

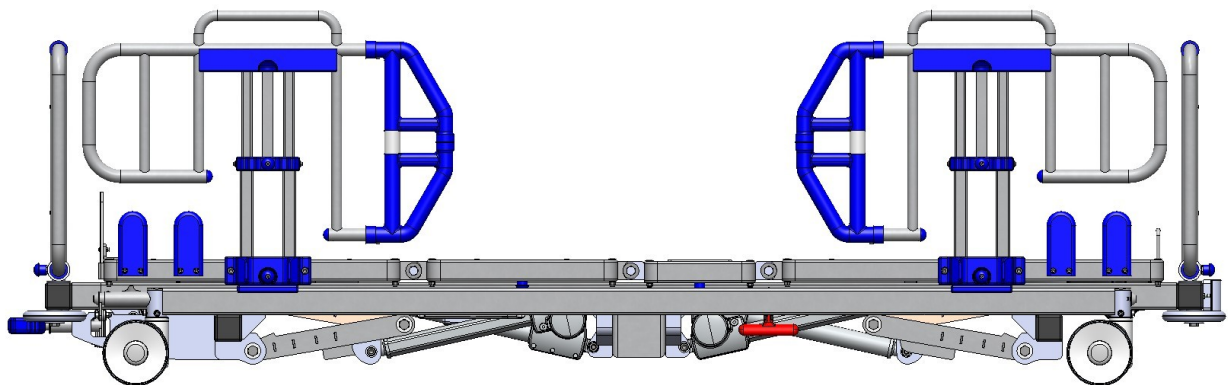
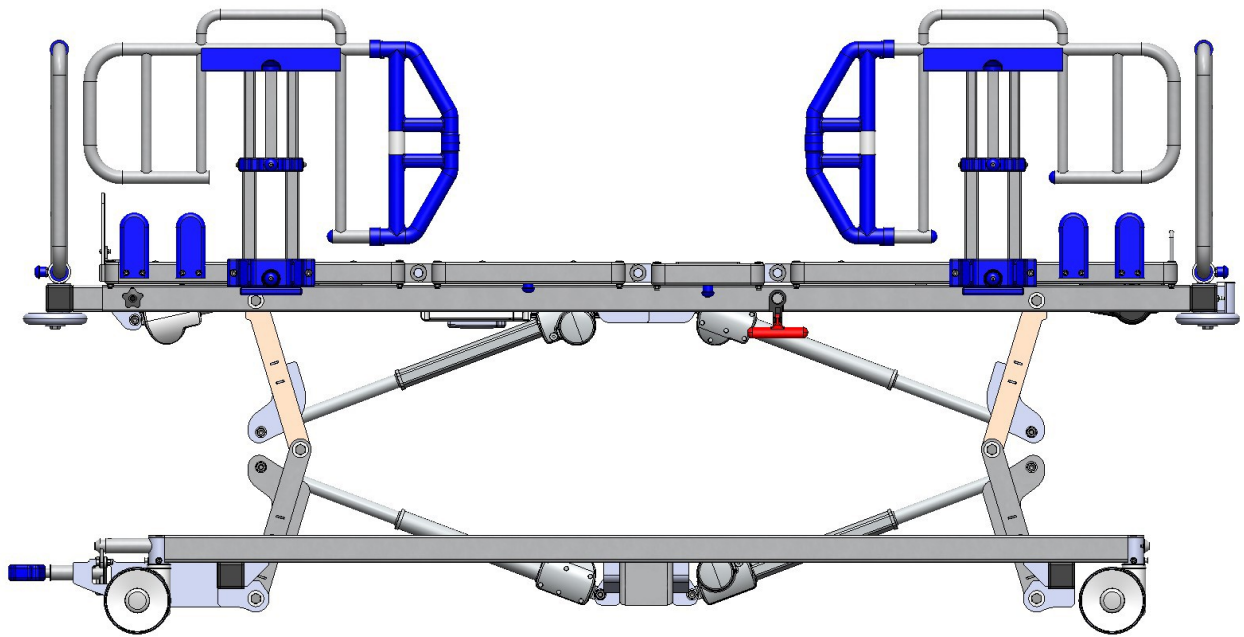
HBB600 BARIATRIC LOW BED

Instructions for Use



HBB600 BARIATRIC LOW BED

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Warnings, Cautions and Notes



WARNING

Indicates possible hazards in procedures or conditions which, if not correctly followed, could result in death, injury or other serious adverse reactions.

YOU WILL FIND THIS SYMBOL
BOTH ON THIS IFU AND ON THE BED!



Caution

Indicates possible hazards in procedures or conditions which, if not correctly followed, could result in equipment damage or failure.

YOU WILL FIND THIS SYMBOL
BOTH ON THIS IFU AND ON THE BED!



Explains or amplifies a procedure or condition.



Indicates an optional item or feature.



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General Warnings



WARNING

Keep these instructions in a safe place; you may need to refer to them later on.

Read and understand these instructions before operating the bed. Carers must be trained in the proper use of this product, its functions and controls, and any accessories.

These instructions are mandatory for the safe and effective use of this product, including the safety of patients and carers.

Unauthorised modifications or repairs to this product may affect its safety and will invalidate any warranty.

The manufacturer accepts no liability for any incident, accident or reduction in performance that may occur as a result of such repairs or modifications.

To avoid the risk of electric shock, this product must only be connected to an electricity supply with a protective earth.

Do not smoke or use naked flames near this equipment and do not expose it to extremes of temperature.

Do not use electrically powered beds in the presence of flammable gases such as anaesthetic agents e.g. in operating theatres.

The bed is intended for indoor use only and should not be used outside a normal hospital environment.

Do not use accessories that have not been designed or approved for use with the bed.

The user should carry out a risk assessment before using the bed with equipment from other suppliers or manufacturers.

Always apply the brakes when the bed is stationary.

To reduce the risk of injury due to falls, lower the bed to an adequate height when the patient is unattended.

Patients should not be left in the Trendelenburg position when unattended. To reduce the risk of overbalancing, do not allow the patient to get on or get off the bed when the mattress platform is in a tilted (head down or foot down) position, or if the bed is not at a height lower than 50cm from the floor.

Continued on next page



WARNING

Where risk assessment indicates that a patient is at high risk of entrapment owing to their medical condition or other circumstances, and where there is no medical benefit from their being left in a contoured position, place the mattress platform in the flat position and disable the controls (Function lockout) when the patient is unattended.

When the bed is operated, make sure that obstacles such as bedside furniture do not restrict its movement.

When moving or operating the bed, take care that any attached accessories (e.g. IV pole) do not strike doors, ceilings, etc.

Hold the head board or foot board when pushing or pulling the bed; do not hold the side rails or any attached accessories.

Before operating the bed, make sure the patient is positioned correctly to avoid entrapment or imbalance.

Take care not to squeeze or trap trailing cables from the handset/ACP or mains cable and other equipment between moving parts of the bed.

Take care not to allow clothing or bed linen to become snagged on moving parts of the bed.

Do not place the bed on an incline greater than 7° as this may, in extreme circumstances, cause the bed to overbalance.

This product complies with the requirements of applicable standards for electromagnetic compatibility (EMC).

However, medical electrical equipment requires special precautions regarding EMC and should be installed and used in accordance with the EMC information in the product service manual.

Medical electrical equipment can be affected by portable and mobile radio frequency communications equipment e.g. cellular telephones.

Continued on next page



WARNING

Before operating the bed, make sure the patient is positioned correctly to avoid entrapment or imbalance.

The safest condition to start a Patient handling and/or to let the Patient getting in and out of the bed, is a height of the mattress platform appropriate to the height and size of the patient himself/herself. Bring the mattress platform at a appropriate height, before operating any patient handling!!! Remember to engage the brake.



WARNING

Incompatible SIDE RAILS and mattresses can cause an entrapment hazard !



WARNING

This medical bed is intended for adult patients and appropriate for obese patients.



WARNING

Safe Working Load of this bed is 600 kg. This bed is capable of supporting heavy load, however dynamic heavy load transfers on its mattress platform, such as overloading its edges or moving a heavy patient when the mattress platform is not at an appropriate height, could cause sudden instability and imbalance of the bed. To avoid potentially dangerous and instability events, keep the bed at a appropriate height whenever dynamic heavy load occurs.

1. Introduction

These instructions contain information for the installation, use and maintenance of the Bariatric Low Bed HBB600. This bed has multiple functions to provide the optimum nursing position for both patient and carer.

Standard features

- Extendable mattress platform sections
- Electrical adjustment of bed height, backrest section, thigh/calf section.
- Auto-Chair facility
- Electrical adjustment of head down tilt (Trendelenburg) and foot down tilt (reverse Trendelenburg)
- Drop split side rails, adjustable height, detachable
- Extendable and removable head board/foot board
- Mattress support surface with removable HPL panels, second section fixed.
- Adjustable length mattress platform
- Electric CPR function and Mechanical CPR function (backrest)
- Battery backup
- Under bed light
- Brake bar at foot side (steering / swivelling / full braked)
- Patient Handset with backlight and Attendant Control Panel (ACP) with function locks
- I.V. pole sockets at head end
- Corner roller buffers
- 125mm dual wheel castors (one steering and conductive, three swivelling)

Optional features

Optional features are specified by the customer at the time of ordering.



Refer to “Accessories” in Chapter 6 for accessory model numbers.

★ I.V. pole fixed height	★ Egress handle
--------------------------	-----------------

Specification labels

The model number of the bed




HBB600 Bariatric Low Bed

and serial number of the bed



XXXX


can be found on the specification label, located on the bed trolley frame.






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MD

REF	HBB600 Bariatric Low Bed					
SN	0 0 0 1					
M	1	2	3	4	5	6
	7	8	9	10	11	12
Y	2024		2025		2026	
	2027		2028		2029	

 = 550 kg


 = 600 kg

 IPX4

Duty Cycle: 10%
Max 2min. ON / 18min. OFF
Input voltage 100V~240V AC (SMPS)
Built-in transformer 32V DC, max 4A

EN 60601-2-52:2016
IEC 60601-1:2005
(EMC) 2014/30/EU





The above label represents the UDI number of each device = UDI-DI + UDI-PI (UDI-DI [GTIN] / PRODUCTION DATE YYMMDD / SERIAL # XXXX)



Refer to the SN serial number to identify the bed for assistance purpose.

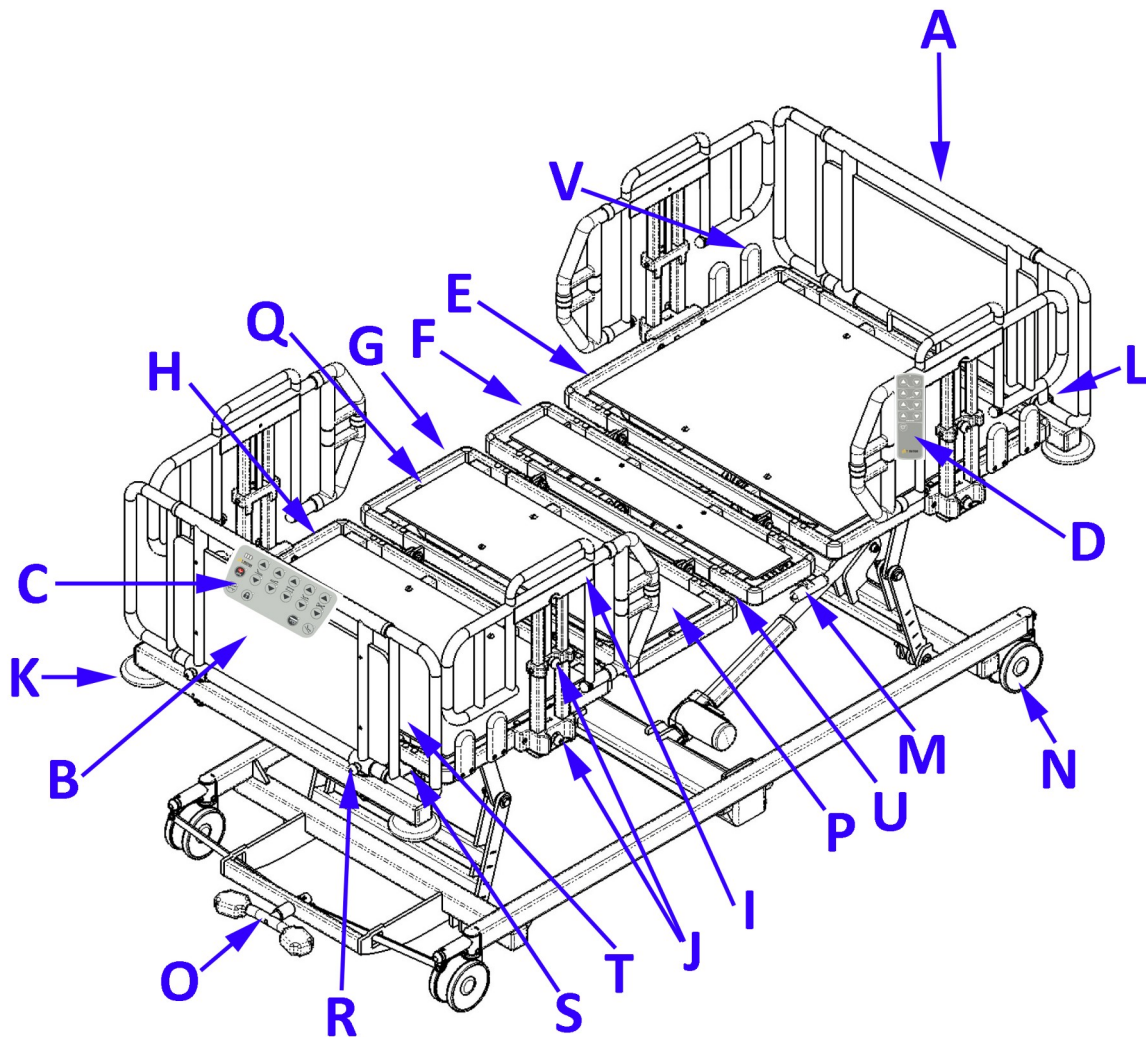


Caution

Before using the bed, ensure that the “Power In” rating on the specification label is compatible with the local electricity supply.

Product overview

- A. Extendable Head board
- B. Extendable Foot board
- C. Attendant Control Panel (ACP)
- D. Patient Handset
- E. Expandable Backrest section
- F. Expandable Seat section
- G. Expandable Thigh section
- H. Expandable Calf section
- I. Side rails (detachable)
- J. Side rail operating knobs
- K. Corner Roller buffer
- L. I.V. pole socket
- M. CPR handle (quick release of the back section)
- N. Conductive and Steering Castor (front right)
- O. Brake/Swivel/Steer pedal
- P. Electric set (control box, battery)
- Q. Expandable sections operating knob
- R. Extendable head/foot boards operating knob
- S. Adjustable length mattress platform
- T. Mattress retainer/mattress extension platform
- U. Under-bed light
- V. Lateral mattress retainer



1. Clinical Applications



WARNING

To ensure the patient can use the bed safely, their age, size and condition should be assessed by a clinically qualified person.
The use of head down tilt (Trendelenburg) or foot down tilt (reverse Trendelenburg) may be contraindicated for certain medical conditions. The tilt facility should only be used under the guidance of a clinically qualified person after assessment of the patient's condition.

