BURMEIER

Instruction Manual

Heavy-duty bed

Gigant II

CE

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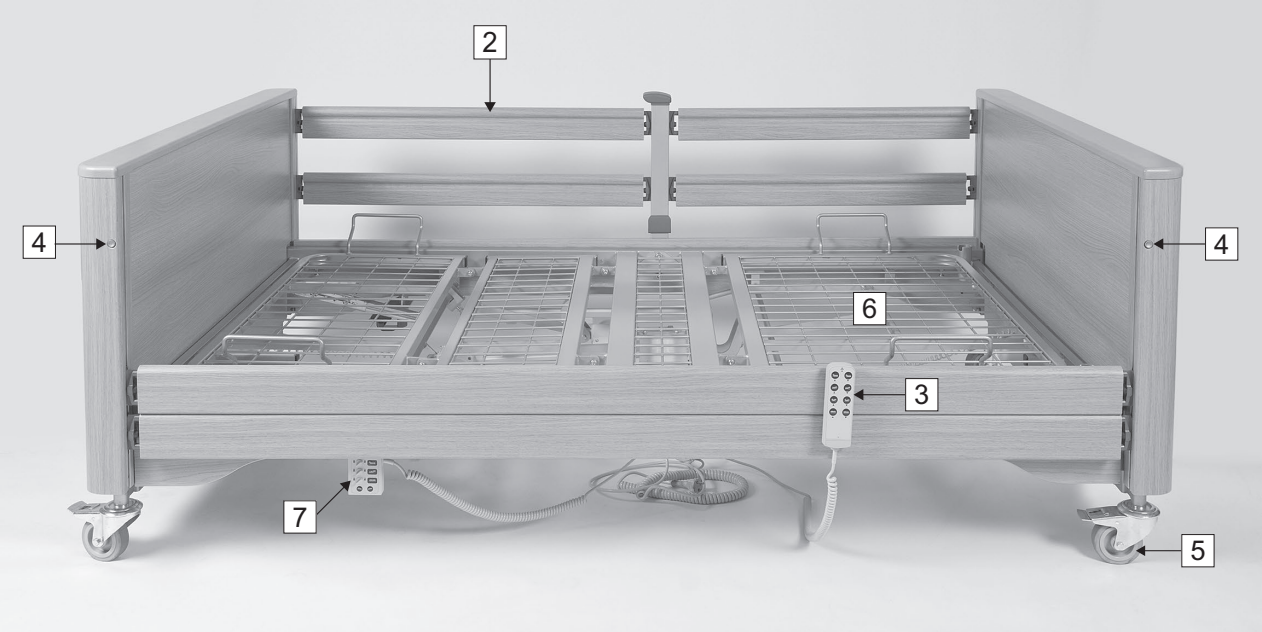
Instruction Manual for heavy-duty bed Gigant II



1	Patient lifting pole(not shown)
2	Safety sides (shown here with special combined safety sides)
3	Handset
4	Release lever for safety sides
5	Castor
6	Backrest
7	Control box
8	Operating lever for the emergency release mechanism of the backrest (not shown)

Advice

In this instruction manual, numbers which appear in square brackets **[ ]** and **bold** type refer to the heavy-duty bed's operating devices as shown in this illustration.

Contents

1 Foreword

Dear Customer,

Burmeier would like to thank you for the confidence you have placed in us and our products in deciding to purchase this heavy-duty bed Gigant II.

Each heavy-duty bed has been tested by the manufacturer for electrical safety and functionality and has left our factory in perfect condition.

This instruction manual informs you as the operator and your users about all the functions necessary to ensure ease of operation and safe handling of this heavy-duty bed on a daily basis.

You should, therefore, also regard this instruction manual as a practical reference book to be kept near the heavy-duty bed and at hand at all times.

We wish you and your users every success in care-giving. We are confident that this product enables us to play an important role in achieving just that.

Burmeier GmbH & Co. KG

Disclaimer

This product is not licensed for use on the North American market. This applies particularly to the United States of America. The distribution and use of the care bed in these markets, also via third parties, is forbidden by the manufacturer.

2 General Information


Advice

The heavy-duty bed Gigant II, hereafter referred to as the bed, the care bed or hospital bed, is manufactured in various models. This instruction manual has been issued for several bed models. It is possible that certain functions or features are described which are not incorporated in your bed.

Instructions for the Operator:

- This care bed fulfils all the requirements of the 93/42/EEC Medical Devices Directive and the latest safety standard DIN EN 60601-2-52:2010 for Medical Beds. It is classified as a class 1 active medical product in accordance with the Medical Products Act (*Medizinproduktegesetz*, German abbreviation: MPG) § 13.
- Please observe your obligations as the operator in accordance with the Medical Devices Operator Ordinance (*Medizinprodukte-Betreiberverordnung, German abbreviation:* MPBetreibV), in order to ensure the permanently safe operation of this medical device with no risk of danger to patients, users or third parties.
- Any item of technical equipment, electrical or otherwise, can prove hazardous if used improperly.
- Read through this instruction manual from start to finish so as to prevent any damage occurring due to incorrect operation.
- You are obligated to instruct users (see Chapter 2.1) in the proper use of this care or hospital bed in accordance with MPBetreibV § 5 (Medical Devices Operator Ordinance)!
- Ensure that users know where this instruction manual is kept, in accordance with the Medical Devices Operator Ordinance (MPBetreibV) § 9.

Instructions for the User:

- Before using a care or hospital bed, the user must check that the bed is fully functional and in perfect working order, and must observe the instructions in the manual in accordance with the Operators of Medical Products Ordinance (MPBetreibV) § 2. The same applies for accessories.
- Read through this instruction manual from start to finish so as to prevent any damage occurring due to incorrect operation.
- This instruction manual contains safety information which must be followed. All users working on and with the heavy-duty bed Gigant II model must be familiar with the contents of this instruction manual and follow the safety information provided.

Before using the care bed for the first time:

- Remove all transport securing devices and packaging film.
- Clean and disinfect the hospital bed prior to first-time use.

2.1 Definition of the Groups of Persons Involved

In this instruction manual, the following groups of persons are defined as:

Operator

Operators (e.g. clinics, hospitals, nursing home operators) are every natural and legal person with property rights to the Gigant II heavy-duty bed. The operator is responsible for the safe operation of this medical device.

Users

Users (e.g. specialist medical personnel, doctors, nurses, care staff etc.) are persons who, on the basis of their training, experience or through instruction, are entitled to operate this bed independently, to carry out work on it or have received instruction in the handling of this care bed. Furthermore, they can recognise and avoid potential dangers and assess the clinical condition of the occupant.

Occupant or patient

In this instruction manual, an occupant or patient is defined as a person who is infirm, ill or disabled and occupies this bed.

It is strongly recommended that the occupant or patient is instructed in the bed's functions important for him/her by the operator or user.

2.2 SAFETY INFORMATION

At the time of leaving the factory, this bed represents state-of-the-art technology and has been tested by an independent testing institute, commissioned on a voluntary basis. The most important objective of the safety information is to prevent personal injuries. Property damage is also to be avoided.

Only use the hospital bed if you are absolutely certain that it is in perfect working order!

2.2.1 Explanation of the safety symbols used

In this instruction manual, the following safety symbols are used:

Risk of injury to persons

This symbol indicates hazards due to electrical voltages. There is danger to life.

This symbol indicates general hazards. There is danger to life and health.

Risk of damage to property

This symbol indicates possible damages to property. It is possible that damages to the drive unit, material or the environment may occur.

Other advice

This symbol indicates a generally useful tip. If you follow it, you will find it easier to operate the bed. Moreover, this tip is provided for your better understanding.

The safety symbols used are not a substitute for the written safety information. Therefore read the safety information and follow the instructions precisely!

All persons who work on or with this bed must be familiar with the contents of this instruction manual and follow all the relevant safety advice.

2.2.2 Safety Information for the Operator

- In order to ensure the permanently safe operation of this medical device, with no risk to patients, occupants, users or third parties, you must observe your obligations in accordance with the Medical Devices Operator Ordinance (MPBetreibV)!
- Using this instruction manual, which must be provided with the bed, ensure that every user is instructed in the safe operation of this bed before using it for the first time.
- Draw every user's attention to the possible hazards that can arise if the bed is improperly used. This applies in particular to the use of electrical drives and side guards!
- If the hospital bed is in long-term use, test the functions and check for any visible damage (see Chapter 6.2) after a reasonable period of time (recommendation: once a year).
- Only permit persons who have been properly instructed to use this bed.
- Always make sure that your personnel is observing the safety instructions!
- Make sure that temporary staff is also sufficiently well instructed in the safe operation of this bed!
- If any other equipment is attached to the bed, (e.g. compressors for positioning systems, etc.), ensure that this is securely fastened and is functioning properly. Pay particular attention to:
  - safe routing of all loose connector cables, tubing, etc.
  - No multiple socket outlets are located under the bed (fire hazard due to penetrating fluids).
  - Chapter 2.3.1 Designated Use of this instruction manual.
    In the case of ambiguity, please consult the manufacturer of the additional equipment.

2.2.3 Safety Information for the User

- Ensure that the operator instructs you in the safe operation of this bed.
- Check each time before using the hospital bed to ensure that it is in perfect working order (see also Chapter 3.8).
- Ensure that no obstacles such as night tables, floor cable ducts or chairs could impede adjustments to the bed.
- If any other equipment is attached to the bed, (e.g. compressors for positioning systems, etc.), ensure that this is securely fastened and is functioning properly. Pay particular attention to:
  - safe routing of all loose connector cables, tubing, etc.
  - Multiple socket outlets which are placed loosely on the floor should not be used. These could lead to electrical hazards as a result of damaged mains cables or penetrating fluids.
    If you have any queries or concerns, consult the manufacturers of this equipment.
- If any damage or malfunction is suspected, take the bed out of service:
  - unplug immediately from the mains supply.
  - Indicate clearly that the bed is "Out of Order"
  - Report this immediately to the operator responsible

- Route the mains cable as well as all other cables in such a way that they cannot be pulled, driven over or damaged by moving parts when the bed is operated.
- Each time you wish to transport the bed, make sure that you unplug the mains plug first and place the mains cable in the existing mains cable holder to ensure that it will not fall off or trail on the floor.
- Do not place multiple socket outlets under the bed. This could cause electrical hazards due to damaged mains cables or penetrating fluids.
- Make sure that the mattress base has travelled to its lowest position before leaving the occupant unattended. In this way, you greatly reduce the risk of the occupant injuring himself/herself as a result of falling when getting in or out of bed.
- Always ensure that the castors are braked before leaving the patient unattended in the bed.
- When not in use, always stow the handset in such a way that it cannot fall off onto the floor (hang it on the hook). Make sure that the cable cannot be damaged by moving parts of the bed.

- In these cases, adjustments must only be performed by or in the presence of a trained person.
- Before carrying out any adjustments, make sure that there are no people, limbs or objects in the way, in order to avoid hazards due to trapping and/or damage to property. This applies particularly when mattress base sections are adjusted to a lower height.
- To safeguard the patient or occupant, and children in particular, against unintentional motorised adjustments, place the handset out of reach (e.g. at the foot end of the bed) or block the adjustment functions of the handset on the control panel, if:
  - the occupant or patient is unable to operate the bed safely or to free himself/herself from potentially dangerous situations;
  - the occupant or patient could be at risk due to inadvertent adjustments of the electric drives.
  - The safety sides are raised (danger that the occupant's limbs could be trapped when adjusting the backrest and thigh rest).
  - Children are left unsupervised in the room with the bed;
- At regular intervals, carry out a visual inspection of the mains cable to check for mechanical damage (scuffing, exposed wires, kinks, pressure points, etc.). Such a check should be performed:
  - whenever the cable has been subjected to any mechanical load, e.g. has been driven over by the bed itself or by an equipment trolley;
  - whenever the cable has been bent, stretched or violently pulled, e.g. due to the bed rolling away while it is still plugged into the wall socket.
  - Whenever the bed has been moved or relocated before plugging it back into the mains supply.
  - Regularly by the user when the bed is in constant operation, and at least once a week.
- Check the strain relief of the mains cable regularly to ensure that the screws are tight and secure.

The safety information found in this instruction manual must always be strictly observed!

2.3 PRODUCT DESCRIPTION

2.3.1 Designated Use

- This heavy-duty bed, hereafter referred to as the bed, is designed for occupancy by extremely overweight (obese) individuals.
- This bed was developed as a comfortable solution for infirm persons in need of care in homes for the elderly, as well as in nursing homes, comparable medical facilities and at home.
- The bed is designed for use during the diagnosis, treatment, alleviation and monitoring of illnesses or to compensate for injuries or disabilities. For detailed use instructions see Chapter 9.6.
- Use in hospitals is only permitted in rooms designed for medical treatment of the application group 0 (in accordance with VDE 0100 part 710, previously VDE 0107). This bed was not designed for any other usage!
- This bed can be used for occupant care under the instruction of a doctor and to assist with the diagnosis, treatment or observation of the occupant. It is therefore equipped with the option to block the handset.
- This bed is not suitable for occupants with a height of less than 150 cm or for children. Please refer to the safety information provided in Chapter 4.3.1and 4.4.2, especially in the case of occupants in poor clinical condition.

This bed may be operated without restrictions with a permanent maximum load of 350 kg (patient or occupant and accessories).

