

CARE DESIGN

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Bakare Beds Version: Rev ¹ Initial Issue Updated: 26.4.22



IMPULSE CARE BED

INSTRUCTION MANUAL



Dear Customers,

By purchasing a care bed from Malsch care & clinic design[®], you have obtained a long-lasting medical product with functions that meet all the requirements of everyday care while maintaining the highest standards of safety.

Thank you very much for the trust you have placed in us.

Our company guarantees carefully selected materials and continuous quality control while employing state-of-the-art production technologies.

Complying with the usage and operating instructions helps to prevent the risk of accidents and preserves the high value of your care bed.

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PRODUCT RANGE



IMPULSE care bed with undercarriage Edition 100 "Style"



IMPULSE care bed with undercarriage Edition XL



IMPULSE care bed with undercarriage Edition 400



IMPULSE care bed with undercarriage Edition 400 LR



IMPULSE care bed with undercarriage Edition 420



IMPULSE care bed with undercarriage Edition 420 LR

SPECIFIC FUNCTION

The care beds made by Betten Malsch GmbH are used in the care of residents with physical limitations. The beds are designed exclusively for this purpose. The functions of these care beds assist the care staff in their daily work and offer convenient solutions for positioning the resident and compensating for certain symptoms experienced by residents of retirement and care homes or comparable medical facilities. This complies with working environment 3 and 5 as stipulated by IEC 60601-2-52:2009/AMD1:2015.

Prior written consent from Betten Malsch GmbH is required if the care beds are to be used for other applications.

The product is intended for use as a care aid or health device. As such, it is subject to the regulations of the relevant insurance associations. The care bed is a medical product with reference to applicable industry standards and regulations. Therefore, this product must only be used under medical supervision.

The care beds described in this instruction manual are intended for adult residents with a body weight of at least 40 kg and a height of at least 146 cm. In accordance with the standard IEC 60601-2-52:2009/AMD1:2015, the beds must not be used by residents whose body weight and height are below these limits or who have a BMI under 17, as the risk of injury is significantly increased for this group.



Caution! The use of incompatible side rails and mattresses can lead to injury as body parts may become trapped.

ENVIRONMENTAL SUSTAINABILITY

Betten Malsch GmbH care beds are manufactured in line with the relevant regulations using state-of-the-art processing technologies and are free from hazardous materials. The materials used to finish surfaces are CFC- and solvent-free.

Care beds that are taken out of service due to their age or irreparable damage must be disposed of in line with local disposal regulations.



Caution! Observe the relevant local regulations when disposing of metal, wood and electrical waste.

NOTE REGARDING THE INSTRUCTIONS MANUAL

The following instructions and guidelines in this instruction manual are intended for care staff or other persons and staff tasked with operating and using the care bed.



The instruction manual must be accessible to personnel at all times to avoid operating errors and to guarantee fault-free operation. The care staff must have a good understanding of the care beds and be trained in their operation before using them for the first time. The instruction manual must be used for this training.

The instruction manual has been written for the IMPULSE care bed. The images, graphics and texts they contain may differ from the equipment supplied.



The manufacturer offers technician training for maintenance and servicing work on their care beds. A certificate obtained as part of this training authorises the holder to carry out technical work independently on the beds.

PICTOGRAMS / SYMBOLS

For better orientation, this instruction manual uses the pictograms described below.



Important!

Instructions labelled in this way must be strictly observed in order to avoid injury or damage!



Information!

This pictogram identifies information relating to the current subject.

SAFETY INSTRUCTIONS

It is important that the following safety instructions are observed to prevent risks to residents and carers and to avoid any damage to the bed:

- The instruction manual must be read and observed before using the care bed.
- $\textbf{ 1t is vital to observe the information given on the rating plate! The information on the rating plate is explained in detail on <math> p. 16$ of this instruction manual.
- ▲ In the event of any faults or defects that could endanger persons, the bed must not be used.
- Electrically adjustable care beds must only be operated by the resident after instruction by trained staff.
- ▲ Before the bed is used for the first time, the operator must ensure that it is safe to use and in good condition.
- ▲ The castors must always be set to the braked position to ensure the resident does not fall when getting into or out of the bed.
- ▲ The bed can be moved into various positions. When doing so, take care to ensure no parts of the body or other objects are located in the adjustment area.
- ▲ Only care staff are permitted to adjust the side rails. When adjusting the position of the sleeping surface, take care to ensure the resident does not come into contact with the side rails to avoid trapping any part of the body.

- The functionality of the side rails must be checked every day. They must not bear any load of over 75 kg vertically or over 50 kg horizontally.
- When using CPR (optional, mechanical emergency lowering of the back rest), always additionally relieve the load on the back rest by hand to prevent the back rest from dropping in an uncontrolled manner.
- The IMPULSE care bed features a battery-operated emergency mode. This allows the one-off lowering of the sleeping surface in the event of a power cut. The 9-V batteries in the control unit must be checked during the annual safety inspection and replaced at least every two years.
- ▲ The hand controller functions can be locked or released on the rear side using the key switch. Check that the locking function has taken effect on the hand controller. ☞ p. 19–20 Hand controller symbols
- The drive system used must be operated using a VDE-approved power source – 100-240 V, 50/60 Hz mains socket.
- The mains connection cable is also protected by a mechanical strain relief device. Nevertheless, take care to ensure that no sharp edges, mechanical stresses or pinch/shear points are present.
- ▲ The design of the hand controller means it can be hung on the bed in such a way that the buttons are not activated inadvertently by squashing between two objects. Take care to ensure that the hand controller is fully accessible and not trapped between the side rail and bedside table.

- ▲ Observe safety distances to walls, window ledges and other furnishings when using the care bed in an resident's room. The safety distances depend on the design and model of the care bed and are based on the height adjustment and the tilting motions of the bed. The minimum distance is 30 mm.
 - Improper use of the bed may cause hazards. Examples of improper use include:
 - Unauthorised activation of the electrical functions
 - Use of the bed by persons with a body weight of less than 40kg or a BMI of less than 17, or a height of less than 146 cm *T* p. 7 Specific function
 - Moving the bed by pulling on the mains cable or side rails
 - More than one person adjusting the bed at the same time
 - Activation of the functions by the resident without prior instruction
 - Pulling the mains cable to disconnect it from the power supply
 - Moving the bed on sloping or unsurfaced ground
 - In line with the standard DIN EN 60601-2-52:2016, when choosing a mattress, it is important that there is a minimum distance of 22 cm between the top of the sleeping surface and the top of the side rails in its fully extended position. The mattress used must meet the applicable safety standards.

- The constant presence of liquid in the area of the motor must be avoided (e.g. incontinence).
- ▲ For safety reasons, the handle on the trapeze bar must be replaced completely every 5 years.
- Servicing and repairs on electrical components must be carried out by specially trained staff and only original replacement parts from the manufacturer must be used.
- ▲ The care bed is not suitable for extended operation beyond a working cycle of two minutes. If the mains adapter is overloaded or if it overheats, it will shut off automatically. Further operation is possible only after a 30-minute cooldown phase. Observe the drive manufacturer's notes on the rating plate!
- ▲ It is essential to avoid obstructing any part of the bed mechanism as this can lead to damage or complete disabling of the drive system due to overheating.
- Likewise, the safe working load must not be exceeded.
- ▲ If an immobile resident remains in the same position for a long period without the use of additional positioning aids, this can lead to pressure sores. The manufacturer of the care bed is not liable for this in any way.
- ▲ Electrically operated care beds are active medical products and must be maintained according to Article 7 of the Medical Devices Operator Ordinance (MedProd-BetrV.) These maintenance measures must be carried out regularly (at

least once per year). This must involve visual and operational inspections of functional and electrical safety in line with VDE0751. ${\mathscr P}$, 46 Maintenance

- Furthermore, electrically operated care beds are electrical appliances and their safety is the responsibility of the employer. The supervisory function of this obligation is the responsibility of the Employers' Liability Insurance Association for Health Service and Welfare Work (BGW) and the Trade Supervisory Board (Gewerbeaufsichtsamt). The regulations of the employers' liability insurance associations apply, particularly those of the German statutory accident insurance body (DGUV), rule 3 of which stipulates regular inspections of movable electrical equipment at a recommended interval of six months, but at least once a year. These inspections may only be carried out by a certified electrician or person with electrical training using specialist measurement and inspection equipment. The inspections according to DGUV rule 3 can be conducted by specialist staff trained by the manufacturer as part of the inspections and maintenance service for medical products.
- Electrically operated care beds are active medical products and must be listed in an inventory for each site in line with Article 13 of the German Medical Devices Operator Ordinance (MedProd-BetrV). It is advisable to also document the correct implementation of the required technical safety checks in this inventory and to specify the date of the next inspection. The required protocols concerning technical safety checks already performed must be appended to the inventory.

