

Spezialbetten



Instruction for use

**Stand: 08/2022
(Rev. 5.0)**

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1 Foreword

Dear customer!

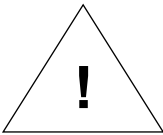




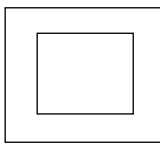
We would like to thank you for the trust you have placed in us and for purchasing our product. We have manufactured this medical product with great care.










Please read the instructions for use carefully before using the product for the first time and always keep them close at hand.

Not all conceivable uses of the device can be covered in these instructions for use. For further information or in the event of problems that are not described in sufficient detail in these instructions for use, please contact your specialist dealer or medical supply store.

2 General notes

2.1 Used symbols

	<p>This warning sign indicates all instructions that are important for safety. Non-observance can lead to accidents or injuries.</p>
	<p>Manufacturer - Indicates the manufacturer of the medical device according to EU Directives 2017/745. The symbol must appear in close proximity to the symbol, together with the name and address of the manufacturer (i.e. the person who places the medical device on the market)</p>
	<p>Conformity symbol according to 2017/745 of the Medical Devices Directive</p>
	<p>Medical Device - Shows the medical device provided by the manufacturer in accordance with EU Directives 2017/745</p>
	<p>Device type B according to IEC 601-1 (Special protection against electric shock)</p>
	<p>Device of protection class II, protective insulation</p>

	<p>Dispose of electrical components in accordance with the legal requirements. Do not dispose of in household waste!</p>
	<p>Date of manufacture - indicates the date when the medical device was manufactured.</p>
	<p>Part number - displays the manufacturer's part number so that the medical device can be identified.</p>
	<p>Serial number - displays the manufacturer's serial number so that a specific medical device can be identified.</p>
	<p>Distributor - indicates the company that distributes the medical device at the location.</p>
	<p>Temperature Limit - indicates the temperature limits to which the medical device can be safely exposed.</p>
	<p>Humidity, Limit - indicates the humidity range to which the medical device can be safely exposed.</p>
	<p>Air Pressure, Limit - indicates the range of air pressure to which the medical device can be safely exposed.</p>
	<p>Observe instruction for use or electronic instruction for use - indicates to the user that it is necessary to observe the instruction for use.</p>

	Unique identifier of a medical device - displays a carrier containing information about a unique identifier of a medical device.
	Safe working load
	Max. patient weight
	Minimum body dimensions/weights of the patient

Table 1: Used symbols

2.2 Type plate

The type plate is attached to the head of the trolley frame. The nameplate allows the product to be clearly identified.

MD

REF

Safe working load:



SN

UDI

CE



ISKO KOCH GmbH
95448 Bayreuth
Egerländer Str. 28

ISKMed



13.01.2022



(01) 0 4251858 50276 5 (11) 220113 (21) 220100FB0005

Figure 1: Exemplary type plate

Figure 1 shows an exemplary type plate. For the exact specifications of your product, please refer to the attached type plate.

2.3 Standards verification

The following national and international norms (standards) are used in the design and verification of the product, labeling and instructions for use.

Standard	Title	Edition
DIN EN 60601-2-52	<i>Medical electrical equipment - Part 2-52: Particular requirements for the safety of medical beds</i>	12/2010
DIN EN 60601-1-6	<i>Serviceability specification</i>	2010
EN 60601-1-2	<i>Electromagnetic compatibility</i>	2015
DIN EN ISO 10993	<i>Biological evaluation of medical devices - Part 1: Assessment and testing</i>	2010
DIN EN 1041	<i>Provision of information by the manufacturer of a medical device</i>	2008
DIN EN ISO 14971	<i>Medical devices - Application of risk management to medical devices</i>	2020

Table 2: Standards verification

3 Safety instructions

- Before operating the bed, you should read this instruction for use carefully (see Medical Devices Operator Ordinance under your national law). It contains important information for the safe and reliable use of the device. Keep the instruction for use for future reference.
- Safety, reliability and performance are guaranteed if the following instructions are observed and the device is used in an expert manner. As the operator, you must comply with the Medical Devices Operator Ordinance under your national law.
- The beds are suitable for both home care (application environment 3, 4), here a maximum patient weight of 135 kg must be observed.
- Ensure that children only have access to the bed under supervision and that no children remain in the danger zone under the bed during its operation.
- The bed should only be set up by authorized personnel.
- The fuse protection on the installation side must not exceed 16A. Before connecting the device, please make sure that the voltage and frequency of your power supply correspond to the specifications on the type plate.
- Ensure a level standing surface when selecting the location for the bed.
- Provide a suitable floor covering if the bed must be moved frequently. Carpets, rugs and loosely laid floor coverings can be damaged or make it difficult to push.
- Connect the power plug firmly to the power socket. When doing so, lay the power supply cable on the floor. Make sure that the bed (especially when moving) does not rest on the cable with its castors. The cable must not be routed through the mechanics of the base! (danger of crushing)
- Damaged power cables can lead to life-threatening situations. These must be replaced immediately.
- Check the power cable for damage at regular intervals (weekly).

- Make sure that the electrical specifications of the device correspond to the local conditions at the installation site.
- When the hand control is not in use, make sure that it is hanging on the bed and not placed in the bed to prevent incorrect operation which could cause damage.
- If the patient is unattended, ensure that the bed is set at its lowest height to allow the easiest possible entry and exit.
- The standing bed may only be operated by competent and instructed persons.
- The standing bed is not intended for transporting patients.

Important for the safety of the patient

- Before standing up, it is essential that the patient is strapped in with all 3 belts around the chest, hips/abdomen, legs/knees.
- Only move the patient to the standing position in the presence of an assistant. Only the assistant or the person treating the patient may operate the electrical functions and must be in constant visual contact with the patient.
- It is essential to prevent parts of a person's body from protruding beyond the lying surface or entering the rear of the bed. (risk of crushing)

4 General product description

4.1 Intended purpose

The Multidorm Flex is infinitely adjustable and ensures a slow raising of the lying surface up to an angle of 85°, adapted to the patient's state of health. The standing bed can be used for so-called standing training. During standing training, the circulation is stimulated again and blood flow is promoted. The standing bed was developed for the therapy of patients who are to be accustomed to standing again, or for better urination and circulation training for bedridden patients.



