

# Duolys



Model Shown : 3065-60



**Electric Examination Couch**  
**3060-60 / 3065-60**

# 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

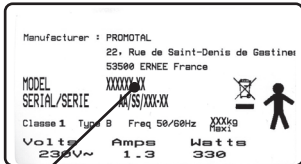
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The descriptions and specifications contained in this Operating Manual are deemed correct at the time of printing.

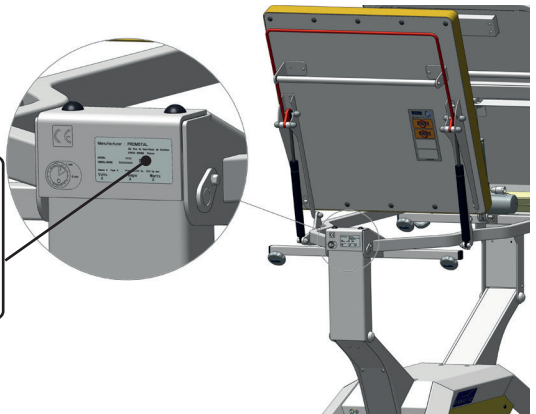
**Promotal**, however, reserves the right to modify its models and its procedures or render them obsolete without notice.




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

## TYPE PLATE



Year(YY)/Week(WW) of manufacture



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# Important information

## Safety symbols



### Warning sign

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

### Remark

Draws your attention to a procedure, practice or situation.



Humidity limitation



Maximum number of stacked pallets



Correct orientation for transportation



Atmospheric pressure limitation



Temperature limitation



Fragile



Keep in a dry place



Not to use sharp objects



Manufacturer



Type B applied part



Protective earth



Dangerous voltage / risk of electrocution



To be disposed off separately from household waste



Equipotential terminal



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



General safety sign



For indoor use only



Refer to the instruction manual / brochure



CE marking



Housing protection classification

### 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.



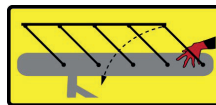
Do not sit on the back rest



Do not sit on the leg rest



You must not use the medical device for transfers



Warning :  
Risk of pinching between the barriers and the seat



### 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
- Assistance handles (accessories)
- Gynecological examination stirrups (accessories)

## **Electrical power supply**



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



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

## **Electromagnetic interference**

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

# Unpacking precautions

## Medical device delivered on a wooden pallet

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

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

## Storage conditions

Room temperature:

-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.

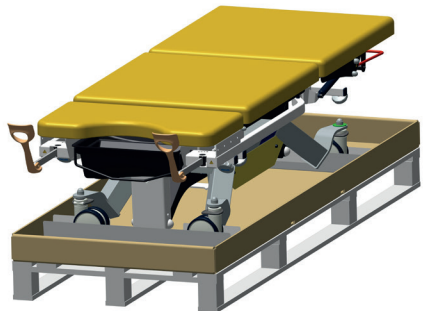
2) If possible, transport the medical device on its pallet up to the final place of use.

*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 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.

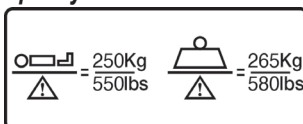
During the consultation, supervision of children is the responsibility of the parents or of the practitioner.



**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**

Electric height adjustment from 46 to 93 cm

Steel structure with epoxy matte white finish

Adjustable tilt angle

External backrest adjustable by double gas spring

Electric central backrest

Upholstery width 73 cm

Seamless removable seat upholstery

Upholstery with M1 flame retardant coating

Manual control

4 independent ø 125 mm wheels, 1 of which at the head side has steering capacity

Integrated retractable stirrups (ref: 3065-60)

removable plastic tray on rail (6 litre capacity)

paper roll holder (Maximum dimension Ø 15 x 60

cm width)

12 cm ground clearance compatible with patient lifting apparatus



# User manual – iDuolys

## Electrical connection

This medical device must be connected to the mains supply.

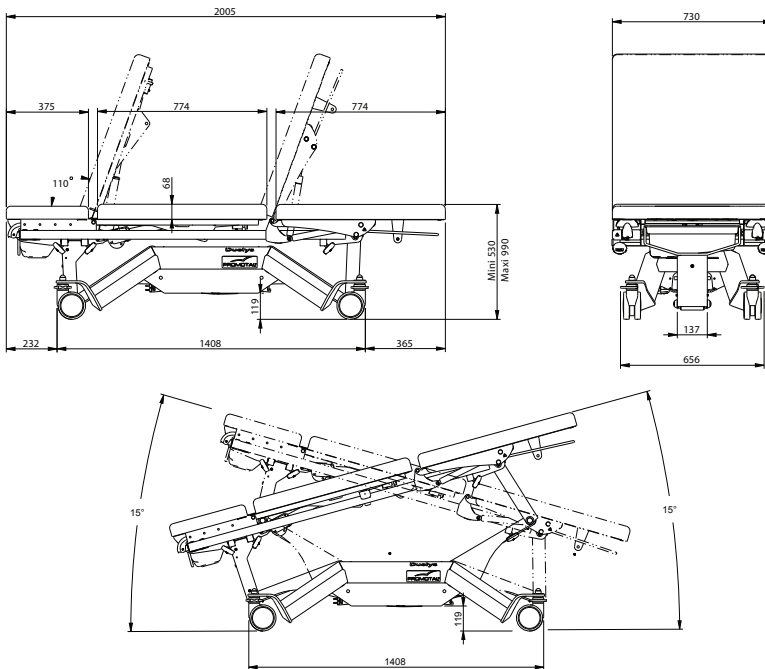
- Connection to the mains supply : 100 V or 240 V (depending on the country)
- Frequency : 50/60 Hz
- Protection classification : Class I/ type B device
- Absorbed power : 575 W
- Intermittent operating mode : 1 min / 9 min