The permitted weight of the occupant depends on the total weight of the accessories attached at the same time (e.g. respirators, infusions,…)

Example:

Safe working load ➔	 **350 kg**
Weight of accessories (with mattress)	 **Maximum permissible occupant weight**
40 kg	310 kg
70 kg	280 kg

- This bed may be operated only by persons who have received instruction in its safe operation.
- This bed is suitable for repeated use. When reusing beds, pay attention to the necessary requirements:
  - Cleaning and Disinfection (see Chapter 5)
  - Maintenance / Repeat Inspections (see Chapter 6).

The heavy-duty bed Gigant II may only be used under the operating conditions described in this instruction manual. Its use for any other type of application is deemed to be contrary to the intended purpose.

Connecting the bed to the mains supply

This bed has no special connectors for potential equalisation. Please pay attention to this before connecting with additional mains-operated electrical (medical) equipment.

If necessary, further advice on additional protective measures can be found:

- in the instruction manuals of these additional mains-operated electrical devices (e.g. compressed air positioning systems, infusion pumps, enteral feeding devices ...)
- in the EN 60601-1-1 standard (Medical electrical equipment, General requirements for safety)
- in the VDE 0100 standard part 710 (previously VDE 0107) (*Starkstromanlagen in Krankenhäusern*, High Voltage Installations in Hospitals)

2.3.2 Special Features

- Bilateral safety sides
- Electronic mattress base height adjustment range from approx. 40 to 80 cm
- Electronic thigh rest adjustment range from 0° to approx. 26°
- Electronic back rest adjustment range from 0° to approx. 70°
- Electronic reverse-Trendelenburg position adjustment range of approx. 12° (requires a power connection for operation)
- Moves on four castors, each of which can be locked separately.
- Mattress base 200 x 120 cm, divided into four sections; external dimensions approx. 220 x 135 cm
- The head section is not removable
- Emergency backrest lowering mechanism

2.3.3 Structural Design

The bed is supplied disassembled to allow it to be transported into any room. It comprises a wooden headboard and footboard panel, a head section, a foot section, a mattress base frame, four side guards for the safety sides and a patient lifting pole with a handle. The bed features four castors, each of which is fitted with a locking brake (see overview Page 2).

Mattress base

The mattress base frame is divided into a backrest, a fixed middle section, a thigh rest and a lower leg rest. All of the rest sections are adjustable. The mattress base's height can be horizontally adjusted. All adjustments are performed by electric drives that are controlled from a handset.

Safety sides

The bed is fitted with continuous safety sides to protect the occupant or patient from accidentally falling out of bed. The safety sides can be raised and lowered in succession to protect the occupant while they are being raised and lowered.

Electrical Adjustment System

The bed's electrical adjustment system is initial fault-intolerant, flame retardant (V0) and comprises:

- the electronic control unit. The control unit generates, via a transformer, a 24 volt extra low voltage which is non-hazardous for patients and users. All electric motors, the handset and the control box, which work on this safe extra low voltage of 24 V, are connected to the central control unit.
- The electric motors for the backrest and the thigh rest.
- Two electrical motors for the height adjustment unit for the mattress base.
- A handset with a stable hook.

- A control box. The control box is the unit where the handset's adjustment functions can be disabled if required for patients in poor clinical condition.

2.3.4 Materials Used

For the most part, the bed was manufactured from steel profiles whose surfaces were finished with a polyester powder coating or a metal coating of zinc or chromium. The headboards and safety sides are wood or wood products whose surfaces have been finished.

All surfaces are recognised as being safe for contact with skin.

3 Assembly and putting into service

The bed is supplied disassembled and has to be assembled on site.

The bed is supplied in the following packaging units:

- Box 1: Mattress base with control unit (70 kg), 4 side guards (16 kg), patient lifting pole (5 kg), floor cable ducts, slider and assembly material.
- Box 2: Head and foot section with electric motors (40 kg)
- Box 3: Wooden headboard panel (14 kg)
- Box 4: Wooden headboard panel (14 kg)

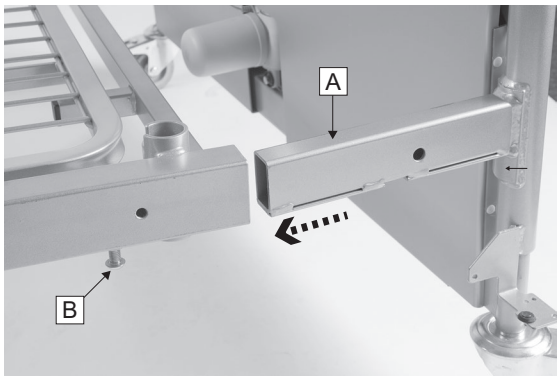
3.1 Assembling the bed

The assembly process for the bed requires two people.

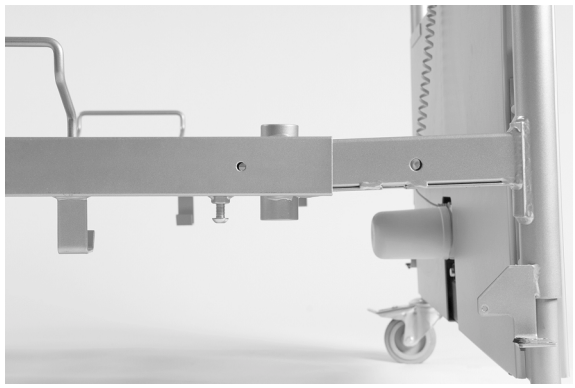
Required tools

- Phillips screwdriver, size 3
- Hexagon socket wrench, size 6

- Remove the protective foil from the cables.
- Open the brakes on all of the castors (see Chapter 4.1).
- Place the mattress base frame flat on the floor with the motors pointing down.
- Undo the two M10 x 20 mm screws at the head section of the mattress base **(B)**; hexagon socket wrench size 6.

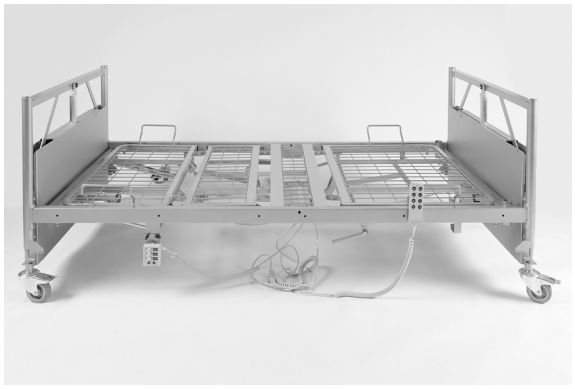


- Lift the mattress base frame at the head section and slide the retainers **(A)** on the head section into the mattress base frame.
- **Note:** The retainers on the head section are approx. 25 cm long.

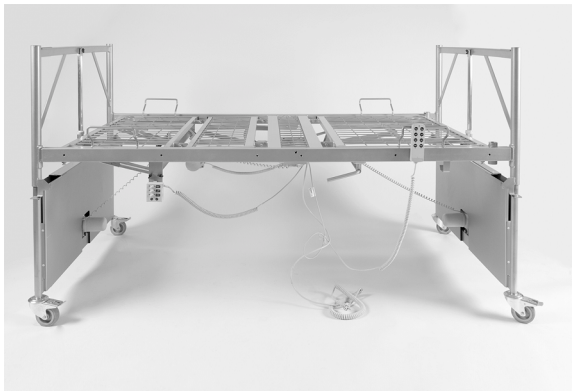


- **Note:** Do not slide the retainers fully in, but leave an approx. 5 cm gap.

- Repeat the above process with the foot section. The retainers on the foot section are approx. 42 cm long.
- **Note:** Do not slide the retainers fully in, but leave an approx. 5 cm gap.

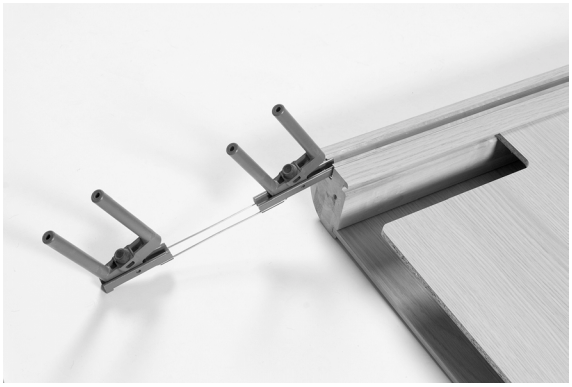


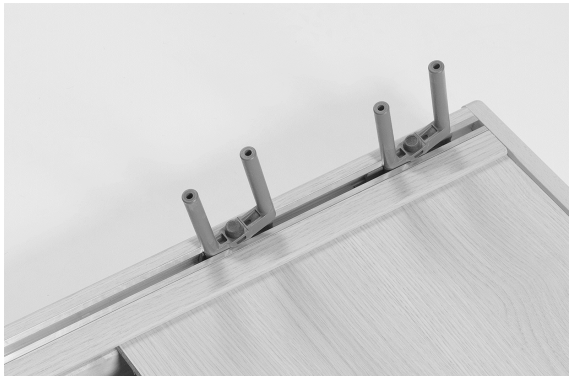
- Raise the bed to its highest position (see Chapter 3.2).



- The tips of the plastic sliders for the safety sides have to be pushed into the guide rails on the bed's head and footboard.

- Push the tips of the plastic sliders for the safety sides into the guide rails on the bed's head and footboard.



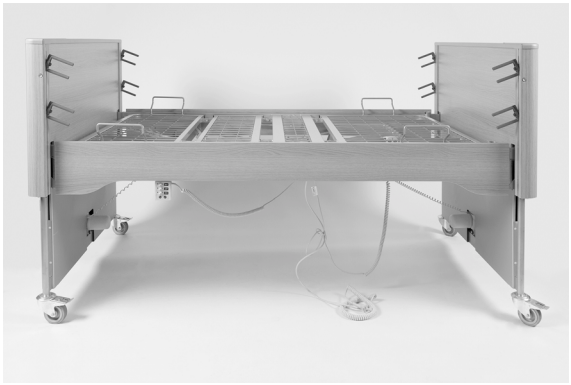


- Insert the end pieces into the guide rails on the bed's head and foot-board.

- Attach the head and footboard panels to the bed's head and foot section respectively and lower them until they reach their limit stops.
- When doing so, the guide rails for the safety sides must be pointing inwards.

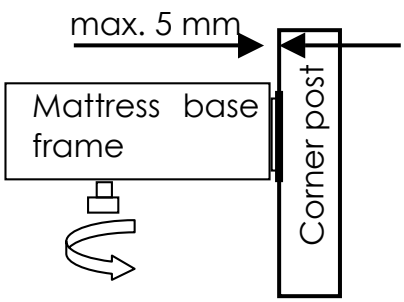
- Screw the head and footboard panels to the sections on the underside of each corner with the Phillips screwdriver.

- Place the wooden side panel against the bed.



- Screw the side panel to the mattress base frame.

- Push the corner posts and mattress base frame together.
- When doing so, make sure that the mattress base frame rests against the head section's corner posts.
- Tighten the M10 x 20 mm screws on both sides; hexagon socket wrench size 6.



- Screw the side panels to the corner posts.

3.2 ELECTRICAL CONNECTION

Warning

Always make sure that all plugs are fully and properly inserted into the control unit when connecting components. This is the only way to ensure a proper seal and faultless operation.

Always put the plug cover back into place on the control unit.

The motor and handset cable must be routed underneath the mattress base frame in such a way that they will not form coils or loops, and so that they cannot become trapped by moving parts.

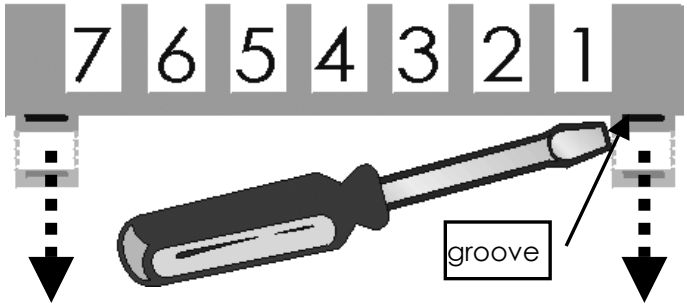
Please take extra care when positioning the mains cable, and make sure that it is outside the reach of moving parts and will not get caught underneath the castors when the bed is moved!

All of the plugs have to be connected to the control unit. To prevent the plugs from being inadvertently disconnected, they are protected with a plug cover.

- Carefully remove the plug cover using a screwdriver (see illustration below). To do so, insert the screwdriver first into one and then the other slot on the caps.
- Insert the plug for the head section's height adjustment motor into socket 3.
- Insert the plug for the foot section's height adjustment motor into socket 4.
- Put the plug cover on the control unit back into place.

Plug assignment of the control unit

- 1 = Backrest motor
- 2 = Thigh rest motor
- 3 = Head section height adjustment motor
- 4 = Foot section height adjustment motor
- 5 = Not assigned (blind plug)
- 6 = Handset
- 7 = Control box



3.3 FITTING THE SAFETY SIDES

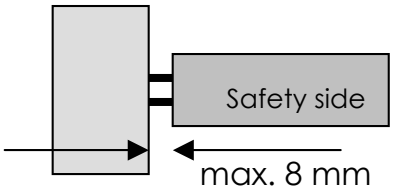
The bed's head and footboard panels are fitted with guide rails with plastic sliders for the safety sides.

To make fitting the safety sides as easy as possible, the head and footboard panels have to be pulled away from the mattress base frame by approx. 50 mm each (see page 20).

- Insert the rails at the foot end of the bed into the sliders. When doing so, the rounded area on the safety sides must point upwards.

