User's Guide







Electric Examination Couch 2050-10 / 2050-15 / 2050-20 2050-30 / 2050-50

Product Identification

Legal Notice

PROMOTAL

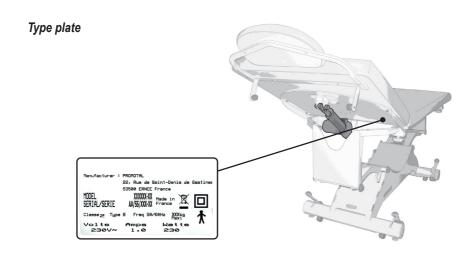
22, rue de Saint-Denis de Gastines B.P. 26 - 53500 ERNÉE Cedex

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.



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Safety symbols



Warning sign

The information marked with this symbol must be read and strictly followed!

Procedure, practice, or condition.



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



Double isolated



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



Equipotential terminal



Refer to the instruction manual / brochure





Housing protection classification



Do not sit on the back rest



Do not sit on the armrests



Do not use the couch for transportation



Warning: Pinching risk between the sides and the seat of the couch



The warning pictograms and signs installed by the manufacturer must not be removed! The manufacturer's responsibility is cancelled if these signals are removed.

Applied parts

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

- PVC upholstery
- Assistance handles (accessories)
- Gynecological examination stirrups (accessories)

Electrical power supply



Class 2 type products are without earth protection due to the use of double isolated electric housing powered by a bipolar cable.

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.

Precautions when unpacking

Material delivered in cardboard packaging

Small, lightweight, easy to handle materiel

In this case, the products can be easily handled without any lifting gear, taking care to position the product according to the directional arrows on the packaging.

In the absence of arrows indicating the top and bottom, use the position of the various product identity labels which are always placed at the top.

Heavy or cumbersome material requiring the

use

of lifting gear

In this case, it is possible to use a fork lift truck, provided it is used correctly.

Before moving, ensure the material is properly positioned, and that the load is evenly balanced.

Dismounted material

These products are delivered unassembled.

The various elements are protected by the following types of packaging:

- plastic (vinyl) packaging
- bubble fi lm packaging / foam or polystyrene
- cardboard packaging.

Products delivered on wooden palettes

Products placed on a wooden palette may easily be moved using a forklift truck, provided this is used correctly. Before moving, ensure the truck is correctly positioned in relation to the palette, and that the whole is stable. Take additional caution when handling very tall or high articles (eg. cupboards).

Storage condition

Ambient Temperature Range : Relative Humidity :

Atmospheric Pressure:

The following conditions must be observed when storing any material:

- The area must be clean, well ventilated and be of a normal temperature.
- Store products away from the elements, and away from direct sunlight.
- The area must not be damp.

-15 °C to +60 °C (+5 °F to 140 °F) 10 % à 90 % (non-condensing) 0.5 bar to 1.05 bar (500 hPa to 1050 hPa)

- The products must not be subject to bumps or jolts.
- Do not store in an area where people are likely to pass.
- Articles must not be stacked on top of each other.
- Articles must remain in their original packaging until fi nal delivery.

Conditions of use

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

Temperature 10 to 40° CRelative humidity 75% maxi.

Unpacking / Installation

When installing, remove all staple clips and carefully remove the cardboard packaging. Fragile parts of the product (upholstery coverings, plastic casings, etc.) may be just below the packaging. Care must be taken with cutting instruments.

Once the packaging has been removed, remove any remaining protective covering.

In the case of packaging on a wooden palette, remove the packaging as above. Depending on the model, the product is fi xed either by screwed fl anges, or by nailed wooden stakes. Use a spanner (for metal fl anges). Use a claw hammer (for wooden stakes). Lift the article off the palette, and remove the remaining protective covering. The product is now ready for use.

Verification

After unpacking the device, follow the steps below:

Check the delivery documents to make sure that the consignment is complete.

Check the external components and look for possible transport damage.

Check that the package contains the device, the accessories and options, the power cord (*if electric DM*) and the Operating guide.

Note:

Authorized CE representative

Countries in the EEC should direct all questions, incidents, and complaints to Promotal's Authorized CE representative listed below :

Promotal 22, rue de Saint-Denis de Gastines 53500 Ernée, FRANCE Téléphone : + 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.

User's Guide – Examination Couch



Intended use

This appliance is designed for use in professional premises only:

Medical practices
Care establishments

This appliance must not be installed in domestic premises.

