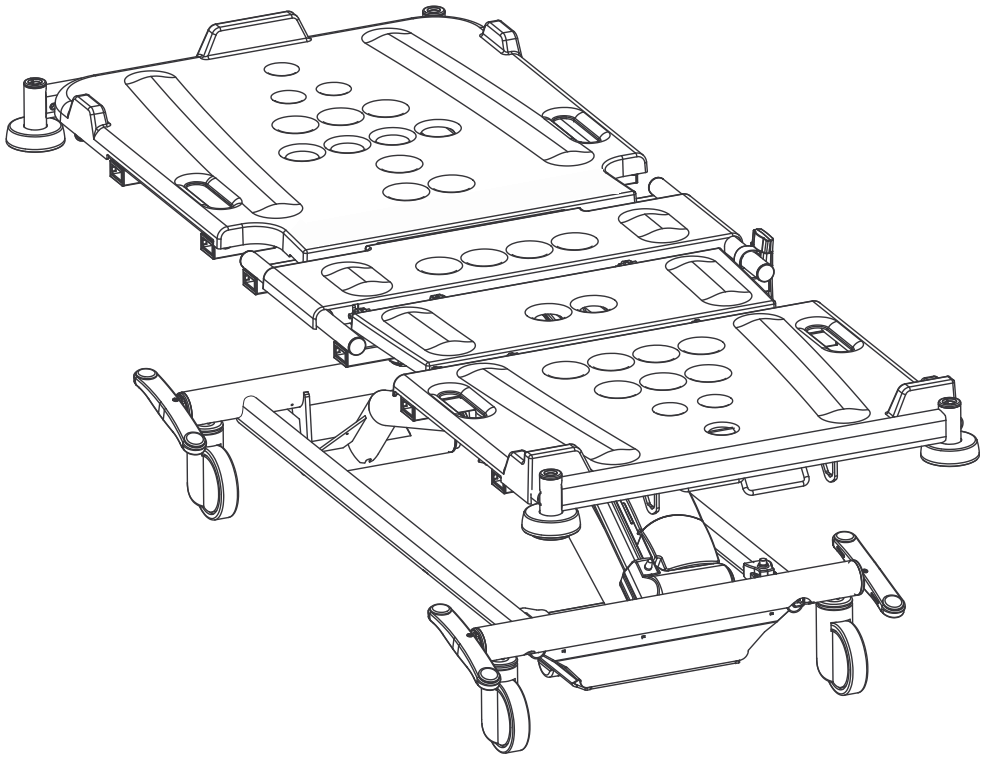
Carena Plus / -Plus W

Instructions for use

ID: DX020370, rev. 1 / 18.12.2023 (en)



Contents

1 Warnings, cautions and notes

1.1 Overview

To ensure optimal patient safety, all users must read this user manual carefully and be familiar with the correct use of the product as well as all warnings, cautions and notes.

Warnings and notes found in this user manual are indicated with symbols as follows:

⚠ WARNING

Please observe to ensure user, maintenance personnel and patient safety.

⚠ CAUTION

Please observe in order to avoid causing damage to the equipment or its parts.

Note: Please observe in order to improve equipment properties.

1.2 General warnings

⚠ WARNING

Use the bed only in facilities made for medical purposes. Read this manual thoroughly, and be familiar with its content prior to using this equipment.

⚠ WARNING

The maximum load capacity of the bed with accessories is 330 kg (SWL). Only one person may be on the bed when making electrically controlled adjustments. The maximum patient load capacity without accessories is 300 kg.

⚠ WARNING

To minimize risk of falling when transporting a patient, raise the side rails to the highest position and adjust the sleeping platform to the lowest possible ergonomic height that is suitable for moving the bed.

⚠ WARNING

Estimate patients' clinical state and risks of using the hospital bed (Danger of falling, trapping and suffocation).

⚠ WARNING

With a very restless or anxious patient using side rails may cause danger of trapping, falling, or suffocation. Consider using alternative protective measures.

⚠ WARNING

Make sure that no external object accidentally activates the device's control functions. For example, the CPR release handle on the back section may be accidentally activated if an air mattress cord or a rescue sheet strap gets caught on it.

⚠ WARNING

If there is a danger of the patient falling out of bed, side rails must always be left in the highest position when the patient is unattended (risk of falling).

⚠ WARNING

If the bed is placed against the wall, side rail facing the wall must be raised up (Risk of squeezing).

⚠ WARNING

If someone other than healthcare professional is allowed to use the functions of the bed, their capability to use the bed safely must be ascertained and they must be fully instructed in the safe use of the functions. If necessary, lock the movements of the bed from the control panel.

⚠ WARNING

If safety precautions, such as raised side rails, are applied to ensure the safety of a patient, make sure that only healthcare personnel removes these safety precautions from use. Instruct family members, visitors or other laypersons about safety precautions and if necessary, supervise that the instructions are followed.

⚠ WARNING

Lying in bed may cause pressure ulcers. If necessary, use counteractive procedures to prevent pressure ulcers.

⚠ WARNING

It is recommended to use a mattress designed to prevent pressure ulcers.

⚠ WARNING

Risk of squeezing and falling! When using other than the device's own accessories, (e.g. CE-marked optional accessories) make sure that no risks are caused to the patient and the usability of the device is not compromised. The use of accessories other than the device’s own can cause unidentified risks to the patient and user, e.g. dangerous squeezing gaps or the stability of the device can be compromised. When installing accessories other than the device's own, the owner or holder of the device must assess and accept the risks involved in installing the optional accessory. The user of the device must assess the safety of using the device and an optional accessory on a patient-by-patient basis. If necessary, lock all adjustment functions which may cause a hazardous situation when using the device with an optional accessory.

⚠ WARNING

To keep impacts on the castors and other mechanical parts to a minimum, always move the bed carefully over thresholds (or similar obstacles) with the leg section in front.

⚠ WARNING

Before adjusting the bed or the side rails, make sure that nothing and nobody is under them or between their mechanisms (risk of crushing).

⚠ WARNING

Use only recommended bed mattresses of the manufacturer (2000 mm x 750/800/850-880 mm x 130 mm). Incompatible mattresses can create hazards.

⚠ WARNING

Make sure that the mattress is set between mattress retention guides. Check mattresses' positioning regularly.

⚠ WARNING

Do not modify this equipment without authorization of the manufacturer.

⚠ WARNING

Stop using the device in case of malfunction in the device or in its accessories. Contact service.

⚠ WARNING

Before transporting the bed, it is recommended that all protruding accessories are removed to minimise the risk of collisions.

⚠ WARNING

If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

⚠ WARNING

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

⚠ WARNING

Do not use the product in oxygen-rich areas or where anaesthetic gases are present.

⚠ WARNING

Ensure that the mains cord of the bed or other equipment is not caught between moving parts of the bed, as this may expose or cut the lead. When adjusting the mattress base into the Trendelenburg or Antitrendelenburg position, ensure that the lead is not caught between the mattress base and base frame. Damaged power leads can result in electric shock.

⚠ WARNING

The device must always be left in its lowest position to ensure safety and to minimize the risk of falling and crushing

⚠ WARNING

Electromagnetic equipment may disturb the hospital bed. Read the EMC instructions and ensure the electromagnetic compatibility in the operating environment to avoid product malfunction.

⚠ WARNING

Risk of falling and squeezing! When using the 3/4 side rails, a restless or anxious patient may fall out of the bed through the gap between the side rail and the foot end or become trapped in it. Assess the risks associated with the use of the side rails on a patient-by-patient basis.

⚠ WARNING

If there is a danger of patient falling out of the bed, the side rails must always be left in the highest position when a patient is unattended (risk of falling).

⚠ WARNING

Always disconnect the power cord before moving the bed. Make sure that the cord is not crushed between the bed's structures or castors.

⚠ WARNING

Never tie the power cord to the bed, because a lifting movement may cut it. Make sure that you can quickly disconnect the power cord in case of emergency.

⚠ WARNING

Never tie the hand control to the bed or to the side rail, because adjustments of the bed and movement of the side rail can damage the wire. Stop using damaged hand control immediately.

⚠ WARNING

Before moving the bed make sure that hand controls' wire is not in danger of crushing under the wheels.

⚠ WARNING

If the power cord is cut or damaged, disconnect it immediately. Risk of electric shock.

⚠ WARNING

Do not operate the motors for more than two (2) minutes at a time. Continuous repetition of movements may overload and damage the motor. If you use electric functions continuously for two minutes, you must not use them again for 18 minutes.

WARNING

Do not bind the power cord to the device because adjusting the device can damage the cord. Disconnecting the power cord from the mains socket is considered as a part of safety measures. Make sure that you can quickly disconnect the power cord in case of an emergency.

WARNING

Do not bind power cords of other devices or other wires to the device. When moving the device or using its functions, make sure that the cords of other devices are not left under the device’s castors or between its structures.

CAUTION

Do not move the bed by pushing or pulling the infusion rod. It can cause damage to the accessory or the bed.

⚠ CAUTION

Ensure that the hand-held control unit(s) wire does not get caught between moving parts of the bed, because their movement may expose or cut the wire. An exposed or cut hand-held control unit wire is not life-threatening, because it operates on a 24 V safety voltage. When adjusting the mattress base into the Trendelenburg or anti-Trendelenburg position, ensure that the wires are not caught between the mattress base and base frame.