- ▲ Proper execution and traceable documentation of the technical checks, maintenance and servicing work prescribed by the manufacturer, as well as the technical safety checks, are required in order to preserve the warranty rights of the purchaser. If the operator of a medical product does not meet their obligations, this could lead to the risk of damage and accidents for which the manufacturer is explicitly not liable.
- A Maintenance work must be carried out and documented by trained staff.
- The bed must be left in the lowest position if the resident is unattended to reduce the risk of injury caused by falling out of bed.
- ▲ If the mains connection cable is damaged, the bed must no longer be used and must immediately be taken out of operation.
- Improper use of the mains connection cable can result in hazards (e.g. electric shock). Examples of this are cable breaks due to kinking, shearing or other mechanical damage.
- ▲ When using other ME devices in conjunction with the care bed, precautions must be taken to prevent damage to the device cable or other components of the ME device resulting from crushing between the movable parts of the medically used bed.
 - The care bed is not suitable for use in the vicinity of active facilities that use high-frequency surgical devices.

▲ The care bed is not suitable for use in HF-shielded rooms used for magnetic resonance imaging in which high-intensity EM disturbance variables occur.

The use of this care bed directly next to or in conjunction with other electrical devices (e.g. stacked) must be avoided as this can lead to faulty operation. If using the bed in the manner described above is absolutely necessary, the devices involved should be subjected to a function test for a longer period of time, in order to rule out malfunction due to interference.

▲ The use of other accessories, transducers and cables other than those specified or provided by Betten Malsch GmbH can cause increased emissions of electromagnetic interference or reduce the electromagnetic interference resistance of the device and lead to faulty operation.

▲ Portable HF communication devices (radio devices) – including their accessories, such as antenna cables and external antennas – must not be used closer than 30 cm to the parts and cables of care beds as designated by Betten Malsch GmbH. Non-observance can impair the performance of the care bed.

The emissions of this device are below the thresholds defined by IEC/CISPR 11:2009, Class A and permit the use of it in industrial environments and hospitals. This device may not provide adequate protection against wireless services if used in residential areas (for which class B is normally required according to CISPR 11). The user may have to implement remedial measures such as relocating or repositioning the device.

Servicing and maintenance tasks may not be performed while the ME device is in use.

TECHNICAL DATA

| Model | Dimensions [cm] | Sleeping surface [cm] | Height adjust- ment [cm] | Weight | Maximum load | Anti-/ Trendelenburg² | Upper leg adjustment | Back rest adjustment | |
|---|--------------------|--------------------------|-----------------------------|-----------------------------|---|---|-------------------------|--|--------------------------------|
| IMPULSE care bed with | 206×100 | 200×90 | 37 to 84* | approx. | 225 kg total 190 kg resident | 17°/14° | 33° | 71° 12 cm mattress | |
| undercarriage Edition 100 | 206×110 | 200×100 | | 120 kg 20 k 15 kg | | | 55 | compensation | |
| | 206×100 | 200×90 | | | | | | | |
| | 174.5×90 | 168.5×80 | | | | | | | |
| IMPULSE | 186×90 | 180×80 | | | | | | | |
| IMPOLSE care bed with | 196×90 | 190×80 | | | 225 kg total | | | 71° 12 cm mattress compensation | |
| undercarriage | 196×100 | 190×90 | 25 to 82* | | approx. 190kg resident 120kg 20kg mattress 15kg accessories | 17°/14° | 33° | | |
| Edition 400 Edition 400 ZB | 206×90 | 200×80 | | | | | | | |
| | 206×120 | 200×110 | | | | | | | |
| | 206×130 | 200×120 | | | | | | | |
| | 226×100 | 220×90 | | | | | | | |
| IMPULSE care bed with undercarriage Edition 400 LR | 206×100 | 200×90 | 26 to 82* | approx. 120 kg | 225 kg total 190 kg resident 20 kg mattress 15 kg accessories | 17°/14° | 33° | 71° 12 cm mattress compensation | |
| IMPULSE care bed with | 206×100 | 200×90 | 27 to 80* | approx. working l | approx. | 200 kg safe working load | | 30° | 70° 12 cm mattress |
| undercarriage Edition 420 | 206 × 90 | 200 × 80 | 27 10 00 | | 165 kg resident | | 50 | compensation | |
| IMPULSE care bed with | 206×100 | 200×90 | apr | approx. 84 kg | approx. worki | 200 kg safe | | 200 | 70° |
| undercarriage Edition 420 LR | 206 x 90 | 200 x 80 | 28 to 81* | | | working load 165 kg resident | | 30° | 12 cm mattress compensation |
| IMPULSE care bed with | 206×110 | 200×100 | 22 40 92* | approx. | | 300 kg total 250 kg resident | | 220 | 71 ° |
| undercarriage Edition XL | 226×110 | 220×100 | | | 160 kg25 kg mattress25 kg accessories | | 33° | 12 cm mattress compensation | |

*measured from sleeping surface frame

LOW-VOLTAGE DRIVE SYSTEM (SMPS external switching power supply)

| Model | IMPULSE care bed with undercarriage Edition 100 | IMPULSE care bed with undercarriage Edition 400 Edition 400ZB | IMPULSE care bed with undercarriage Edition 400 LR | IMPULSE care bed with undercarriage Edition 420 Edition 420 LR | IMPULSE care bed with undercarriage Edition XL |
|-----------------------|--|---|---|--|---|
| Electrical connection | 100-240 V AC 50/60 Hz | | | | |
| Output voltage | 35 V DC 2 A 35 V DC 2,5 A | | | 35 V DC 2,5 A | |
| Over-current off | 7.5-11.5A DC | | | | |
| Over-voltage off | 45 V DC | | | | |
| Standby operation | max. 0,5 W | | | | |
| Protection | IPX4 | | | | |
| Protection class | II | | | | |

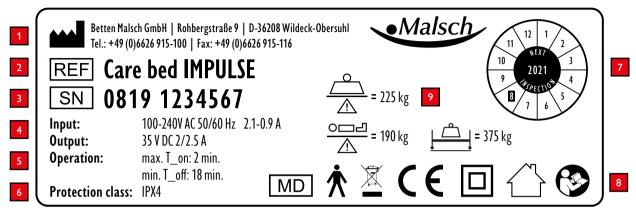
Pressure force

| Lifting system force | 2×3000 N | 2×3000 N | 1×8000 N | 2×6000 N |
|----------------------|--------------------|----------|----------|----------|
| RS adjustment force | 2×3000 N | 2×3000 N | 2×4000 N | 3×3000 N |
| Motor running time | 2 min./off 18 min. | | | |

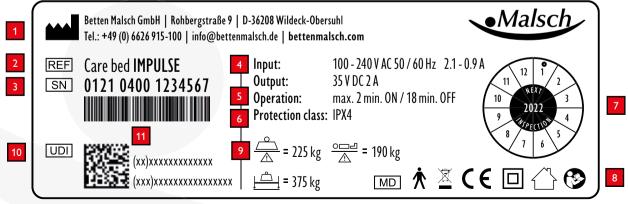
Data on operation, transport and storage

| Operating temperature range | +10°C to +40°C | |
|-------------------------------------|---------------------|--|
| Transport/storage temperature range | +5°C to +50°C | |
| Relative humidity | 30% to 75% | |
| Atmospheric pressure range | 700 hPa to 1060 hPa | |
| Operating volume | 54dB (A) | |
| Operating altitude | max. 3000 m | |

RATING PLATE



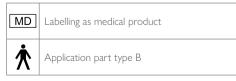
Example illustration of a rating plate of an IMPULSE without UDI



Example illustration of a rating plate of an IMPULSE with UDI

The rating plate is located on the underside of the sleeping surface, at the head of the bed on the right. To inspect the rating plate, raise the head section to the upper position.

- 1. Address of manufacturer
- 2. Model ID
- 3. Serial number
- 4. Electrical voltage, frequency, power consumption
- 5. Operating time of the motorised adjustment system: please take note of this information to prevent overheating. For example, the bed must not be operated continuously for more than 2 minutes, and after 2 minutes of continuous operation, it must be switched off for at least 18 minutes.
- Protection of electrical equipment against splash water "Only use in dry areas"; protection rating class II (double insulation, protective insulation)
- 7. Indicates the next technical check after delivery in line with VDE0751-1
- 8. Explanation of the symbols used on the rating plate:



| X | Directive 2002/96/EC relating to old electrical and electronic equipment |
|------------|--|
| CE | Conformity marking in line with the Medical Device Directive |
| | Protection rating class IPX4 and protection rating class II |
| \bigcirc | "Only use in dry areas" |
| Ⅎ | "Observe the instruction manual" |

9. Explanation of the symbols used on the rating plate:

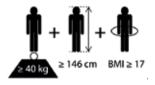
| | Safe working load |
|-----------|--|
| | Maximum permissible weight of the resident |
| <u>بگ</u> | Maximum total weight of the medical product including resident (Bed weight plus maximum permissible weight of resident) |

- 10. 2D-Barcode (GS1 Data Matrix) DI + PI = UDI
- 11. DI (Device Identifier) PI (Product Information Number)

Labels

A separate sticker to the right of the rating plate refers to the labels described below:

Symbol: Label indicating beds for adults used for medical purposes in line with IEC 60601-2-52:2009/AMD:2015



The care bed is approved for adult residents with a body weight of at least 40kg and a height of at least 146 cm. In accordance with the standard IEC 60601-2-52:2009/AMD1:2015, the care bed must not be used by residents whose body weight and height are below these limits or who have a BMI under 17, as the risk of injury is significantly increased for this group.

