Malsch
care & clinic design®

CARE DESIGN

AURA

INSTRUCTION MANUAL

Malsch
care & clinic design®

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.

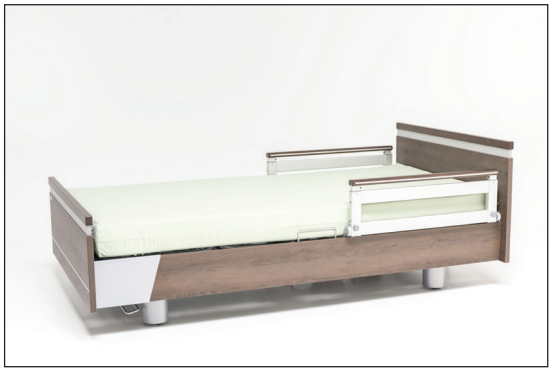
We would like to thank you for the trust you have placed in us.

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.

CONTENTS

PRODUCT RANGE



Aura low care bed

SPECIFIC FUNCTION

Betten Malsch GmbH care beds are used in the care sector and in senior citizen facilities. These beds are designed exclusively for this purpose. The comfort and functionality offered by the care beds make life easier for staff as they carry out their caring duties. The beds also facilitate the positioning, compensation and relief of disabilities for people in nursing homes and care facilities.

If the care beds are to be used for other applications, prior written agreement from Betten Malsch GmbH is required.

The product is intended for use as a care aid or assistive device. As such, it is subject to the regulations of the relevant insurance associations. The care bed is considered a medical product with regard 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 occupants 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 occupants whose body weight and height is 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 FOR USE

The following instructions and guidelines in this 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 Aura 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 ease of reference, we sometimes use pictograms in this manual as follows:

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.

Observe service instructions! We can supply you with special service instructions for accessories or complex work instructions. You will find these in the Service area at bettenmalsch.de.

SAFETY INSTRUCTIONS

1. The instruction manual must be read and observed before using the care bed.

2. It is vital to observe the information given on the rating plate! The information given on the rating plate is explained in detail on *P. 13* of this instruction manual.

3. In the event of any faults or defects that could endanger persons, the bed must not be used.

4. Electrically-adjustable care beds must only be operated by the occupant after instruction by trained staff.

5. Before the bed is used for the first time, the operator must be satisfied that it is safe to use and in good condition.

6. The castors must always be placed in the braked position to ensure the occupant does not fall when getting into or out of the bed.

7. 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.

8. Only care staff may adjust the side rails. When adjusting the position of the reclining surface, care should be taken to ensure the occupant does not come into contact with the side rails in order to avoid trapping any part of the body.

9. 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.

10. 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 dropping in an uncontrolled manner.

11. The Aura care bed features a battery-operated emergency mode. This allows the one-off lowering of the reclining 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.

12. 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. 14 Hand controller symbols*

13. The drive system used must be operated using a VDE-approved power source – 220 V, 50/60 Hz mains socket.

14. In addition, the mains cable is protected by a mechanical strain relief. Nevertheless, take care to ensure that no sharp edges, mechanical stresses or pinch/shear points are present.

15. 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.

16. Observe safety distances to walls, window ledges and other furnishings when using the care bed in an occupant'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.

17. Improper use of the bed may cause hazards.
Examples of improper use are:

⚠ Unauthorised activation of the electrical functions

⚠ Use of the bed by children under the age of 12

⚠ 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 occupant without prior instruction

⚠ Pulling on the mains cable to disconnect it from the power supply

⚠ Moving the bed on a sloping or rough surface

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

⚠ In line with the standard 60601-2-52:2010, when choosing a mattress it is important that there is a minimum distance of 22 cm between the top of the reclining surface and the top of the side rail in its fully extended position. The mattress used must meet the applicable safety standards.

⚠ Liquid permanently present in the motorised area must be avoided (e.g. incontinence).

⚠ For safety reasons, the handle on the trapeze bar must be replaced completely every five 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. It can then only be operated again after a cooling period of approx. 30 minutes. (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 mechanism due to overheating.

⚠ Likewise, the safe working load must not be exceeded.