This table is designed to be used only by healthcare staff. This examining table is used to perform interventions under the best possible safety conditions.



This table is not designed to be used as a stretcher.

Authorisation to use

Only health professionals (doctors, caregivers) and/or qualified members of the technical staff can handle or use the couch.

Patients and companions must not intervene directly on the couch. They must not have access to the couch controls.

This medical device must not be used in the presence of anaesthetics that are flammable in air or comburant gases such as oxygen or nitrous oxide in order to prevent all risks of explosion.

Patient weight capacity

Features

Electric variable height from $54~\mathrm{cm}$ to $94~\mathrm{cm}$ Steel frame with light grey epoxy finish

Gas-spring assisted or electric backrest

Flat upholstery with class M1 flame retardant covering

Hand control

Adjustable levellers under base

Block'n Roll - Integrated retractable castor system (ref: 2050-30 and 2050-50)

Paper roll holder (max length 50 cm - ø 12.5)

Mobile hoist compatibility - clearance of 12 cm



User's Guide – Examination Couch

Electrical connections

This table must be connected to the main electricity supply.

Connection to the supply: 120 V or 230 V (depending on country)

Frequency: 50/60 Hz

Protection Classification / Degree of electric shock protection: Class 2 / B

Power input: 200 W

 $Intermittent \ function \ mode: \\ 1 \ min \ / \ 9 \ min$

Maximum operating altitude: 2000 m



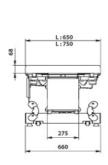


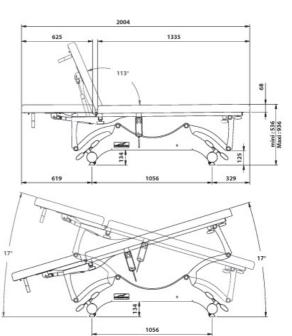
Caution

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.

If the chair is not to be used for a prolonged period of time, it should be switched off and disconnected from the mains.

Dimensions



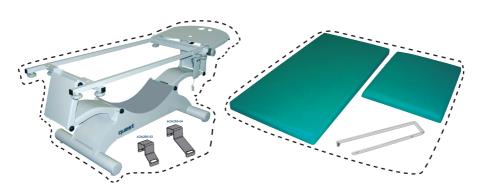


Assembling instruction

The table is delivered dismounted.

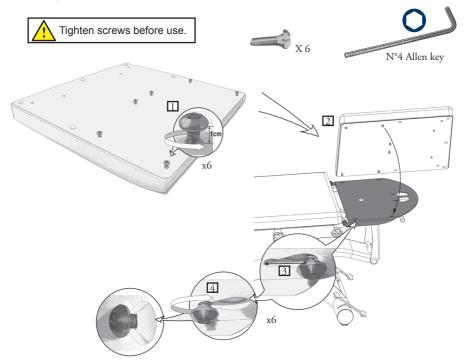
The packaging contains 2 boxes :

the upholstery, the paper roll holder. the frame, support handle.



Assembling the upholstery

Upholstery Backrest



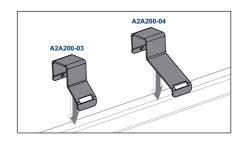
Assembling instruction

Assembling the support handle

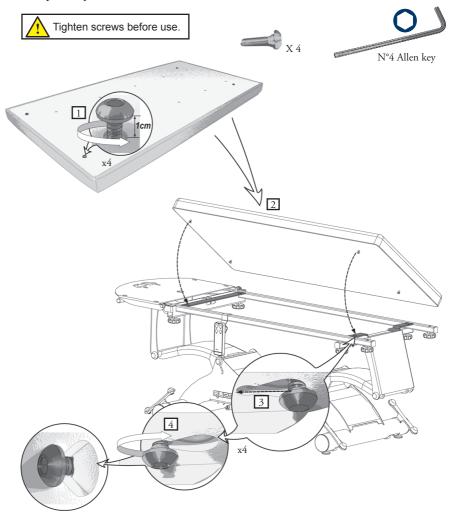
Select the corressponding hard control support to the relevant upholstery:

- **A2A200-03** / 600150-65, 600151-65
- **A2A200-04** / 600150-70, 600150-75, 600151-75

The support handle, located between the upholstery and the frame, may be moved or installed on the other side. Remove the mounting screw from under the frame to do so.



Upholstery Seat



Using the Couch



Safety:

For safety reasons, and in order to avoid malfunctioning, no objects should be placed under the seat cushion or between the moving parts of the couch.