4.2 Indication

Supply to/for

- Circulation training
- Activation of respiration
- Stimulation of bladder and bowel activity
- Decubitus prophylaxis
- Perception training
- contracture prophylaxis

4.3 Contraindication

The following patients are not eligible for the standing bed application:

- In case of decubitus especially in the hip and leg area
- In case of extreme deformation and non-weight-bearing capacity of the lower extremities
- In case of massive cardiovascular problems
- In case of severe dizziness, which makes it impossible to stand up independently or partially independently.
- In case of severe anxiety

4.4 Equipment features

The Multidorm Flex has the following features:

- Central brake system with total locking
- 3-part belt system, two pads 23 cm x 60 cm (chest, hips), one pad 23 cm x 47 cm (fixation of legs)
- Mechanical emergency lowering of the standing function for easy operation with gas spring support
- Footboard for attaching and detaching
- Hand control with comfort function
- Possibility of single function locking on the lying surface

The standard version of these types of beds has a 90x200 cm lying surface with pre-stressed spring slats. Depending on the type, the beds are equipped with up to four electrically operated functions:

Type	electric height adjustment	electric standing function	electric head adjustment	electric knee adjustment
SB-009-0	Yes	Yes	Yes	No
SB-011-0	Yes	Yes	Yes	Yes

Table 3: Equipment features

The drives for the adjustment functions consist of electromechanical linear motors with maintenance-free permanent lubrication. The drives are operated via a hand switch, which is connected to the control unit via a spiral cable. The bed has four single-braked castors.

The drives and the hand switch are galvanically isolated from the mains voltage and are operated with a low voltage (DC 24 V).

5 Assembly information

5.1 Basic information for assembly

The bed should only be assembled by authorised personnel. The fuse on the installation side must not exceed 16A.

Before connecting the device, please ensure that the voltage and frequency of your mains supply correspond to the specifications on the type plate.

Ensure that the bed is placed on a level surface when selecting its location. Ensure a suitable floor covering if the bed has to be moved frequently. Carpets, rugs and loosely laid floor coverings can be damaged or make it difficult to push the bed.

Connect the mains plug firmly to the mains socket. When doing so, lay the mains connection cable on the floor. When doing so, ensure that the bed (especially when moving) is not standing with its castors on the cable. The cable must not be fed through the mechanics of the bed base! (danger of crushing)



Damage to the electrical mains cable by running over it or clamping it can have fatal consequences.



Before moving the bed or dismantling it for transport, the mains connection cable must be wound up and secured to the intended device on the chassis.



The Multidorm Flex is intended for indoor use only as an aid for standing therapy and for care in the home, in clinics, rehabilitation facilities, or nursing and care homes. Technical modifications or unauthorized types of use may cause hazards and are therefore prohibited without exceptions.

5.2 Mounting the wooden parts

(standing bed type SB-009-0, SB-011-0 without wooden side rails)

The side boards (paddle-shaped curved) are screwed to the metal frame with the supplied screws, washers and nuts M6. (cf. Figure 2)

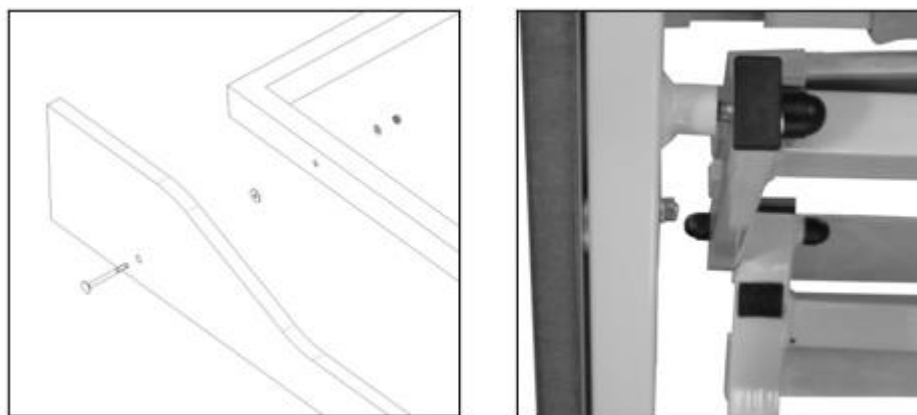


Figure 2: Side board screw connection

After mounting the side boards, the head and foot boards are mounted. The enclosed countersunk screws are inserted through the head or foot board and through the side boards, screwed on the inside in the large cup holes with four M6 nuts each and covered with the enclosed brown plastic caps. (cf. Figure 3)

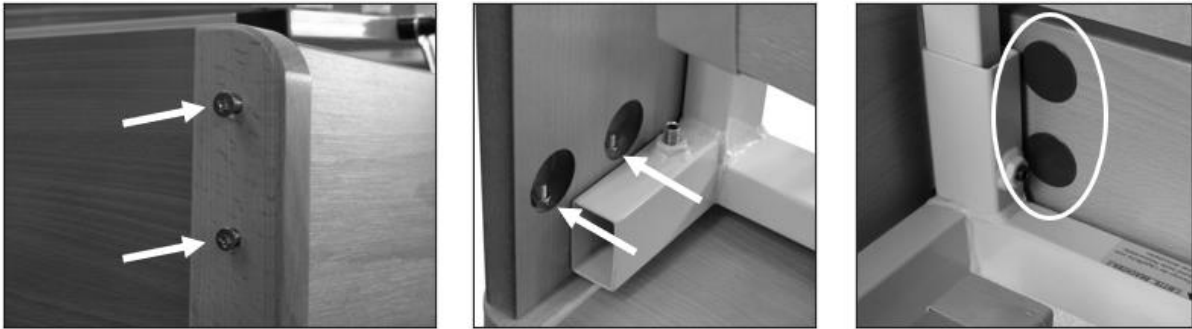


Figure 3: Head/footboard screw connection

After mounting the wooden surround, the insert board (foot board) can be inserted into the sleeves provided for this purpose and fastened with the set screws (cf. Figure 4). The matching Allen key is included in the scope of delivery and is attached to the insertion board

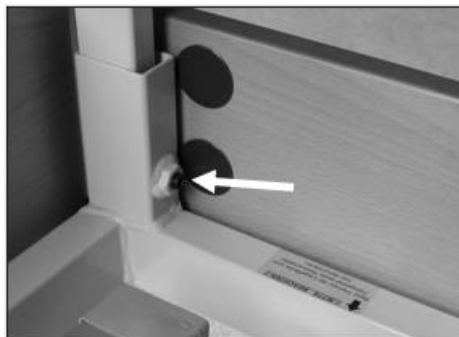


Figure 4: Fixation footboard



The insertion board (foot board) should only be installed if the patient is to be placed in the standing position, as otherwise the view in the lying position and possibly the care of the patient will be impaired.