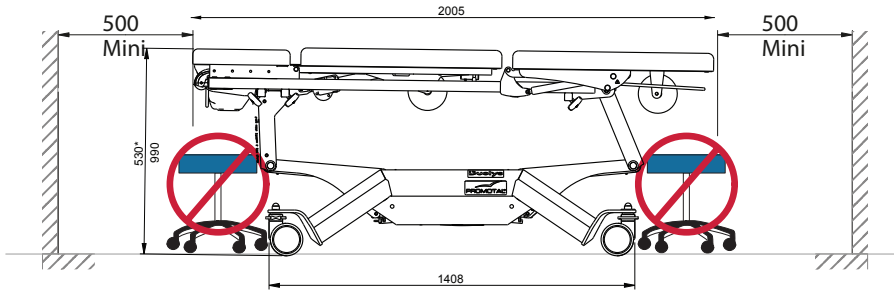
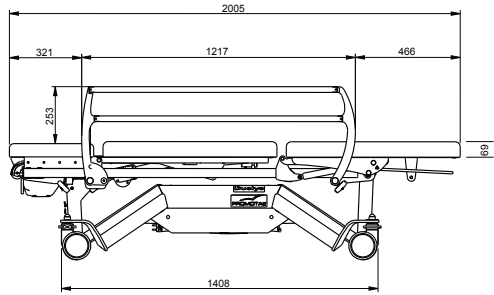
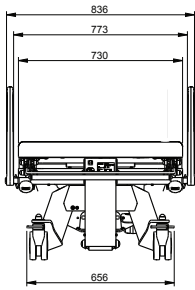
### Caution

a power cut could prevent the patient support from being lowered to the low position. The patient exit must be carried out in the best possible conditions of safety.

## Dimensions / Installation precautions





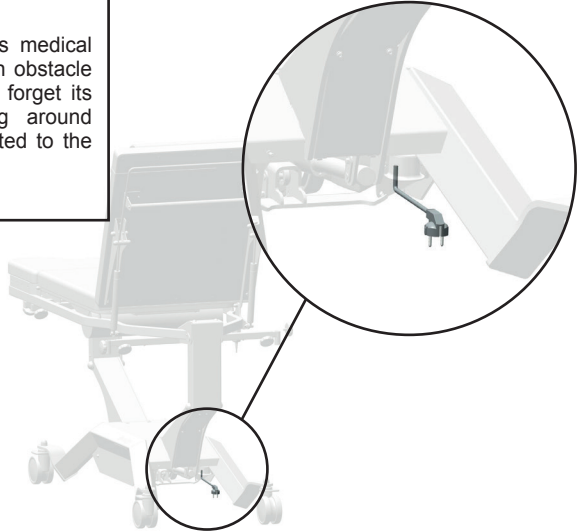


**Caution**

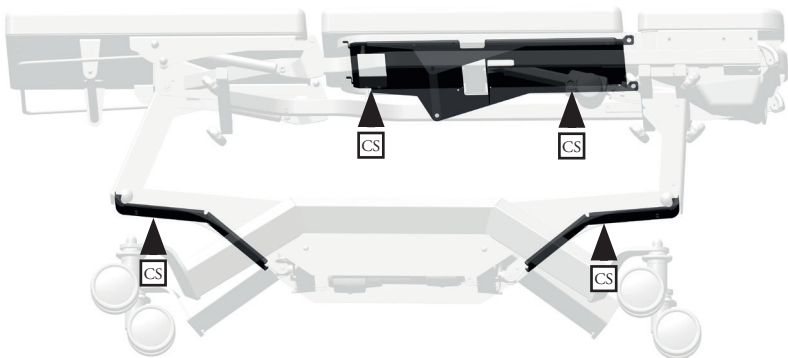
To avoid malfunctions and for safety reasons, no objects must be left under the chair's seat or between its moving frames.

**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.



### *Perimeter protection for the user*



To avoid the risk of pinching between the upper frame and the base of the medical device, the couch has safety sensors (CS) that stop all movement in the event of pressure.

**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 the position memory function, movements can be interrupted by pushing on one of the command buttons for the couch or, as a last resort, by disconnecting the power supply cord.

**Safety note**

When using the pre-programmed positions, default QE1, QE2, chair position, couch position), do not leave the patient on the couch without supervision.

**Safety note**

Unplug the power supply cable before moving the MD.