Caution

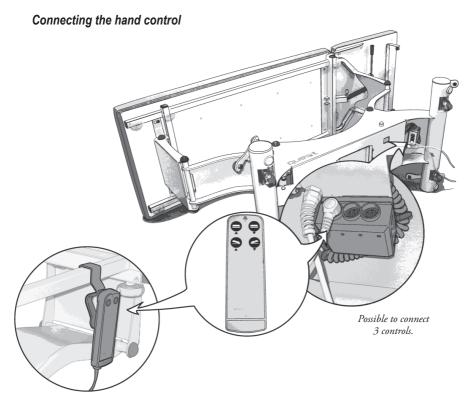


the supply cable for this medical device may represent an obstacle and cause falls. Do not forget its presence when moving around the device once connected to the mains supply.

<u>^!\</u>

Safety note

Unplug the power supply cable before moving the MD.



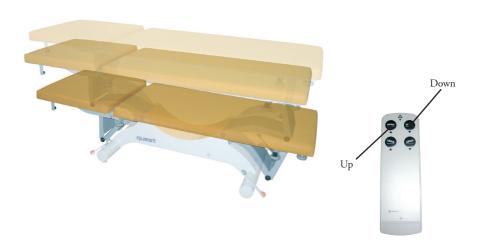
Using the hand control

To achieve the desired position, simply apply and maintain pressure on the hand control. As soon as this pressure is released, the movement will stop.

The couch is fitted with an internal device to limit the high and low positions.

Adjusting the height

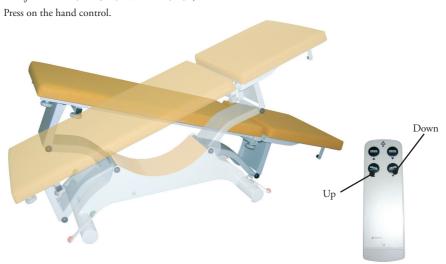
Press on the hand control.



Note: After a lot of use, a gap may appear when in the horizontal position. Placing the table in the low (or high) position will reinitialize the motors.

Adjusting the trendelenburg position

(for models 2050-20, 2050-30 and 2050-50)

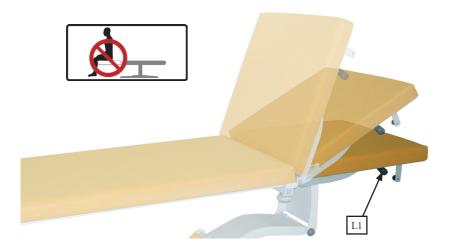


Adjusting the backrest tilt

(for models 2050-10, 2050-15, 2050-20 and 2050-30)

With one hand, move the lever (L1) either up

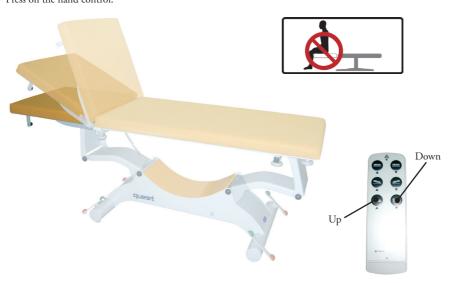
or down, with the other hand lower or raise the backrest he patient must inct lean with his / her full weight on the backrest during this procedure.



Adjusting the backrest tilt

(for models 2050-50)

Press on the hand control.



Using the Couch

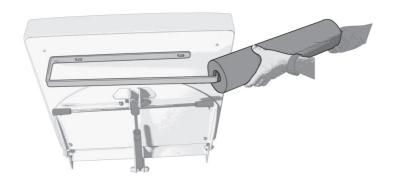
Paper roll Installation of the paper roll holder N°4 Allen key

Using the paper roll

Cover the upholstery with paper before use.



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



The levellers

Adjusting the levellers

Screw or unscrew the leveller to the desired height.



Block'n Rolf

(for models 2050-15, 2050-30 and 2050-50) Using the Block'n Roll



Caution

Must not be use with the patient, This system is only to be used to move the table for cleaning purposes.

Working position



Moving position







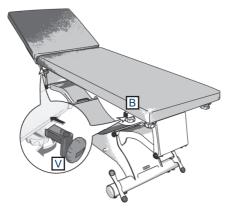
Caution

Ensure the table is in a working position before placing a patient on the table.