Intended purpose

The bed is suitable for use in Application Environments 1, 2 and 3 as defined in UNI CEI EN 60601-2-52:2016

Application Environment 1

Intensive/critical care provided in a hospital where 24-hour medical supervision and constant monitoring is required, e.g. ITU, ICU and CCU.

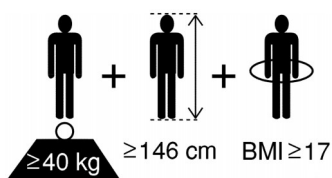
Application Environment 2

Acute care provided in a hospital or other medical facility where medical supervision and monitoring is required, e.g. general medical and surgical wards.

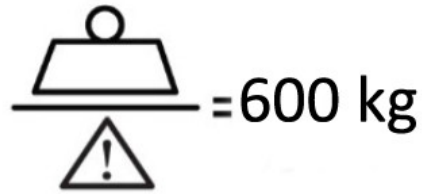
Application Environment 3

Long term care in a medical area where medical supervision is required and monitoring is provided if necessary, e.g. nursing homes and geriatric facilities.

Indications and intended patient group

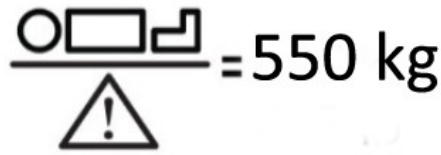


This Bariatric Low Bed is for adults and it is appropriate for high dependency obese Patients who pose a movement and handling risk and/or whose clinical condition requires that they are positioned with minimal physical handling. Particularly this bed, with its mattress platform minimum height of 23 cm, is able to provide safer conditions of entering and exiting the bed for those Patients who need a very low height from the ground, reducing the risk of potential falls and providing to Carers an aid in attending to those Patients. The use of this bed is reserved for medical personnel, professionals and/or people aware of the content of its IFU. Patients with a moderate amount of independence can, at the Carer's discretion, use the controls to adjust their own position. The mattress platform can be positioned to assist with treatment of a Patient as required within the clinical settings defined in Application Environments 1, 2 and 3. The correct use of this medical device, according to the supplied IFU, represents a valid support to improve Patient's health.



The safe working load of the bed is 600kg (1322lb).

Contra-indications



The maximum recommended patient weight is 550kg (1212lb)

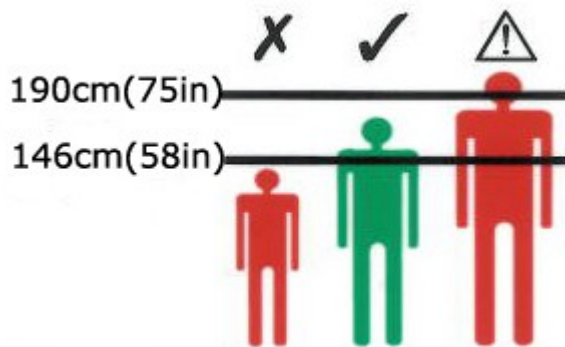
The safe working load is calculated as follows (in accordance with UNI CEI EN 60601-2-52:2016):

Maximum patient weight	550kg
Mattress	12kg
Accessories (including attached loads)	38kg
TOTAL	600kg



WARNING

If the combined weight of the mattress and accessories exceeds 50kg, the maximum patient weight must be reduced accordingly.



The recommended patient height is between 146cm and 190cm.

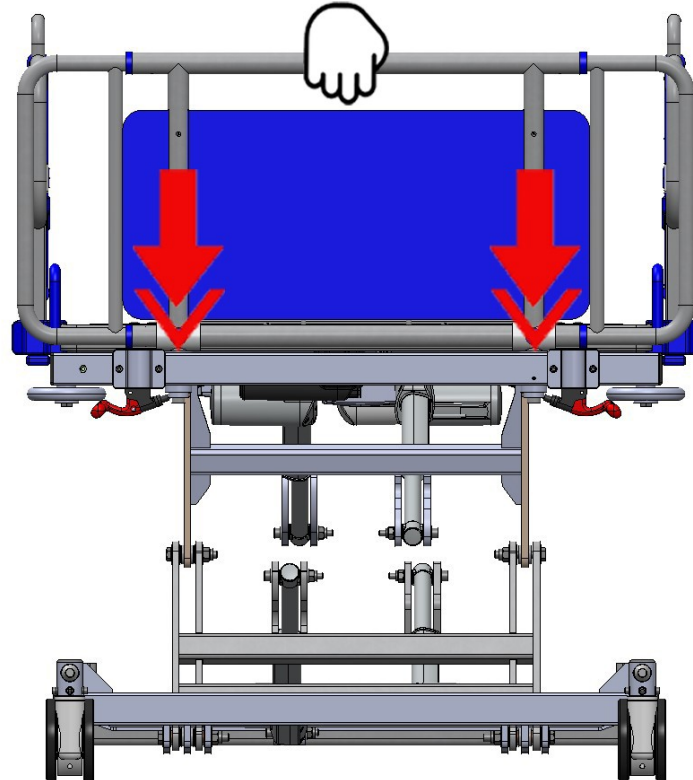
At the discretion of the carer, patients taller than 185-190cm may be accommodated by extending the bed – refer to “Bed length adjustment” in Chapter 4.

Ensure that patient’s height does not exceed the “In-bed length” shown in Chapter 7.

3. Installation

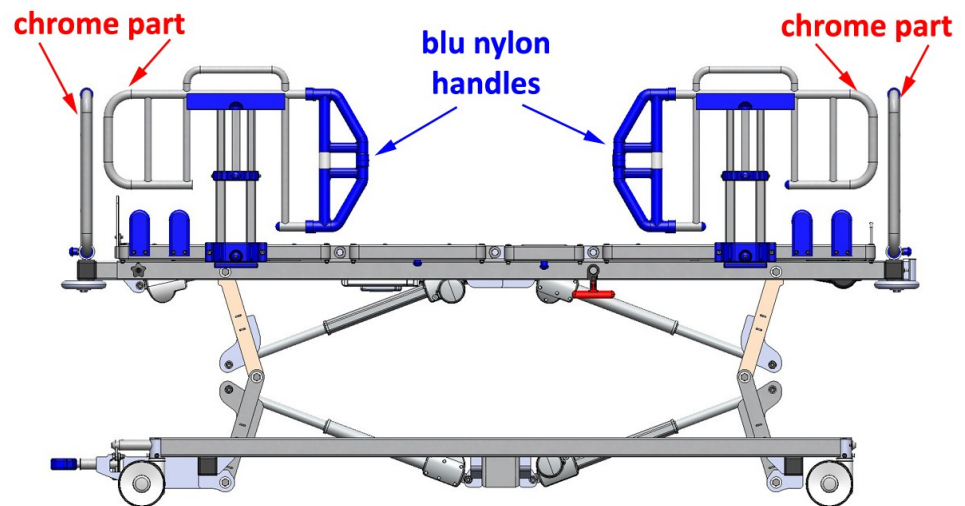
To install head and foot boards (n.2)

Insert the head board and the foot board in their sockets.

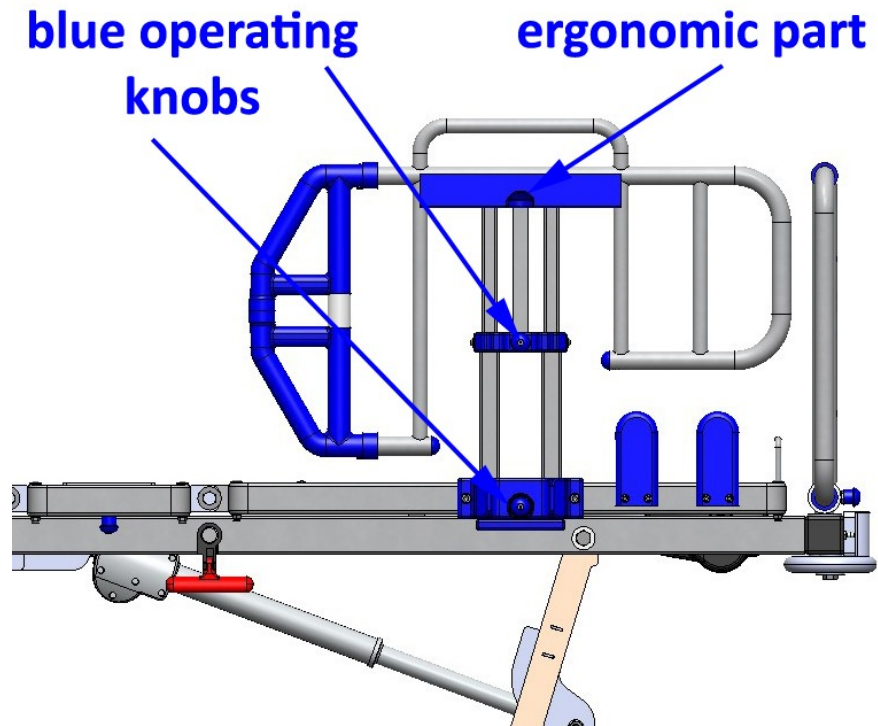


To install (or to remove) the side rails (n.4)

The bed is supplied with n.4 side rails (equal two by two diagonally), which can be installed only in the way the image below shows:



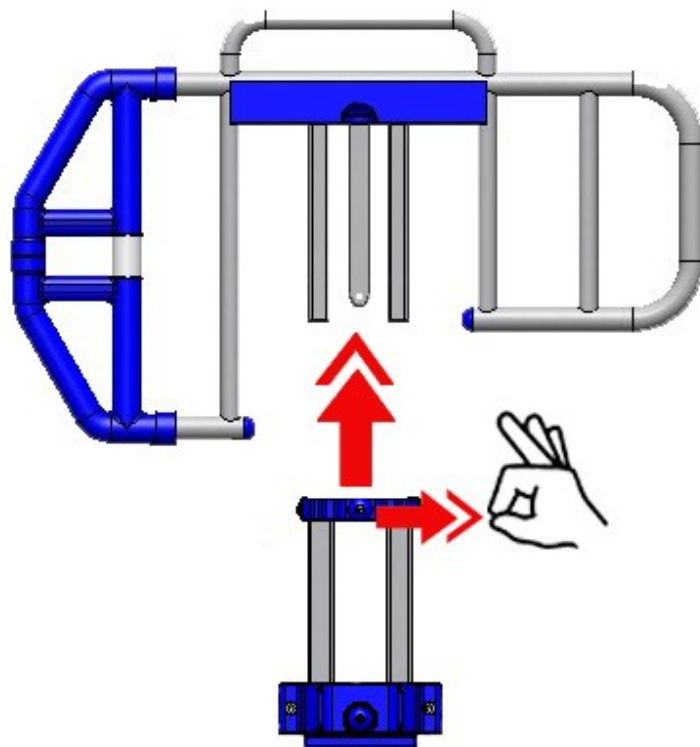
1. the chrome part of the frame of the side rails must always face the chrome part of the frame of the head and foot boards (see picture above).
2. the blue nylon handles must always face each other on the same side of the bed. (see picture above)
3. the side rails must always have the blue operating knobs and the ergonomic part (see the picture below) facing outside of the bed.



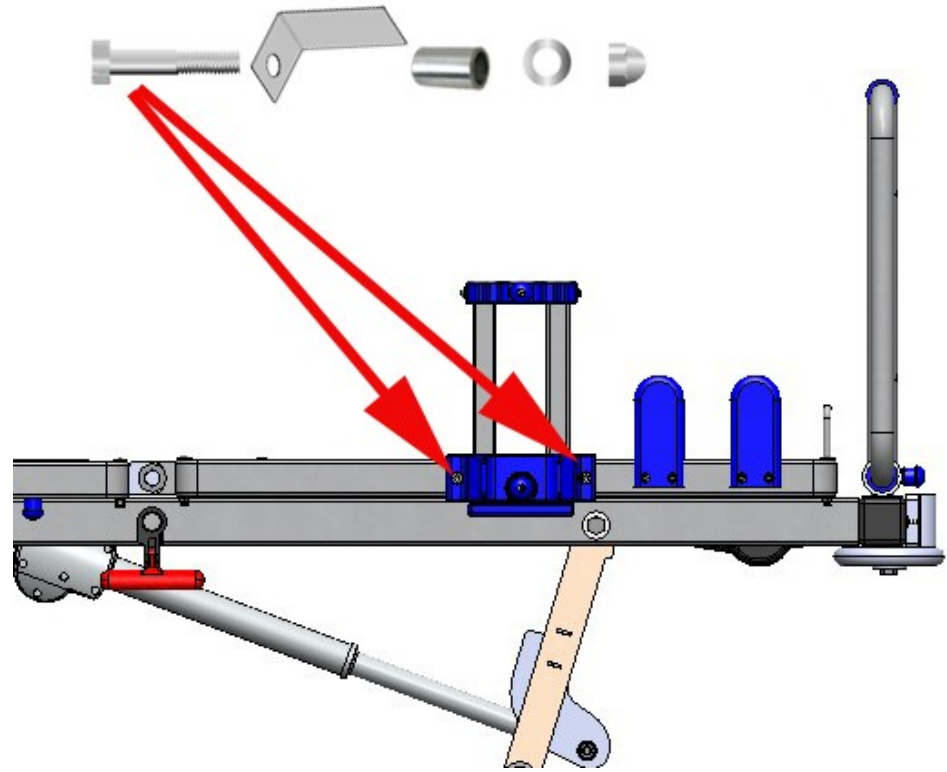
Only the pair of side rails on the diagonal can possibly be interchangeable in position.

To install the supplied side rails:

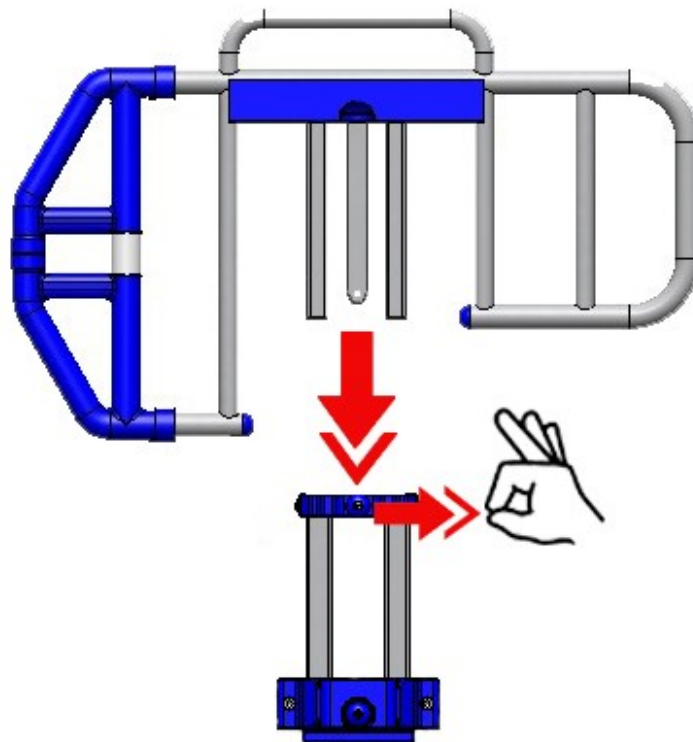
1. separate the upper part of the side rail from its lower part by pulling the upper blue knob and then remove the upper part.



