DUPONT

Cinetis

USER'S GUIDE

ALZHEIMER BED

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CINETIS bed with 2 & 3 functions and kneebreak

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PLEASE CAREFULLY READ THE INSTRUCTIONS BEFORE USING THIS BED.

- NEVER USE A DEFECTIVE BED.

- THE BED SHOULD BE COMMISSIONED AND USED BY QUALIFIED AND TRAINED STAFF.

- MAXIMUM PATIENT WEIGHT 135 kg.

- IS SUITABLE FOR ADULTS WHOSE HEIGHT IS BETWEEN 1.46 M AND 1.85 M.

- IS NOT SUITABLE FOR CHILDREN YOUNGER THAN 12.

- HEIGHT OF THE MATTRESSES THAT CAN BE USED WITH THIS BED: FROM 12 TO 14 CM.

- APPLICATION ENVIRONMENT: 3 - 4 - 5

I - SPECIFICATIONS

Weight	
Maximum user weight:	135 kg
Max. lifting capacity with accessories:	170 kg
2-function bed without accessories:	83 kg
Dimensions	
Bed without panels (wxl):	91 x 200 cm
Bed wit MDF panels (wxl):	91 x 205 cm
Assembled bed into the box:	200 x 94 x 20 cm
Heights	
Min. bed base/floor	19 cm
Max. bed base/floor	80 cm
Clearance under the wheelbase	13 cm
Angles	
Backrest	70°
Legrest	16°
Materials	Steel frame and epoxy RAL 7035 paint
Wheels	double tyre, dia. 75 mm with brake
Power supply	230 VAC 50 Hz 1A class IIa
Protection	IP66
Applied parts	type B
Duty cycle	2 minutes operating for 18 minutes idle
Sound level	45 dB(A)
Lifetime	10,000 up/down cycles
Compliance	NF EN 60601-2-52 Dir. 93/42 EEC
Equipment	supports for IV pole and, L and R trapeze bar

Options:

Trapeze bar (maximum traction 75 kg) – IV pole
Foot and head panels – Remote control cord
Metal or wooden rails.

II - INTENDED USE AND WARNING

2.0 Application environment according to EN 60601-2-52 standard

- The bed is designed for 3, 4, and 5 application environments. It is not suitable for 1 and 2 application environments, that is to say for intensive care units.

2.1 Intended use

- The bed can be used exclusively indoors at home or in community, on a flat and stable floor. It should be handled by qualified and trained staff who knows how to use this kind of device.
- The bed is designed for the sleeping arrangements of one adult, ill or disabled, in order to improve his/her comfort and to simplify the nursing staff's work.
- The bed and its equipment should be prescribed by a healthcare professional, who will make sure the equipment is perfectly adapted to the patient's pathology and needs.
- The bed is equipped with a backrest, and as the case may be, with mechanical or electric legrest. Those functions are intended to relieve the efforts in the body soft tissues. You must check the tilt angles of the backrest and of the legrest are compatible with the patient's pathology. Foam pressure-relief mattresses can be used as a complement to reduce bedsore risks.
- If the patient is not watched over, and unless otherwise medically specified, the bed base should be laid down flat and in the lowest position in order to avoid any fall risk that could lead to injuries. The remote control should be locked in security position.
- The bed can be used to take the patient from one place to another, but exclusively indoors. To move the bed, you should use the footboard or the headboard, but you should never exert too much stress in order not to damage them. The bed should not be used inside a vehicle to transport the patient.

Do not use the bed for other purposes than the ones for which it was designed.

2.2 Intended user

- The bed is suitable for patients older than 12 and whose height is between 1m46 and 1m85. The bed is not suitable for children and persons whose morphologies may lead to a catching risk of one of the body parts between the bed edges and the rails. It is the responsibility of the professional installing the bed to make sure the patient's morphology is compatible with the bed and its rails.
- The patient and the persons likely to handle the bed should have sufficient physical and mental capacities to use the bed safely; some treatments may reduce the perception or the balance of the patient or third parties.

2.3 Dimensions of the mattresses that can be used with the bed

- Only mattresses whose dimensions are (lxwxh) 190 x 90 x 12 to 14 cm thick can be used with this bed.
Using a mattress thinner than 12 cm leads to catching risks of one body part between the rail bottom and the upper part of the mattress.
Using a mattress thicker than 14 cm leads to fall risks over the rail.

Do not use water or air mattress. Only use polyurethane foam mattresses.

2.4 Rails
Only use the rails provided by Dupont Médical (wooden or metal rails).

Analysis of the bed rail risk/benefit ratio:
The rails are used to prevent patients from falling when they are sleeping. They do not prevent patients to voluntarily get out of beds. Many accidents occur when the patient tries to get out of the bed with the rails installed.

In some cases, the rail prevents falls, but may present other risks: injuries, asphyxia, when a limb, the head or the thorax is trapped in the rail. Thus, it is necessary to analyse the risk/benefit ratio of the rail before deciding whether to use it or not.

This assessment should consider the following points:
- Number, quality and training of the supervision staff.
- Patient's physical and mental condition, his/her lucidity, movement coordination, physical weakness, atony, height, build, agitation.

A decision protocol for the use of the rails should be regularly written and revised.

Accessories such as rail safety nets or padded protections for rails can be ordered.

2.5 Bed lifetime

The bed lifetime is ten years or 10,000 cycles if appropriate maintenance is realised as recommended in this manual. The lifetime is calculated according to an average of 3 up/down manoeuvres per day; it can be increased or reduced depending on the use frequency, range of motion, patient's weight, and respect of the use instructions given in this manual.

2.6 Installation

The bed commissioning should be realised by a professional such as the renter or the distributor whose responsibility is to:

- Install the device and check its performance.
- Train the patient, his/her family, the nursing staff and any other person who, for any reason, may work very nearby, to use and handle the bed, and particularly inform them about the risks associated to the movement of some bed parts.
- Make sure those instructions were understood.
-Both half bed bases should be totally fitted and the screw knobs firmly tightened.
- The rails should be installed with care.
The rail locking system should be placed on the leg side; check the rail locking mechanism in upper position properly works.
- The bed is delivered without mattress nor sleeping element. It is the installer's responsibility to check the sleeping accessories are suitable for the patient's pathology and for the bed specifications. Follow the installation instructions provided with the devices interested.

- The electric cables should be positioned so that they cannot be pinched nor cut when the bed is moved. The bed power supply cord should be connected to a class II 230 V single-phase mains socket (without any earth electrode) and should be positioned so that it cannot be crushed by the wheels or any other part of the bed. These same precautions apply to the cables coming from other devices connected to the patient such as an electrocardiograph for example.

If moving the bed, make sure to wind the power supply cord onto the winder located on the headboard, onto the wheel base.

- The weight limits indicated in the specifications should not be exceeded.

- The different functions of the bed should be checked: lifting/lowering the bed base, the backrest, the legrest, performance of the brakes, attachment and performance of the rails, trapeze bars and panels.

- Do not install the bed near a heat source such as a radiator or a window whose radiation may significantly increase the temperature of the metal parts.

- The bed should only be used with the accessories suggested in this manual. The bed should be installed in a cleared environment so that the up and down movements of the different bed parts are free and will not collide with other equipment such as a table, a chair, a wall, or any other material being near the bed.

- No accessory other than the ones described in this manual should be used with the bed. When installing those accessories or options, check the bed is operational before using it.

- The bed should absolutely be revised once a year or more often if the use conditions require it. In case of abnormal functioning or damaged component, you must immediately stop using the device and have it revised. Any intervention should be recorded in the maintenance book provided at the end of this manual. Check as often as possible the condition of the power supply cord, which should be replaced as soon as it has the slightest crush or cut sign.

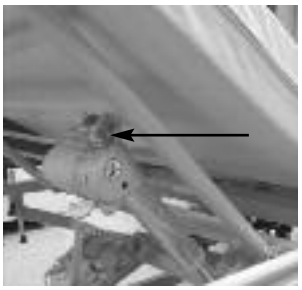
- If, after being used a first time, the bed is attributed to another user, it should be totally revised, and then cleaned or disinfected before being commissioned again. Those interventions should be recorded in the maintenance book provided at the end of this manual. Do not use any apparatus or high-pressure water jet to wash the bed.

