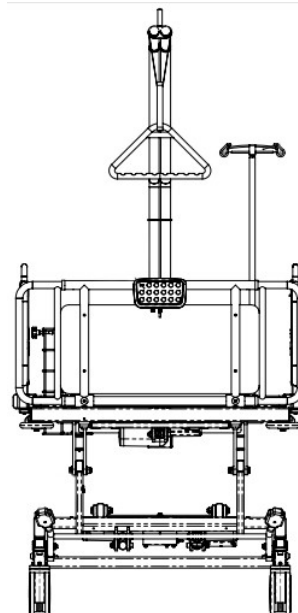
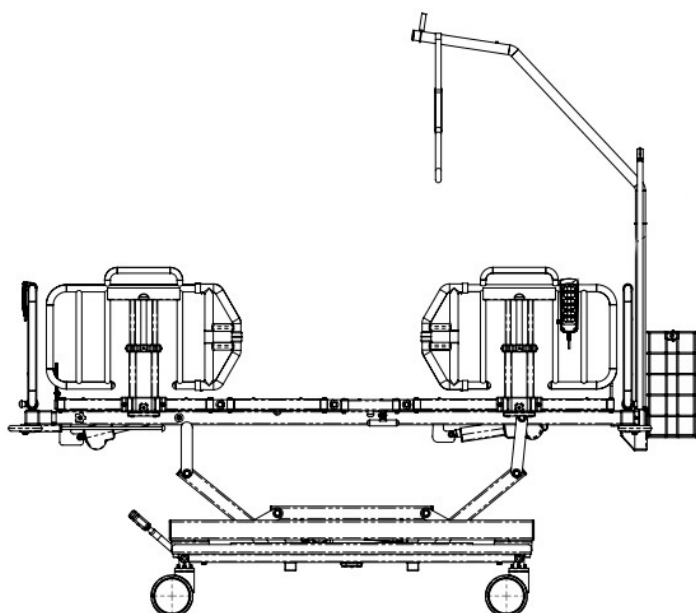
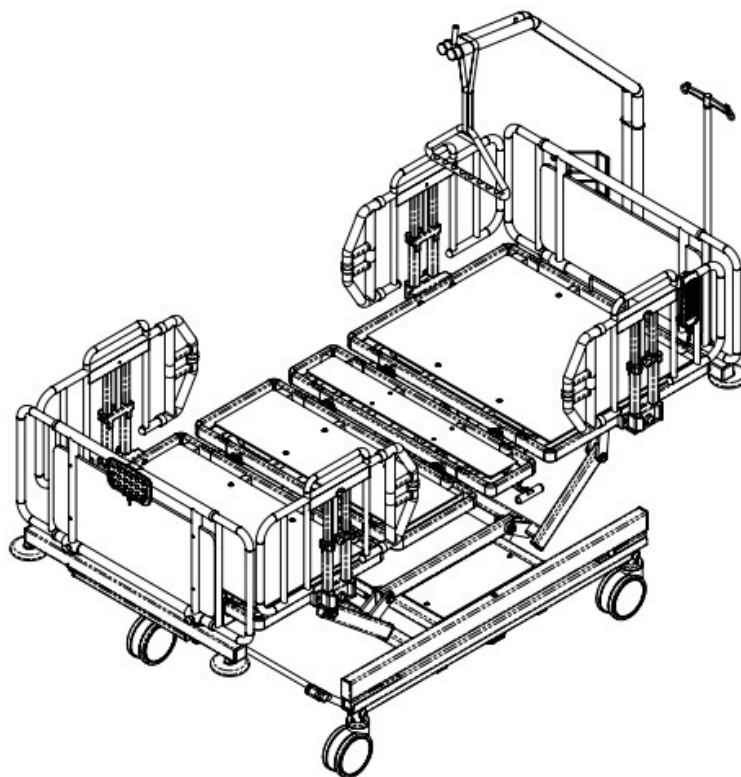


HBB500 BARIATRIC BED

Instructions for Use



HBB500 BARIATRIC BED

Healthniture S.r.l. - Via della Vittoria 33, 20025 Legnano (MI) ITALY - email: bariatric@healthniture.com

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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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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 its minimum 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 off the bed when the mattress platform is in a tilted (head down or foot down) position, or if the bed is not at its minimum height.

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. lifting 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 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 of this bed to operate Patient handling and getting in and out, is its minimum height and brake ON.

Lower the bed at its minimum height before operating any patient handling!!!



WARNING

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



WARNING

Incompatible SIDE RAILS and mattresses can cause an entrapment hazard !



WARNING

Safe Working Load of this bed is 500 kg and it 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 its minimum height, could cause sudden instability and imbalance of the bed. To avoid potentially dangerous and instability events, keep the bed at its minimum height whenever dynamic heavy load occurs.

1. Introduction

These instructions contain information for the installation, use and maintenance of the Bariatric Bed HBB500. 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 (*or Fixed width removable foot board*)
- Mattress support surface with removable HPL panels, second section fixed.
- Adjustable length mattress platform
- Electric CPR function and Mechanical CPR function
- Battery backup
- Linen tray
- Under bed light
- Full width 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 and oxygen bottle sockets at head end
- Corner roller buffers
- 150mm dual wheel castors (one steering and conductive, three swivelling)
- ANTIMICROBIAL White Epoxy Powder Coated RAL 9016

Optional features

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



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

★ Oxygen bottle holder	★ Lifting pole with integrated I.V. hooks
★ I.V. pole fixed height	★ Egress handle

Specification labels

The model number of the bed



HBB500 Bariatric Bed

and serial number of the bed



X X X X

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



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20025 Legnano (MI) ITALY
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www.healthniture.com



REF	HBB500 Bariatric Bed											
SN	0001											
1	2	3	4	5	6							
7	8	9	10	11	12							
2021		2022		2023								