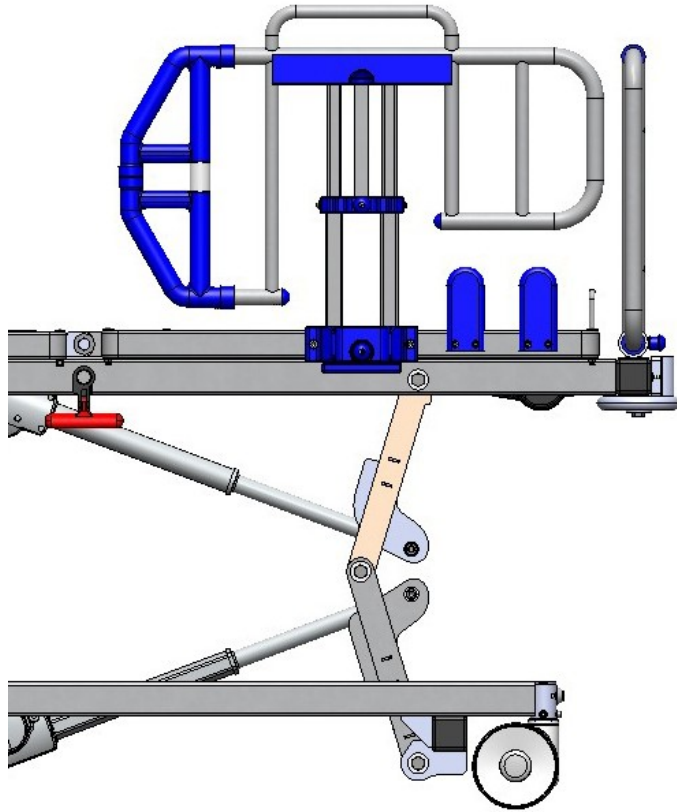
2. screw the blue base block of the lower part to the frame of the extendable sections (the side sides must be mounted using the supplied Allen screws, stainless steel bushings, folded metal sheets for the electric connectivity, washers and nuts into the holes provided on the first and on the fourth sections).



3. Insert the upper part of the side rail into its lower part, sliding the upper chrome tubes into the lower chrome tubes: pull the upper release blue knob and also slide the central locking plate into its seat in the middle, release the blue knob and wait for the locking audible “click” between the upper and lower parts.



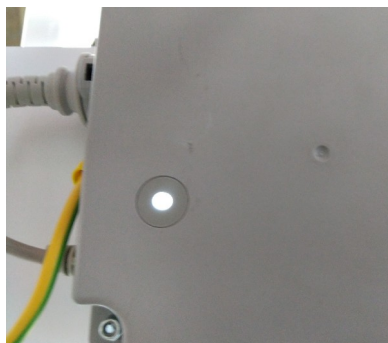
4. To remove the side rail, hold the upper chrome handle and with the other hand pull the BLUE knob (release of the central chrome plate). Remove the upper part of the side rail. (Point 1. on page 15)



A label on each side rail indicates they are detachable.

Electric connection

Connect the mains plug to a suitable socket outlet. Make sure the mains plug is easily accessible so it can be disconnected quickly in an emergency. When the bed is connected to the electricity supply, a WHITE indicator will light on the Transformer. (The electric set is located underneath the mattress platform. Bring the bed at its maximum height to reach the electric set, if needed).



Three solid ORANGE indicators, at left side of the Attendant Control Panel, will light if the battery is fully charged or they will flash, if the battery is on charge.



A GREEN indicator on the emergency battery underneath the mattress platform will flash too when the battery is on charge (see OPERATIONS at page 45). To keep the battery in stock (not mounted on the bed) as a spare part, switch it OFF.



To isolate the bed from the electricity supply, disconnect the mains plug from the socket outlet.

Potential equalisation terminal



A potential equalisation terminal is located at the head end of the bed. When other electrical equipment is within reach of the patient or carer, potential differences between the equipment can be minimised by connecting together their potential equalisation terminals.





WARNING

If the power cord or mains plug is damaged, the complete assembly must be replaced by authorised service personnel.

Do not remove the fitted plug, or use a rewirable plug or adapter.

Make sure the power supply cord is not stretched, kinked or crushed.

Do not allow the power supply cord to trail on the floor where it may cause a trip hazard.

Make sure the power supply cord does not become entangled with moving parts of the bed.



Caution

Before the first use, or if the bed has been unused for more than three months, connect the bed to the electricity supply for at least 24 hours to allow the backup battery to recharge fully.

Failure to do this may reduce the life of the battery.

The bed should be positioned with the roller buffers at least 8cm from the rear wall to prevent the head board striking the wall when the bed is in head down tilt (Trendelenburg).



Recommended positioning from rear wall at least 8cm from the corner roller buffer

Mattress



WARNING

Always use a mattress of the correct size and type. Incompatible mattresses can create hazards.

Entrapment hazards may exist when using a very soft mattress, even if it is the correct size.

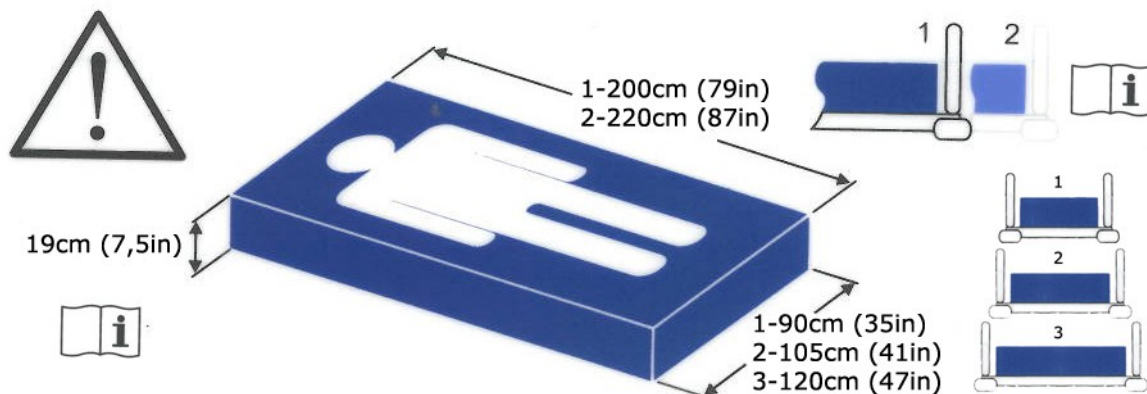
The maximum recommended mattress thickness for use with side rails is 19cm.

Read the instructions for use supplied with the mattress.

Where the maximum patient weight specified for the mattress is different to that specified for the bed, the lower value applies.

Mattress size label

A label on the frame indicates the correct mattress size: (thickness measure must be read as the maximum value possible.)



The numbers 1, 2, 3 on the label indicate different mattress platform widths and 1, 2 different mattress platform lengths; refer to “Bed length adjustment” in Chapter 4.

Mattress and side rails

When choosing bed and mattress combinations, it is important to consider the use of side rails based on clinical assessment of each individual patient and in line with local policy.

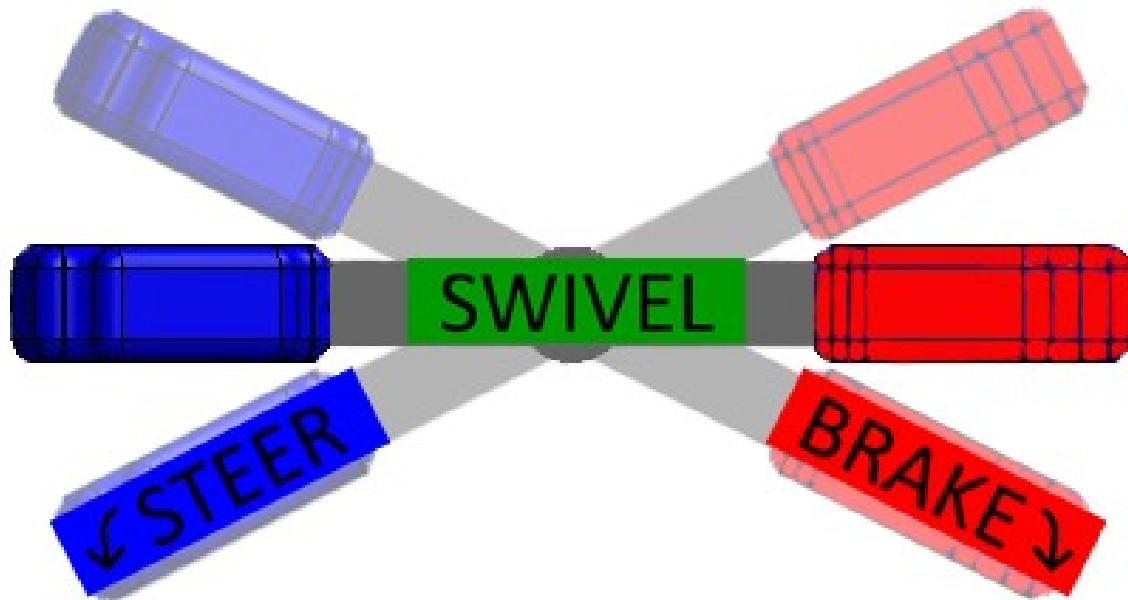
When assessing the suitability of a mattress for use with side rails, the following factors should be considered:

- The bed is designed to provide an acceptable side rail height when used with a foam mattress up to 19cm thick.

- Specialist powered air / foam replacement mattresses will typically envelop the patient when loaded and can generally be deeper than a foam mattress without compromising safety. Other makes of specialist mattress replacement must be assessed individually prior to use to verify sufficient clearance is maintained.
- Mattress overlays are not recommended for use with this bed.
- To ensure compliance with EN 60601-2-52:2016, an approved mattress should be used. Compliance with this standard when using other mattresses must be validated by the user.
- For more information on suitable mattresses and mattress replacements, contact your local approved distributor.

4. Operation

Brakes and Steering The brake pedal is at the foot end of the bed and has three positions as shown below.



Press the LEFT side of the pedal all the way down to activate the steering castor: once engaged, it will rotate in a straight direction, it won't swivel and helps to keep the bed on a straight line when moving.

IF the pedal is in BRAKE position, then press its LEFT side until it is going to be almost parallel to the ground.
 IF the pedal is in STEER position, then press its RIGHT side until it is going to be almost parallel to the ground.
 Then all four castors are free to rotate and swivel.

Press the RIGHT side of the pedal all the way down to activate the brakes on all 4 castors simultaneously.



WARNING

Use of the pedal brake: as the brake pedal is located only at foot side, the bed has to be manoeuvred from foot side to allow a quick apply of the brake in case of need. If the bed is manoeuvred at head side, a second operator is needed at foot side to be able in any case to apply the brake, if needed.



WARNING

Operate the brake pedals with your feet while wearing suitable shoes. Do not operate the pedals with your hands.



Caution

The brake pedal in the neutral position (SWIVEL) is positioned so as not to pose a potential hazard to the operators' feet. However when the pedal is activated and pressed in its left side (STEER) or in its right side (BRAKE), it will end its stroke very close to the floor. Pay attention not to leave anything under the pedal!

Using the steering castor

Position the bed so that all the castors line up in the direction of travel. Push down the LEFT side of the pedal to engage the steering castor and move the bed by pushing it from the foot end.



*The steering castor is at right head side.
The steering castor is conductive too.*



Pulling or pushing the bed to its adequate height becomes essential to be able to transmit the right force for movement, taking advantage of your centre of gravity, your weight and placing one leg before the other for the initial thrust.



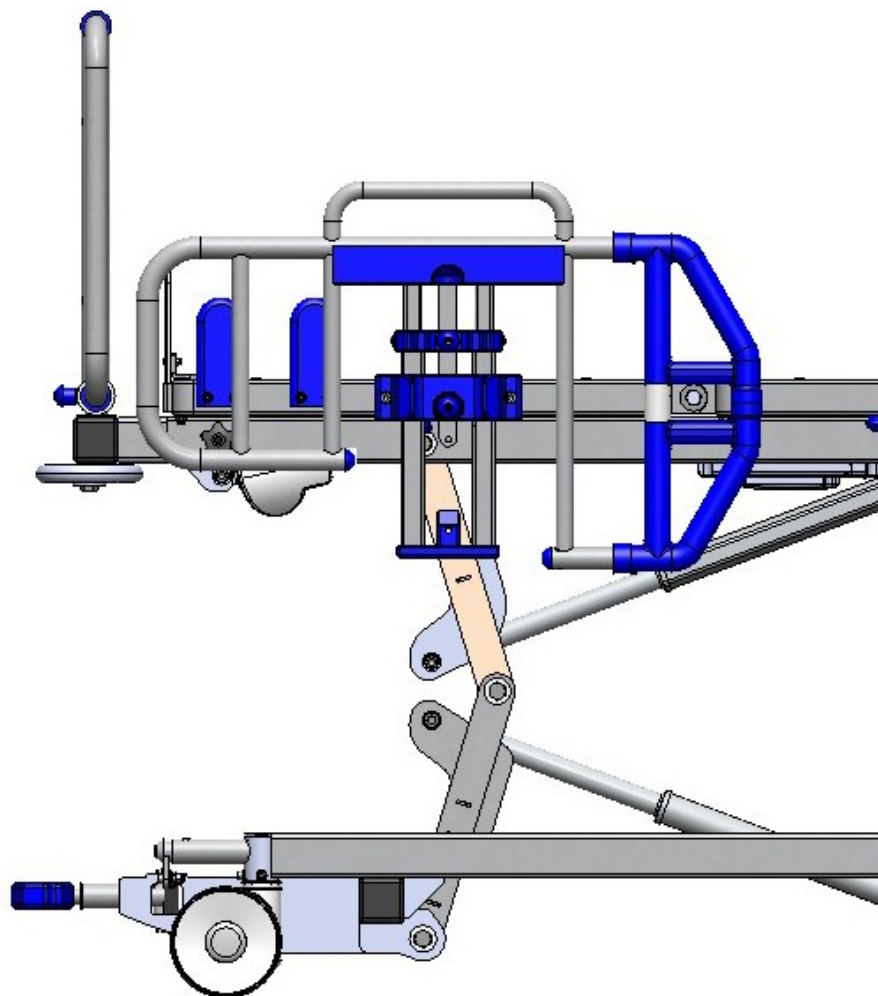
WARNING

When switching from STEER (pedal fully down on the left) to SWIVEL (pedal almost parallel to the floor), or from BRAKE (pedal fully down on the right) to SWIVEL (pedal almost parallel to the floor), it is important in some cases to **MAKE SURE** that the castors have completely disengaged the STEER or BRAKE function: **THEREFORE PAY ATTENTION TO UNUSUAL NOISES COMING FROM THE CASTORS** and if necessary, press the pedal lightly to the right or left again to **FINALIZE** the release of the STEER or BRAKE function.

