# medstrom solo® LUXE

# USER MANUAL

PRO00040
Revision 3.0

medstrom+
Improved Patient Outcomes

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medstrom solo® LUXE

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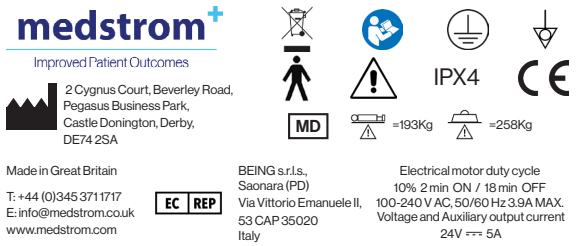
| | |
|---|---|
| | This User Manual contains safety information and operating instructions.<br>Please retain for future reference. |

## 1. Notifications Used in the Manual

| | |
|---|---|
| | **Warning:**<br>There is a risk to safety. Please read this safety instruction and note any warning labels on the bed. |
| | **Caution:**<br>There is a risk of damage to equipment. Please read this instruction. |
| **Important:** | Important information that provides further details for a procedure or condition.. |
| **Note:** | A note that provides further explanation or advice. |

## 2. Identification of Labels Affixed to Bed



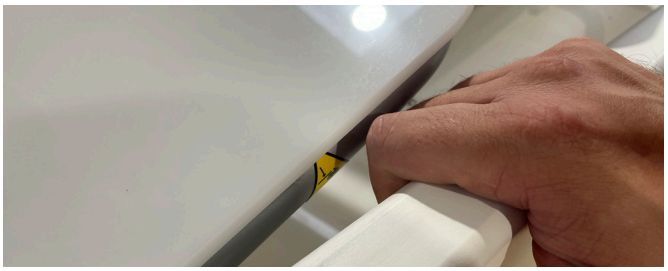

Reference label showing the manufacturer's type. See following table for explanations of the symbols.

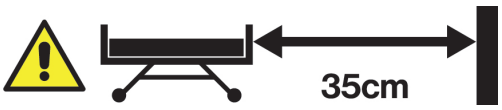
Label indicating the location of a possible trapping hazard:

Risk of trapping feet.

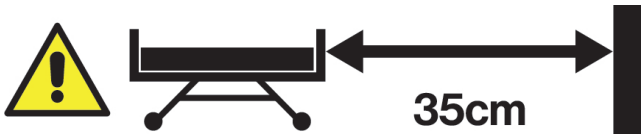
Label indicating the location of a possible trapping hazard:

Risk of trapping fingers/hands.






This label defines the required gap to be left between the head of the bed and the wall.

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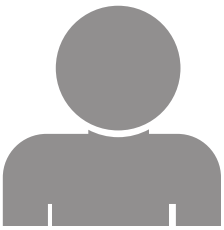
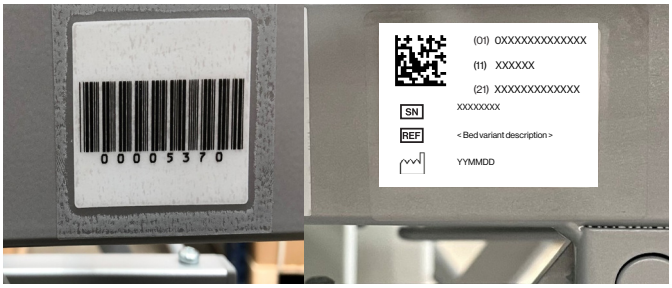
| | |
|---|---|
| Brake ⬇ ⬆ AutoSteer<br>Brake Pedal Label | |
| AutoSteer ⬇ ⬆ FreeMove<br>AutoSteer Pedal Label | |
|  <br>Indicates head section of the bed. | |
| <br>Indicates foot section of the bed. | |
| X X X X X X X X<br>(01) 0XXXXXXXXXXXXX<br>(11) XXXXXX<br>(21) XXXXXXXXXXXXX<br>SN XXXXXXXX<br>REF < Bed variant description ><br>YYMMDD<br>Serial Number Label and Barcode<br>Reference label showing the serial number of the bed as well as product reference and manufacturing date. |  |
| PASS ELECTRICAL TEST<br>S/N:<br>TEST DATE:<br>NEXT TEST:<br>TESTED BY:<br>Electrical Safety Test Label<br>Demonstrates that the that the bed has been tested. | |

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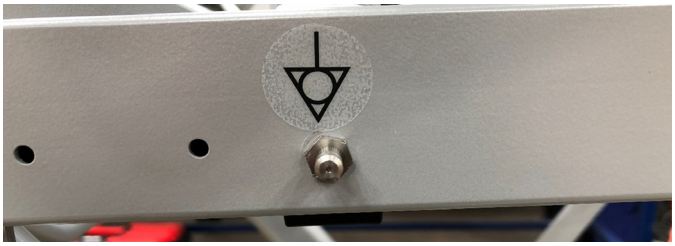
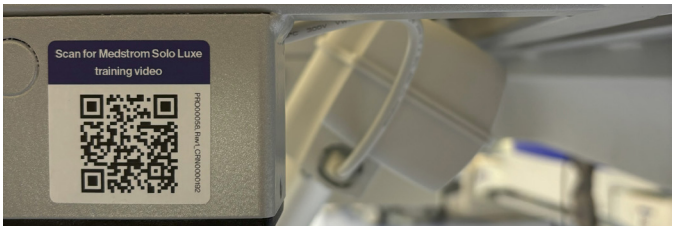
| | |
|---|---|
| Earth Point Label |  |
| Scan for Medstrom Solo Luxe User Manual<br>PRO00057Rev1, CRN-0000092<br>Solo Luxe QR User Manual<br>Acute configurations only | |
| Scan for Medstrom Solo Luxe training video<br>PRO00056, Rev1, CRN0000092<br>Solo Luxe Training Video QR Label |  |
| medstrom+ Improved Patient Outcomes<br>Medstrom Ltd<br>2 Cygnus Court, Beverley Road<br>Pegasus Business Park, Castle Donington<br>Derby, DE74 2SA<br>+44 (0)345 371 1717 www.medstrom.com<br>**7777FA00085**<br>Acute Sleep Deck<br>Foot Section<br>See instructions for maximum mattress height<br>Acute Sleep Deck Foot Section Label<br>Acute configurations only | |
| medstrom+ Improved Patient Outcomes<br>Medstrom Ltd<br>2 Cygnus Court, Beverley Road<br>Pegasus Business Park, Castle Donington<br>Derby, DE74 2SA<br>+44 (0)345 371 1717 www.medstrom.com<br>**7777FA00086**<br>Acute Sleep Deck<br>Lower Mid Section<br>See instructions for maximum mattress height<br>Acute Sleep Deck Lower Mid Section Label<br>Acute configurations only | |
| medstrom+ Improved Patient Outcomes<br>Medstrom Ltd<br>2 Cygnus Court, Beverley Road<br>Pegasus Business Park, Castle Donington<br>Derby, DE74 2SA<br>+44 (0)345 371 1717 www.medstrom.com<br>**7777FA00087**<br>Acute Sleep Deck<br>Mid Section<br>See instructions for maximum mattress height<br>Acute Sleep Deck Mid Section Label<br>Acute configurations only | |
| medstrom+ Improved Patient Outcomes<br>Medstrom Ltd<br>2 Cygnus Court, Beverley Road<br>Pegasus Business Park, Castle Donington<br>Derby, DE74 2SA<br>+44 (0)345 371 1717 www.medstrom.com<br>**7777FA00088**<br>Acute Sleep Deck<br>Backrest Section<br>See instructions for maximum mattress height<br>Acute Sleep Deck Back Rest Section Label<br>Acute configurations only | |

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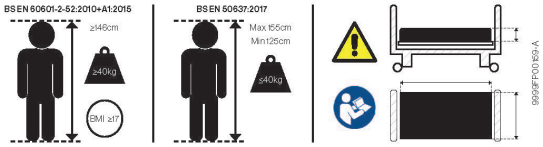
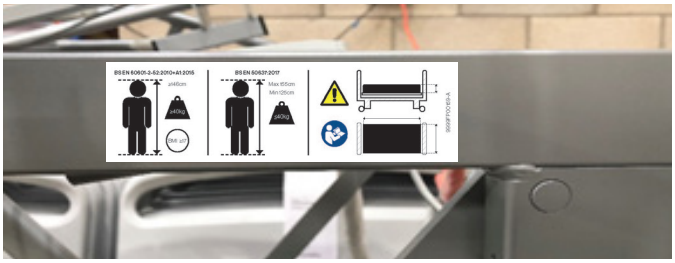
Label indicating where to recharge the bed, plus a dynamic QR code to access online instructions for the use of the bed (secure configuration only).