- The Cinetis bed was designed to be lowered very low and should be used with care as some bed elements may have a risk of pinching as for example the distance between the wheels and the frame, or the free distance under the bed. Do not engage or disengage the brakes when the bed is in upper position.

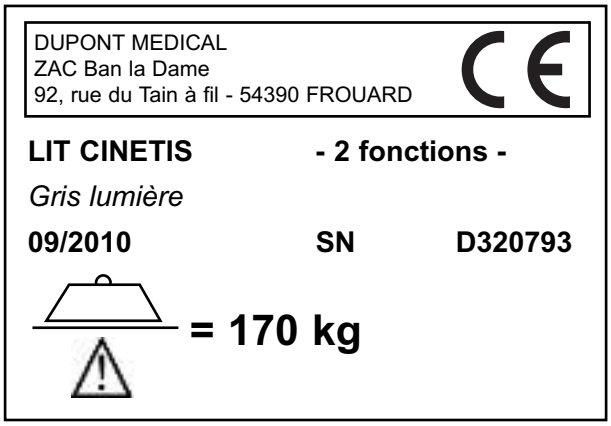
2.7 Lower the backrest in case of power outage

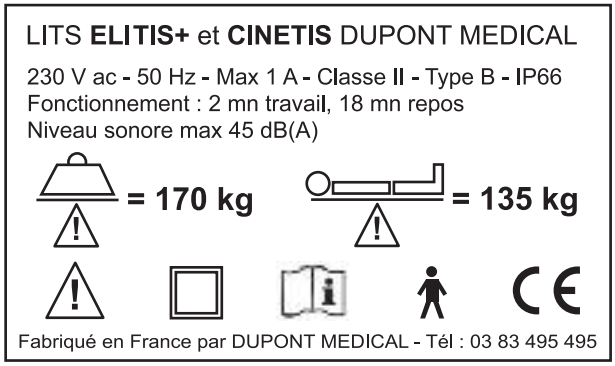
Hold the half-bed base, hold the cylinder body, and remove the pin. Slowly lower the half-bed base.

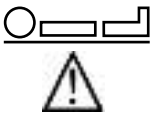
Caution: This operation should be realised by two persons taking into account the risk of pinching.



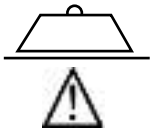
2.8 Used symbols







Maximum patient weight



Maximum weight of the patient and accessories: mattress, rails, panels

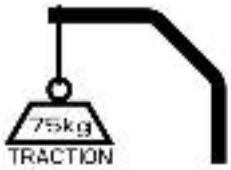
Warning

Use instructions

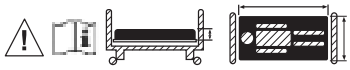
Compliance to directive 93/42 EEC

Class II device

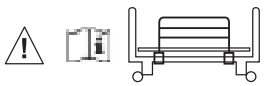
Type B applied part



Maximum weight supported by the trapeze bar



Respect the dimensions indicated in 2.3.



Respect the indications provided in 2.4, 4.5.

III - PACKAGING AND ASSEMBLY

A) DISASSEMBLED BED DELIVERED IN A BOX 2,000 x 940 x 200 mm

CAUTION: the set weighs 83 kg; do not try to lift the bed alone.

1. Take the bed out of the box either by lifting it with the help of two persons, or by cutting the box edges and rolling the bed.

2. Check all the cable positioning according to photos 1, 2, and 3. Wind the power supply cord so that it cannot be crushed by the wheels.

3. The bed is ready to be used. You just have to check it properly works after connecting the power supply cord.

IV. OPTIONS AND ACCESSORIES

Only the accessories and options provided by DUPONT MEDICAL should be used.

4.1 Footboard and headboard

Assembling the brackets:
Position both flat head screws (rep 1 fig. 21) outside the panel, hit both screw heads with a mallet to create a mark in the wood. Placer the bracket (rep 3 fig. 21), screw both nuts (rep 2 fig.21). Moderately tighten.

Assembling the panels onto the bed:
When both brackets are assembled, you just have to put the panel in the front or at the back of the bed and to fit both brackets into the bed tubes. Adjust the distance between the panel and the bed ends, and then tighten with the knurled knobs.

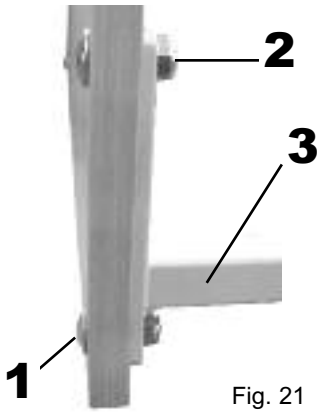


Fig. 21

4.2 IV pole

The bed is equipped with two IV pole supports (rep 3 fig.23) placed on either side of the headboard. Those supports can fit with ∅ 19 mm tubes; the length once fitted is 53 mm.

4.3 Trapeze bar

The trapeze bar (rep **1** fig. 23) can be positioned on the right or on the left of the headboard. You just have to fit the trapeze bar foot into one of both supports and to position the centring pin (rep **2** fig. 23) into one of the notches for a parallel or centred positioning of the trapeze bar against the bed.
The triangle (fig. 24) should be placed above the trapeze bar by sliding the strap inside both metal rods.

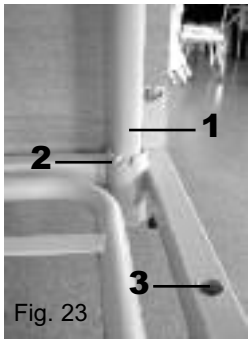


Fig. 23

4.4 Urine bottle holder

The bed can be equipped with two urine bottle holder supports (rep **1** fig. 25) placed on either side of the bed. Those supports can be fitted with ∅-8-mm accessories.
Do not use it when the bed is in very low position.

4.5 Folding metal rails

See assembling detail on page 12

⚠ CAUTION:
- The rail constitutes an element essential to the patient safety; strictly respect the indications in this paragraph.
- Respect the assembly direction; the rail locking mechanism should be on the footboard side.
- Check the axles are locked into the bearings.
- Check the locking mechanism properly works when the rail is in upper position.

Assembling the rail onto the bed:
On the floor, position the rail lengthwise of the bed by placing both axles opposite the assembly bearings and the locking knob on the footboard side. Take the rail by one of its ends, press the black knob located at the bottom of the rail and push the axle by about 1 cm into its housing (fig.: 26). Take the other rail end, press the second black knob to push the second axle by about 1 cm, and then simultaneously press both black knobs until the rail stops against the bed. Firmly pull the rail outwards the bed to check both axles are completely engaged and locked.

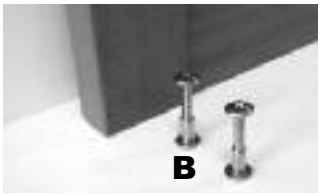

Fig. 26

To remove the rail, repeat the same operations in the opposite way. Check the rail properly works: pull the locking knob downwards, and then lower the rail by pulling the handle to the footboard. Push back the rail to the headboard, without using the locking knob, until the rail locks in upper position, and then move it backwards and forwards to check the locking mechanism properly works.

4.6 Assembling the panels and wooden rails
(MODERNE Pack finish)

Some detailed assembly instructions are provided with the set of panels and wood rails.

a) Assembling the brackets onto the panels
Use the retaining screws (B) to assemble the brackets onto the panels (fig. 21).



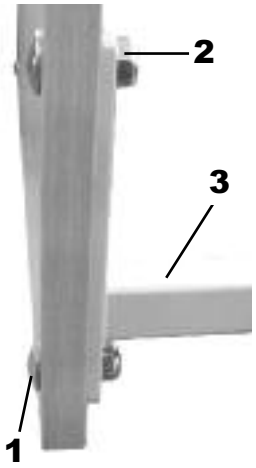


Fig. 21

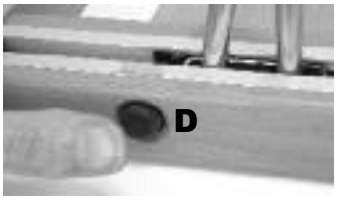
b) Final assembly
- Assemble the head panel onto the bed.
- Push the 4 rail elements onto the fasteners located on the head panel.
- Push the foot panel onto the bed without pushing it completely.
- Push the free ends of the rail elements onto the rear panel.
- Completely push the foot panel, and then firmly screw.