⚠ CAUTION

Use the equipotential bonding cable series with patient monitoring equipment.

2 General

2.1 About this user manual

The user manual has been written for the medical staff and it provides information on the use and features of the Carena hospital bed.

Read the manual in its entirety before using the product. The user manual is regarded as a part of the product. Keep the user manual for future reference.

Information about the maintenance and service of the product is provided in the *Carena hospital bed maintenance manual DO1099.*

2.2 Intended purpose

Carena hospital beds are designed to be used by healthcare professionals with patients over a minimum height of 146cm, body weight equal or over 40Kg and BMI, body mass index equal or over 17 in application environment 1, 2, 3 and 5 of standard EN 60601-2-52: 2010.

Carena hospital beds are an active non-invasive Class I medical devices (EU Medical Device Regulation 2017/745, rule 13) for short- and long -term use and intended to be used for a patient's sleeping and care platform for the duration of monitoring, healing, diagnosing illness, and when giving medical treatments for injuries and to compensate patient functional limitations. The device is not intended for home use.

Appropriate application environments are:

• intensive care in a hospital

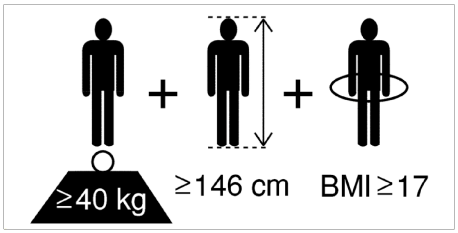
• acute care ward in a hospital, health center or equivalent institution

• wards in hospitals or other equivalent institution offering long-term care

• outpatient care in hospitals, private clinic`s or equivalent institutions

The bed must not be used on explosive dangerous environments where flammable anaesthetic gases, cleaning agents and similar are used.

Physical description of an adult:



⚠ WARNING

If a patient is taller than 185 cm and/or physically restless or confused, the risk of falling down, trapping and suffocation increases.

⚠ WARNING

If patient's height, weight, or BMI is below given figures, the risk of entrapment between a siderail and/or bed structures increases.

2.3 User groups

The Owner or Holder is any natural or legal person who have ownership of the product. The owner is responsible for the safe use of the product and is responsible for ensuring that the product is always used safely including maintenance, cleaning and disposal. It is the responsibility of the holder to ensure that all users, including temporary staff, have received appropriate training in the use of the equipment and are familiar with the risks involved in using the equipment and the dangers of improper use.

The Intended User is a person who, by virtue of his education, experience or familiarization, is capable of operating the device, must be able to anticipate and identify risks associated with the use of the device and be able to assess the patient's clinical status, suitability to use the device and treatment risks. It is the user’s responsibility to ensure that the treatment meets the requirements of all applicable local laws and regulations.

A Patient is a person who needs device for treatment; is weak, ill, injured or needs the device otherwise to compensate functional limitations, e.g. handicapped persons. .

Obligation for incident reporting: User and/or patient should report any serious incident that has occurred in relation to this device to the manufacturer (Lojer Oy) and the competent authority of the Member State in which the user and/or patient is established

2.4 Standards and directives

As a manufacturer of medical devices and products for health care, Lojer Oy pays the greatest attention to the quality of both its products and its operational processes. Lojer’s products are CE-labelled and the company's quality management system complies with EU directives for medical devices, and is certified according to ISO 9001 and ISO 13485 standards. The company's environmental management system is ISO 14001 certified.

The bed fulfils standards EN 60601-1-2 (EMC), EN 60601-1, and EN 60601- 2-52. The device is in conformity with requirements of Medical Device Directive 93/42/EEC and EU Medical Device Regulation 2017/745 and is marked with a CE marking. The device is classified as Class I medical device.

2.5 Liability

The contents of this manual may be amended by Lojer, without prior notice or any further obligations, in order to make changes and improvements. The reproduction, including partial reproduction, or translation of any part of this manual is forbidden without the written consent of Lojer.

Lojer reserves the right to change, cancel or otherwise amend the data contained in this document at any time and for any reason without prior notice because Lojer is constantly seeking new solutions which lead to product evolution. Lojer therefore reserves the right to make changes to the supplied product in terms of shape, fittings, technology and performances.

With regard to translations into languages other than English, reference must always be made to the English edition of this manual. To be able to use the device safely and efficiently, we recommend that you read this manual and inspect the included images.

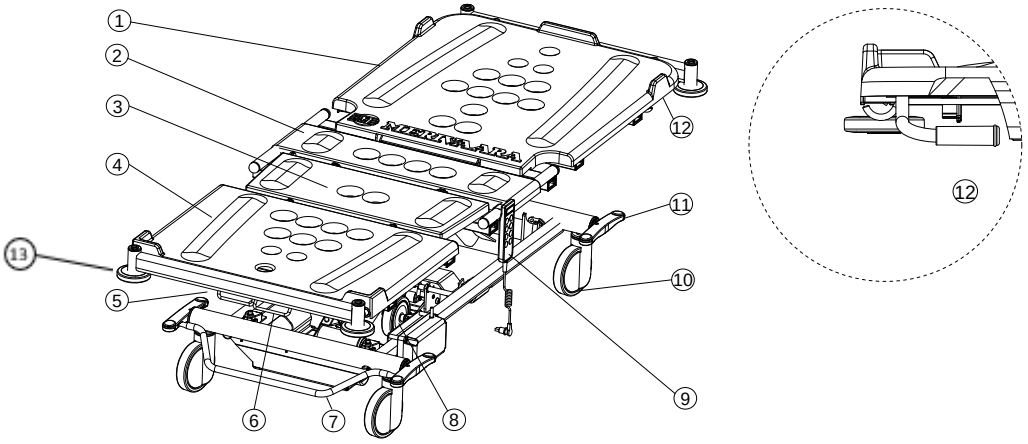
Lojer does not take responsibility of the consequences if the system contains other suppliers' material or components. All parts of the system must be tested according to IEC/EN 60601-1.

This user manual is regarded as a part of the product. It must be kept in close vicinity of the product at all times.

3 Main parts

3.1 Description of main parts

Table 1. Main parts of Carena



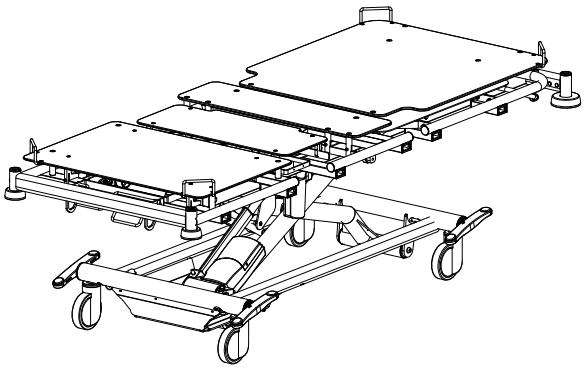
1. Back section
2. Seat section
3. Thigh section
4. Foot section
5. Manual adjustment of leg section
6. Trendelenburg adjuster handle
7. Brake pedal bar
8. Fifth wheel
9. Hand control
10. Tracking castor
11. Brake pedal
12. Back section quick-release handle
13. Bumper wheel

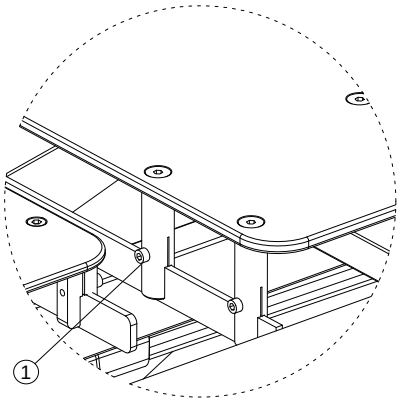
3.2 X-ray mattress base

⚠ WARNING

Risk of falling! Make sure that side rails LX40332 are used with the X-ray mattress base.

The raised mattress base is intended for intensive and monitoring use with x-ray cassettes. The mattress base is fixed with a hex screw (1). The X-ray mattress base weights about 20 kg. Note that the weight of the mattress base affects the maximum load capacity.





⚠ WARNING

Before attaching the bed as a part of electrical ME equipment, for example, intravenous, internal heart treatments or electrocardiogram device or similar, connect potential equalization of the bed to hospital`s potential equalization connection.

The raised mattress base can also be fitted as an accessory to a bed that has a single constant mattress base. The bed can be supplemented with Carena accessories to facilitate patient care. Suitable accessories are available, for example, in the following equipment groups:

- Anesthesia
- Infusion
- Supports, planes, baskets and side rails
- Catheter and drainage bag holders.

⚠ WARNING

Incompatible side rails and mattresses can be an entrapment hazard to a patient. Use only Lojer Carena accessories.

4 Use

4.1 Before use

To ensure optimal patient safety, all users must read these instructions carefully and be familiar with the correct use as well as all warnings and observations.

⚠ CAUTION

If the bed has been in cold temperatures during transport or storage, allow it to warm up at room temperature for at least 12 hours before recharging the battery or connecting power. This ensures that the possible condensed humidity has time to evaporate.