Symbol: Label indicating replaceable mattresses in line with IEC 60601-2-52:2009/AMD:2015 – please observe the information and instruction manuals for the mattresses.



The following table contains information concerning mattress sizes depending on the sleeping surface dimensions:

| Mattress size [cm] | Sleeping surface dimensions [cm] | Volumetric weight [kg/m³] |
|-----------------------|-------------------------------------|------------------------------|
| 78×200×12/14 | 80×200* | 35 - 50 |
| 88×200×12/14 | 90×200 | 35 - 50 |
| 98×200×12/14 | 100×200* | 35 - 50 |
| 108×200×12/14 | 110×200* | 35 - 50 |
| 118×200×12/14 | 120×200* | 35 - 50 |

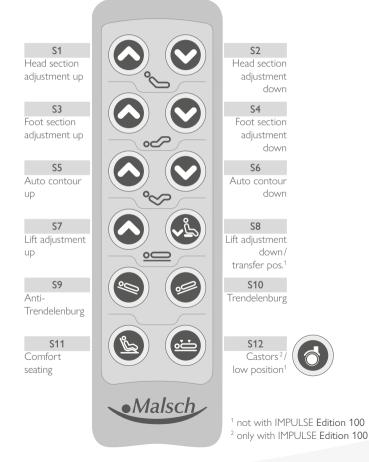
* Optional special sizes

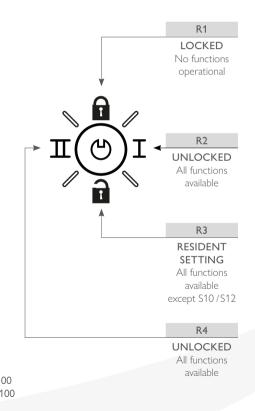
HAND CONTROLLER SYMBOLS HC-146

IMPULSE care bed with undercarriage Edition 100/Edition 400/Edition 400LR/Edition XL (design with axial tilting sleeping surface)

Locking function

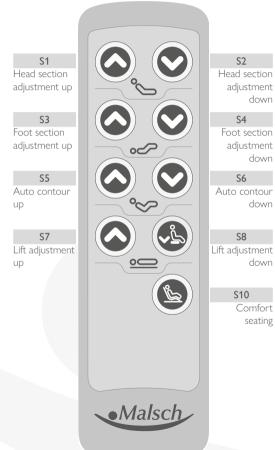
Positioned on the back of the hand controller for restricting operation by resident.





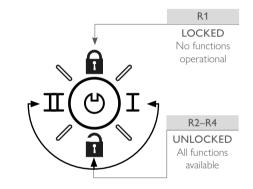
HAND CONTROLLER SYMBOLS HC-146

IMPULSE care bed with undercarriage Edition XL (design <u>without</u> axial tilting sleeping surface)



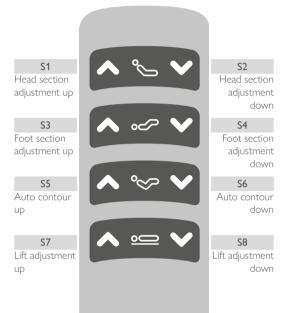
Locking function

Positioned on the back of the hand controller for restricting operation by resident.



HAND CONTROLLER SYMBOLS HC-147

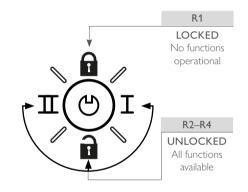
IMPULSE care bed with undercarriage Edition 420/Edition 420LR



Malsch

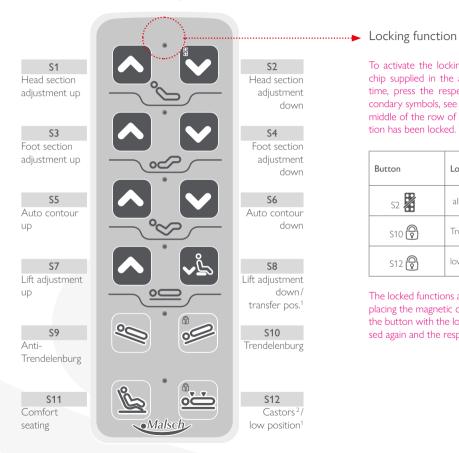
Locking function

Positioned on the back of the hand controller for restricting operation by resident.



HAND CONTROLLER SYMBOLS HB-400

IMPULSE care bed with undercarriage Editionen 400/400LR/500

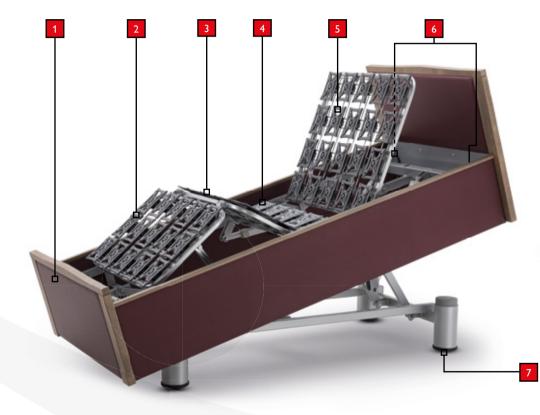


To activate the locking function, place the magnetic chip supplied in the area marked red. At the same time, press the respective blocking button (for secondary symbols, see table). A red lighted LED in the middle of the row of buttons confirms that the function has been locked.

| Button | Locking |
|--------|------------------------|
| S2 | all functions |
| S10 🕞 | Trendelenburg position |
| S12 🕞 | low position |

The locked functions are released in the same way. By placing the magnetic chip and simultaneously pressing the button with the lock symbol, the function is released again and the respective LED goes out.

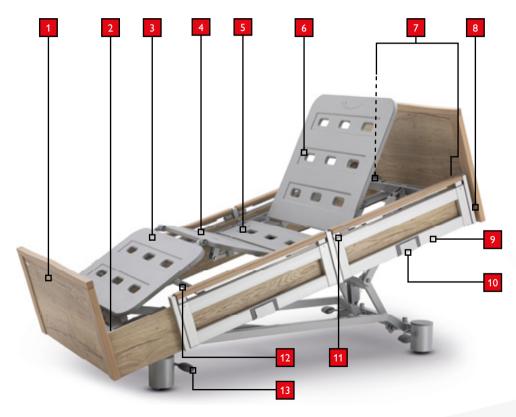
IMPULSE care bed with undercarriage Edition 100



- 1. Head/foot board
- 2. Adjustable lower leg section
- 3. Adjustable upper leg section
- 4. Seat section (fixed)
- 5. Adjustable back rest
- 6. Trapeze bar mounts on both sides at head end of sleeping surface
- 7. Stand with electronic castor positioning

IMPULSE care bed with undercarriage Edition 400

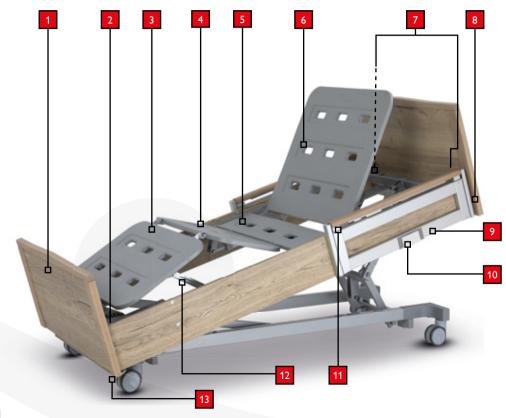
Design with vertically telescopic side rails with one-handed operation, split on both sides (EVGS 7.5.31)



- 1. Head/foot board
- Integrated two-stage bed extension (+10/+20 cm)
- 3. Adjustable lower leg section
- 4. Adjustable upper leg section
- 5. Seat section (fixed)
- 6. Adjustable back rest
- 7. Trapeze bar mounts on both sides at head and foot end of sleeping surface
- 8. Mechanical CPR emergency lowering of the back rest (optional)
- 9. Telescopic side rails (VGS)
- 10. Unlocking side rails (one-handed operation)
- 11. Telescopic side rail movement
- 12. Lower leg section adjustable notched bracket
- Foot pedal for arresting each axle
 (▲ ▼) of covered 50 mm castors