4.7 Using the wooden rails

4.7.1 Assemble the rail
Take the centre of the upper rail element and pull upwards until it automatically locks.

CAUTION: Make sure the locking mechanism of the rail properly works at the head and foot levels.

4.7.2 Lower the rail
Slightly lift the end of the upper rail part. While pressing knob (D), accompany and lower the rail. Repeat the operation on the other end.



CAUTION: Check the space between the upper parts and the lower parts of the rail is free before lowering the rail. There is a risk of pinching.

4.8 Remote control cable

The remote control cable fastens onto the bed base frame with the clip (rep 1 fig.28).

Fig 28

Note:
- After installing the bed and accessories, check they properly work.
- When installing the bed, correctly inform the user about how to use the bed and its accessories.
Knowing well the product may prevent accidents and moving.
- If the product is used with other devices, make sure there is no risk of mutual interference.
- Make sure the bed is installed in a roomy enough place so that it cannot knock over the elements around it when lifting and lowering.

V. USING THE CINETIS BED

5.1 Use recommendations

- The bed has numerous moving parts, which constitute so many risks of pinching; always be very careful when you handle them and know well the bed architecture before any use.
- The bed reflects the actions a person makes on the remote control (as the case may be, 4 to 8 keys to lift and lower the bed base, the backrest, or both functions at a time); so, you must always use it consistently with its environment.
- The bed motion devices are not 100% waterproof; therefore, avoid exposing them to any liquid splattering (IP 66 protection).
- Avoid any contact or proximity with a significant heat source when the wooden headboards are installed.
- Disconnect the power supply cord as soon as the bed is not used.

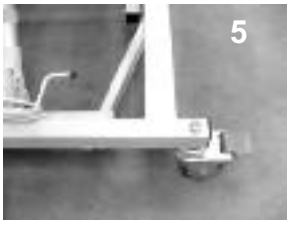
5.2 Use with a patient lift

The patient lifts compatible with the CINETIS bed should have their forks lower than 125 mm.

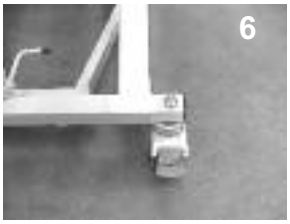
When using a patient lift, never leave the bed in the lowest position (recommended floor/bed base height: 40 cm minimum).

5.3 Using the bed in lower position

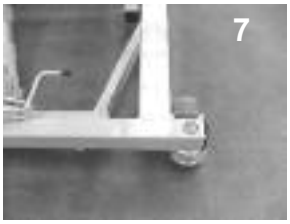
Check the wheels, located on the bed feet, are not directed outwards. There is a risk of contact between the rail adjustment knob and the wheel, as well as a risk of pinching for the foot.



Incorrect wheel position

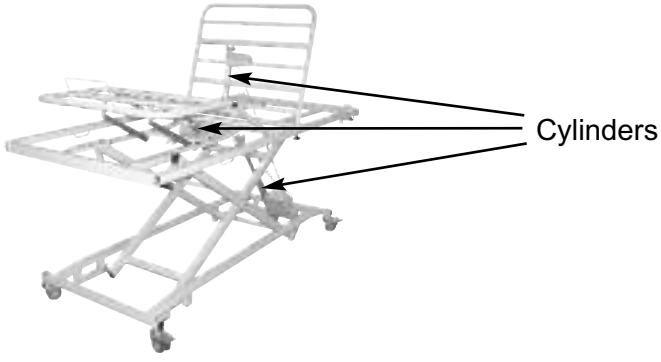


Correct wheel position

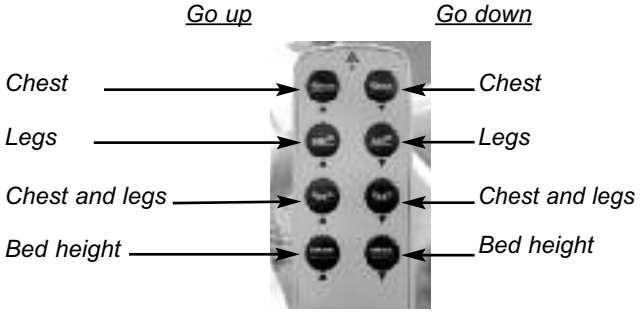


Correct wheel position

5.4 Bed with 3 functions and kneebreak

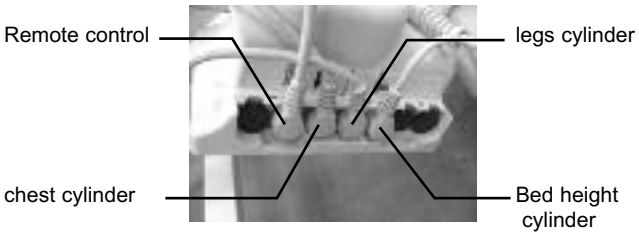


The remote control:



The remote control can be locked with a magnetic key.

Connection of the cables to the cylinder supply box.



5.5 Possible problems

CAUTION: The cylinder should only be used discontinuously, that is to say: 2 minutes operating, and then 18 minutes resting.

- For a 2-minute operation, a 18-minute resting period should be observed. Do not exceed 2 minutes operating in continuous. Any duty cycle exceeding the above cycle can damage the lifting assembly (cylinder/control box). This damage is excluded from the warranty.
- In case of bed overload or locking, a safety system integrated into the control box triggers and the bed cannot be used anymore. Return the control box to Dupont Médical.

Not to tear off the connector on the backrest side when lifting the bed, at the level of the main power supply box, check the free length of the cable between the cylinder and the power supply box is the maximum upper position.

VI. BED MAINTENANCE

6.1 Cleaning
(Every month or when necessary, and to be performed by a competent staff)

- Before cleaning the bed, disconnect the power supply cord.
- Clean the patient lift with a soft cloth dampened with soapy solution, then rinse, and carefully dry.
- Do not use aggressive detergent; do not soak; do not clean in an apparatus, nor with high-pressure water jet.

6.2 Disinfecting
(When necessary, and to be performed by a competent staff)

- Disinfect with detergents and disinfecting solutions (ANIOS brand) sprayed on the external device areas. It is a foaming solution that does not require rinsing, but only drying.

6.3 Routine maintenance
(Every month or when necessary, and to be performed by a competent staff)

The routine maintenance consists in checking the system functionality:
- With the bed positioned on a flat floor, check its 4 wheels are touching the floor.
- When the brakes are engaged, the bed should not be moved (flat and adhered floor).
- Check the wheel tyres are not used and are not deeply cut; check the wheels rotate freely and without excessive play.
- Check the various assemblies making sure the screws, pins, and adjustment knobs are present and properly work.
- Operate the bed with nobody in, check the bed base and the backrest move steadily with no noise.
- Check the plastic protective housings and casings are not broken or cracked, and all parts are present.
- Check the condition of the connecting cables: power supply cord, remote control and cylinder; if a cable shows a slight burn, wear, or impact sign, or if the wires are visible, immediately stop using the patient lift, and have the cables replaced by the engineering department.

6.4 Preventive maintenance
(Every year or when necessary, and to be performed by a competent staff)

It is recommended to have the bed controlled every year. The yearly maintenance should be performed by skilled technical staff experienced with electromechanical device maintenance.
The maintenance tasks do not require particular tools; adequate tools should be used according to the best industry practices.
Mechanical fastening, plays, and adjustments should be realised according to the best industry practices.

NOTE: Systematically disconnect the power supply cord before any intervention.

6.4.1 Mechanical control:

- Check the weldings. Visual inspection (no crack).
- Check the alignments. Visual inspection.
- Control and lubricate the cylinder fasteners, the hinge pins, and the ball bearing raceways.
- Correct the fitting of all the parts, control the ball bearing play.
- Disassemble, clean, and lubricate the front and rear wheels.