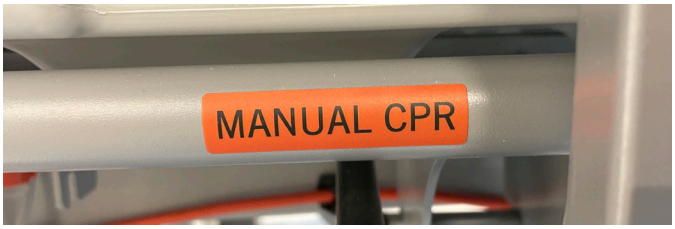



Recommended patient size for the bed as well as indication to review user manual for recommended mattress size.



MANUAL CPR

Manual CPR label.




**Reference Label Symbols:**

| | | |
|---|---|---|
| | Waste Electrical and Electronic Equipment (WEEE) Directive | Waste Electrical and Electronic Equipment must not be disposed of through general waste streams. Please contact an authorised disposal facility or Medstrom Ltd. |
| | Refer to User Manual | Refer to this manual before operating. |
| | Operating Instructions | Identifies the user manual that contains the safety information and operating instructions for the equipment. |
| | Protective Earth (Ground) | Terminal is intended for connection to an external conductor for protection against electrical shock in case of a fault, or is the terminal of a protective earth (ground) electrode. |
| | Equipotentiality (Equipotential Earth) | Identifies terminals which, when connected together, bring the various parts of the equipment to the same potential. |
| | Type B applied part | Identifies a type B applied part complying with *IEC 60601-1. Classification of protection against electrical shock.* |

Continued...

| | | |
|---|---|---|
| | Caution | There is a risk of damage to equipment. |
| IPX4 | Ingress Protection (IP) Rating | IPX4: Water splashing against the equipment from any direction will have no harmful effect. |
| CE | CE Mark | Signifies that this product meets the General Safety and Performance Requirements (GSPR) of the European Medical Device Regulations. |
| MD | Medical Device | Identifies the equipment as a medical device. |
| | Maximum Patient Weight | The maximum weight of patient that the equipment is rated for (193 kg). |
| | Maximum Safe Working Load | The maximum safe working load (weight) (258 kg). |
| | Manufacturer | The manufacturer of the equipment (i.e. Medstrom) and their address. |
| REF | Reference | Manufacturer's reference catalogue number/identifier, i.e. Solo Luxe. |
| | Date of Manufacture | The date that the equipment was manufactured. |
| EC REP | EC Rep | Identifies the Authorized Representative in the European Union. |
| CH REP | CH Rep | Identifies the Authorized Representative in Switzerland. |

## 3. Intended Use of the Bed

This bed is designed for use in hospitals, nursing homes, for long duration rehabilitation centres, elderly care facilities, mental health centres, paediatric units and other specialised care facilities. It is designed and suitable for use with adults (as defined by the EN 60601-2-52:2010+A1:2015 standard), as well as children or adults with atypical anatomy (as defined by the BS EN 50637 standard). It is designed to provide for comfortable sleep and for smooth transfers into and out of bed. The bed ensures the highest level of care for patients, and staff with a safe working height up to 81 cm and an ultra-low height of 21 cm.

The bed is designed for IEC 60601-2-52 Application Environments 1, 2, 3 and 5, where medical care or medical supervision and control is provided, and where electro-medical devices are provided to help maintain and/or improve the condition of patients. The bed is intended for use with adults in: Acute Care, Long-Term Care and Outpatient Care where that care is provided in a hospital or other medical facility.

## 4. General Information

**Important:**

Read this user manual carefully before use and retain for future reference.

The Medstrom Luxe bed is provided in the following configurations, with features suitable for each setting:

- Acute configuration (see section "7. Bed Features").
- Secure configuration (see section "7. Bed Features").

## 5. Precautions for Use

**Important:**

Read this user manual carefully before first use of the bed and any subsequent bed maintenance.

### 5.1. General Precautions

The following is a list of general precautions which should be followed when using the bed:

**Warnings:**

The bed is an electrical device with a risk of electric shock. Personnel using the bed must be informed and trained to potential risks related to electrical appliances.

It is essential to know how the product works to achieve the desired result during handling.

It is essential to comply with the use and recommendations described in this manual to ensure the security and integrity of the different users.

- The use and handling of a medical bed can cause injury if due precautions are not taken. It is essential that any person handling the bed is authorised, trained and made aware of the consequences of all actions and how not to cause involuntary movements.
- Incompatible mattresses can create hazards. See section "7.1. Dimensions" for dimensions and recommendations.
- If using the bed with other medical equipment not supplied by Medstrom e.g. mattresses, the compatibility of the equipment must be assessed for potential risks.
- Do not allow sitting on the bed if the sleep deck and mattress are not completely flat.
- Do not load the bed beyond the recommended safe working load – 258 kg.
- Do not use the electrical functions of the bed in excess of their designed mode of operation (duty cycle), two minutes on/18 minutes off.

**Important:**
As a safety feature, when the actuators of the bed are used too intensively, the bed will go into 'safe mode' and shut down. The bed will return to its normal functions after returning to normal temperature. This return to normal temperature may take several hours.

- If the mains cable is in use, ensure that it is not trailing beneath the bed when the bed is moved, as this could result in damage to the cable.
- Always unwind the mains cable fully when it is connected to the mains power outlet.
- Maintenance of the bed must be performed only by qualified personnel.
- When moving the bed, ensure that there is enough space to allow for the movement, in order to avoid damage to the bed, its environment, or causing injury to any person.
- Keep the space around the bed free from any obstructions so that it can be articulated into any of its full range of movements without causing damage to anything or any potential injury to anyone.
- When preparing to move the bed elsewhere, ensure that there is ample space to operate the bed without any obstructions that could create a hazard or cause damage to anything or any potential injury to anyone.
- The electrical and electronic fittings and components used on the bed are not explosion proof and therefore the bed is not suitable for use in hazardous areas, e.g. the bed must not be used in a full oxygen tent.
- Motorised bed mechanisms can cause serious injury.
- Before use of the bed, assess the needs of, and potential risks to, each individual patient.
- The side rails should be fully up and locked, or fully down and locked, to avoid risk of entrapment.
- Do adopt special safety measures when the bed is to be used by confused patients, e.g. put the bed in a lower position, use safety mats, use protective covers and barriers, enhanced surveillance.
- Movement of the bed could cause damage to soft or improperly installed floor coverings.
- For the Secure configuration and for the security of patients, the mains cable should be disconnected and stored safely away from potential harm.
- Only accessories supplied or authorised by Medstrom should be used in conjunction with an appropriate risk assessment for patient safety.
- Any serious incident that occurs in connection with the bed should be reported both to the manufacturer and the competent authority of the Country or Member State in which the facility is located.

**Avoid Ignition Sources:**

- Don't smoke in bed/on the mattress.
- Don't burn candles in the same room as the bed/mattress.
- Don't use matches or lighters in the vicinity of the bed/mattress.
- Don't have electrical equipment in the vicinity of the bed/mattress, e.g. a television over the bed.
- Don't use electric blankets in combination with the bed/mattress.
- Don't have fires and heaters in the vicinity of the bed/mattress.
- Don't place hot items such as hair dryers or heated appliances on the bed or mattress.
- If you use a mobility aid keep it within reach of your bed or device.

## 5.2. Bed Frame Compatibility

**⚠ Caution:**
Where the mattress used on the bed is not supplied by Medstrom, the compatibility with the bed frame should be assessed independently.

## 5.3. Contraindications

If any contraindication(s) exists for an individual patient, carry out and record a risk assessment before determining, as a minimum:

- Is this medical device a suitable and safe choice for the patient?
- Should the patient have access to the wireless handset?
- Should any function(s) be locked out via the caregiver handset?
- Are any other safety actions required?
- The bed is not intended for use in ambulances or other mobile medical units.
- The bed is not designed for surgical procedures or as an operating table.
- The bed contains materials and components not suitable for MRI or certain diagnostic imaging rooms.

## 5.4. Potential Risk of Entrapment

The bed has been designed in accordance with IEC 60601 and BS EN 50637 standards to reduce or eliminate the risk of entrapment and/or injury. However, please review the pictorial representations below, which highlight those parts of the bed where small risks remain.

The gap between side rail and sleep deck.

The gap between the underside of the side rail post and the floor in the Secure configuration.

The gap between the underside of the head/foot board and the floor.

The gap between the side rails.

## 5.5. Installation and Commissioning

**Warnings:**

Position the bed in such a way that there is always access to the mains power outlet. Do not pull on the mains cable to remove the plug from the mains power outlet.

Before using the bed, ensure that the power requirements of the bed are compatible with the available mains power outlet. The power requirements are provided on the bed reference label and in section “7.2. Technical Specifications”.

New beds are partly dismantled for ease of shipment and require some reassembly prior to use. If the installation is not carried out by Medstrom, proceed as follows:

1. Remove the protective wrapping, securing straps and cable ties.
2. Check that all pin connectors are present and firmly connected to their connections and that the cables are not pinched. Unused connections are sealed to prevent damage from electrostatic discharge.

**Warning:**

If any electrical assembly or wiring is replaced or repaired, the appropriate electrical safety checks must be made by an authorized individual before returning the bed to use.