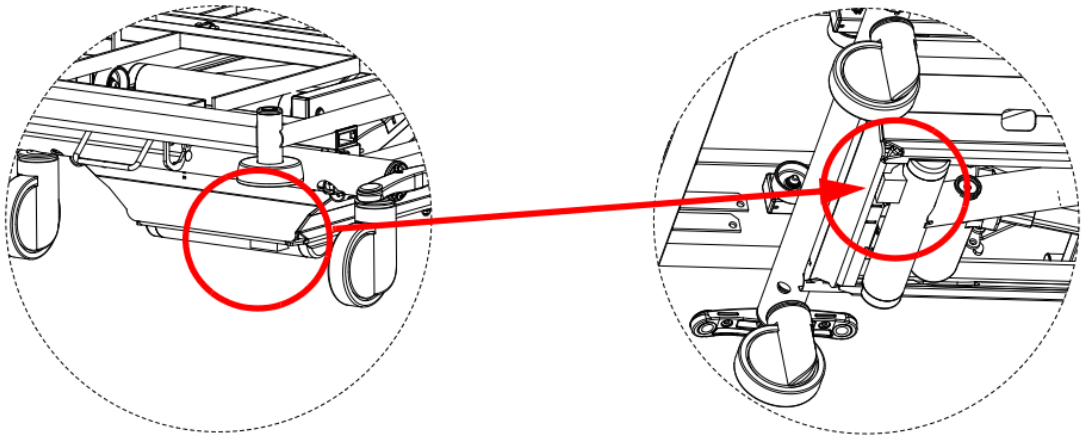
The hospital bed is shipped pre-assembled. Check for possible damages caused during the transport and remove the transport support block before using the product.

Note: Cardboard packing materials are recyclable. Wood and plastics are energy waste.

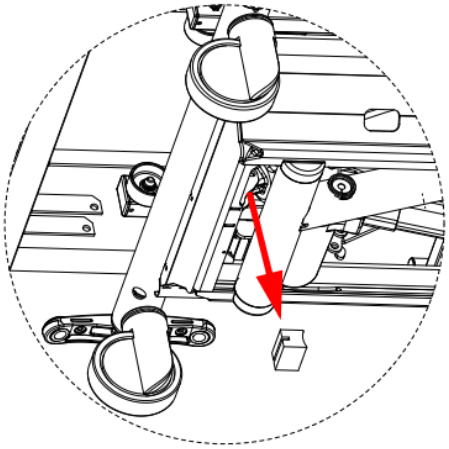
4.1.1 Remove the transport support block

Note: The bed is electrically locked during transport and storage. Remove the locking by pressing the height adjustment up and Trendelenburg for 5 seconds until a beep sound is heard. Refer to 4.2.6 Hand control unit operation, page 20.

The transport support block is located under the bed on the side of the leg section.



Use the hand control to move the bed up and then remove the transfer support part which is located under the bed. Refer to 4.2.6 Hand control unit operation, page 20.



4.2 Adjustments and features

4.2.1 Back section quick release

⚠ WARNING

Make sure that no external object accidentally activates the device's control functions. For example, the CPR release handle on the back section may be accidentally activated if an air mattress cord or a rescue sheet strap gets caught on it.

⚠ WARNING

Make sure your hands are not between the backrest and the upper frame parts when using the CPR mechanism. Use the CPR function only in emergencies and be particularly careful when using the function (danger of crushing).

⚠ WARNING

There is a danger of crushing when the lift support is in place and the back section is adjusted.

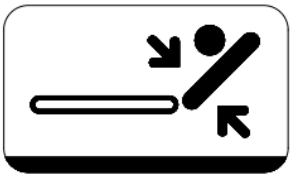
⚠ WARNING

Raising the back, thigh, and/or leg section increases risks for squeezing, suffocation, and falling from bed.

⚠ WARNING

Make sure that your hands are not between the backrest and the upper frame parts when you adjust the backrest. (danger of crushing).

- Support the back section with one hand when you press the red quick-release lever with the other.
- The back section moves freely and has a dampening feature for smoother and safer lowering.



⚠ WARNING

When you use the quick-release lever, limit the back section movement by holding the bed back section frame with your free hand.

4.2.2 Central braking system and tracking castor

- When the pedal is up, the tracking castor locks in the desired tracking position.
- When a pedal is in the middle position, all castors turn.
- When a pedal is down, all castors lock.

⚠ WARNING

Do not park the device on inclined surface. Unlocking the wheels on inclined surface can cause danger.

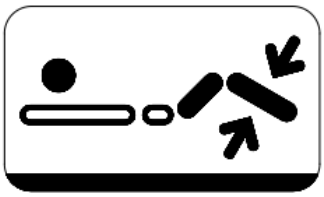
The central braking system can also be controlled with a single brake pedal. The pedals are located at the end of the base frame. When one pedal side marked with red is pressed down, the brakes are applied.

4.2.3 Leg section adjustment

⚠ WARNING

Make sure that nothing and nobody is between the leg rest and upper frame when you adjust the leg section (danger of crushing).

- Lift the leg section adjuster bar and use your free hand to adjust the leg section frame tube.
- All adjustments are made electrically by pressing the buttons on the hand-held control unit. Press the button of the function you desire. The selected function continues operating until you release the button or the outermost position is reached.



4.2.4 Trendelenburg and anti-Trendelenburg adjustment

⚠ WARNING

Turn the Trendelenburg adjuster handle and limit the bed mattress base by holding the bed frame tubing with your free hand.

⚠ WARNING

Danger of crushing between bed surface and lower frame when Trendelenburg or Anti-Trendelenburg adjustment is used. Make sure nothing or nobody is underneath the bed when using Trendelenburg/Anti-Trendelenburg -adjustment.

⚠ WARNING

Make sure that you return the bed to its horizontal position after Trendelenburg / anti- Trendelenburg position.

⚠ WARNING

Adjust the bed surface to the horizontal position before adjusting bed height. Never leave a patient unsupervised in Trendelenburg position.

⚠ WARNING

Be careful when making Trendelenburg or Anti-Trendelenburg adjustments. Patient's weight may tilt the bed.

⚠ WARNING

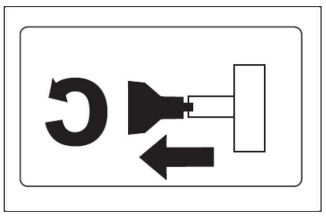
Make sure that no external object accidentally activates the device's control functions. For example, the CPR release handle on the back section may be accidentally activated if an air mattress cord or a rescue sheet strap gets caught on it.

- You can make Trendelenburg adjustments by controlling the bed tilt with the buttons of the hand-held control unit or mechanically by using the adjuster handle bar as a quick release.

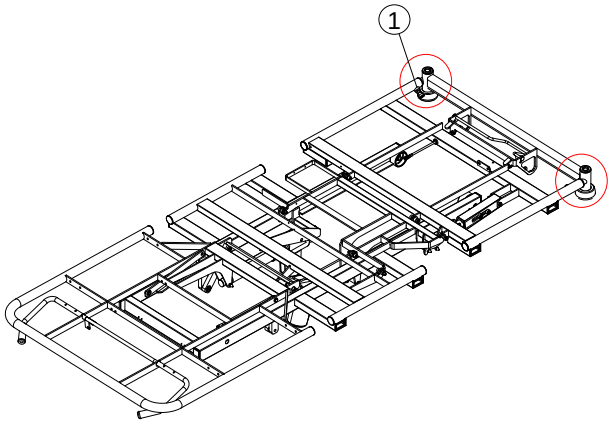
4.2.5 Extendable leg section

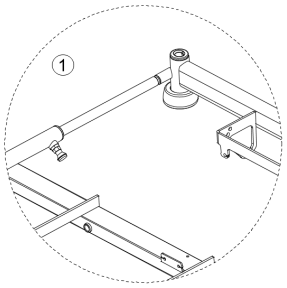
When adjusting the leg section to inner or outer position:

1. Pull out both index pins (1) and turn the knob 90° clockwise or anticlockwise to release the extension section.
2. Pull the leg section evenly out, and turn the pins back to the index slots.
3. Pull the extension section outwards until the pins lock into place.
4. Set the protective tray or protective ABS cover in place.



Index pin operation





⚠ CAUTION

When the leg section is in the outmost position, do not not sit on the extension section or place extra weight on it.

⚠ CAUTION

Make sure that both pins are locked in place when the leg section is either in inner or outer position.

⚠ CAUTION

The protective tray or protective ABS cover must always be in place when the extension section of the leg section is in use.

4.2.6 Hand control unit operation

⚠ WARNING

Prevent deliberate or accidental misuse of the hand control unit by placing the hand control unit out of reach of restless patients and children or by locking the movements of the bed from the nurse's control panel.

⚠ WARNING

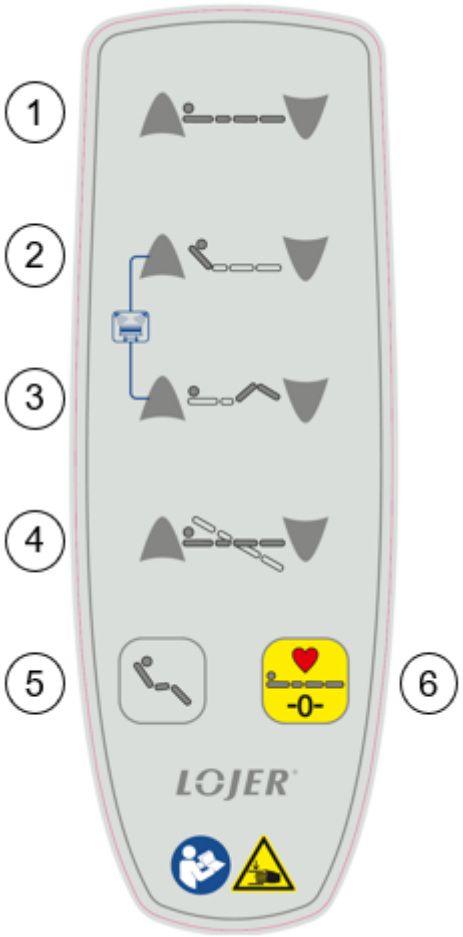
Release the push button of the hand control to stop any movement of the bed. In case of malfunction, press the push button of a reverse movement in the hand control or nurse's control board. The movement stops as long as the button is pushed. The movement of beds without a battery can be stopped by unplugging the bed's power cord.