6.4.2 Electrical control:

- Check the remote control.
- Control the control box (no burn sign around the sockets, no crack).
- Control the cylinders (variable height, backrest and legrest) as stated above.
- Check the condition of the electric cables: replace the cables if they have wear and/or burn signs, if the sheath is cut, or if the sockets and plugs have damage signs (on the side of the power supply and on the side of the device).

The worn or malfunctioning parts should be replaced with original parts provided by DUPONT MEDICAL.

Note: depending on the duty cycle, the manufacturer of the electric cylinder recommends replacing them every five years or 10,000 up/down cycles.

6.4.3 Maintenance book:
Every maintenance operation or intervention should be recorded in the service book attached to these instructions.

6.5 Shipping, storage, and disposal

- The bed should be returned or transported in its original packaging.
- Before storing the bed, clean it totally and check it works properly. Store the bed in a dry place away from dust and humidity.
- When commissioning after storing, check it works properly before using it.
- Storage temperature: 0 to + 50°C; Humidity: 10 to 90%
- Service temperature: +10 to + 40°C; Humidity: 30 to 90%
- The disposal of defective parts and packaging should be performed by approved waste treatment centres.

VII. LIABILITY AND WARRANTY CONDITIONS

The metal structure of the CINETIS BED and the cylinders have a 5-year parts and labour warranty if they are normally used according to the above instructions.
The remote control has a 3-month warranty. The other bed parts (rail, trapeze bar, handle, etc.) have a 12-month warranty. Negligence, handling errors and accidents are excluded from the warranty.

Any modification or addition of accessories without DUPONT MEDICAL's written consent will de facto exclude the product from the warranty and from DUPONT MEDICAL liability.

The regular checks and inspections mentioned in the previous paragraph should be performed by a competent staff and recorded in the maintenance book. Out of the warranty period, our liability will not be entailed if you do not respect these controls and inspections.

VIII - BEFORE CONTACTING DUPONT MEDICAL CUSTOMER SERVICE

Calling the Customer Service can often be avoided!

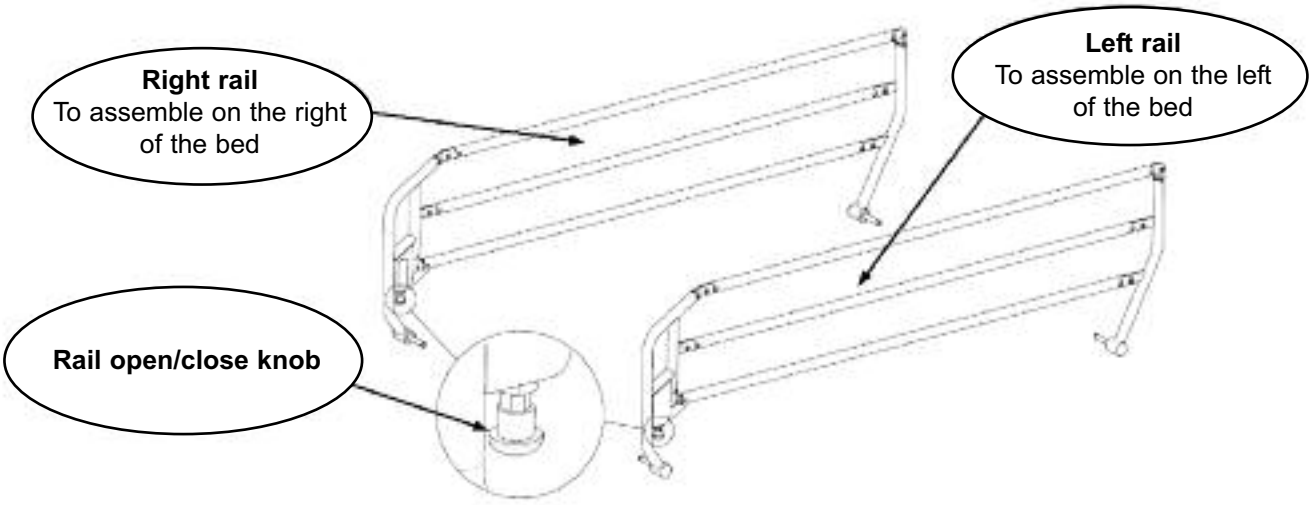
If your CINETIS bed does not perfectly works, please perform the following controls first:

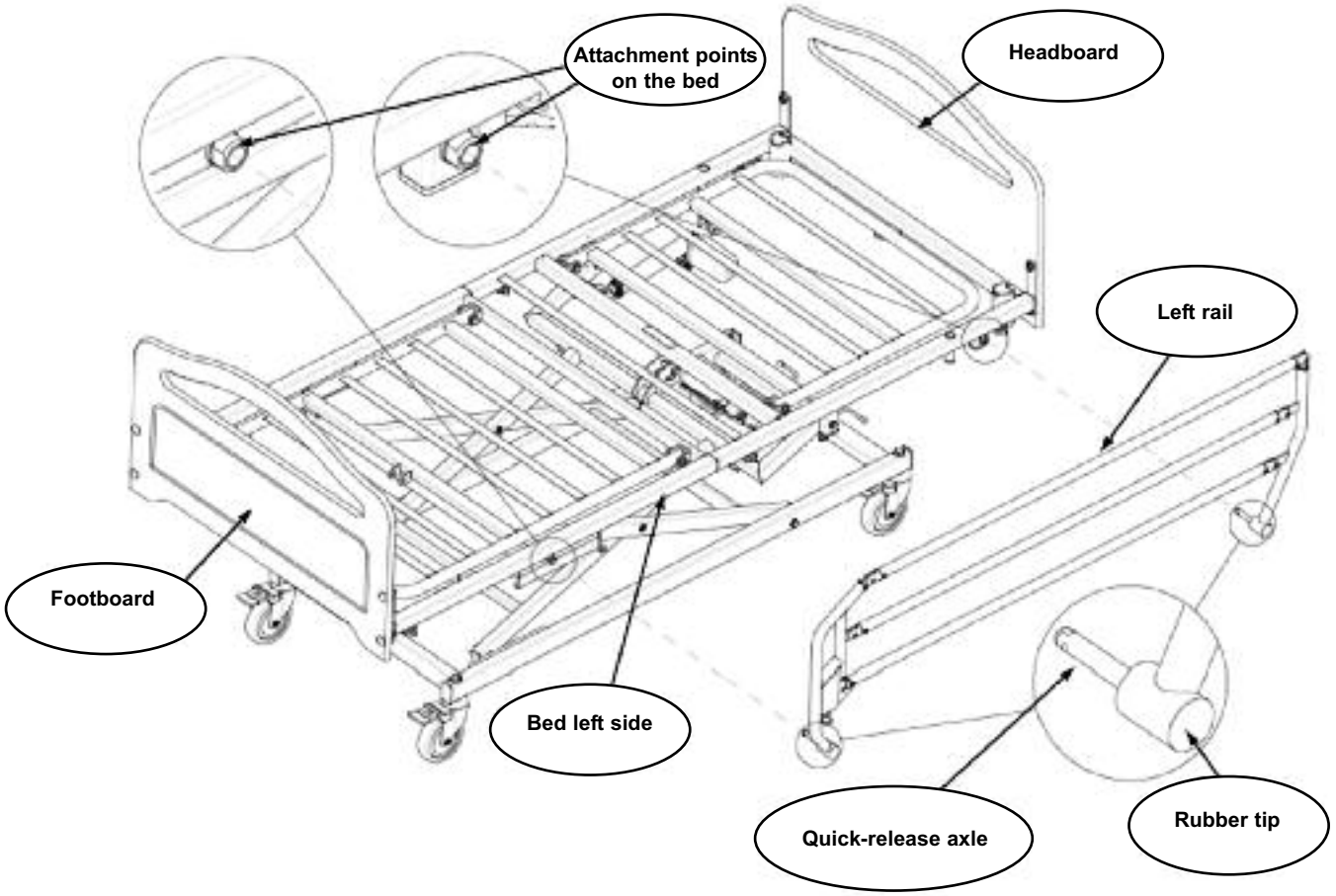
Problem	Possible cause	Solution
- Nothing happens when one of the remote control keys is pressed.	- The remote control is locked.	- Unlock the remote control with the magnetic key.
	- The remote control cord is not correctly plugged in its slot.	- Correctly plug the plug.
	- The remote control cable is cut.	- Replace the remote control.
	- The cylinder plug is not correctly plugged.	- Correctly plug the plug.
	- One cylinder cord is cut.	- Replace the cylinder.
	- The 2 min./18 min. duty cycle was not respected.	- Send the cylinder for an inspection to Dupont Medical Customer Service.
	- The pinion or the nut supporting the lifting tube is damaged.	- Send the cylinder for an inspection to Dupont Medical Customer Service.
	- The power supply cord is not correctly connected.	- Check the connection to the mains outlet.
	- There is no voltage on the mains outlet.	- Check the wall socket is a mains socket.
- A cylinder produces abnormal noise.	- An overload is present.	- Eliminate the overload (170 kg).
	- An object touches the bed.	- Remove the object.
	- The cylinder is damaged.	- Replace the cylinder.