# Using the individual control

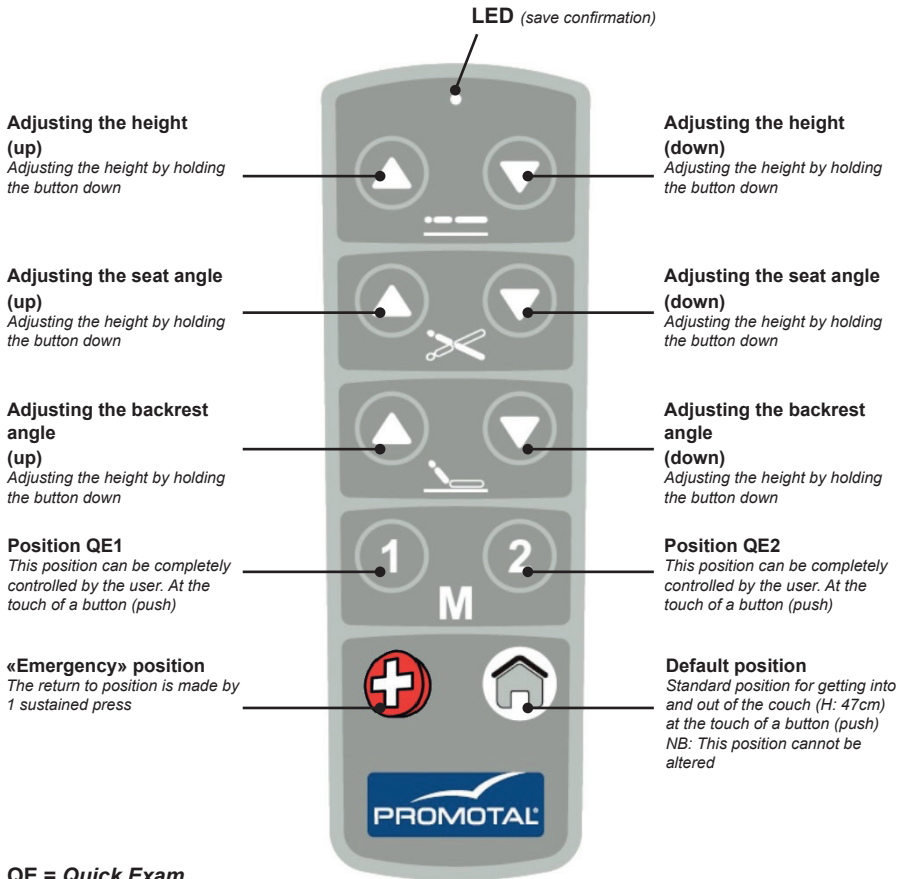
## Manual command

### Presentation



#### Safety note

When using the pre-programmed positions, (welcome, QE1, QE2, chair position, couch position), do not leave the patient on the couch without supervision.



**QE = Quick Exam**

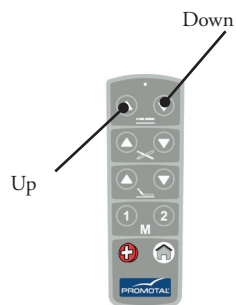
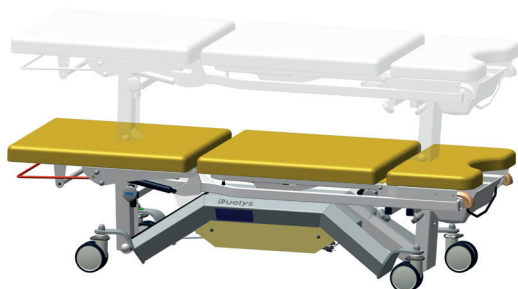


#### Safety note

When using the position memory function, movements can be interrupted by pushing on one of the command buttons for the couch or, as a last resort, by disconnecting the power supply cord.

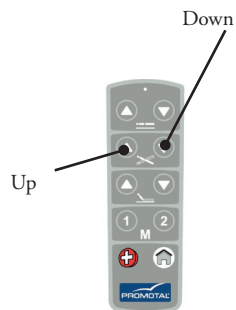
## ***Adjusting the height***

The position below is obtained by pressing on the manual control.



## ***Adjusting the trendelenburg position***

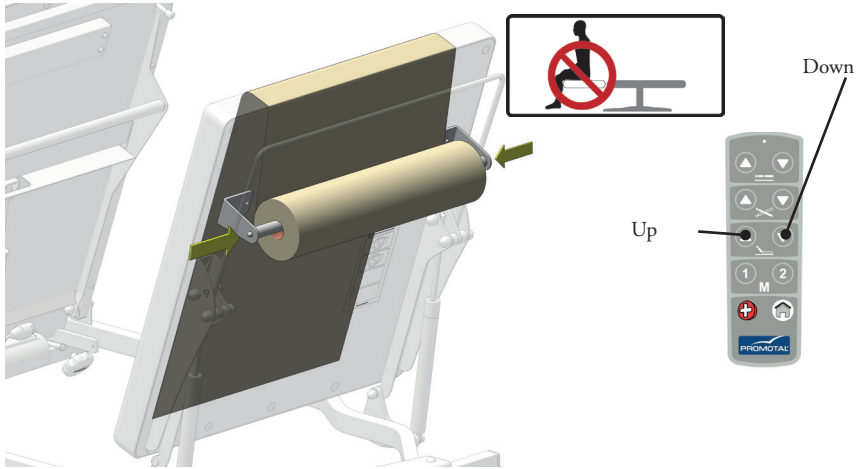
The position below is obtained by pressing on the manual control.



# Using the individual control


## Adjusting the backrest tilt

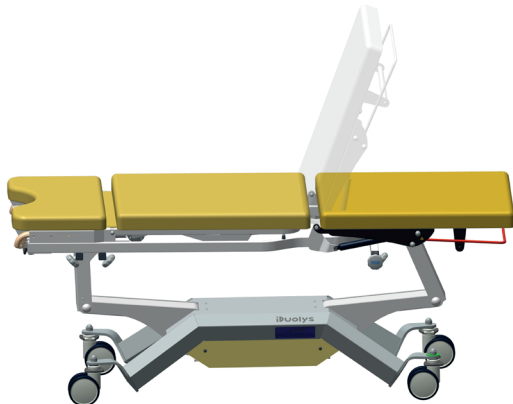
The position below is obtained by pressing on the manual control.



## Adjusting the backrest tilt

With one hand, move the lever (L1) either up or down, with the other hand lower or raise the backrest to the desired position.

 The patient must not lean with his / her full weight on the backrest during this procedure.



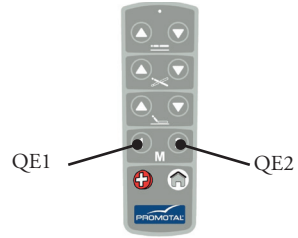
## Position QE1 et QE2

The QE1 and QE2 buttons are factory-set but cannot be modified. To enter a new position for buttons QE1 and QE2, simply adjust the couch to the desired position and then press and hold the QE1 (or QE2) button for 6 seconds.

This is stored once the LED located above the command bar blinks.


The position can now be recalled by pressing once on the QE1 or QE2 button.


*NB: When using the stored positions, movements can be interrupted simply by pushing on one of the programme buttons (default, QE1, QE2 or QE), any of the commands available on the couch.*



# Using the individual control

## «Emergency» position

The return to position is made by 1 sustained press on the .

Return to a standard position by pressing once on the button .

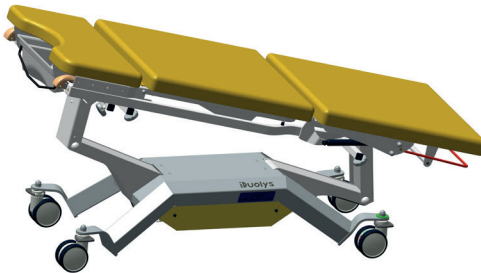
*NB: This position cannot be modified.*



### Warning

It is strictly forbidden to leave the patient alone and unattended in this position.