⚠ WARNING

If the patient is allowed to use adjustment functions of the bed without supervision, the patient must be fully instructed in safe use of functions and patient's capacity to understand the functions must be ascertained.

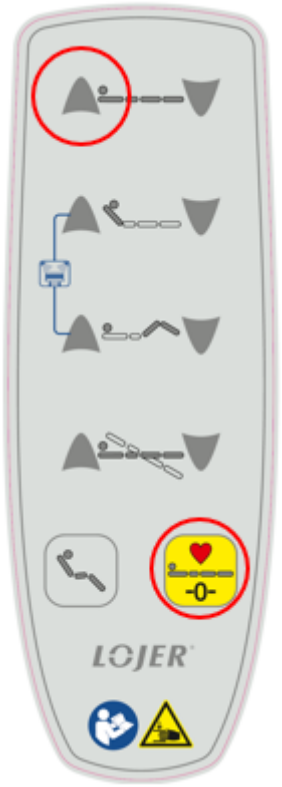
The hospital bed has a hand control unit and a optional control panel for adjusting functions. The hand control unit is intended primarily for use by the patient and nurse control panel by the nurse. The hand control unit has buttons for height adjustment, for lifting and lowering the thigh and leg parts. In addition, the hand control unit has a combination button for simultaneous adjustment of different parts, e. g. combined back and leg adjustment. The hand control unit also has an Anti-Trendelenburg and 0-position or CPR adjustment function. The 0-position or CPR function drives all the sections to the lowest position. The Anti-Trendelenburg adjustment inclines beds mattress surface. The hand control has no LED lights. The lights that indicate the charging or operating mode are located in the control panel. The controls have a hook that allows them to be hung on e.g. the bed's side rails or bed ends. The hand control has a hook that allows it to be hung on e.g. the bed's side rail or bed end.

Controls are shown below:



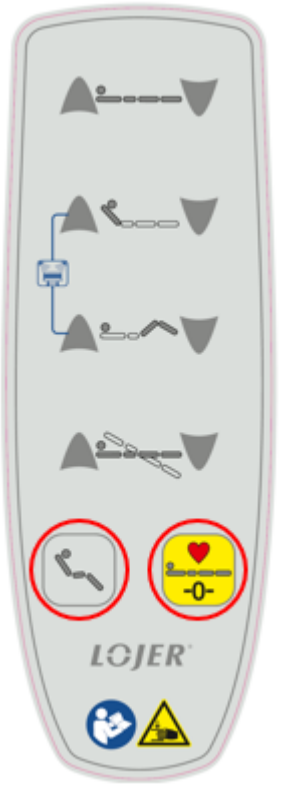
1	Height adjustment up/down
2	Back section adjustment up/down
3	Leg section adjustment up/down
4	Trendelenburg/Anti-Trendelenburg adjustment
5	Sitting position
6	CPR position (0 or zero function, all movement to down position)

To lock all movements, press the highlighted buttons simultaneously for five (5) seconds.



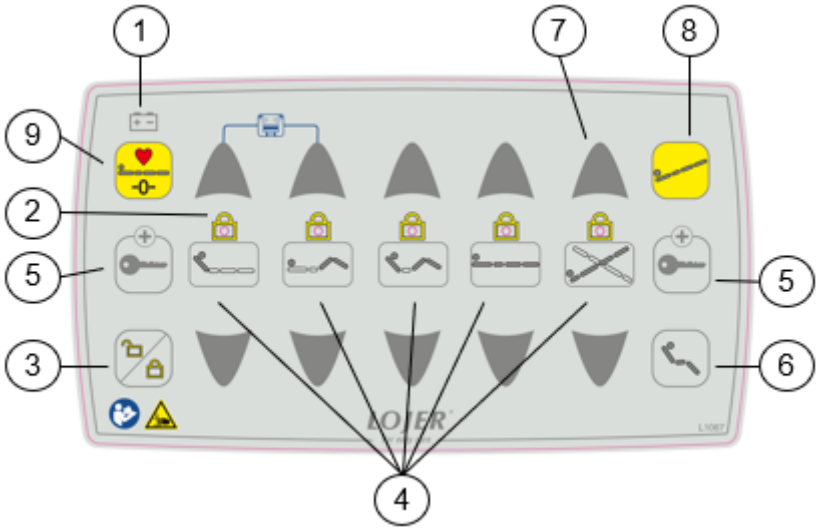
Note:

Trendelenburg adjustment is locked by default in the hand control unit for better patient safety. Lock and open the Trendelenburg adjustment by pressing the Trendelenburg and anti-Trendelenburg adjustment buttons simultaneously for five (5) seconds until a beep sound is heard.



4.2.7 Optional control devices

The nurse control panel is a separate control unit. It can be used like a hand control unit to control functions of the bed or, if necessary, to prevent functions made by hand control unit. The nurse control panel is located at the foot end of the bed. The control has a hook that allows it to be hung on the bed's bed end. The functions of the hand control can be blocked by locking the corresponding function in the operator control panel either individually or alternatively by locking all functions. The battery-powered models are supplied with control panel as standard equipment for safety reasons.



1 Battery indicator led (blinking: charging)

2 Locking status LED (on: functions locked on both controls, blinking: functions locked on hand control)

3 Locking/unlocking button (all adjustment functions)

4 Locking/unlocking of individual adjustment functions

5 Locking override (press with the desired movement button)

6 Sitting position (Fowler position, back- and leg rest up and tilting bed)

7 Direction buttons (push the arrow symbol above or below the movement symbol)

8 Trendelenburg

9 CPR position (0 or zero function, all movement to down position)

⚠ WARNING

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment (Lojer Oy.) can result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING

Carena Plus accessories ACO panel (Linak ACO516-00), Hand control unit (Linak HB8X327-00), lithium-ion Battery (Linak BA2116112110) and lead acid battery (Linak BA1916111100) can affect compliance of the ME Equipment or ME System with the requirements of Clause 7 (emissions) and Clause 8 (immunity).

4.3 Operating the battery

As an accessory, the beds can have a lithium-ion battery or a lead acid battery. The battery back-up is meant to be used only in emergencies, for example, when the mains power is not available during transfer of bed with a patient or during mains power supply failure. The duty cycle is 10% max. 2 min ON /18 min OFF.

The led light of the nurse control panel indicates the voltage level during use of the device. The blinking light indicates that battery capacity has decreased under 50 % of its full capacity. The battery gives a sound signal and stops the movement for a while when battery capacity is low. If the charge level is low , drive one movement at a time. Do not use hand control buttons which drive several movements simultaneously.

⚠ WARNING

Do not use bed functions daily only with battery power. Battery back-up use is intended only for emergency situations when there is no mains power is available. The bed must be connected to mains whenever possible. When the bed is connected to mains power, the battery charges automatically.

⚠ WARNING

Battery drains empty within few months after it is disconnected from mains. Always charge the battery, if the bed is intended to be kept in storage. Disconnect or recharge the battery if the storage time is more than six months.

⚠ WARNING

Beds equipped with a battery operate normally during power shutdown or when not connected to mains as long as there is power in the battery. With the nurse control panel you can lock the unwanted functions. Test to make sure functions are locked.

⚠ WARNING

Devices containing a lithium-ion battery must be transported in accordance with UN3481 and/or national regulations for the transport of dangerous goods (ADR).

⚠ WARNING

Batteries must be disposed of in an environmentally friendly manner at the appropriate facilities according national guidance and laws.