IX - WEIGHT OF THE MAIN COMPONENTS

Frame + wheels	19 kg	145 x 65 x 22 cm
Crosspieces	16 kg	104 x 87 x 12 cm
Head half bed base	19 kg	100 x 91 x 15 cm
Foot half bed base	24 kg	122 x 91 x 10 cm
Cylinders + box	10 kg	50 x 30 x 16 cm
MDF panels (with box of accessories)	14 kg	98 x 78 x 15 cm
Moderne, Segment, and Louis Philippe panels (with box of accessories)	19,5 kg	110 x 90 x 35 cm
Rails + trapeze bar	22 kg	190 x 50 x 15 cm
Total weight of all the components into 2 boxes	124 kg	

X. ASSEMBLING THE METAL RAILS



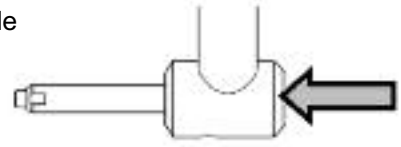


Fastening the rail onto the bed is possible thanks to 2 “quick-release” axles that are activated by the installer:

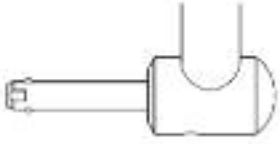
- The axle unlocks when you finger press the rubber tip located on the axle end.

- The axle automatically locks when you stop pressing the rubber tip.

Unlocked axle



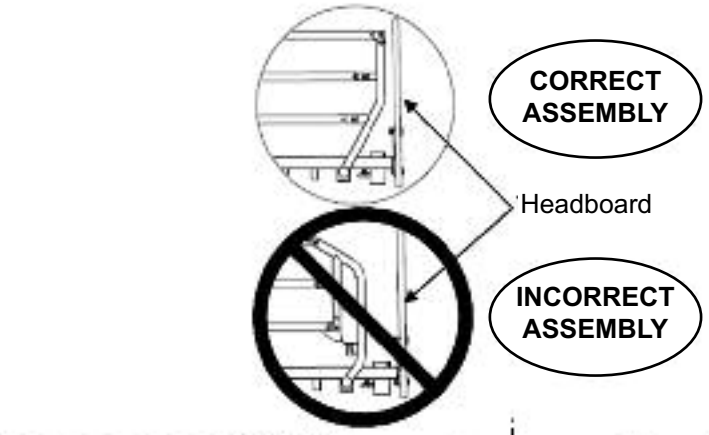
Locked axle



RESPECT THE ASSEMBLY DIRECTION OF THE RAILS

CAUTION: Make sure to select the appropriate rail (right or left rail) depending on the bed side to equip. After the assembly, the rail open/close button should be on the footboard side.

CAUTION: There is a risk for the patient if the rail is not correctly assembled (inverted rail).



Assembly procedure

1. Lay the rail on the floor, lengthwise the bed, placing the rail axles in front of the respective attachment points on the bed.

2. Lift the rail taking it by one of both ends (here, left end), and place the axle in front of its attachment point on the bed.

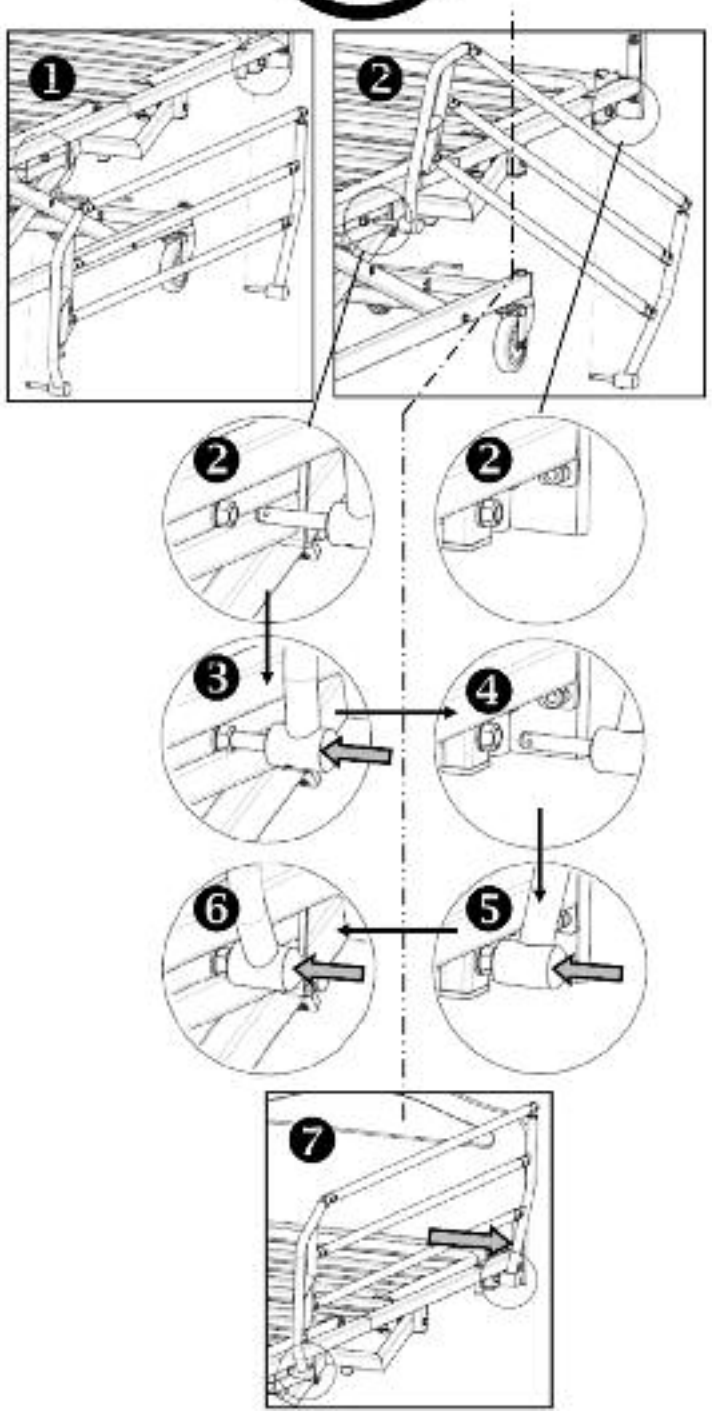
3. Unlock the axle by firmly pressing the rubber tip, and then push the axle by a few centimetres (2-3 cm) in its housing. Stop pressing the tip.

4. Lift the other rail end (here, right end), and then place the axle in front of its attachment point on the bed.

5. Unlock the axle by firmly pressing the rubber tip, and then completely push the axle in its housing until it is in contact with the bed. Stop pressing the tip.

6. On the other rail end, completely push the axle into its housing until it is in contact with the bed.

7. Firmly pull the rail outwards the bed to check both axles are completely engaged and locked.



To remove the rail, perform the operations described above in the opposite way.