Accessories

Pair of Clamps

(reference 166)



Installing the Clamps

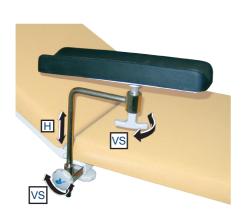
Take the stopper (B) out of the square tube if necessary. Loosen the nuts (V), and put the pair of clamps ref.166 (E) into position in the square tubes. Tighten the nuts.

The clamps accept accessories with a diameter of 16 mm.



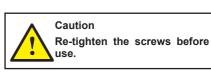
Arm rest

(reference 2536)



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.







Caution

Clamps are necessary to install these accessories. (réf. : 166)

Pair of stirrups

(reference 850)

Installing the stirrups





Tighten screws before use.





Caution

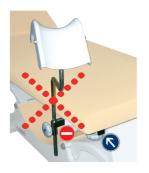
Clamps are necessary to install these accessories.

(réf.: 166)

Pair of legrests

(reference 840)

Installing the legrests





Tighten screws before use.





Caution

Clamps are necessary to install these accessories.

(réf. : 166)



Pair of covers for legrests (reference 861)

2 hook IV pole

(reference 985-01)

Installing the IV pole



Tighten screws before use.



Caution

Clamps are necessary to install these accessories.

(réf.: 166)



Auto-blocking I.V. pole

(reference 2985-01)



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.

Installing the IV pole

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



Caution

Clamps are necessary to install these accessories.

(réf. : 166)



Tighten screws before use.

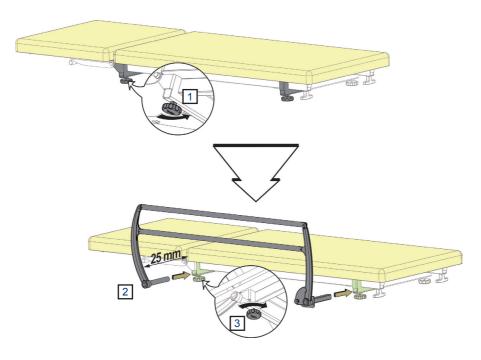


The pair of barriers

(reference 85114-01)

Installing the pair of barriers

- 1. Unscrew the screw.
- 2. Insert the pair of barriers. Approach the barriers to obtain a spacing of 25 mm beteween the barriers and the upholstery.
- 3. Tighten the screw.



Using the pair of barriers

To raise the pair of barriers

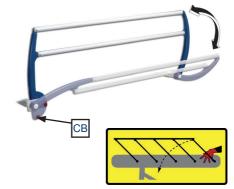
Take hold of the upper part, and lift it to its maximum height until it clicks into place.

To lower the pair of barriers

Hold the rail with one hand, and activate the lever (CB) to unlock the system with the other hand, then guide it down to its lowest position.



Ensure the side rails are correctly locked in position before use.



Headrest

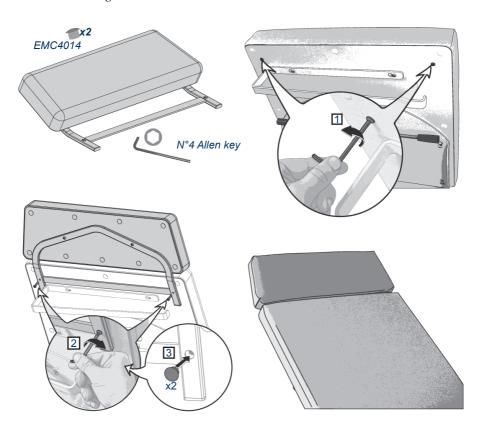
(reference 1102-10)



Backrest extension

(reference 2055-01)

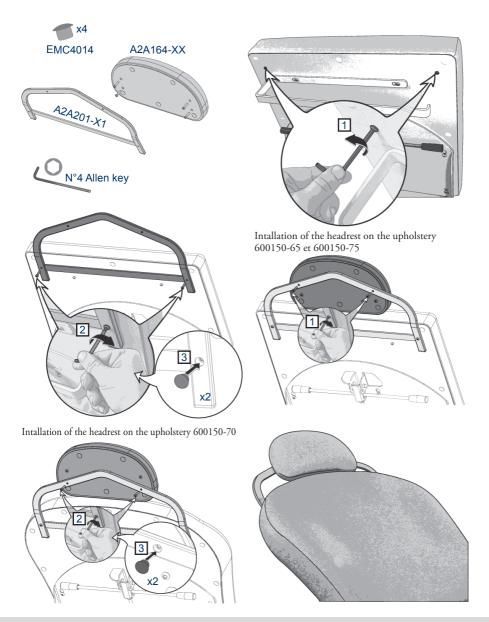
Installating the Backrest extension



Headrest

(reference 2054-01)

