

Pflegebetten



Instruction for use

Stand: 08/2022
(Rev. 4.0)

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1 Foreword

Dear customer!

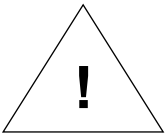




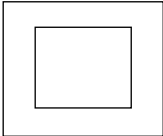
We would like to thank you for the trust you have placed in us and for purchasing our product. We have manufactured this medical product with great care.








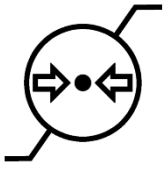

Please read the instructions for use carefully before using the product for the first time and always keep them close at hand.

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 frame. The nameplate allows the product to be clearly identified.

MD

REF

Safe working load:



SN

UDI



(01) 0 4251858 50276 5 (11) 220302 (21) 220300FB0005



ISKO KOCH GmbH
95448 Bayreuth
Egerländer Str. 28



Wellell UK Limited
Unit 33 Mackenzie Way
UK - WR49GN Worcester



02.03.2022

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 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.

4 General product description

4.1 Intended purpose

The beds are suitable for both home care and general care in nursing homes, but are intended only for patients over the age of 12. The bed may only be operated by competent and instructed persons.



4.2 Indication

For immobile patients, as well as patients with limited mobility, if e.g.

- It is necessary to adopt an ergonomic sitting position in bed (e.g. for personal hygiene, eating, carrying out meaningful activities such as reading or watching television, communication, etc.).
- Secure contact of the feet to the floor is required to get in and out of bed.
- For transfer, e.g. to a wheelchair, the bed must be height-adjustable.
- The lack of physical strength of the patient or caregiver does not permit manual adjustment of the bed.

4.3 Contraindication

The caregivers must make sure that the user is mentally capable of handling an electrically adjustable care bed. Otherwise, all electrical functions on the bed must be switched off by the key switch and, in addition, the hand control must be secured against access by the patient.

If the patient suffers from severe anxiety, which is triggered by the use of the bed, it must not be used.

4.4 Equipment features

These modular care beds have five electrically operated functions – backrest, leg rest, backrest & leg rest combined and bed height. These are powered by linear actuators each of which is sealed, uses maintenance-free permanent lubrication and is ingress protected to IPX4 standard.

The functions are operated using a 4-function auto-profile hand control connected to the main Controller via a spiral cable. The hand control & main control are ingress protected to IPX4.

All electrical functions are isolated from the mains power supply & operated at 24v DC low voltage.

A 240v mains electrical ‘safety connector’ is supplied. This can reduce the likelihood of damage or injury if the bed is moved before being unplugged from the mains power supply socket.

The mattress support is constructed from metal mesh which allows the mattress to breathe and so prolongs its life.

The bed is supplied complete with timber ‘lift & lock’ side rails together with a lifting pole and grab Handle. Each castor features a simple to operate brake.

5 Assembly information

5.1 Basic information for assembly

- The bed should be assembled by suitably competent persons.
- Ensure that the local electricity mains voltage corresponds to that marked on the main controller label before connecting to the supply.
- Ensure that cables from actuators are plugged into the main controller correctly.
- The fuse in the mains 'safety connector' plug should not exceed 5amps.
- The bed should be located on a level surface & not sited on loose floor coverings.
- The cable from the mains electricity supply must be routed clear of the lifting mechanism & castors to avoid danger of shearing or 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 Assembling the lying surface

Push the two parts of the lying surface together and screw them tightly with the grub screw with hexagon socket. The lying surface is correctly mounted when no air gap is visible at the joints of the frame and the two parts can no longer be separated after fastening.



Figure 2: Connection of the lying surface parts

The entire lying surface can now be placed on the chassis. After that, only the plugs of the drives have to be connected with the control unit according to the marking on the plug cables and the sticker on the control box.

5.3 Mounting the wooden border

Insert the head and foot boards into the holders on the lying surface and screw tight.

Slide the sliding pieces into the sliding rail of the head or foot board as shown and secure them with the knurled screw and the retaining piece.