XI - ELECTROMAGNETIC COMPATIBILITY: EMISSIONS

- The presence of long distance transmitters and receivers, such as diffusion transmitters (TV and radio antenna towers), amateur radio stations and other devices may lead to malfunctioning. In case of doubt, do not use the bed anymore until the problem is solved.
- Using the bed may lead to malfunctioning of some sensitive equipment. In case of doubt, do not use the bed anymore until the problem is solved.
- In case of accidental and uncontrolled movements of the bed electric parts, immediately disconnect the power supply cord.

<table>
<tr><td colspan="3">Manufacturer’s directives and statement: electromagnetic emissions
The ELITIS+ or CINETIS bed is designed to be used in the electromagnetic environment specified below. The user should make sure the bed is used in such an environment.</td></tr>
<tr><td>Emission testing</td><td>Compliance</td><td>Electromagnetic environment: recommendations</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Elitis+ or Cinetis bed only uses RF energy for its internal functioning. Thus, the RF emissions are very low and should not be likely to cause interferences in a nearby electronic instrument.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The Elitis+ or Cinetis bed is suitable for being used in any institution, including in domestic premises and in premises directly connected to the public low voltage power supply network supplying household buildings.</td></tr>
<tr><td>Harmonic emissions
EIC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/flicker emissions
EIC 61000-3-3</td><td>Compliant</td></tr>
</table>

XII - ELECTROMAGNETIC COMPATIBILITY: IMMUNITY

Manufacturer's directives and statement: electromagnetic immunity
The ELITIS+ or CINETIS bed is designed to be used in the electromagnetic environment specified below. The user should make sure the bed is used in such an environment.

Immunity testing	EIC 60601 testing level	Compliance level	Electromagnetic environment: directives
Electrostatic discharges (ESD) EIC 61000-4-2	+/- 6 kV when in contact +/- 8 kV in the air	+/- 6 kV when in contact +/- 8 kV in the air	The floors should be made of wood, concrete, or ceramic tiles. If the floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transients/bursts EIC 61000-4-4	+/- 2 kV for power lines +/- 1 kV for input/output lines	+/- 2 kV for power lines +/- 1 kV for input/output lines	The power supply network quality should be the one of a typical commercial or hospital environment.
Voltage impulses EIC 61000-4-5	+/- 1 kV in differential mode +/- 2 kV in common mode	+/- 1 kV in differential mode +/- 2 kV in common mode	The power supply network quality should be the one of a typical commercial or hospital environment.
Brownouts, brief outages, and voltage variations on power supply input lines EIC 61000-4-11	<5% UT (brownout > 95% of UT) for 0.5 cycle. 40% UT (brownout = 60% of UT) for 5 cycles. 70% UT (brownout = 30% of UT) for 25 cycles. <5% UT (brownout > 95% of UT) for 5 seconds.	<5% UT (brownout > 95% of UT) for 0.5 cycle. 40% UT (brownout = 60% of UT) for 5 cycles. 70% UT (brownout = 30% of UT) for 25 cycles. <5% UT (brownout > 95% of UT) for 5 seconds.	The power supply network quality should be the one of a typical commercial or hospital environment. If the bed user wants to use it continuously during power outages, it is recommended to power the bed with uninterruptible supply or with a battery.
Magnetic field at the electric network frequency (50/60 Hz) EIC 61000-4-8	3 A/m	0.3 A/m	The magnetic fields at the electric network frequency should have the levels typical of a representative place located in a typical commercial or hospital environment.

Note: UT is the alternative network voltage before applying the testing level.

XIII - MANUFACTURER'S DIRECTIVES AND STATEMENT

Manufacturer's directives and statement: electromagnetic immunity

The ELITIS+ or CINETIS bed is designed to be used in the electromagnetic environment specified below. The user should make sure the bed is used in such an environment.

Immunity testing	EIC 60601 testing level	Compliance level	Electromagnetic environment: directives
Conducted RF EIC 61000-4-6	**3 Veff from 150 KHz to 80 MHz**	**3 V** **3 V/m**	The mobile and portable RF communication devices should no be used too close of any part of the bed, included the cables; the recommended separation distance, calculated from the equation applicable to the transmitter frequency, should be respected. **Recommended separation distance** d=[1.17] √P d=[1.17] √P from 80 MHz to 800 MHz d=[2.23] √P from 80 MHz to 800 MHz Where P is the maximum output power of the transmitter in watts (W), according to the transmitter manufacturer, and where d is the recommended separation distance in (m). The field intensities of the fixed RF transmitters, determined by an electromagnetic investigation on site (a), should be lower than the compliance level in every frequency range (b). Some interferences may occur near the instrument marked with the following symbol: 
Radiated RF EIC 61000-4-3	**3 V/m from 80 MHz to 2.5 GHz**		

NOTE 1: At 80 MHz and 800 MHz, the highest frequency range applies.

NOTE 2: Those directives may not apply in every situation. The electromagnetic propagation is affected by the absorption and by the reflections of structures, objects, and persons.

(a) The field intensities of fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and land mobile radios, amateur radio, AM and FM diffusions and TV diffusion, cannot be anticipated with precision. To assess the electromagnetic environment due to fixed RF transmitters, you should consider an electromagnetic investigation on site. If the field intensity, measured where the bed is used, is higher than the applicable RF compliance level stated above, you should observe the bed to check it works normally. If you see that the bed abnormally works, some further actions may be necessary to reorientate or reposition the bed.

(b) In the frequency range from 150 KHz to 80 MHz, the field intensities should be lower than 3 V/m.

XIV - RECOMMENDED SEPARATION DISTANCES BETWEEN MOBILE AND PORTABLE RF COMMUNICATION INSTRUMENTS AND THE BED.

Recommended separation distances between mobile and portable RF communication instruments and the bed.

The bed was designed to be used in an electromagnetic environment in which radiated RF interferences are controlled. The bed user may contribute to prevent electromagnetic interferences by maintaining a minimum distance between mobile and portable RF communication transmitters and the bed, as recommended below, according to the maximum transmission power of the communication instrument.

Rated maximum transmission power of the transmitter W	Separation distance according to the transmitter frequency (m)		
	From 150 KHz to 80 MHz $d = [1.17]\sqrt{P}$	**From 80 MHz to 800 MHz** $d = [1.17]\sqrt{P}$	**From 800 MHz to 2.5 GHz** $d = [2.33]\sqrt{P}$
0.01	0.12	0.12	0.37
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters whose rated maximum transmission power is not stated above, the recommended separation distance d in metres (m) can be estimated by using the equation applicable tot he transmitter frequency, where P is the maximum output power of the transmitter in watts (W), according to the manufacturer of this latter.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the highest frequency range applies.

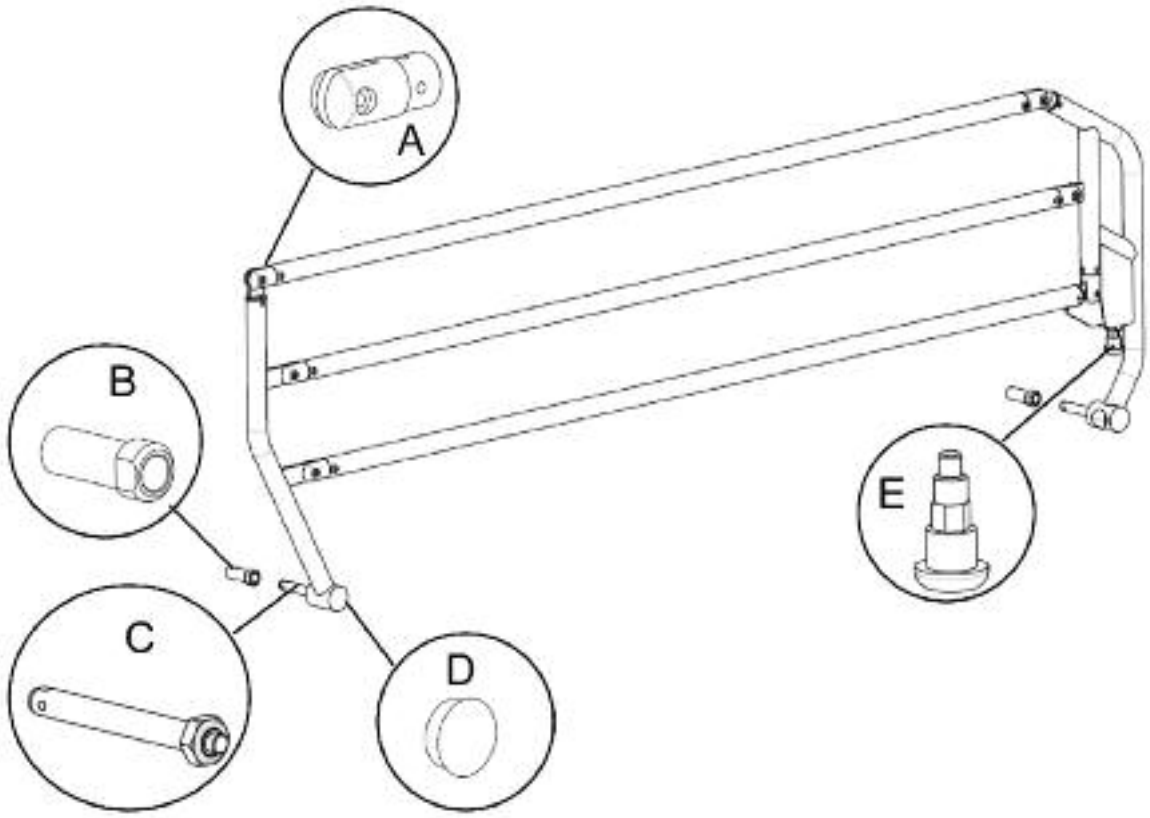
NOTE 2: Those directives may not apply in every situation. The electromagnetic propagation is affected by the absorption and by the reflections of structures, objects, and persons.

