



Instruction for use

Stand: 04/2022
(Rev. 2.0)

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1 Foreword

Dear customer!

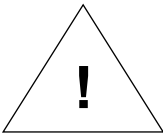




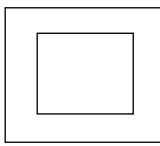
We would like to thank you for the trust you have placed in us and for purchasing our product. We have manufactured this medical product with great care.










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>

	<p>Unique identifier of a medical device - displays a carrier containing information about a unique identifier of a medical device.</p>
	<p>Safe working load</p>
	<p>Max. patient weight</p>
	<p>The product must be taken to separate waste collection in the European Union. Disposal with normal household waste is not permitted.</p>
	<p>Minimum body dimensions/weights of the patient</p>

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



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



ISKO KOCH GmbH
95448 Bayreuth
Egerländer Str. 28

ISKMed



13.01.2022

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 1: 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 Multidorm Mobil 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 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.....
- Provide a suitable floor covering if the 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 rollers. 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 from 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.

4 General product description

4.1 Intended purpose

The folding bed is a medical aid which can lead to the patient's renewed participation in his environment and to the minimisation of physical stress for both the patient and the carer. An electrical adjustment of the lying surface makes it easier to position the patient according to the treatment. In addition, the electric folding mechanism of the folding bed provides a quick way of folding the nursing bed. Finally, the folded nursing bed makes it easier to reposition the patient in other rooms.



4.2 Indication

Motor-operated care beds relieve the caregiver through the motor adjustment possibilities in the care of no longer spontaneously mobile, over large parts of the day bedridden care patients, if the care is carried out completely or partially in bed and with necessary external operation, if the caregiver because of his own insufficient / reduced strength or already existing disease (s) of the own musculoskeletal system can not sufficiently cope with the manual adjustment.

4.3 Contraindication

The carer must ensure that the user is mentally capable of handling an electrically adjustable healthcare bed. If this is not the case, all electrical functions on the hand control must be switched off and the hand control must also be secured against access by the patient. If individual functions could be dangerous for the user, they must be made impossible by switching them off.

4.4 Equipment features

The folding bed has the following electrical functions:

Type	electr. height adjustment	electr. head adjustment	electr. knee adjustment	electr. folding mechanism
KP-011-0-IL	Yes	Yes	Yes	Yes

Table 2: Electrical functions

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 rollers.

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 informationen

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.

5.2 Setting up the Multidorm Mobil

After unpacking the delivered nursing home bed, the completely assembled bed stands with you in the folded state as shown in Figure 2.



Figure 2: Multidorm mobile in the folded state

The set-up works as follows:

1. Brake either at the head end or at the foot end both castors of one side of the bed (arrow Figure 2) with the castor lock.
One side of the bed must be fixed so that the bed does not move back and forth in an uncontrolled manner and so that the lying surface can unfold in one direction
2. Connect the power supply cable to the power supply (socket).

When doing so, please make sure that the supply line lies freely on the floor and is not crushed when the unbraked side of the bed starts to move.

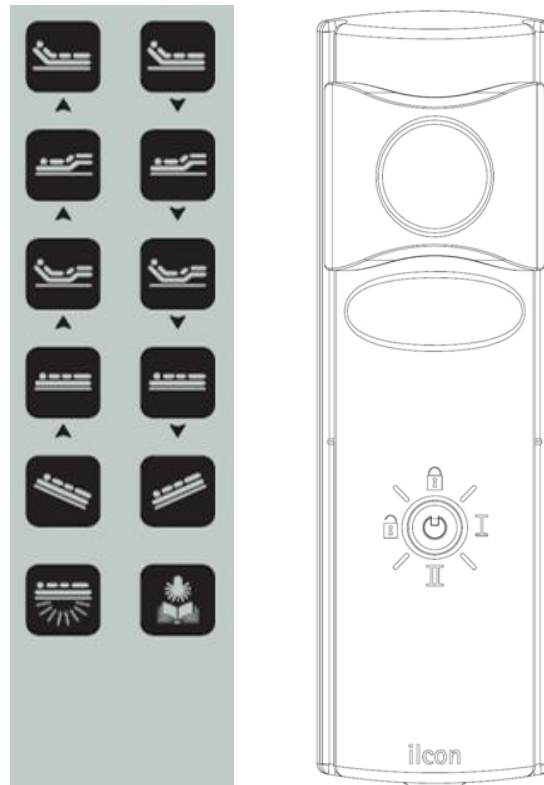


Figure 3: Front and back of the hand control

Description of the different locking groups:

- Closed: Underbed lighting, locking of all functions
- Open: First four rows of buttons (head, knee, comfort, height) + under-bed lighting.
- Position I: First five rows of buttons (head, knee, comfort, height, trend/antitrend) + under-bed lighting
- Position II: Fold out and in

3. Folding out the lying surface

Before starting the unfolding process, make sure that there is enough free space for this process and that the bed does not come up against any obstacles.

Now you can start the unfolding process with the help of the hand switch. To do this, please set the arrow on the back of the manual switch to position II. In this position, the bed can be folded out and in. Now simultaneously press and hold down the left key in the fourth row of keys and the right key in the sixth row of keys until the bed is fully extended, i.e. the lying surface has been brought into a horizontal position. To be able to operate the bed afterwards, you must again set the arrow on the back of the hand control to position I or to the open lock, depending on which functionality is desired.

If the bed is not fully unfolded, all other functions are blocked by the programmed control unit. This is to prevent collisions or malfunctions.

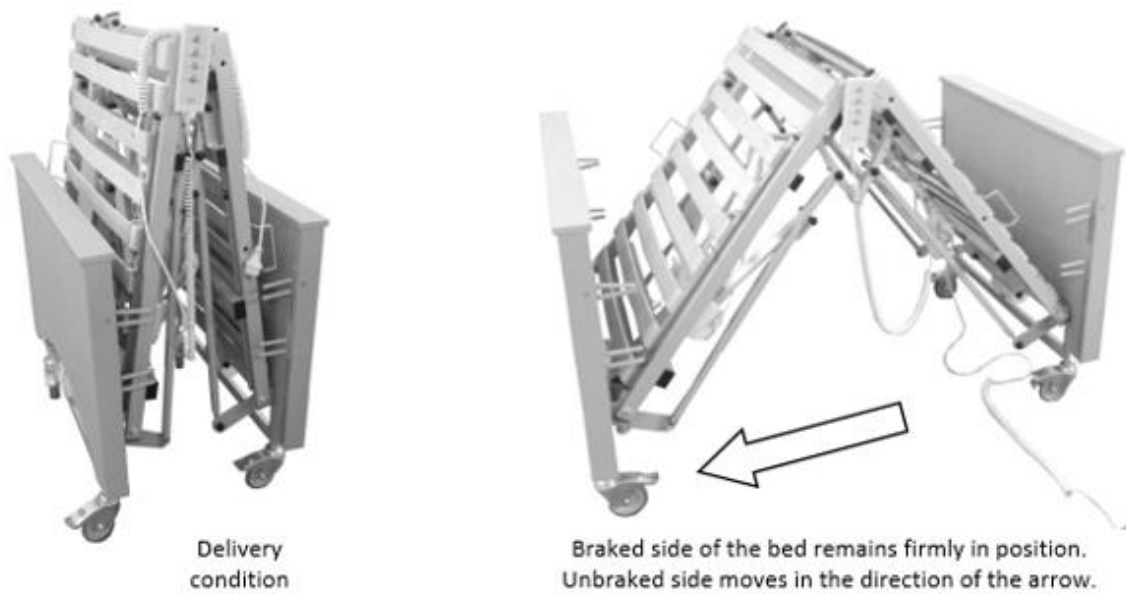


Figure 4: Folding out



Please ensure that the rollers of the bed do not roll over the supply line during the fold-out procedure. Risk of crushing!



Ensure that there are not objects or persons in the movement space of the bed during the fold-out

1. Folding in the lying surface

Before folding, all parts not belonging to the bed (such as mattress, bedding, pillows, stand-up aids or other additional devices, ...) must be dismantled from the lying surface and removed from the bed. The side rails and all objects lying under the bed must also be dismantled or removed. One side of the bed (head or foot side) must be braked, the other side remains unbraked so that the castors can run freely.

