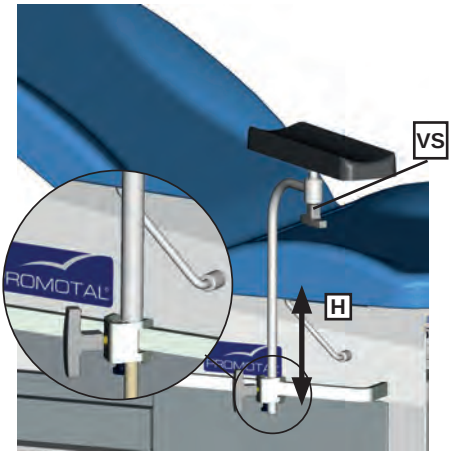
Only accessories designed and provided by Promotal for this medical device are authorised for use.

Arm Rest

(reference 236-01)

Adjusting the arm rest

The standard arm rests can be adjusted in height (H) and can be positioned in all directions due to the ball and socket joint underneath the armrest. To adjust the armrests, loosen the screws (VS) and position as desired.



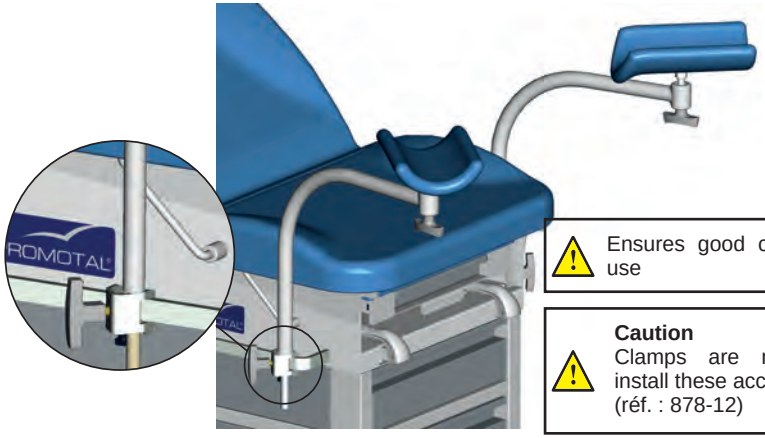
Ensures good clamping with each use

Caution
Clamps are necessary to install these accessories.
(réf. : 878-12)

Pair of legrests GOEPPEL

(reference 245-01)

Installing the legrests



Ensures good clamping with each use

Caution
Clamps are necessary to install these accessories.
(réf. : 878-12)

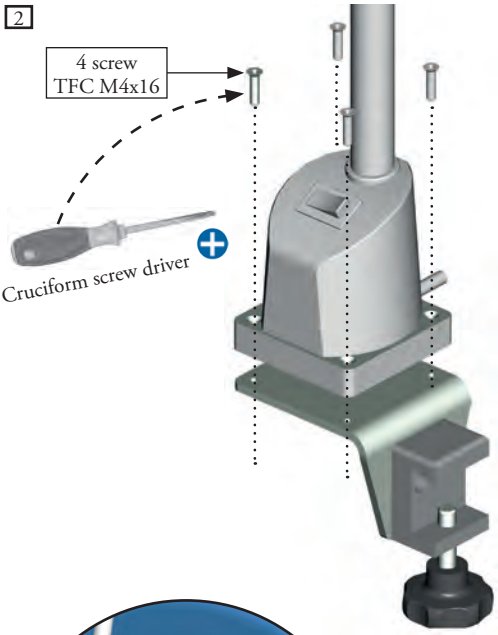
Lamp holder
(reference 295-01)