SPARE PART LIST

Only spare parts and components provided by DUPONT MEDICAL can be used to repair the bed.

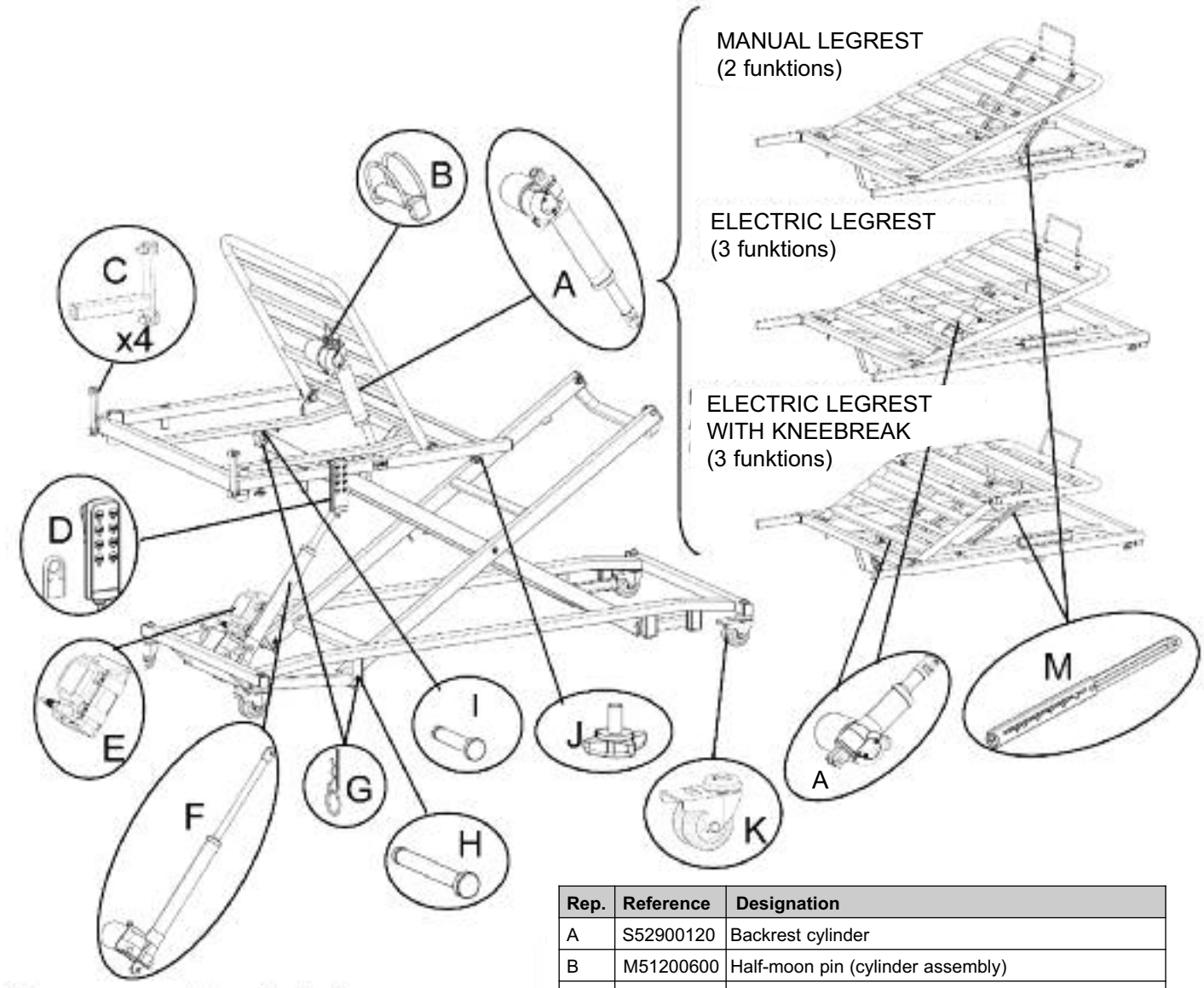
In case of unsolved technical problems, please contact the Customer Service:

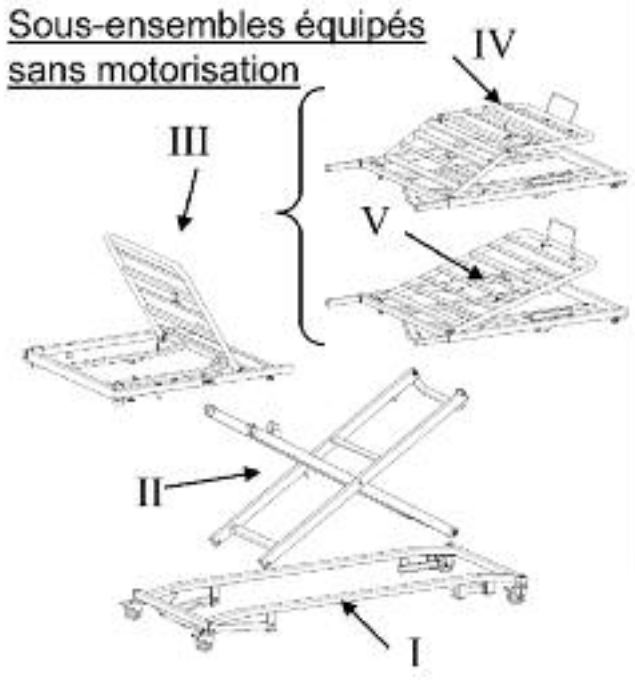
Tel.: 03 83 49 54 51
Fax: 03 83 49 43 91
Email: sav@dupont-medical.com



Rep.	Reference	Designation
A	S44214400	Plastic clevis
B	S44214500	Quick-release bearing
C	S44214600	Quick-release axle
D	S44214700	Rubber cap
E	M52200500	Lock

When the bed is used without any rails or IV pole, it is necessary to cap the free holes.