- Now insert the rails at the other end (head end) of the bed into the sliders.
- Push the sliders at the head end with the safety sides attached to the guide rail up.

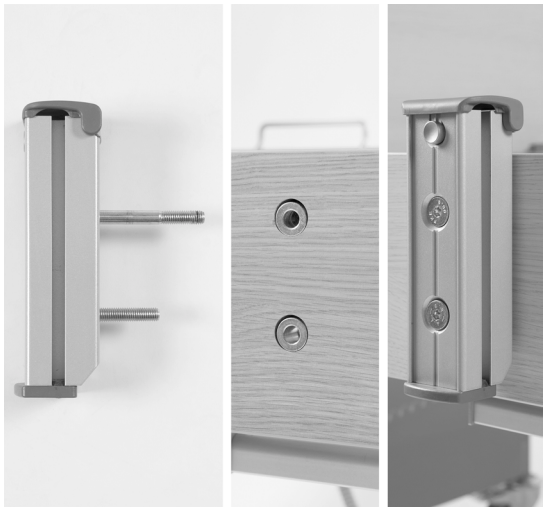
- Check the remaining gap between the end of the safety side and the guide rail: max. 8 mm
- If necessary, reduce this gap by pushing the corner post further into the mattress base frame (see Chapter 3.1).
- Fit the other safety side in the same way.



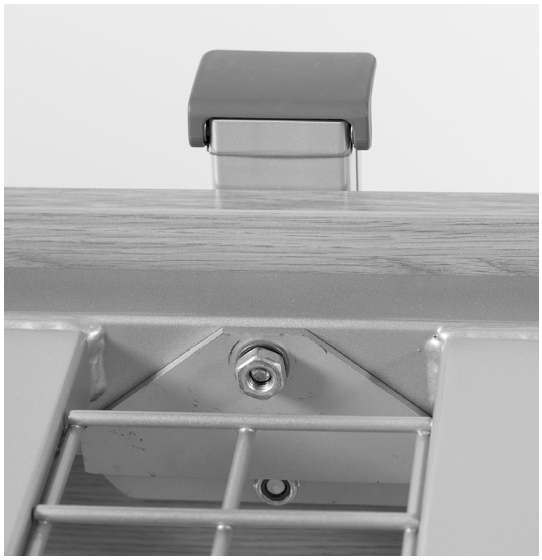
3.4 FITTING SPLIT SAFETY SIDES (OPTIONAL)

In order to enable patients to get into and out of the bed by themselves, it is also possible to fit the bed with a split safety side.

- Insert the holder into the retaining holes on the side panel.



- Screw the holder to the panel on the inside of the bed.



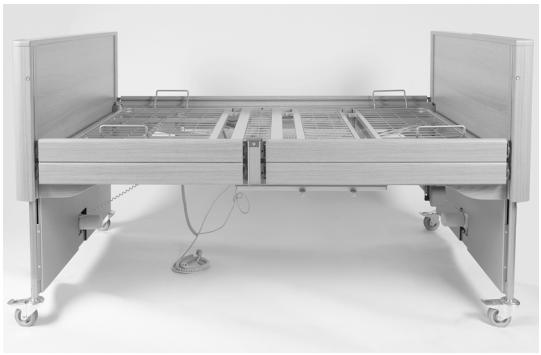
- Insert the decorative panel into the holder.

- Insert the plastic cover into the holder.

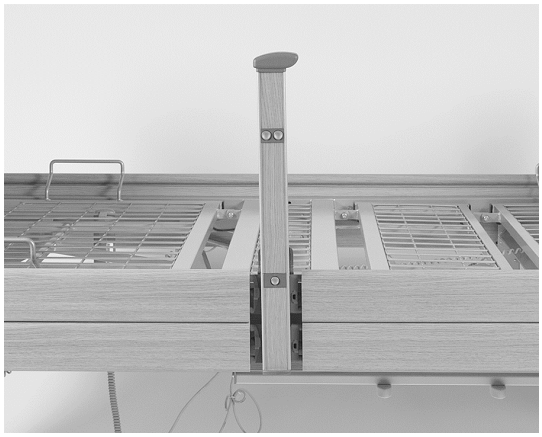
- Insert the shorter safety sides at the foot end of the bed into the sliders. When doing so, the rounded area on the safety sides must point upwards.

- Insert the plastic sliders on the other side of the rails.
- Insert the plastic sliders into the centre holder.

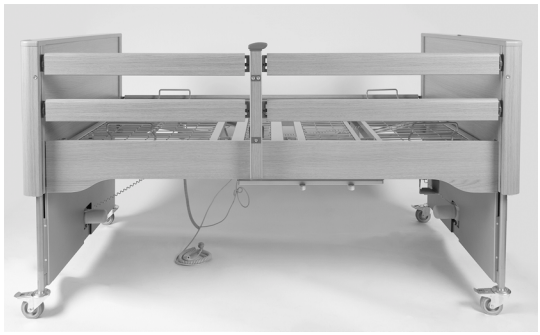
- Fully push the safety sides into the holder.
- Repeat these steps for the safety sides at the head end of the bed.



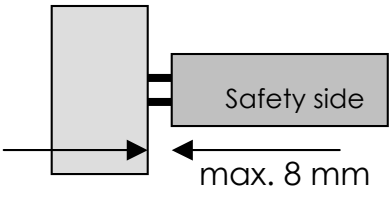
- Attach the top end of the centre post into the holder.



- Open the locking mechanisms,
- Pull all of the safety sides up.
- Make sure that all of the safety sides are locked again.



- Check the remaining gap between the end of the safety side and the guide rail: max. 8 mm
- If necessary, reduce this gap by pushing the corner post further into the mattress base frame (see Chapter 3.1).



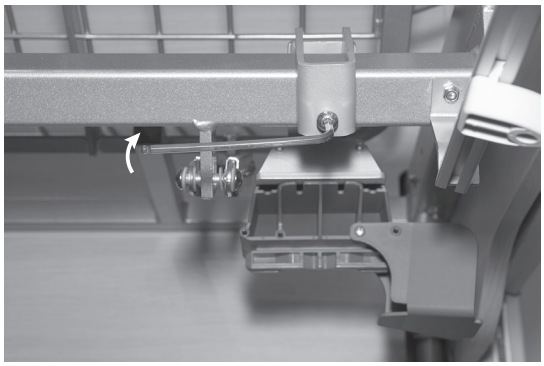
3.5 FITTING THE PARKING ELEMENT

- Adjust the bed to its highest position.

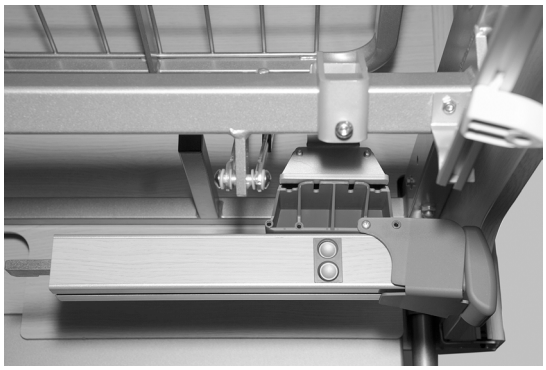
The parking element must be fitted on the same side as the split safety sides.

- Place the parking element on the cross beam at the foot end.

- Please note that:
  - The parking element must not collide with the rastomat.
  - The head of the inserted post must not protrude beyond the side element.
- Screw the parking element in place (5 mm Allen key).



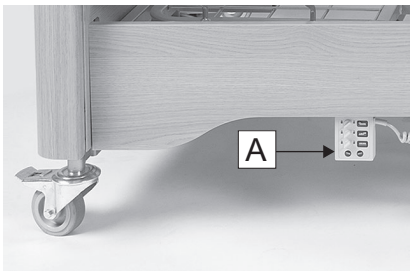
The protruding edge of the knob should be facing downwards when the post is in its correct parking position.



3.6 FITTING THE CONTROL BOX

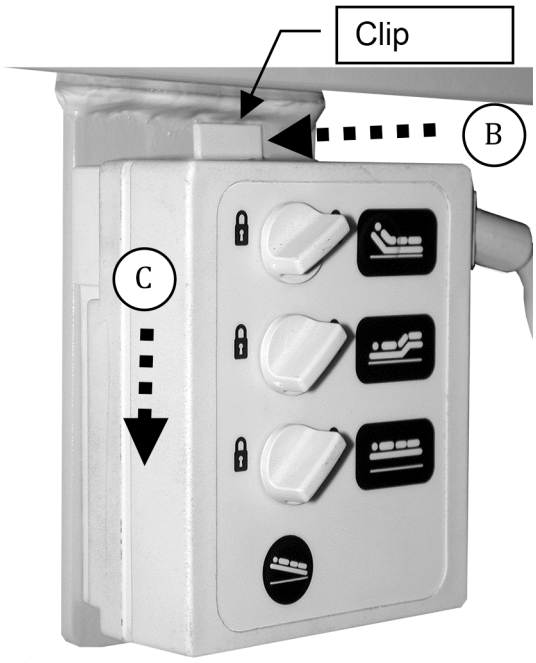
If considered necessary by the attending doctor in view of a patient's clinical condition, the bed's drives can also be individually locked on the control box **(A)** (see Chapter 4.2.3).

The control box **(A)** has to be fitted on the long side of the bed at the food end under the mattress base. The bed is fitted with corresponding holders in this area on both sides of the bed.



- The control box cable **(A)** must be routed underneath the mattress base in such a way that it cannot become trapped by moving parts.
- Push the control box **(A)** onto the holder on the mattress base frame.
- Test the control box's functions **(A)**.

Depending on local circumstances and requirements, the control box can be fitted both on the right or left side of the bed.



- Press on the clip **(B)** on the holder on the mattress base frame and push the control box downwards **(C)**.
- You will now be able to remove the control box and fit it on the other side of the bed.
- The control box cable must be routed underneath the mattress base in such a way that it cannot become trapped by moving parts.

3.7 STRAIN RELIEF OF MAINS CABLE

The strain relief for the mains cable is also located underneath the mattress base frame.

Always make sure that the strain relief is securely fastened and effective when fitting it.

3.8 CHECKLIST: INSPECTION PERFORMED BY THE USER

Type of inspection		ok	Not ok	Description of defect
Visual inspection of the electrical components				
Handset	Damage, foil			
Handset cable	Damage, routing of cable			
Mains cable	Damage, routing of cable			
Control box	Damage, foil			
Visual inspection of the mechanical components				
Patient lifting pole, location sleeves	Damage			
Bed frame	Damage, deformations			
Mattress base	Damage			
Wooden head & foot panels	Damage, splinters			
Safety sides	Damage, splinters			
Performance check of the electrical components				
Handset, locking functions	Functional test			
Control box	Function test, locking functions			
Performance check of the mechanical components				
Castors	Locking the brake, moving			
Emergency release of backrest	Test according to instruction manual			
Safety sides	Locking in place, release			
Lower leg rest	Engage			
Accessories (e.g. patient lifting pole, grab handle)	Fastening, damage			
Inspector's signature:	**Inspection results:**			**Date:**

If damage or a malfunction is suspected, the heavy-duty bed must be withdrawn from service immediately and disconnected from the mains supply until the defective parts have been repaired or replaced!
Report this immediately to the operator!

3.9 LOCATION REQUIREMENTS

- There must be sufficient room available to accommodate the bed's entire range of adjustments. Furniture, window sills, etc. must not impede adjustments.
- Before using the bed on parquet flooring, check whether the castors could leave marks on the parquet varnish. The bed can be used on tiles, carpet, linoleum or laminate flooring without causing any damage.
- To prevent dents to floor coverings, the substrate should comply with the recommendations of FEB (*Fachverband der Hersteller elastischer Bodenbeläge e.V.* = Association of Manufacturers of Resilient Floor Coverings) (Technical Information No. 3 - Maintaining the value of resilient floor coverings) (http://www.feb-ev.com).
- A properly installed 230 Volt mains socket must be available close (as close as possible) to the bed.
- If any other additional equipment is attached to the bed, (e.g. compressors for positioning systems, etc.), ensure that this is securely fastened and is functioning properly. Pay special attention here to the safe routing of all loose connector cables, tubing, etc. If you have any queries or concerns, consult the manufacturer of the additional equipment or Burmeier.

Minimise, as far as possible, the risk of fire due to external influences. Instruct users on these points:

- Use only flame-retardant mattresses and bedding if possible.
- Avoid smoking in bed, since the mattress and bedding used may not be resistant to smokers' accessories.
- Only use additional equipment (e.g. electric blankets) and other electrical devices (e.g. lamps, radios) that are in perfect working order!
  - Ensure that this equipment is used only for the purpose intended.
  - Ensure that this equipment is not inadvertently placed on or under the bedding (danger of overheating)!
- Avoid using extension cables or multiple socket bars under the bed (risk of fire due to penetrating fluids).
- Extension cables and/or multiple socket outlets should not be used at all.

3.10 PUTTING INTO SERVICE

No electrical measurements are necessary prior to putting this bed into service for the first time, since the bed has been tested by the manufacturer for electrical safety and functionality and left our factory in perfect condition.

Before putting the bed into service for the first time:

- Remove all transport securing devices and packaging film.
- Clean and disinfect the care bed.
- Once the bed has been assembled, all of its functions etc have to be inspected as specified in the checklist in chapter 3.8.