5.3 Mounting the wooden parts with wooden side rails (Standing bed type SB-009-H, SB-011-H)

Attach the headboard and footboard to the bed frame using the screws and nuts included in the accessory pack. Then slide the side rails with the plastic sliders into the guide rails from below. (cf. Figure 5)

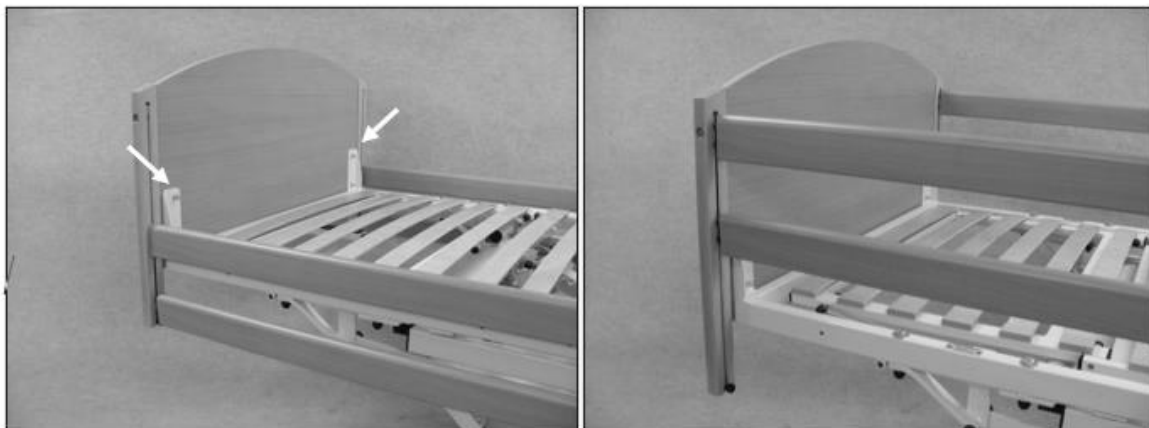


Figure 5: Mounting wooden edging

To prevent the side rails from sliding out of the rails when the side rail is lowered, a cap screw with a cap nut must be fastened to the end of each aluminum profile as a stopper. (cf. Figure 6)

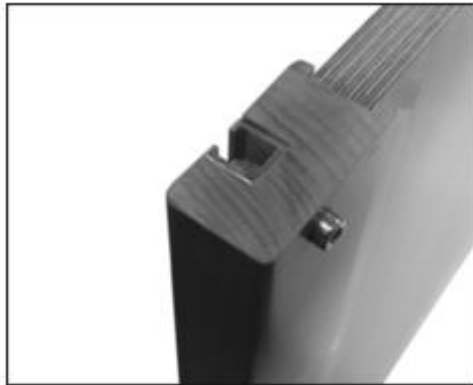


Figure 6: Side rail fuse

5.4 Properties wooden side rails

Bed rails provide simple mechanical protection to prevent a patient from falling out of bed. These are one-piece grids with a bar height of 110 mm, which extend over an entire side of the bed and are snapped into place at the headboard or footboard.



Only ISKO KOCH original side rails may be used. The use of side rails that are not compatible with this bed may result in hazards.

5.5 Bed extension options

5.5.1 Extension at the foot end by 10 cm

To extend the standing bed at the foot end, you need the extended foot traverse (1), which must be mounted instead of the existing foot traverse. The foot board must be removed from the existing traverse and attached to the new traverse. In addition, the foot section of the lying surface is extended with a plug-in part (2). This insertion part must still be provided with the holes for the end caps (8) of the springwood bar. The extension must also be connected to the existing foot section (7).

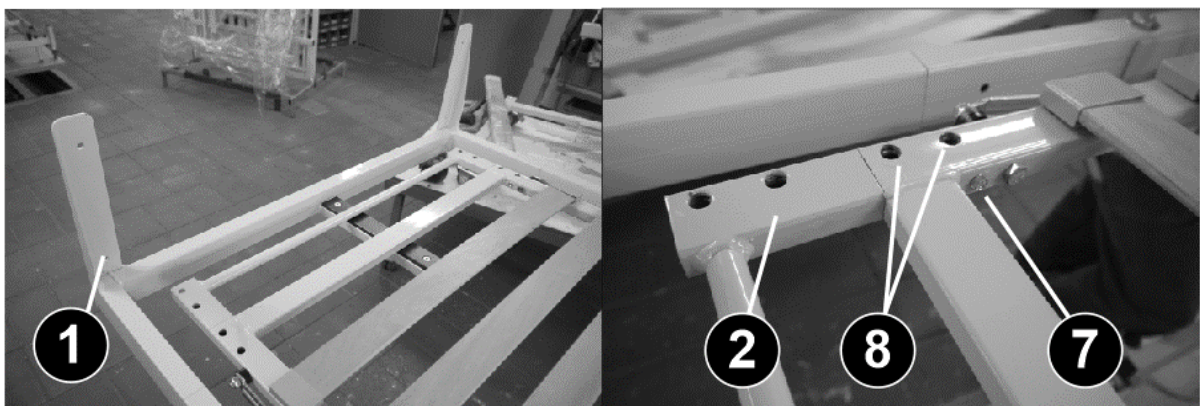


Figure 7: Extension at the foot end by 10 cm

In addition to the extensions, the appropriate length of the side rails must also be considered. In addition, a 5 cm extension must be built into the height motor.

5.5.2 Extension at the head end by 10 cm

To extend the standing bed at the head end, you need the extended head traverse (3), which must be mounted instead of the existing head traverse. The head board must be removed from the existing crossbar and attached to the new crossbar. In addition, the head section of the lying surface is extended with two small insertion parts (4). The insertion parts must still be provided with the holes for the end caps of the springwood bar (5). The extensions must also be connected to the existing headboard (6).

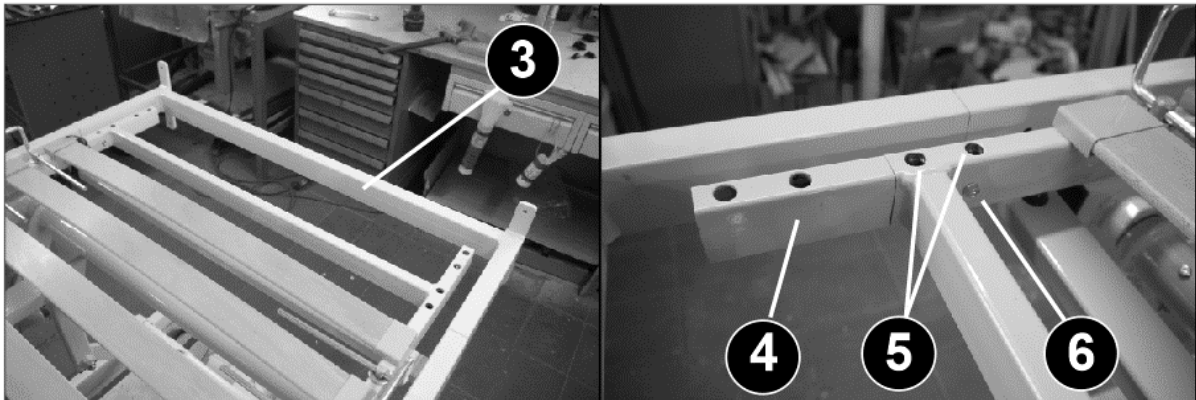


Figure 8: Extension at the head end by 10 cm

In addition to the extensions, the appropriate length of the side rails must also be considered.