⚠ If an immobile occupant remains in the same position for a long period without the use of 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 medical products. As such, they are subject to safety inspections in line with the German Medical Device Directive (MPG) and

§ 6 of the German Medical Device Operator Ordinance (MedProd-BetrV). These regular safety inspections must be carried out at least once a year. This must involve visual and operational inspections of functional and electrical safety in line with VDE0751.
☞ *P. 29 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 Association for Health Service and Welfare Work apply in the place of work (abbreviated to BGV, formerly VBG). In particular, BGV A2 (formerly VBG "Electrical Units and Equipment") applies. This requires regular inspection 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. Inspections in line with BGV A2 can be carried out by specialist staff trained by the manufacturer as part of the technical safety checks for medical products, as these BGV inspections are included in the technical safety checks.

⚠ Electrically operated care beds are active medical products and must be listed in an inventory for each site in line with the German Medical Device Operator Ordinance (MedProd-BetrV). We recommend you also document correct implementation of the required technical safety checks in this inventory and note 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.

⚠ Any maintenance work is to be carried out in line with VDE0751-1 and the subsequent technical safety inspection is to be documented.

TECHNICAL DATA

Dimensions	approx. 206 x 100 cm
Reclining surface (RS):	200 x 90 cm
Height adjustment:	approx. 25 to 82 cm*

*measured from the reclining surface frame

Back rest adjustment:	71° back rest recline 12 cm mattress compensation
Upper leg adjustment:	43°
Trendelenburg:	14°
Reverse Trendelenburg:	17°
Maximum load:	225 kg (190 kg occupant weight + 20 kg mattress + 15 kg accessories)
Weight:	approx. 120 kg

Low-voltage drive system

(SMPS external switching power supply)

Electrical connection:	240 V≈ 50 Hz
Output voltage:	35 V= 2 A
Over-current off:	7.5–11.5 A
Over-voltage off:	45 V=
Standby operation:	max. 0.5 watt
Protection:	IPX4
Protection class:	II
Lifting system force:	2 x 3000 N
RS adjustment force:	2 x 3000 N
Motor running time:	2 min/off 18 min

RATING PLATE

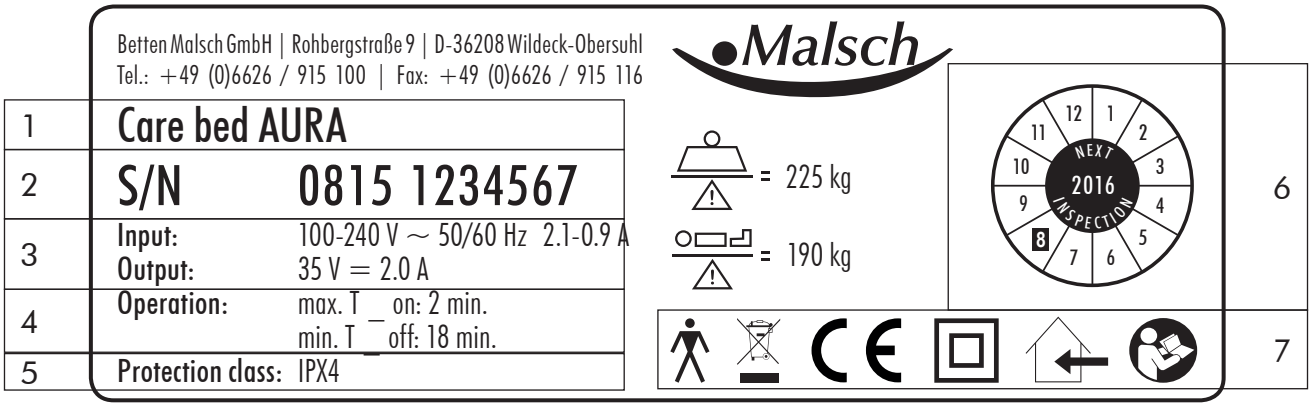


Illustration of a rating plate example on an Aura care bed; standard design with mains connection

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

1. Model ID
2. Serial number
3. Electrical voltage, frequency, power consumption
4. Operating time of the electrical adjustment system: please take note of this information to prevent overheating. For example, the bed can only be continuously operated for max. 2 min. within an 18 min. period.
5. Protection of electrical equipment from water spray "Only use in dry areas"; Protection Rating Class II (double insulation, protective insulation)
6. Indicates the next technical check after delivery in line with VDE0751-1