= 450 kg



= 500 kg



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

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



Control Box and S.W. spec. code:
#TC21-491-421-00-AAA00-271-2
Ver.:1.0



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

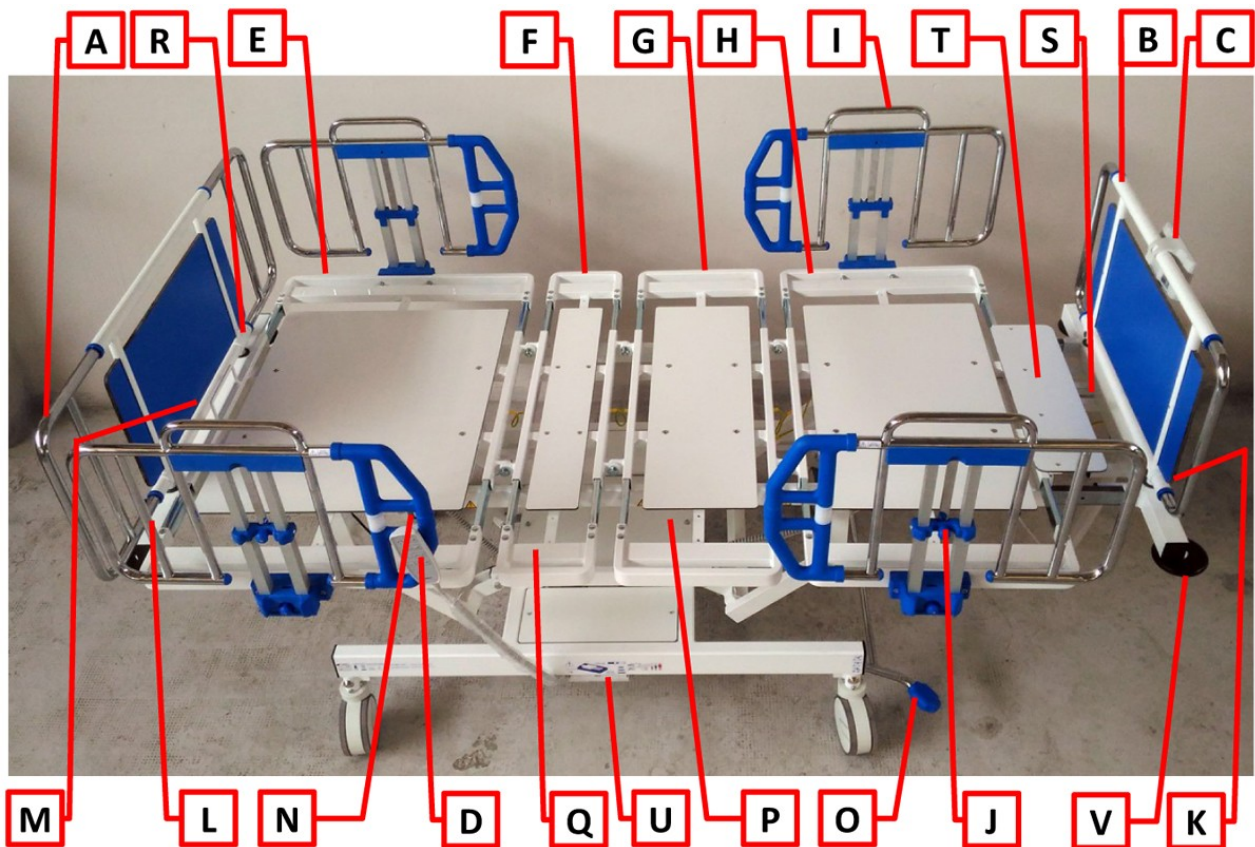


Caution

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 | L. I.V. pole socket/Oxygen bottle holder socket |
| B. Extendable <i>or Fixed Width</i> Foot board | M. Lifting pole socket |
| C. Attendant Control Panel (ACP) | N. Conductive and Steering Castor (front right) |
| D. Patient Handset | O. Brake/Swivelling/Steering pedal |
| E. Expandable Backrest section | P. Electric set (control box, battery) |
| F. Expandable Seat section (+CPR handle) | Q. Expandable sections operating knob |
| G. Expandable Thigh section | R. Extendable head board operating knob |
| H. Expandable Calf section | S. Adjustable length mattress platform |
| I. Side rails (detachable) | T. Mattress retainer/mattress extension platform |
| J. Side rail operating knobs | U. Under-bed light |
| K. Linen tray | V. Corner Roller buffer |



2. 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.

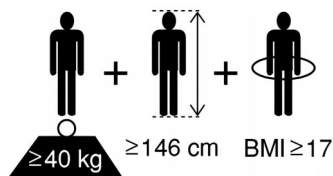
Application Environment 2

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 bed is for adults (UNI CEI EN 60601-2-52:2016) 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.

The use of this bed is reserved for medical personnel, professionals and/or people aware of the content of this IFU.

Patients with a moderate amount of independence can, at the carer's discretion, use the controls to adjust their own position.

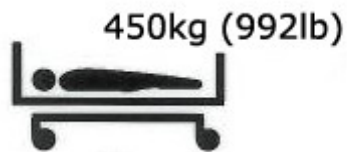
The mattress platform can be positioned to assist with treatment of a patient as required within the clinical settings defined in Application Environments 1, 2 and 3.

The correct use of this medical device, according to this IFU, represents a valid support to improve patient's health.

Contra-indications



The safe working load of the bed is 500kg (1102lb).



The maximum recommended patient weight is 450kg (992lb).

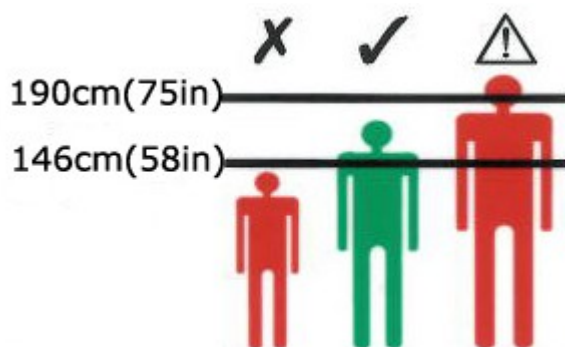
The safe working load is calculated as follows (in accordance with UNI CEI EN 60601-2-52:2016):

Maximum patient weight	450kg
Mattress	12kg
Accessories (including attached loads)	38kg
TOTAL	500kg



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

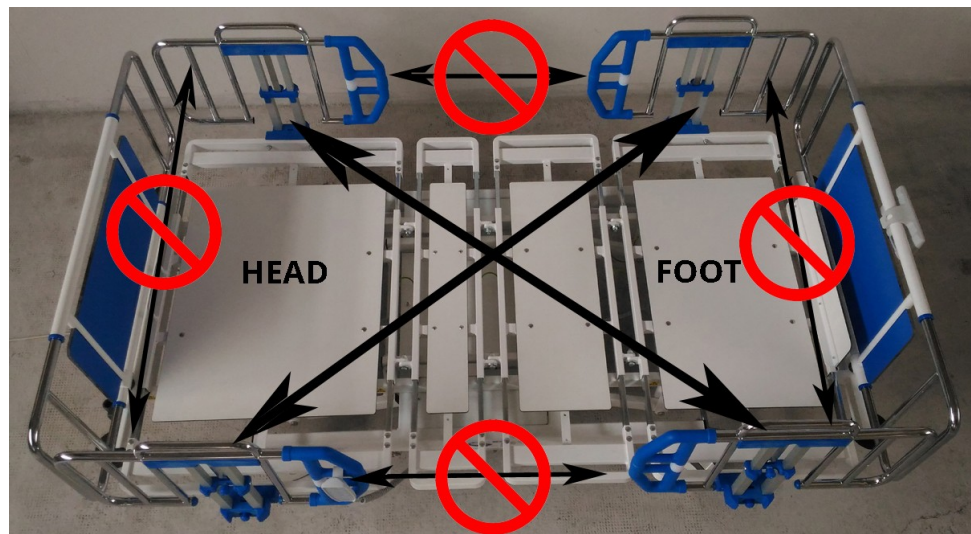
To install head and foot boards (n.2)

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

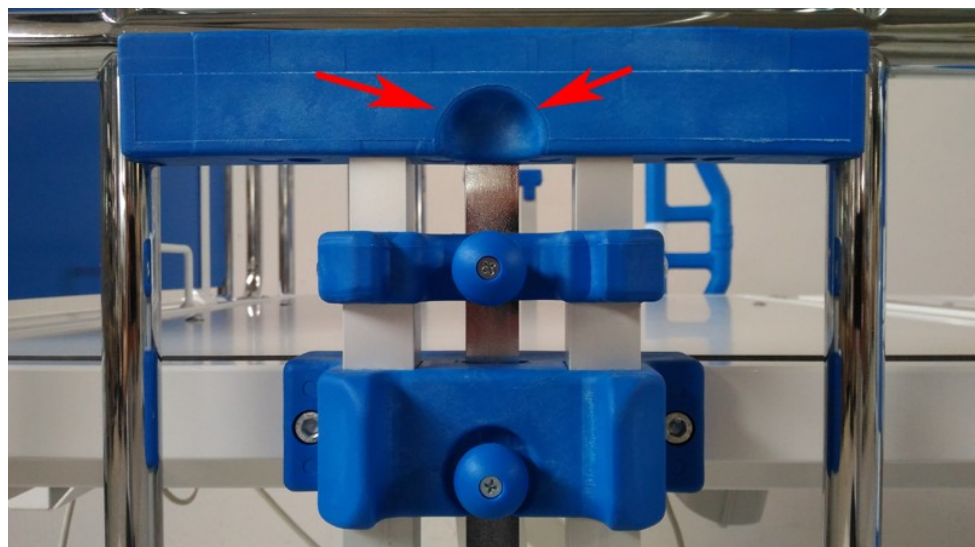


To install and remove the side rails (n.4)

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

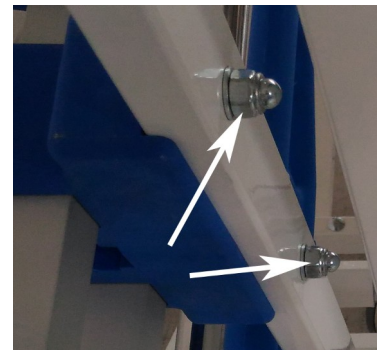
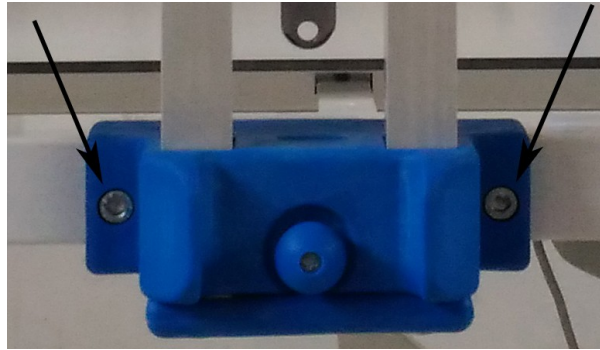


1. the chrome tube of the side rails must always face the chrome tubes of the head and foot boards (see image above).
2. the blue plastic handles must always face each other on the same side of the bed. (see image above)
3. the side rails must always have the ergonomic part (see arrows in the image below) facing the outside of the bed.