Each time, before putting the bed into service, the user must check that:

- the bed has been cleaned and disinfected.
- The castors are braked.
- The electricity supply is compatible with the bed (230 V A/C, 50/60 Hertz).
- The mains cable is connected and routed in such a way that it cannot be damaged.
- The mains cable, drive cables and handset cable cannot be damaged by moving parts of the bed;
- No obstacles such as night tables, floor cable ducts or chairs will inhibit adjustments.
- All of the bed's adjustment mechanisms work properly and have been checked (see Chapter 4.2 and 4.3).

The heavy-duty bed must only be put into operation once these checks have been carried out.

3.11 DISASSEMBLING THE BED

- Move the back and leg rests into a horizontal position.
- Lower the mattress base to approx. 50 cm over the floor.
- Unplug the mains plug from the socket.
- Remove the patient lifting pole.
- Remove the washers from under the cleats for the head and footboard.
- Remove first one and then the other safety side. To do so, slightly lift the safety sides up, press the release lever and then slowly lower them. Do not allow the safety sides to drop!
- Insert the sliders back into the guide rails.
- Remove the plug cover from the control unit.
- Unplug the plugs for the height adjustment motors from the control unit.
- Undo the screws on the head section and pull it out of the mattress base frame.
- Repeat the process with the foot section.
- Before transporting or moving the bed, screw back in all of the screws you previously undid and reattach the plug cover.

4 Operation

4.1 MOVING AND BRAKING THE BED

The bed is equipped with four castors **[5]**. Each of these castors can be individually locked (braked). The bed can also be moved when occupied.

- As a rule, always apply the brakes when the bed is not being moved.
- As a rule, always brake the bed when it is occupied and left unattended.
- Never position the bed on uneven ground when it is occupied. It is not permitted to position the bed on sloping surfaces, as the significantly greater load on the bed from the patients' weight might cause the brakes to slip.
- The bed must only be moved with the mattress base frame in its lowest position.
- The bed is not suitable for being moved often and over long distances outside the room in corridors, across thresholds or on very uneven ground.
- Each time before moving the bed, ensure that:
  - the mains cable cannot be stretched, driven over or damaged in any other way.
  - When moving the bed, the mains cable is always stowed in the designated mains cable holder and does not trail on the floor.
  - Cables, tubes or leads belonging to any other additional equipment that may be attached to the bed are sufficiently secured and cannot be damaged.

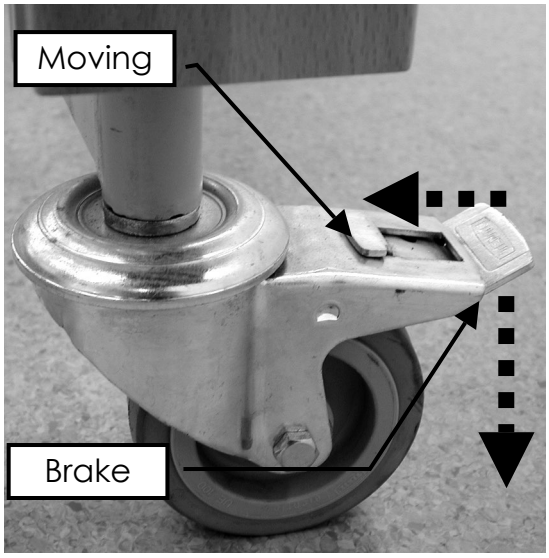
Otherwise, the mains cable could sustain damage as a result of being torn off, driven over or crushed. This damage could lead to electrical hazards and malfunctions.

When occupied by an overweight patient or occupant, the bed should only be moved inside the room it is located in. The bed should not generally be used to transport occupants over longer distances, along corridors and over ground sills.

To move the bed, each of the four castors have to be individually unlocked.

Moving the bed:
Push the foot lever up towards the bed with your foot.

Brake:
Push the foot lever down with your foot.



Warning

- In order to avoid toe injuries, wear closed shoes (and not sandals) when operating the bed.
- Make sure that at least three of the castors have their brakes applied.

4.2 Electrical Adjustment Options

4.2.1 Special Safety Information on the Electrical Adjustment System

Danger

- This heavy-duty bed must not be used in combination with high-frequency surgical equipment or in explosive environments!
- When using accessories:
  Make sure that any attached accessories will not produce any crushing or shearing zones when the bed sections are adjusted. If this cannot be ensured, the user must block the handset using the control panel or the control box!
- When making any adjustments, always make sure that this does not pose a hazard to patient, user, other persons', and especially playing children's limbs and that they will not become trapped underneath the rests or the mattress base.

- Ensure that no obstacles such as night tables, floor cable ducts or chairs could impede adjustments to the bed.
- Ensure that there are no objects on the undercarriage.
- When routing the handset cable, ensure that it can not be damaged by any moving parts of the bed.
- Ensure that the mains cable and handset cable cannot be driven over or otherwise crushed when the bed is moved.

- Electrical adjustments are only possible when the bed is properly connected to the mains supply.
- Continuous operation must not exceed two minutes! After this time, a rest period of at least 18 minutes must be observed. (Alternative: one minute continuous operation followed by a nine minute rest period, etc.)
- When the load is too high, an electronic overload switch is activated and the control unit is automatically switched off. Once the cause of the overload has been removed, the drive unit system will operate again as normal.
- In the case of malfunctions, an electronic overload switch deactivates the drives in order to protect the control unit and motor. Once the malfunction has been remedied, adjustments are once again possible via the handset.
- For safety reasons, if the maximum operation time is purposely disregarded, a thermal safety device will permanently cut off the power supply to prevent the drive unit system from overheating due to continuous operation.
- The adjustment range for all functions is electrically / mechanically limited to the permitted ranges.

As electromedical equipment, this bed is subject to special safety procedures with respect to electromagnetic compatibility (EMC).

For this reason, observe the following instructions when installing and operating the bed:

- Portable and mobile high-frequency communication devices (e.g. cordless telephones, mobile telephones, baby monitors, Wifi, radios, etc.) can influence the operation of electromedical equipment. These influences have been minimised by means of the robust, interference-resistant design of the electrical adjustment features of this bed.

- As with every electrical device, even if all the specified

EMC limiting values are observed during operation, disruptions from and to other nearby high-frequency communication devices cannot be completely ruled out (e.g. "crackling" in a radio).
In such rare cases, increase the distance between the devices or align them differently, and make sure that they do not use the same electrical outlet, or switch the disruptive/disrupted device off temporarily.

Use of defibrillators

This hospital bed is defibrillation-proof even without a potential equalisation connection. Observe the information contained in the instruction manuals of the defibrillators as well.

Please note that it is not possible to remove the bed's head section in the event the bed's occupant is being resuscitated.

4.2.2 Handset

The bed's electrical adjustment mechanisms can be controlled with the handset **[3]**.

The adjustment range for all functions is electrically / mechanically limited to the permitted ranges.

The bed can only be adjusted when the LED on the handset is orange.

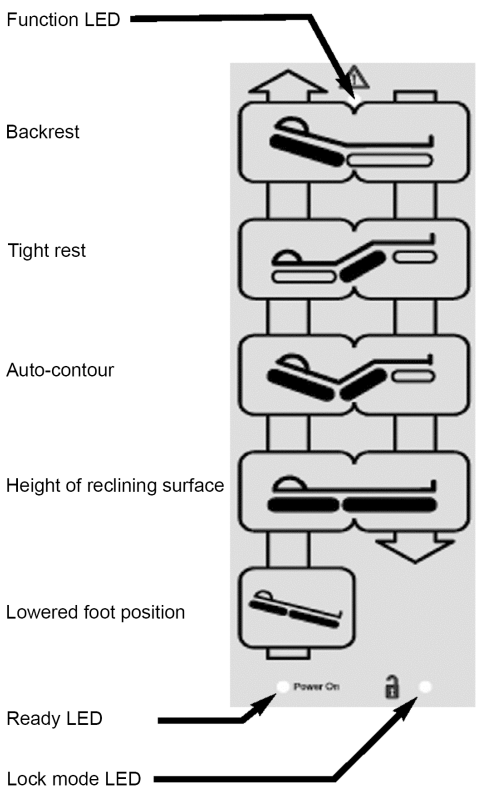
For safety reasons, the handset features a number of locking functions. These locking functions can be used to lock the handset functions and prevent the bed from being adjusted to protect patients' in poor clinical condition.

The handset and control box are connected to one another. This means that it is only possible to use the adjustment functions on the handset if the corresponding function is activated on the control box.

- The handset can be hung on the bed with its elastic hook.
- The spiral cable allows for a maximum freedom of movement.
- The handset is waterproof and washable (IP 66).

Using the handset

- Explain the handset functions to the patient!
- The electric motors will operate for as long as the corresponding button is kept being pressed. The green LED on the handset will light up when the drive motor is operating.
- Any of the motors will only operate if the corresponding function has been enabled on the control box.
- With the exception of the reverse-Trendelenburg position, all of the bed's adjustment options work in both directions.



The following basic rule applies to the keys:

raise

lower

Adjusting the backrest

This button can be used to change the backrest's level of elevation.

Adjusting the thigh rest

This button can be used to change the thigh rest's level of elevation.

Activating the Autocontour function

This button can be used to simultaneously change the backrest's and thigh rest's level of elevation. Using this function will prevent the patient from sliding down the bed to the foot section.

Adjusting the mattress base height

This button can be used to change the mattress base's height.

If the bed is in the reverse-Trendelenburg position, this function will automatically cause the mattress base to move into a horizontal position when it is moved into its lowest or highest position.

Adjusting the reverse-Trendelenburg position

Pressing this button will move the mattress base into the reverse-Trendelenburg position
. This button can only be used to activate the "Lower" ▼ function.

If the bed is in the reverse-Trendelenburg position, this function will automatically cause the mattress base to move into a horizontal position when it is moved into its lowest or highest position.

- Always unlock the brakes on the two castors at the head and foot section before moving the bed into the reverse-Trendelenburg position to protect the floor from potential damage.

Locking function, sensor area for magnetic key

Warning

The handset must be kept away from magnetic objects and strong magnetic fields at all times.

Failure to do so might cause the locking function to be unintentionally activated or deactivated.

Advice

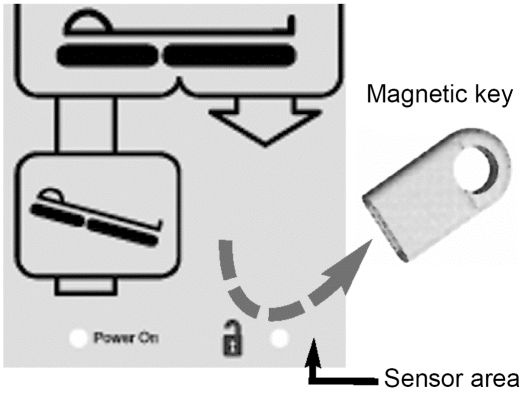
The locking function will be automatically activated again after incidences such as a power cut or change in location.

Move the magnetic key over the sensor area. It is only possible to adjust the bed if the mode LED is green.

If the locking mode LED **is not lit up**, all of the adjustment functions are locked.

If the locking mode LED **is green**, all of the adjustment functions are enabled.

If the looking mode LED is *orange*, all of the adjustment functions will be enabled for 40 seconds only. If the bed is adjusted during this 40 second window, the locking function will be activated again once the adjustment is complete.

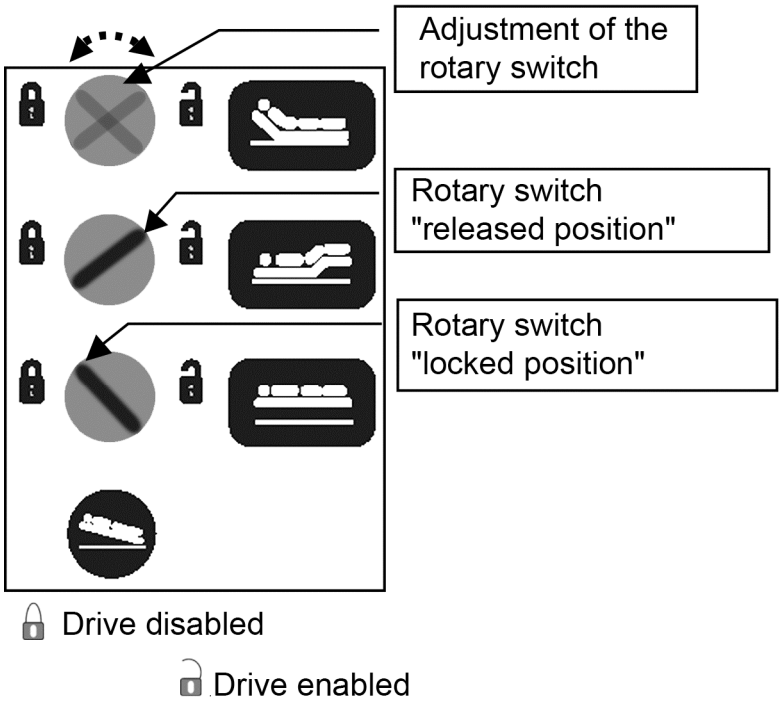


4.2.3 Control box

Since this bed is suitable for occupancy by a patient undergoing medical treatment or care and may be used during diagnostic and treatment procedures and for monitoring purposes, it has been fitted with a control box for controlling its electronic adjustment functions.

The control box is attached to the bed on its long side at the foot end, underneath the mattress base and outside the patient's reach.

- The control box must only be used by authorised users!
- It is only possible to use the handset to adjust the bed electronically if the corresponding rotary switch is set to *Unlocked*.
- If the rotary switch is set to *Locked*, the unit will emit an alarm sound if a corresponding button is pressed on the handset.
- The rotary switch must always be turned up to the limit stop.
- The relevant lock must always be checked by pressing the corresponding button on the handset!