**We decline any responsibility in case of non respect of this clause**



«Emergency» position



## Welcome position

The position can be recalled by pressing once on the button .

*NB: This position cannot be modified.*



Welcome position

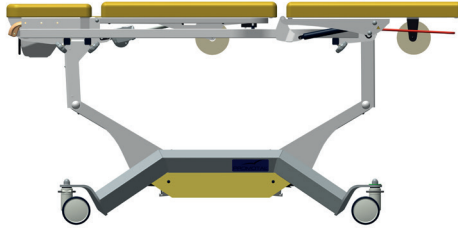




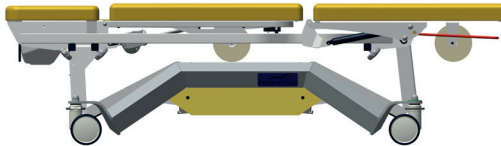
## Procedure for registering your base position. 🏠

*If there is a paper roll on the central backrest follow the instructions below.*

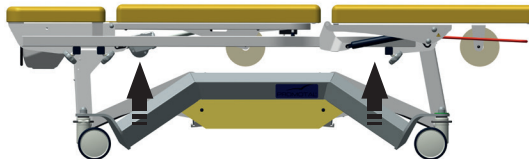
1. Move the couch into this position



2. Lower the couch by pressing the 🏠 button



3. The paper roll comes into contact with the base of the couch and the seat rises two centimetres.



4. Hold down the 🏠 button for 6 seconds and wait until the LED flashes 5 times.

*Note: Every time the 🏠 button is pressed, the couch will move to this new position.*

# Using the Couch

## Paper roll

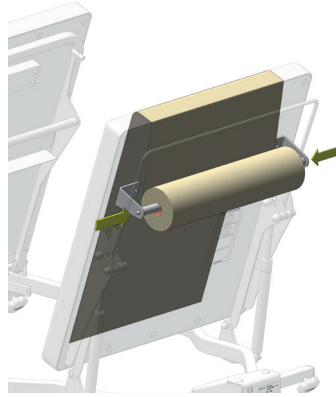
### Installing the paper roll

The paper roll is positioned on an axis with spring clips at each end. Press these springs to remove the paper roll.

Cover the upholstery with paper before use.



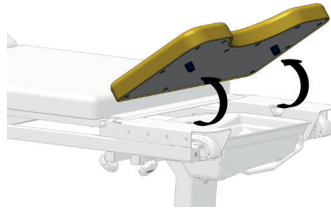
Caution follow the indications provided well obtain a greater longevity of the material.



## Removing the upholstery

Raise the base by doing the 2 studs (P).

(Operation to be carried out for regular cleaning)

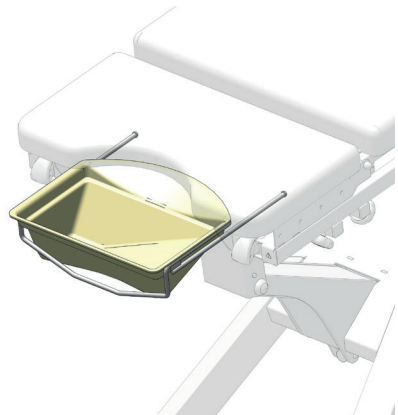


## Plastic pan

(6 liters)

The plastic pan is removable to ensure easy cleaning, it can be moved towards the front and also be placed under the seat.

- Pull the handle underneath the seat, to move the pan forward.
- Remove the pan.



Caution ensure the plastic pan is correctly positionde.

## Mechanical braking on individual and steering wheels

### Using the castors

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

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

1: The wheels move freely.

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


3: Directional position:

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

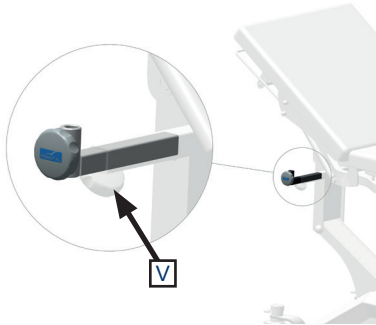


### Caution

Ensure brakes are fully engaged before installing a patient.

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

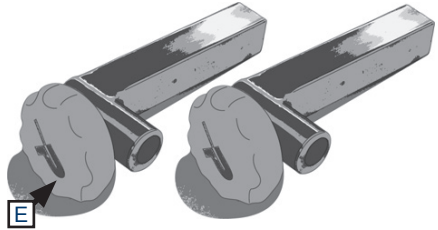
## Pair of Clamps (reference 166)



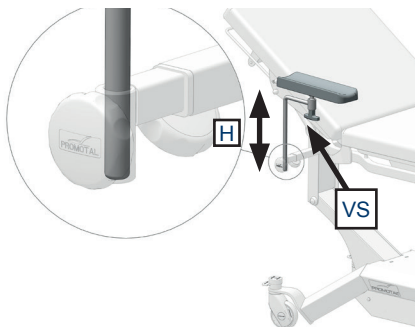
### Installing the Clamps

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**  
Re-tighten the screws before use.