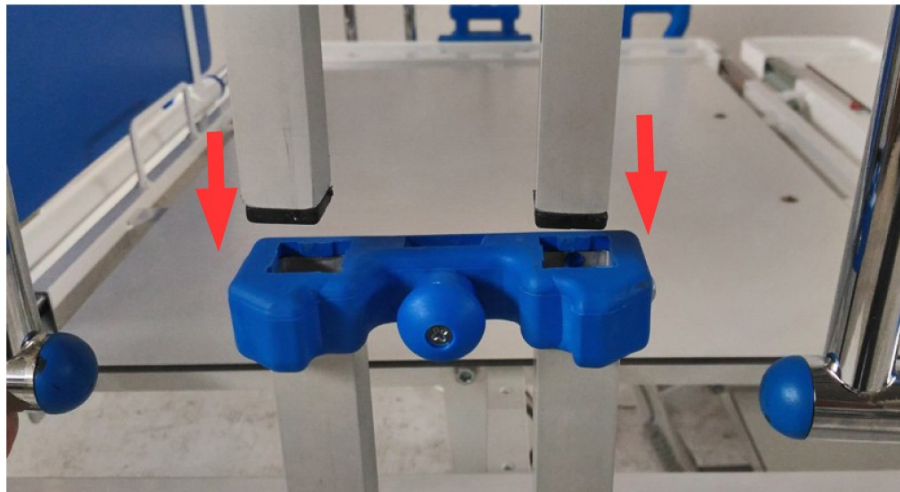


Only the side rails of the same diagonal pair can possibly be interchangeable in position.

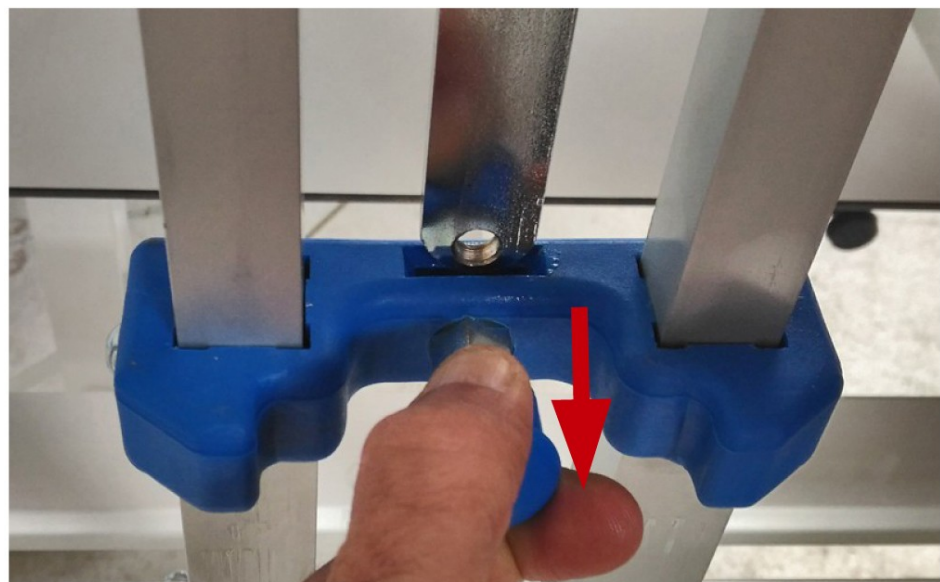
To install the supplied side rails, screw the blue base part to the frame of the expandable sections (side rails go to first and to fourth sections).



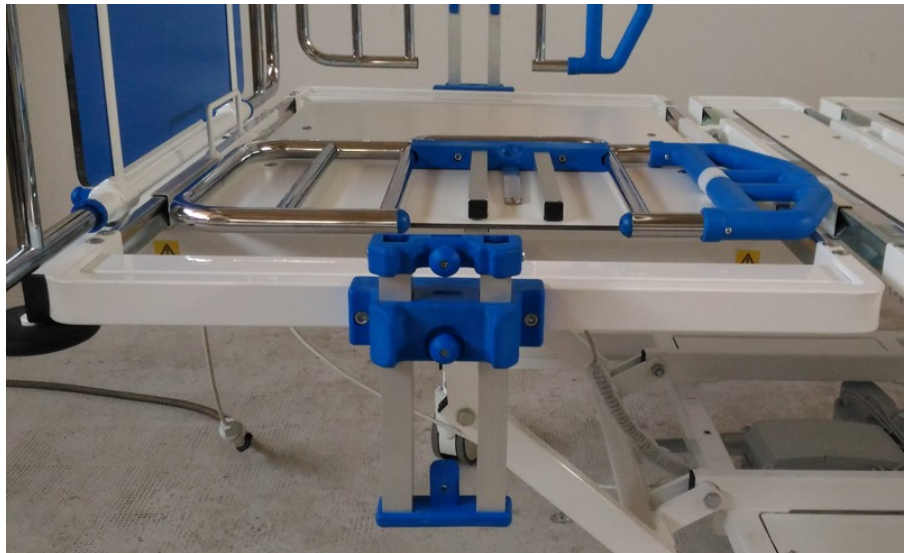
Slide the aluminium tubes into the nylon blue central parts:



Pull the upper blue operating knob and slide the central chrome plated rail into its socket and release the operating knob until it will make an audible “click” to be securely fastened.



To **remove** the upper part of the side rail, pull the upper operating knob and holding the top side rail handle, pull out the side rail.



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 GREEN indicator will light on the control box. (The electric set is located underneath the mattress platform, covered with a plastic laminated panel, unscrew the panel to reach the 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.



Cable storage

When not in use or before moving the bed, take the power supply cord, coil it up around the retractable linen tray at foot side.



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.

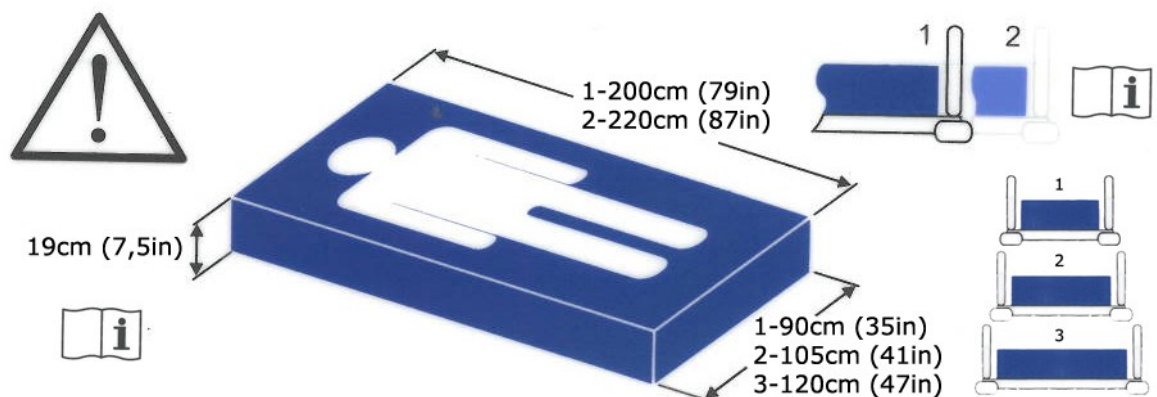
The maximum recommended mattress thickness for use with side rails is 19cm.

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 on the label indicate different mattress platform widths and 1,2,3 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



WARNING

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

Brakes and Steering

The brake pedals at the foot end of the bed have three positions as shown



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.



STEER: the steering castor is locked and rotate in a straight position, it can't swivel and helps to keep the bed on a straight line when moving.



FREE: all four castors are free to rotate and swivel.



BRAKE: brakes are applied on all four castors.

Using the steering castor

Position the bed so that all the castors line up in the direction of travel. Raise the pedals to lock the steering castor and move the bed by pushing it from the opposite end.