Side Rails

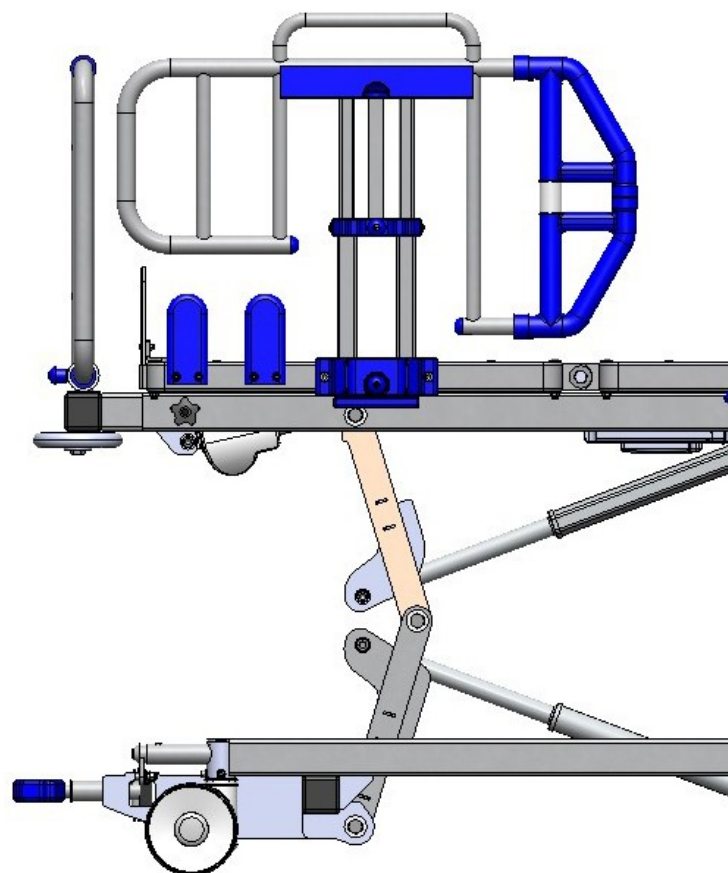
The bed is fitted with n.4 drop split side rails, adjustable height and detachable.

They can be adjusted on three different height levels:



First level (all down – mattress level)

Second level (mid)



Third level (all up)



WARNING

The clinically qualified person responsible should consider the age, size and condition of the patient before allowing the use of side rails.

Side rails are not intended to restrain patients who make a deliberate attempt to exit the bed.

The bed must only be used with the side rails supplied. Do not use another manufacturer's side rails.

Ensure that the mattress is suitable for use with side rails - refer to Chapter 3 for guidance.

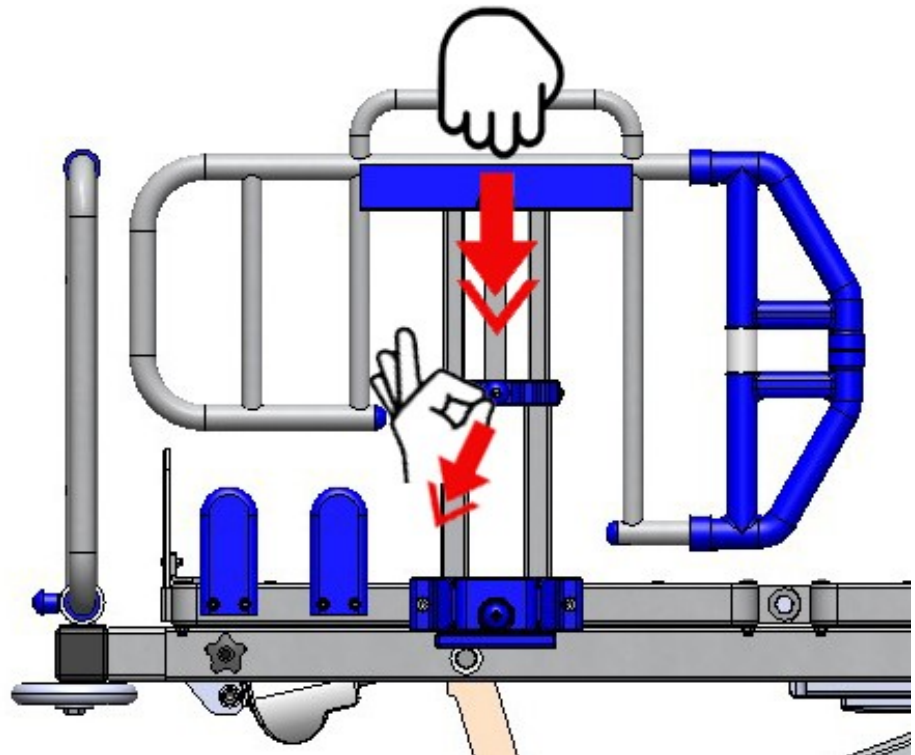
Operation



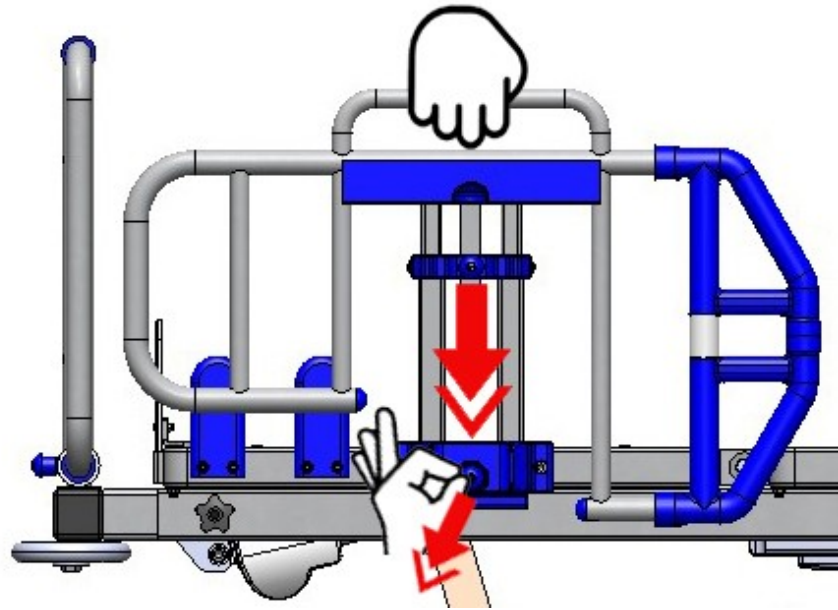
Side rails are detachable.

To lower the side rail

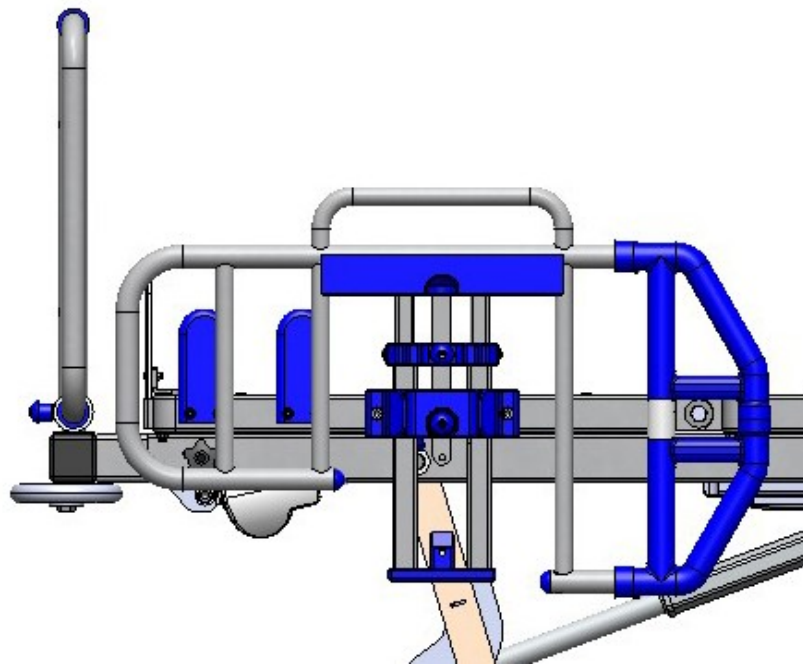
Hold the top side rail handle (third level) and pull the UPPER blue operating knob, push down the side rail which will slide at the second level (mid) of height:



pull the LOWER blue operating knob and push down the side rail at the first level (all down):



so that the side rail folds down to the mattress level:

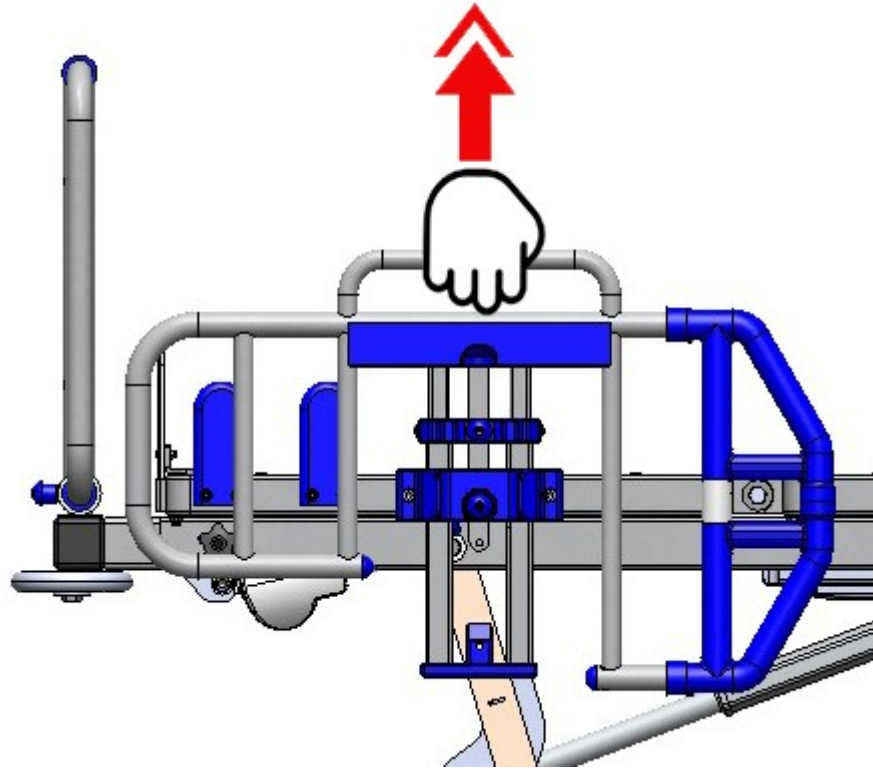


Caution

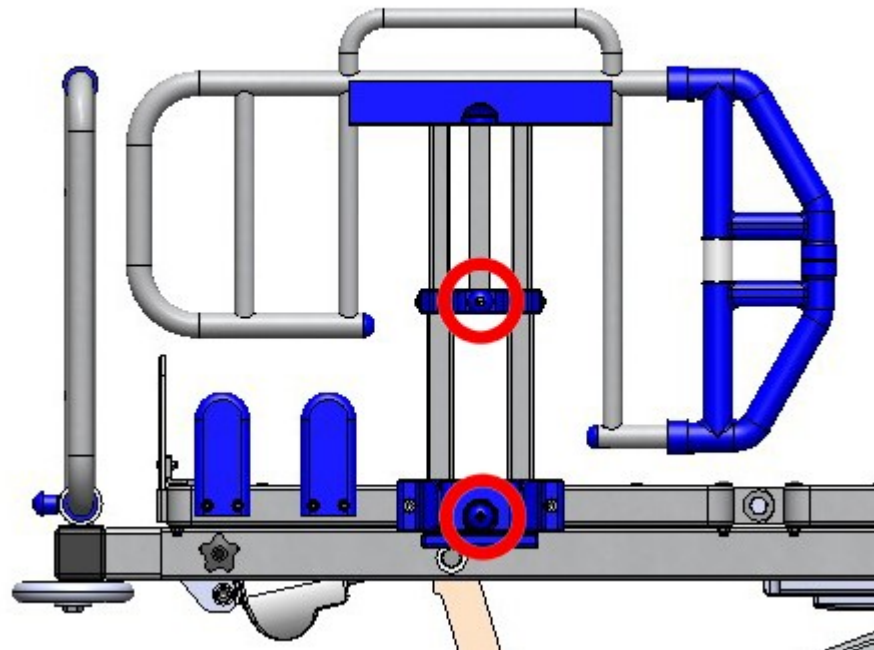
When the mattress platform height is between 23 cm (its minimum height) and 32.5 cm from the floor and the side rails are also positioned at their minimum height, their distance from the floor is between 25 mm and 120 mm respectively and could potentially trap a foot. Be careful of the clearance under the side rails at those heights!

**To raise
the side rail**

Grab the top side rail handle and pull it up:



until the UPPER and LOWER operating knobs are locked to the top raised position (third level) with an audible “click”.



When the side rail is raised at its maximum top height (third level), then you can adjust it at the second level of height (see how to lower the side rail at page 25).



Side rails are designed to avoid potential finger entrapment: if the side rail drops down without any control, the gap $\geq 25\text{mm}$ between the nylon mouldings, where the vertical rails slide, assures safety.



Side rails are designed and supplied with two internal ergonomic nylon handles to facilitate the patient safety grab.



WARNING

Make sure the operating knob is securely engaged when the side rail is raised. Do not leave the side rail in the raised position if the operating knob did not make an audible “click”.

Extendable head/foot board

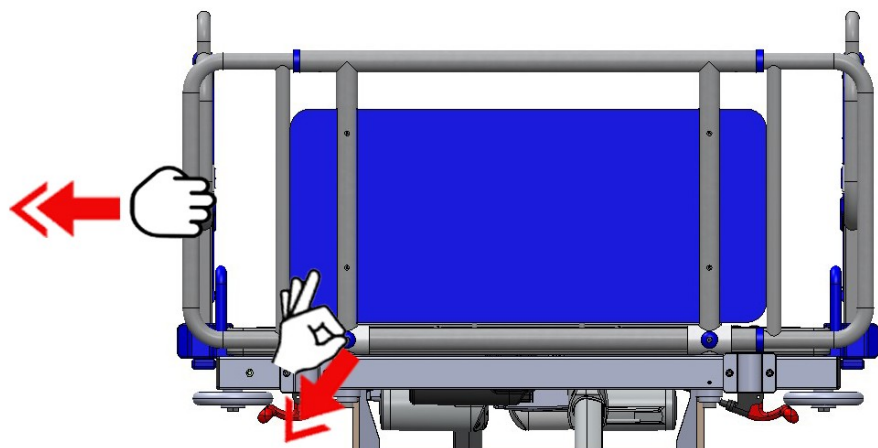
Head/foot boards are extendable. **This is needed whenever the mattress platform sections are extended.**

The gap between the head/foot board and the safety side rail must be less than 6 cm.

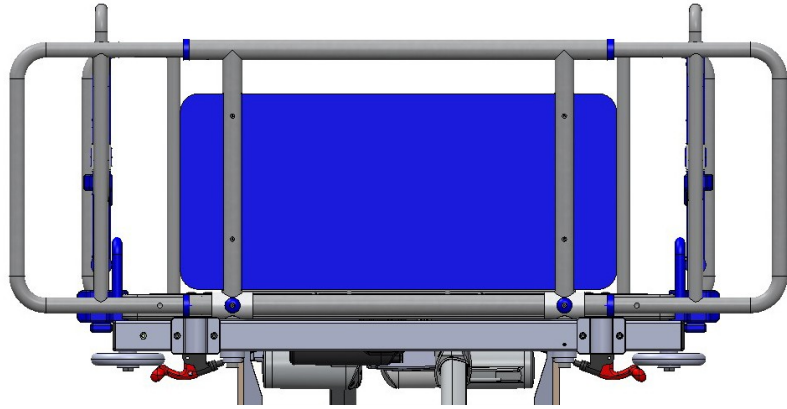
Head/foot boards can be easily lifted off and removed from the bed for closer access to the patient.