3. Fit the headboard and footboards to the bed.
4. Thoroughly clean the bed, in accordance with the procedures in section “10. Operational Maintenance”.
5. Position the bed in its use location, ensuring there is enough space to accommodate all bed movements while avoiding damage to the bed or the environment and/or injuring the patient, caregiver or any visitor.
6. Check that the mains cable will not be strained when connected to the mains power outlet.
7. Connect the mains cable, located at the head end of the bed, to the mains power outlet.

**Note**: An equipotential terminal, used to earth the bed, is situated under the sleep deck.

8. Pair the wireless handset to the control box of the bed.
9. If an option, remove mains cable and store in a safe place.

**Note:** For UK use, the cable is provided with a BS1363A, 5A, 3-pin plug.

**Warning:**

When routing cables from other equipment around the bed, check that those cables are not, and cannot be, squeezed, pinched or squashed by any part of the bed.

**Caution:**

Be aware that:

- You should not change the configuration of the bed without the written permission of the manufacturer.
- Users, patients and their families should be informed of the safety rules to be followed when using the bed.
- The bed comes with a quick user guide (QUG) and training video, these can be accessed via the QR code link on the frame of the bed.

### Caution: Electromagnetic Compatibility

Precautions must be taken regarding electromagnetic compatibility (EMC).

- Interference with the bed's electrical/electronic system may be caused by the proximity of communications equipment, mobile phones or other medical equipment such as magnetic resonance imaging (MRI) or active high frequency surgical equipment.
- Caution should be exercised with regard to the use of other electronic equipment in close proximity to the bed. If such usage is unavoidable, the bed and the adjacent electronic equipment should be closely monitored to verify normal operation. If abnormal operation is observed, cease usage of the electronic equipment until an acceptable configuration has been determined and verified.
- The use of cables and accessories other than those specified by Medstrom may negatively affect EMC performance.

### Caution: Lithium-ion Battery Pack

Secure configuration: The bed is battery powered using a rechargeable long-life lithium-ion battery pack.

When a bleeping sound is heard whilst operating the bed, this indicates a low charge condition. To recharge the battery, connect the bed to the mains power outlet for a minimum of 6 hours (a full recharge can take up to 10 hours).

### 5.5.1. Battery Test

Check the condition of the batteries using the following procedure:

1. Ensure that the bed has been connected to the mains power outlet for a minimum of 24 hours.
2. Disconnect the bed from the mains power outlet.
3. Apply a load to the sleep deck.
4. Raise and lower the bed height, from minimum to maximum height, three times.
5. If the bed again fails to operate satisfactorily, the battery is not holding sufficient charge and should be replaced.

## 6. Transport and Storage

### Warning:

This product is not designed for the general transportation of patients, it is designed for patient transportation within the application environments stated in section "3. Intended Use of the Bed". For general patient transportation use equipment that is specifically designed for that purpose.

- The bed is designed for use in temperatures between 5°C and 40°C.
- The sleep deck must be set flat, the bed height should be set to the low position, all bed movement functions should be locked-out, and the brake must be applied.
- The bed must be shut down as stated in section "6.1. Shutdown Procedure".
- Use suitable padding materials to protect the bed from the effects of impact and friction.
- During transport in a vehicle the bed should be restrained to prevent movement.
- Do not use a forklift.
- Beds should not be stacked on top of each other.
- No load should be placed on top of a bed during storage.

## 6.1. Shutdown Procedure

1. Secure configuration only: Disconnect the mains cable from the mains power supply and store in a safe place.
2. Lock out all bed movement functions as described in section “8.1. Wireless Handset”.

# 7. Bed Features

Certified characteristics are safety, electromagnetic compatibility, mechanical safety and fitness for use of the bed and its accessories.

Standard feature across all models:

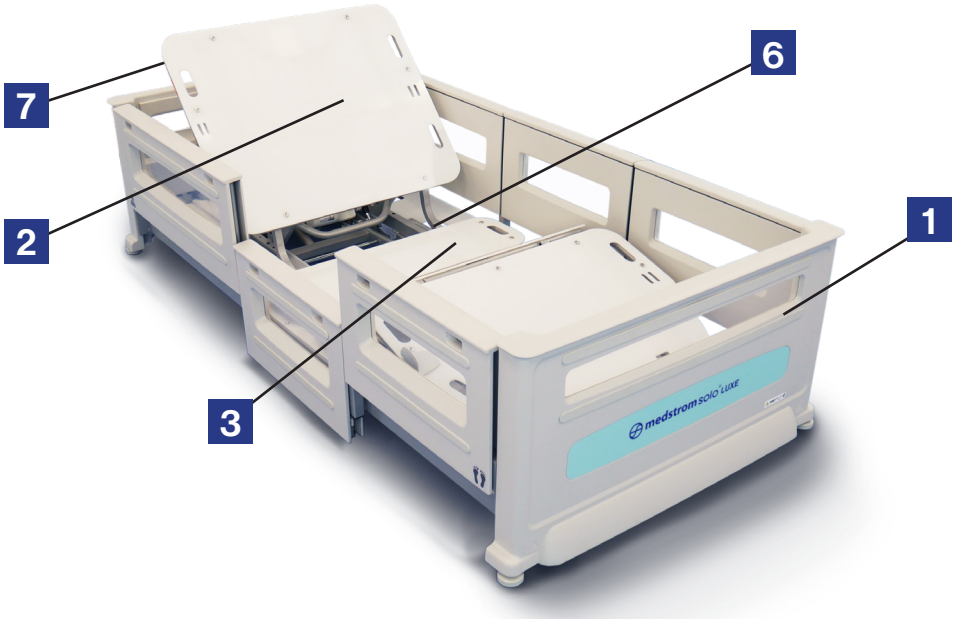
- Full coverage side rails (3-segment) each side.
- Wireless handset with electric height, back rest and knee rest adjustment.
- One button cardiac chair position and back to flat.
- Electric Trendelenburg/reverse Trendelenburg.
- Electric CPR.
- Custom height setting.
- Bilateral manual CPR function.
- 2D movement of the back rest by 23 cm (eliminates patient migration and associated shear/friction on the patient’s skin).
- Four 100 mm bogie castors (one anti-static) with front access to brake/AutoSteer pedal and head end access to AutoSteer/FreeMove pedal.

Acute configuration features:

- Removable, easy to clean sleep deck panels.
- Fixed power cable.
- Removable head and footboards.
- Standard battery back-up.
- Patient helper port access and traction port access.
- Underbed light.
- Catheter bag holder.

Secure configuration features:

- Fixed head and footboards.
- Removable power cable.
- Fixed (non removable) anti-intrusion plates and sleep deck to prevent access under the bed.
- Long-life lithium ion battery.
- Covers over patient helper and traction ports



| Number | Name |
|---|---|
| 1 | Head/Footboard (fixed for Secure configurations) |
| 2 | Back rest |
| 3 | Knee rest |
| 4 | AtuoSteer™ / FreeMove™ pedal |

| Number | Name |
|---|---|
| 5 | Brake / AutoSteer™ bar |
| 6 | Sleep Deck (fixed for Secure configuration) |
| 7 | CPR handle |
| 8 | 3-segment side rails |

## 7.1. Dimensions

| Description | Dimensions |
|---|---|
| Height of sleep deck in high position | 83 cm |
| Height of sleep deck in low position | 21 cm |
| Total length | 227 cm |
| Total width | 106 cm |
| Dimension of sleep deck | 206 cm x 91 cm |
| Height of side rail from sleep deck | 37 cm |
| Recommended mattress height with 3-segment side rails | Minimum: 14 cm<br>Maximum: 25 cm when using a specialist mattress) |
| Recommended mattress size | 206 cm x 91 cm (+/- 2 cm) |
| Head/Footboard height from sleep deck | 37 cm |
| Weight of bed (no mattress or accessories) | 176 kg |
| Back rest angle | 70° |
| Leg section angle (acute configuration) | 20° |
| Knee rest angle | 30° |
| Trendelenburg angle | +14° |
| Reverse Trendelenburg angle | -14° |

**Warning:**

Incompatible mattresses can create hazards. Specialist mattresses require a local risk assessment.

Many specialty mattresses feature immersion therapy which allows the patient to sink into the surface of the mattress, thus reducing the risk of patient falls.