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

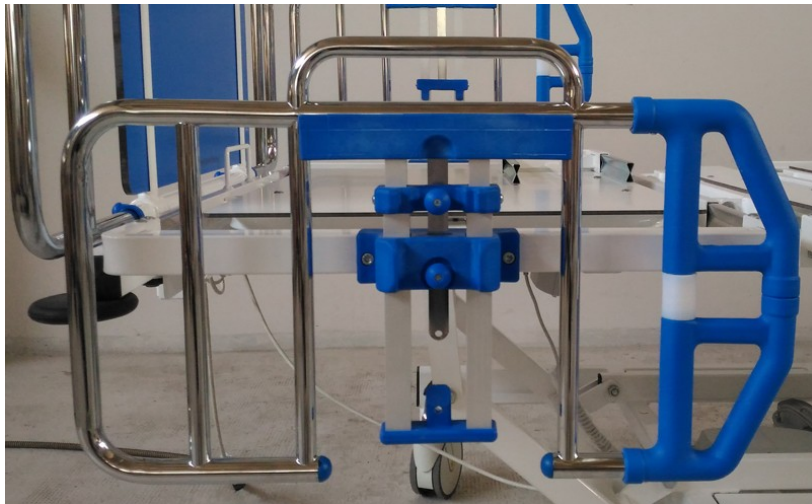


Pulling or pushing the bed to its right height becomes essential to be able to transmit the right force for movement, taking advantage of your centre of gravity, your weight and placing one leg before the other for the initial thrust.

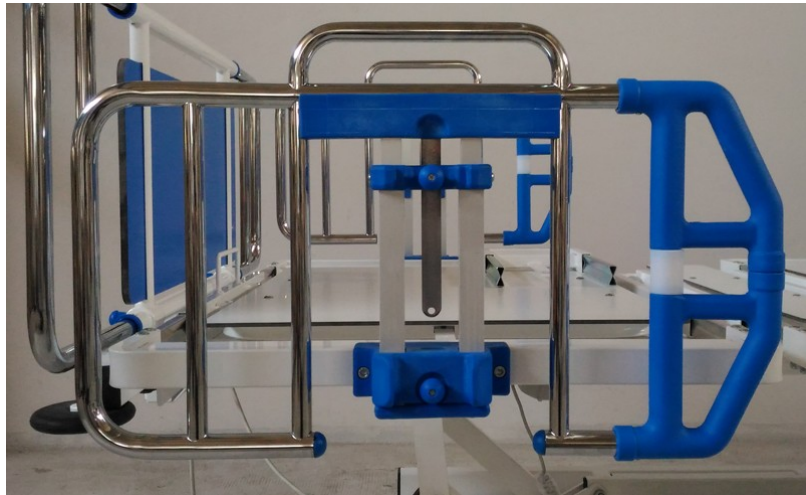
Side rails

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

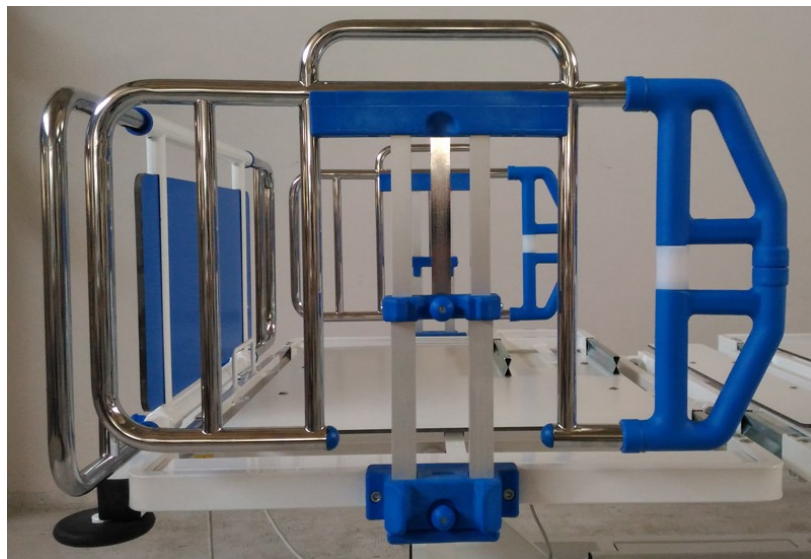
They can be adjusted on three different height levels:



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



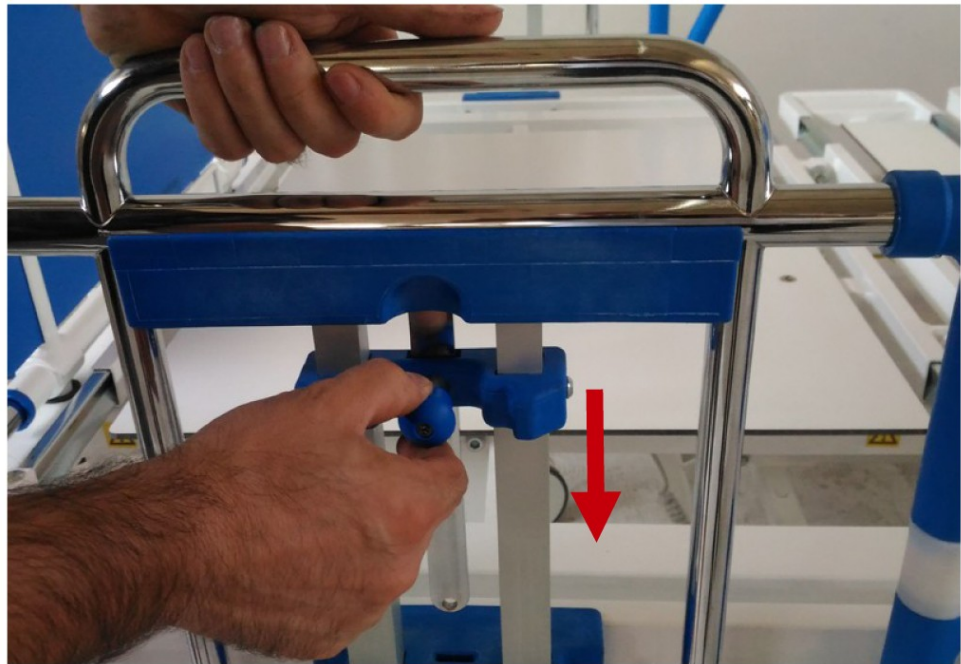
Side rails are detachable.

To lower the side rail

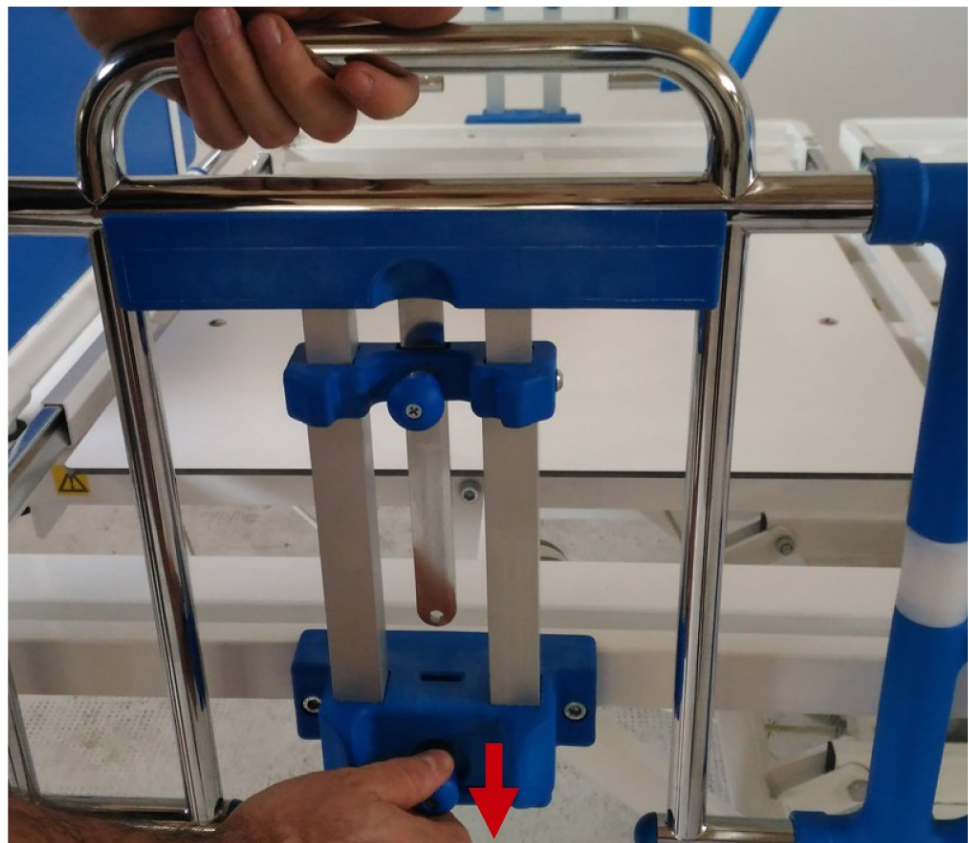
Hold the top side rail handle (third level) and pull the UPPER blue operating knob:



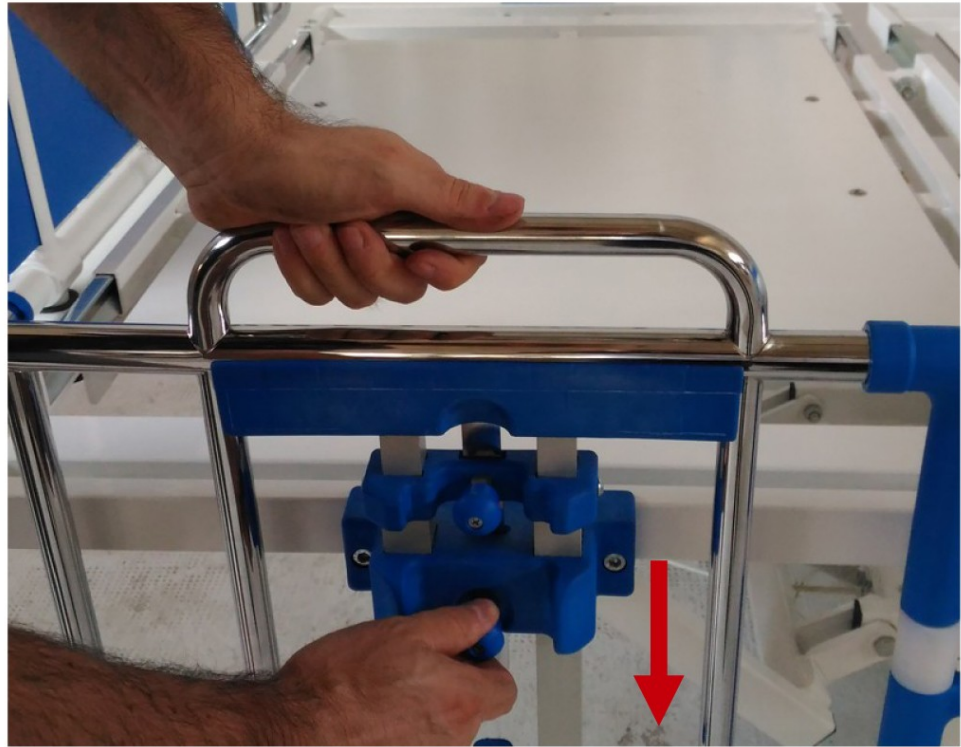
push down the side rail which will slide at the second level (mid) of height:



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

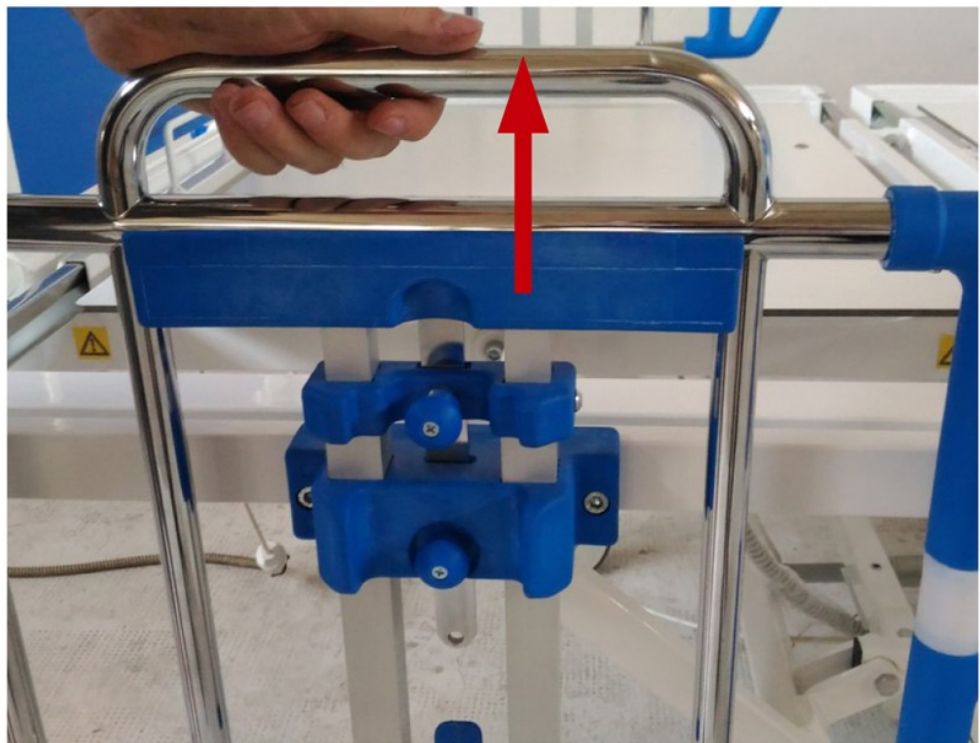


so that the side rail folds down below the mattress platform:

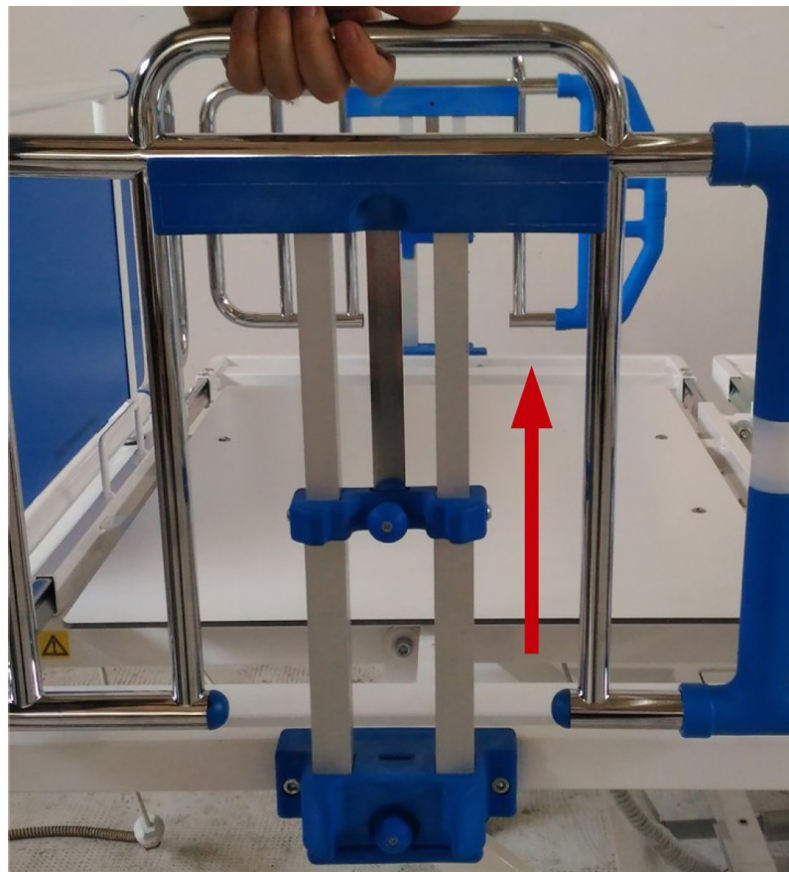
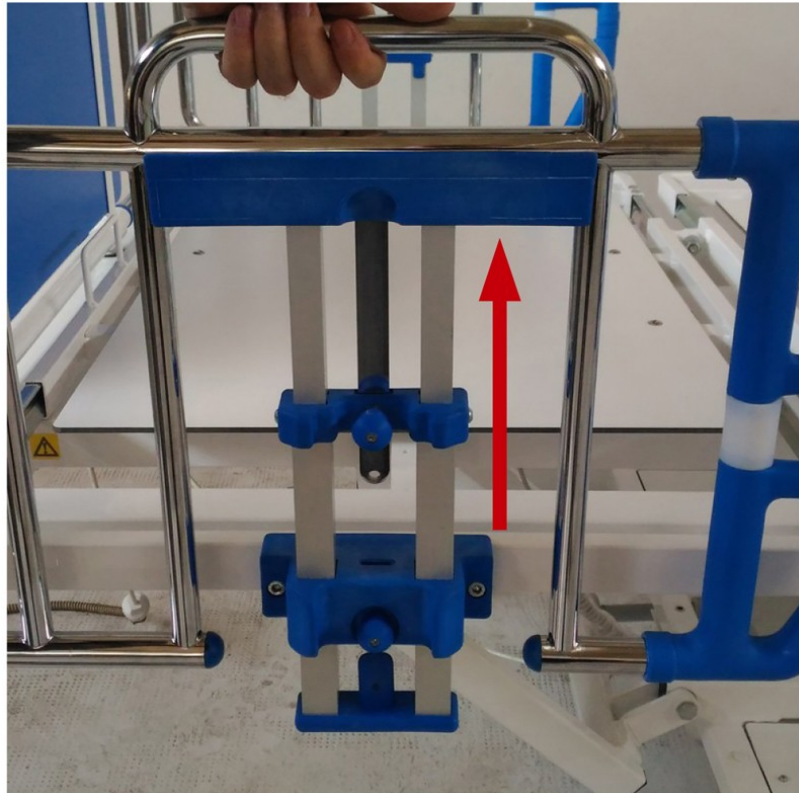


**To raise
the side rail**

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 23) or leave it at the third level (maximum top height).