7. Explanation of the terms used on the rating plate:

Application part type B

Directive 2002/96/EC relating to old electrical and electronic equipment

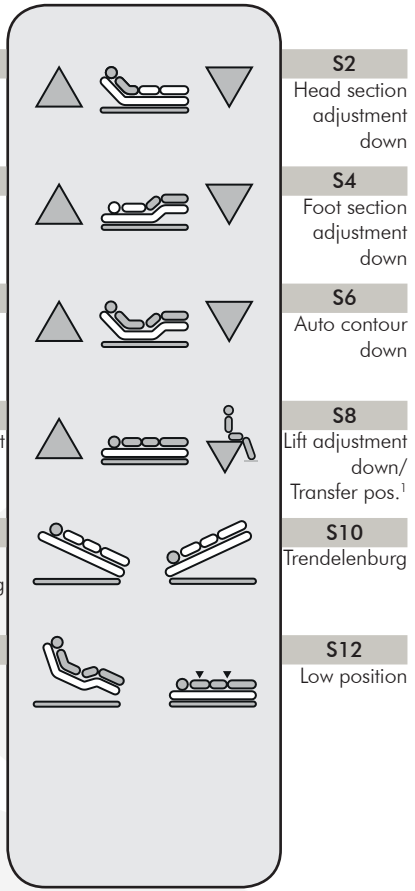
Conformity marking in line with the Medical Device Directive

Protection Rating Class II (double insulation, protective insulation)