Operation to EXTEND

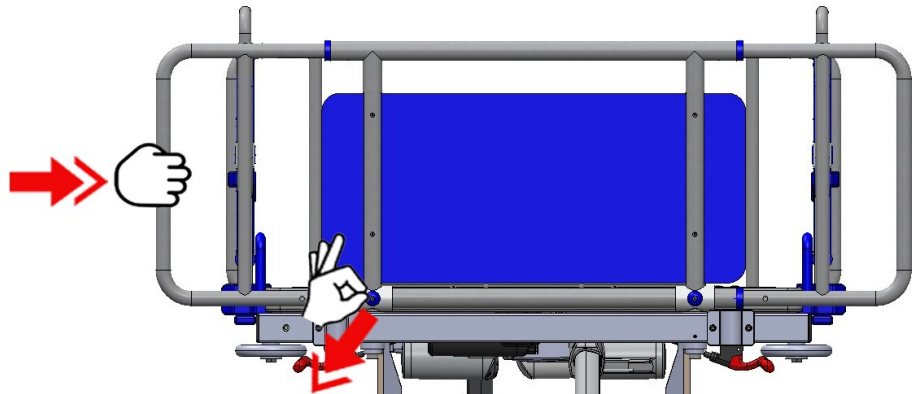
To extend the head/foot boards, grab the chrome plated extension tube at right/left side, pull the blue operating knob, pull out the chrome plated extension tube (while releasing the blue operating knob) until it locks with an audible “click”.



to SHORTEN



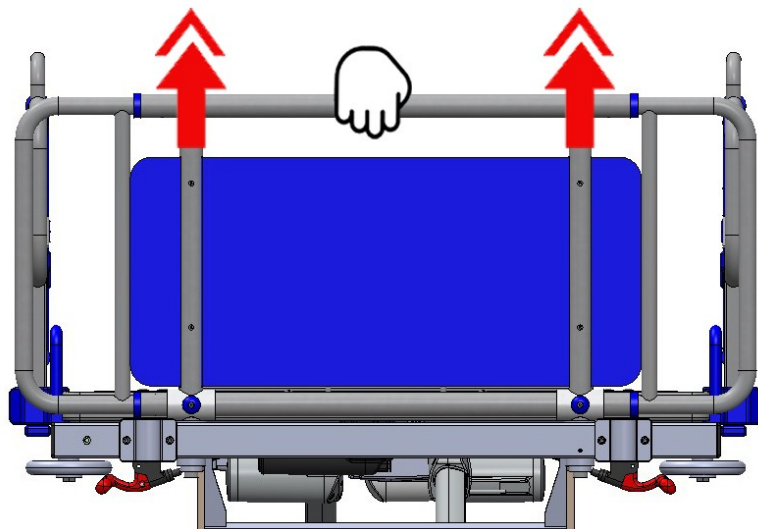
To shorten the head/foot board, pull the blue operating knob, grab the chrome plated extension tube at right/left side and push it inside until the lower part of the tube locks with an audible “click”.



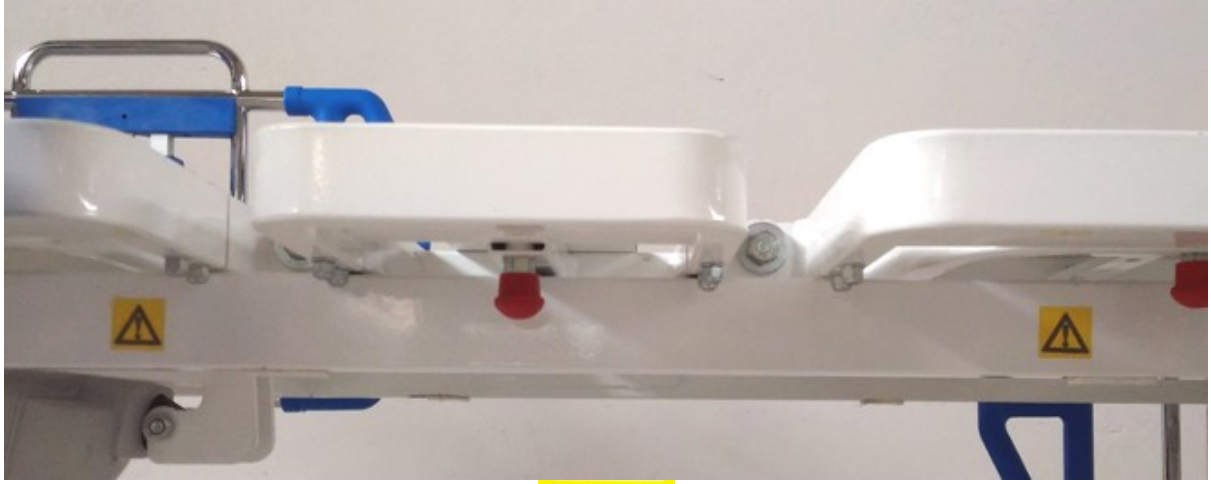
Head/Foot boards are detachable.

to REMOVE

To remove the head/foot board grab the upper frame and lift the board up. To put them back in place grab the upper frame and place the two tapered inserts inside their sockets.



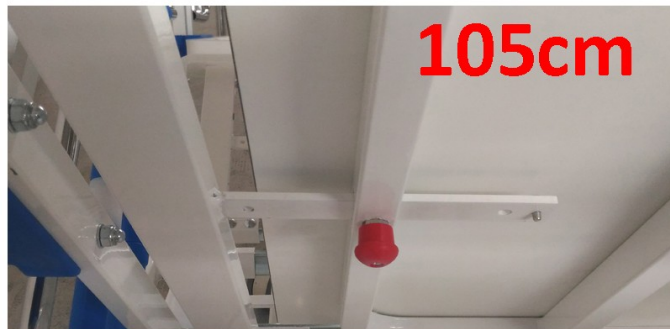
Mattress platform sections potential contact points are identified by this symbol.



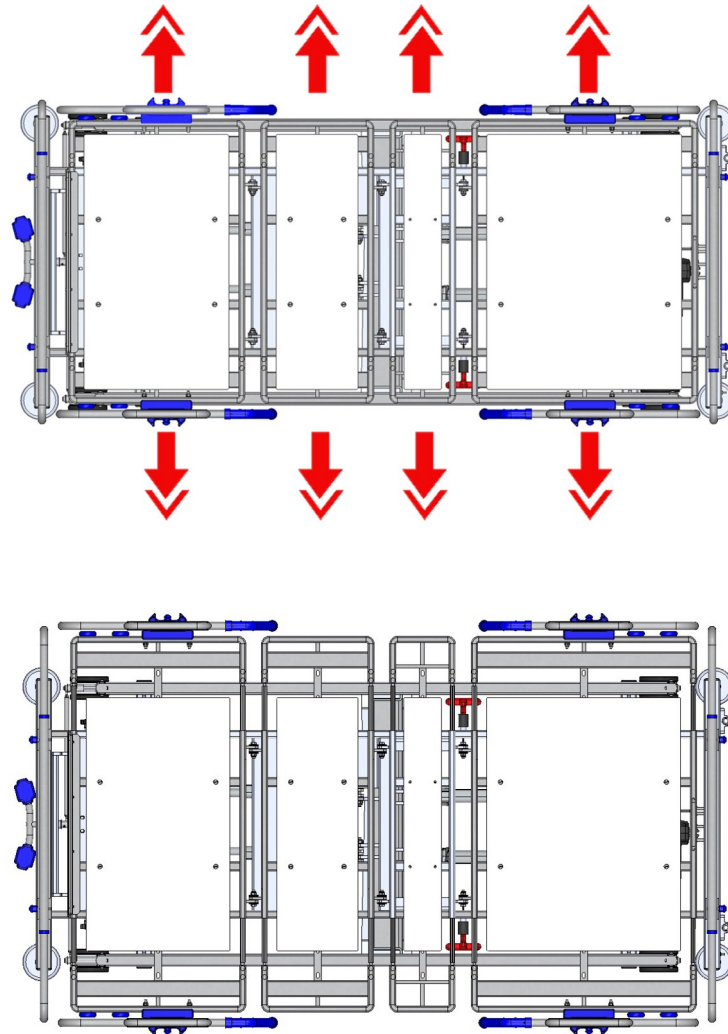
Keep hands and fingers away from those areas!!!

**Extendable
mattress platform
sections**

The bariatric low bed is supplied with extendable mattress platform sections, from 90cm to 105cm and to 120cm.



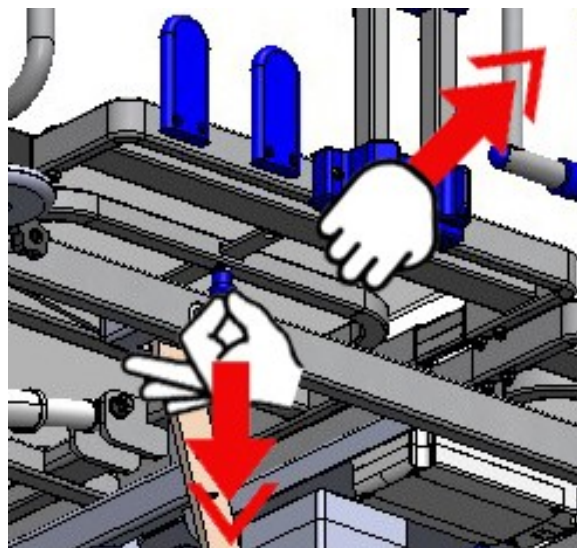
When a plus size patient is accommodated into the bed, the sections must be extended at 120cm.



Operation

TO EXTEND the sections

To extend the eight sections, grab with one hand the middle of a section frame, pull the corresponding RED operating knob underneath that section with the other hand and pull out the extension frame:



release the operating knob until it locks with an audible “click”. The first extension is at 105cm and the second extension is at 120cm.

TO SHORTEN the sections

To shorten the sections, just reverse the operation: grab each section frame, pull the RED operating knob underneath that section, push the extension frame, release the BLUE operating knob until it locks with an audible “click”.



WARNING

Whenever the sections of the mattress platform are extended, the head/foot boards must be extended too accordingly.

[SEE Extendable head/foot board in chapter 4]



WARNING

Whenever the sections of the mattress platform are closed at 90cm and the sections are adjusted with handset or ACP, pay attention at the potential finger entrapment with the lower frame in any movement.



Electric CPR will bring the mattress platform at 50 cm height.

ELECTRIC CPR backrest release

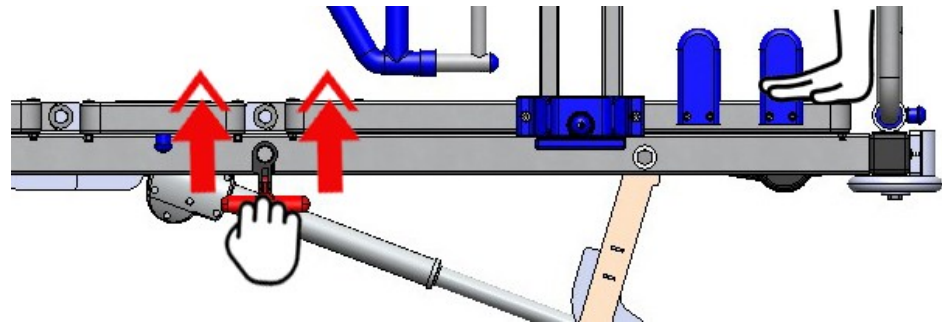
Electric CPR control is located on the ACP (Attendant Control Panel). If an emergency procedure has to be taken out, press the CPR button to lower the backrest and all other platform sections and levelling the bed. This enables cardio-pulmonary resuscitation procedure to be carried out.



**MECHANICAL CPR
quick release of
the backrest**

The levers to activate the mechanical quick release of the backrest are located on the bed frame side member, between the first and the second section, on both sides of the bed. Grab the RED lever and press it upwards to release the actuator and with the other hand slightly press from above the external edge of the first section.

KEEP YOUR HANDS OUT OF THE AREA UNDERNEATH THE SECTION!!!



A gas spring 800 Newton is mounted parallel to the actuator underneath the back section. The gas spring will slow down the free fall of the back section, once the mechanical release will be activated.



WARNING

When using MECHANICAL QUICK RELEASE (MECHANICAL CPR OPERATION) the back section is going to move flat under the weight of the patient, KEEP YOUR HANDS AND ANY OBJECT OUT OF THE AREA BEHIND THE BACK SECTION DURING THE MECHANICAL CPR OPERATION!!!

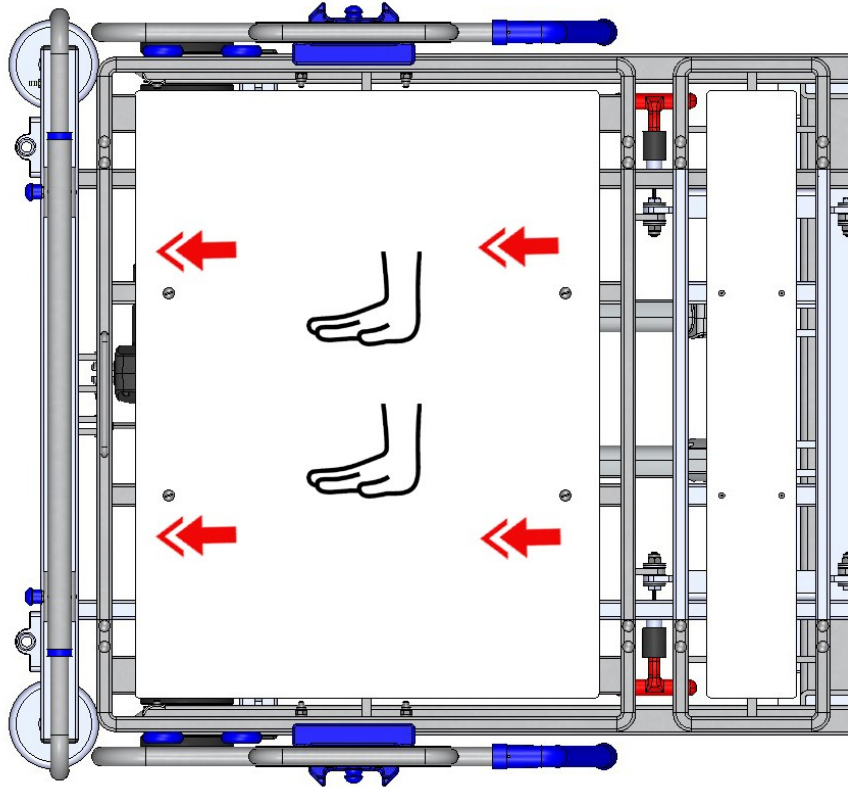


From its top height with maximum profile and tilt, electric CPR is taking maximum 23 seconds to lower the backrest, thigh and calf sections and make the bed flat. Mechanical quick release of the backrest is faster, but works only for backrest section.