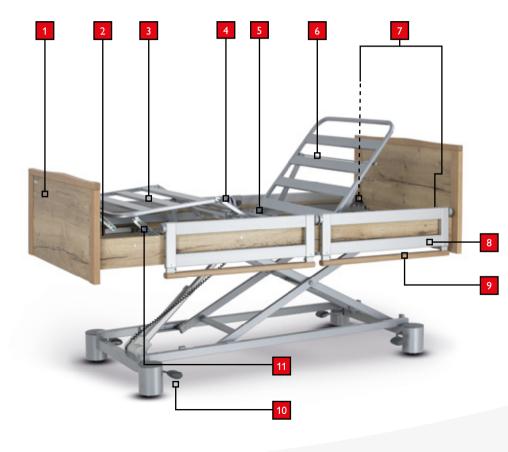
IMPULSE care bed with undercarriage Edition 400LR

Design with vertically telescopic side rails with one-handed operation, head-end (EVGSK 7.5.31)



- 1. Head/foot board
- Integrated two-stage bed extension (+10/+20 cm)
- 3. Adjustable lower leg section
- 4. Adjustable upper leg section
- 5. Seat section (fixed)
- 6. Adjustable back rest
- 7. Trapeze bar mounts on both sides at head and foot end of sleeping surface
- 8. Mechanical CPR emergency lowering of the back rest (optional)
- 9. Telescopic side rails (VGS)
- 10. Unlocking side rails (one-handed operation)
- 11. Telescopic side rail movement
- 12. Lower leg section adjustable notched bracket
- Foot pedal with central brake (▲) and fixed direction (▼) of the double castors

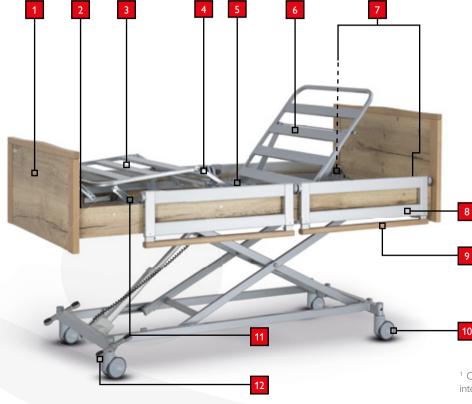
IMPULSE care bed with undercarriage Edition 420 Design with swivelling side rails, split on both sides (GS V3)



- 1. Head/foot board
- 2. Integrated two-stage bed extension (+10/+20 cm)
- 3. Adjustable lower leg section
- 4. Adjustable upper leg section
- 5. Seat section (fixed)
- 6. Adjustable back rest
- 7. Trapeze bar mounts on both sides at head and foot end of sleeping surface
- 8. Swivelling side rails (GS V2¹)
- 9. Telescopic side rail movement
- 10. Lower leg section adjustable notched bracket
- Foot pedal for arresting each axle
 (▲ ▼) of covered 50 mm castors

¹ Only on versions without integrated bed extension, otherwise V3

IMPULSE care bed with undercarriage Edition 420 LR Design with swivelling side rails, split on both sides (GS V3)

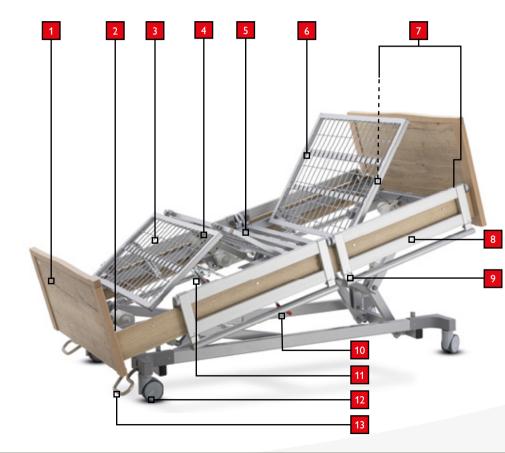


- Head/foot board 1.
- 2. Integrated two-stage bed extension (+10/+20 cm)
- 3. Adjustable lower leg section
- Adjustable upper leg section 4.
- Seat section (fixed) 5.
- Adjustable back rest 6.
- 7. Trapeze bar mounts on both sides at head and foot end of sleeping surface
- 8. Swivelling side rails (GS $V2^1$)
- 9. Telescopic side rail movement
- 125 mm double castors 10
- 11. Lower leg section adjustable notched bracket
- Foot pedal with central brake (\checkmark), 12. fixed direction (\blacktriangle) and free wheel (-) of the double castors

¹ Only on variants without integrated bed extension, otherwise V3

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IMPULSE care bed with undercarriage Edition XL Design with swivelling side rails, split on both sides (GS V3)



- 1. Head/foot board
- 2. Integrated two-stage bed extension (+ 10/+ 20 cm)
- 3. Adjustable lower leg section
- 4. Adjustable upper leg section
- 5. Seat section (fixed)
- 6. Adjustable back rest
- 7. Trapeze bar mounts on both sides at head and foot end of sleeping surface
- 8. Swivelling side rails (GS V2¹)
- 9. Telescopic side rail movement
- 10. CPR emergency lowering (optional, design with GS)
- 11. Lower leg section adjustable notched bracket
- 12. 125 mm double castors
- Foot pedal with central brake (▼), fixed direction (▲) and free wheel
 (−) of the double castors

¹ Only on variants without integrated bed extension, otherwise V3

DESCRIPTION OF FUNCTION

Depending on the design and type of care bed, the bed can be adjusted into various positions by adjusting the back rest, the upper leg section, the lower leg section and the height of the bed:

Back rest

Use the corresponding buttons on the hand controller to adjust the back rest.



(Back rest operating buttons)

When raised, the back rest can be adjusted by 120 mm over its usual length to the head board or 100 mm with Edt. $420/420 \, LR$ (optional). Undercarriage Edition $420/420 \, LR$ optionally available with 100 mm mattress compensation of the backrest.

This function (mattress compensation) allows the resident to sit in a comfortable position while avoiding compression of the buttocks area and without compressing or restricting the stomach or upper body.

Mechanical back rest release/CPR (option)

Model for VGS Handle at head end on a level with the side rails.

When operating the mechanical release, hold the backrest firmly in the current



position and, if possible, relieve some of the load. Pull the release to disengage the back rest and lower it manually into the end position.

Model for GS/ Model without side rail

Handle at the middle of the bed underneath the side panel.

When operating the mechanical release, hold the backrest firmly in the current position and, if possible, relieve some of the load. Pull the release to disengage the back rest and lower it manually into the end position.



Press the S1 button on the hand controller again to reactivate electrical back rest adjustment.



Caution! Before pressing the lever, ensure that there are no objects or parts of the body below the back rest. Manually relieve the weight on the back rest during adjustment to prevent it falling in an uncontrolled manner.

¹Undercarriage Edition 400/400 LR/100/XL

Upper/lower leg section

Use the corresponding buttons on the hand controller to adjust the upper leg section.



(Upper leg section operating buttons)

Care staff can move the lower leg section into a horizontal position (extended leg elevation) using the adjustable notched bracket.

Auto contour

Use the corresponding buttons on the hand controller to adjust the auto contour.



(Auto contour operating buttons)

Using the button function adjusts the back rest and upper leg section equally.

This function must only be used with mobile residents and residents without any physical problems.



Caution! Please consider resident safety when adjusting the auto contour! Ensure that no body parts or any objects are located in the area of the lifting mechanism.

Height adjustment

Use the corresponding buttons on the hand controller to adjust the height.



(Height adjustment operating buttons)



Caution! Please consider resident safety when adjusting the height. Ensure that no body parts or any objects are located in the area of the lifting mechanism.

Transfer position

(only with IMPULSE care bed with undercarriage $Edition\;400$ and IMPULSE care bed with undercarriage $Edition\;400\,LR)$

The transfer position facilitates optimum mounting and dismounting with the seat area of the bed at a sitting height. Hold the operating button down until the position is reached.



(Transfer position operating button)

Low position/fall prevention

(only with IMPULSE care bed with undercarriage $Edition\;400$ and IMPULSE care bed with undercarriage $Edition\;400\,LR)$

Use the corresponding buttons on the hand controller to adjust the bed to the low position.



(Low position operating button)

Press the button to lower the bed from the transfer position to the low position.

The undercarriages Editions 420/420LR are adjusted to the low position by means of the S8 button on the hand controller without intermediate stop.



Caution! Before pressing the button, be sure that the lowered split side rails are pushed in ($\mathcal{T} p$. 38, Fig. 1) and there are no body parts or any objects under the bed!