•

Locking the backrest

Set the rotary switch to 🔒: When using the Autocontour button on the handset, only the thigh rest will be active.

Locking the thigh rest

Set the rotary switch to 🔒: When using the Autocontour button on the handset, only the backrest will be active.

Locking the mattress base heigh adjustment function

Set the rotary switch to 🔒: When this function is locked, the reverse-Trendelenburg position and Trendelenburg position will also be locked.

Adjusting the Reverse-Trendelenburg position

Pressing this button will move the mattress base into the reverse Trendelenburg position. If the mattress base is at its lowest position, pressing this button will raise the head section.

Always unlock the brakes on the castors at the foot section before activating this function to avoid damaging the floor covering.

- The mattress base must only be moved into the Trendelenburg position on the instruction of a doctor or specialist medical personnel and where required for treatment.
- Improper or inappropriate use of this position can put patients at risk.
- It is only possible to move the bed into these positions if the bed is connected to the mains power supply.

4.2.4 Emergency release of backrest

In the event of power supply outages or electrical drive system failures, the raised backrest can be lowered by hand.

Pictogram on operating lever **[9]**

- The backrest must only lowered if all of the brakes on the castors are braked.
- Take hold of the backrest's frame with one hand.
- Use your other hand to pull the operating lever **[9]** for emergency lowering upwards. Doing so will cause the backrest motor to decouple.
- The backrest can now be lowered.
  The backrest will only be held in position when the operating lever is released.
- If the bed's operation has returned to normal after the emergency backrest lower (power supply has been restored), it can be adjusted with the handset again.

Advice

- Since the backrest is electronically adjustable, the operating lever **[9]** is only designed for lowering the backrest in an emergency and not for permanent use!
- In contrast to normal care beds, the head section of this heavy-duty bed cannot be removed. This factor always has to be taken into account when assigning the bed to a patient.

4.3 MECHANICAL ADJUSTMENT OPTIONS

- In order to avoid damage, ensure that no obstacles such as furniture or sloped ceilings could impede adjustments to the bed, which could result in damage.
- When making any adjustments, always make sure that this does not pose a hazard to patient, user, other persons', and especially playing children's limbs and that will not become trapped underneath the rests or the mattress base.

4.3.1 Lower leg rest

The lower leg rest is fitted with two adjustable telescopic fittings (Rastomat), that allow the lower leg rest to be individually inclined. This way an orthopaedic position (stepped bed with legs bent and raised), a sloping position of the lower leg rest or an outstretched and raised position of the legs can be achieved.

When occupied by a person, the lower leg rest must always be adjusted by two people

Raising the rest by hand

The lower leg rest can only be activated if the thigh rest is activated.

- Raise the lower leg rest by evenly pulling it up by the two rounded corners of the frame - as opposed to the mattress retainer - until it reaches the required position.
- When doing so, the action is only complete when the lower leg rest engages on both sides of the bed on its own.

Lowering the rest by hand

- Slightly raise the lower leg rest by evenly pulling it up by the two rounded corners of the frame.
- Lower the lower leg rest slowly.

The lower leg rest must only ever be raised and lowered by holding on to the rounded corners of the frame. Otherwise, there is a danger of crushing your fingers.

There is risk of injury if the lower leg rest falls uncontrollably.

Lowering the rest with the handset

If the thigh rest is lowered using the handset, the lower leg rest will be automatically lowered as well.

4.4 Attachments and Optional Equipment

4.4.1 Location sleeve for patient's lifting pole

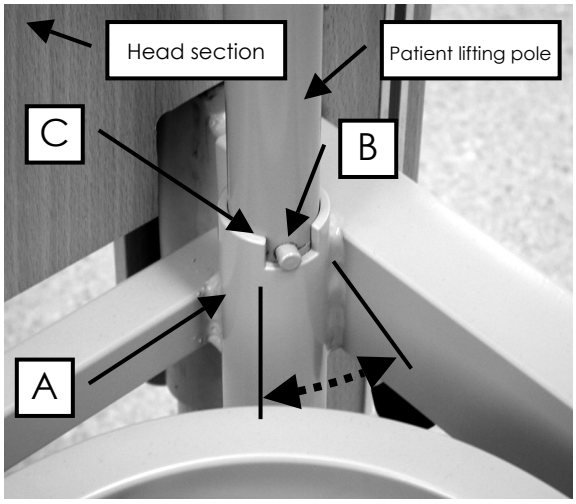
The corners of the mattress base frame at the head end of the bed are each fitted with a round sleeve **(A)** with a notch **(C)** at the top. These sleeves are the location sleeves for the patient lifting pole. The patient lifting pole should be fitted in that side of the bed on which the patient or occupant will be getting into and out of the bed. This will provide assistance for the occupant when getting in and out of bed.

The maximum loading capacity of the front end of the patient lifting pole is 75 kg.

- The loading capacity is designed to allow a reclining, overweight patient to raise him/herself into a seated position without another person's assistance.
- Do not use the patient lifting pole to lift patients.
- It is also important to prevent overweight patients to bring their entire bodyweight to bear on the patient lifting pool (e.g. when getting out of bed).

Fitting the pole

- Insert the patient lifting pole into the sleeve. The metal pin **(B)** on the patient's lifting pole must be located in the notch of the sleeve. This will limit the swivel range of the patient lifting pole.



Removing the pole

- Pull the patient lifting pole up and out of the sleeve.

Swivel range of the patient's lifting pole

- The swivel range of the patient lifting pole is limited to the area over the bed **(A)**.
- Do not swing the patient lifting pole out beyond the limits of the bed **(B)**.
- There is a danger that the bed will tip up when weight is applied to the pole.
- Therefore the metal pin of the patient lifting pole must always sit in the sleeve's notch!

4.4.2 Grab handle (triangular handle)

A grab handle can be attached to the patient lifting pole (accessory, not included in scope of supply). The patient can use this grab handle to sit up and readjust his/her position.

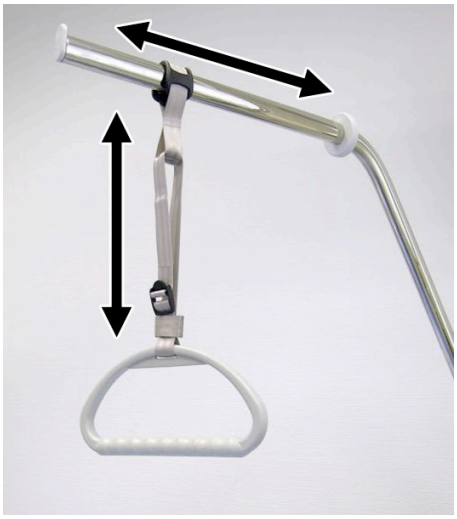
Advice

Check the grab handle and belt regularly for damage (see Chapter 3.8). Replace damaged grab handles or belts immediately.

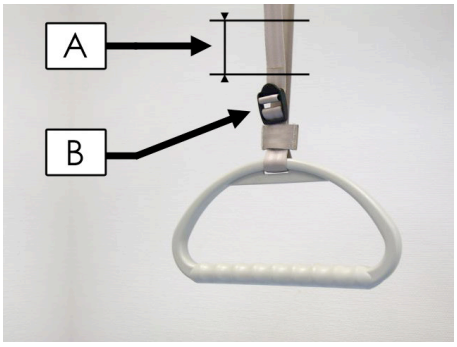
Service life

A date is printed on the grab handle. In normal use, the grab handle has a service life of at least five years. After this period, a visual and functional inspection must be carried out every six months to determine whether the handle may continue to be used.

- Push the fixed loop of the grab handle over the first bolt on the patient lifting pole.
- Check whether the grab handle is secure by strongly pulling it downwards.
- **Note:** The maximum loading capacity at the front end of the patient lifting pole is 75 kg.
- The height of the grab handle can be adjusted using the strap.
- Make sure that the strap is correctly threaded through the buckle.



- Make sure that the end of the strap projects at least 3 cm **(A)** out from the buckle **(B)**.



4.4.3 Mains cable holder

The head section of the bed is fitted with a mains cable holder on each side of the bed underneath the mattress base frame.

- The mains cable must always be hooked into the mains cable holder before the bed is moved.
- The cable must not be allowed to contact the ground, as this could cause damage to the cable as a result of being torn off, crushed or driven over.

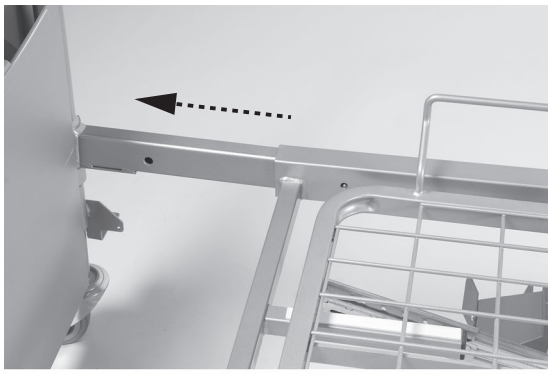
Danger of death due to electric shock!

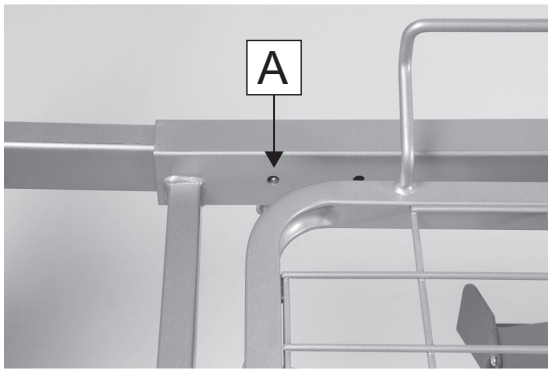
- If a damaged mains cable continues to be used, this can lead to electric shock, fire and other hazards as well as malfunctions.
- Damaged mains cables must be replaced immediately. If the bed's mains cable is damaged, please contact Burmeier's customer service department. The address is given in Chapter 6.3.

4.5 BED EXTENSION

This bed is equipped with an extension section at the foot end of the bed. The mattress base can be extended by 20 cm. The gap created by extending the bed has to be filled with a solid and a foam insert and the safety sides' side guards exchanged for longer ones (accessories, see Chapter 8).

Extending the mattress base (200 > 220 cm)





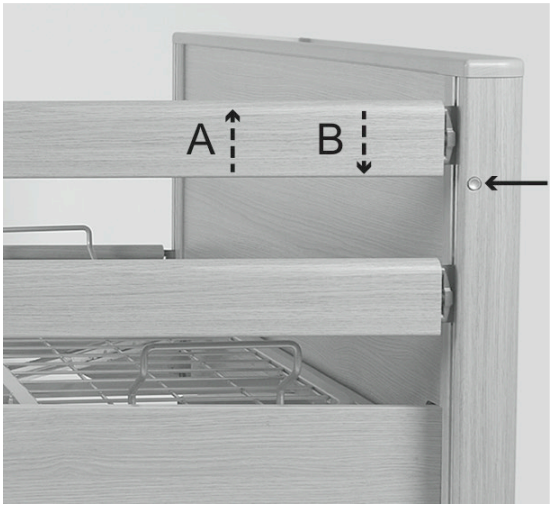
- The bed must not be occupied when extending it!
- Apply the brakes at the head section.
- Remove the side guards (see Chapter 3.11).
- Remove the safety sides (see Chapter 3.1).
- Open the brakes at the foot section.
- Loosen the screws underneath the mattress base frame on both sides at the foot end.
- Pull out the foot section to such an extend that the knobs **(A)** on both sides engage.
- Tighten the two screws again.
- Check that the knobs are firmly locked in place by pushing forward and back on the foot section!
- Insert the solid and the foam insert into the gap in the bed.
- Apply the brakes at the foot section of the bed.
- Reattach the safety sides (see Chapter 3.1).
- Fit the 220 cm long side guards (see Chapter 3.3).

Shortening the mattress base (220 > 200 cm)

- Apply the brakes at the head section.
- Remove the solid and the foam insert.
- Remove the side rails.
- Remove the safety side panels.
- Open the brakes at the foot section.
- Loosen the screws underneath the mattress base frame on both sides at the foot end.
- Push the two knobs on both sides into the mattress base frame and simultaneously push the foot section into the mattress base frame up to the limit stop.
- Reattach the safety side panels.
- Tighten the two screws again.
- Check that the knobs are firmly locked in place by pushing forward and back on the foot section!
- Apply the brakes at the foot section of the bed.
- Attach the 200 cm long side guards.

4.6 SAFETY SIDES

Raising the sides



- Pull up each of the safety sides in succession inside the guide rials until the push-button clicks into place at the highest position. Now it should not be possible to push the rails either up or down.
- Check that they are securely in place by pushing down on them.

Lowering the sides

- Pull the safety side **(A)** slightly up.
- Press on the push-button and then lower the safety side **(B)**. Do not allow the safety side to drop!
- Repeat this procedure for the other sides.

4.6.1 Special Safety Information for safety sides

Safety sides protect the occupant or patient from accidentally falling out of bed. They are not intended as a device to prevent the occupant or patient from intentionally leaving the bed.

If not used properly, there is a considerable danger of strangulation for the occupant. Please, therefore, bear in mind the following instructions.