4.4 List of accessories

100009890	Bed end, detachable 80 cm*
A42179800	Bed end, detachable 85 cm*
100009990	Bed end, detachable 90 cm*
A41935200	Bed end collapsible detachable 80 cm*
A42179900	Bed end collapsible detachable 85 cm*
A41982900	Bed end collapsible detachable 90 cm*
A41974400	1-sect. foldable side rail chromed, Pair*
A41974400P	1-sect. foldable side rail RAL9006, Pair*
A42362500	3/4 Side rail, chromed, Pair*
A42362500P	3/4 Side rail, Painted RAL9006, Pair*
LX40332	1-sect. foldable side rail, X-ray, Pair*
A41884100	Lifting pole; tube, adapter, handle
A42066600	Lift support and hand control adapter*
A43242200	Mattress retention guide, grid base*
A41842500	Lift support
A41856300	5th wheel*
128009784	Journal basket
128009769	Monitor and utility tray
100000499, 60121	Infusion rod, 4 hooks
60122	Infusion rod, 4 hooks, bended
100000713	Infusion bag holder for lifting pole
100006675	Adapter for infusion rod
A42097900	Drainage bag holder (seat section)
128009790	Urine bottle holder
100005870	Oxygen bottle holder, 5 kg
100000701	Accessory rail
A41987307	Hook for electrical cable
A41988100	Potential equalisation system
A42968600	Attendant control panel Carena Plus
A41956301	Li-Ion Battery Carena Plus
R284BA19	Lead acid Battery Carena Plus

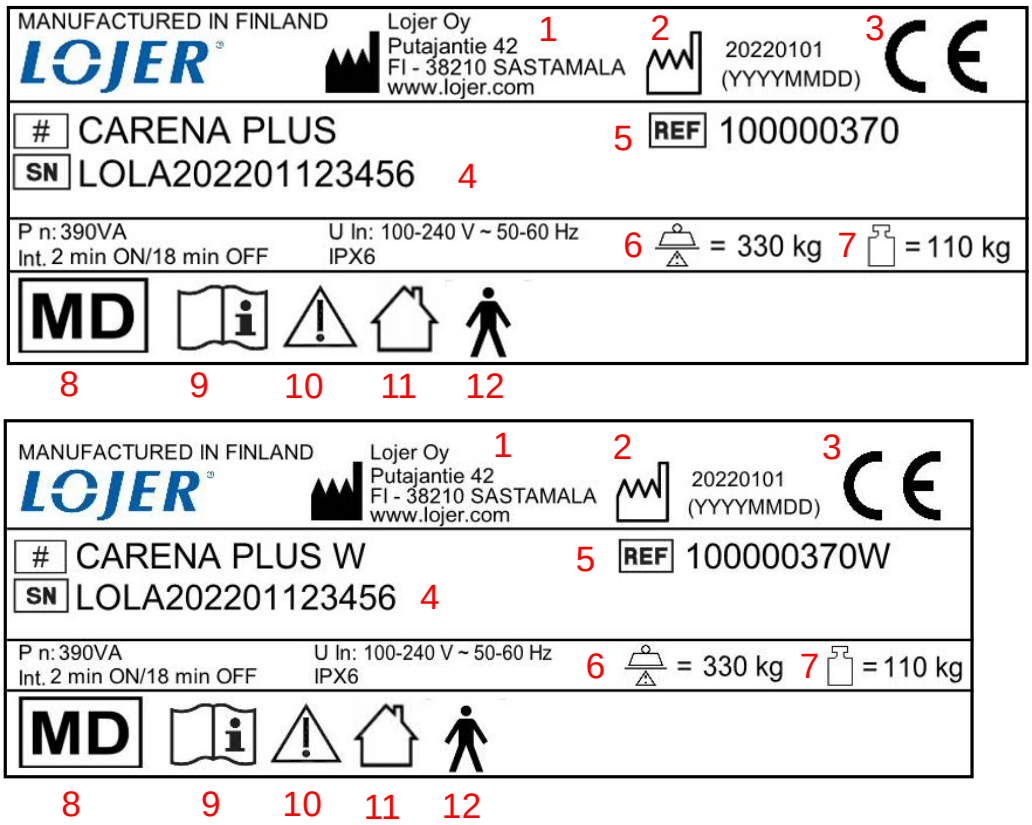
* Machine washable

5 Technical Data

5.1 Identification plates

The identification plate is located under the back section. Check the product information printed on the identification plate before use. Pictures on this page are for illustrative purposes only.

Figure 1. Identification plates of Carena hospital beds



1 Manufacturer
2 Date of manufacture
3 CE mark
4 SN Serial Number
5 Product catalogue number
6 Safe working load SWL
7 Weight of device

8 Medical device
9 Follow instructions for use
10 Caution
11 For indoor use
12 B type device

Note: Safe working load: SWL 330 kg

5.2 Labeling and symbols

	Equipotential bonding
	B-type applied part
	Follow instructions for use
	Maximum safe working load (includes patient, mattress and accessories.
CE	Marking in accordance with EU Medical Device Regulation 2017/745.

5.2.1 Symbols and label markings

Table 2. Packaging labels

	This way up
	Fragile
	Keep dry

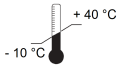
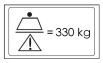
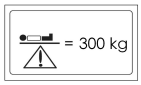
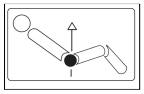
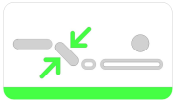
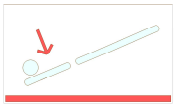
	Transport temperature
	Keep away from heat

Table 3. Labels used on the product

	Safe working load
	Maximum patient weight
	Incompatible mattresses can create hazards
	Incompatible side rails can create hazards
	Do not sit on top of the leg section when it is adjusted into an upward position. The maximum load is 150 kg per bed end if the load is directed only on to other bed end.
	Place the patient along the base observing the joints.
	Thigh section adjustment

	Manual Trendelenburg adjustment

5.3 Specifications

5.3.1 Environmental specifications

Table 4. Environmental specifications

Ambient temperature	+10 to +40 °C
Ambient pressure	700 to 1060 mbar
Relative humidity	30% to 75%
Transport temperature	- 10 to +40 °C
Storage temperature	+10 to +40 °C

5.3.2 Classification Data

⚠ WARNING

The safe working load (SWL) is the maximum allowed load including the patient, mattress and possible accessories. Overloading may cause a risk of serious injury.

Table 5. Classification data

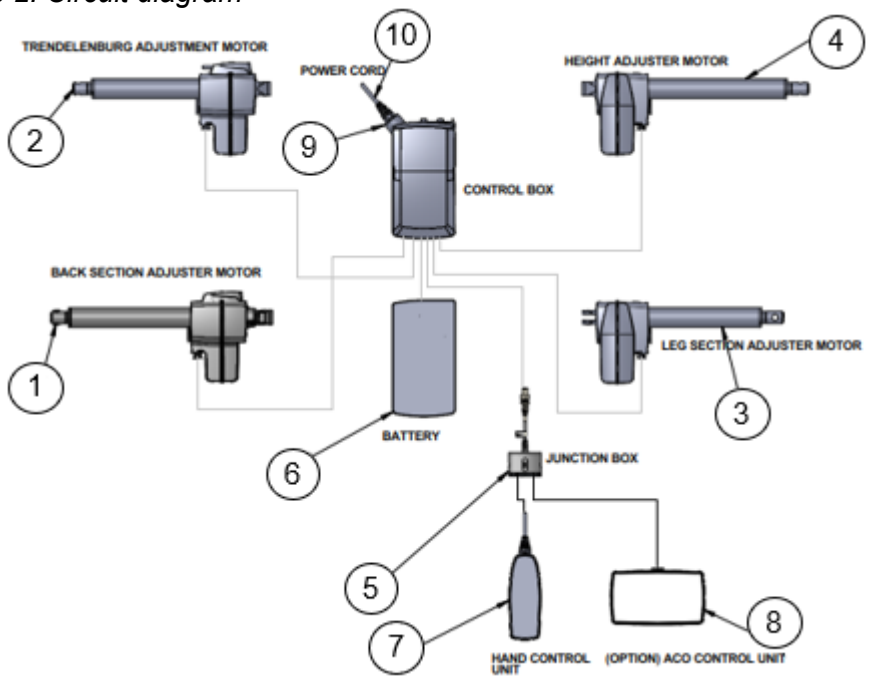
Electric shock protection	Class I equipment
Degree of electric protection	B-type
Enclosure class	IPX6 / IPX6 Washable
Cleaning and disinfecting	According to instructions in this manual
Maximum uninterrupted operating time	2 minutes/ 18 minutes (ED 10%)
Protection against flammable anaesthetic gases	Do not use with combustible gases
Safe working load (SWL)	330 kg (including patient, mattresses and accessories)
Maximum patient weight	300 kg
Maximum weight of accessories	45 kg (max. patient weight 265 kg if mattress weight 20 kg)
Maximum weight of mattress	20 kg
Expected life time	10 years

5.3.3 Electrical specifications

Table 6. Electrical specifications

Input voltage	100–240 V~
Frequency	50 or 60 Hz
Power input	390 VA
Battery pack (accessory)	2.1 Ah lithium-ion battery or 1.2 Ah lead acid battery
Output voltage	24 V ⎓
Maximum noise level	52 dB

Figure 2. Circuit diagram



Part number	Product code	Product name
1	R28471336227	Actuator, back section
2	R28471336228	Actuator, Trendelenburg
3	R28471336230	Actuator, leg section
4	R28471336229	Actuator, height
5	R284MJB2009	Modular junction box
6	R284BA21	Battery Li-ion BA21
7	R284HB85X	Hand control
8	R284ACOX	Nurse control panel
9	R284CO6	Control box
10	R284SML912367-C	Power cord

Control box channel	Part to be connected
1	Actuator, back section
2	Actuator, Trendelenburg

3	Actuator, leg section
4	Actuator, height
5	Modular junction box
6	Battery

5.3.4 Weights and dimensions

Table 7. Weights and dimensions

Mattress Dimensions (Width x Length x Height)	80 cm bed: 75 x 200 x 13 cm mattress; 85 cm bed: 80 x 200 x 13 cm mattress; 90 cm bed: 85–88 x 200 x 13 cm mattress
Mattress base	4–sectional
Weight kg	100–110 kg X-ray mattress base B = 80 cm + 18.5 kg and B = 90 cm + 20.5 kg
Length (A)	2154 mm (without corner rollers)
Width (B)	800 mm, 850 mm, or 900 mm, with bumper wheels = B + 100 mm
Height (C)	300 mm–928 mm (depending on the castor size and mattress base)
Lower leg section (D)	572 mm
Upper leg section (D)	315 mm
Seat (F)	239 mm
Back section (G)	900 mm
Lower frame length (H)	1200 mm (from center of the castor)
Lower frame width (I)	805 mm
Castors Ø	125/150/200 mm (closed and antistatic), and an optional 5th wheel
Ground clearance (J)	15.5-19.5 cm (depending on the castor size)