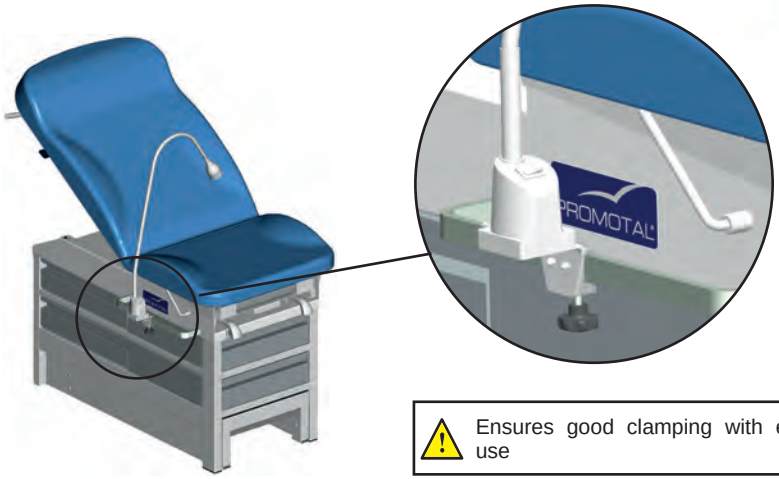
⚠ Ensures good clamping with each use

Fixing of the lamp on the support

1

2





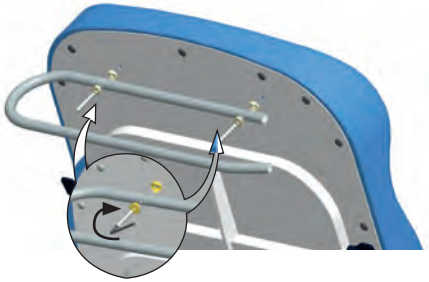
⚠ Ensures good clamping with each use

Adjustable paper-roll holder
(reference 2056-02)

Installating the paper roll holder

N°4 Allen key

1. Remove the standard paper roll holder.



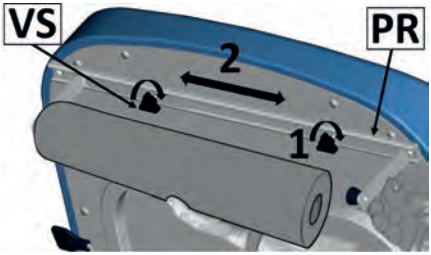
2. Replace the paper roll holder.

Installation of the paper roll

The paper roll is positioned on a mobile axis with adjustable hooks at each end.

1. Unscrew the screw handle (VS).
2. To remove the paper roll holder 1/2 slightly (PR).
3. Insert the paper roll.

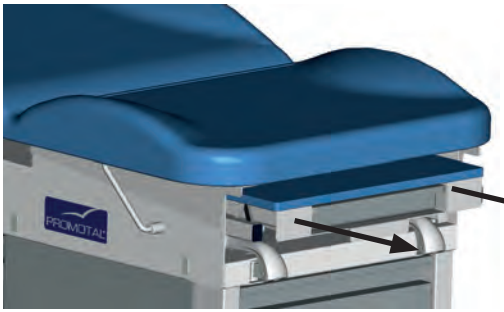
Cover the upholstery with paper before use.



Leg rest flush with seat

(reference 272-01)

Using the leg rest



Caution
The leg rest should only be used to support the patient's legs. Under no circumstances should it support the person's entire weight. Accordingly, the leg rest must be pushed in when the patient is getting on or off the table. We decline all liability in the event of non-compliance with this clause.

Caution
Maximum permissible load : 25 kg

Caution
Ensure that the leg rest is correctly positioned before use.

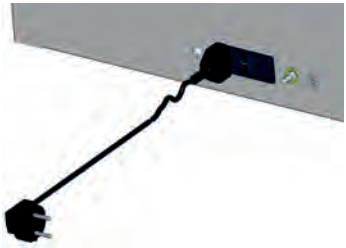
Additional mains plug and equipotential terminal

(reference 240-01EU / 240-01UK / 240-01US)

Available only in EU, UK & US standard

Safety note
By connecting a medical device to the additional mains plug, the unit becomes an Electro-medical system according to the standard EN 60601-1. The user must ensure that the EM system is in conformity with the standard EN 60601-1 (article 16).

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.



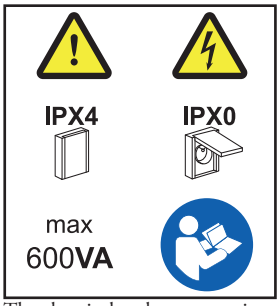
Safety note
Unplug the power supply cable before moving the MD.

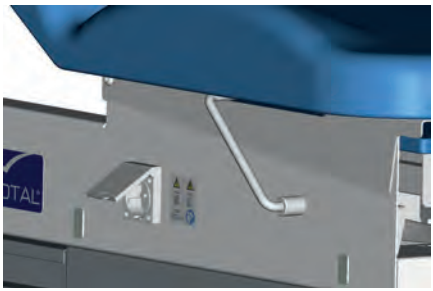
Using the additional mains plug

- Characteristics : 120 V or 230 V depending on the country
  2,5 A maxi

The power consumed in a single event must not exceed 600VA.