Trendelenburg position

(not with IMPULSE care bed with undercarriage Edition XL and Editions $420/420\,\text{LR})$

Use the corresponding buttons on the hand controller to adjust the bed to the Trendelenburg position.



(Trendelenburg position button)

Care beds with HC-146/HC-147:

The Trendelenburg position is blocked for safety reasons when the bed is in resident setting.

Care staff can release the block using the key switch on the back of the hand controller (position R2 – FREE). *T* p. 19 Hand controller symbols



After this, the bed can be moved into the Trendelenburg position using the S10 button on the hand controller. The incline of the sleeping surface is listed in the table on \mathscr{P} p. 14 Technical data.

Care beds with HB-400:

The locking function of the Trendelenburg position is activated with the aid of the magnetic chip supplied (@ p. 22, Locked Function Hand controller HB-400). The locked function is released in the same way.



Caution! The Trendelenburg function cannot be implemented if a power supply failure occurs in combination with an empty battery or if the lifting motors fail. In this case, the resident must be relocated to another bed as required.



Warning! The Trendelenburg position must only be used if prescribed by a doctor. Improper use can result in lasting injury to residents.

Anti-Trendelenburg position

(not with IMPULSE care bed with undercarriage $Edition \; XL$ and $Editions \; 420/420 \, LR)$

Use the appropriate button on the hand controller to adjust the bed to the anti-Trendelenburg position (feet lowered).



(Anti-Trendelenburg operating button)

The incline of the sleeping surface is listed in the table on *T* p. 14 Technical data.



Caution! Please consider resident safety when adjusting the bed inclination. Ensure that no body parts or any objects are located in the area of the lifting mechanism.

Comfort sitting position

(not with IMPULSE care bed with undercarriage Editions $420/420\,LR)$

Use the corresponding buttons on the hand controller to adjust the comfort sitting position.



(Comfort sitting position operating buttons)

Pressing the button moves the bed quickly into a comfortable sitting position by simultaneously adjusting the sleeping surface and the lifting mechanism.

This function must only be used with mobile residents and residents without any physical problems.



Caution! Please consider resident safety when adjusting the bed to the comfort sitting position. Ensure that no body parts or any objects are located in the area of the lifting mechanism.

Hand controller locking function

The electrical unit combines state-of-the-art technology and single-fault safety.

The locking function is a further safety precaution.

Operating locking function hand controller HC-146/HC-147:

The locking function is located on the back of the hand controller and can be operated by staff with a key switch. By turning the key switch to the various switch positions, it is possible to restrict the hand controller functions. Symbols $\ensuremath{\mathscr{T}}$ p. 19-20.

Operation locking function hand controller HB-400:

To activate the locking function, place the magnetic chip supplied in the area marked red. At the same time, press the respective blocking button (for secondary symbols, see table $\[mathbb{m}\]p$, 22-20). A red lighted LED in the middle of the row of buttons confirms that the function has been locked.

The locked functions are released in the same way. By placing the magnetic chip and simultaneously pressing the button with the lock symbol, the function is released again and the respective LED goes out r p. 22-20.

Braking and transport

IMPULSE care bed with undercarriage Edition 100

The sleeping surface is in the lowest position. Enable the castors by pressing the S8 button on the hand controller and pressing the castor button at the same time.



(Enable castors operating buttons)

The IMPULSE Edition 100 model is now in transport mode. Press the S7 button on the hand controller (height adjustment up) to retract the castors and position the bed on its feet.



(Retract castors/brake operating buttons)



On the IMPULSE care bed with undercarriage Edition 100 (only mobile in low position), the S8 button on the hand controller has a double function.



Caution! Transport mode must only be used whilst the bed is being moved. After moving the bed, disable the castors by moving the sleeping surface back to a raised position.

IMPULSE care bed with undercarriage Edition 400/420

The IMPULSE care beds with undercarriage Edition 400 and Edition 420 (mobile at any positioning height) have one central castor brake per axle, which is operated mechanically using a foot pedal accessible from both sides.



The IMPULSE care beds with undercarriage Edition 400 and Edition 420 have two different adjustment options:

- 1. Castors braked (foot pedal down)
- 2. Castors enabled for 360° movement (foot pedal up)

IMPULSE care bed with undercarriage Edition 400 LR and Edition XL

The IMPULSE care beds with undercarriage Edition 400 LR and Edition XL have one central castor brake, which is operated mechanically with a central foot pedal. The foot pedal is located in the central foot area of the chassis.

The IMPULSE care beds with undercarriage Edition 400 LR and Edition XL have three different adjustment options:



- 1. Castors centrally braked (foot pedal down)
- 2. 4 castors enabled for 360° movement (foot pedal in the middle)
- 3. 1 castor set to a fixed direction (foot pedal up)

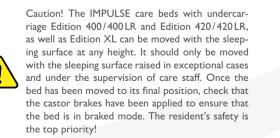
IMPULSE care bed with undercarriage Edition 420 LR

The IMPULSE Edition 420 LR model with optional castor sizes of 100 mm or 125 mm (mobile in any positioning height) has one central castor brake, which is operated mechanically with a central foot pedal. The foot pedal is located on both sides near the foot end axle.



The IMPULSE care beds with undercarriage Edition 420 LR model has three different adjustment options:

- 1. Central braking of the castors (foot pedal at the bottom)
- 2. 4 castors enabled for 360° movement (horizontal foot pedal)
- 3. 1 castor set to a fixed direction (external foot pedal up)



Adjust DS side rails

Full-length side rails

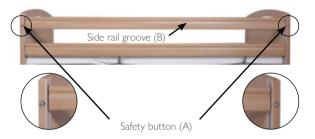
In the down position, the side rails are located on top of one another next to the sleeping surface frame.

1. Raising function:

Lift the upper side rail by the side rail groove (B) until you hear the safety button (A) lock into place on both sides.



Caution! Check that the side rail is locked in place by rattling it several times.



2. Lowering function:

Slightly lift the upper side rail by the side rail groove (B), while at the same time pushing in the safety button (A). Slowly lower the side rail to the lowest position. Repeat the process at the other end of the bed.



Caution! When lowering and raising the side rails, please be extremely careful not to trap fingers, hands or any other parts of the body between the side rails and the sleeping surface frame.



Caution! For disorientated or undernourished residents, we strongly recommend using side rail padding to prevent limbs from becoming trapped between the side rail gaps, which could lead to injury. DS side rail dimensions

Adjust GS side rails

Split side rails

- In standby position, the side rails are located next to the sleeping surface. In this position, they prevent the mattress from slipping. (Fig. 1)
- The side rails are raised by swiveling them upwards. In the middle position, they prevent the resident from falling out of bed. When raised at the head end, they also provide standing and mobility assistance for the resident. (Fig. 2)
- 3. The upright side rail is released by means of two spring catches in the side bars below the height adjustment handrail and positioned at its maximum height. Perform telescopic adjustments using both hands simultaneously when moving the rail upwards or downwards to prevent jamming. (Fig. 3) **Do not force the movement!**
- 4. To lower the telescoping side rail height extension, proceed the same way as to raise it.
- To swivel the side rails back to the standby position, press the indicated latches on the lower side rail bar inwards simultaneously and initiate the tilting motion. (Fig. 4)



Caution! When raising the side rails and side rail height extensions, ensure and check that the latches engage securely. Always use both hands to move this element! Caution! Activate the low position on the IMPULSE care bed with undercarriage Edition 400/400 LR and Edition 420/420 LR only with retracted side rails! (Fig. 1)



VGS side rail dimensions

Adjust VGS side rails

Vertically retractable split side rails

In standby position, the side rails are located next to the sleeping surface. In this position, they prevent the mattress from slipping.

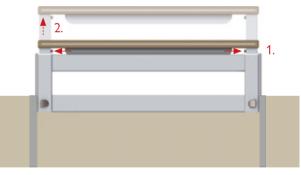
- To raise the side rails, pull them upwards with both hands until they engage with an audible click. In the middle position, they prevent the resident from falling out of bed. When raised at the head end, they also provide standing and mobility assistance for the resident. (Fig. A, 1.)
- 2. The side rail extension can be released using the two spring catches below the handrail for telescopic movement and adjusted to its maximum height. Pull the rail upwards using both hands simultaneously (Fig. B, 1./2). Take care not to tilt and jam the element. Follow these actions in reverse to lower the rail. Do not force the movement!
- To lower the side rails, push the two release slides inwards with both hands (Fig. A, 2) and lower the side rails carefully into the standby position.



Caution! When raising the side rails and side rail height extensions, ensure and check that the latches engage securely. Always use both hands to move this element!









Adjust EVGS side rails

Vertically retractable split side rails with one-handed operation

In standby position, the side rails are located next to the sleeping surface. In this position, they prevent the mattress from slipping.