Figure 3. Basic dimensions

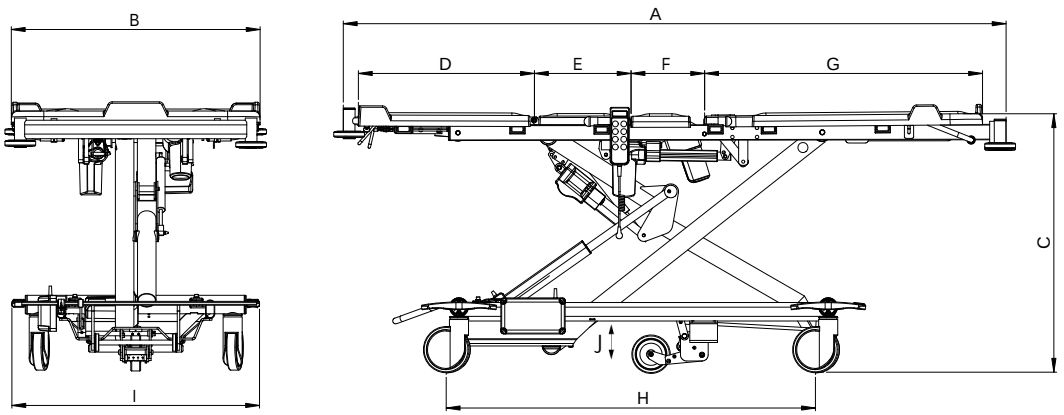
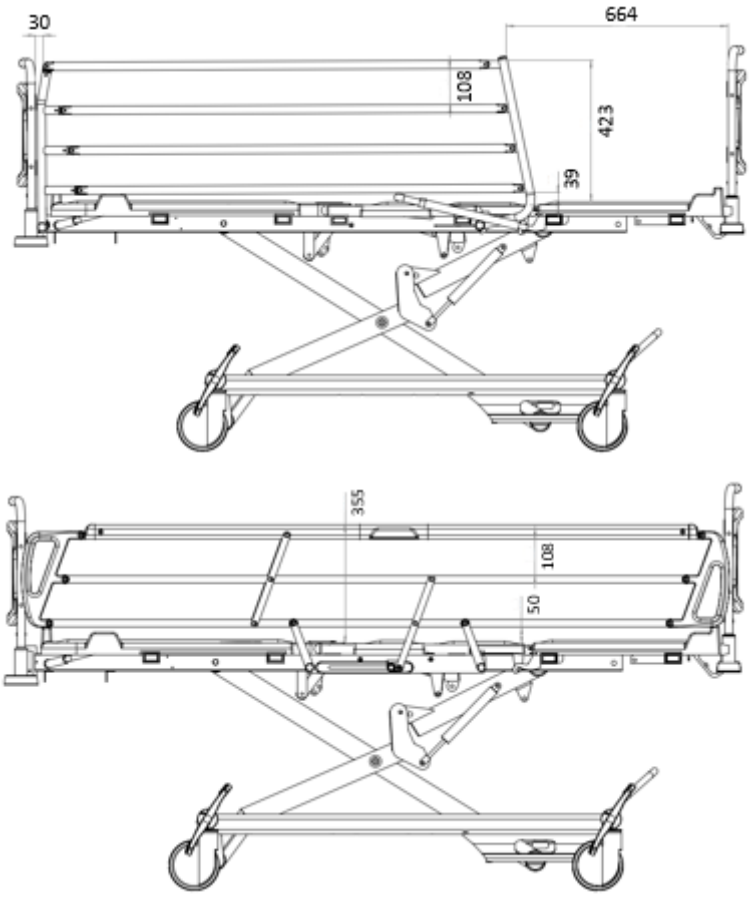


Figure 3. Basic dimentsions (continued)

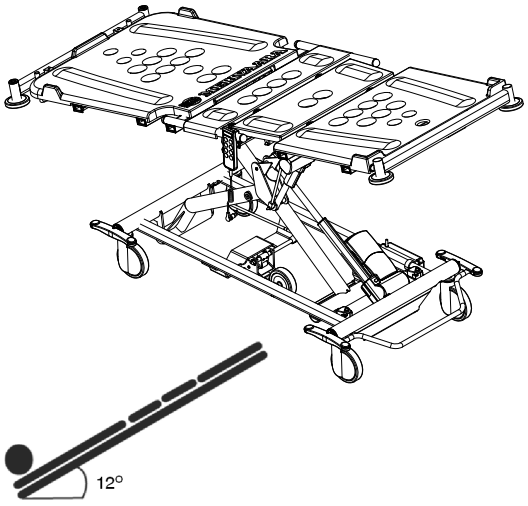


5.3.5 Surface materials

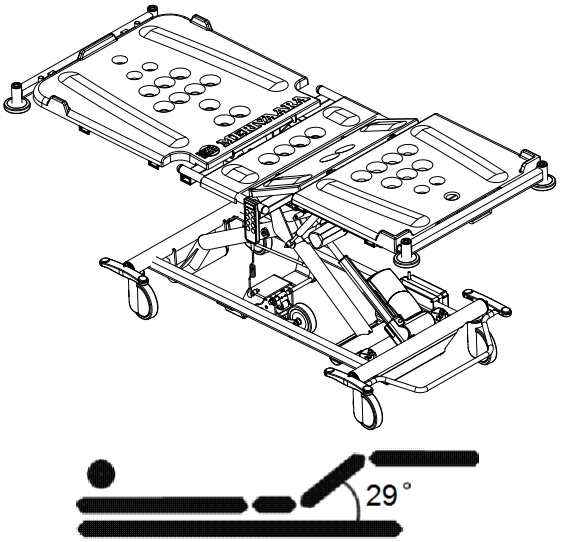
Table 8. Surface materials

Surface	Material
Frame parts	Epoxy-powder coat
Pedal bar, frame parts	Chroming
X-ray mattress base	Laminate
Bar links	ABS (acrylonitrile/butadiene/styrene)
Bumper rollers, rail mounting brackets	PP (polypropylene)
Actuators, control box	PC/ABS (polycarbonate)
Pedal pad	TPE (thermoplastic elastomer)
Hand-held control unit	PPE/HIPS (modified polyphenylene ether/ polystyrene)
Mattress base	ABS (acrylonitrile/butadiene/styrene) or galvanized steel or chromed steel