Only use in dry areas

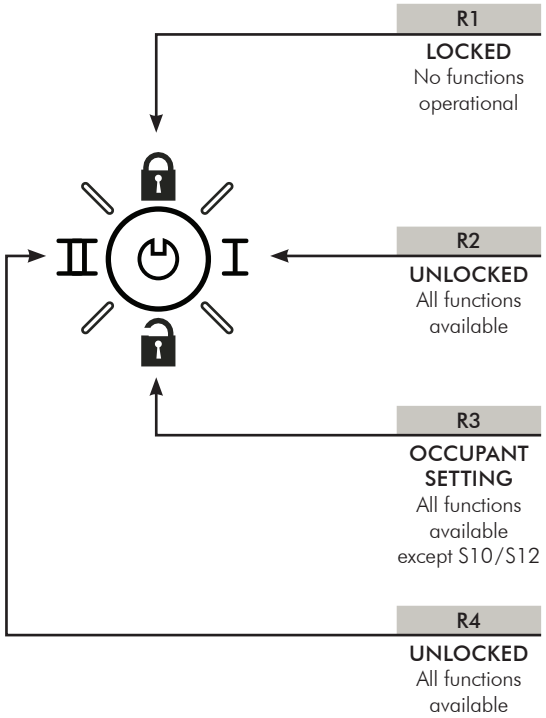
Observe the operating instructions

HAND CONTROLLER SYMBOLS

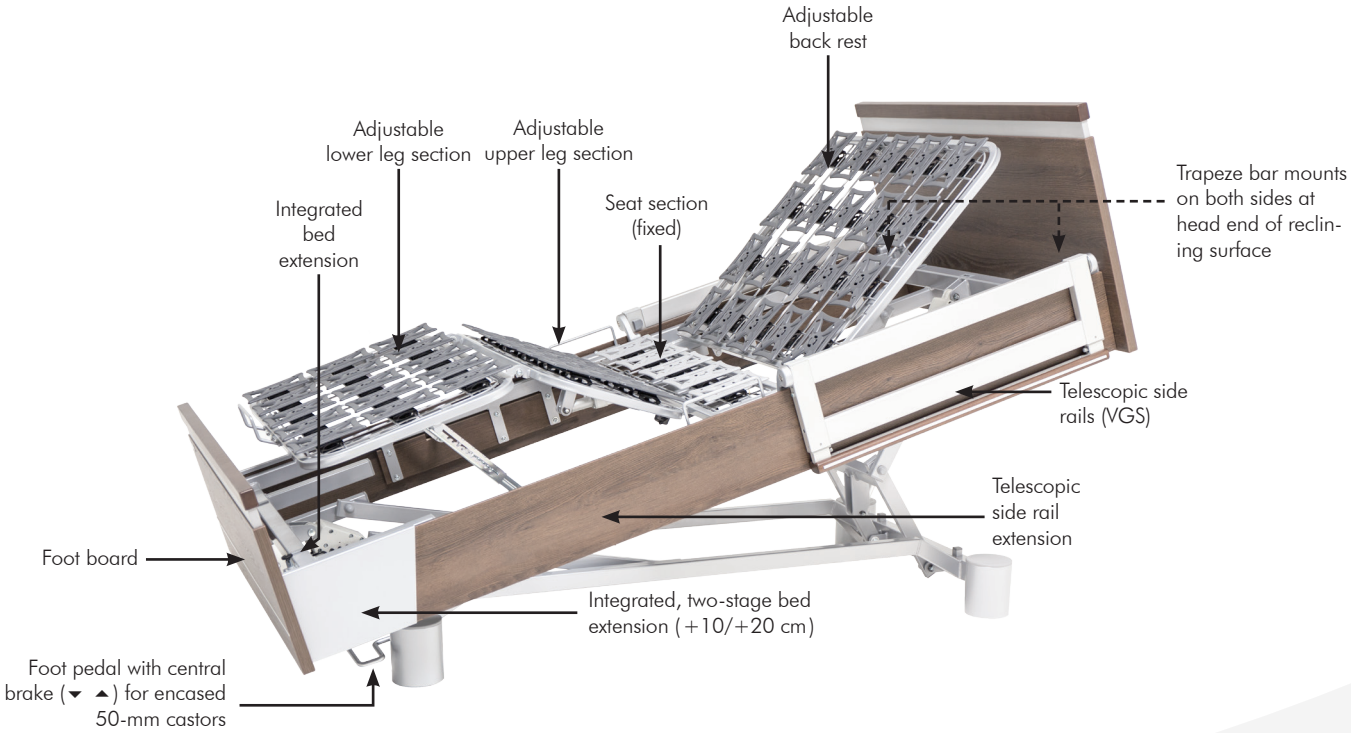


Locking function

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



FUNCTIONS


Adjustable back rest
Adjustable lower leg section
Adjustable upper leg section
Integrated bed extension
Seat section (fixed)
Trapeze bar mounts on both sides at head end of reclining surface
Telescopic side rails (VGS)
Telescopic side rail extension
Foot board
Integrated, two-stage bed extension (+10/+20 cm)
Foot pedal with central brake (▼ ▲) for encased 50-mm castors

Depending on the design and type of care bed, the bed can be put into the following 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.

This function (mattress compensation) allows the occupant to sit in a comfortable position without compressing or restricting the stomach or upper body.

Mechanical backrest release/CPR

(optional)

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 backrest 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.

Upper leg section

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

(Upper leg section operating buttons)

For safety reasons, this position must only be adjusted by medical personnel.

The horizontal position of the lower leg section can be adjusted by care staff using the finely notched bracket. (extended leg elevation)

Height adjustment

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

(Height adjustment operating buttons)

Caution! Please consider occupant safety when adjusting the height. Ensure that no foreign objects are located in the area of the lifting mechanism.

Transfer position

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

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.

Caution! Ensure that there are no objects below the bed before pressing the button!

Comfort sitting position

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

(Comfort sitting position operating button)

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

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

Caution! Please consider occupant safety when setting the comfort sitting position. Ensure that no foreign objects are located in the area of the lifting mechanism.

Auto contour

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

(Auto contour operating buttons)

When this function is activated, the back and upper leg sections are adjusted equally so that the occupant can be brought into an upright sitting position.

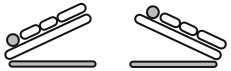
This function must only be used with mobile occupants and occupants without any physical problems.

Caution! Please consider occupant safety when setting the auto contour. Ensure that no foreign objects are located in the area of the lifting mechanism.

Trendelenburg/ reverse Trendelenburg position

The Aura care bed features reclining surface inclination as standard.

The head or foot height is set using the button on the hand controller.



(Trendelenburg/anti-Trendelenburg operating buttons)

Caution! Please consider occupant safety when adjusting the bed inclination. Ensure that no foreign objects are located in the area of the lifting mechanism. This function must only be activated by specialist staff and must be locked on the back of the hand controller by specialist staff. Incorrect settings may result in serious injury to the occupant.

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. It is located on the back of the hand controller and can be operated by staff with a key switch. In the event that the electrical drives fail, the functions can be disabled using the corresponding rotary switch.

Operation:

Hand controller functions can be restricted by turning the key switch to the different switch positions. Symbols ☞ *P. 14*

Braking and moving

The Aura care bed (mobile at any positioning height) has one central castor brake that is operated mechanically using a brake stirrup at the foot end of the bed. The brake stirrup is as wide as the entire chassis making it accessible from both sides.