## 7.2. Technical Specifications

| Description | Dimensions |
|---|---|
| **Mechanical** | |
| Safe working load | 258 kg (193 kg patient, 65 kg for a mattress plus bedding and accessories) |
| Castors | Four multi-directional double castors x 100 mm (one anti-static) |
| Brake and steer | Brake/AutoSteer™ at foot end<br>AutoSteer™/FreeMove™ at head end |
| **Electrical** | |
| Power Input | Voltage 100-240 V ac 50/60 Hz |
| | Current 3.9 A Max |
| Mode of operation (duty cycle) | Non-continuous: 2 min. on/18 min. off |
| Output voltage of the transformer | 24-26 VCC |
| Amperage | 5 A max per channel, 5 A max total on secondary |
| Electric power | 0.5 W idle, 200 W max full load |
| Electronic protection | Individual in case of overload. Durability of non-resettable thermal circuit breaker relays. |
| Fuses | Electronic overcharge protection |
| Wireless Handset | Linak type HB200 |
| Power supply unit | Linak type CO61-BT-Mk2 |
| Power supply wire | 3 x 1.5 mm² PVC sleeve– interchangeable |
| Variable height motor | Linak type LA40 – 6000N |
| Back rest motor | Linak type LA27 – 3500N |
| Knee rest motor | Linak type LA27 – 3000N |
| Protective grounding class | Class I |
| Class of protection against dust and water | IPX4 for wireless handset HB200 |
| | IPX6 for control box |
| Classification of the device | Type B according to IEC 60601 |
| Battery back-up (secure configuration) | BA22 Lithium-ion |
| Battery back-up (acute configuration) | BA19 Standard |
| **Environmental Conditions of Use and Storage** | |
| Use temperature | From 5°C to 40°C |
| Storage temperature | From -5°C to 50°C |
| Thermal cut-out reset time | Up to 5 hours |
| Humidity | From 20% to 90% - to 30° without condensation |
| Atmospheric pressure | 700 to 1060 hPa |
| Maximum temperature of parts | 59.8°C (for electrical boxes) |
| Sound level | 41 dB |

**Warning:**

The bed is fitted with an overload alarm which is contained within the control box and is intended to protect the actuators of the bed only. If the safe working load is exceeded an audible warning sound will play and the electrical operations of the bed will cease to function until the weight is within the safe working load limit.

## 8. Instructions for Use

**Warnings:**

For your safety, before using the bed, it is essential to verify that:

- The mattress you intend using is compatible with the bed.
- The recommended mattress dimensions are 206 cm x 91 cm (+/- 2 cm).
- The recommended mattress depth is 14 cm. Maximum depth of 25 cm when using a specialist mattress.

The overall condition of the patient must be risk assessed to ensure compatibility with the use of side rails.

Ensure no obstacle or person hinders, or may hinder, the movement of the side rails during use to avoid injury or jamming.

Ensure the brake and steer pedals are applied properly in the locked position when the bed is stationary.

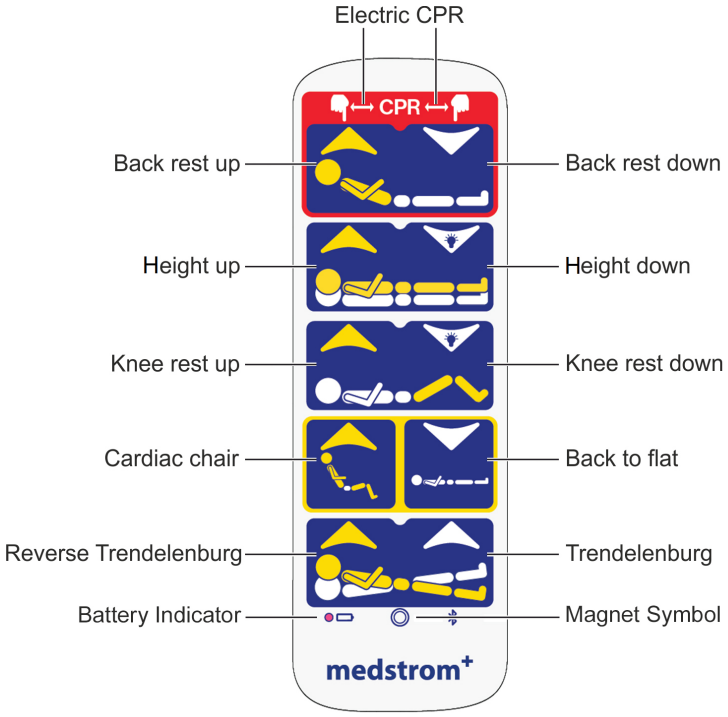
Mattress and side rail combinations that are incompatible with the dimensions that are provided in this document can cause an entrapment hazard.

**Warning:**

Keep clear of the bed when it is being operated. Severe injury can result from crushing by moving parts.

Be aware that bed sections can be operated under battery power even when the mains cable is disconnected from a mains power outlet.

### 8.1. Wireless Handset




| Control | Action |
|---|---|
| Electric CPR buttons | Press and hold the back rest up and down buttons simultaneously. This will flatten the sleep deck and set the bed to a height suitable to perform CPR. |
| Back rest buttons | Press and hold the up/down button to raise or lower the back rest to the desired angle. |

| Control | Action |
|---|---|
| Bed height buttons | Press and hold the up/down button to raise or lower the sleep deck. |
| Knee rest buttons | Press and hold the up/down button to raise or lower the knee rest to the desired angle. |
| Cardiac chair/back to flat buttons | Cardiac chair:<br>• Press and hold the up cardiac chair button. The back rest will raise to 45° and the knee rest will raise to 30°. The bed will then go into the reverse Trendelenburg position.<br>Back to flat:<br>• To return the bed to the flat position, press and hold the down cardiac chair (back to flat) button. |
| Custom bed exit height setting | Press and hold the cardiac chair button and back to flat button simultaneously for 10 seconds to set the correct bed exit height for an individual patient (see section "8.5.6. Storing a Custom Bed Exit Height in the Memory"). |
| Trendelenburg / Reverse Trendelenburg buttons | Press and hold the Trendelenburg button. This will flatten the sleep deck, pause it for two seconds, then tilt the sleep deck head downwards utilising the height actuators.<br>Press and hold the reverse Trendelenburg button. This will flatten the sleep deck, pause it for two seconds, then tilt the sleep deck head upwards utilising the height actuators. |
| Function lock-out | To lock out the handset, hold the magnet over the circle symbol just above the Medstrom logo and press the reverse Trendelenburg button until the battery light on the left illuminates (after two or three seconds). The handset is then locked (light will illuminate when pressing any function and that function will not move).<br>To unlock, use the magnet again and press the Trendelenburg button until the battery light goes out (after two or three seconds). The handset is then unlocked. |

**Note:** It is necessary to keep pressing the function button for the entire duration of the desired movement. An exception to this is when lowering the bed height to its minimum, the bed goes down and reaches a height of 21 cm from the floor. At 24 cm the bed pauses to indicate a risk of entrapment if an object or bodily part is located between the bed and the floor. To continue lowering to the lowest position, release the button, then press it again. This will lower the bed to the ultra-low position. An audible signal will sound to alert the user of the reduction of the space between the floor and the bed.

## 8.2. Recharging the Battery

A fully charged battery (secure configuration only) will provide sufficient power to operate one full bed movement each day for 28 days.

1. Locate the charging point under the backrest, patient right-side (label indicates where).
2. Connect mains cable to the charging point and plug the 3-pin plug into the mains power socket.

**Note:** For a very low or empty battery allow up to 10 hours to fully charge.

## 8.3. Side Rail Operation

The bed is fitted with 3-segment side rails on each side of the bed. These are positioned on the bed in compliance with safety clearances required by the safety regulations and to aid patients with mobilising safely and comfortably. Each side rail (head, middle, foot) is lowered using a trigger mechanism built into the outside of each rail. 3-segment side rails cannot be removed by the end user.

The rails are designed to prevent patient falls whilst in the bed and to avoid the risk of entrapment. The use of side rails should be risk assessed for individual patients.

Beds are supplied with six side rails installed:

- Left-hand side rail (head end).
- Left-hand side rail (middle).
- Left-hand side rail (foot end).
- Right-hand side rail (head end).
- Right-hand side rail (middle).
- Right-hand side rail (foot end).

### 8.3.1. 3-Segment Side Rail Operation

- To raise a side rail into position, lift from the centre of the top rail and lock into place (there will be an audible click to indicate when in place correctly).

**Warning:**
Do not lift from the underside of side rail.

- To lower a side rail, click and release both trigger handles of the side rail. Keep hold of side rail and lower gently into position.

### 8.3.2. Automatic Side Rail Locking (Secure configuration only)

When the bed is lowered to the ultra-low position, the side rails are automatically locked in place creating a “box-bed” configuration. The brake is also automatically engaged when the bed is lowered to the ultra-low position.

To set this function, lower each side rail first using the release triggers on each rail.

Lower the bed and it will automatically stop at 24 cm, sounding an alarm to remind caregivers to ensure no feet or items can be trapped. Continue to lower the bed to the ultra-low position (21 cm). Check that the side rails are locked into place by gently pulling them upwards to ensure they cannot move.

**Warning:**
Side rails are designed for easy operation. There is an extremely small risk of pinching fingers when articulating the sleep deck and lowering the side rail when holding on to the handle area.

## 8.4. Variable Bed Height Function

When the down bed height button is pressed and held, the bed will lower and stop at a pre-set height of 24 cm, before it reaches its lowest position. The bed will sound an alarm after it reaches the 24 cm position.