5.6 Disassembling the care bed

If necessary, for example for transport, the care beds can be easily dismantled as described, but in reverse order. Re-assembling the bed after dismantling should only be done by authorized personnel.

6 Operation

6.1 Operating the side rails and retaining bars

Raise wooden side rail:

Pull the upper side rail upwards until the detent mechanism audibly clicks it into place.

Lower wooden side rail:

Raise the upper side rail until the release button can be pressed, keep it pressed, and lower the side parts.



The side rails can only fulfill their safety function when the head rest and the foot rest are lowered!



If a patient is left unsupervised with the side rails raised, the bed should always be lowered as low down as possible to avoid the danger of falling out by climbing over the rails.



Only the original ISKO side rails as delivered should be used! A minimum climb over height of 22cm above the uncompressed mattress edge should always be maintained.



When the side rails are raised, the grab rails must be removed from the nursing bed. Only use the grab rails when the side rails are lowered.

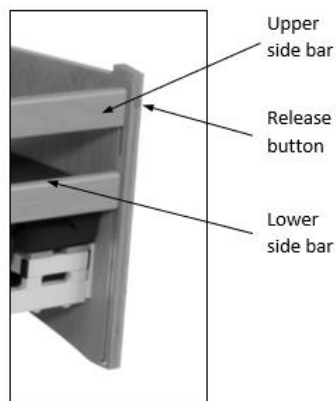


Figure 9: Description side rails and release button

6.2 Operating the metal side rails

Insert the metal side rails as shown in the adjacent figure and make sure that the latching mechanism audibly engages. To lower, pull out the detent pin and slowly lower the grille. (cf. Figure 10)

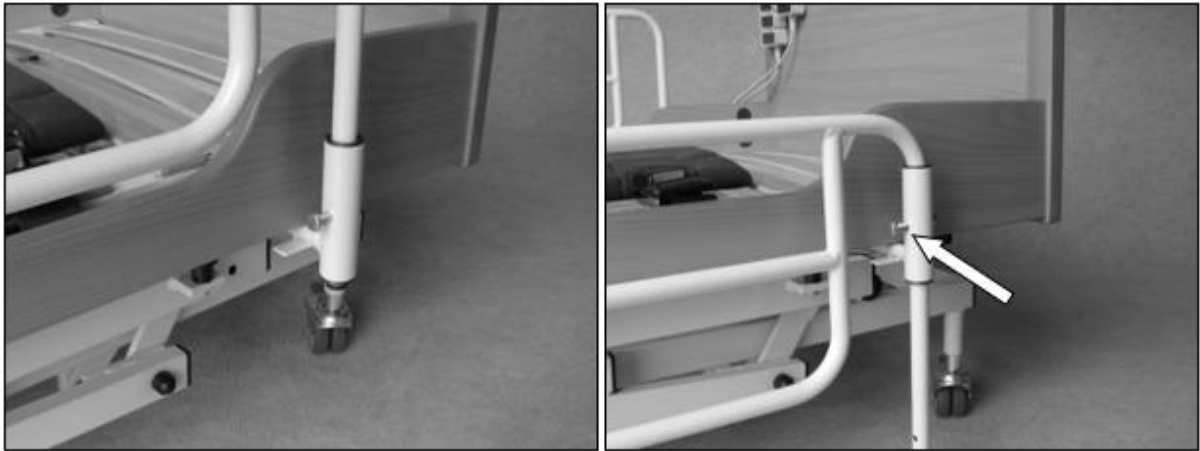


Figure 10: Operating the metal side rails



Be sure to hold the side rails before operating the latching mechanism.



There is a risk of injury if the metal side rails are operated improperly!

6.3 Operating the belt system

The belts are passed around the frame of the standing bed - not around the moving parts of the headboard or knee bend or through the mattress brackets - and then looped into the lock tongues as described below.

6.3.1 Adjusting the mattress support brackets

The four mattress support brackets of the lying surface must be adjusted in such a way that there is a min. distance of 2.5 cm between the support bracket and the side rail. The mattress is pressed into the area of the retaining brackets.

A belt set consists of a chest, abdominal and leg pad (cf. Figure 11). The belts are used to secure the patient during the standing procedure.

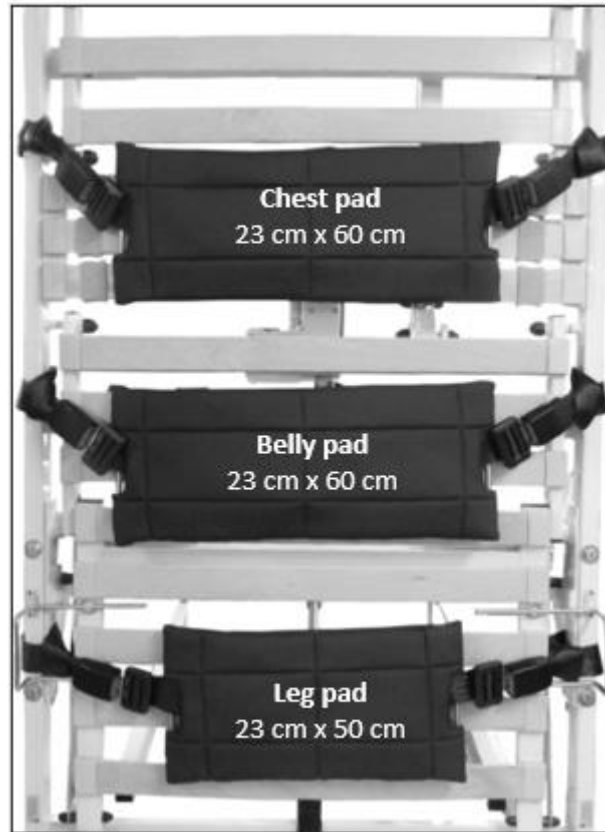


Figure 11: Upholstered belts for fixation of the patient

6.3.2 Passing the belt buckle through the bed frame



Figure 12: Passing the belt buckle through the bed frame

Place the approx. 30 cm long belt loop of the belt buckle between the wooden edge and the lying surface around the metal spar of the lying surface frame and bring it to the front. To fasten, then guide the belt buckle through the loop and tighten it. (cf. Figure 12)



Do not guide belts around moving parts (headboard, knee bend) or mattress brackets!