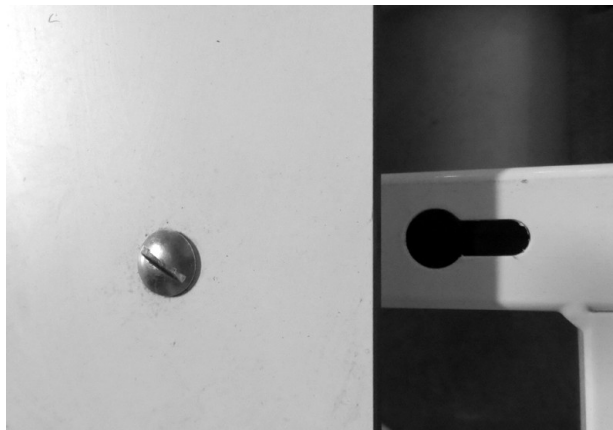
Mattress support panels removal

Operation

Mattress support panels are removable for a deep cleaning and maintenance, except the second section panel which is fixed. Press the panel and Push it towards head side of the bed to release it. It will slide forward for 1 cm and then it will be free to be removed.



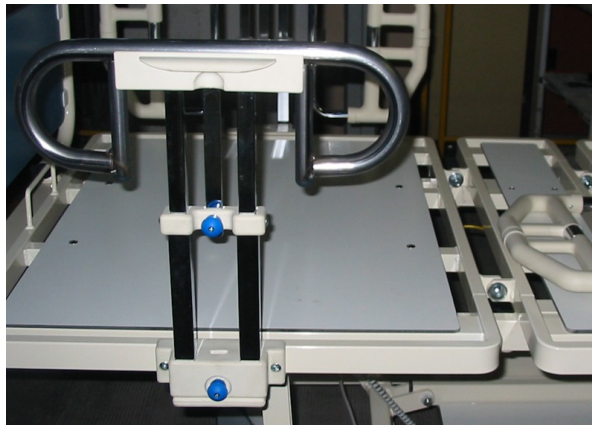
The locking system of the panels is made of a keyhole shape in which the pivot can be locked in the narrow side and can be released in the wider one.



Egress handle

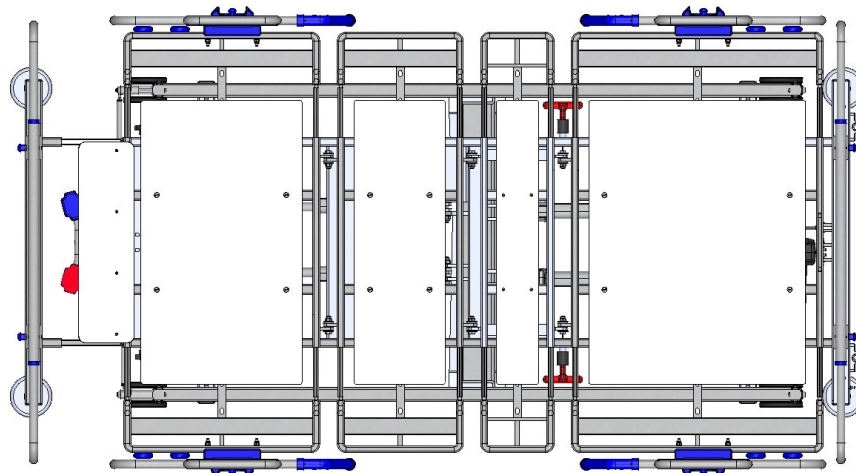
This accessory can be used in place of the standard side rail ONLY to make the egress of the patient from the bed easier and more comfortable. It was not designed to have the same function of the safety side rail the bed is originally equipped with.

Its adjustment operation is the same of standard side rail at page 23.



Bed length adjustment

The length of the bed is adjustable to an extended position (+ 22 cm), to accommodate very tall patients.



WARNING

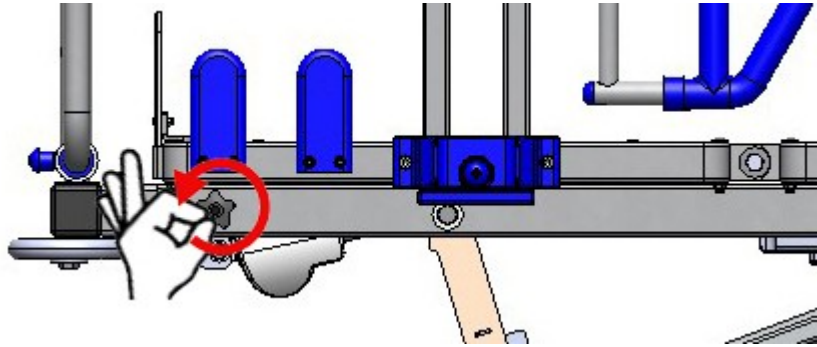
Install a suitable foam mattress extension (squab) at the foot end when the bed is extended.

Always adjust the bed frame and mattress platform to the same length and make sure both are latched securely in position.

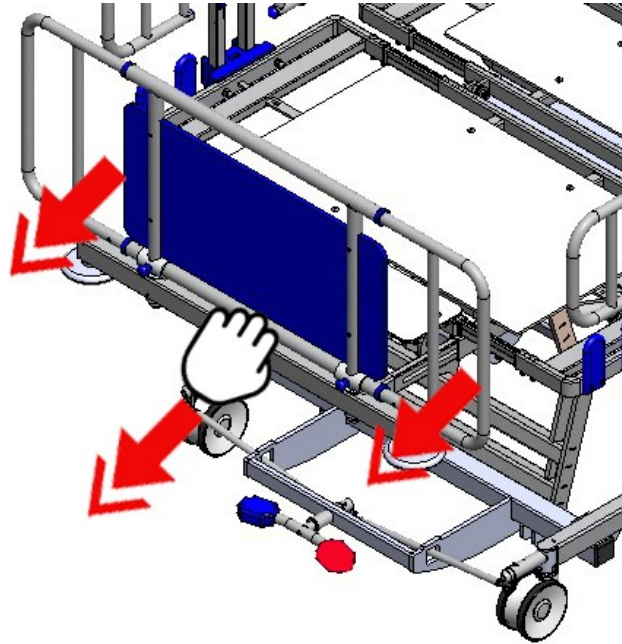
Level the mattress platform before adjusting the bed length.

Operation

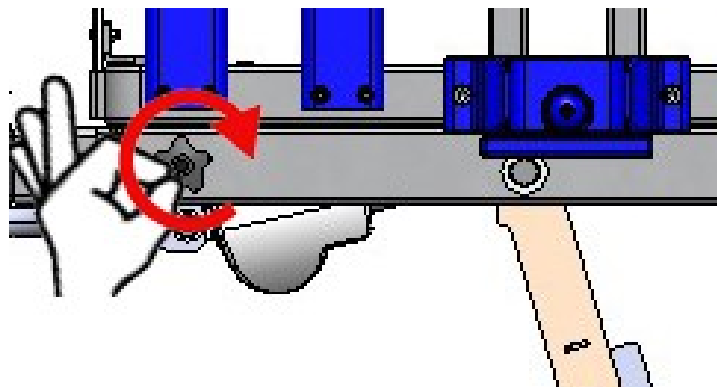
Turn counter-clockwise the two black hand wheel knobs (placed at right side and left side of the foot frame) below the foot section, to unlock the foot extension: now the foot extension is free to move.



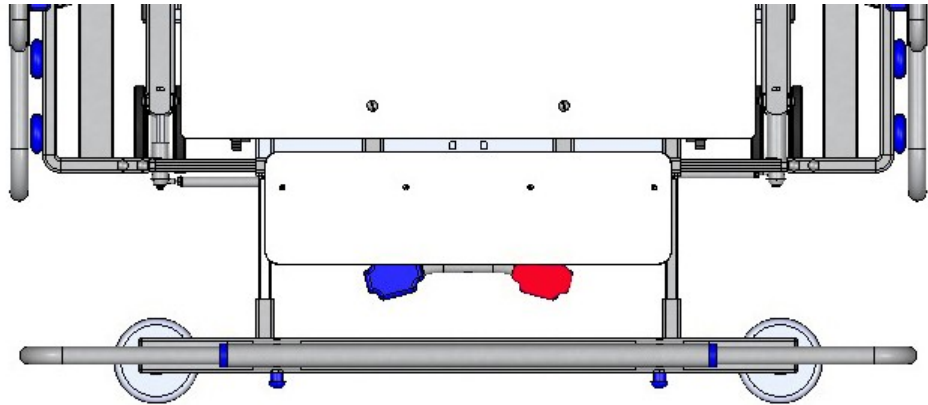
Pull the foot extension frame out



turn clockwise the two hand wheel knobs until securely fastened to lock them: the foot extension now is securely fastened.



Extract the foot mattress retainer from its socket at foot end, turn it 90° and place the shorter side of its frame into the socket so to have an additional extension of the mattress support panel.





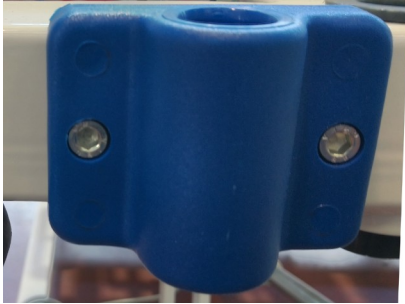
To restore the foot extension (shorten the bed): firstly put the mattress retainer panel back into its original position (Pull out the mattress holder panel from the flat position, turn it over and position it vertically with the shorter side of plastic laminate insert in its socket, with its metal insert frame facing inward the bed), then turn counter-clockwise the two hand wheel knobs to unlock the extension: now the foot extension is free to move, push it back to its original closed position, turn clockwise the two hand wheels knobs until securely fastened and locked: now the foot extension is securely fastened.




WARNING

Do not sit on the foot extension part of the bed when extended, it can cause imbalance of the bed!

<p>I.V. pole fixed height </p>	<p>I.V. pole chrome plated with two hooks.</p>  <p>I.V. hooks safe working load is max 4kg overall.</p>
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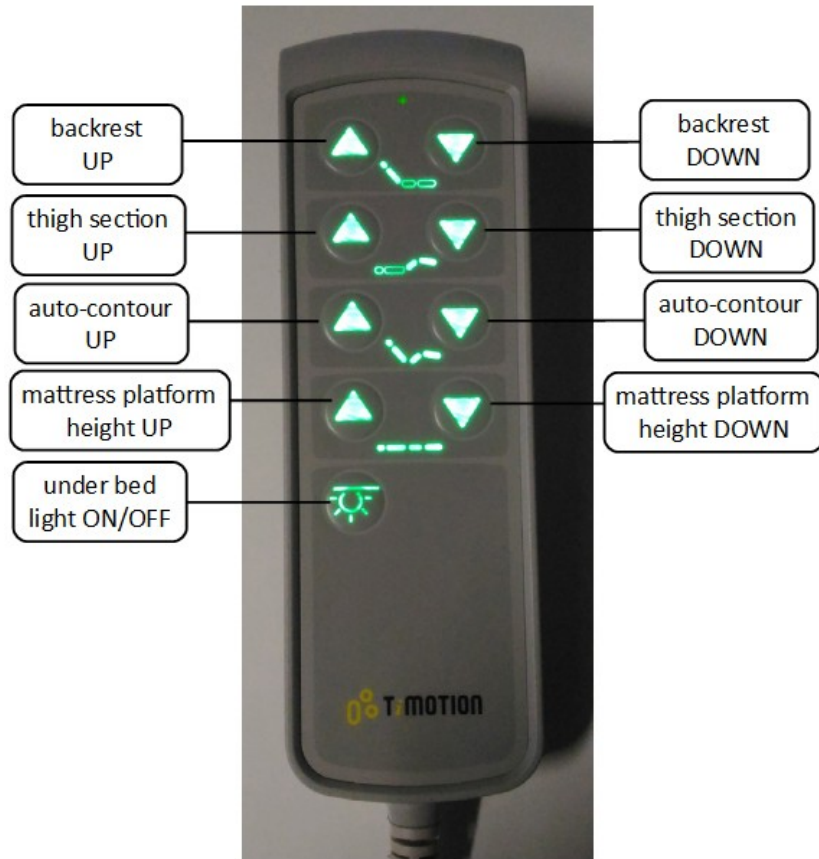
<p>I.V. pole sockets</p> <p>Operation</p>	<p>I.V. pole fixed height sockets are located at head end, behind the head board.</p>  <p>Place the I.V. pole in one of the two sockets until the tube is completely inside the socket.</p>
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<p>Under-bed light (night-light)</p>	<p>The bed is supplied with under bed light on a side, underneath the right side of the mattress platform frame. See next paragraph for operation.</p> 
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<p>Adjusting the mattress platform</p> <p>Operation</p>	<p>The bed is provided with two control handsets: a patient handset with basic controls only and a more comprehensive Attendant Control Panel with locks (ACP – Nurse handset) for use by the carer. The functions on both handsets are described separately over the next few pages.</p> <p>To adjust the mattress platform: press and hold the appropriate button until the required position is achieved. Movement will continue until the button is released or the limit of actuator stroke is reached.</p>
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Patient Handset

The patient handset can be positioned on either side of the bed through its clip.



Operation

BACKREST:

these buttons raise and lower the backrest.

The backrest reaches an angle approximately 50° above the horizontal.

THIGH SECTION:

These buttons raise and lower the thigh section.

When the thigh section is raised from the flat position (34°), the calf section will be in the Fowler position (9° angled downwards).

AUTO-CONTOUR (Fowler):

The Auto-Contour up button simultaneously raises the backrest and thigh sections to provide upright patient profiling; the raised thigh section prevents the patient sliding down the bed.

The Auto-Contour down button returns the backrest and thigh sections to a flat position.

MATTRESS PLATFORM HEIGHT:

these buttons raise and lower the mattress platform.

Minimum height: 23cm

Maximum height: 70cm

UNDER-BED LIGHT:

this button switches ON the under bed light, located at a side of the bed, under the mattress platform frame.

To switch the light OFF, just push the button again.



WARNING

If the patient handset or ACP is dropped onto a hard surface, check that all the buttons work correctly afterwards.



The patient handset is supplied with green background lighting for easy usage in dark surroundings



The Under-Bed Light is not working whenever the emergency battery is running out of charge.

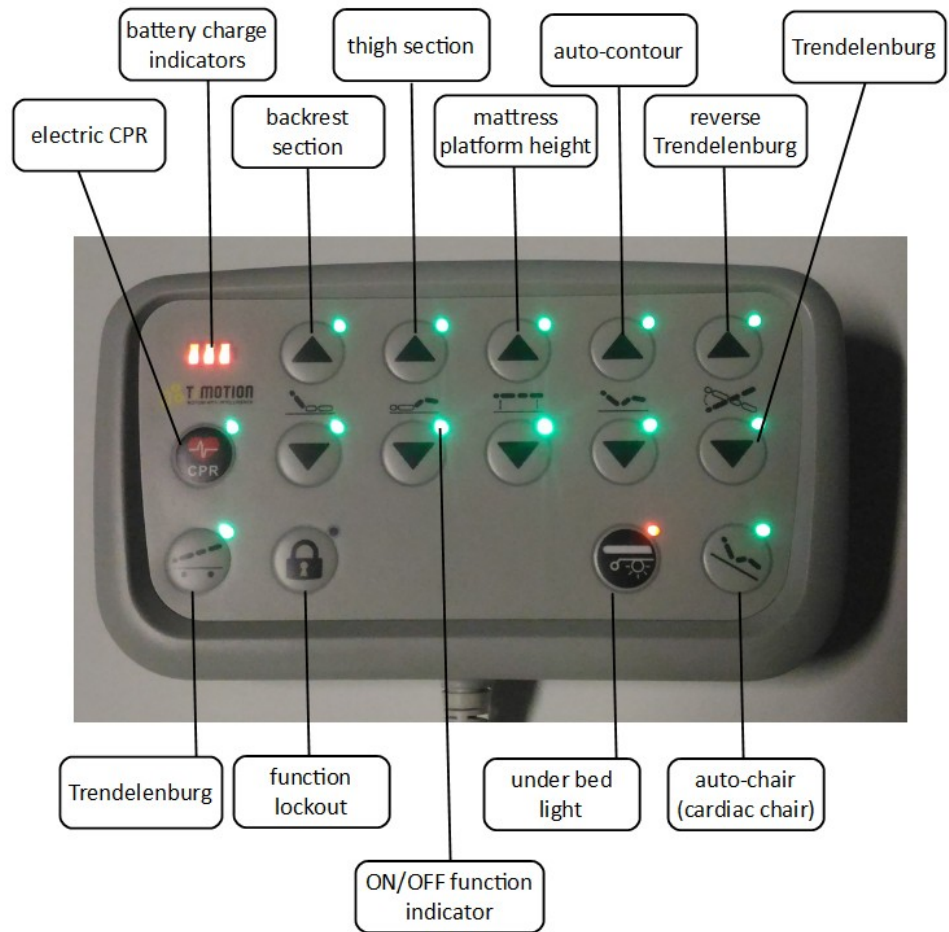


WARNING

**Store the handset on the side rail using the clip on the back; this will help to prevent accidental operation of the controls.
The patient should be shown how to use the handset by the carer.**

Attendant Control Panel (ACP – Nurse handset)

The ACP is located on the foot board through its clip.