Side rails are designed to avoid potential finger entrapment: if the side rail drops down without any control, the 25mm gap between the nylon mouldings, where the aluminium 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	<p>Head/foot boards are extendable. <u>This is needed whenever the mattress platform sections are extended.</u></p> <p>The gap between the head/foot board and the safety side rail must be less than 6 cm.</p>
Operation EXTENSION	<p>Head/foot boards can be easily lifted off and removed from the bed for closer access to the patient.</p> <p>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”.</p> <div data-bbox="587 1404 1292 2013"></div>

SHORTEN

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



REMOVAL

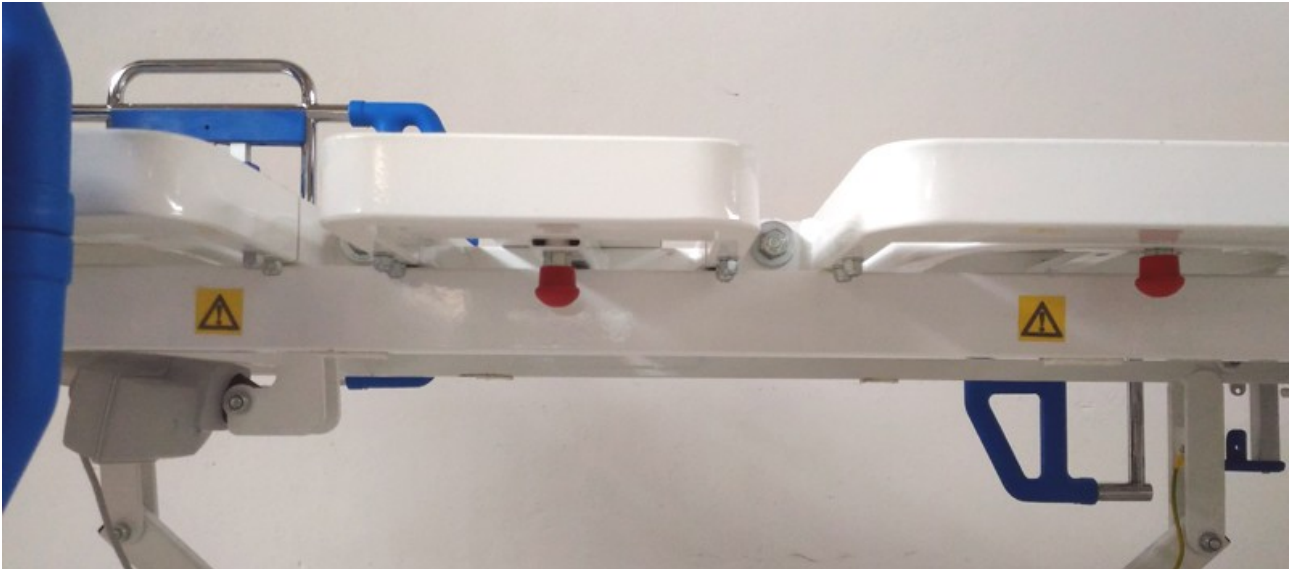
To remove the head/foot board grab the upper frame and lift the board up.

To put them back in place grab the upper frame and place the two tapered inserts inside their sockets.



Head/Foot boards are detachable.

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



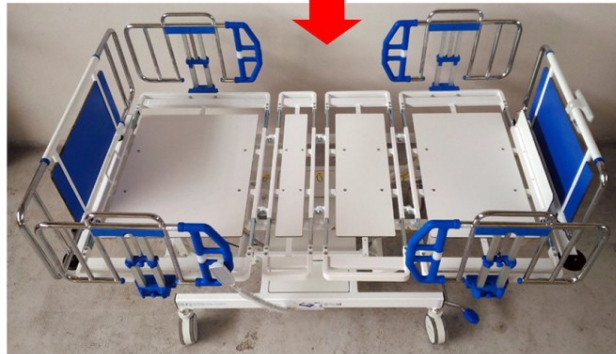
Keep hands and fingers away from these areas!!!

**Extendable
mattress platform
sections**

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



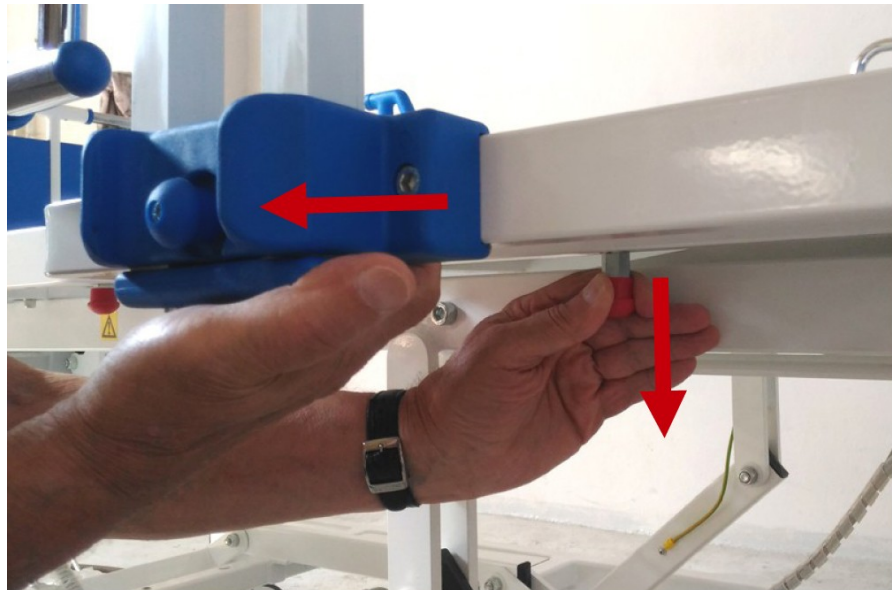
When an obese patient is accommodated into the bed, the sections must be extended at 120cm.



Operation

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

TO EXTEND the sections



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 procedure: grab each section frame, pull the BLUE operating knob underneath that section, push the extension frame, release the BLUE operating knob until it locks with an audible “click”.

**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, plus levelling and lowering the bed. This enables cardio-pulmonary resuscitation procedure to be carried out.



**MECHANICAL CPR
quick release of
the backrest**

The bilateral levers to activate the quick release of the backrest are located on the second extendable sections of the mattress platform. Pull one of the two levers upwards to quickly lower the backrest.



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.

<p>Mattress support panels removal</p> <p>Operation</p>	<p>Mattress supports panels are removable for deep cleaning and maintenance, except the second section panel which is fixed. Push towards head side of the bed the plastic laminate panel to release it, it will slide for 1 cm and then remove it.</p> <div data-bbox="443 560 860 1113" data-label="Image"> </div> <div data-bbox="884 546 1273 1104" data-label="Image"> </div>
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<p>Egress handle ↔</p>	<p>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.</p> <p>Its adjustment operation is the same of standard side rail at page 20.</p> <div data-bbox="533 1386 1390 2002" data-label="Image"> </div>
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Bed length adjustment

The length of the bed is adjustable to an extended position (+ 20 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

Locate the left and right black hand wheel knobs (showed below in the red circle) at foot end of the bed, underneath the mattress platform:



Turn 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.

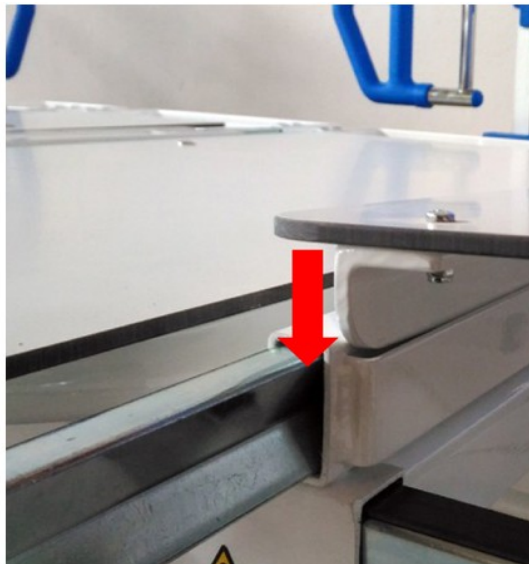
Pull the foot extension frame out and then turn back the two hand wheel knobs until securely fastened to lock them: the foot extension now is securely fastened.