6.3.3 Passing the belt through the belt tongue

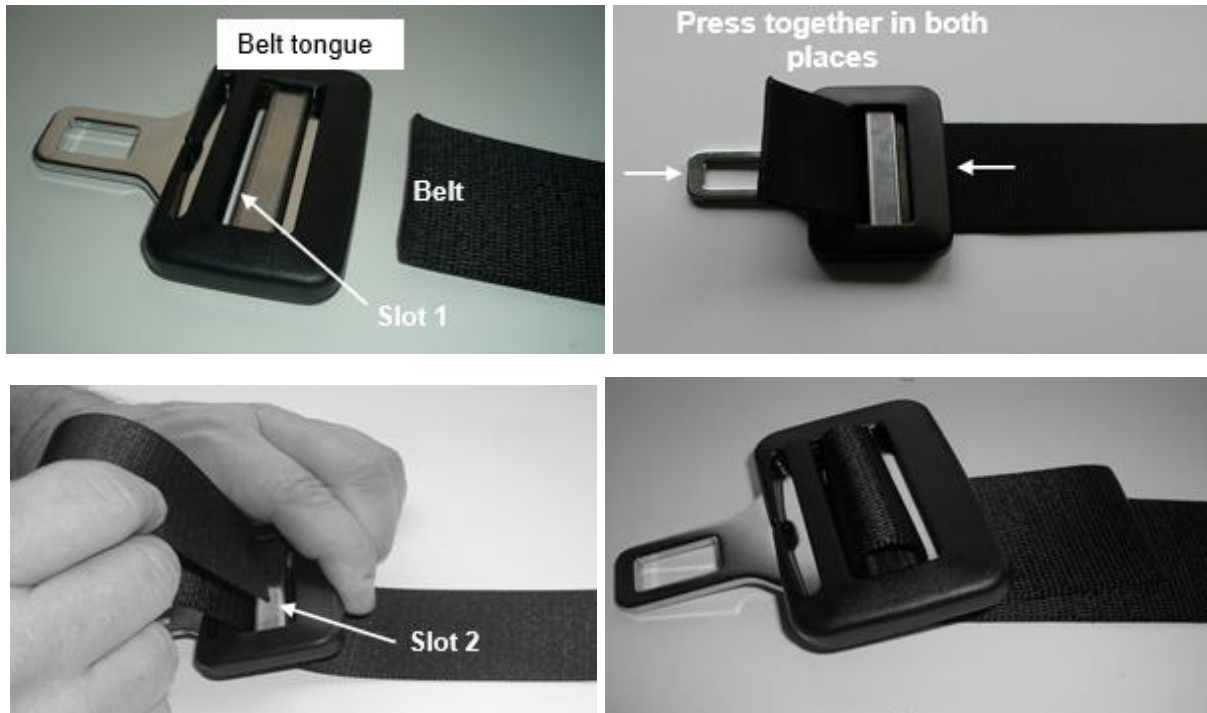


Figure 13: Procedure for looping in the belt

Push the belt under the belt tongue through slot 1. Pressing the belt tongue together creates a second opening (slot 2), which guides the belt back again. (cf. Figure 13)

The length of the belt can thus be individually adjusted to each patient.



The patient must not be placed in the standing position until he has been adequately secured with the belt system!

6.4 Operating the functions

6.4.1 Operation via the hand control

All electrical functions are controlled and adjusted with the hand control. Each row of keys is shown according to its function. (cf. Figure 14)

An authorized dealer can, if necessary, precisely adjust the standing position to your wishes and/or nursing needs.

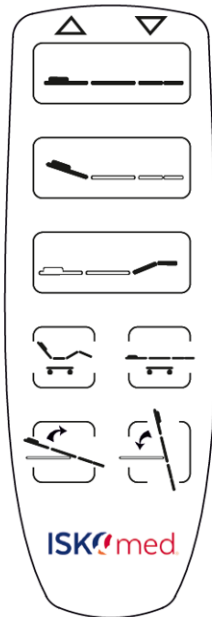


Figure 14: Patient hand control

The three basic functions of a healthcare bed can be controlled with the three upper rows of buttons (height adjustment, head section adjustment and knee bend adjustment).

The lowest row of buttons enables standing and tilting back from any position of the bed. After pressing the standing function, the head section and the knee bend are moved back if necessary and the height is moved up before the standing function is initiated. To start this function, the "Stand" key must always be pressed twice in quick succession.

In the standing function, the standing bed can be brought closer to the floor by pressing the top row of keys (right) - height adjustment. Before reaching the floor, the function switches off automatically.

The penultimate row of keys has a comfort function on the left, medium height; standing function slightly tilted; head and leg section slightly tilted. This means that a comfort position can be reached with a single keystroke. This means that the environment controls only need to emit one signal, which makes them much easier for the patient to operate.

The penultimate row of keys has a recline or strap-on function on the right. The head section and knee bend are moved down and the height is set to a middle position. Fixation of the patient is recommended in this position.

6.4.2 ACP - single-function and shut-off box

The Multidorm Flex has an additional operator panel which is firmly bolted to the side of the frame. This has the following functions.

Individual function locking

The ACP is a lock box and it can be used to lock the functions of the upper row individually. To do this, press the key button and simultaneously one or more symbols of the upper row of keys. (The yellow indicator light lights up on locked functions).

Control of bed functions with the additional control panel

If the keys of the upper row are pressed and the up or down arrow is pressed at the same time, the bed can be controlled via the ACP. The combined functions cannot be controlled here - i.e. only the functions of the upper row of keys.

Adjustment angle presetting

The maximum adjustment angles of the individual functions can be set or reduced at the factory or by authorized specialists. If there is a medical reason for limiting the angle of adjustment, it is no longer necessary to switch off the entire function.



To adjust or reduce the individual adjustment angles, please contact your specialist dealer.

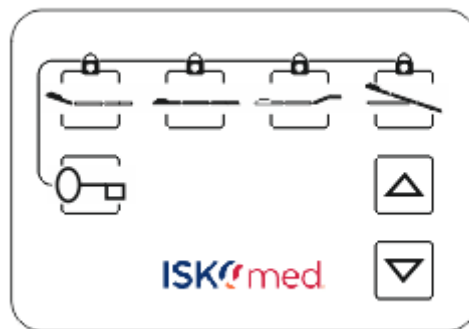


Figure 15: ACC operator panel

The control lamp lights up, i.e. the function is locked. The lockable functions are each marked with a lock. (cf. Figure 15)

6.4.3 Operating the shock storage function (Accessories with article number: SB-036-0)

All electrical functions are controlled and adjusted with the hand control. Each row of keys is shown according to its function. In addition to the standard functions, the hand control can also be used to move the patient into a shock position or head-down position.

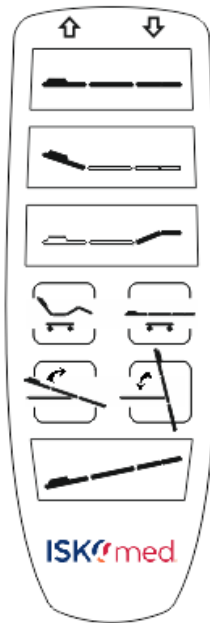


Figure 16: Hand control with shock storage function

The three basic functions of a healthcare bed can be controlled with the three upper rows of buttons (height adjustment, head section adjustment and knee bend adjustment).