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

## Pair of stirrups

(reference 850)

*Installing the stirrups*



Ensures good clamping with each use



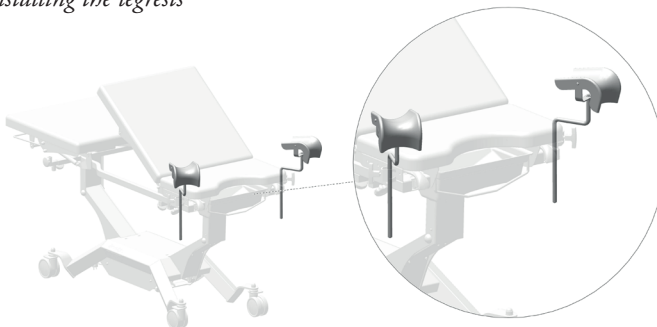
### Caution

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

## Pair of legrests

(reference 840)

*Installing the legrests*



Ensures good clamping with each use




### Caution

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

## Pair of covers for legrests

(reference 861)

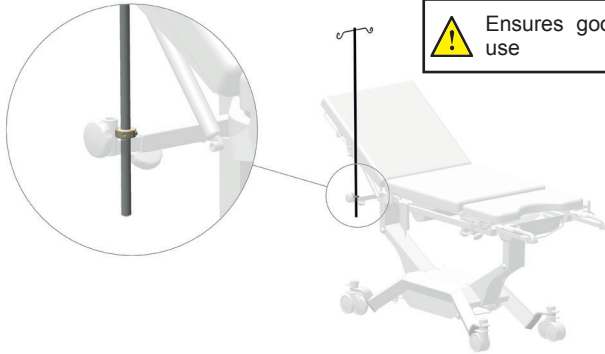



 Only accessories designed and provided by Promotal for this medical device are authorised for use.


## 2 hook IV pole

(reference 985-01)

*Installing the IV pole*



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

 Ensures good clamping with each use

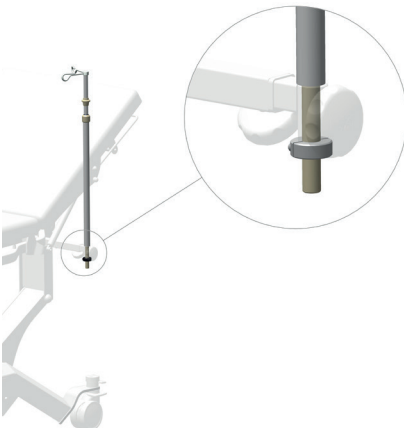
## Auto-blocking I.V. pole


(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. : 166)

 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.



## Headrest

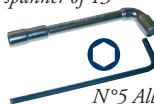
(reference 1102-10)



## Rails 25x10 with clamps

(Only accessories for models 23065-40, 3065-50, 3065-60)  
(reference 2065-78)

Box spanner of 13



N°5 Allen key

### Installing the rail

On each side :

1x A3A105-02

Seat rail

4x A3A105-XX

Stainless steel spacer tube

4x ECX4008

Safety nut D.8

4x RDN0008

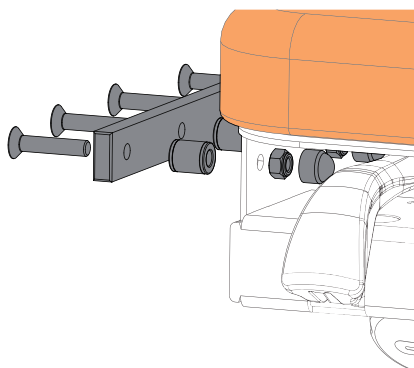
Grey nut cover D.8

4x VXM3084

Screw



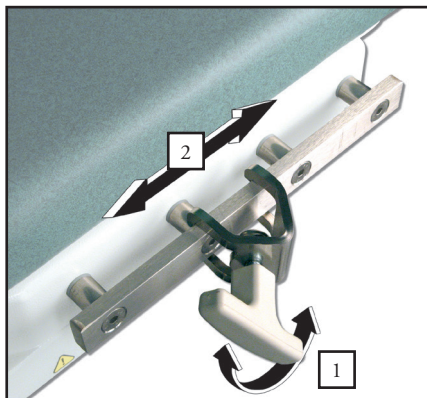
Check that the parts are secure before use.




### Installing the Clamps

Insert The clamps on the rails.

The clamps accept accessories with  $\varnothing 16$  and  $\varnothing 18$ .



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

## Clamp

(reference 878-12)



### Caution

Mounting this accessory requires the use of rails (25x10)



Compatible with accessories:  
ref. 840, 850, 2536, 985-01, 2985-01.



Ensures good clamping with each use



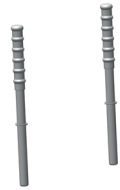
## Push handles

(reference 856)