In its lowest position, the sleep deck is 21 cm from the floor.

If a custom height has been programmed, the bed will stop at that custom height and at 24 cm.

The bed can be positioned at any height between the highest and lowest positions.

Maximum care height for the bed is 81 cm.

The brake will engage automatically when the bed reaches its lowest position. The bed must be raised by 5 cm from the lowest height (21 cm + 5 cm) in order to access the brake and allow the bed to be moved. The lowest height position of the bed should be risk-assessed for patients at high risk of falling.

It is recommended that periodically the bed is placed into either the highest or lowest position to maintain the precision of the height adjustment software.

**Operation:**

The height of the bed is adjusted using the wireless handset. Press the up button to go up or the down button to go down to the desired height.

**Warnings:**

For patients who may be at risk of injury from falls, carry out a risk assessment to determine if leaving the bed at the low height may reduce the risk of injury.

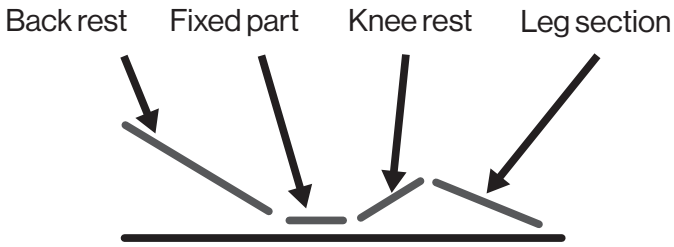
Under certain circumstances it may be necessary to prevent patient operation of the bed functions, this can be done using the selective lock out function on the wireless handset.

Hoists and under-bed tables cannot fit under the bed when it is in its ultra-low position.

## 8.5. Sleep Deck Articulation Functions

The sleep deck can be articulated using the following functions:

- Back rest function.
- Manual CPR function.
- Electric CPR function.
- Knee rest and leg sections function.
- Cardiac chair function.
- Storing a custom bed exit height in the memory.
- Trendelenburg/Reverse Trendelenburg function.




Articulated sections of the sleep deck

### 8.5.1. Back Rest Function

This allows angle adjustment of the back rest.

The back rest will pause at the 30° and 45° angles when it is raised or lowered. This eliminates the need for angle indicators.

The 2D back rest design eliminates patient migration, particularly when the cardiac chair button is used. This gives better comfort to the patient and reduces the risk of shear.

The back rest angle is adjustable from 0 to 70°.

Electric adjustment of the back rest only occurs with the use of the wireless handset.

**Operation:**

- Press the back rest up button to raise the back rest, or the back rest down button to lower the back rest.

**Caution:**
This bed is equipped with both manual and electric CPR functions. The manual CPR function uses a damper to assist with controlling the back rest movement. The electric CPR function is operated by simultaneously pressing the two (up/down) back rest buttons.

### 8.5.2. Manual CPR Function

The manual CPR function is a quick way of setting the back rest horizontal in readiness to perform CPR.

Bilateral CPR handles

**Operation:**

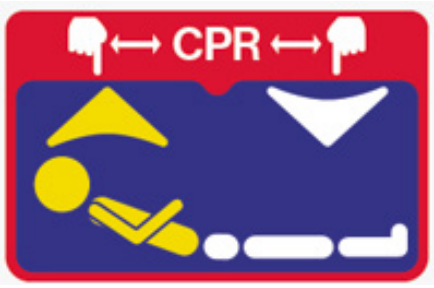
The following operation should only be performed if the bed is occupied. The electric back rest function will operate normally.

- Lower the side rails if they are raised.
- Remove the headboard from the head end of the bed frame (not available if non removable headboard option).
- Pull and hold either of the orange CPR handles and lower the back rest until flat.
- Release the CPR handles.

**Caution:**
This function should not be used as a simple back rest tilt adjustment. Improper use of the manual CPR release handles may degrade and damage the mechanism.

### 8.5.3. Electric CPR Function

The electric CPR function flattens the sleep deck within seconds and sets the bed to a height suitable to perform CPR.

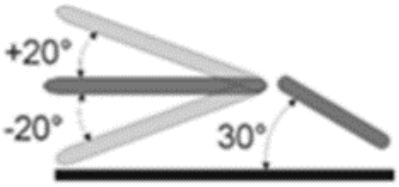


**Operation:**

- To operate the electric CPR function using the wireless handset, press and hold the up and down back rest buttons simultaneously.
- This will set the sleep deck to the flat position and to a height appropriate for CPR.

### 8.5.4. Knee Rest and Leg Sections Function

This function allows adjustment of the knee section as well as the leg sections of the bed via the telescopic ratchet.




Range of movement of the knee rest and leg sections

**Operation:**

- Press the knee rest up button to raise the knee rest, or the knee rest down button to lower the knee rest.

### 8.5.5. Cardiac Chair Function

The cardiac chair function allows the patient to be placed in a full chair position. It combines movement of the back rest and the knee rest with the reverse Trendelenburg position in a continuous motion, using only one button.

**Operation:**

- Press and hold the up cardiac chair button using the wireless handset. The back rest will raise to 45° and the knee rest will raise to 30°. The bed will then go into the reverse Trendelenburg position.
- To revert the bed to flat, press and hold the down cardiac chair (back to flat) button.

### 8.5.6. Storing a Custom Bed Exit Height in the Memory

This function allows the 'bed exit position' to be set for each patient. This promotes safe patient mobilisation. The exit position ensures that the bed is at the correct height for the patient to get their feet flat on the floor prior to raising themselves to exit the bed. This greatly reduces the risk of falls during mobilisation.

It is recommended that a custom exit position is set for every patient when they are first placed on the bed.

**Operation:**

- Using the wireless handset, put the bed at the height where the patient's feet are flat on the floor and their hips and knees are at an approximately 90° angle.
- Then, simultaneously press the up cardiac chair button and the down cardiac chair (back to flat) button for 10 seconds.
- A beep will sound when the bed height position is registered and stored in the memory. The bed will now stop at this position when raising or lowering the bed until the process is repeated for the next patient.

### 8.5.7. Trendelenburg/Reverse Trendelenburg Function

This function should be used with the sleep deck in the flat position. Tilting the sleep deck without first setting it back to flat will provoke a downward sliding of the patient.

**Operation:**

The Trendelenburg (feet up) function allows you to tilt the whole bed backward and down.

- Using the wireless handset press and hold the down cardiac chair (back to flat) button to set the sleep deck to the flat position.
- Then press and hold the right-hand up Trendelenburg/reverse Trendelenburg button until the bed reaches the desired feet up angle.
- To return the sleep deck to the flat position, press and hold the left-hand up Trendelenburg/reverse Trendelenburg button. The function will pause to indicate when the sleep deck is back to horizontal. Release the button.
- Continuing to hold the left-hand up Trendelenburg/reverse Trendelenburg button would allow the reverse Trendelenburg (feet down) movement to begin.

The reverse Trendelenburg (feet down) function allows you to tilt the whole bed forward and down.

- Using the wireless handset, press and hold the down cardiac chair (back to flat) button to set the sleep deck to the flat position.
- Then press and hold the left-hand up Trendelenburg/reverse Trendelenburg button until the bed reaches the desired feet down angle.
- To return the sleep deck to the flat position, press and hold the right-hand up Trendelenburg/reverse Trendelenburg button. The function will pause to indicate when the sleep deck is back to horizontal. Release the button.
- Continuing to hold the right-hand up Trendelenburg/reverse Trendelenburg button would allow the Trendelenburg (feet up) movement to begin.

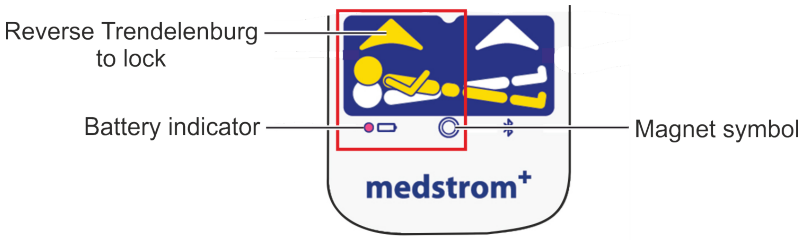
**⚠ Caution:**

The Trendelenburg/reverse Trendelenburg positions are related to clinical indications and should be used only upon prescription and by a competent person.

Only use the Trendelenburg/reverse Trendelenburg function when the brake is locked. Ensure there is sufficient head space around the bed to accommodate the manoeuvre.

### 8.5.8. Lockout of Functions

To lock out the wireless handset, hold the magnet over the magnet symbol, just above the Medstrom logo, and press the reverse Trendelenburg button until the battery light on the left illuminates (after two or three seconds). The wireless handset is then locked. The light will illuminate when pressing any function and that function will not move.




To unlock, use the magnet again and press the Trendelenburg button until the battery light goes out (after two or three seconds). The wireless handset is then unlocked.

### 8.5.9. Under-Bed Light (Acute configuration)

The under-bed light is standard in the acute configuration and comprises an LED light unit, fitted under the bed platform, to assist the patient with getting in and out of the bed at night.