The fifth row of buttons enables standing and tilting back from any position of the bed. After pressing the standing function, the head section and the knee bend are moved back if necessary and the height is raised before the standing function is initiated. To start this function, the "Stand" key must always be pressed twice in quick succession.

In the standing function, the standing bed can be brought closer to the floor by pressing the top row of keys (right) - height adjustment. Before reaching the floor, the function switches off automatically.

The fourth row of keys has an armchair function on the left, medium height; standing function slightly tilted; head and leg section slightly tilted. This means that a comfort position can be reached at the touch of a button. This means that the environment controls only need to emit one signal, which makes them much easier for the patient to operate.

The fourth row of keys has a recline or strap-on function on the right. The head section and knee bend are moved down and the height is set to a middle position. Fixation of the patient is recommended in this position.

The last row of keys controls the shock positioning of the patient. During shock positioning, a head-down position is created. When shock positioning is initiated, the bed always moves to the horizontal position and the height motor is completely extended. The bed then lowers on the head side.

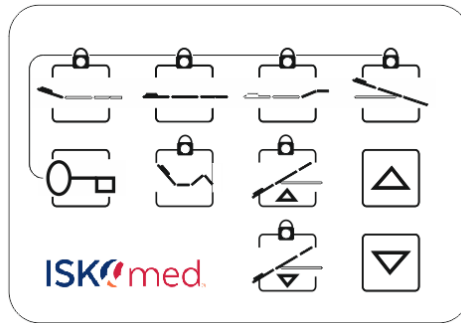


Figure 17: ACC operator panel with shock storage function



The initiation of the shock positioning position is only permitted by trained personnel who have been medically trained for this purpose.

The control lamp lights up, i.e. the function is locked. This only applies to the upper row of keys; the function can also be locked for the second and third rows of keys. However, without a control lamp lighting up. The lockable functions are each marked with a lock. (cf. Figure 17)

Individual function locking

The ACP is a lock box and it can be used to lock the functions of the upper row individually. To do this, press the key button and simultaneously one or more symbols of the upper row of keys. (The yellow indicator light lights up on locked functions).

Control of bed functions with the additional control panel

If the keys of the upper row are pressed and the up or down arrow is pressed at the same time, the bed can be controlled via the ACP. The combined functions cannot be controlled here - i.e. only the functions of the upper row of keys.

Adjustment angle presetting

The maximum adjustment angles of the individual functions can be set or reduced at the factory or by authorized specialists. If there is a medical reason for limiting the angle of adjustment, it is no longer necessary to switch off the entire function.



To adjust or reduce the individual adjustment angles, please contact your specialist dealer.

Comfort

In the comfort function, the middle height; standing function is tilted slightly; head and leg sections are slightly tilted. This means that a comfort position can be reached at the touch of a button. This means that the environment controls only need to emit one signal, which makes them much easier for the patient to operate.

Shock storage

The shock positioning function can be used to place the standing bed or the treated patient in a Trendelenburg position. This function can also be controlled on the ACP box. When the shock position is initiated, the standing function moves down to the horizontal position, the height moves up and the bed lowers on the head side.

6.5 Operating the central brake function

The Multidorm Flex has a central braking system that can be operated via 4 pedal levers. There are 3 different lever positions possible.

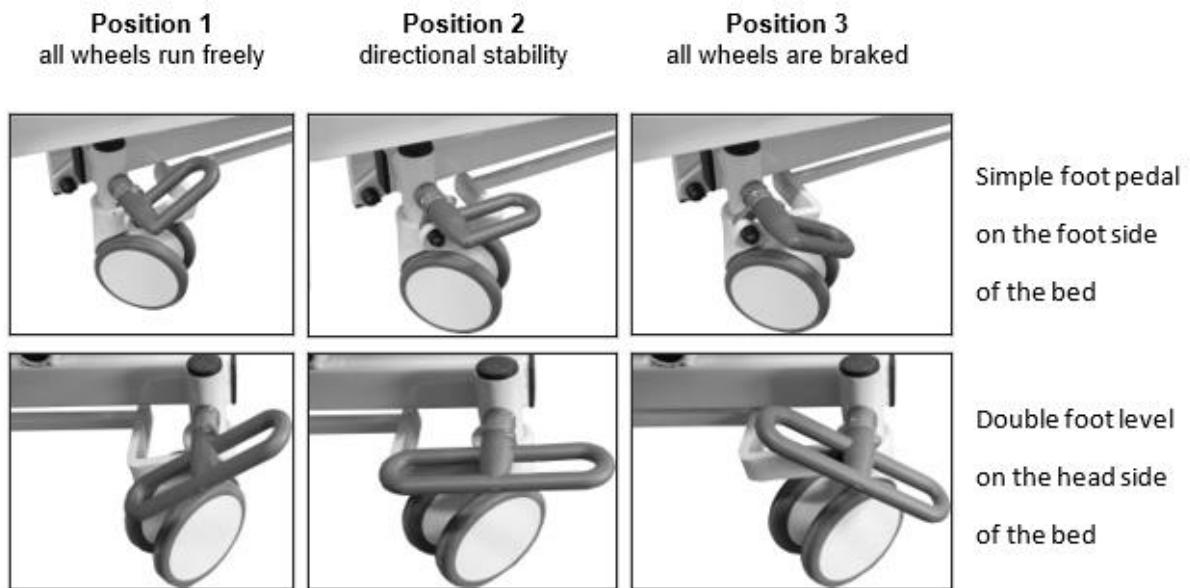


Figure 18: Central brake system

6.6 Mechanical emergency lowering from the standing function



The "Emergency lowering of the lying surface" procedure described below should always be performed by two assistants!

In the event of a power failure, a manual emergency lowering device has been installed in the standing bed for tilting the lying surface to the horizontal position. A clamping lever is attached to the left side of the lifting device. To move the lying surface manually from the standing position to the horizontal position, proceed as follows:

- Pull out the cotter pin at the end of the threaded rod
- Operate the tensioning lever and unscrew the threaded rod completely
- Press motor down for the standing function - Motor swivels downward
- Slowly swivel the lying surface into the horizontal position
(cf. Figure 19)