Operation

ELECTRIC CPR:

If for emergency reasons is needed to level the mattress platform and all the sections, then press and hold the CPR button. The mattress platform will move to a height of 50 cm and will level the sections (backrest-legrest). The CPR button overrides the function lockout settings.

[For faster emergency procedure directly apply the MECHANICAL CPR device to drop the backrest].

BATTERY CHARGE INDICATOR:

If the ACP battery indicators flash ORANGE, the battery is charging. If the ACP battery indicators are steady ORANGE, the battery is fully charged. The more battery indicators are steady, the more the battery is charged (maximum three indicators).

BACKREST SECTION:

these buttons raise and lower the backrest (upper button to raise, lower button to lower).

The backrest reaches an angle approximately 50° above the horizontal.

THIGH SECTION:

These buttons raise and lower the thigh section (upper button to raise, lower button to lower).

When the thigh section is raised from the flat position (34°), the calf section will be in the Fowler position (9° angled downwards).

FUNCTION LOCKOUT

MATTRESS PLATFORM HEIGHT:

these buttons raise and lower the mattress platform (upper button to raise, lower button to lower).

Minimum height: 23cm

Maximum height: 70cm

AUTO-CONTOUR (Fowler):

The Auto-Contour up button simultaneously raises the backrest and thigh sections to provide upright patient profiling; the raised thigh section prevents the patient sliding down the bed.

The Auto-Contour down button returns the backrest and thigh sections to a flat position.

REVERSE TRENDELENBURG:

This button lowers the foot end of the mattress platform (maximum 12°).

TRENDELENBURG:

This button lowers the head end of the mattress platform (maximum 12°). The mattress platform will go into Trendelenburg position once it will reach 64 cm height from the ground.

AUTO-CHAIR (cardiac-chair):

The Auto-Chair button simultaneously raises the backrest (50°) and thigh sections (34°), then lower the foot end of the mattress platform into a chair position.

UNDER BED LIGHT:

This button switch on the light under bed. When its light indicator is ORANGE the light is OFF. When its light indicator is GREEN, the light is ON.

ON/OFF FUNCTION INDICATORS & FUNCTION LOCKOUT

Function lockout can be used to prevent operation of the controls, e.g. when inadvertent movement of the mattress platform could injure the patient.

The indicators above each function show its status:

GREEN light = movement ON (function unlocked on ACP as well as on patient Handset).

ORANGE light = movement OFF (function locked on ACP as well as on patient Handset)

To selectively lock (prevent) movements: press the Function Lockout button and for 3 seconds the corresponding movement to lock. The light of that movement will turn from green to ORANGE.

To lock all the movements, press the Function Lockout button and for three seconds the auto-chair button. When all movements are locked, CPR and TRENDELENBURG movements will work for Emergencies (Under bed light will work too).

To unlock (allow) previously locked movements:

press the Function Lock button and the corresponding movement to

unlock.



Thigh section lock, will lock Auto-Contour and Auto-Chair too.



Backrest section lock, will lock Auto-Contour and Auto-Chair too.



Mattress platform height lock, will lock Reverse Trendelenburg, Trendelenburg and Auto-Chair too.



When total lock of the movements (press Function Lockout + Auto-Chair) is activated, CPR and TRENDELENBURG movements will work for Emergencies (Under bed light will work as well).



WARNING

Store the ACP on the tube frame of the foot board using the clip on the back; this will help to prevent accidental operation of the controls and to keep the ACP out of the reach of the patient.

Backup emergency battery

The backup emergency battery allows operation of the bed for short periods when it is disconnected from the electricity supply or in emergency situations when the electricity supply is not available.



Operations

Battery charge level is displayed on the ACP:



On the top of the battery there are the ON and OFF switches.

Button	Operation	Action
ON	Press 1sec	Turned ON and discharging (operative bed)
OFF	Press 3sec	Turned OFF / STOP discharging (storage of bed or battery)

The battery of a new bed supplied is turned OFF. It will turn ON AUTOMATICALLY when the bed will be connected to the mains, otherwise turn it ON, before making the bed fully operative.

On the top of the battery there is also a LED INDICATOR.

Status	Capacity	Led	
Hi-charging	>80%	GREEN	Continuous on (STEADY)
Charging	<80%	GREEN	Short blinking (1 sec / 1 sec)
Hi-battery	>25%	GREEN	Long blinking (0.5 sec / 4 sec)
Low-Battery	<25%	ORANGE	Long blinking (0.5 sec / 4 sec)
Protection	<20%	-----	Off
Failure	-	ORANGE	Continuous on (STEADY) (When you see the failure status indication, please contact the seller).

Maintenance

To recharge the battery connect the bed to the electricity supply. Allow at least 10 hours to recharge the battery when it is completely discharged. While the battery is recharging, the ACP battery indicator will flash ORANGE. The ACP indicator will be steady ORANGE when the battery will be fully charged.

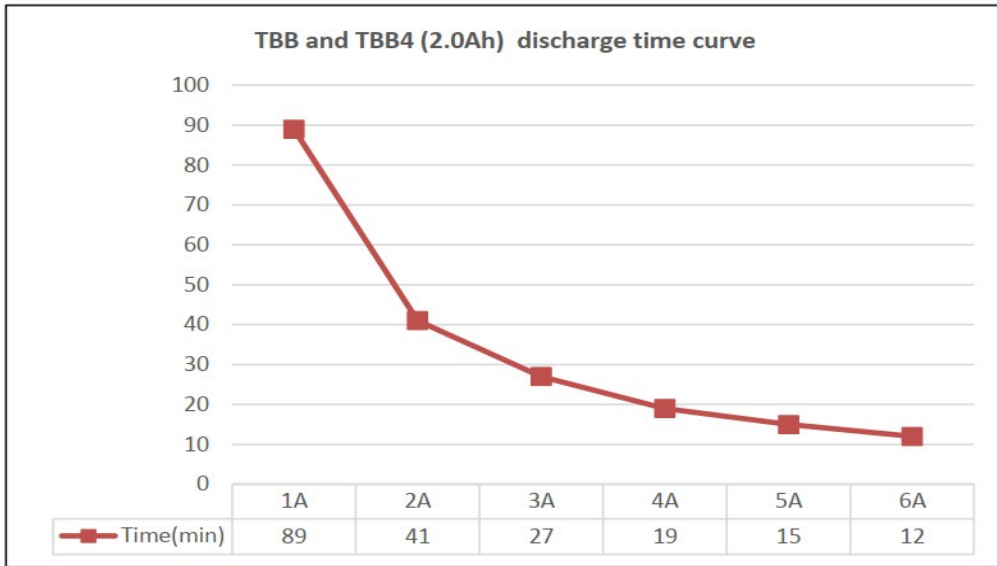
The product should be charged continuously at least 24hrs under following circumstances:


- Before long period without AC-in
- First operation after long period storage

Storage of the battery (Turned OFF)

Period (including shipping)	Capacity	Status
3 months	79%	usable
6 months	58%	please charge before use
> 6months	< 58%	too long storage period, battery capacity harmed *Be sure to charge 24hrs every 6 months least


Remarks	From Hi charging status (around 80%) to fully charged (in warranty period > 90% max capacity), it needs around additional 10hrs charging. When seeing the failure status indication, please liaise with the seller.
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WARNING

Emergency battery DUTY CYCLE: 10%
2 minute continuous use followed by 18 minutes not in use.



Caution

To ensure the battery is kept fully charged and prevent damage to the battery, the bed should be connected to the electricity supply at all times during normal use.

The battery is intended for occasional and emergency short term use. Its life will be reduced if it is used to power the bed for long periods.

Duty Cycle Lockout

Duty cycle is 10%, MAX 2min ON, 18min OFF.



Caution

Duty cycle lockout

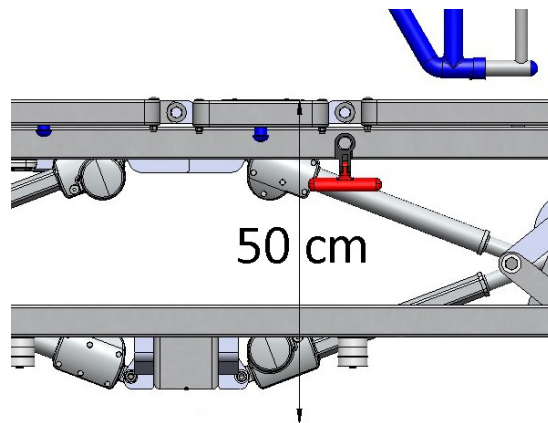
Continuous operation of the controls for more than 2 minutes at full load and an internal temperature of the control box more than 40°C, may exceed the duty cycle of the bed's electrical system, causing the control box to stop functioning until cooled down.

Use of mobile floor lifter for plus-size patients (ARJO Tenor)

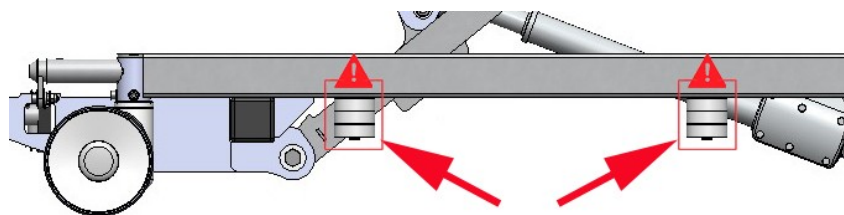
Operation

The use of a mobile lifter is possible under the following operative conditions:

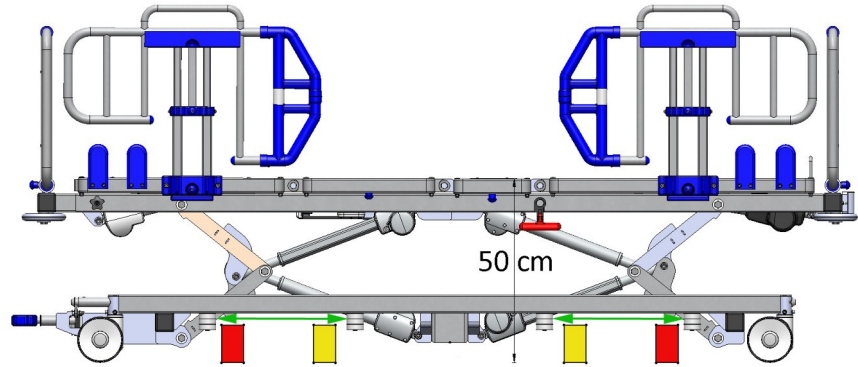
- Bring the mattress platform of the bed to a height equal to 50 cm or greater than 50 cm. **The height of 50 cm can be identified by the operator when, during the standard hi-low procedure using the handset or ACP, the mattress platform will STOP each and every time is passing from that level of height of 50 cm, both starting from the bottom and starting from the top. (The mattress platform will stop its movement and to continue the hi-low it will be necessary to lift the finger from the button and press it again).**



- Please note the n.4 black plastic bumpers located under the bed trolley, which delimit the area where the legs of the lifter must go.



- Drive the lifter with its legs under the bed trolley in the available operative area to a depth deemed appropriate.



Please see that the RED SHAPES in figure represents the size of the Max External Width of the legs of the Tenor lifter, while the YELLOW SHAPES represent its Min External Width. The bumpers mounted on the bed trolley delimit the available operative area, where the lifter can be utilised in safety.



Caution

The mobile lifter taken into account in this operative instruction is **ARJO Tenor**.

Before using any other mobile lifter in combination with this bed, please be aware of the dimensions of the available operative area under the bed and in which the legs of the lifter will go.



WARNING

DO NOT use the mobile floor lifter when the mattress platform of the bed is placed at a height lower than 50 cm from the floor: the legs of the lifter would intercept the bed height actuators with the concrete risk of damaging them!



WARNING

Do not allow the mains plug or power supply cord to get wet.



Caution

**Do not use abrasive compounds or pads,
or phenol-based disinfectants.
Do not use jet stream cleaning or wash tunnels.
Do not remove grease from the actuator pistons.**



WARNING

**The procedures below must be carried out by suitably trained and
qualified personnel.
Failure to do so may result in injury or an unsafe product.**

Decontamination



Remove the side rails from the bed to allow better decontamination on beds.



The bed should be cleaned and disinfected weekly, and before a new patient uses the bed.

Cleaning operations	<p>Remove the mattress and any accessories from the bed. Head/foot boards and mattress platform sheets should be removed from the bed for cleaning. Wearing suitable protective clothing, clean all surfaces with a disposable cloth moistened in hand hot water and a neutral detergent. Start by cleaning the upper sections of the bed and work along all horizontal surfaces. Work methodically towards the lower sections of the bed and clean the wheels last. Take extra care to clean areas that may trap dust or dirt. Wipe over with a new disposable cloth moistened with clean water, and dry with disposable paper towels. Allow the cleaned parts to dry before replacing the mattress.</p>
Disinfection operations	<p>After cleaning the bed as described above, wipe all surfaces with sodium dichloroisocyanurate (NaDCC) at a concentration of 1,000 parts per million (0.1%) of available chlorine. In the case of pooling body fluids, e.g. blood, the concentration of NaDCC should be increased to 10,000 parts per million (1%) of available chlorine.</p>
Use of other disinfectants	<p>The manufacturer recommends sodium dichloroisocyanurate (NaDCC) as a disinfectant because it is effective, stable and has a fairly neutral pH. Many other disinfectants are used in healthcare facilities, and it is not possible for the manufacturer to test each one to determine whether it may affect the appearance or performance of the bed. If facility protocols require the use of a disinfectant other than NaDCC (e.g. diluted bleach or hydrogen peroxide), it should be used with care and in accordance with the manufacturer's instructions.</p>
Preventive maintenance	<p>This product is subject to wear and tear during use. To ensure that it continues to perform within its original specification, preventive maintenance procedures should be carried out at the intervals shown.</p>



WARNING

This list indicates the minimum recommended level of preventive maintenance.

More frequent inspections should be carried out when the product is subjected to heavy use or aggressive environments, or where required by local regulations.