*Setting up the handles*

*iDuolys 3060-60*

1. Unscrew the tightening wheels
2. Put the handles in place
3. Screw in the tightening wheels

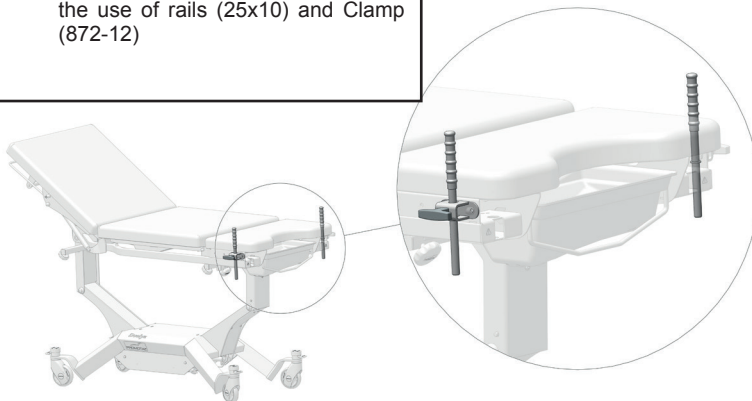


Ensures good clamping with each use

*iDuolys 3065-60*



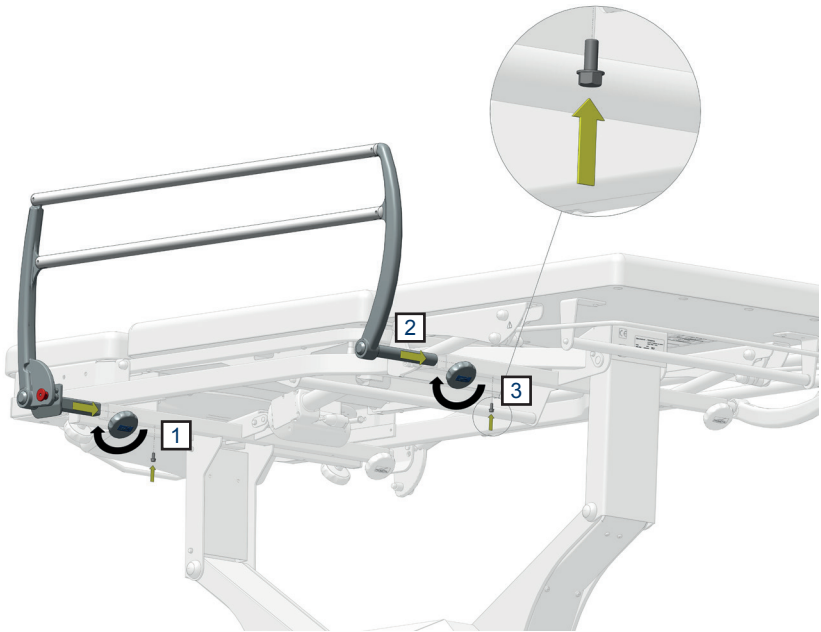
**Caution**  
Mounting this accessory requires the use of rails (25x10) and Clamp (872-12)



## 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 between the barriers and the upholstery.*
3. Tighten the screw.



### Using the pair of barriers


#### To raise the pair of barriers

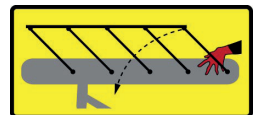
Take hold of the upper part, and lift it to its maximum height until it clicks into place.

#### 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.



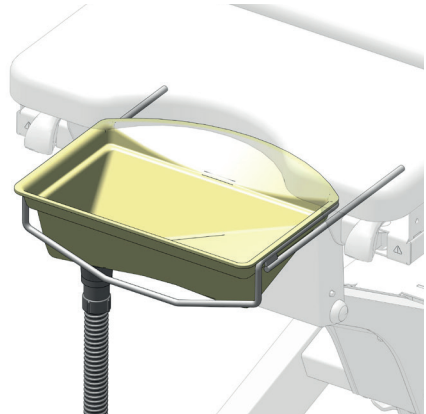
## **Plastic bowl with drainage tube**

*(reference 2061-20)*

Sliding plastic removable bowl (6 liters) with drainage tube (150 cm).

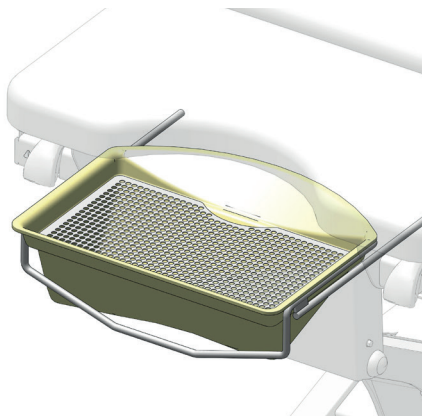
The plastic pan is removable to ensure easy cleaning, it can be moved towards the front and also be placed under the seat.

- Pull the handle underneath the seat, to move the pan forward.
- Remove the pan.



## **Splash guard cover**

*(reference 12677-01)*



## Foot pedal 3051-10, 3051-20 (Wireless)

### Presentation



#### Safety note

When using the pre-programmed positions, (welcome and QE1), do not leave the patient on the couch without supervision.



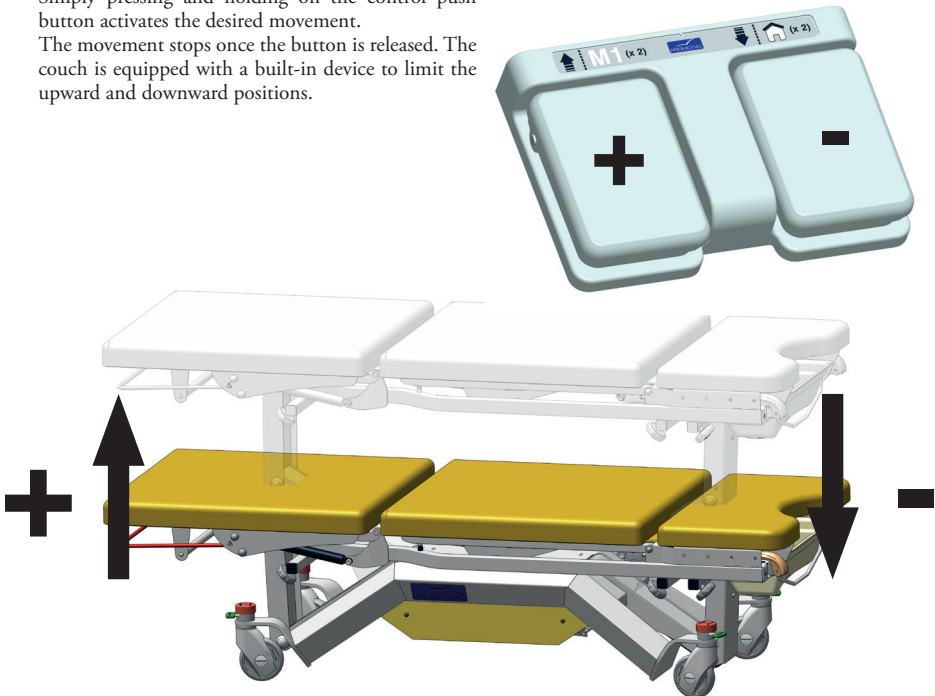
#### Safety note

When using the position memory function, movements can be interrupted by pushing on one of the command buttons for the couch or, as a last resort, by disconnecting the power supply cord.

### Using the pedal control

Simply pressing and holding on the control push button activates the desired movement.


The movement stops once the button is released. The couch is equipped with a built-in device to limit the upward and downward positions.