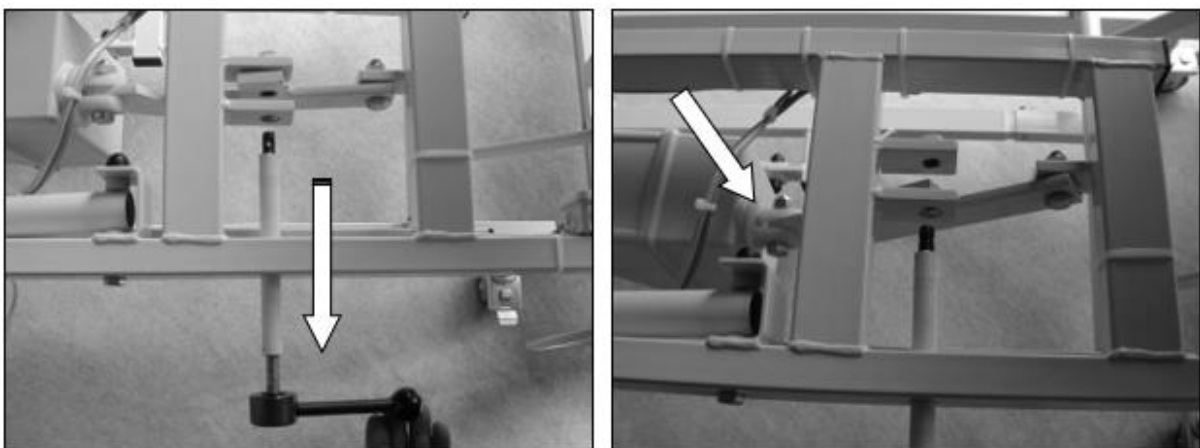


Figure 19: Procedure for unlocking the standing motor



Two built-in gas springs make it easy to tilt the lying surface back to the horizontal position with patients in bed without much effort. (2 assistants required)

Before the patient gets out of bed, the lying surface should be secured against unintentional, rapid folding up. To do this, the belt tongue attached to the bed frame is turned upwards by 90° so that the belt tongue can be inserted into the belt buckle of the patient restraint belt when the lying surface is folded back manually. If the patient now gets out of bed, the lying surface is prevented from folding up by the restraining belt. Proceed as shown in Figure 20.



This safety device for the lying surface may only be used when the emergency lowering is activated (drive is swiveled downwards)



Figure 20: Procedure for securing the lying surface against folding up

6.7 Operating instructions

- After the bed has been assembled and before it is used by a patient, check that all connections and the whole bed itself are firmly secured.
- Check that all drives are working faultlessly.
- If a care bed is not fully capable of functioning, it should be taken out of use immediately.
- Make sure that there are no objects such as wastepaper bins, side tables, chairs etc. in the movement space of the bed.
- In order to avoid the risk of injury, it is not permitted for any part of the patient's body to protrude out from the lying surface, nor for feet to rest on the bed underframe when operating the adjustment functions.
- Before moving the bed, the mains plug should be removed from the socket in order to avoid damage to the electrics.
- When there is a patient in the bed, the maximum height of a threshold over which the bed can be pushed is 2 cm.
- Make sure to maintain the duty cycle. Never make lengthy and unnecessary electrical adjustments. Once the thermal protection switch in the control unit has been triggered after 6 min/h, the control unit has to be replaced by an authorized specialist!



The installation of ancillary equipment such as insulin pumps, ventilators etc. is not permitted unless equipotential bonding has been made in advance.



The cables for any ancillary equipment must not be led under the base of the bed! (Danger of crushing)

6.8 Mattresses approved for use

This bed is intended to be used with a divided, fire-retardant mattress according to DIN 13014 and DIN 597, with a minimum volume weight of 35 Kg/m³ (RG35), a compression resistance of min. 4.2 kPa, a maximum height of 12 cm, a minimum width of 88 cm and a minimum length of 197 cm (mattress and foot block together).



For safety reasons, a distance of 22 cm must be maintained between the upper edge of the mattress (unloaded) and the upper edge of the uppermost wooden side rails (side rails in upper position).



Mattresses with high volume weights are only permitted if the weight of the mattress and the patient combined does not exceed the safe working load of the bed.

7 Ambient conditions

According to DIN EN 60601-2-52, the medical device can be used in the following application environment:

Application environment 3:

Long-term care in a medical setting where medical supervision is required and monitoring is provided as necessary; an ME device may be provided for a medical procedure to maintain, improve, or support the patient's condition.

Application environment 4:

ME device to alleviate or compensate for an injury, disability or illness in home care.

A maximum noise level of 49 dB (A) occurs during adjustment of the electric drives.

7.1 Storage conditions

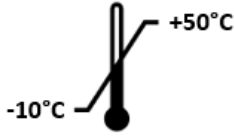
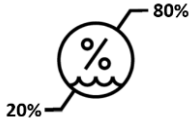
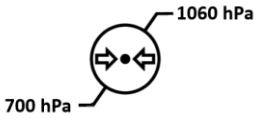
Storage conditions	min. -10 °C max. +50 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 4: Storage conditions

7.2 Operating conditions

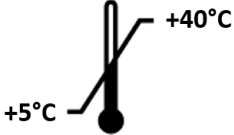
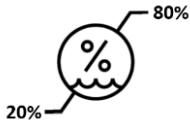
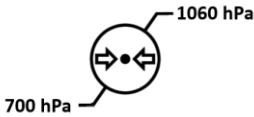
Operating conditions	min. +5 °C max. +40 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 5: Operating conditions

8 Technical data



Designation	Type SB-011-H/0
Nominal voltage	~230 V/50Hz
Rated power	690 VA
Device type B according to IEC 601-1	
Protection class	
Sound power level	63 dB(A)
IP protection class for drive components:	
Control unit	IPX4
Manual button unit	IPX4
Actuators	IPX4
Duty cycle switch on duration 10%	maximal 6 min/h
Max. patient weight	135 kg
Safe working load	170 kg
Dimensions of lying area	200 x 90 cm
Dimensions of the nursing bed:	
Total weight including patient lifter and wooden parts	175 kg
Height adjustment (measured without mattress)	from 40 to 80 cm
Adjustment angle thigh support	0° to 48°
Adjustment angle head rest	0° to 72°
Adjustment angle standing function	Up to 85° (if the bed is extended to 2.2 m, the standing angle is reduced to 75°)
Height of the standing function	229 cm
Minimum room height (for 200 cm mattress)	239 cm

Table 6: Technical data



Reparations may only be carried out by ISKO qualified personnel or by persons authorized and trained by ISKO with comprehensive product knowledge. In case of non-compliance with this provision, any warranty and liability claims will be rejected.

9 Used materials

The medical device is manufactured as a welded tubular steel construction. The surfaces are powder coated or galvanized. All wooden parts are either laminated or lacquered. The surfaces of this product are unthinkable for the skin from the point of view of health.

10 Service and care

All household cleaners without ammonia and scouring agents are permissible for cleaning the tube parts, the lying surface and the wooden parts with a damp cloth. Solvents (e.g. nitro) destroy the coating of the tubes and the lying surface!

Mechanical cleaning (e.g. scraping, sanding) or jet cleaning of the bed is not permitted. All pivots of the moving parts, including the bearing eyes on the adjustment device, are provided with maintenance-free slide bearings and must not be oiled or greased.

11 Service life of the product

At an expected average level of use in home care, the service life of the bed is approximately 10 years. Lack of maintenance and excessive stress on the product can significantly reduce the service life of the bed. The expected service life in professional nursing home use is approx. 7 years.