Installating the Headrest



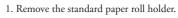
Adjustable paper-roll holder

(reference 2056-02)

Installating the paper roll holder



N°4 Allen key

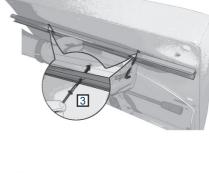




3. Replace the paper roll holder.

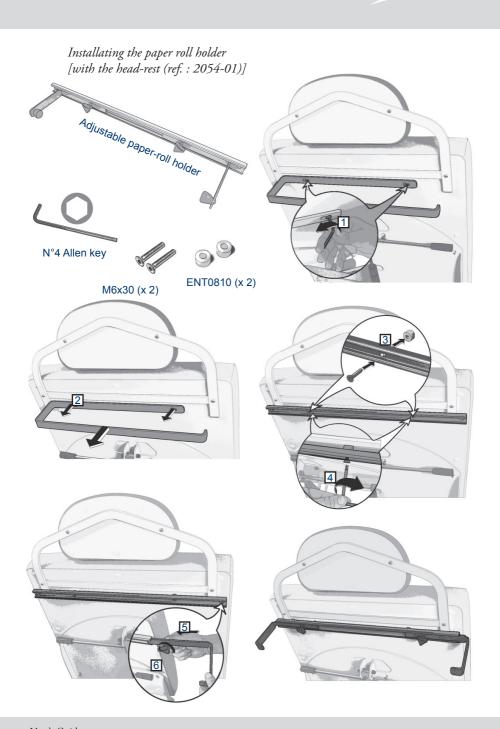


5. Replace the paper foil holder.







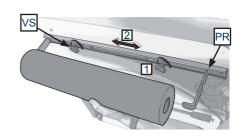


Installation of the paper roll

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

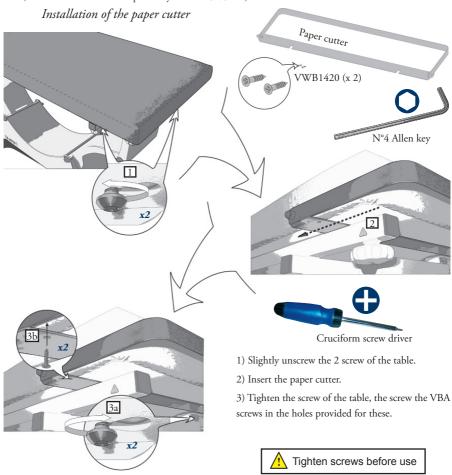
- 1. Unscrew the screw handle (VS).
- 2. To remove the paper roll holder 1/2 slightly (PR).
- 3. Insert the paper roll.

Cover the upholstery with paper before use.



Paper cutter

(reference 2052-65 and 2052-75) (Reference relative to the upholstery chosen 65/75 cm)



Using the paper cutter

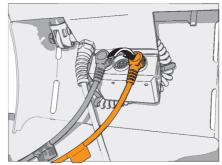
- 1) Slide the paper under the paper cutter.
- 2) Replace the paper cutter.



The pedal control

(reference 2051-10) (for model 2050-10 and 2050-15) Installation of the pedal control (Cf: page 16)

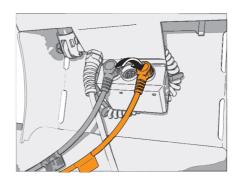




The pedal control

(reference 2051-21) (for model 2050-20 and 2050-30) Installation of the pedal control (Cf: page 16)





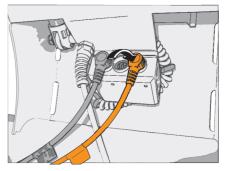
Accessories

The pedal control

(reference 2051-31) (for model 2050-50)

Installation of the pedal control (Cf: page 16)





Castors with brakes

(reference 81036) (for models 2050-10 and 2050-20)

Using the castors



Caution:

Must not be use with the patient, This system is only to be used to move the table for cleaning purposes.





(Reference 81036)



Caution

Ensure brakes are fully engaged before installing a patient.