**Operation:**

- To turn on the under-bed light, simultaneously press the down bed height button and the down knee rest button on the wireless handset and hold both for four seconds.
- To turn off the under-bed light, simultaneously press the down bed height button and the down knee rest button on the wireless handset.

## 8.6. Braking System

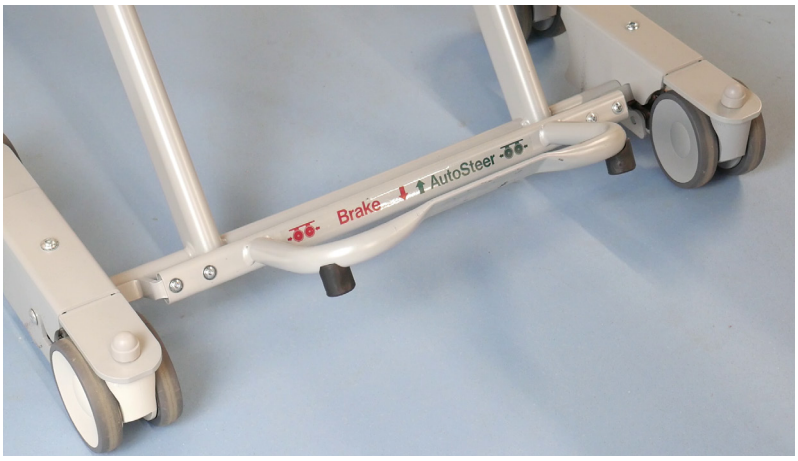
The brake is located at the foot end of the bed.

The brake should be applied (locked/pedal in the down position) at all times that the bed is stationary.

The bed has been designed such that the brake is applied automatically when the bed height is set to its lowest position of 21 cm. Whilst in this position it is not possible to release the brake. In order to access the brake, the bed must be raised by at least 5 cm above the lowest height setting (21 cm +5 cm).

**Operation:**

- To apply the brake, using one foot, press down the brake bar at the foot end of the bed.
- To release the brake, using one foot, insert the toes under the brake bar and lift up (AutoSteer™ mode).




Brake released – brake bar in up position.

**Warning:**
Maintenance of the brake should only be carried out by an authorised Medstrom technician.

**Caution:**
The brake function of the bed satisfies the requirements of the basic safety and essential performance standard to both BS EN 50637 and IEC 60601-2-52. This requires the brake system to be certified to hold the bed stationary when it is at an angle of 6° relative to the horizontal plane on a concrete floor covered with a vinyl coating of 2 mm to 4 mm thick, in normal use.

**Caution:**
Be mindful of possible trapping of a foot when setting the bed height to its lowest position as the brake bar is automatically applied in the lowest position.

**Caution:**
If the bed does not have to be moved, it is strongly advised to apply the brake to avoid potential falls when a patient is accessing or exiting the bed.

Before stopping the bed in its final position, ensure that nothing will prevent normal movement of the bed; up, down or sideways.

## 8.7. Steering System - AutoSteer™ and FreeMove™

The Medstrom Solo® Luxe bed is equipped with four multi-directional castors, in two castor assemblies at the foot and head end of the bed.

The steering lock acts on the front set of castors on the castor assemblies at the head end of the bed. The steering lock is applied or released using the AutoSteer™ pedal at the head end of the bed.

- When the steering lock is applied, AutoSteer™ pedal down, the front castors are locked in the straight-ahead position. This allows for easier control of bed movement and prevents lateral (sideways) movement of the bed (AutoSteer™ mode).
- When the steering lock is released, AutoSteer™ pedal up, the front castors are released. This allows the bed to be moved in any direction, including lateral (sideways) movement (FreeMove™ mode).

The brake and steering should be applied (locked/pedals in the down position) at all times that the bed is stationary.

**Operation:**

- To apply the steering lock, using one foot, press down the AutoSteer™ pedal at the head end of the bed.
- To release the steering lock, using one foot, insert the toes under the AutoSteer™ pedal and lift up.

Steering lock applied – AutoSteer™ pedal in down position.

## 8.8. Moving the Bed

It is recommended that when moving the bed it should be pushed and steered from the foot end of the bed.

When travelling in a straight line along corridors or when leaving the bed unattended, the steering lock should be applied, by putting the AutoSteer™ pedal in the down (locked) position. This will allow controlled movement of the bed with reduced effort, significantly reducing the force required to move the bed, and helps steer the bed around tight corners, with or without the patient being in the bed (AutoSteer™ mode).

When lateral (sideways) movement of the bed is required, the steering lock should be released, by putting the AutoSteer™ pedal in the up (released) position. This will allow movement of the bed in any direction (FreeMove™ mode).

To locate the bed into a bed space, make sure steering lock is applied, AutoSteer™ pedal in the down (locked) position, and push the bed into place in a straight line. When the bed is in position, apply the brake. Ensure the brake bar is in the down (locked) position.

The brake and steering should be applied (locked/pedal in the down position) at all times that the bed is stationary.

**Operation:**

- For small movements of the bed, if the mains cable is still connected to the mains power outlet, check that the mains cable is not being pulled tight and being stressed.
- For larger movements, where the mains cable is still connected to the mains power outlet, disconnect the mains cable from the mains power outlet, and stow it safely to avoid it trailing on the floor.
- Check that no device or accessory is connected to the mains power outlet before moving the bed.

- Release the brake, with brake bar in the up (released) position, and leave the steering lock applied, AutoSteer™ pedal in the down (locked) position.
- Manoeuvre the bed by holding either the headboard or footboard, ideally the footboard.
- When locating the bed in a bed space or patient room, check that no obstacle will prevent normal movement of the bed; up, down or sideways.

**Caution:**
It is advised to position the bed at least 35 cm from the wall during installation. This will ensure that if the Trendelenburg/Reverse Trendelenburg function is used the bed will not touch the wall.

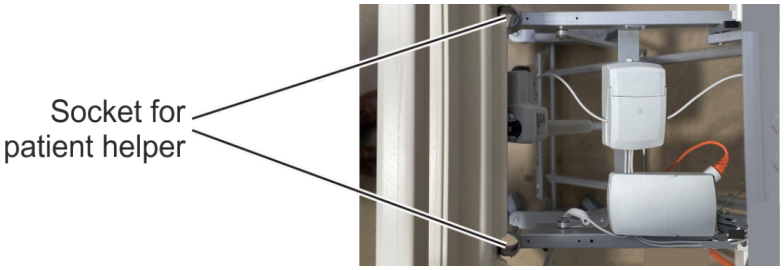
## 9. Accessories

The acute configuration of the Medstrom Solo® Luxe bed is designed to fit the following Medstrom accessories:

- Patient helper.
- Mobile IV poles.
- Oxygen holder.
- Tracking.
- Docking station.
- Full and half traction.

There are:

- Two sockets for a patient helper between the headboard and backrest.




**Warning:**
Only accessories supplied by the manufacturer must be used.

### 9.1. Patient Helper

Maximum load for the patient helper is 75 kg.

Patient helper with adjustable handle.
Part No. 9999AC00122GRY

## 9.2. Mobile IV Poles

**Warning:**

ONLY use approved accessories.

**Intended use:** The IV pole is for hanging fluid bags only. Do not clamp or attach other equipment to any part of the IV Pole.

- NEVER clamp equipment over the manufacturer label on the IV pole. It is important that the label and the QR code remain visible at all times.
- ALWAYS read the instructions for use supplied with the IV pole.
- Scan the QR code on the IV pole to read the latest version of the instructions for use.
- Scan the QR code on the bed to access and read the current instructions for use.

The bed and the head and foot sections of the bed are all height adjustable. The side rails move with the head and foot sections of the bed. The IV pole moves up and down with the bed frame.

Failure to check for the possibility of a collision between fixed and moving parts of the bed may result in a safety hazard.

ALWAYS check the surrounding area for obstructions BEFORE adjusting the height of the bed or the backrest. Failure to check for the possibility of a collision between fixed height objects and moving parts of the bed may result in a safety hazard.

In the event of a collision, equipment may be damaged or fall onto the floor, bed, patient, other person or other equipment.

If in doubt, STOP, then contact your local Medstrom representative or local safety team for advice and support.

The maximum load of an IV pole is 2 kg per hook.

**Important:**

**Reminder of intended use:** The IV poles are for hanging fluid bags only. Do not clamp or attach other equipment to any part of the IV pole.

To adjust the height, lift up the adjuster, adjust the height to the required level and release the adjuster.

Mobile IV stand and height adjuster.

# 10. Operational Maintenance

**Warning:**
The bed is not designed for automatic cleaning - only manual cleaning should be undertaken.

**Caution:**
Using detergent/disinfectant products does involve some risk. Always wear personal protective equipment (PPE), follow the instructions and avoid mixing different products.