Options (supplemental power socket) consists of 2 sockets, one on each side of the base of the couch.





The electrical sockets are equipped with hinged covers.

When these covers are closed, the examination couch is protected against sprays of water (IP X4 according to European standard 60 529). If one of the covers is open (i.e. each time one the sockets is in use), this protection is no longer present.

Equipotential terminal

This medical device is of electrical class 1. It must only be connected to a supply network equipped with protective earth.

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.

Notes

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 gas spring

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.

Fuse replacement

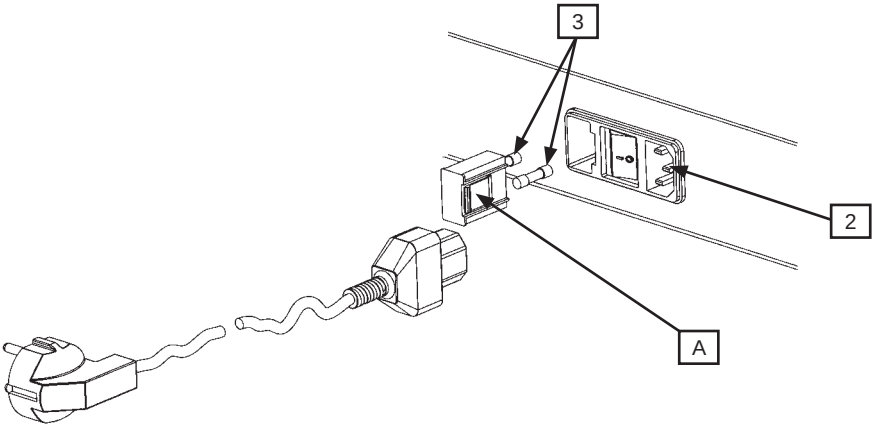
(Only if option 240-01EU or 240-01UL or 240-01US is present)

1. Remove all power to unit by unplugging unit's power cord.
2. Using a fl at tipped screwdriver, gently release the plastic spring clip (A) on both sides of fuse drawer (1) then pull fuse drawer from fuse housing (2).
3. Pull both fuses (3) out of fuse drawer (1) and inspect. Check the fuses for any indication that they have blown ; i.e. burnt look, fuse cord melted through, etc. Discard fuses (3) if blown and replace them.

EQUIPMENT ALERT

Use fuses of the same voltage rating, amperage rating, and type. Failure to do so could result in damage to the equipment.

4. If necessary, obtain new fuse(s) (3). The replacement fuse(s) must be a 250 VAC, 6.3 amp, IEC 127 rated, 5 x 20 mm, Type T "Slo-Blo".
5. Insert fuse(s) (3) into fuse drawer (1).
6. Insert fuse drawer (1) into fuse housing (2) until fuse drawer snaps into place (both side of use drawer are locked into fuse housing).
7. Plug in power cord to equipment. If fuse blows again, call your Promotal distributor.



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

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) years[1] 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 profi ts or lose of use.

No Authorization

No person or fi rm 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.

CE DECLARATION OF CONFORMITY

We,
Promotal

22, rue de Saint-Denis de Gastines
53500 Ernée
FRANCE

Hereby declare in sole responsability that the medical device :

Model number : Kompact 235-10 / 235-15

Description : Examination table

is a medical device, class I,

we certify that the above-mentioned product meets the folowing requirements :
directive 93/42/EEC of the Council of the 14/06/93
(Medical device / appendices I and VII / decree 95-292 of the 16th March 1995),

all European standards applicable to it,
and herefore carries CE marking.

Year in which CE marking was first affixed *(Medical Device)* : **2020**

Ernée,
1 july 2020

Rudolf MOURADIAN
President

Promotal
22, rue de Saint-Denis de Gastines, 53500 Ernée - FRANCE
Tél. : +33 (0)2 43 05 17 76, Fax : + 33 (0)2 43 05 72 00, www.promotal.com

S.A.S. au capital de 4 290 660 € - R.C.S. LAVAL Siret 421 156 720 00011 - TVA FR 67 421 156 720 - APE 3250A

CE

PROMOTAL - FRANCE
www.promotal.com
DIC235-10_2720EN