- To raise the side rails, pull them upwards with both hands until they engage with an audible click. In the middle position, they prevent the resident from falling out of bed. When raised at the head end, they also provide standing and mobility assistance for the resident. (Fig. A, 1.)
- 2. The side rail extension can be released using the two spring catches below the handrail for telescopic movement and adjusted to its maximum height. Pull the rail upwards using both hands simultaneously (Fig. B, 1./2). Take care not to tilt and jam the element. Follow these actions in reverse to lower the rail. Do not force the movement!
- To lower the side rails, pull the release handle forward with one hand (Fig. A, 2.) and carefully lower the side rails into the standby position.



Caution! When raising the side rails and side rail height extensions, ensure and check that the latches engage securely. Always use both hands to move this element!

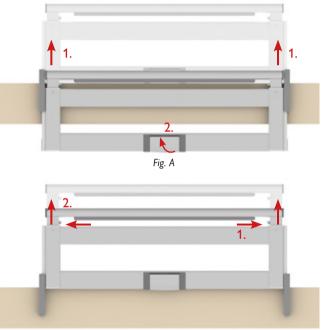
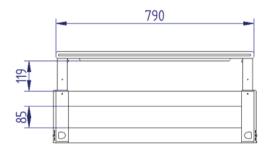


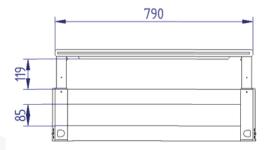
Fig. B

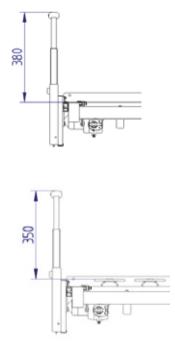
VGS side rail dimensions

When using the ABS/metal lattice sleeping surface



When using the comfort sleeping surface





Integrated bed extension

Beds equipped at the factory with an integrated bed extension (optional) can be extended by up to 20 cm without tools. For this to be possible, the side rail bars of full-length side rails must be replaced.

This function is activated in three stages and without tools using the two locking bolts at the bottom foot end of the sleeping surface:

- On the IMPULSE care beds with undercarriage Editions 400/400 LR, pull both locking bolts upwards and then rotate them about a quarter turn to the right until they reach the locking point. On the IMPULSE care beds with undercarriage Editions 420/420 LR, the locking bolts point laterally inwards. The mode of operation is analogous to the chassis editions described above. The bed extension is now unlocked.
- Reach below the foot board and carefully pull out the bed extension by approx. 10 cm or 20 cm.
- 3. Finally, turn the locking bolts back to their original positions. Afterwards, push the bed extension back carefully until the mechanism engages.



Caution! A mattress insert (accessory) must be used with 20 cm extensions. To use a mattress insert, first pull the bed extension out as far as it will go. Once the insert has been positioned, continue as described in point 3.



Caution! The sleeping surface extension must only be activated by authorised specialist staff.

IMPULSE care bed with undercarriage $Editions\;400/400\,LR$ and $Edition\;XL$



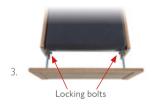
IMPULSE care bed with undercarriage Editions 420/420LR















Caution! For reasons of safety, it is essential to replace existing safety elements and attachments if the sleeping surface extension is activated on beds with full-length side rails!

MAINTENANCE

The manufacturer is only liable for the safety and reliability of the product if it is serviced regularly and used in line with the safety instructions. If any significant faults are found during maintenance work which mean the safe operation of the product cannot be guaranteed, the product must be taken out of use. Maintenance work must be carried out at least once a year.



Any faults that impair the function and safety of the care bed must be resolved before the bed is used again and must be reported to the responsible person.

Only original replacement parts from Betten Malsch GmbH are permitted to be used.



Service and maintenance tasks must not be conducted when the bed is occupied. The resident or the care staff must not conduct maintenance tasks.

Procedure

1. Visual inspection

Check the welded structures for cracked weld seams and for plastic deformation and wear. The welded structures include the undercarriage and the sleeping surface with the moving interior components. Also check that all screw joints are firmly connected.

2. Level of protection and functionality check of the side rails

During the functionality check, check whether the side rails can be easily locked in place and that no impermissible wear or deformation is visible.

The spacing requirements stated in DIN EN 60601-2-52 are used to check the level of protection. This is shown by the following diagram and table.

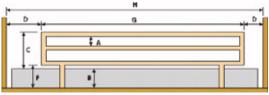


Fig. 1 (dimensions of a single-piece side rail)

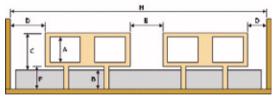


Fig. 2 (dimensions of a split side rail)

Check whether the required spacings are also complied with under load. Check dimensions A and D using a test tool in line with DIN EN 60601-2-52. The test force for dimension A is 250 N.

| Dim | ensions | Requirement [mm] | |
|-----|---|-------------------------------------|--|
| A | The largest dimension in at least one direction between components of the side rail/handrail in all commonly used positions. | A ≤ 120 | |
| В | Thickness of the normally used mattress without compression as stated by the manufacturer | As stated by the manufacturer | |
| С | Distance from the upper edge of the side rail to the upper edge of the mattress without compression with the sleeping surface in a level position. | C ≥ 220 | |
| D | Distance between head/foot board or accessories to the side rail/handrail is parallel to the sleeping surface in a level position. This also applies to extended foot sections. | D ≤ 60 or D ≥ 318 | |
| E | Distance between split side rails with sleeping surface in a level position. | E ≤ 60 or E ≥ 318 | |

| F | The largest dimension in at least one direc- tion of every opening below the side rail | If $D \ge 250$; F ≤ 60 |
|---|---|--------------------------------|
| F | | If $D \le 60$; F \le 120 |
| G | Length of the side rail(s) | G ≥ 2/3 H |
| Н | Inner distance between head and foot board without any extension of these parts | No requirements |

3. Functionality check of brakes

Depending on the variant, the functionality of the brakes must be checked in every position. Check whether the brakes of electrical brake systems fully retract and extend.

4. Functionality check of the lifting motors

Move all lifting motors to their end position and back again. When doing so, please observe the following points:

- Any unusual noises generated
- Synchronism of the lifting motors
- Smooth operation of the lifting motors
- Correct path of the lifting motors
- Lifting motors must switch off automatically once they reach the end position

The travel path of the lifting motors may vary depending on the model variant. If in doubt, please contact our customer service.

5. Visual inspection of mains connection cables

Check the following points on the mains connection cable:

- Visually inspect and check the function of the strain relief and kink protection
- Visually inspect insulation parts
- Visually inspect connection cables (damage, crushing)
- Visually inspect mains connection plug
- Visually inspect cable hooks

6. Visual inspection of wiring

Check the following points:

- Damage to the cables
- Correct cable routing
- Plug connections and pull-out protection firmly connected

7. Visual inspection of housing

The housings must be checked for external damage and intact seals.

8. Battery replacement

The battery must be replaced in line with specifications at least every 2 years or after every case of emergency lowering.

9. Measurements in line with DIN EN 62353

Check the electrical components of the care bed as specified in DIN EN 62353. Leakage current is measured using substitute leakage test. The limit is $\leq 500~\mu A.$

10. Visual inspection grab handle for trapeze bar

Check that the plastic components and straps show no signs of damage. The grab handles must be replaced every 5 years.

Battery replacement

The 9-V block battery/batteries must be changed at 2-year intervals and after every actuation of the electrical emergency lowering function in order to guarantee the functional capability of emergency lowering. Only use brand batteries and please dispose of old batteries in an environmentally friendly manner.

The two 9-V block batteries are inserted in the motor control unit housing below the mounting panel. The pull-out slots are secured with a screw. This must be removed beforehand.



MAINTENANCE INTERVALS

Every 2 years and after every emergency lowering

Replace the two 9-V block batteries

Annually

Inspection and maintenance

As required

- Lubricate mechanical components
- Replace worn components if a defect occurs.

DELIVERY AND ASSEMBLY

Betten Malsch GmbH care beds are generally delivered fully assembled, or are assembled on site by company technicians or contractual partners.

Check the delivered bed against documentation for completeness and conformity.

Any defects or damage must be pointed out to the freight company immediately and noted on the delivery document.

Signing of the delivery documents by both parties is obligatory before commissioning.

If necessary, e.g. for maintenance, simple assembly procedures can also be performed by professional authorised persons.



After maintenance and servicing work has been completed, check the functionality of electrical systems.

i

The manufacturer offers technician training for maintenance and servicing work on their care beds. A certificate obtained as part of this training authorises the holder to carry out technical work independently on the beds.

DISPOSAL INSTRUCTIONS

The service life of the care bed is specified as 10 years if used appropriately.