## 10.1. Cleaning Guidelines

The bed should be cleaned and disinfected weekly and between patients, following these guidelines:

- Unplug the bed (if the mains cable is connected), and lock out all of its electric functions using the wireless handset (see section "8.5.8. Lockout of Functions").
- Ensure that the mains cable plug does not come into contact with any liquid.
- Check that electrical connections are secure.
- Check that electrical components do not show any signs of wear likely to allow the penetration of liquid.
- Do not wash the bed in a wash tunnel, using a water jet or with any sort of pressure equipment.
- Avoid saturating areas containing electrical connections or electrical components. Once cleaned, dry areas carefully to avoid any risk of moisture remaining, in particular in the area of electrical connections.

**Warning:**
If there is any doubt or concern about the penetration of liquid into electrical connections or electrical components, it is strongly recommended that the bed should not be reconnected to the mains power outlet and the maintenance department advised.

- Clean surfaces with a soft cloth, warm water and a mild detergent/disinfectant solution. Ideally use the cleaning/disinfection solution recommended by the care facility, following the dilution instructions carefully.
- The use of abrasive products or materials is forbidden.
- Products such as petrol, ketonic solvents, concentrated alkali or acid products, chlorine-based solvents or dissolvent risk causing permanent damage to the surfaces and should not be used.
- Non-ionic detergents diluted to 5%, bleach diluted to 10%, and ammonia-based products diluted to 5% may be used.
- Stains left by coloured substances such as eosin, betadine, etc., as well as food products, should be cleaned as quickly as possible to avoid the risk of contamination to the patient.
- For stubborn stains, the use of pure disinfection products is possible locally, as long as the necessary precautions are taken.
- Areas showing traces of cuts or deep scratches should be repaired to avoid the risk of infiltration and deterioration of the protective surface.

## 10.2. Sources of Dirt and Contamination

Sources of dirt and contamination of a medical bed in use are:

- Fabric dust coming from the bedding.
- Food residues.
- Ink.
- Antiseptic liquids.
- Vomit, urine, excrement, blood, etc.

It is necessary to take three types of cleaning/disinfection or bio-cleaning of the bed into consideration:

1. Daily bio-cleaning of the areas of high risk.
2. Bio-cleaning at the start and on the transfer of the patient, and, as a minimum, every month for high and moderate risk areas.
3. Full bio-cleaning of the bed after the departure of a patient presenting risk of infection, and, as a minimum, every two months.

## 10.3. Recommended Cleaning Procedures

Healthcare establishments are divided into sectors in terms of the risk of infection.

Frequency and methods of cleaning and disinfection are adapted according to the evaluated risk.

The level of infection risk in one room with a patient being cared for is moderate. It is much higher if the patient presents an identifiable infection risk.

Cleaning or disinfection of a medical bed, although not in direct contact with the patient and in particular damaged areas, should be performed regularly. Certain areas of the bed are more subject to contamination given the frequency of contact with caregivers' and patients' hands. The bed can be broken down into three areas:

**High Contamination Level Areas**

- Handle areas of the headboard and footboard.
- Side rails.
- Wireless handset.
- Acute configuration accessories (patient helper, mobile IV poles, oxygen holder, tracking, docking station etc.).

**Moderate Contamination Level Areas**

- Bed headboard and footboard.
- Upper surfaces of the bed.
- Brake bar and AutoSteer™ pedal.
- Anti-intrusion panels.

**Low Contamination Level Areas**

- Metal structure of the bed.
- Underside surfaces of the bed.
- Electric actuators.
- Wheels.

### 10.3.1. Daily Bio-Cleaning Procedure

This procedure can be carried out with the patient still in the bed. The objective being to ensure good hygiene of the parts regularly in contact with caregivers' and/or patients' hands.

- Carefully clean the handle areas of the headboard and footboard, side rails and wireless handset.
- Eliminate all traces of dirt apparent on the other parts of the bed.

**Important:**

Clean the side rail in the upright position.

### 10.3.2. Monthly Bio-Cleaning Procedure or Bio-Cleaning Procedure on the Departure of a Patient

This procedure is carried out without a patient in the bed. The objective being to disinfect all parts of the bed that regularly come into contact with hands, plus areas dirtied by liquid deposits, secretions, dust and food residues, etc.

- Use locally approved cleaning materials and detergent/disinfectant solutions.
- Release the brake and move the bed away from the wall to give access all-round the bed; then reapply the brake.
- Put the bed in the flat position and set to a suitable working height.
- If the bed is plugged in, remove the mains cable from the mains power outlet and lock out all electrical functions using the wireless handset.

**Cleaning the Foot End of the Bed**

- Clean the footboard and the bed frame cross-member that holds the footboard.
- Lift the foot end of the mattress and fold over towards the head end of the bed. Clean the upper surfaces of the bed, the inner side of the side rails and then the underside of the mattress.
- Fold the mattress back into place. Clean the outer side of the side rails.

**Cleaning the Head End of the Bed**

- Clean the headboard and the bed frame cross-member that holds the headboard.
- Clean the wireless handset and cable, side rails and both orange CPR release handles.
- Lift the head end of the mattress and fold over towards the foot end of the bed. Clean the upper surfaces of the bed, the inner side of the side rails and then the underside of the mattress.
- Fold the mattress back into place. Clean the outer side of the side rails.
- Clean the AutoSteer™ pedal.
- Release the brake and re-position the bed against the wall; then reapply the brake.
- Clean the brake bar.
- Reconnect the bed to the mains power outlet and unlock the function lock outs on the wireless handset using the key as shown in section "8.5.8. Lockout of Functions".

### 10.3.3. Full Bio-Cleaning Procedure for the Bed

This procedure is carried out without the patient in the bed. The objective is to disinfect the whole bed after it has been occupied by a contaminated patient or periodically every two months.

This operation should also be carried out before first using the bed.

- Use locally approved cleaning materials and detergent/disinfectant solution.
- Release the brake and move the bed away from the wall to give access all round the bed. Re-apply the brake.
- Remove the mattress.
- On the acute configuration remove the sleep deck parts, the headboard and footboard.

**Warning:**
The central part protects the power supply unit, its connections and two sensors.

- Adjust the bed base to a suitable working height and raise all the hinged sections using the wireless handset.
- Unplug the bed and lock out all electrical functions using the wireless handset as shown in section “8.5.8. Lockout of Functions”.

**Cleaning the Upper Part of the Bed**

- Lower all three side rails first on both sides of the bed.
- Clean the wireless handset and cable, the bed frame cross member that holds the footboard and headboard.
- Clean the frame parts that hold the sleep deck, the main frame and the bed legs.

**Cleaning the Lower Part of the Bed**

- Raise all three side rails first on both sides of the bed.
- Clean the inside and outside of all six side rails.
- Clean the bed chassis, the main frame and both orange CPR handles.
- Working down the bed, clean the bed legs, the elevation arms and the castors.
- Clean the AutoSteer™ pedal.
- Clean both surfaces of the various plastic parts of the sleep deck. On the acute configuration put them back in place (be careful to make sure they are positioned correctly on the curved tubing).
- Clean the headboard and footboard. On the acute configuration reposition them on the bed.
- Release the brake and re-position the bed against the wall. Re-apply the brake.
- Clean the brake bar.
- Reconnect the bed to the mains power outlet and unlock the function lock outs on the wireless as shown in section “8.5.8. Lockout of Functions”.
- Set the bed to the flat position using the wireless handset.
- Clean the mattress and replace it on the bed.

## 11. Electromagnetic Compatibility (EMC):

**Warning:**
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Solo Luxe bed, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The purpose of this testing is to ensure the Solo Luxe bed is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of Solo Luxe bed.

**Warning:**
Normal operation of the Solo Luxe bed can be affected by using a mobile or a microwave oven. HF surgical equipment, magnetic resonance imaging or other radio radiant equipment near this product may cause malfunction or lead to loss of essential performance.