Danger

- Only use technically perfect, undamaged safety sides that securely engage!
- Before using the safety sides, assess and take into consideration the clinical condition and particular physical build of the relevant occupant:
  - For example, if the occupant is extremely confused or very restless, avoid using safety sides as much as possible and make use of alternative safety measures such as restraint sheets, etc.
  - For especially small, slim occupants, additional protective measures for reducing the space between the side guards of the safety sides may be necessary. In these cases, use safety side polyfoam covers (accessory), posey belts, etc. This is the only way to effectively guarantee occupant safety and reduce the

risk of the occupant becoming trapped or slipping through the sides.

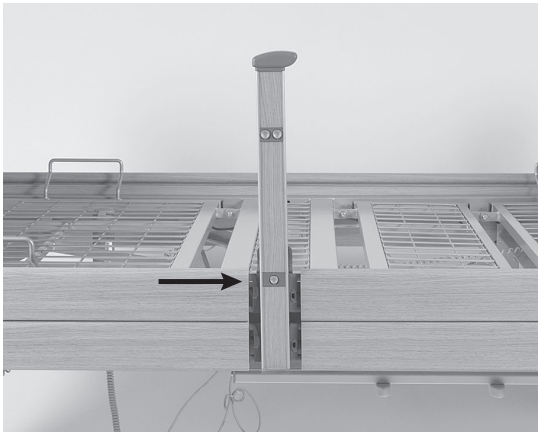
- Only use suitable mattresses that are not too soft in accordance with DIN 13014, with a density of at least 50 kg/m³ and a height of at least 12 cm to a maximum of 19 cm (see chapter 8).
- If special mattresses are used (for prevention or therapy), e.g. mattresses to prevent bedsores, the safety sides have to be raised in such a way as to reach a height of at least 22 mm above the non-occupied mattress.
  If this height specification is not observed, the operator must take additional/alternative measures on his own responsibility and according to his assessment of the risks in view of the clinical condition of the occupant, such as:
  - providing additional safety systems for the patient,
  - arranging for the patient to be regularly checked,
  - issuing internal instructions for the users.
- When the safety sides are raised, the electrical adjustment of the backrest and thigh rest must always be blocked:
  - attach the handset out of reach of the occupant (e.g. at the foot end of the bed).
    or:
  - Block the handset adjustment options.

Otherwise there is a danger of limbs being crushed or trapped by the safety sides if the occupant inadvertently activates the handset. The effectiveness of the safety sides can also be reduced if any of the mattress base sections are raised to a high level. Place the handset out of reach (e.g. at the foot end of the bed) or block the handset adjustment options.

4.7 PARKING POSITION OF POST (APPLIES FOR SPLIT SAFETY SIDES ONLY)

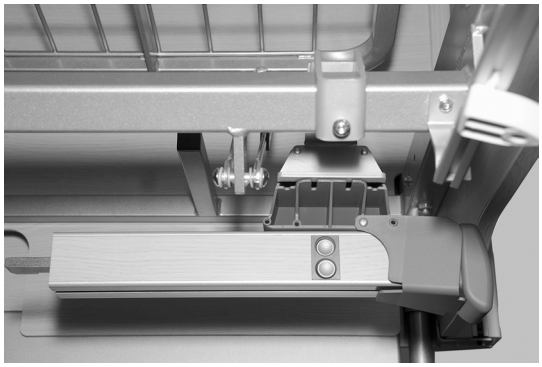
The top post section can be removed when the safety sides are lowered.

- Press the release button.
- Lift out the top section of the post.



The top section of the post can be stored in the parking element when the safety sides are lowered.

The protruding edge of the knob should be facing downwards when the post is in its correct parking position.



5 Cleaning and Disinfection


Advice

This heavy-duty bed is not suitable for washing with a machine or for being cleaned inside a decontamination unit. It is only suitable for manual cleaning and disinfection. To extend the bed's service life and preserve its operability, always follow the instructions provided in this chapter.

5.1 General Information on Cleaning and Disinfection

Cleaning is the most important measure and requirement for a successful chemical disinfection.

When the bed is occupied by the same occupant or patient, routine cleaning of the bed is generally sufficient. Disinfection of the undercarriage is only necessary when it has been visibly contaminated with infectious or potentially infectious materials (blood, stool, pus) or, if in the presence of an infectious disease, under doctor's orders.

Before a new occupant or patient occupies the bed, it must first be cleaned and disinfected by wiping!


Warning

Before cleaning or disinfecting:

- Unplug the mains plug and store it in such a way that it does not come into excessive contact with water or other cleaning solutions.
- Ensure that none of the electrical component parts show any signs of external damage. If these instructions are disregarded, water or cleaning agents may penetrate the system, resulting in malfunctions or damage to the electrical component parts.
- Lock the drives on the control box.
- The electrical components must not be cleaned with a water jet, a high pressure cleaner or other similar devices!

On completing cleaning:

- Before operating the bed again, ensure that there is no residual moisture on the electrical contacts by drying or blow-drying the mains plug.

- If you suspect that water or cleaning solutions have penetrated electrical components:

- Do not plug the bed into the mains socket. If the bed is already plugged in, pull the mains plug out of the socket immediately.
- Label the bed as "FAULTY" and take it out of service at once.
- Report this to the operator immediately.

Failure to follow this safety advice could result in considerable damage to the equipment and lead to subsequent malfunctions!

5.2 Cleaning and Disinfection Instructions

- Remove the bed linen and send it to the laundry service.
- Clean all surfaces, including the slatted bed frame and mattress base made of synthetic or metal slats, with a mild and environmentally friendly cleaning agent. This also applies for the handset.
  - If the bed has been visibly contaminated with infectious or potentially infectious materials, the bed should subsequently be disinfected by wiping it with one of the disinfection media approved by the DGHM (*Deutsche Gesellschaft für Hygiene und Mikrobiologie*, German Society for Hygiene and Microbiology) that is suitable for the relevant surfaces. The same applies to all beds that have been occupied by occupants who have notifiable diseases according to § 6 of the *Infektionsschutzgesetz* (IfSG, Protection against Infection Act), bacterial infections, or infections with multiple-resistant pathogens (e.g. MRSA, VRE), as well as all beds in intensive care stations and infectious disease clinics. For all disinfections, the concentrations given in the DGHM list must be observed.
  - Disinfection of the castors is only necessary when they have been visibly contaminated with infectious or potentially infectious materials.

5.3 INSTRUCTING USERS AND TRAINED STAFF

In order to ensure that cleaning and disinfection are properly conducted, we recommend that users and trained staff are appropriately instructed.

When providing instruction, observe the following points:

- A clean bed must be transported in such a way that it will not become dirty or contaminated.
- Staff should be informed of the special measures required for cleaning and disinfection and carry out the procedure in a reliable manner (the operator should specify the operating procedure or the individual procedural steps).
  Care must be taken that only disinfection agents approved by the DGHM (German Society for Hygiene and Microbiology) are used, and that these are used only in the DGHM approved concentrations.
  The disinfection agent must be suitable for use with the surfaces to be disinfected.
- For this activity, staff should be provided with disposable aprons and gloves which are impermeable to fluids.
- When cleaning the bed, only use fresh, clean cloths and send them to the laundry service once cleaning is finished.
- When cleaning/disinfecting work has been completed, the staff must disinfect their hands before carrying out other tasks.
  The staff should be equipped with a suitable pump dispenser containing a disinfection medium for hands.
- The immediate cleaning of the bed on site has the advantage that no "dirty" beds or bed components come into contract with clean beds. In this way, the transfer of potentially infectious germs, which may be found on used undercarriages, is prevented.
  A transfer of germs in terms of a nosocomial infection can be safely avoided by consistently and thoroughly following these recommendations.
- When the bed is not immediately reused, it should be stored (covered) in such a way that it is protected from dust, inadvertent dirt and contamination.

5.4 Cleaning and Disinfection Agents

Pay attention to the following recommendations to ensure that the bed functions and usability are preserved as long as possible:

- Do not use scouring agents, care products for stainless steel and abrasive cleaning agents or scouring pads. These substances can damage the surfaces.
- Cleaning and decontaminating agents must have a pH value of 5 - 8 at the specified concentrations.
- The chloride content of the solutions prepared for use must not exceed 100 mg/l.
- We recommend (damp) wipe cleaning. When selecting cleaning agents, ensure that the ones chosen are mild (gentle to skin and surfaces) and environmentally friendly. A standard household cleaner can generally be used.
- Ensure that after cleaning/ disinfection no liquid residues remain on the metallic parts of the bed (avoid drops on the edges). Otherwise corrosion can not be excluded in these areas in the long term.
- Despite the excellent mechanical resistance, scratches, markings, etc., which permeate the entire coating should be resealed using a suitable medium to prevent the penetration of moisture. For further information, consult Burmeier or a specialist of your choice.

- As a rule, aldehyde-based disinfection media have the advantage that they have a wide range of impact, a relatively low protein effect and are environmentally friendly. The main disadvantage of these agents is their potential to cause allergies and irritation.
- Glucoprotamine-based formulations do not have this disadvantage and are equally effective, although most are somewhat more expensive.
- Disinfection media based on compounds which could potentially release chlorine may be corrosive for metals, synthetics, rubbers and other materials over longer contact periods or when concentrations are too high. Furthermore, these media have a higher so-called protein effect, are mucous membrane irritants and demonstrate poor environmental compatibility.

- For disinfection by wiping, most cleaning and disinfection agents usually used in hospitals or care facilities, such as cold and hot water, detergents, alkaline solutions and alcohols, can be used.

- These agents must not contain any substances that could change the surface structure or the adhesive properties of the plastic materials.

The following cleaning agents were successfully tested and approved by us:

Manufacturer	Designation	Concentration according to manufacturer
Antiseptica	Biguacid-S	0.5% solution
B. Braun	Meliseptol rapid Meliseptol	Working solution 50ml/m2
Bode Chemie	Bacillol AF	Working solution 50ml/m2
Ecolab	Incidin Plus	0.5% solution
Fresenius-Kabi	Ultrasol-F	0.5% solution
Lysoform	Amocid	1.5% solution
Schülke	Buraton 10 F	5% solution

Please consult the appropriate manufacturer before using any other agents. Only alternative agents with an equivalent composition may be used, to prevent any damage to the bed as a result.

5.5 Handling Cleaning and Disinfection Agents

- Pay attention to the exact dosage! We recommend the use of automated dosing instruments.
- Always prepare solutions with cold water in order to avoid the formation of vapours which are mucous membrane irritants.
- Wear gloves, in order to avoid direct skin contact.
- Do not keep prepared surface disinfection solutions in open containers with floating cleaning cloths. Be sure to close all containers!
- Use sealable bottles with pump dispensers for moistening the cleaning cloths.
- Ventilate the room after the disinfection has been completed.
- Disinfect by wiping; do not disinfect by spraying! When spraying, a large portion of the disinfection medium is released as spray and could be inhaled.
- Furthermore, the wiping effect plays a significant role.
- Do not use alcohols for the disinfection of large surfaces.

6 Maintenance

Legal principles

In accordance with the

- German Medical Devices Operator Ordinance § 4 (Maintenance)
- *Berufsgenossenschafts-Vorschrift* BGV A3 (Directive of the German Employers Liability Insurance Association, Testing of mobile electrical equipment in industrial use),

operators of care beds are obliged to preserve the safe operating condition of medical devices throughout their entire service life. This also includes regularly carrying out expert maintenance as well as safety checks.

Information for the operator

This bed has been designed and built to work safely over a long period of time. When operated and used properly, this bed's expected service life is 2 to 8 years. The bed's service life depends on the conditions within and frequency at which it is used.

Frequently transporting, assembling and disassembling the bed, improper operation and long-term use may cause damage, defects and wear to the bed over time. These deficiencies can cause hazards if they are not recognised and corrected immediately.

For this reason there are legal principles for conducting regular inspections in order to guarantee the safe condition of this medical product.

In accordance with § 4 of the German Medical Devices Operator Ordinance, maintaining the bed is the operator's responsibility. In accordance with the above, the operator and users of the bed have to perform the routine inspections and functional checks described in the following.

Instruct users about the following inspections that are required to be performed.

6.1 By the User

As well as the extensive routine inspections performed by specialist technical personnel, the bed also has to be checked at shorter regular intervals by non-technical users (care staff, family carers etc.), and briefly visually inspected and its functions tested every time before being occupied by a new occupant.

- If damage or a malfunction is suspected, the bed must be withdrawn from service immediately and disconnected from the mains supply until the defective parts have been repaired or replaced!
- Please contact the relevant operator if the parts of the bed have to be replaced or repaired.

Recommendation:

Check all electrical and mechanical components once a month. In addition to the above, check the mains cable and handset every time they have been subjected to mechanical stress and after the bed has been moved.

When doing so, please use the checklist shown below:

Checklist: Inspection performed by the user

Type of inspection		**ok**	**Not ok**	**Description of defect**
Visual inspection of the electrical components				
Handset, cable	Damage, routing of cable			
Mains cable	Damage, routing of cable			
Handset	Damage, foil			
Control box	Damage, routing of cable			
Visual inspection of the mechanical components				
Patient lifting pole, location sleeves	Damage, deformations			
Bed frame	Damage, deformations			
Sprung slats	Damage, splinters			
Wooden head & foot panels	Damage, splinters			
Mattress base frame	Damage, deformation			
Side guards	Damage, splinters			
Performance check of the electrical components				
Handset	Function test, locking functions			
Control box	Function test, locking functions			
Performance check of the mechanical components				
Castors	Locking the brake, moving			
Emergency release of backrest	Test according to instruction manual			
Socket screws	Securely fastened			
Safety sides	Safe locking, release			
Lower leg rest	Engage			
Accessories (e.g. patient lifting pole, grab handle)	Fastening, damage			
Inspector's signature:	**Inspection results:**			**Date:**

6.2 By the Operator

In accordance with § 4 of the German Medical Devices Operator Ordinance, the operator of this bed must regularly inspect the bed every time after is has been set up again, after every maintenance and during regular use to ensure it is in a safe condition.