**WARNING**

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



Pull out the mattress retainer panel at foot end (item “T” at page 11), turn it over and position it flat with the metal insert in its socket.



To restore the foot extension (shorten the bed): firstly put 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 plastic laminate insert in its socket, facing the metal insert inward the bed), then turn 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 the two hand wheels knobs back until securely fastened and locked (see page 32): now the foot extension is securely fastened.




Linen tray


The linen tray is used for supporting clean linen when the bed sheets need a change.

Pull out the linen tray from its closed position below the foot board.

After use, push the linen tray back to its closed position.




I.V. pole fixed height ↔	<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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I.V. pole fixed height sockets Operation	<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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The two black nylon sockets placed at head end, behind the head board, can be used for I.V. pole fixed height and/or for oxygen bottle holder.

Oxygen bottle holder ↔	<p>Oxygen bottle holder is designed to accommodate AD, CD, DD, PD, RD, ZD, D cylinders (according to <i>Medical Gas Cylinder Data Chart</i>). Oxygen bottle holder dimension is 370×140mm.</p>  <p>Use the black hand-wheel to lock the tank. Safe working load is 10kg.</p>
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Oxygen bottle holder sockets

Operation

Oxygen bottle holder sockets are located at head end, behind the head board.

Place the oxygen bottle holder in one of the two sockets until the metal insert is completely inside the socket.



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

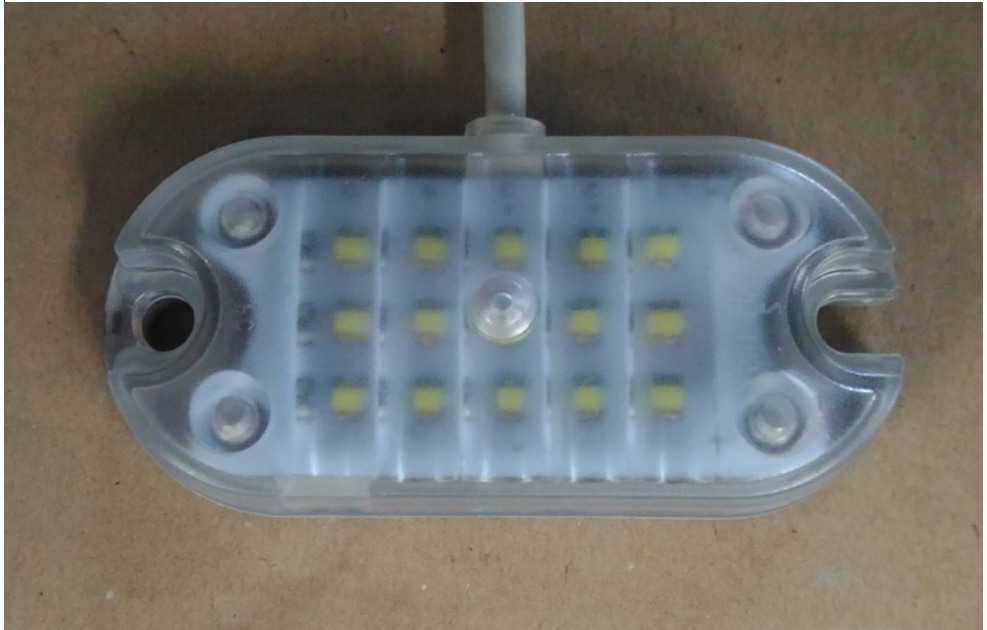
Whenever the sections of the mattress platform are closed at 90cm and the sections are adjusted with handset or ACP, pay attention at the potential finger entrapment with the lower frame in any movement.

Adjusting the mattress platform	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.
Operation	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.



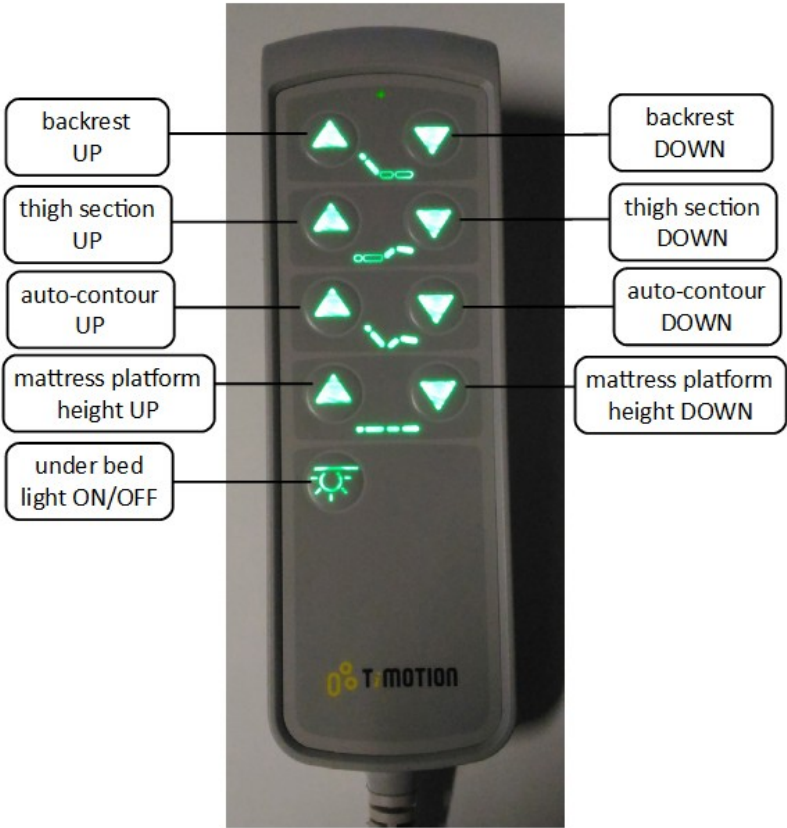
WARNING

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

Under-bed light (night-light)	<p>The bed is supplied with under bed light on a side, underneath the trolley frame. See next paragraph for operation.</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 (32°), the calf section will be in the Fowler position (7° angled downwards).

AUTO-CONTOUR:
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 mattress platform to a flat position.

MATTRESS PLATFORM HEIGHT:
these buttons raise and lower the mattress platform.
Minimum height: 43cm
Maximum height: 79cm

UNDER-BED LIGHT:
this button switches ON the under bed light, located at a side of the bed, under the trolley frame.
To switch the light OFF, just push the button again.



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.



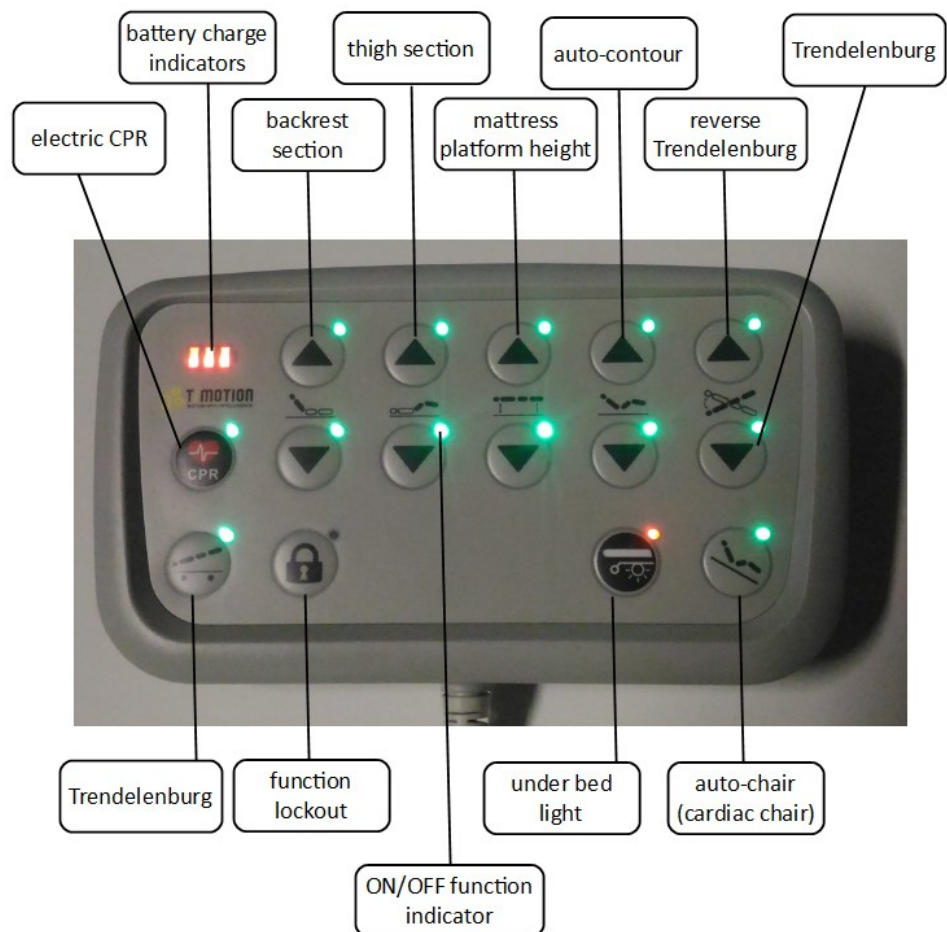
WARNING

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.