| Table 2-1: Guidance and Manufacturer's Declaration—Electromagnetic Emissions (IEC 60601-1-2) | | |
|---|---|---|
| The Solo Luxe bed is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the Solo Luxe bed should ensure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance Level IEC 60601-1-2** | **Electromagnetic Environment Guidance** |
| **Radiated Emissions**<br>FCC Part 15:2016<br>CISPR 11:2015+A2:2019 | **Class A** | The Solo Luxe bed uses RF energy only for receiving control functionality. Testing completed shows that RF emissions are low and do not cause any interference with nearby electronic equipment. |
| **Conducted Emissions (Minimum)**<br>FCC Part 15:2016<br>CISPR 11:2015+A2:2019 | **Class A** | The Solo Luxe bed is suitable for use in all professional healthcare establishments directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| **Conducted Emissions (Maximum)**<br>FCC Part 15:2016<br>CISPR 11:2015+A2:2019 | | |

| Table 2-2: Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC 60601-1-2) | | | | |
|---|---|---|---|---|
| The Solo Luxe bed is intended for use in the electromagnetic environment specified below.<br>The customer or the use of the Solo Luxe bed should ensure that it is used in such environment. The impact on electromagnetic interference from unique medical emitters such as electrocautery devices, electrosurgical units, and diathermy equipment has not been determined. These EM emitters should be avoided. | | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment Guidance** | |
| Electrostatic Discharge (ESD)<br>IEC 61000-4-2 | ± 8 kV contact<br>± 15 kV air | Compliance level met or exceeded | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. | |
| Electrical Fast Transient/Burst<br>IEC 61000-4-4 | ± 2 kV for power supply lines | Compliance level met or exceeded | Mains power quality should be that of a typical commercial and/or hospital environment. | |
| Surge<br>IEC 61000-4-5 | ± 1 kV line to line<br>± 2 kV line to earth | Compliance level met or exceeded | Mains power quality should be that of a typical commercial and/or hospital environment. | |
| Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply.<br>IEC 61000-4-11<br>(see Note 1) | < 5 % UT (> 95% dip in UT) for 0.5 cycle<br>40% UT (60% dip in UT) for 5 cycles<br>70% UT (30% dip in UT) for 25 cycles<br>< 5% UT (95% dip in UT) for 5 seconds | Compliance level met or exceeded | Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the Solo Luxe bed requires continued operation during power mains interruptions, it is recommended that the Solo Luxe bed be powered from an uninterruptible power supply or a battery. | |
| Power Frequency Magnetic Field<br>IEC 61000-4-8 | 30 A/m (50/60 Hz) | Compliance level met or exceeded | Professional Healthcare Levels | |
| Proximity Magnetic Fields Immunity<br>IEC 61000-4-39 | 30 kHz CW 8A/m<br>135.2 kHz PM 65 A/m<br>13.56 MHz PM 7.5 A/m | Compliance level met or exceeded | Professional Healthcare Levels | |
| Conducted RF<br>IEC 61000-4-6 | 150 kHz – 80 MHz 6Vrms outside ISM bands*<br>150 kHz – 80 MHz 6Vrms in ISM bands*.<br>(V1) | Compliance level met or exceeded | Portable and mobile RF communications equipment, including cables, should be used no closer to any part of the Solo Luxe bed than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance:<br>**$d=2\times\sqrt{P}$** | |
| Radiated RF<br>IEC 61000-4-3 | 80 MHz – 2.7 GHz 3 V/m<br>(E1)<br>380–390 MHz 27 V/m<br>430–470 MHz 28 V/m<br>704–787 MHz 9 V/m<br>800–960 MHz 28 V/m | Compliance level met or exceeded | $d=4\times\sqrt{P}$<br>80 MHz to 800 MHz | **$d=7.7\times\sqrt{P}$**<br>800 MHz to 2.7GHz |
| | | | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. | |

| Table 2-2: Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC 60601-1-2) | | | |
|---|---|---|---|
| The Solo Luxe bed is intended for use in the electromagnetic environment specified below.<br>The customer or the use of the Solo Luxe bed should ensure that it is used in such environment. The impact on electromagnetic interference from unique medical emitters such as electrocautery devices, electrosurgical units, and diathermy equipment has not been determined. These EM emitters should be avoided. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment Guidance** |
| | 1700–1990 MHz 28 V/m<br>2400–2570 MHz 28 V/m<br>5100–5800 MHz 9 V/m | | <br>Interference may occur in the vicinity of equipment marked with this symbol:<br><br>Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. |
| **NOTE 1:**<br>**NOTE 2:**<br>**NOTE 3:** | UT is the AC mains voltage before application of the test level.<br>At 80 MHz and 800 MHz, the higher frequency range applies.<br>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. | | |

* The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Solo Luxe bed is used exceeds the applicable RF compliance level above, the Solo Luxe bed should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Solo Luxe bed. Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

## 12. Warranty, Servicing and Maintenance

Medstrom reserves the right to make changes to the design, characteristics and models without prior notice.

The only warranty Medstrom makes is the express written warranty extended on the sale or rental of its products.

**Warranty may lose its validity in the following cases:**

- Disassembly of mechanical or electrical parts of the bed without consultation and approval of the manufacturer.
- Replacement parts are not supplied by the manufacturer.
- Work on the electrical parts or gas cylinders by un-approved personnel.
- Degradation of coatings or materials from shock, friction and scratches.
- Abnormal use of bed not following the precautions and recommendations, including SWL and maximum/minimum patient weights, resulting in degradation of the bed or its environment.
- Medstrom do not approve disinfectants. Disinfectants are locally approved by each establishment.
- Use of cleaning products without respecting appropriate dilution proportions.
- Washing with a water pressure jet.
- Crushing or cutting the mains cable or the control cables.
- Intensive use of electric bed functions beyond the recommended service factor.
- Use of a bed that indicates a mechanical or electrical malfunction.
- Stacking of beds during storage.
- The manufacturer, assembler or installer cannot be held responsible for the safety, reliability or the characteristics of the device if it is not used in a safe electrical environment.
- Accommodating the bed complies with the relevant recommendations, and the device is used in accordance with the instructions for use.

**Warnings:**

- It is prohibited to modify the bed.
- Use only spare parts approved by the manufacturer.
- Any item damaged must be replaced before using the bed.
- Disposal of the product is necessary if the essential requirements are no longer met, especially when the product no longer has its original features.
- On disposal, product must be rendered unusable.
- Please observe the environmental regulations of the country in which the product is being disposed of.
- The manufacturer specifies that the mattress is not an element of the bed and is not part of this manual.

## 12.1. Service Checklist Form

| | Pass | Fail | Comment |
|---|---|---|---|
| **General Condition** | | | |
| **Castors**: Rotate through 360°, check fixings are secure. | | | |
| **Brake mechanism**: Lock in position, condition of brake castors. | | | |
| **Steer mechanism**: Lock in position. | | | |
| **Side rails**: Free from damage and scratches. Slide up and down smoothly and lock into place correctly. Remain in locked position when in ultra-low position if Secure configuration. | | | |
| **Frame**: Free from distortion, cracks in welds, fastening points secure, spacers. | | | |
| **Sleep deck**: Securing points in place, free from damage, check retaining clips. Secure configurations should be fixed in place. | | | |
| **Wireless handset**: All functions working, free from damage. | | | |
| **Headboard/footboard**: Locate in position, free from damage. Secure configurations should be fixed in place. | | | |
| **Labels**: All labels applied, i.e. serial number, SWL, model, asset label, brake/steer. | | | |
| **Electrics**: Check cables for wear and tear, damage and secure connections (bed must not be connected to mains power during these checks) Secure configurations are supplied with a removable mains cable. | | | |
| **Functionality** | | | |
| **Raise and lower**: Operate to set positions. | | | |
| **Back rest section**: Operate to set positions, pause at 30° and 45° angles. | | | |
| **Knee rest**: Operate to set positions. | | | |
| **Reverse Trendelenburg/Trendelenburg**: Operate to set positions. | | | |
| **Lateral bed movement**: Bed can be moved with ease in lateral direction (FreeMove™). | | | |
| **Side rails**: Lock in upright position, release mechanism operational and locked when in ultra-low position (21 cm) if Secure configuration. | | | |
| **Castors**: Braking - remains in position when applied. | | | |
| **Castors**: Steer - travels in straight line when steering lock is applied (AutoSteer™). | | | |

| | Pass | Fail | Comment |
|---|---|---|---|
| **Features** | | | |
| **Ultra-low position**: Operational beyond standard low position. | | | |
| **CPR**: Operational via the wireless handsets, puts bed at height and in a flat position. | | | |
| **Manual CPR**: Releases back rest section to flat position once handle is pulled. | | | |
| **Under-bed light**: Illuminated once selected from the wireless handsets for Acute configuration. | | | |
| **Custom height**: Sets custom height to designated position from the wireless handsets. | | | |
| **Bed reset (calibration)**: Recalibrates control box with actuators operated from wireless handsets (raise bed up to highest, then lowest position. Same process with back rest and knee rests). | | | |
| **Egress**: Bed will initially raise if in low position. | | | |
| **Date:** | | | |
| **Signed:** | | | |

## 13. Manufacturer's Details

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EC REP

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53 CAP 35020
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**CH Representative:**

CH REP

CHRN-IM-20000224
Med-Innova SA
Chemin des Quatre-Vents 7F, 1166 PERROY
Switzerland

For further information relating to technical characteristics, maintenance or after sales service, please consult the bed's technical manual available on request.

CE

Product Numbers:

- Solo Luxe Acute UK: SOLOLUXFGACU01-B-UK
- Solo Luxe Acute EU: SOLOLUXFGACU01-B-EU
- Solo Luxe Secure UK: SOLOLUXFGSEC01-B-UK
- Solo Luxe Secure EU: SOLOLUXFGSEC01–B–EU

GTIN Numbers:

| Product | Variant | Region | GTIN |
|---|---|---|---|
| Solo Luxe | Acute configuration | UK | 05060467210553 |
| | | EU | 05060467210560 |
| | Secure Configuration | UK | 05060467211024 |
| | | EU | 05060467211031 |

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