12 Disinfection

- In order to ensure that the bed functions properly, each ISKO bed should be cleaned, disinfected and checked after each use so that it can be used again immediately.
- Improper cleaning/disinfection of the bed can cause hazards.
- Depending on the degree of soiling, we recommend cleaning the bed with a damp cloth or similar.
- For wipe and spray disinfection, disinfectants in their intended concentration can be used. (see manufacturer's instructions)
- The dilution ratio recommended by the manufacturers in the respective instructions for use must be used.



Solvents are not permitted.

Abrasives or scouring sponges must not be used.

12.1 Specifications of detergents and disinfectants

- The working solutions should normally be used freshly prepared.
- The concentrations given should not be exceeded or fallen below.
- They must not contain corrosive or caustic components.
- They must not contain any substances that alter the surface structure or the adhesion properties of the materials.
- Lubricants must not be attacked by cleaning and disinfecting agents.



Under no circumstances should soap or washing-active substances be added to the disinfectant. In the case of products containing alcohol, there is a risk of explosion and fire when applied over large areas.



The use of unsuitable detergents and disinfectants can cause damage to the surface coating for which ISKO KOCH GmbH cannot be held liable.

13 Operational faults and solutions

	Fault	Measure
1	None of the motors respond to the switch actuation.	<p>Check plug connection and interlock between the hand control cable and the control unit.</p> <p>Check plug connection and interlock between motor cables and control unit.</p> <p>Check the plug connection between the power supply cable and the control unit. (green LED on the electrical control unit must light up).</p> <p>Check whether all functions are enabled on the ACP box. (no LED must light up)</p>
2	A motor does not respond to the switch actuation	<p>Check plug connection between the motor cable and control box.</p> <p>Check plug connection between the hand control and control box.</p> <p>Check whether all functions are enabled on the ACP box. (no LED may light up)</p>
3	all 4 LEDs on the ACP box are flashing	<p>Reset/Initialization</p> <p>Hold down the second row of keys simultaneously (really simultaneously) and together until the interrupted signal tone changes to a continuous tone (after approx. 5 seconds).</p> <p>Immediately after the reset (simultaneous pressing of the 2nd row of keys), the first row of keys is held down simultaneously for initialization until a long signal tone sounds. During this process, the motors may search for their end position.</p> <p>During initialization, the drives are only moved at 50 % speed and perform the following sequence:</p> <ol style="list-style-type: none"> 1. Drive in leg section completely 2. Drive in backrest completely 3. Drive out height completely 4. Drive in standing drive completely 5. Drive in height drive completely <p>*0. Drive out shock motor if necessary (however, the height motor is extended completely first to prevent damage to the bed).</p> <p>After initialization, all functions must be unlocked again on the side control panel.</p>

Table 7: Operational faults and solutions



For issues which cannot be rectified using the aforementioned instructions; any changes, new settings or repairs to the bed may only be implemented by the manufacturer directly, or by a workshop authorised by the manufacturer.

14 Recommended accessories

Article	Order number
Lifting pole - for center mounting	SB-024-3
Foot plate angle adjustable negative	SB-030-0
Worktable (wood)	SB-025-0
Worktable (Plexiglas)	SB-029-0
Arm bars	SB-031-0
Shock storage	SB-036-0
Battery back-up	SB-041-0
Head fixation with mounting	SB-181-0
Belt system for standing bed (leather)	SB-032-5
Counterweight	SB-270-0

Table 8: Recommended accessories

15 Maintenance

15.1 Legal basis

The Medical Device Regulation (EU) 2017/745 (MDR) as well as national laws and regulations require operators of medical devices to ensure a safe operating condition of the medical device during the entire period of use.

15.2 Maintenance intervals

As a requirement of the Medical Device Operator Ordinance §4 (Maintenance), a thorough visual inspection (1), a functional test (2) and a current discharge test (3) must be performed in accordance with DIN EN 62353:2015-10 after the medical device has been in operation for at least two years.

(1) During the visual inspection, particular attention must be paid to the following points:

- tight fit of all screw connections
- mobility of the pivot points
- Checking the power supply cable for pinching or shearing points
- check of the strain relief of the power supply line

(2) During the functional test, special attention shall be paid to the following points:

- Function of all electrically operated movements
- Fully extend and retract all motors on the nursing bed (without mattress; without patient) until they switch off by themselves. (Limit switches in the motors must switch off with an audible click).
- Functionality of the brakes
- Mobility and function of the side rails
- Mobility of the triggers
- Check of the hand switch

Functional tests and current leakage tests may only be carried out by ISKO specialist personnel or by persons authorized and trained by ISKO with comprehensive product knowledge.

15.3 Spare parts

All spare parts for this medical device must be ordered from ISKO KOCH GmbH, stating the serial number, order number and article number (these can be found on the type plate attached to the medical device).

To ensure that the functional safety and any warranty claims remain valid, only original ISKO KOCH GmbH parts are to be used for the spare parts.

ISKO KOCH GmbH

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E-Mail: info@isko-koch.de

15.4 Notes on documentation

According to the Medical Device Operator Regulation and Medical Device Regulation (EU) 2017/745 (MDR), there is a documentation obligation for:

- Maintenance
- Incidents / near misses

If extraordinary hazards for the product are foreseeable at the installation site of the care bed (supply line lies on the floor; children playing; pets; ...), the electrical lines in particular must be constantly checked and suitable measures taken to avert hazards.

16 Reuse

Before each reuse of the care bed, a thorough visual and functional check of all electrically operated functions as well as a current leakage test according to DIN EN 62353:2015-10 must be performed as described under the item Maintenance intervals. The points on service and care & maintenance mentioned in the operating instructions must always be observed when cleaning the bed.

17 Disposal

17.1 Disposal of the device

Disposal of the device and accessories, if any, should be carried out in an environmentally friendly manner and in accordance with the legal regulations. Please adhere to the valid waste separation regulations! If there are any uncertainties in this matter, please contact your local municipality or waste disposal company.



17.2 Disposal of the electrical components

*if electrical components are included in the medical device

According to Directive 2012/19/EU - WEEE2, this medical device is classified as an electrical device. All electrical components are free of unauthorized ingredients classified as harmful according to RoHS II Directive 2011/65/EU. In addition, replaced electrical components must be disposed of in accordance with European directives (see Directive 2012/19/EU - WEEE2).

17.3 Disposal of the packaging

The EU Waste Framework Directive 2008/98/EC is decisive for the handling during the disposal of the packaging. Reusable materials must be fed into a recycling cycle in accordance with national regulations.

18 Declaration of Conformity

As the manufacturer, we declare under our sole responsibility that our standing beds complies with the basic requirements of the EC Directive for

Medical devices 2017/745, Annex II



ISKO KOCH GmbH

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