Face slit in head-cushion

(reference 2231-65 and 2231-75)

This upholstery only correponds to the following

reference : 600150-65 600150-75

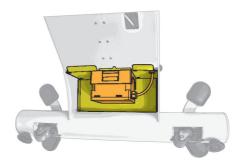






Accumulator

(references 2092)



Technical characteristics of the accumulator

Voltage: 24 V DC 1.2 Ah capacity:: T 15 A Fuse...: IPX6 Protection index: Type of accumulator....: Gel plomb

Charge time: approx. 14 h (depending on the power unit)

Lifespan...:: approx. 1000 cycles

(depending on conditions of use of the chair)

Discharge time: approximately 1 year (storage)

Safety symbols for the accumulator





Do not dispose of item in household waste



Protection index against solids and liquids



Recycling



Use in dry rooms only



Pollutants contained: lead, among others



Fuse

To guarantee product safety, a seal is attached to all products.



Opening the product damages the seal, thus indicating that the product has been modified or falsified.

This nullifies the guarantee in any case.



Safety:

For safety reasons, and in order to avoid malfunctioning, no objects should be placed under the seat cushion or between the moving parts of the couch.

Protection Classe 1 and equipotential terminal

(references 2059-01)

Electrical connection: Class 1

Connection to the supply: 120 V or 230 V (depending on country)

Frequency: 50/60 Hz

Protection Classification / Degree of electric shock protection : Class 1 / B $\,$

Power input : 200 WIntermittent function mode : 1 min / 9 min

Intermittent function mode : 1 min / Maximum operating altitude : 2000 m





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

Equipotential terminal

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



Caution:

The 85114-01 barriers are not compatible with this DM in class 1.

Lifespan of the Medical Device

This medical device was designed for a service life of 10 years, excluding wear parts in normal working conditions. This duration may change depending on the frequency of use.

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

The wear parts are:

- The upholstery
- The knobs and screws

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

For any intervention, please contact your local authorized dealer, indicating the serial number of the device.

Obligatory/specific maintenance

Once per year:

- Check the screws and the rods.
- Check the articulated parts.
- Check the structure did not undergo any deformation.
- · Control the various connections.
- Note this information and the date in the maintenance notebook.

End of the device's useful life

Your dealer is responsible for reclaiming and processing this device at the end of its service life.

Do not hesitate to contact Promotal, if necessary. We will suggest to you a solution to process this equipment in the best conditions.



Equipment warning

All mattresses with torn covers must be promptly replaced in order to guarantee optimum functionality of this DM.



Material warning Do not dismount the equipment

If a defect is detected, immediately contact your retailer or the aftersales department of your retailer (cf Warranty Information) for a complete diagnosis. If a doubt remains, do not use the equipment.

Access to electric components

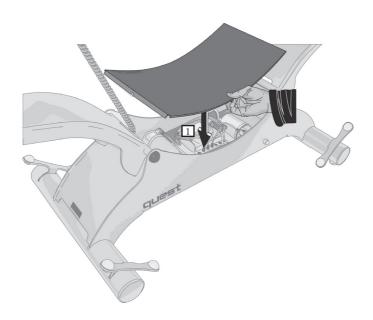
(only in the case of malfunctioning),

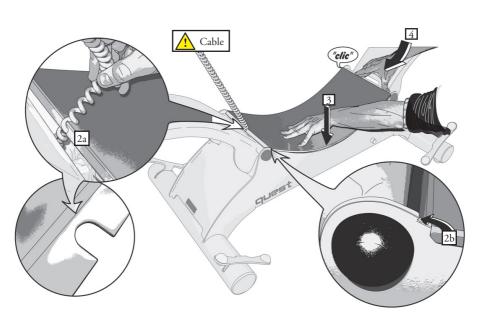
Dismounting the color plate
Use a flat screwdriver to remove the plate.



Lifespan of the Medical Device

Re-fit the protection cover





MAINTENANCE NOTEBOOK

	Type of intervention - corrective action					
Product Reference: Serial number (cf. label): Manufacturing date (start date of warranty):	Name of technician					
	Date					

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

Note

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) years* 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 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.

^{*} 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: Quest 2050-10 / 2050-15 / 2050-20

2050-30 / 2050-50

Description: Electric Examination Couch
Basic UDI-DI: 37014094BASEQUEST4U

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: 2007

Signed in Ernée,

On 26 May 2021

Rudolf MOURADIAN

Chairman

Promotal

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

Tel.: +33 (0)2 43 05 17 76 Fax : +33 (0)2 43 05 72 00 <u>www.promotal.com</u>



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