Failure to carry out these checks, or continuing to use the product if a fault is found, may compromise the safety of both the patient and carer.

Preventive maintenance can help to prevent accidents.

Actions to be done by carer	Daily	Weekly
Check operation of side rails	X	
Check patient handset and its cable		X
Check ACP and its cable		X
Visually check castors		X
Visually check power supply cord and mains plug		X
Check the mattress for damage and fluid ingress		X
Check the functional operations of the central brake system foot pedal	X	
Check for correct fitting of the locking pin on removable side rails and extendable head/foot boards.		X
Check the Mechanical Quick Release of the backrest (Mechanical CPR), test it with empty bed (please notice that at empty bed the gas pump will highly oppose to the mechanical descent of the backrest)		X
Operate a SOFTWARE RESET: SIMULTANEOUSLY PRESS the 2 HI-LOW push buttons on the ACP/patient handset for some seconds, until you will see the mattress platform moving to its maximum height, the backrest and legrest eventually will go down and at the end of this process the led lights of the ACP/Handset will blink.		X

Actions to be done by qualified personnel.	Yearly
By carer: keep in mind also during daily use the occurrence of signs of malfunction and/or suspected degradation of the original conditions of the device reported by these tests, so that a preventive intervention would be possible.	
Carry out a full test of all electrical bed positioning functions (backrest, height, tilt, etc.)	✓
Check that the bed operates correctly using the backup battery as described in the next section Battery test .	✓
Check operation the of castors, paying special attention to braking and steering functions	✓
Check that the bed extensions lock securely	✓
Examine the power supply cord and mains plug – if damaged, replace the complete assembly; do not use a rewirable plug	✓
Examine all accessible flexible cables for damage and deterioration	✓
Check all accessible nuts, bolts and other fasteners are present and correctly tightened	✓
Check any accessories fitted to the bed, paying particular attention to fasteners and moving parts	✓
Check the wire of the Mechanical Quick Release of the backrest (Mechanical CPR) and notice if its tension is functional to the release of the backrest	✓

Battery test	<p>Check the condition of the backup battery by carrying out the following test.</p> <ol style="list-style-type: none"> 1. Disconnect the bed from the electricity supply. 2. Raise the mattress platform to maximum height 3. Raise the backrest and thigh sections as far as they will go. 4. Press and hold the CPR button and lower the mattress platform to its programmed height. 5. Apply maximum head down tilt (Trendelenburg). 6. Return the mattress platform to the level position. 7. Apply maximum foot down tilt (reverse Trendelenburg). <p>If this test is not completed successfully, connect the bed to the electricity supply for at least 10 hours to recharge the battery then perform the test again. If the bed fails a second time, contact the seller.</p>
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	<p>To maintain best performance see:</p> <ul style="list-style-type: none"> - chapter 7. Technical data / Electrical & Safety data / backup battery. - chapter 7. Technical data / Transportation and storage / Caution.
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Troubleshooting	If the equipment fails to operate correctly, the table below suggests some simple checks and corrective actions. If these steps fail to resolve the problem, contact the seller.
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Symptom	Possible cause	Action
The bed is working only with the battery and not with Mains.	<ul style="list-style-type: none"> - Faulty Transformer - Faulty EMC Box 	<p>ACTION TO BE DONE ONLY BY TECHNICAL STAFF. To understand which one of the two is faulty, start to test the Transformer: disconnect the cable coming from the EMC Box into the Transformer, temporary take a Mains Lead cable (n.2 poles) from the HBB500 Bariatric Bed (Baros-TiMotion version manufactured from 2020 on) (see that HBB600 Mains Lead cable is n.3 poles, while HBB500 is n.2 poles), connect the female plug to the Transformer and the male plug to the wall. See if the bed is working. If it does, EMC Box is probably faulty. If it does not work the faulty part is the Transformer.</p>
Bed movements are inoperative	For some reasons such as plug in and plug out of some connection cables, the control box can go in stand by (no function allowed).	RESET the control box function in this way: simultaneously press the HI-LOW buttons on the patient handset or on the ACP. The bed will go to its maximum height (70 cm) and the lights on the handset/ACP will flash for a few seconds, this means the reset has been done.
One or more bed movement inoperative	Function(s) locked on ACP	Unlock function(s) on ACP
Bed is difficult to manoeuvre around corners.	Brake pedals in "Steer" position.	Bring the brake pedals in the "Swivel" position.
Control box is not working after it worked for more than 2 minutes continuously.	Duty cycle of electrical system exceeded.	Refer to section Duty cycle lockout on the IFU / or make a reset of the software (refer to the first line of this scheme)

Intermittent functioning of the height actuators under heavy load.	The height operation at once under heavy extreme load (600kg) could not allow the progressive fluidity of the grease around the piston of the actuator and the control box is cutting power to height actuators.	When control box is cutting the power, just release the push button and press it again, release and press, until the height operation will go without interruptions. The bed is capable to support and operate under heavy extreme load (600kg - and more...) and even if sometimes the control box could cut the power, it can stand that operation even if only slower.
Mechanical quick release lever is not able to release the back section actuator.	The wire is loose and does not have the optimal tension.	Adjust the regulator (ferrule) of the cable mounted on the lever support: turn the regulator (ferrule) outwards to increase the tension of the wire and check if it works.
Brake pedal is not working correctly in any of the three positions.	Some parts could be loose.	Check the length of the brake bars – Refer to page 17 of the Service Manual for further details.

Product Lifetime	The lifetime of this equipment is typically ten (10) years. “Lifetime” is defined as the period during which the product will maintain the specified performance and safety, provided it has been maintained and operated in conditions of normal use in accordance with the requirements in these instructions.
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6. Accessories

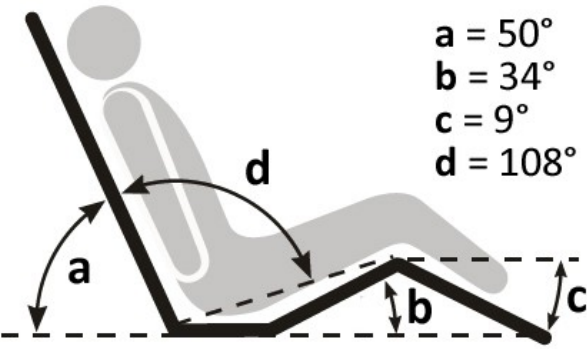
Recommended accessories range are shown in the table below.

Accessory	Product Code
I.V. pole fixed height	500699
Egress handle	500930

7. Technical data

General data	
Safe working load	600kg
Maximum patient weight	550kg
Product weight	234kg approx.
Audible noise	50dB approx.
Operating conditions	

Temperature	5°C to 40°C
Relative humidity	20% to 90% at 30°C, non-condensing
Atmospheric pressure	700hPa to 1060hPa
Electrical & Safety data	
Input Voltage	100V-240V~, 50/60Hz, 180VA
Output Voltage	31.5V, 5A
Duty cycle	10% (Max 2 min. ON, 18 min. OFF)
Safety Standards	Medical device class I classified in accordance to: IEC 60601-1:2005 IEC 60601-2-52:2016
Other Safety standards	Requirements of Regulation (EU) 2017/745 MDR of the European Parliament and of the Council of April, 5th 2017 (BASIC UDI-DI # 805387974HBB600C6)
Electric shock protection	Class I
EMC	Complies with EN 60601-1-2 (2014/30/EU)
Potential equalisation terminal	Complies with EN 60601-1 (DIN 42801)
Ingress protection	IPX4 (Electric set is IP66)
Backup emergency battery	Type: Lead Acid Capacity: 2Ah (0.1C discharge, 200mA) Input Voltage: 29-45V DC Output Voltage: 24V DC, 2.0A Operation temperature: from 5°C to 45°C Duty cycle: 10% (2 min on / 18 min off) Charging: with integrated charger in battery. Charging time: approx. 10 hours. Storage Temperature: 0°-40°C Storage Humidity: 10%-93% Storage Atmosphere: 86KPa-1006Kpa
Dimensions <i>Subject to normal manufacturing variations</i>	
Overall length	
<i>Position 1 (Short)</i>	230cm
<i>Position 2 (Extended)</i>	246cm
In-bed length	
<i>Position 1 (Short)</i>	200cm
<i>Position 2 (Extended)</i>	222cm
Overall width	

<i>Position 1 (Short)</i>	106cm
<i>Position 2 (Extended)</i>	136cm
In-bed width	
<i>Position 1 (Short)</i>	90cm
<i>Position 2 (Medium)</i>	105cm
<i>Position 3 (Extended)</i>	120cm
Height of mattress platform (centre of seat section to floor)	
<i>Height adjustment</i>	23cm to 70cm
<i>Floor clearance</i>	13,5cm
Head down tilt angle (TR)	12°
Foot down tilt angle (RTR)	12°
Mattress size (refer to Chapter 3 for details)	
<i>Position 1 (Short)</i>	200cm x 90cm, 12.5 to 19cm thick
<i>Position 2 (Medium)</i>	200cm x 105cm, 12.5 to 19cm thick
<i>Position 3 (Extended)</i>	200cm x 120cm, 12.5 to 19cm thick
Mattress platform angles	 <p> $a = 50^\circ$ $b = 34^\circ$ $c = 9^\circ$ $d = 108^\circ$ </p>



Caution

If the bed is stored for a long time, it should be connected to the electricity supply for 24 hours (at least every six months from bed manufacturing date) to recharge the backup battery, otherwise the battery may become unserviceable.

Environmental protection

Incorrect disposal of this equipment and its component parts, particularly actuators, batteries and other electrical devices, may produce substances that are hazardous to the environment. To minimise these hazards, contact the seller for information on correct disposal.








Transportation and storage








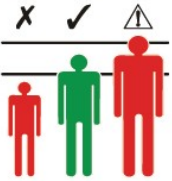
Handle with care. Do not drop. Avoid shock or violent impact.

This equipment should be stored in a clean, dry and well-ventilated area which meets the following conditions:

Operation temperature	+5°C to +40°C
Stock temperature	-10°C to 50°C
Relative humidity	20% to 90% at 30°C, non-condensing
Atmospheric pressure	700hPa to 1060hPa

Symbols

	Safe Working Load
	Maximum patient weight
	Alternating current (AC)
	Caution
	Refer to instructions for use
	Type B applied part. Applied parts are considered to be: Upper frame section, Bed controls, Side Rails, Head and Foot Boards
	Manufacturer / date of manufacture

	Complies with the European MDR 2017
	Waste Electrical and Electronic Equipment (WEEE) - do not dispose of this product in general household or commercial waste
	Serial number
	Model number
	Potential equalisation terminal
	Protective earth (ground)
	Recommended mattress size
	Recommended patient height

8. Warranty and Service

Warranty has a validity of 2 years (24 months) from the date of delivery of the product and covers the defects arising within 2 years from delivery.

The manufacturer ensures the replacement of defective original parts, only if used under normal conditions and maintained following the details written in this IFU and for this reason, at the sole discretion of its technicians.

What is not covered by this Warranty:

- Damaged parts for normal wear and tear or misuse / bad or poor maintenance of the product.
- Parts damaged by assembly or use that do not comply with the requirements and indications of this IFU.

It is understood that the Warranty will automatically lapse if any changes to the Product have been made without the written consent of the manufacturer or non-original components and / or non-original accessories have been mounted on the bed.

The manufacturer also declines any responsibility for Civil Liability arising from improper use of the bed and / or not complying with the operating and maintenance rules of this IFU.

All costs for any damage suffered during transport will be charged to the recipient, as well as the supply of spare parts and the possible putting into service of the parts.

We recommend that you check immediately after purchase that the product is visually in good condition and read this IFU carefully before using it.

For each request for spare parts, the code of the bed (RF) and its Serial Number (SN) must be specified.

For service, maintenance and any questions regarding this product, please contact the manufacturer (bariatric@healthniture.com) or your own local distributor.

9. Electromagnetic Compatibility (EMC)



Caution

The use of non-approved accessories may result in increased emissions or reduced immunity of the equipment. A list of approved accessories is included in the product instructions for use. See chapter 6 – Accessories. When this equipment is used adjacent to other electronic devices, the user should observe the equipment to verify normal operation.

EMC Test report

Test report FNL 005/2025

Rev.: 1 of 2025-03-28

8 SUMMARY AND TEST RESULT

Emission	Test method	Result
Standard reference	EN 60601-1-2	//
Conducted emission	EN 60601-1-2 (Par.6.1)	PASSED
Radiated emission	EN 60601-1-2 (Par.6.1)	PASSED
Harmonic emission	EN 60601-1-2 (Par.6.1.3.1)	PASSED
Flicker emission	EN 60601-1-2 (Par.6.1.3.2)	PASSED

Immunity	Test method	Result
Standard reference	EN 60601-1-2	//
Electrostatic discharge immunity	EN 60601-1-2 (Tab.4)	PASSED
RF radiated immunity	EN 60601-1-2 (Tab.4)	PASSED
Burst immunity	EN 60601-1-2 (Tab.5)	PASSED
Surge immunity	EN 60601-1-2 (Tab.5)	PASSED
RF conducted immunity	EN 60601-1-2 (Tab.5)	PASSED
Voltage dips and variation immunity	EN 60601-1-2 (Tab.5)	PASSED

Test legend result	
PASSED	The equipment under test complies with the standard requirements
NOT PASSED	The equipment under test doesn't complies with the standard requirements
NOT APPLICABLE	The test is not applicable for the equipment under test



The full version of the EMC Test is available under request. Please send an email request to the seller.

10. AFTER SALE SURVEILLANCE REPORTING FORM

This form, according to the Medical Devices Regulation (EU) 2017/745 MDR, is supplied in this IFU to allow any of the following subject involved: CUSTOMER, USER, PATIENT or MEDICAL STAFF to inform the MANUFACTURER of any issue or reportable event spotted regarding the use of HBB600 Bariatric Low Bed, in order to let the manufacturer take corrective and/or preventive actions in accordance with information on this medical device and its performance. This process allows the identification of problems with the design, manufacture or use of this medical device in order to enhance patient and users safety.

The aim of this after sale surveillance system is to actively and systematically gather, record and analyse relevant data on the quality, performance and safety of this device throughout its entire lifetime. This allows the manufacturer to continuously update the risk-benefit assessment and to initiate necessary measures without delay.

A yearly report will be edited on the basis of the informations collected and followed by effective actions to keep this medical device functional and safe.

Please fill in this report all the relevant informations collected regarding any reportable event and send it by email to bariatric@healthniture.com.

AFTER SALE SURVEILLANCE REPORTING FORM					N°
detected by the operator:					date:
reported by:	CUSTOMER	USER	PATIENT	MEDICAL STAFF	MANUFACTURER
detected during:	USE	ASSISTANCE	MANUFACTURING PROCESS	OTHER	
description of what detected / reported:					
analysis of possible causes:					
received by the Management on:					
decisions made for treatment:					
No action	Further surveillance actions		Share informations with users		
IFU amendment	Corrective action on future production	Corrective action on devices already on the market		Product recall	
action manager:			to be performed by: (date)		
action verifier:			checked on: (date)		
result detected:	POSITIVE		NEGATIVE		
for the following reasons:					
Notes:					
see new action N° ... of (date)...					

AFTER SALE SURVEILLANCE REPORTING FORM Rev. 0 – November 1st, 2020 - Healthniture S.r.l.