<p>Operation</p>	<p>ELECTRIC CPR: If for emergency reasons is needed to flatten the mattress platform and all the sections out, then press and hold the CPR button. The CPR button overrides the function lockout settings. [For faster emergency procedure directly apply the MECHANICAL CPR device to drop the backrest.].</p> <p>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).</p> <p>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.</p> <p>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 (32°), the calf section will be in the Fowler position (7° angled downwards).</p> <p>MATTRESS PLATFORM HEIGHT: these buttons raise and lower the mattress platform (upper button to raise, lower button to lower). Minimum height: 43cm Maximum height: 79cm</p> <p>AUTO-CONTOUR: The Auto-Contour upper 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 lower button returns the mattress platform to a flat position.</p> <p>REVERSE TRENDLENBURG: This button lowers the foot end of the mattress platform (maximum 12°).</p> <p>TRENDLENBURG: This button lowers the head end of the mattress platform (maximum 12°).</p> <p>AUTO-CHAIR (cardiac-chair): The Auto-Chair button simultaneously raises the backrest (50°) and thigh sections (22°), then lower the foot end of the mattress platform into a chair position.</p>
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FUNCTION LOCKOUT

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.

Maintenance

Storage of the battery (Turned OFF)

Remarks

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).

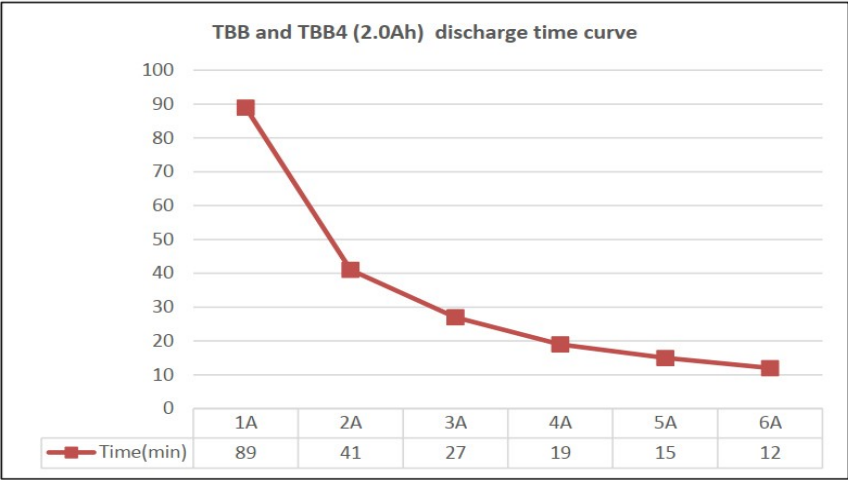
To recharge the battery connect the bed to the electricity supply. Allow at least 10 hours to recharge the battery when it is completely discharged. While the battery is recharging, the ACP battery indicator will flash ORANGE. The ACP indicator will be steady ORANGE when the battery will be fully charged.

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

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

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

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.





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.



WARNING

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



WARNING

Disconnect the bed from the electricity supply before starting any cleaning or maintenance activity.

The bed will still operate on battery power if the function has not been locked on the ACP.



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.

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.</p> <p>Head/foot boards and mattress platform sheets should be removed from the bed for cleaning.</p> <p>Wearing suitable protective clothing, clean all surfaces with a disposable cloth moistened in hand hot water and a neutral detergent.</p> <p>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.</p> <p>Wipe over with a new disposable cloth moistened with clean water, and dry with disposable paper towels.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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	✓	
Check patient handset and cable		✓
Check ACP and cable		✓
Visually check castors		✓
Visually check power supply cord and mains plug		✓
Check the mattress for damage and fluid ingress		✓
Examine the lifting pole, belt and handle ★	✓	
Check for correct fitting of the locking pin on removable side rails and extendable head/foot boards.		✓
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 oppose to the descent of the backrest)		✓



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.

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 linen tray remains in its closed position when maximum foot down tilt is applied.	✓
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 extension locks 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 minimum 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> <p><u>To maintain best performance see:</u></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
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: - Remove the Mains plug for 10 seconds and then re-plug it. - Simultaneously press the height buttons on the patient handset, until the ACP lights flash and, when they stop flashing, release them.
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.	Place brake pedals in the “free” 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 in Chapter 4.
Intermittent functioning of the height actuators under heavy load.	The height operation at once under heavy extreme load (500kg) 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 (500kg) 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 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.

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.

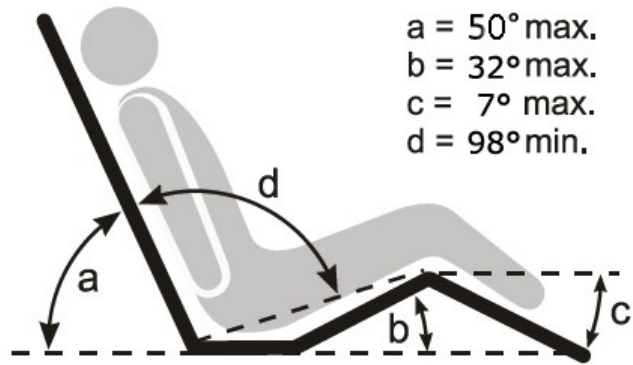
Accessory	Product Code
Lifting pole with integrated IV hooks	500933
I.V. pole fixed height	500699
Oxygen bottle holder	200376
Egress handle	500930

7. Technical data

General data	
Safe working load	500kg
Maximum patient weight	450kg
Product weight	200kg 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 AC, 50/60 Hz (Transformer SMPS Max 4A)
Output Voltage	32V, 8A-10A
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 # 805387974HBB500BZ)
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>	220cm
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>	43cm to 79cm (VARIANT "L" 39cm to 75cm)
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



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



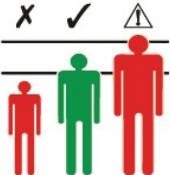
Handle with care. Do not drop. Avoid shock or violent impact.

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

Emission	Standard	Result
Generic reference standard	EN 60601-1-2	Compliance
Conducted emission	EN 55016-1-2	Compliance
Conducted emission	EN 55016-1-2	Compliance
Harmonic emission	EN 61000-3-2	Compliance
Flicker emission	EN 61000-3-3	Compliance

Immunity	Standard	Result
Generic reference standard	EN 60601-1-2	Compliance
ESD immunity	EN 61000-4-2	Compliance
Radiated electromagnetic field immunity	EN 61000-4-3	Compliance
Burst immunity	EN 61000-4-4	Compliance
Surge immunity	EN 61000-4-5	Compliance
RF conducted immunity	EN 61000-4-6	Compliance
50Hz magnetic field immunity	EN 61000-4-8	Compliance
Dips and voltage variation immunity	EN 61000-4-11	Compliance

Test legend symbols result		
Compliance	C	The equipment configured as described in this document complies with the standard required.
Non Compliance	NC	The equipment configured as described in this document doesn't complies with the standard required.
Compliance with reserve	CR	The result obtained doesn't give the tolerance margin from the limit. The equipment might not to be compliant considering the manufacturing tolerances and the components used in the production line.
Compliance with modification	CM	Modification to the equipment under test needed to comply with the standard test. The modification reported in the test report shall be adopted in the next equipment.
Not applicable	NA	The test is not applicable
Not required	NR	The test is not required by the commitment



*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 HBB500 Bariatric 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.