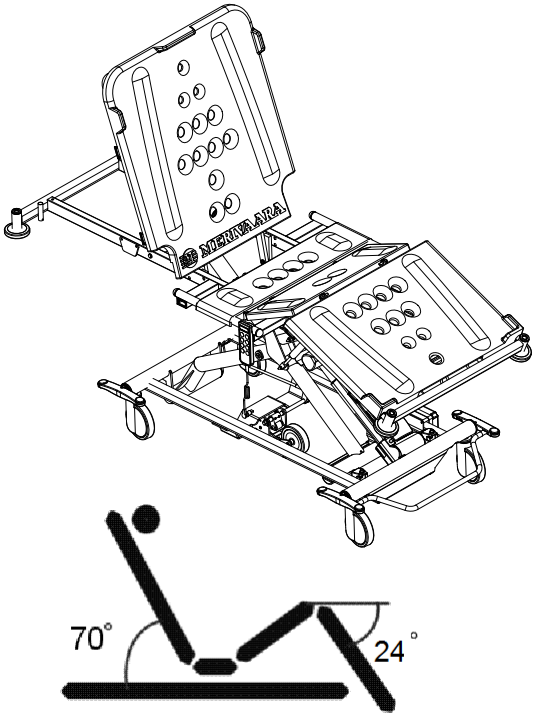
5.3.6 Adjustment ranges



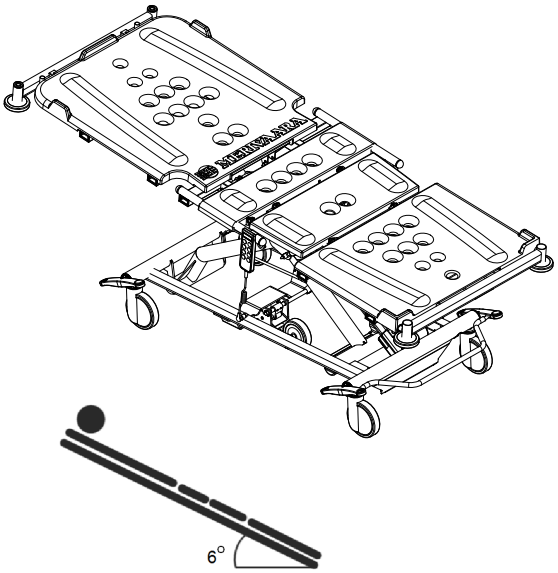
Trendelenburg adjustment



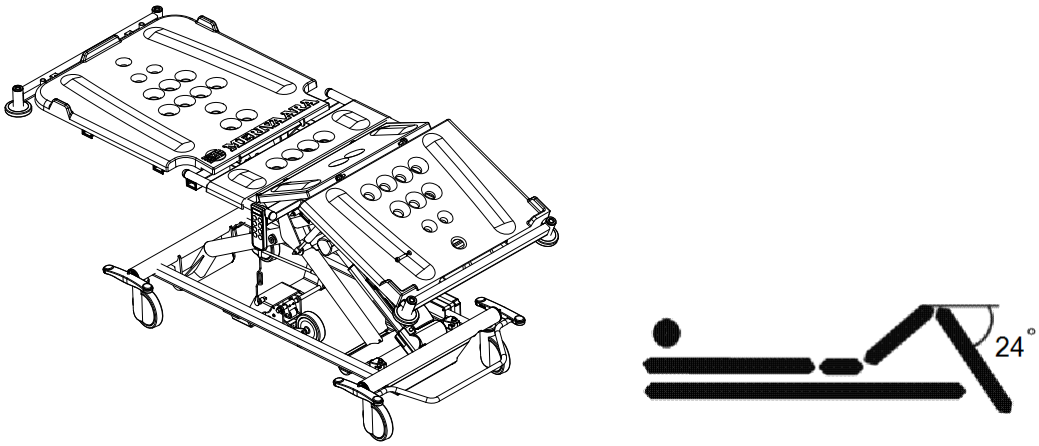
Leg section adjustment, lower leg horizontally set



Mattress base adjustment ranges



Anti-Trendelenburg adjustment



Leg section adjustment, lower leg in outermost position

6 Cleaning

6.1 Cleaning warnings and cautions

⚠ WARNING

Before starting cleaning or servicing, make sure that the power cord is disconnected and that the device's functions have been locked. Check by testing the functions.

⚠ WARNING

Devices equipped with a battery system can be adjusted even when the power cord is unplugged or during a power outage as long there is power in the batteries. The operations of the device may be prevented by locking the locking feature.

⚠ WARNING

All surfaces must be allowed to dry after cleaning or disinfecting before using the device or its accessories.

⚠ CAUTION

Clean the product as instructed before use.

⚠ CAUTION

Do not use any unsuitable cleaners or disinfectants for cleaning and disinfecting the device. See the instructions below. Follow the respective manufacturer's instructions.

⚠ CAUTION

Allow the surface of electric components to cool off before carrying out maintenance or cleaning procedures.

⚠ CAUTION

Avoid moisture entering the connection points. Excessive moisture can cause liquid pooling and damage the device.

⚠ CAUTION

Never wash the device with a water spray or mechanically or at high temperature or in high humidity if the device is not suitable for water/machine washing.

⚠ CAUTION

Disregarding of the guidelines presented in this user manual can result in loss of the product warranty.

6.2 Machine cleaning (only Carena Plus 370 W)

⚠ CAUTION

A maximum temperature of 85 °C must not be exceeded during a wash cycle. An excessively high wash temperature may cause plastic parts to become brittle and deform the bed materials. This can result in bed malfunctions.

⚠ CAUTION

During the washing, disinfection, and rinsing procedure the temperature of the bed must not exceed 70 °C.

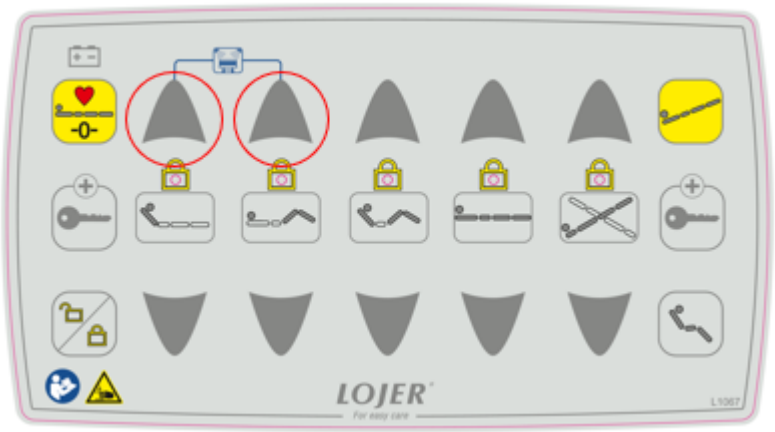
⚠ CAUTION

The pressure of the jet sprays inside the machine cleaning system must not exceed 5 to 8 bar.

The following washing procedure is recommended. The washing procedure is compliant with the IEC/EN 60601-2-52 (section 201.11.6.6.101 (b)) standard on machine-washable medical beds:

- 2 min. wash at 70 °C, using water with a pH of 5-8 and a detergent and disinfectant solution of 0.5%
- 20 sec. rinse at 85 °C, using water with a pH of 5-8 and a rinsing agent solution of 0.2%.

1. Remove the mattress and accessories unsuitable for machine washing before cleaning. Machine washable accessories are listed in the list of accessories.
2. Adjust the bed into the washing position from the hand control unit or nurse panel with pressing back- and leg section up until position is set and a beep sound is heard.



3. Put the main cord onto the bed.
4. Place the hand control unit onto the bed end frame.

The bed must cool down for 10-20 minutes after the machine washing before it can be used.

Always perform a start-up test after machine washing and check the condition of the power cable. Always allow the bed to dry thoroughly before returning it to use. If necessary, dry the bed carefully with a clean cloth.

Depending on the utilisation rate, machine washing decreases the service life of electrical components. Check replacement intervals for electrical components in the Carena maintenance manual DO1099.

⚠ WARNING

After washing, let the bed cool for at least 10 min. and shake the mains socket plug to make sure that there is no water left in the power cord plug before connecting to the wall socket (Danger of electric shock).

⚠ WARNING

Let the bed cool and dry it after washing before service, cleaning, or switching it off. Do not cover wet or damp beds. Note that bed surfaces are hot when the bed is moved from the washing chamber after wash,. Wear protective gloves (danger of burns).

6.3 Manual cleaning

Clean the device aseptically following the work order: From top to bottom and from clean-est to dirtiest. Take into account the following things when cleaning the device:

- The device cannot be machine washed (excluding Carena Plus 370 W).
- Clean stains and visible dirt as soon as possible.
  - Blood and secretion stains should be removed immediately after they appear.
  - Some substances used in care work may cause permanent stains.
- Make sure that the power cord is disconnected and that the device's functions have been locked.
- To guarantee successful cleaning, if necessary, remove the accessories of the device.
  - Remember to clean the accessories before reattaching or storing them.
- The surfaces shouldalways be cleaned before disinfection.
  - Follow the cleaning instructions given by the detergent manufacturers.
- In order to keep the surfaces in good condition, clean the device regularly.
  - Always clean the device between patients.
  - Take into consideration facility-specific the cleaning and disinfecting in-structions when cleaning the device.
- Any surface should not be subject to long-term exposure by any type of liquids.

6.3.1 Frame and other hard surfaces

- Clean all surfaces with a damp (micro)fiber cloth and a mild detergent solution (neutral pH 6–8 or weakly alkaline pH 8–10). Pay special attention to thorough cleaning of contact surfaces.
  - Do not use e.g. any solvents, abrasive cleanings agents or scouring pads as they can damage the surfaces.
- Use a soft brush to clean difficult stains, corners and other hard to reach places.
- Remove detergent residues or excess detergent by wiping the surfaces with a cloth dampened with clean water (follow the respective detergent manufacturer's instructions).
- Allow the surfaces to fully dry before using or storing the device

6.4 Disinfecting

The surfaces should always be cleaned before disinfection. Use disinfectant only if justified (e.g. to prevent the transmission of harmful microbes) as disinfection agents might change the surface structure of materials over time.
• Blood and urine stains should be removed immediately after they appear.
• Follow the disinfecting instructions given by the disinfectant manufacturers.
• Any surface should not be subject to long-term exposure by any type of liquids.

6.4.1 All surfacess

• Disinfect the surfaces with a damp (micro)fiber cloth, using disinfectants suitable for disinfecting medical devices, in accordance with the respective manufacturer's intended purpose and instructions for use.
    • For example, peroxygen or chlorine-based substances can be used to clean and disinfect secretion stains.
        • Clean and disinfect the device’s castors when they have been visibly contaminated.
• Allow the surfaces to fully dry before using or storing the device.

7 Maintenance and service

7.1 Safety during maintenance

Mark the date when the product has been taken into use next to the type plate of the bed or otherwise maintain and update records with trusted approvals from the Lojer Oy or a person who has authorization at the facility. The date will provide a reference for annual servicing. Remember to mark the bed with the date when performing the annual servicing, so that the following service date will not require a separate reminder. The annual maintenance procedures must be documented. Maintain the service records.

⚠ WARNING

Before starting service, make sure that the mains lead is disconnected and the functions have been locked. Check by using the hand control unit.

⚠ WARNING

If a bed has a battery system, the bed's adjustment functions operate even after the power cord has been unplugged or during power failure, if the battery has charge. If necessary, the functions of the bed can be locked by using the nurse control panel or disconnecting the battery supply cord.

⚠ WARNING

All electrical repairs must be performed by a licensed electrician.

⚠ WARNING

Maintenance allowed only to persons specialized to Carena service work.

⚠ CAUTION

Maintenance must be authorized by your sales representative or Lojer After Sales only.