The Aura care bed has 3 different setting 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)

Caution! The Aura care bed can be moved with the reclining surface at any height setting. It should only be moved with the reclining surface raised in exceptional cases and under the supervision of care staff. Once the bed has been moved to its final position, check that the castor brakes have been applied to ensure that the bed is in braked mode. The occupant's safety is the top priority!

Side rail adjustment

Split side rails

1. In the standby position, the side rails are located next to the reclining surface. In this position, they prevent the mattress from slipping.
2. To raise the side rail, pull it upwards with both hands until it engages with an audible click. This middle-height head-end side rail setting is suitable for use as an occupant mobility support. (Fig. A, 1)
3. Release the side rail for telescopic movement using the two spring catches below the hand rail and adjust it to the 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!**
4. To lower the side rail, push the two release slides inwards with both hands (Fig. A, 2) and lower the side rail carefully into the rest 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!

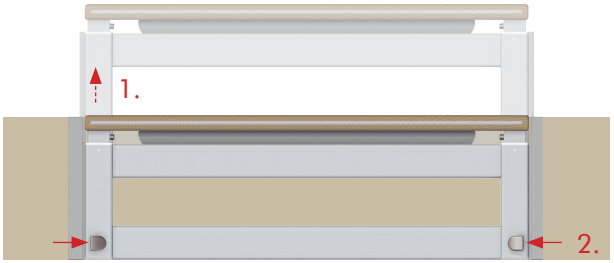


Fig. A

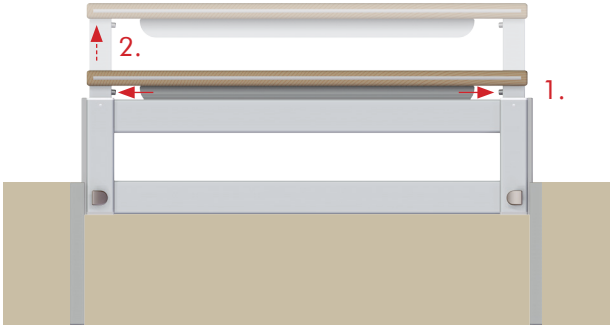
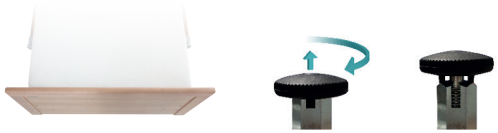


Fig. B

1.



2.

3.

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

Integrated bed extension

The reclining surface of the Aura can be extended by up to 20 cm without tools and without compromising its appearance.

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

1. Pull both locking bolts upwards and then turn to the right until they engage. The bed extension is now unlocked.

2. 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. 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. Continue as described in point 3 after positioning the insert.

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

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.

We offer comprehensive service instructions for expert authorised staff for the assembly of head/foot boards/reclining surfaces and for the installation/replacement of reclining surface motors.

After service and maintenance work has been completed, the functionality of electrical systems must be checked.

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.

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 reclining surface frame. Please ensure that the bolt is properly seated in the notch provided on the mount.

Its safe working load is 75 kg.

IV drip holder

The IV drip holder can be inserted in the sockets provided on the reclining 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 reclining 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 holder

The additional, optional hand controller holder is used to position the hand controller within reach of the occupant.

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

Horizontal hand controller

Alternatively, the optional horizontal hand controller can be connected to the control unit to allow the reclining occupant easy access to the functions.

Caution! The horizontal hand controller must not be used as an aid to rising or as a grip.

Caution! The additional hand controller must only be fitted by authorised specialist staff.

Integrated bed linen holder
(optional)

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

TROUBLESHOOTING

Drives cannot be operated using the hand controller	Mains cable is not plugged in	Plug in the mains cable
	Socket not live	Check socket
	Cable plug connection not firmly connected	Check plug connections on the motor and hand controller
	Hand controller or drive is faulty	Inform the operator, specialist retailer or Betten Malsch GmbH
	Mains cut-off not activated (only for ICS control units)	Activate the mains cut-off by pressing the green button
	Functions locked on the hand controller	Enable functions on the hand controller
Motorised adjustment system is not functioning properly	There is an obstruction in the adjustment area	Check moving parts and remove any obstructions
	The safe working load has been exceeded	Reduce the load

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	Motor plugs have been mixed up	Check that the cables are connected correctly or inform your operator, specialist retailer or Betten Malsch GmbH
The side rails can no longer be properly adjusted	The mechanism is obstructed or bent	Check all moving parts and remove any obstructions, or contact our customer service team
Castors do not brake or cannot be rolled	Obstructions have become trapped in the castors	Remove obstructions
	The castor system is faulty	Contact our customer service team

PRODUCT SAFETY

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

Standard	Comment
Medical product in line with 93/42/EEC	Medical Device Directive (CE marking)
MPG	German Medical Devices Act
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

Disinfection

The care bed must be disinfected regularly and at least before every change of occupant. 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 detergents Terralin, Perform and Sagrotan-Med or equivalent detergents 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.