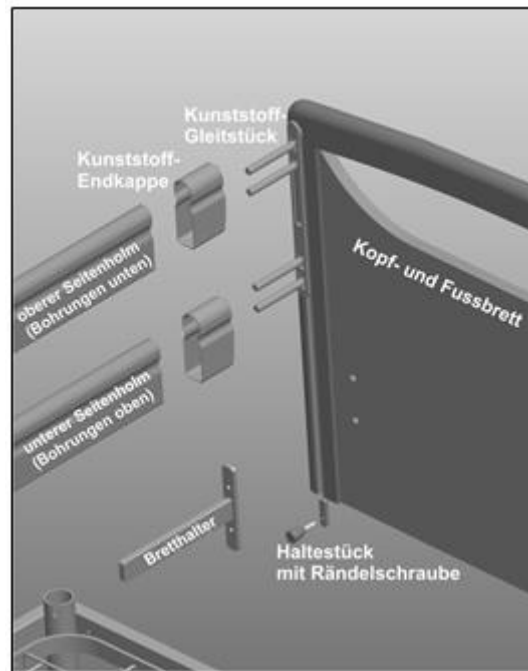


Figure 3: Mounting the wooden parts

Insert the slats of the side rail on the foot section side. (slats in lowest position)

Insert the sliding pieces on the headboard side into the batten holes as shown, then slide them into the sliding rail on the headboard and secure them with the knurled screw and the retaining piece.



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

5.4 Extension options

5.4.1 Option 1 Length 210 cm

The two 5 cm long extension pieces are to be mounted on the head and foot sides as shown in Figure 4. This generates a 210 cm lying surface that is 10 cm longer. Also install the longer side rails. These are also 10 cm longer than in the standard version of the bed.

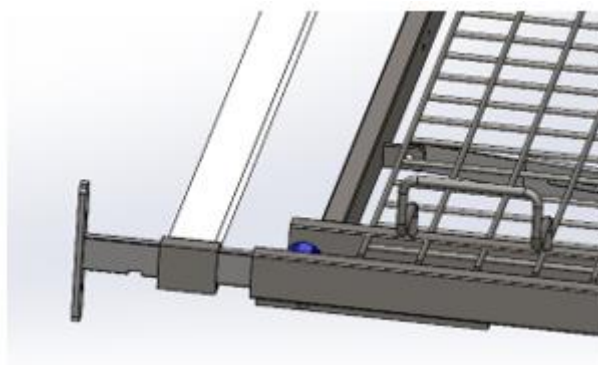


Figure 4: Possibility of extension to 210 length

5.4.2 Option 2 Length 220 cm

For the bed extension to 220 cm, a 5 cm from the previous subchapter is used on the head side. In addition, the bed is extended on the foot side with a 15 cm extension piece. For this purpose, the lying surface and the corresponding lying surface frame are extended.

5.5 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

To raise side rails:

Hold the upper side rail at the head-end and slide up the channel until the locating pin engages with a click. Repeat at the foot-end.

To lower side rails:

Hold the upper side rail at the foot-end and lift slightly to 'unlock' the release button on the side of the foot board. Press and hold the release button and gently lower the side rails until they rest on the stop at the bottom of the track. Repeat at the head-end.

Where it is necessary to take apart and re-fit the siderail finger assemblies, it is essential that they are re-fitted correctly to ensure correct operation and maintain the BS EN 60601-2-52 gaps between rails, preventing entrapment.

To retain the siderails in their lower position an end stop/closure is fitted to the aluminium track during production. This should be removed by unscrewing partially until the screw is free of its locating hole in the aluminium track and sliding from the bottom of the track as a complete assembly.

NOTE: for relevant models, correct fitting of the slider connector (wire loop) is vital. It must be positioned around

the upper finger of each pair. On some bed models the two piece finger assembly components are replaced by a single-piece finger set, with no wire loop or plastic spacer.