These inspections have to be repeated as part of the regular maintenance work performed depending on the bed's conditions of use as specified in § 4 of the German Medical Devices Operator Ordinance (MPBetreibV) and of the inspections in accordance with BGV A3 required under the German Employers Liability Insurance Association regulations for mobile electrical equipment in industrial use.

- Observe this order for the inspection according to DIN EN 62353:

I. Visual inspection

II. Electrical measurements

III. Performance test

- In accordance with § 4 MPBetreibV, the performance test and the evaluation and documentation of the test results must only be performed by an expert with the relevant knowledge and experience required to perform the same properly.
- The electrical measurements in accordance with DIN EN 62353 can also be performed by a person with electrotechnical training [in terms of BGV A3] and with additional medical and device-specific know-how if suitable measurement equipment is available.
- The test results must only be evaluated and documented by a qualified electrician with additional medical and device-specific know-how.

Test procedure

■ Leakage current test: direct or differential current in accordance with DIN EN 62353

■ Perform a leakage current test in accordance with the instructions provided by the test device manufacturer.

Limit value:

■ Leakage current I leak lower than 0.1 mA.

Inspection Interval:

As a guide, we recommend performing this inspection once a year and to extend this interval to no more than two years at your own risk in consideration of the bed's conditions of use and if it is possible to verifably observe the 2 % error rate (see BGV A3:§ 5, table1B).

If damage or a malfunction is suspected, the slatted bed frame must be withdrawn from service immediately and disconnected from the mains supply until the defective parts have been repaired or replaced!

Please use the inspection report templates included below for your inspections.

Inspection Report following an inspection of electromedical equipment according to DIN EN 62353 (VDE 0751-1): 2008-08 - Page 1 of 2

Customer / med. facility / practice:						
Address:						
Carried out: ☐ Repeat inspection ☐ Inspection prior to initial operation (reference value)						
☐ _____ ☐ Inspection following repair/servicing						
Equipment type: ☐ Hospital bed ☒ Care bed				**Protection class:** ☐ I ☒ II		
Bed type: Gigant II				**Inventory number:**		
Location:				**Serial number:**		
Manufacturer: Burmeier GmbH & Co. KG				**User-specific parts:** none		
Testing equipment used (type/inventory no.):				1.		
MPG classification: Class I,				2.		
I. Visual inspection **What?**	**Check for?**			**ok**	**Not ok**	**Description of defect**
Visual inspection of the electrical components						
Stickers and type plates	Present, legible					
Control unit housing	Correct position, damage					
Handset	Damage					
Control box	Damage					
Motor cable, handset cable, mains cable	Damage, routing					
Mains cable holder	Securely fastened					
Plug and plug cover on control unit	Available, correct position					
Visual inspection of the mechanical components						
Stickers and type plates	Present, legible					
Patient lifting pole, sleeve; grab handles	Damage, cracks, deformations					
Bed frame	Damage, deformations					
Bowden cable, emergency backrest lowering mechanism, backrest	Routing, kinks					
Wooden head & foot panels	Splinters					
Castors	Damage					
Mattress base	Damage					
Safety sides	Damage, splinters					
Welded seams	Split welded seams					
Connecting elements	Secure fastened, complete					
Wearing parts, such as joints	Damage					
II. Electrical measurement according to DIN EN 62353 (VDE 07051-1) 2008-08 leakage current, direct						
1. Plug the bed mains cable into the test socket.						
2. Connect the measuring instrument probe to an exposed, conductive part of the undercarriage (screws, etc.).						
3. Activate the motors using the handset for the duration of the measurements.						
4. Start measurement procedure on the measuring instrument.						
	Limit value	Value of first measurement	Current value			
Result: Bed prot. class II (type B)	0.1 mA	mA	mA			

Inspection Report following an inspection of electromedical equipment according to DIN EN 62353 (VDE 0751-1): 2008-08 - Page 2 of 2

III. Performance test What?	Check for?	ok	Not ok	Description of defect
Performance check of the electrical components				
End of travel cut-out for motors	Automatic cut-out			
Handset	Test according to instruction manual			
Control box	Test according to instruction manual			
Control unit and motors	Noise level			
Control unit and motors	Test according to instruction manual			
Plug and plug cover on control unit	Test according to instruction manual			
Strain relief of mains cable	Available, correct position			
Performance check of the mechanical components				
Joints and pivots	Smooth operation			
Emergency release of backrest	Adjusting, secure fixing			
Castors	Effectiveness: Braking, steering lock			
Safety sides	Locking in place, release			
Lower leg rest	Engage			
Accessories (e.g. patient lifting pole, grab handle)	Fixing, damage, suitability, load-bearing capacity			

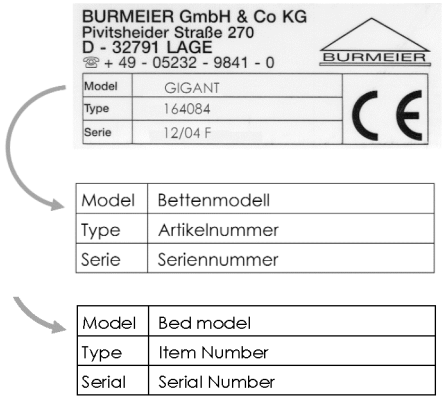
Inspection results:

All values within permissible range: ☐ yes ☐ no	**Next inspection date:**
Inspection passed: ☐ yes ☐ no	
If inspection was not passed:	☐ Defective, do not use bed! => Repair ☐ Defective, do not use bed! => Take out of service ☐ Bed does not meet the safety standards
Test approval sticker applied:	☐ yes ☐ no
Documents that form part of this inspection report:	
Comments:	

Inspected on:	**Inspector:**	**Signature:**
Evaluated on:	**Operator/Expert:**	**Signature:**

Replacement parts

The relevant replacement parts are available from Burmeier upon specifying the item number, order number and serial number. The necessary details are found on the type plate on the cross tubing of the mattress base frame.



Model	Bettenmodell
Type	Artikelnummer
Serie	Seriennummer

Model	Bed model
Type	Item Number
Serial	Serial Number

6.3 MANUFACTURER'S ADDRESS

In order to maintain operational safety and the right to claim under warranty, only original Burmeier replacement parts may be used!

To order replacement parts, or make customer service requests or for other queries, please contact:

Burmeier GmbH & Co. KG

(A company of the Stiegelmeyer Group)

Pivitsheider Straße 270

D-32791 Lage/Lippe

Tel.: +49 (0) 52 32 / 98 41- 0

Fax: +49 (0) 52 32 / 98 41- 41

E-mail: auftrags-zentrum@burmeier.de

6.4 Replacement of Electrical Components

6.4.1 Special safety information on replacing electrical components

Danger of death due to electric shock!

- Before commencing any work on electrical equipment, always unplug the mains cable from the electrical socket!
- Any work and/or repairs to the electrical equipment may only be carried out by the ice engineers, the drive manufacturer or qualified and authorised electricians in compliance with all the relevant VDE and safety regulations!
- On no account should the user attempt to rectify malfunctions in the electrical equipment!

- The bed must be in the home position (with the mattress base horizontal) in order to remove the motors.
  Otherwise, there is a danger of crushing due to parts of the mattress base falling.
- The components of the electrical system are maintenance-free and must not be opened.
  If a malfunction occurs, the relevant component must be replaced in its entirety!

- When replacing individual components, make sure that the plugs have undamaged O-rings and are inserted into the control unit as far as they will go.
- The yellow sealing ring on the plug must be fully immersed in the plug coupling.
- Attention! Do not use force. If it is not possible to insert the plugs, turn these around 180° and insert them again.
- This is the only way to ensure a proper seal and faultless operation.

6.4.2 Replacing the mains supply cable

- Open the strain relief for the mains cable attached in the centre underneath the mattress base.
- Take the mains cable out of the strain relief lug.
- Unplug the IEC connector from the control unit. To do so, press down on the red securing clip through the slot in the plug socket (see picture on the next page).
- Replace the mains cable. The red securing clip must lock into place. This prevents the IEC connector from being inadvertently pulled out of the control unit.
- Correctly reattach the strain relief to the strain relief lug.
- Run a function test of the electrical adjustments as well as an electrical measurement in accordance with Chapter 6.2 !

Before commencing any work - replacing the mains supply cable and replacing the handset - unplug the mains cable from the electrical socket!

6.4.3 Replacing the handset

- Carefully open the lock on the protective cover over the plug with a screwdriver and then pull it off the control unit to remove it.
- Unplug the handset plug from the control unit.
- Replace the old handset with a new one. Make sure that the O-ring on the plug is not damaged. It seals the plug within the control unit.
- When routing the handset cable, ensure that it can not be damaged by any moving parts of the bed.
- Put the plug cover back in place. This prevents all the plugs from being pulled out of the control unit.
- After this, test the bed adjustment functions to ensure that they work!

6.4.4 Plug assignment of the control unit

All of the plugs have to be connected to the control unit. To prevent the plugs from being inadvertently disconnected, they are secured with a cover. When changing plugs, this has to be carefully unlocked using a screwdriver and then slid away to one side.

- **1** = Backrest motor
- **2** = Thigh rest motor
- **3** = Mattress base height motor, head section
- **4** = Mattress base height motor, foot section
- **5** = Not assigned (blind plug)
- **6** = Handset
- **7** = Control box

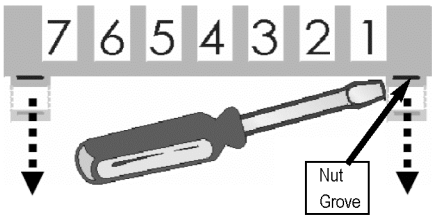


Illustration: Plug assignment of the control unit

7 Troubleshooting

The following table is a guide for rectifying faults:

Problem	Possible Causes	Solution
Handset/ Drive unit system - No function	• Mains cable not plugged in • No power supply to socket • Handset plug not correctly inserted • Handset or drive unit system is defective • Functions are locked on control box	• Insert mains cable • Check socket and fuse box • Check connector plugs • Inform your operator about any necessary repairs • Unlock function
Drives only operate for a short time when buttons are pressed	• Weight on the bed is too high • Bed is blocked by an obstacle	• Reduce load • Remove obstacle
Operation is not possible despite proper power supply	• Control unit has shut off temporarily due to over-heating • Control unit defective	• Observe max. duty cycle: after 2/18 min; allow control unit to cool down for approx. 30 minutes • Replace the control unit Notify your operator about the necessary repairs
The LED on the handset does not come on when pressing the buttons or is on permanently	• Control unit error • The motor has reached its end position • The locking function is activated • The drive load has been exceeded	• Inform your operator about any necessary repairs • Move the motor out of its end position • Unlock the control box • Reduce load
The unit emits a continuous or long signal sound without the handset buttons' being pressed	• Control unit is defective.	• Inform your operator about any necessary repairs
Individual drives operate in one direction only	• Defective handset, drive unit or control unit	• Inform your operator about any necessary repairs
The wrong function is activated when handset buttons are pressed	• Internal motor plugs incorrectly connected	• Inform your operator about any necessary repairs

8 Accessories

The bed must only be operated with original BURMEIER accessories. BURMEIER does not accept any responsibility for accidents, defects and hazards that arise from the use of other accessories.

When using safety sides, drip stands etc. on electronically adjustable beds, the following must be strictly observed:

Make sure that the arrangement of accessories does not produce any crush or shearing zones for the patient when the back and leg rests are adjusted. If this cannot be guaranteed, the user must safely prevent the patient from adjusting the back and leg rests.

To do so, place the handset out of reach (e.g. at the foot end of the bed) or block the handset adjustment options.