MAINTENANCE

The manufacturer is only liable for the safety and reliability of the product if it is maintained 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.

The regulations of the general operator ordinance and the regulations for the use of electrically adjustable furniture stipulated by the German Medical Device Operator Ordinance (§6 MPBetreibV) apply. Likewise, the provisions of the German Accident Prevention and Insurance Association (BGV A3) on electrical units and equipment apply in line with the German Ordinance on Industrial Safety and Health (BetrSichV, TRBS, DIN VDE 0701-0702).

We offer inspection plans for servicing our care beds in a separate service guide.

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 spare parts from Betten Malsch GmbH are permitted to be used.

STORAGE

The following steps must be taken when storing care beds.

- ⚠ Disconnect the mains plug and store it for transport.
- ⚠ Charge the battery regularly (optional) 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, moisture, heat etc.).

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

WARRANTY AND SERVICE

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

The care beds are guaranteed for 24 months
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 / 915 128
Fax: +49 (0)6626 915 127

info@bettenmalsch.de
bettenmalsch.com

DECLARATION OF CONFORMITY

Malsch
care & clinic design

DE

EG-Konformitätserklärung

nach der EG-Richtlinie für Medizinprodukte 93/42/EWG, Anhang VII

Hiermit erklärt der Hersteller

Betten Malsch GmbH
Rohbergstraße 9
36208 Wildeck-Obersuhl, Deutschland

Tel. +49 (0)6626 - 915 100
Fax +49 (0)6626 - 915 116

dass die Produkte

Pflegebett Aura
Pflegebett Ambiente

den „grundlegenden Anforderungen" und Bestimmungen gemäß Anhang I der Richtlinie 93/42/EWG über Medizinprodukte entspricht.

Das bezeichnende Produkt wurde unter Anwendung der harmonisierten Normen

DIN EN 1970:2000 + A1:2007
Verstellbare Betten für behinderte Menschen

DIN EN 60601-2-52:2010
Sicherheit für elektrisch betriebene Pflegebetten

produziert.

Das bezeichnende Produkt wurde unter Anwendung des Qualitätsmanagementsystem gemäß

DIN EN ISO 9001:2008
Zertifikat Nr. 73 100 1297

DIN EN ISO 14001:2009
Zertifikat Nr. 73 104 1297

entwickelt, hergestellt und geprüft.

Die Konformität des Qualitätsmanagementsystems wird bescheinigt durch:

TÜV CERT-Zertifizierungsstelle des TÜV Hessen

Bei einer mit uns nicht abgestimmten Änderung des oben genannten Produktes verliert diese Erklärung ihre Gültigkeit.

EN

EC declaration of conformity

in accordance with the EC Directive 93/42/EEC, appendix VII concerning medical devices

The manufacturer

Betten Malsch GmbH
Rohbergstraße 9
36208 Wildeck-Obersuhl, Germany

Tel. +49 (0)6626 - 915 100
Fax +49 (0)6626 - 915 116

hereby declares, under its sole responsibility, that the following products:

Aura care bed
Ambiente care bed

fulfill the „fundamental requirements" and stipulations in accordance with appendix I of the EC Directive 93/42/EEC concerning medical devices.

The specified products were produced in line with the harmonised standards

DIN EN 1970:2000 + A1:2007
Adjustable beds for disabled persons

DIN EN 60601-2-52:2010
Particular requirements for basic safety and essential performance of electrically operated medical beds

The specified products were developed, manufactured and tested on the basis of the quality management system in accordance with

DIN EN ISO 9001:2008
certificate no. 73 100 1297

DIN EN ISO 14001:2009
certificate no. 73 104 1297

The conformity of the quality management system is certified by:

TÜV CERT-certification authority of the TÜV Hessen (German Association for Technical Inspection, State of Hesse)

The present declaration shall become null and void should any alterations be made to the products specified above without our express approval.