⚠ CAUTION

Do not modify routing of cables or other components during maintenance procedures. Use recommended spare parts only.

⚠ CAUTION

The bed should be cleaned carefully after maintenance procedures.

⚠ CAUTION

Daily, monthly and annual maintenance and inspections are presented in user and maintenance manuals. If the instructions are not observed it may result damage to the equipment.

7.2 Daily inspection

- When you clean the bed, inspect the bed visually and check for any loose screws or parts, for example, accessory clamps, cracks, surface damage or missing parts.
- Fix the detected damage without delay. If the surface of electrical cables or components is damaged, replace the defective cord or component immediately.
- If the surface is damaged, treat the surface according to the instructions of the manufacturer to avoid general corrosion.

Machine washable Carena bed model

- Before machine wash, check that all protective caps of the bed are in place. Replace the missing caps immediately.
- When you clean the bed using a machine washer system, test the bed functions properly by fully extending and retracting all adjustments of the bed.

7.3 Monthly inspection

- Test the bed functions by fully extending and retracting all its adjustments. Make the necessary repairs and adjustments.
- Check the leads of the electrical components and the sound of the actuators.

7.4 Semi-annual inspection

- Start with the daily inspection routine and clean the bed. If necessary, make corrective measures.
- Lubricate the joints and cables.
- Visually check the bed for any leaks and stains.
- If the surface of electrical cables or components is damaged, replace the defective cord or component immediately.
- Check the bed functions properly by fully extending and retracting all the bed adjustments.

- If painted surfaces are damaged, touch-up paint the damaged areas according to the instructions of the manufacturer to avoid general corrosion.

7.5 Annual maintenance

⚠ CAUTION

Only trained service personnel is allowed to do annual maintenance work.

- Clean and lubricate all bed joints and quick release cables with light machine oil.
- Lubricate leg section guide rails by using a good quality lithium-soap grease of medium consistency and the type that is normally used for rolling element bearings.
- Check the condition of mattresses, side and guide rails, gas springs, release levers and cables. Adjust cables, if necessary.
- Check all bed functions by fully extending and retracting different sections.
- Check the conductivity of the electronic components' GND and grounding cables. The value must be less than 0.2 ohm.
- Replace gas springs and batteries every 5 years.
- Actuators' service life is 10 years at the maximum from the date of purchase.
- Inspection of battery
- Inspection of devices' warning labels

7.6 Contact information

Manufacturer

Lojer Oy

Putajantie 42

FI-38201 Sastamala

Tel. +358 10 830 6700

email: info@lojer.com

https://www.lojer.com

Service

Tel: +358 10 830 6750

email: service@lojer.com

Further information on service and spare parts is also available from your local Lojer dealer (refer to https://www.lojer.com/en/contact/distributors).

7.7 Troubleshooting

PROBLEM	CAUSE	PROCEDURE
The bed pulls to one side when moved pushing.	A castor is sticking or worn.	Check and replace the castor.
Mattress base angle adjustments do not remain in place.	• Faulty gas spring. • Gas spring is installed incorrectly.	Replace the gas spring.
Actuator does not work.	• Actuator connection has become loose	Re-connect to the control unit.
	• Hand-held control unit connection has become loose.	Re-connect to the control unit. Check the correct connection of equipment and connectors. The equipment and connectors are numbered in the Connection schematic section.
	• Mains cable out of socket or control unit.	Plug the mains cable back into the wall socket.
	• Distribution fuse blown	Contact Service. **NOTE!** Replacements can only be performed by an authorised service representative.
	• Faulty limit switch	Contact service
	• Faulty actuator (motor)	Contact service
	• Current limit of the control unit exceeded due to overloading of the actuator.	Only one person may be on the bed when running the actuator.
Hand control unit does not work.	• Hand control unit connection has become loose. • Faulty wire or hand-held control unit.	Re-connect to control unit. Contact service.
The function action does not correspond to the function button selected.	Actuator cords are incorrectly connected to the control box.	Re-connect the cables to the control unit in numerical order.

8 Guidance and manufacturer's declaration

8.1 Electromagnetic compatibility

This equipment has been tested according to IEC/EN 60601-1– 2 to ensure proper electromagnetic compatibility. Portable and mobile RF communications equipment can affect the equipment.

Other products used in the vicinity of this equipment should also comply with this standard.

This equipment may emit levels of EM energy that cause EMI in other devices in the vicinity, and the potential for RF emissions that affect other devices.

⚠ WARNING

Use of this equipment adjacent to or stacked with other equipment must be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment must be observed to verify that they are operating normally. The manufacturer of the ME Equipment or ME System may provide a description or list of equipment with which the ME Equipment or ME System has been tested in a stacked or adjacent configuration and with which stacked or adjacent use resulted in normal operation.

⚠ WARNING

Extremely strong EM disturbances may cause unintended movement of the equipment, also abnormal operation in indication lights may occur.

⚠ WARNING

Use the equipment only in facilities made for medical purposes equipped with electromagnetic environment specified in this guide. The customer or the user of this equipment must assure that these are used in such an environment.

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) must be used no closer than 30 cm (12 inches) to any part of the ME equipment or ME system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may result.

Note: The emissions characteristics of this equipment make it suitable for use industrial areas and hospitals (CISPR 11 class A). If it is used in residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and manufacturer's declaration - Electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	GROUP 1	The product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The product is suitable for use in all establishment other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 9. Electromagnetic immunity

Guidance and manufacturer's declaration - Electromagnetic immunity			
This bed is intended for use in the electromagnetic environment specified below. The customer or the user of the this product must assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601–1–2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air	The antistatic properties of the bed depend on the use of original mattress set and the use of conductive floor material.
Electrical fast transient/ burst immunity test IEC/EN 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	The quality of the mains power must be that of a typical hospital environment. The equipment is mainly operated with an internal battery.
Surge immunity test IEC/EN 61000-4-5	Line to line 1kV Line to ground 2 kV	Line to line 1kV Line to ground 2 kV	The quality of the mains power must be that of a typical hospital environment. The equipment is mainly operated with an internal battery.
Immunity to conducted disturbances, induced by radio-frequency fields IEC/EN 61000-4-6	0.15 - 80 MHz 3 Vrms	0.15 - 80 MHz 3 Vrms	Portable and mobile RF communications equipment can affect the bed and must be used no closer to any part of the bed, including cables, than the recommended separation distance, which is calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $E = \frac{6}{d}\sqrt{P}$ Where **P** is the maximum power in W **d** is the minimum separation distance in (m), and **E** is the IMMUNITY TEST LEVEL in V/m. Interference may occur in the vicinity of equipment marked with symbol: 
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Hospital bed can be used together with medical devices complying IEC/ EN 60601-1-2.

Table 9. Electromagnetic immunity (continued)

Guidance and manufacturer's declaration - Electromagnetic immunity			
Voltage dips, short interruptions and voltage variations immunity test IEC/ EN 61000-4-11	30% 500 ms 60% 100 ms 100% 10 ms 100% 5000 ms	30% 500 ms 60% 100 ms 100% 10 ms 100% 5000 ms	The quality of the mains power must be that of a typical hospital environment. The equipment is mainly operated with an internal battery.
a 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 must be considered. If the measured field strength in the location in which the Carena hospital bed is used exceeds the applicable RF compliance level above, the Carena hospital bed must be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Carena hospital bed. b Over the frequency range 150 kHz to 80 MHz, field strengths must be less than 3 V/m.			

Table 10. Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and hospital bed			
The bed is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the bed can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and bed as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1**: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

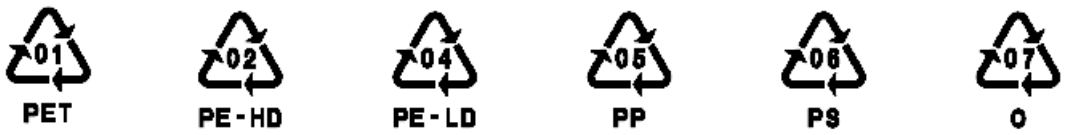
9 Recycling

9.1 Metals and plastics

When disposing of the product or replacing any of its parts, check the recyclability of each item. A majority of the metals are surface-treated and of stainless steel. In addition, aluminium is used as well as small quantities of aluminium bronze and zinc die-cast components.

When recycling plastic parts, determine the material type. Refer to the 5.3.5 Surface materials, page 31 to confirm whether or not recycling is possible. For more information about recycling, contact your local waste management facility or visit related sites on the internet.

Recycling symbols below are marked on parts that are made of plastic. Products marked with these symbols can be used as energy waste.



9.2 Gas springs

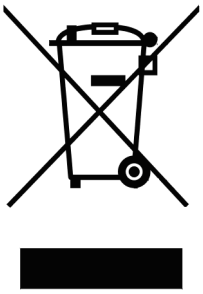
⚠ WARNING

Releasing of nitrogen gas is strictly prohibited! Recycle the gas springs according to your local recycling regulations. Dismantling is only allowed by a professional. Do not open – high pressure.

9.3 Electronic waste and batteries

Electronic components and devices must be disposed of according to local waste regulations.

The symbol below informs that the product contains electronic devices and cannot be disposed of with general waste. In such cases, the product must be separately disposed of; it cannot be included in municipal waste.



Note: Batteries need to be disposed of according to local waste regulations.

⚠ WARNING

Damaged batteries must be transported and disposed of as hazardous waste.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