Disposal instructions

- The operator must ensure that none of the components being disposed of are infectious/contaminated.
- If the bed is scrapped, the wood, plastic and metal parts used in its construction must be separated and disposed of properly.
- If you have any questions, contact your local authority, waste-disposal company or our customer service.

Electrical component disposal

- This bed is electrically adjustable and classified as a commercially used electrical device according to WEEE Directive 2012/19/EU (implemented in Germany in the electrical equipment act).
- The electrical components used are free from banned harmful substances in line with the 2010/65/EU.
- Replaced electrical components (drives, control units, hand controllers etc.) of these beds must be treated as electronic waste in line with the WEEE Directive and disposed of properly.

Battery disposal

- Any individual removed batteries that can no longer be used must be disposed of properly as defined by Directive 2006/66/EC (implemented in Germany in the battery legislation) and must not be discarded with domestic waste.
- For information on this matter, contact your local waste-disposal company or our Service department.

In other countries outside Germany/the EU, the relevant, applicable national requirements must be observed.

ACCESSORIES (OPTIONAL)

Trapeze bar

The trapeze bar can be inserted to the left and right of the head end in the designated mounting sockets on the sleeping surface frame. Please ensure that the bolt is properly seated in the notch provided on the mount.

Its safe working load is $75 \, \text{kg}$.

IV drip holder

The IV drip holder can be inserted in the sockets provided on the sleeping surface frame to the left or right of the head/foot end.

The IV drip holder is only intended for attaching IV drips and not for hanging up other accessories or similar objects.

The maximum load is 8 kg (2 kg per hook).

Bedside light

The bedside light is attached to the mount provided on the sleeping surface frame in the same way as the trapeze bar.



Caution! For safety reasons, the bedside light must only be used with the care bed manufacturer's original adapter and must only be fitted by authorised specialist staff.









Follow the safety instructions in the bedside light instruction manual.

Hand controller bracket

The additional, optional hand controller bracket is used to position the hand controller within reach of the resident.





Caution! The hand controller bracket is flexible and must not be used as an aid to standing up or as a handle.

Integrated bed linen holder

The integrated bed linen holder can be easily extended by pulling at the base of the foot board. This hygienic shelf directly on the bed simplifies changing the bed linen.



TROUBLESHOOTING

| Malfunction | Possible cause | Possible solution | | |
|-------------------------------------|---|--|--|--------------------------|
| | Mains cable is not plugged in | Plug in the mains cable | | Drive after of op |
| | Socket not live Check socket Cable plug connection not firmly connected Check plug connections on the motor and hand controller | | | |
| Drives cannot be operated using the | | | | Oppo |
| hand controller | Hand controller or drive is faulty | Inform the oper- ator, specialised dealer or our customer service | | opera contr |
| | Functions locked on the hand controller | Release the func- tion on the hand controller (@ p. 19–20) | | The s no lo erly a |
| Motorised adjust- ment system is | There is an obstruction in the adjustment area | Check moving parts and remove any obstructions | | Caste |
| not functioning properly | The safe working load has been exceeded | Reduce the load | | rolled |

| Drives cut out after a long period of operation | The adjustment time or safe working load has been exceeded and the control unit has reacted to overheating | Allow the drive system to cool down sufficiently. |
|---|--|--|
| Opposite function activates when operating the hand controller buttons | | Check that the ca- bles are connected correctly or inform your operator, specialist retailer or our customer service |
| The side rails can no longer be prop- erly adjusted | The mechanism is obstructed or bent | Check all moving parts and remove any obstructions or contact our customer service |
| Castors do not | Obstructions have become trapped in the castors | Remove obstruc- tions |
| brake or cannot be rolled | The castor system is faulty | Contact our customer service team |
| | | |

PRODUCT SAFETY

This product bears the CE seal and therefore meets the requirements of German and European safety standards applicable to the product.

| Standard | Comment | | |
|---------------------------|--|--|--|
| MPDG | Medical devices implementation act | | |
| VO (EU) 2017/745 | Europäische Medizinprodukteverordnung (Medical Device Regulation, MDR) | | |
| DIN EN ISO 13485 | Quality management for medical products | | |
| DIN EN ISO 9001 | Quality management systems | | |
| DIN EN ISO 14001 | Environmental management systems | | |
| DIN EN ISO 14971 | Risk analysis | | |
| DIN EN 12182 | Technical aids for disabled persons | | |
| DIN EN 60601-2-52 | Medical electrical equipment | | |
| DIN EN 60601-1 | Medical electrical equipment | | |
| DIN EN 60601-1-2 | EMC – electromagnetic compatibility | | |
| DIN EN 12530/DIN EN 12531 | Medical castors | | |
| DIN EN ISO 15223-1 | Symbols for labelling medical products | | |
| DIN EN 1041 | Symbols and information accompanying medical products | | |
| DIN 33402-1 | Human body dimensions | | |
| DIN 68861-1 | Furniture surfaces | | |
| BfArM recommendation | German Federal Institute for Drugs and Medical Devices | | |

CLEANING AND DISINFECTION

Disinfection

The care bed must be disinfected regularly and at least before every change of resident. All detergents in line with DIN EN 12720 are suitable for wipe-down disinfection of the bed. The care bed must not be disinfected in inline washing systems or using water spray. Betten Malsch GmbH recommends the care products listed by the RKI for disinfection.

The detergents used for disinfection must only be used in line with the manufacturer's instructions.



Caution! Under no circumstances use abrasives, cleaning pads or stainless-steel cleaners for cleaning. Before using any disinfectants, please consider the dosage and any potential hazards that may be caused by combining them with other substances. Remove the plug from the mains socket when disinfecting the care bed and protect the drive system from moisture.



We provide separate instructions for cleaning and disinfecting our care beds.

Care of wooden parts

Malsch care beds only use wooden parts that are finished in compliance with the DIN 68861-1A standard. The aim is to produce a comfortable design, maximum functionality and a high level of practical use. To ensure you are able to enjoy this product for as long as possible, we recommend cleaning with commercial furniture cleaning products and polishes.

Even after extremely careful selection and sorting of our wooden materials, the wood is subject to a natural ageing process. Over time, environmental influences such as air humidity, heat and UV radiation can cause changes in the colour of real wood surfaces, even when they are treated. Solid wood elements are a natural product with an individual grain and characteristics. Slight colour and shading differences within the same delivery are natural and technically unavoidable. For these reasons, relative shading and colour differences and marks due to natural growth patterns in real wood do not constitute a fault and Betten Malsch GmbH can accept no liability or warranty claims for these.

SAFE DECOMMISSIONING / STORAGE

Proceed as follows to safely decommission the bed or prepare the bed for storage:

- Disconnect the bed from the power by pulling out the mains plug.
- Activate the brake system.

Storage

- Charge the (optional) battery regularly to prevent deep discharge.
- Remove any accessories such as bed lamps, trapeze bars etc.
- Cover the care beds so that the wooden parts and the frame cannot be damaged.
- Mark the storage date clearly on the bed (so that maintenance intervals can be observed).
- Lock the hand controller.



Caution! The same conditions apply to the storage location of care beds as to the working environment (temperature, humidity, heat, etc.)



The manufacturer's transport aid must be used to transport the beds.

ELECTROMAGNETIC COMPATIBILITY (EMC)

The bed is intended for operation in the electromagnetic environments listed below. The customer or user of the bed must ensure that it is used in a suitable environment.

Guidelines and manufacturers' declarations - electromagnetic emissions

| Emission measurement | Compliance | Electromagnetic environment directive | |
|--|------------|---|--|
| RF emissions, CISPR 11 | Group 1 | The bed uses HF energy exclusively for its internal functions. There- fore, it produces very low HF emissions and it is unlikely that nearby electronic devices will be adversely affected. | |
| RF emissions, CISPR 11 | Class A | The bed is suitable for use in all facilities including residential areas and | |
| HF emissions IEC 61000-3-2 | Class A | those that are directly connected to a public supply network that also supplies buildings used for residential purposes. | |
| Voltage fluctuations and flicker IEC 61000-3-3 | Compliant | | |