FR

Déclaration de conformité CE

selon la directive européenne 93/42/CEE relative aux dispositifs médicaux, annexe VII

Le fabricant

Betten Malsch GmbH
Rohbergstraße 9
36208 Wildeck-Obersuhl, RFA

Tél. +49 (0)6626 - 915 100
Fax +49 (0)6626 - 915 116

déclare par la présente que les produits

lit médicalisé Aura
lit médicalisé Ambiente

sont en conformité avec les « exigences fondamentales » et les dispositions de l'annexe I de la directive européenne 93/42 CEE relative aux dispositifs médicaux.

Le produit désigné a été développé, fabriqué et testé dans le cadre d'un système de gestion qualité répondant aux normes harmonisées

DIN EN 1970:2000 + A1:2007
Lits réglables pour personnes handicapées

DIN EN 60601-2-52:2010
Sécurité pour lits médicalisés à moteur électrique.

Le produit désigné a été développé, fabriqué et testé dans le cadre d'un système de gestion qualité répondant aux normes

DIN EN ISO 9001:2008
Certificat n° 73 100 1297

DIN EN ISO 14001:2009
Certificat n° 73 104 1297

La conformité du système de gestion qualité a été certifiée par:

L'organisme de certification TÜV CERT du TÜV Hessen

La présente déclaration devient caduque en cas de modification apportée au produit susmentionné sans notre accord.

Wildeck, den 06.01.2016

Rayk Malsch
Geschäftsführer /CEO / Gérant

Betten Malsch GmbH
Geschäftsführer: Rayk Malsch
Amtsgericht Bad Hersfeld, HRB 1510
Erfüllungsort: Wildeck
Steuernummer: 025/229/35183
USt-Ident.-Nr.: DE 223 637 968

Firmenzentrale
Rohbergstraße 9
D-36208 Wildeck-Obersuhl
Tel.: +49 (0)6626 / 915 100
Fax: +49 (0)6626 / 915 116
E-Mail: info@bettenmalsch.de

Deutsche Bank AG
IBAN: DE14 5327 0012 0864 3553 01
BIC: DEUTDEFF532
VR-Bank Nordrhön eG
IBAN: DE25 5306 1230 0003 4000 00
BIC: GENODEF1HUE

TÜV PROFI CERT

CERTIFICATES


TÜV PROFI CERT

CERTIFICATE

Management system as per

DIN EN ISO 13485:2012

Evidence of conformity with the above standard(s) has been furnished and is certified in accordance with TÜV PROFICERT procedures for

Malsch core & clinic design

Betten Malsch GmbH
Rohbergstraße 9
36208 Wildeck - Obersuhl / Germany

scope:

Development, manufacturing and distribution of clinic- and health care bed systems, room furnishing

Certificate registration No. **73 105 1297**	Certificate valid from 2017-07-11 to **2020-07-10**
Audit report No. 4310 8904	First certification 2017-07-11


TÜV PROFI CERT

CERTIFICATE

Management system as per

DIN EN ISO 9001:2015

Evidence of conformity with the above standard(s) has been furnished and is certified in accordance with TÜV PROFICERT procedures for

Malsch core & clinic design

Betten Malsch GmbH
Rohbergstraße 9
D-36208 Wildeck - Obersuhl

scope:

Development, manufacturing and distribution of clinic- and health care bed systems, room furnishing

Certificate registration No. **73 100 1297**	Certificate valid from 2016-10-01 to **2019-09-30**
Audit report No. 4306 3642	First certification 2004-07-21


TÜV PROFI CERT

CERTIFICATE

Management system as per

DIN EN ISO 14001:2015

Evidence of conformity with the above standard(s) has been furnished and is certified in accordance with TÜV PROFICERT procedures for

Malsch core & clinic design

Betten Malsch GmbH
Rohbergstraße 9
D-36208 Wildeck - Obersuhl

scope:

Development, manufacturing and distribution of clinic- and health care bed systems, room furnishing

Certificate registration No. **73 104 1297**	Certificate valid from 2016-10-01 to **2019-09-30**
Audit report No. 4306 3642	First certification 2013-10-01

Art. no.
EN, Edition 07/2017, Rev. 1.2
Colours may vary

Betten Malsch GmbH | Rohbergstraße 9 | 36208 Wildeck-Obersuhl | Germany
Tel.: +49 (0)6626 / 915 100 | Fax: +49 (0)6626 915 116
bettenmalsch.com | info@bettenmalsch.de