Rep.	Reference	Designation
A	S52900120	Backrest cylinder
B	M51200600	Half-moon pin (cylinder assembly)
C	S34201000	Set of 4 attachment brackets for panels, with fastenings
D	S52900140	2-function remote control with magnetic key
	S52900150	3-function remote control with magnetic key
	S52903200	Magnetic key alone
E	S52900200	Supply box for 2/3-function cylinders
F	S52900190	Levelling cylinder
G	S44213000	Beta pin
H	S44213100	Lower hinge pin
I	S44213200	Upper hinge pin
J	S44212900	Adjustment knob
K	S44200300	Dia. 75-mm wheel with brake
L	S52900170	Kneebreak or legrest cylinder
M	S52200400	Legrest rack
I	S24204900	Base (equipped assembly)
II	S24205000	Crosspieces (equipped assembly)
III	S24205100	Head half-bed base (equipped assembly)
IV	S24205200	2/3-function foot half-bed base (equipped assembly)
V	S24205300	Kneebreak foot half-bed base (equipped assembly)

XVI - RANGE OF BED ACCESSORIES

>> LIFTIS TABLE

Height-adjustable with hydraulic cylinder; it will easily adjust to the patient.
Plate: 77 x 39 cm
Height: from 71 to 114 cm
Maximum supported weight: 15 kg
Ref.: SA 4212000

>> SAFETY NETS (two)

Ref. : S242 23300

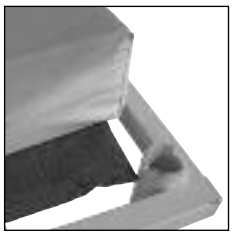
>> PANEL CARRYING BAG

Ref. : S242 23100

>> BED BASE COVER

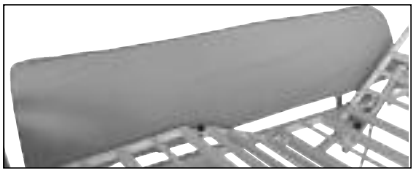
(under the mattress)

Ref. : S242 23400



>> PADDED RAIL PROTECTIONS (two)

Réf. : S242 23200

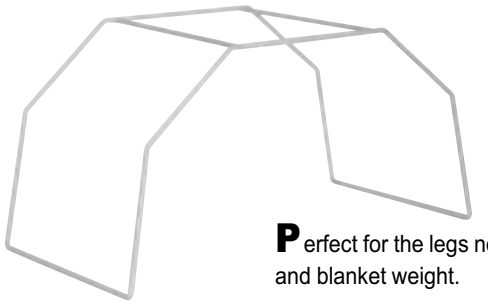


>> BACKREST

Angle adjustable from 25 to 75°.
To be comfortably sitting to read or eat in your bed.

Width: 55 cm
Maximum supported weight: 100 kg
Ref.: SA 411 1000

>> BED CRADLE

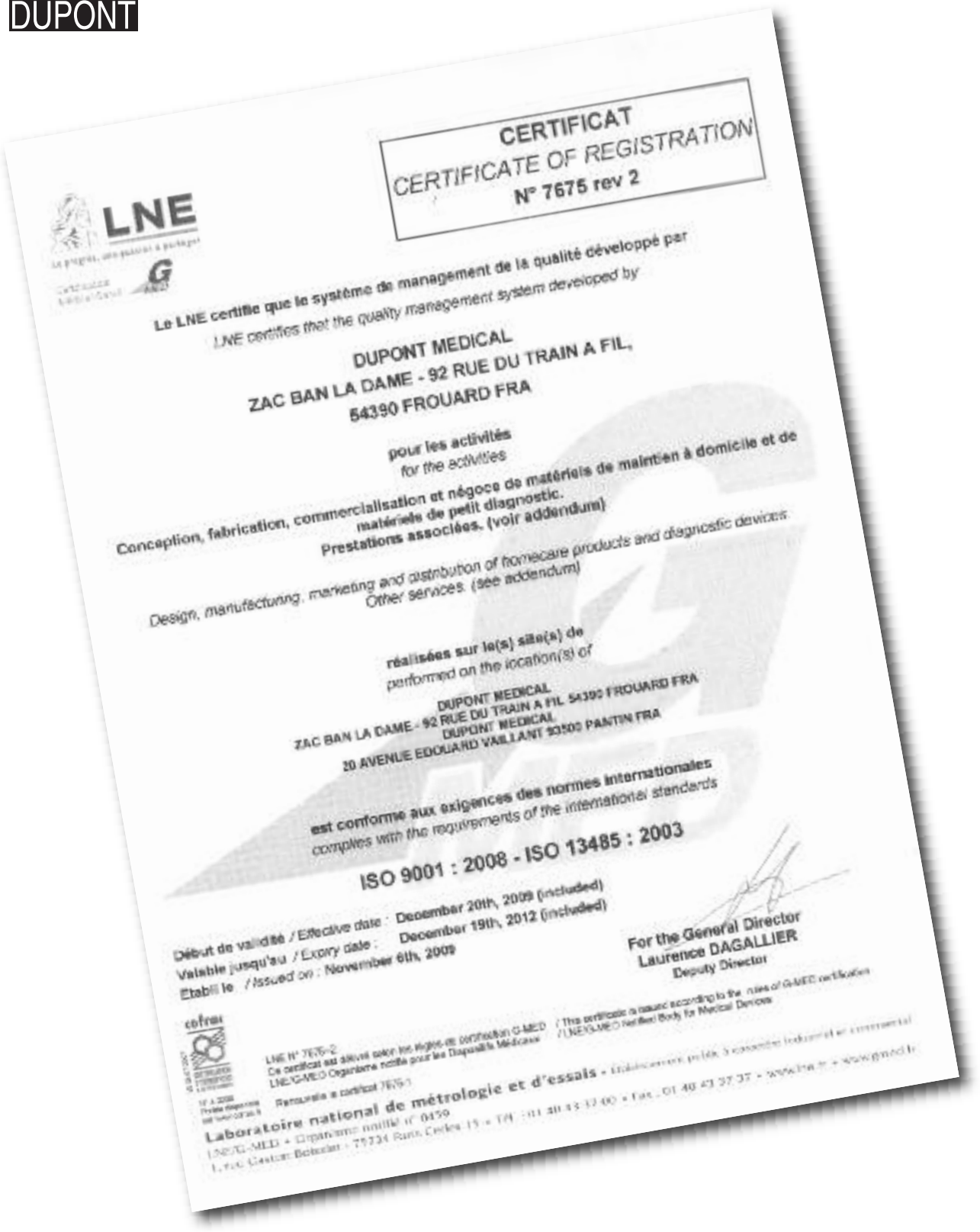


Perfect for the legs not supporting the sheet and blanket weight.

Height: 33 cm - Width: from 50 to 64 cm
Depth: 34 cm - Ref.: SA 414 1000

DUPONT

Cinetis



CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 7675 rev 2

LNE

Le LNE certifie que le système de management de la qualité développé par
LNE certifies that the quality management system developed by

DUPONT MEDICAL
ZAC BAN LA DAME - 92 RUE DU TRAIN A FIL,
54390 FROUARD FRA

pour les activités
for the activities

Conception, fabrication, commercialisation et négoce de matériels de maintien à domicile et de matériels de petit diagnostic.
Prestations associées. (voir addendum)

Design, manufacturing, marketing and distribution of homecare products and diagnostic devices
Other services. (see addendum)

réalisées sur le(s) site(s) de
performed on the location(s) of

DUPONT MEDICAL
ZAC BAN LA DAME - 92 RUE DU TRAIN A FIL 54390 FROUARD FRA
DUPONT MEDICAL
20 AVENUE EDOUARD VAILLANT 93500 PANTIN FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 9001 : 2008 - ISO 13485 : 2003

Début de validité / Effective date : December 20th, 2009 (included)
Valable jusqu'au / Expiry date : December 19th, 2012 (included)
Etabli le / Issued on : November 6th, 2009

For the General Director
Laurence DAGALLIER
Deputy Director

cofrac

LNE N° 7675-2
Ce certificat est délivré selon les règles de certification G-MED / This certificate is issued according to the rules of G-MED certification
LNE/G-MED Organisme notifié pour les Dispositifs Médicaux / LNE/G-MED Notified Body for Medical Devices

Renouvelé le certificat 7675-1

Laboratoire national de métrologie et d'essais - Etablissement public à caractère industriel et commercial
LNE/G-MED - Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 - Tél. : 01 40 43 37 00 - Fax : 01 40 43 37 37 - www.lne.fr - www.gmed.fr

CE

Réf. : M54037400 - Version US - 03/2011 - rév.0

DUPONT MEDICAL
BP19 - ZAC de Ban la Dame - 92 rue du train à fil
54390 FROUARD - France
Tél. +33 (0)3 83 495 495 - Fax +33 (0)3 83 495 496
www.dupont-medical.com

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