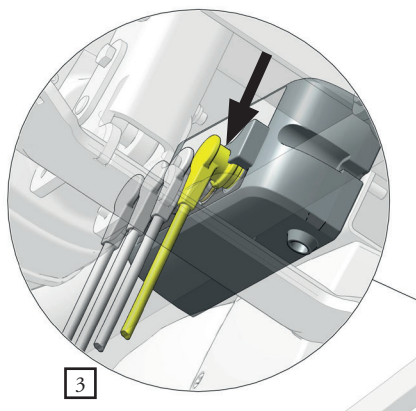
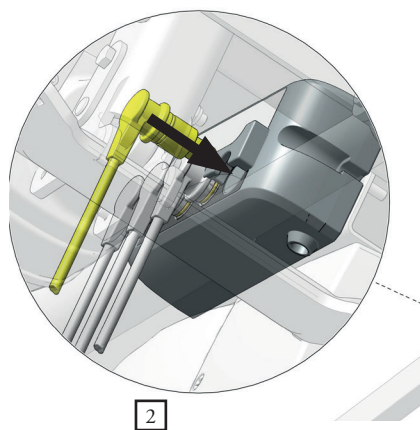
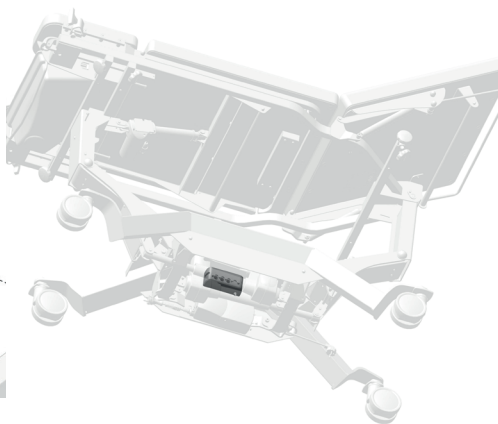
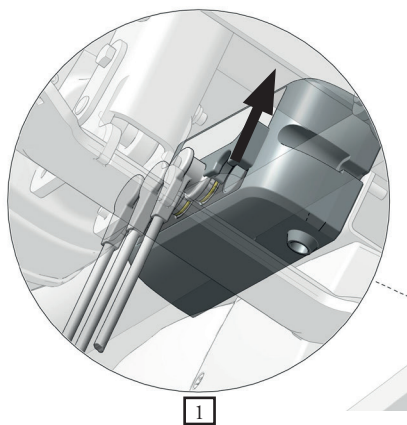
It is possible to select pre-programmed positions using the pedal control.

Note : These positions are factory-set and cannot be modified by the user.

Press twice on the left side of the lift pedal to select examination position QE1.

Press twice on the left side of the lift pedal to select the welcome position .

## Setting up the control unit 3051-10



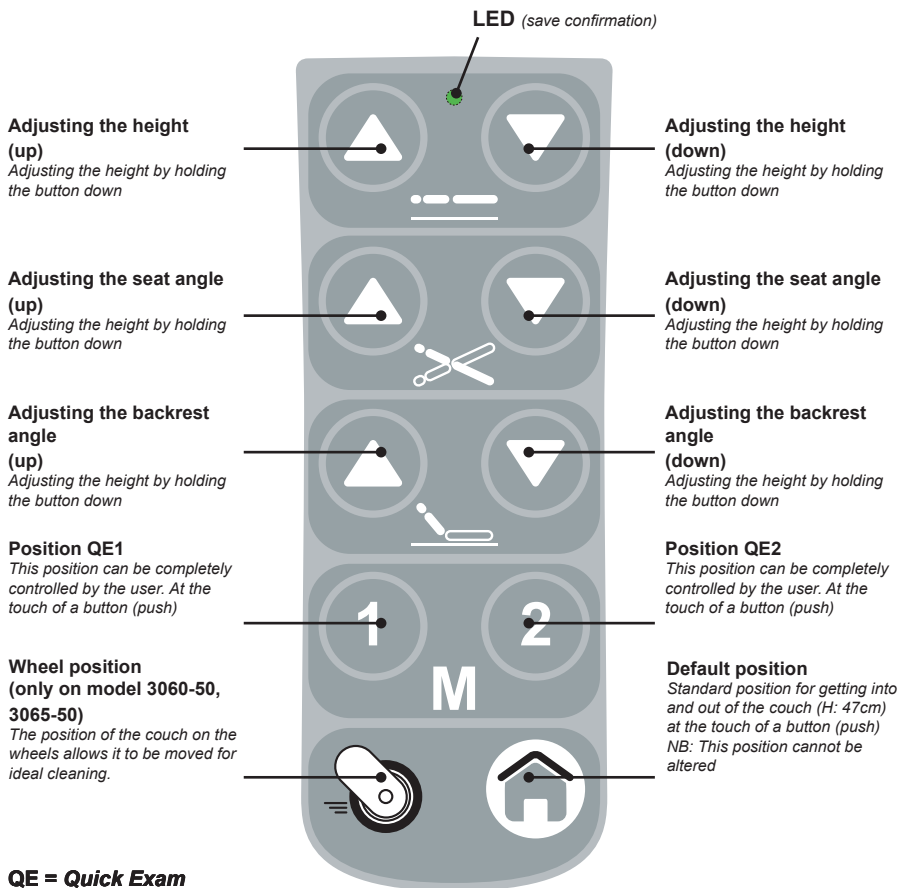
## Wireless 3041-20 manual control for ref. 3060-60 and 3065-60

### Presentation



#### Safety note

When using the pre-programmed positions, (welcome, QE1, QE2, chair position, couch position), do not leave the patient on the couch without supervision.



#### Safety note

When using the position memory function, movements can be interrupted by pushing on one of the command buttons for the couch or, as a last resort, by disconnecting the power supply cord.

## Accumulator

(reference 3092-01)

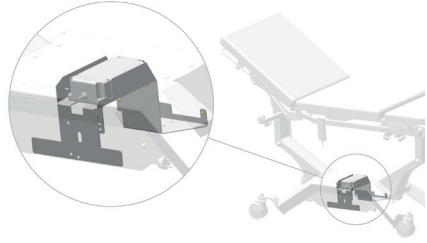
(Built in to the device's power supply system)

(Note: the couch can functions the same in «Battery mode» or in «Mains mode».