Now you can start the folding process with the help of the manual switch. To do this, move the arrow on the back of the manual switch to position II. Now simultaneously press the right key in the fourth row of keys and the right key in the sixth row of keys until the bed is completely retracted, i.e. the lying surface is completely folded.

When the key combination is pressed, the bed starts to move. It does not matter in which starting position the motors are.

First, the head section and knee bend are moved to the horizontal position. Then both lift motors move the lying surface all the way down.



Please ensure that the rollers of the bed do not roll over the supply line during the folding procedure. Risk of crushing!



Ensure that there are not objects or persons in the movement space of the bed during the folding procedure!

5.3 Assembly of the wooden side rails (without assembling tools)

When fitting the wooden side rails, always ensure that the lower side rail is fitted with the upper and middle holes. In contrast, the upper side rail must be mounted using the lower and middle hole. (c.f. Figure 5)

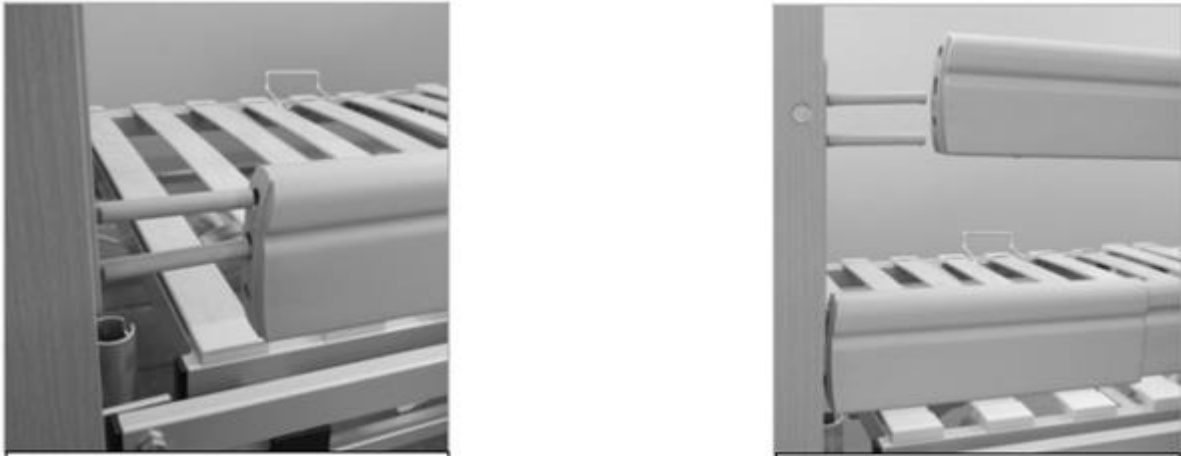


Figure 5: Assembly lower and upper side rail



Please ensure that the upper and lower side rails are not interchanged during assembly.

Before mounting the side rail, the plastic length adjuster must be pushed out on one side. As shown in pic. 4.7, please press the locking button - move the plastic cover until the button engages in the second hole. In this way the side rail can be pushed onto the locating pins on one side.



Please pay attention to the correct drillings.