Guidelines and manufacturers' declarations - electromagnetic resistance

| Phenomena | EMC basic standard or test procedure | Environments in domestic health care areas | Compliance level | Electromagnetic environment directives |
|-----------------------------|--|--|--|---|
| Static electricity | IEC 61000-4-2 | ±8 kV contact | ±8 kV contact | The flooring material must consist of wood or |
| discharge | | ±2 kV; ±4 kV; ±8 kV; ±15 kV air discharge | ±2 kV; ±4 kV; ±8 kV; ±15 kV air discharge | concrete. If synthetic materials are used, the relative humidity must be at least 30%. |
| High-frequency | IEC 61000-4-3 | 10 V/m | 10 V/m | Portable and mobile radio devices must not |
| electromagnet- ic fields | | 80 MHz to 2.7 GHz | 80 MHz to 2.7 GHz | be used closer to the care bed and its cables than the recommended distance calculated |
| | | | 80% AM at 1 kHz | using the equation applicable to the frequency of the transmitter. |

| Magnetic | IEC 61000-4-8 | 30 A/m | 30 A/m | Power-frequency magnetic fields must | | |
|---|---|---|---|---|--|--|
| fields with energetic rated frequencies | | 50/60 Hz | 50/60 Hz | correspond to the typical value found in the business and hospital environments | | |
| Electrical | IEC 61000-4-4 | ±2 kV | ±2 kV | The power supply quality must correspond | | |
| fast transient disturbances/ bursts | | 100 kHz repetition frequency | | to that of a typical business or hospital environment. | | |
| Surge voltage | IEC 61000-4-5 | ±0.5; ±1 kV | ±0.5; ±1 kV | The power supply quality must correspond | | |
| Cable to cable | - | | | to that of a typical business or hospital environment. | | |
| Surge voltage | IEC 61000-4-5 | ±0.5; ±1 kV; ±2 kV | ±0.5; ±1 kV; ±2 | The power supply quality must correspond | | |
| Cable to ground | | | | to that of a typical business or hospital environment. | | |
| Conducted disturbances | IEC 61000-4-6 | 3 V | 3 V | | | |
| induced by high-frequency fields | | 6 V in ISM and amateur radio frequency bands | 6 V in ISM and amateur radio frequency bands | - | | |
| Voltage dips | IEC 61000-4-11 | 0% UT; ½ cycle | 0% UT; ½ cycle | The power supply quality must correspond | | |
| | 270 and 3 0% UT; 1 and 70% UT; | at 0, 45, 90, 135, 180, 225, 270 and 315 degrees | at 0, 45, 90, 135, 180, 225, 270 and 315 degrees | to that of a typical business or hospital environment. | | |
| | | 70% UT; 25/30 cycles | 0% UT; 1 cycle and 70% UT; 25/30 cycles | If the user of the bed requires continued func- tionality even in the event of power supply disruptions, it is advisable to supply the bed with power from an uninterruptible power supply or from a battery. | | |
| | | Single-phase: at 0 degrees | Single-phase: at 0 degrees | | | |
| Power failures | IEC 61000-4-11 | 0 % UT; 250 / 300 cycles | 0% UT; 250/300 cycles | | | |

Interference resistance of enclosure ports to high-frequency wireless communication equipment

| Test frequency [MHz] | Band [MHz] | Service | Modulation | Maximum power [W] | Distance [m] | Immunity test level [V/m] |
|-------------------------|--------------|---|--|----------------------|--------------|------------------------------|
| 385 | 380 to 390 | TETRA 400 | Pulse modulation 16 Hz | 1.8 | 0.3 | 27 |
| 450 | 430 to 470 | GMRS 460, FRS 460 | Frequency modulation ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710 | 704 to 787 | LTE band 13, 17 | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| 145 | - | | | | | |
| 780 | - | | | | | |
| 810 | 800 to 960 | GSM 800/900, | Pulse modulation 18 Hz | 2 | 0.3 | 28 |
| 870 | - | TETRA 800, iDEN 820, | | | | |
| 930 | | CDMA 850, LTE Band 5 | | | | |
| 1,720 | 1700 to 1990 | | | 2 | 0.3 | 28 |
| 1,845 | | CDMA 1900; GSM 1900; | 217 Hz | | | |
| 1,970 | - | DECT; LTE band 1, 3,4,5; UMTS | | | | |
| 2,450 | 2400 to 2570 | Bluetooth; WLAN 802.11 b/g/n, RFID 2450 LTE band 7 | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 5,240 | 5100 to 5800 | WLAN 802.11 a/n | Pulse modulation | 0.2 | 0.3 | 9 |
| 5,500 | | | 217 Hz | | | |
| 5,785 | | | | | | |

WARRANTY AND SERVICE

DECLARATION OF CONFORMITY

By purchasing a care bed from Betten Malsch GmbH, you have chosen a premium, high-quality product.

Malsch care beds are covered by a 24-month warranty calculated from the date of purchase.

In the event of material or manufacturing faults occurring within the warranty period, the bed will be replaced or repaired free of charge.

This excludes faults and errors caused by inappropriate handling or external influences.

Our normal terms of business and delivery apply.

If you have any questions, please contact us on the following numbers:

Customer service

Phone: +49 (0) 6626 915-100 Fax: +49 (0) 6626 915-127

info@bettenmalsch.de bettenmalsch.com

| Product award 2016 | AN GN RD IER | Malsch care & clinic design |
|--|--|--|
| DE LO | | EN |
| EG-Konformitätserkläru | ng | EC Declaration of Conformity |
| nach der Verordnung (EU) 2017/745 d und des Rates vom 5. April 2017 über | es europäischen Parlaments | in accordance with Regulation (EU) 2017/745 of the European Parla- ment and of the Council of S April 2017 concerning medical devices, Annew IV |
| Der Hersteller Betten Malsch GmbH Rohbergstraße 9 36208 Wildeck-Obersuhl, Deutschlan Tel. +49 (0) 6626 915-116 erklirt in alleinger Verantwortung, dass | | Avise.iv. The manufacturer Betten Malch GmbH Rohbergstraß Rohbergstraß Bolz Schuller Jéc08 Wildsch-Ohersahl, Germany Phone: +490 (06:66:915-100) Fax: +49 (0) 66:26 915-116 |
| Produkte den grundlegenden Anforden der Verordnung (EU) 2017/745 für Me- und gemäß der Anhänge II, III und VIII (zugeordnet werden: | ungen und Bestimmungen dizinprodukte entsprechen | declares under its sole responsibility that the devices named below comply with the essential requirements and provisions of Regulation (EU) 2017/95 for medical devices and are assigned to risk class I in accordance with Annexes II, III and VIII (Rule 1.13): |
| Produktnamen: Pflegebett AURA Pflegebett IMPULSE Pflegebett AYLEEN | | Product names: Care bed AURA Care bed MPULSE Care bed AYLEEN |
| Basis UDI-DI: 4065848MALSCH-PKL | 10002V | Basic UDI-DI: 4065848MALSCH-PKL00002V |
| Die bezeichneten Produkte wurden um Richtlinien und harmonisierten Normer | | The designated products have been produced in application of the following directives and harmonised standards: |
| Elektrische Sicherheit: IEC 60601-1 | A2:2019 | Electrical safety: IEC 60601-1 A2:2019 |
| Mechanische Sicherheit: IEC 60601- | 2-52:2009+A1:2015 | Mechanical safety: IEC 60601-2-52:2009+A1:2015 |
| EMV: IEC 60601-1-2:2014 | | EMC: IEC 60601-1-2:2014 |
| Gebrauchstauglichkeit: IEC 60601-1-6:2010+A1:2013 IEC 62366-1:2015+CCR1:2016 | | Usability: IEC 60601-1-6:2010+A1:2013 IEC 62366-1:2015+COR1:2016 |
| Risikomanagement: DIN EN ISO 14 | 971-2020-07 | Risk Management: DIN EN ISO 14971:2020-07 |
| Richtlinie zur Beschränkung gefähr Richtlinie 2011/65/EU | licher Stoffe RoHS | Directive on the Restriction of Hazardous Substances RoHS Directive 2011/65/EU |
| Durch die Einhaltung der Bestimmungen werden die Anförderungen zur Anbring erfüllt. Aufgrund der Spezifikation als M Produkt und Verpackung spättestens ab UDI-Kennzeichnung versehen. Eine Kor Entwicklungsdokumentation sowie des Zertifizierung nach DIN EN ISO 13485 | ung einer CE-Kennzeichnung edizinprodukt Klasse I werden Mai 2025 zusätzlich mit einer formität der Produkt- und QM-Systems wird durch die | By complying with the provisions of Regulation (EU) 2017/745, the requirements for allowing a CE marking are Allifect. Due to the specification as medical device calls. I the product and packaging will additionally be provided with a LDI marking from May 2025 at the tasts. Continning of the product and development documentation as well as the QM system is confirmed by certification according to DIN RN ISC 11465/2016. |
| Bei einer mit uns nicht abgestimmt genannten Produktes verliert diese | | In the event of a modification of the above-mentioned produc not agreed with us, this declaration loses its validity. |
| Wildeck, den 23.04.2021 | Geschäftsführer / CEC | 07 Gérant |
| | | Deutsche Bank AG |

CERTIFICATES



Item no. 91300 100002.1 DE, Stand 05/2021, Rev. 2.1 Colours may vary

Subject to technical changes

Bakare Beds Version: Rev ¹ Initial Issue Updated: 26.4.22

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