### Charging the accumulator

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

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



### Accumulator safety symbols



Certification standard



Do not throw the product away with household waste

**IP66**

Protection rating



Recyclable



Use in dry conditions only

**Pb**

Contains pollutants Lead, etc.



Fuses

### Technical characteristics of the accumulator

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

# Options

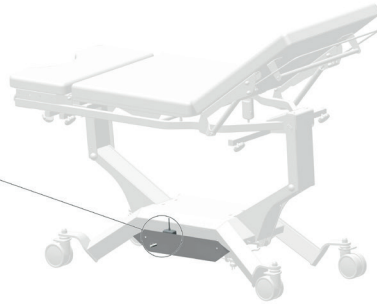
## Circuit breaker

(reference 3058-01)

Using the circuit breaker

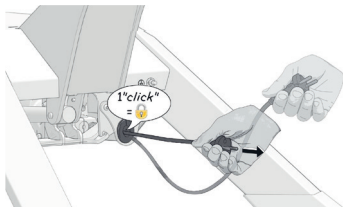
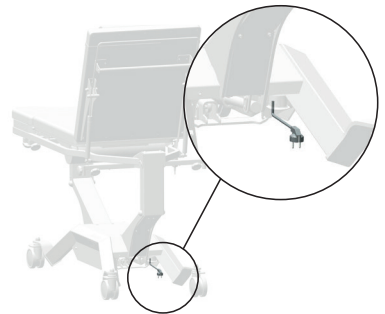
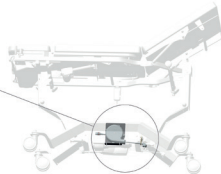
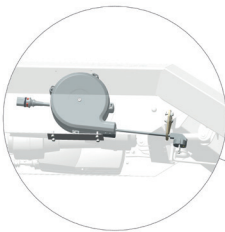
Withdraw the key to completely immobilise the couch.

Re-insert the key to use the couch again.

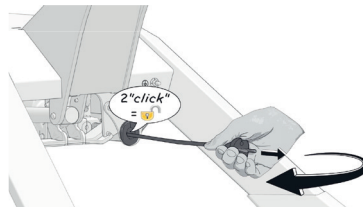


## Reel for electric cable

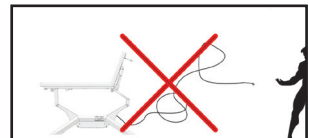
(reference 3032-01)



Leaving the cable



Arranging the cable





## Supplemental power socket

(reference 30400-01)

Available exclusively and standard EU & UK

### Safety note



When a medical device is connected to the supplemental power socket, the system becomes an medical electrical device in accordance with Standard EN 60601-1. It is the responsibility of the user to ensure compliance of the medical electrical system with standard EN 60601-1 (Article 16)

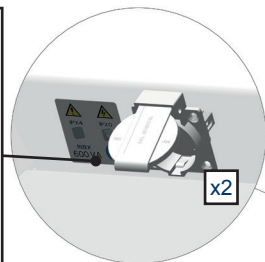
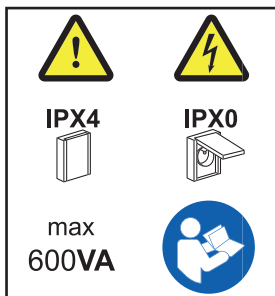
### Using the supplemental power socket

- Properties : 120 V or 230 V depending on the country  
2.6A AC max



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

Options 30400-01 (supplemental power socket) consists of 2 sockets, one on each side of the base of the couch.



When simultaneously using products 30400-01 & 3058-01 (supplemental power socket and the circuit breaker), the sockets remain continuously powered, even if the safety key is withdrawn.

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.

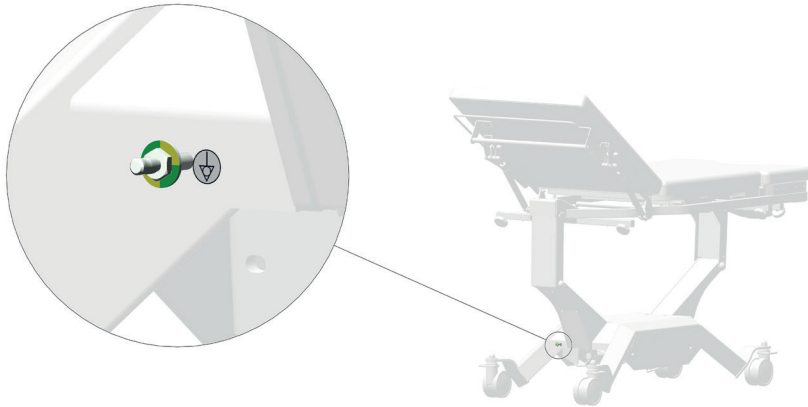
# Options

## **Equipotential terminal**

*(reference 2059-01)*



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



### **Remark**

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



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

## Replacing used batteries in the foot pedal

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

### Wireless foot pedal 3051-20



### Wireless manual control 3041-20 / 3041-25



# Lifespan of the Medical Device

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

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

*The wear parts are:*

- The upholstery.
- The electric cylinders.

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 14).

## **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.



# 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<sup>1</sup> from the date of purchase.

### *Obligations*

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

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

### *Exclusions*

- This warranty does not extend to :

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

### *Exclusive Remedy*

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

### *No Authorization*

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

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

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<sup>1</sup> 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: iDuolys 3060-60 / 3065-60

Description: Electric Examination Couch

Basic UDI-DI: 37014094IDUOLYSM2

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: 2019

Signed in Ernée,

On 26 May 2021



Rudolf MOURADIAN

Chairman

Promotal

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

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Fax : +33 (0)2 43 05 72 00 [www.promotal.com](http://www.promotal.com)

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