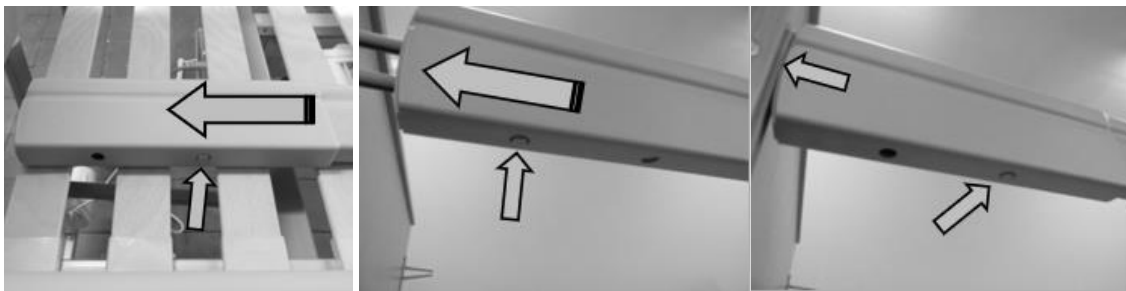


Figure 6: Sequence assembly extendable side rail

Now, by also pressing the locking button there and pushing the plastic length compensation in the direction of the wooden case, the side rail can also be installed on the opposite side. The locking button must engage in the second hole. The length compensation parts are spring-loaded to the silk spars and must be installed so that no air gap is visible between the wooden case and the side rails, either at the head end or at the foot end. The locking knobs must engage in the holes.

5.4 Disassembling the care bed

If necessary, e.g. for transport, the care beds can be dismantled with little effort as described but in reverse order. Reassembly after dismantling the bed should be carried out by authorised personnel.

6 Operation

6.1 Operating the side rails and holding brackets

Raise wooden side rails:

Pull the upper side rail as high as possible until the latching mechanism audibly snaps into place.

Lower wooden side rails:

Lift upper side rail until the trigger can be pressed. Keep the trigger pressed and lower side parts.

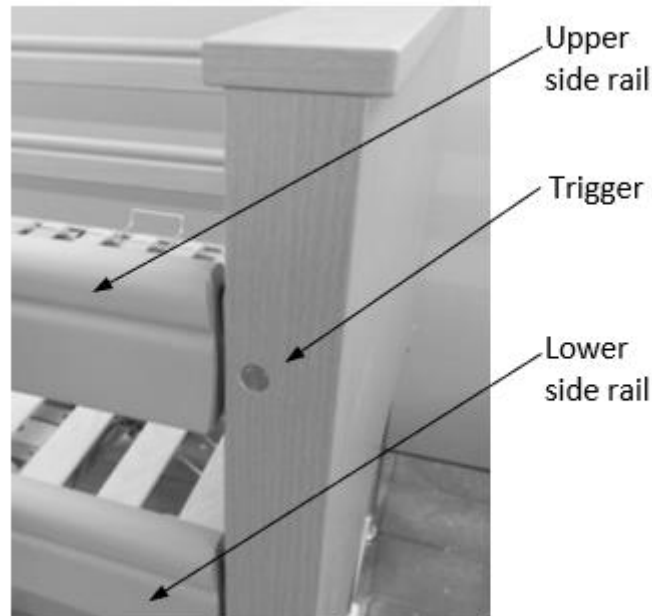


Figure 7: Side rail operation



The side rails only fulfil the protective function when the head section and foot section are lowered.



If a patient with raised side rails is left unattended, to prevent the risk of falling when climbing over the rails, the bed must always be in lowest height position!



Only use the original delivered ISKO-KOCH side rails! The climb height of min. 22cm from the upper edge of the unladen mattress must always be guaranteed.

6.2 Locking function

Move the arrow on the back of the handset to the closed lock position. This locks all functions.

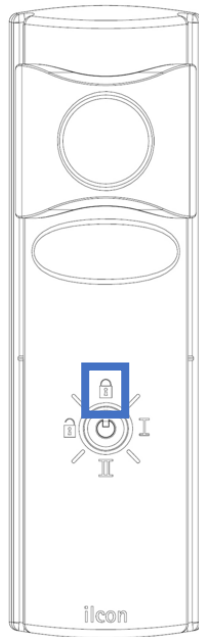


Figure 8: Locking option via the hand control

6.3 Operating the functions

All electrical functions are operated with the manual switch. Each row of keys is labeled according to its function.



Figure 9: Operating the functions

Each upward or downward movement of the head section, the height adjustment and the knee bend is effected by pressing the respective key on the hand control. The keys are marked with symbols according to their function. The holder on the back of the hand control enables its universal fixation to the wooden border.

The functions can be locked with the key.



When the nursing staff is absent, the operating elements must be locked!

6.4 Operating the brake castors

The bed should always be braked at the place of installation with the help of the castor brake.