Mattress requirements

Basic dimensions:	
Length x width	200 x 120 cm
Thickness/height	10 - 16 cm
Foam density	min. 40 kg/m^3
Compression hardness	min. 4.5 kPa
Applicable standards:	DIN 13014
	DIN 597 Part 1 and 2

9 Technical data

9.1 Dimensions and Weights

Bed when assembled and with safety sides

Mattress base	:	200 x 120 cm
External dimensions	:	approx. 220 x 135 cm
Total weight	:	159 kg
Safe working load	:	350 kg

Bed when disassembled

Head & footboard (wooden panels)	:	14 kg each
Head and foot section, incl. motors	:	20 kg each
Mattress base frame with motors	:	70 kg
Rails of the safety sides	:	4 kg each
Patient lifting pole	:	5 kg
Side panel	:	4.2 kg

9.2 Electrical Data

Control unit

Type	:	SG 300 Care
Input voltage	:	AC 230 V, ± 10 %, 50 Hz
max. current input	:	AC 2.0 A
Fuse	:	T 0.8 A – T 1 A
Output voltage	:	24 V DC
Output current	:	max. DC 7.5 A
Duty cycle	:	Intermittent duty, 2 min ON / 18 min OFF
Safety class	:	IP 66, splash-proof
Classification	:	Protection class II, Type B, MPG classification Class I, not for use in explosive atmospheres

Control box

Type	:	DEWERT - control box
Safety class	:	IP 44

Handset

Type	:	DEWERT IPROXX
Safety class	:	IP 66

Mains cable: (coiled, anti-kink, with strain relief)

Type	:	H05 BQ-F 2 x 0.75 mm^2 (EPR quality)

Electric motor for mattress base height

Type	:	DEWERT Megamat 2 MBZ
Force push/pull	:	4,000 N
Input voltage	:	24 V DC
Output current	:	max. 3.7 A
Duty cycle	:	Intermittent duty: 2 min ON / 18 min OFF
Safety class	:	IP 66

Electrical motor for backrest

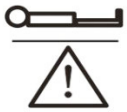
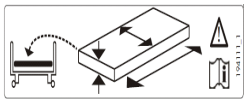
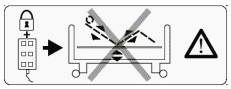
Type	:	DEWERT Megamat MPZ
Force push/pull	:	4,000 N
Input voltage	:	24 V DC
Output current	:	max. 5.0 A
Duty cycle	:	Intermittent duty: 2 min ON / 18 min OFF
Safety class	:	IP 44

Electrical motor for thigh rest

Type	:	DEWERT Megamat 2 MCZ
Force push/pull	:	4,000 N
Input voltage	:	24 V DC
Output current	:	max. 3.0 A
Duty cycle	:	Intermittent duty: 2 min ON / 18 min OFF
Safety class	:	IP 44

Noise level during adjustment: max. 48 dB(A)

Explanation of the graphical symbols used

Symbols	Meaning
	Device with Type B applied part in accordance with EN 60601-1 (special protection against electric shock)
	Transformer with thermal fuse
	Safety transformer to VDE 0551
	Protection Class II device, shock-proof
	Connecting pin for potential equalisation in accordance with IEC 601-1
	Attention! Pay attention to the instruction manual
	Only for use in enclosed spaces - do not use outdoors
IP 44	The electrical equipment offers protection against internal dust deposits and is splash-proof from all sides
IP 66	The electrical equipment offers protection against internal dust deposits and is jet-proof from all sides
	Mark of conformity in accordance with the Medical Device Directive 93/42, EEC Appendix VII
	**Safe working load** (= max. permissible weight of occupant, mattress and all attached accessories)
	**Max. weight of occupant** (= max. permissible weight of occupant; this is dependent on the total weight of all the accessories attached to the bed and is always less than the safe working load)
	Only use mattress dimensions that are approved by the manufacturer.
	Block the handset if the occupant could be at risk due to inadvertent motorised adjustments

9.3 AMBIENT CONDITIONS

The following ambient conditions must be maintained:

In storage

	Minimum	Maximum
Storage temperature:	+5 °C	+50 °C
Relative humidity :	50 %	70 %

During operation

	Minimum	Maximum
Ambient temperature:	+10 °C	+40 °C
Relative humidity :	20 % to	90 % (not condensed)
Air pressure:	700 hPa	1060 hPa

9.4 TECHNICAL INFORMATION ON ELECTROMAGNETIC COMPATIBILITY (EMC)

To ensure EMC, only use cables and accessories approved by the manufacturer.

- The use of accessories, sensors or cables other than those approved, with the exception of sensors and cables sold by the equipment manufacturer as replacement parts for internal components, can result in an increase in the transmission level or a reduction in the immunity level of the equipment.
- The equipment may not be used directly next to or on top of other equipment.
- If it is necessary to use the equipment in this way, you must check to ensure that it functions properly in the required configuration.

Guidelines and Manufacturer's Declaration – Electromagnetic Emissions –		
The BED is intended for use in the electromagnetic environment described below. The operator or user of the BED should ensure that it is used in such an environment.		
Interference emission measurements	**Compliance**	**Electromagnetic environment guidelines**
HF emissions to CISPR 11	Group 1	The BED uses HF energy for its internal functions only.
HF emissions to CISPR 11	Class B	The BED is intended for use in all types of establishment including residential and the like that are directly connected to a public supply network that also serves buildings that are used for residential purposes.
Harmonics according to IEC 61000-3-2	Class D	
Voltage fluctuations/ flicker acc. to IEC 61000-3-3	Complies	
HF emissions according to CISPR 14-1	Complies	The BED is not intended for connection to other technical equipment.

Guidelines and Manufacturer's Declaration – Resistance to Electromagnetic Interference –			
The BED is intended for use in the electromagnetic environment described below. The operator or user of the BED should ensure that it is used in such an environment.			
Interference resistance testing	**IEC 60601 - test limit**	**Compliance level**	**Electromagnetic environment guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	+/-6 kV contact discharge +/-8 kV air discharge	+/- 20 kV contact discharge +/-20 kV air discharge	Floors should be made of wood and concrete or be tiled with ceramic tiles. If the floor is covered with a synthetic flooring material, the relative air humidity must be at least 30%. Can be used when higher ESD levels are present.
Short, transient electrical disturbances / bursts according to IEC 61000-4-4	+/-2 kV for network cables +/ -1 kV for input and output cables	+/-2 kV for network cables Not applicable	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment.
Surges according to IEC 61000-4-5	+/-1 kV transversal voltage +/-2 kV longitudinal voltage	+/-1 kV transversal voltage +/-2 kV longitudinal voltage	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment.
Voltage dips, short interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for half a period 40 % U_T (60 % dip in U_T) for 5 periods 70 % U_T (30 % dip in U_T) for 25 periods <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for half a period 40 % U_T (60 % dip in U_T) for 5 periods 70 % U_T (30 % dip in U_T) for 25 periods <5 % U_T (>95 % dip in U_T) for 5 s	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment. If the person using the BED requires continuous bed adjustments despite any interruptions in the energy supply, it is recommended that the BED be connected to an uninterruptible electricity supply or a battery.
Supply frequency magnetic fields (50/60Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Network frequency magnetic fields should be equivalent to those to be found in a typical business or hospital environment.
Note:	U_T is the AC network voltage before the test level is applied.		

Guidelines and Manufacturer's Declaration – Resistance to Electromagnetic Interference –			
The BED is intended for use in the electromagnetic environment described below. The operator or user of the BED should ensure that it is used in such an environment.			
Interference resistance testing	**IEC 60601 - test limit**	**Compliance level**	**Electromagnetic environment guidelines**
			Portable and mobile radio devices should not be used in closer proximity to the BED, including the cables, than the recommended protection distance calculated for the appropriate transmission frequency. Recommended protection distance:
Radiated HF interference according to IEC 61000-4-6	3 V_{eff} for 150 kHz to 80 MHz	3 V_{eff} for 150 kHz to 80 MHz	$d = 1.17\ (P)^{1/2}$
Radiated HF interference according to IEC 61000-4-3	3 V/m for 80 MHz to 2500 MHz	3 V/m for 80 MHz to 2500 MHz	$d = 1.17\ (P)^{1/2}$ for 80 MHz to 800 MHz $d = 2.33\ (P)^{1/2}$ for 800 MHz to 2.5 GHz with **P** as the maximum rated power of the transmitter in watts (W) according to the manufacturer of the transmitter and **d** as the recommended protection distance in metres (m).[b] According to an in-situ test, the field strength of stationary radio transmitters should be lower, for all frequencies, than the compliance level[d]. Interference is possible when in the vicinity of equipment bearing the following sign. 
Note 1:	The higher frequency range applies for 80 MHz and 800 MHz.		
Note 2:	These guidelines may not be applicable in all circumstances. The propagation of electromagnetic interference is affected by buildings, objects and people due to absorption and reflection.		
[c]	The field strength of stationary transmitters, such as base stations for cordless telephones and for public mobile radio devices, amateur radio stations, and AM and FM radio and television transmitters cannot be predicted exactly by theoretical means. In order to determine the electromagnetic environment with regard to the transmitter, a study of the location should be considered. If the field strength measured at the location where the BED is to be used exceeds the upper compliance limit, the BED should be monitored to check that it functions properly. Should any unusual performance characteristics be observed, additional measures could be necessary, such as turning the BED or moving it to a different location.		
[d]	Across the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.		

Guidelines and Manufacturer's Declaration – Resistance to Electromagnetic Interference – Recommended protection distances between portable or mobile HF communication devices and the BED			
The BED is intended for use in an electromagnetic environment in which radiated HF interference is controlled. The operator or user of the BED can help to avoid electromagnetic interference by keeping a minimum distance between the BED and any portable or mobile communications devices (transmitters) – irrespective of the output characteristics of the communications device, as described below.			
Power rating of the transmitter [W]	**Protection distance (d) dependent on the transmission frequency [m]**		
	150 kHz to 80 MHz $d = 1.2\ (P)^{1/2}$	**80 MHz to 800 MHz** $d = 1.2\ (P)^{1/2}$	**800 MHz to 2.5 GHz** $d = 2.3\ (P)^{1/2}$
0.01	0.2	0.2	0.3
0.1	0.4	0.4	0.8
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
	For transmitters whose maximum power rating is not listed in the above table, the distance can be determined using the equation given in the relevant column, where P is the maximum power rating of the transmitter in watts (W) as stated by the manufacturer of the transmitter.		
Note 1:	The higher frequency range applies for 80 MHz and 800 MHz.		
Note 2:	These guidelines may not be applicable in all circumstances. The propagation of electromagnetic interference is affected by buildings, objects and people due to absorption and reflection.		

9.5 Applied Standards / Directives

- 93/ 42/EEC Medical Devices Directive
- DIN EN 62353 2008-08 Repeat testing of (VDE 0751) medical electrical units.
- EN 14971: 2013-04 Risk Analysis for Medical Devices
- EN 60601-1: 2006 Medical Electrical Equipment, Safety
- EN 60601-1-2/A1:2007 Electromagnetic Compatibility
- DIN EN 60601-2-52:2010-12 Particular requirements for the safety and essential performance of medical beds
- Classified as a Class I medical device (in accordance with the medical devices act § 13).
- Additional safety requirements for care beds of the supreme German state authority dated 22 May 2001.

9.6 CLASSIFICATION

- This hospital bed fulfils all the requirements of the 93/42/EEC Medical Devices Directive.
- This bed is classified as a class I medical product (in accordance with the Medical Products Act § 13).
- For use in the following application groups according to IEC 60601-2-52:

3:	Long-term care in a medical facility in which medical supervision is required and monitoring is provided if required. A medical electrical device used in medical procedures can be provided to help maintain or improve the condition of the occupant. (e.g. retirement and nursing homes, rehabilitation facilities and geriatric institutions)
4:	Home care. A medical electrical device is used to alleviate or compensate for injuries, disabilities or illnesses.

- Active medical device; equipment with type B application component.
- UMDNS Code:

Bed (electrically adjustable)	10-347

9.7 Disposal Instructions

- The operator must ensure that all components of the bed that are to be disposed of are not infectious or contaminated.
- If the bed is to be scrapped, the synthetic and metallic parts are to be separated and disposed of properly.
- If you have any queries, you can contact your local municipal waste company or our service department. The address is given in Section 6.3 on page 64.

Disposal of electrical parts

- This bed – since it is electrically adjustable – is classified as industrial electrical equipment in accordance with the WEEE Directive 2002/96/EC (law governing electrical equipment).
- The electrical components used are free from prohibited hazardous substances in compliance with the RoHS directive.
- Replaced electrical components (drives, control units, handsets, etc.) must be treated as electric scrap (in accordance with the WEEE Directive) and disposed of accordingly.
- The operator of this bed is legally obliged to send the electrical components directly to the manufacturer and not to dispose of them at municipal waste collection points. Stiegelmeyer and its service and sales partners will take these components back.
- The return of these components is covered by our General Terms and Conditions.

Disposal of rechargeable batteries

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- Batteries which are no longer usable and have been removed must be properly disposed of in accordance with battery regulations and do not belong in household waste.
- If you have any queries, you can contact your local municipal waste company or our service department. The address is given in Chapter 6.3.

Disposal of gas springs/hydraulic units

Any gas springs and hydraulic units are primarily constructed from metal and plastic and can be recycled.

Before disposing of these according to the manufacturer's instructions, it is important to drain off the oil and dispose of it properly.

Please note in this connection:

The release mechanism must not be activated if gas springs are removed. These devices are under pressure.

Careless release could cause injury!

Gas springs must first be depressurised according to the manufacturer's instructions before disposal. This information can be obtained upon request from the gas spring manufacturer (see type plate).

10 Declaration of Conformity

EC declaration of conformity

We, hereby declare

Joh. Stiegelmeyer GmbH & Co. KG
Ackerstraße 42
D – 32051 Herford,

under sole responsibility as the manufacturer that the product model named below:

Heavy-duty bed GIGANT II

in the version submitted complies with the regulations of the EC Directive 93/42/EEC for Medical Products , last amended by Directive 2007/47/EC dated 5 September 2007.

It is categorised as a Class 1 active medical device.

The relevant technical documentation is kept by the manufacturer's safety representative.

To evaluate the conformity to the Directives, all applicable parts of the following standards were referred to:

Harmonised standards:

EN 14971:2009-10	Risk Analysis for Medical Devices
EN 60601-1:2006	Safety for Electromedical Equipment
EN 60601-1-2:2007	Electromagnetic Compatibility
EN 60601-1-6:2010	Medical electrical equipment: with fitness for use
DIN EN 60601-2-52:2010	Particular requirements for the safety and and essential performance of medical beds

National standards/ specifications:

Additional safety requirements for care beds of the supreme German state authority dated 22 May 2001.

International standards:

IEC 60601-2-52:2009	Particular requirements for the safety and essential performance of medical beds
IEC 62366:2007-10	Medical electrical equipment: with fitness for use

Herford, 23/04/2014

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