Figure 10: Exemplary castors in braked and unbraked condition

6.5 Patient lifting pole with handle

There is a mounting for the lifting pole on both sides of the lying surface at the head of our care beds. When fitting the lifting pole, ensure that lifter tube with the metal bolt is pushed far enough into the socket bushing so that the metal bolt is fully located in the recessed slot on the socket bushing. Thus the lifting pole is fixed in its position and can not be swung out over the lying surface (cf. Figure 11)

The included grab handle is used for the user to stand upright and can be individually adjusted to the correct height with the webbing.

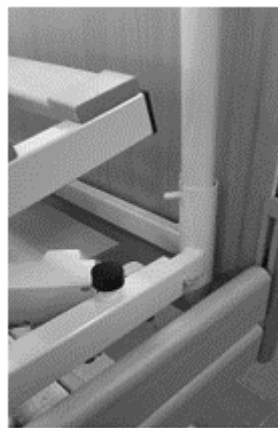


Figure 11: Patient lifting pole mount at the head end



The lifter is not suitable for therapeutic purposes.



The maximum load capacity of the lifter is 75 Kg



The metal bolt on the lifter tube must always be located in the recess slot. Danger of toppling over!



Check the grab handle and the webbing strap for damage at regular intervals. Damaged parts should be changed immediately!

The grab handle which is delivered is designed to assist the user to sit up and can be individually adjusted to the correct height with the webbing strap and the adjusting buckle (cf. Figure 12). The range of adjustment is from 670mm to 870mm. (Measured without mattress)



Figure 12: Adjustable grab handle

6.6 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 waste paper 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)

6.7 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



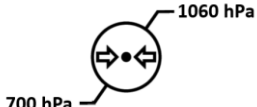
Storage conditions	min. -10 °C max. +50 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 3: Storage conditions

7.2 Operating conditions

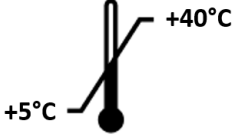

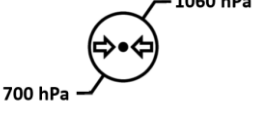
Storage conditions	min. +5 °C max. +40 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 4: Operating conditions

8 Technical data



Name	Type KP-011-0-IL
Nominal voltage	~230 V/50Hz
Rated output	140 VA
Device type B in accordance with IEC 601-1	
Protection class II	
IP protection class for drive components:	
Control unit	IP 54
Hand control	IP 54
Drives	IP 54
Power-on time 10%	maximum 6 minutes/hour
Safe working load/max. patient weight	175 kg / 135 kg
Dimensions the lying surface	200cm x 90cm
Dimensions of the nursing bed:	
Bed complete without side rails	69,7 kg
Wooden cladding of the lifting mechanism (1 piece)	2,8 kg
Wooden side rails (4 pieces)	8,5 kg
Patient trapeze bar with handle	5,5 kg
Height adjustment (measured without mattress)	from 39.5cm to 89cm
Adjustment angle thigh support	0° to 43°
Adjustment angle head piece	0° to 62°

Table 5: 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.	Check plug connection between the hand control and control box. Check plug connection between the motor cables and control box. Check the plug connection of the power cord.
2	A motor does not respond to the switch actuation	Check plug connection between the motor cable and control box. Check plug connection between the hand control and control box.
3	Error number 1 or 2	For initialization, press the left and right keys simultaneously in the fourth row of keys until the motors have retracted completely. After initialization, the drives can be used again

Table 6: 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
Mattress RG 35 (according to DIN 13014 with 120mm height) (flame retardant according to DIN 597 part 1 and 2)	NS-039-0
Incontinence cover high quality, 3 sides with zip	NS-040-0
Side rail cladding made of composite (recommended for patients with impaired perception)	NS-049-0
Side rail increase (to be attached, increase by 16cm)	NS-058-0

Table 7: 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 leakage 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

Egerländer Straße 28

95448 Bayreuth

Tel.: +49(0)921/150845-0 (Monday – Thursday 8:00 – 17:00 pm & Friday 8:00 – 16:00 pm)

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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 folding beds complies with the basic requirements of the EC Directive for

Medical devices 2017/745, Annex II



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