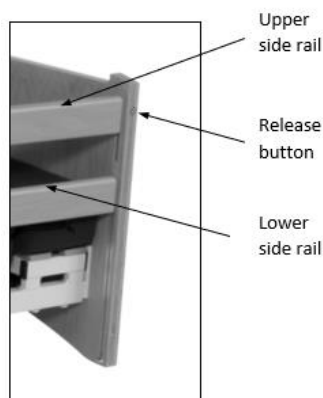


Figure 5: Description side rails and release button



The side rails can only fulfill their safety function when the head rest and the footrest 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 bars.



Only the original 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 hand rails must be removed from the nursing bed. Only use the grab rails when the side rails are lowered.

6.2 Operating the functions

Curadorm Comfort beds are fitted with an auto-profile/function-lock hand control similar to the one pictured. This controls the independent operation of the back-rest, leg-rest & bed height. It also allows the back-rest and leg-rest to be operated simultaneously using just one button. (cf. Figure 6)

It allows any or all functions to be locked using the special 'key' provided – inserting and turning clockwise to lock or anti-clockwise to un-lock.

The 4 buttons to the left control the 'raise' functions and the 4 buttons to the right control the 'lower' functions. Each button carries a pictogram to denote its function.

A clip on the rear of the hand control allows it to be positioned conveniently on a siderail.



Figure 6: Hand control

Switch-off function on the hand control

Turning the on/off knob with the key locks or unlocks the respective function. If the function is active, a green dot appears above the on/off button and the button is in the vertical position. (cf. Figure 6)



In the absence of care personnel, locking of the controls is required!

6.3 Operating the brake castors

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



Figure 7: Exemplary castors in braked and unbraked condition

6.4 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 lug is pushed far enough into the socket bushing so that the lug is fully located in the recessed slot on the socket bushing. Thus, the lifting pole is fixed in its position and cannot be swung out over the lying surface (cf. Figure 8)

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

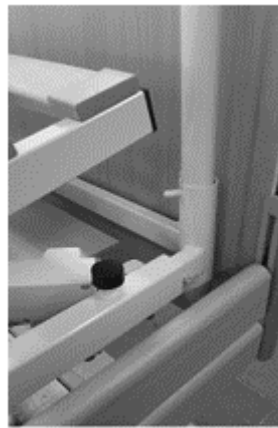


Figure 8: Patient lifting pole mount at the head end



The lifter is not suitable for therapeutic purposes.



The maximum load capacity of the lifter is 75 Kg



The lug 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 9). The range of adjustment is from 670mm to 870mm. (Measured without mattress)



Figure 9: Adjustable grab handle

6.5 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 laid under the base of the bed! (Danger of crushing)

6.6 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).

If a mattress cover is damaged, bodily (or other) fluids can pass through and contaminate the inner core, creating the potential for cross-infection.

It is therefore recommended that a frequent inspection of mattress covers is undertaken to inspect for damage, such as holes, cuts or tears. The inner core of the mattress should also be inspected for signs of staining or contamination.

Should damage to the cover occur, it should be disposed of safely and replaced. The inner core of foam mattresses cannot be de-contaminated and should be disposed of safely.



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 rail (side bars 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

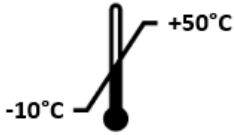

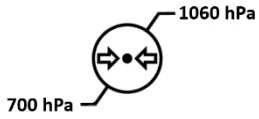
Temperature range	min. -10 °C max. +50 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 3: Storage conditions

7.2 Operating conditions

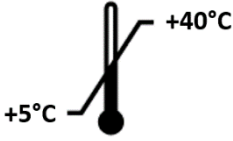

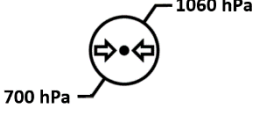


Temperature range	min. +5 °C max. +40 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 4: Operating conditions

8 Technical data

Designation	Curadorm Comfort			
Artikelnummer	NS-011-FA	NS-011-0	NS-011-100200	NS-011-120200
Nominal voltage	~230 V / 50Hz			
Rated power	160 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	IPx6			
Hand control	IPx4			
Actuators	IPx4			
Duty cycle switch on duration 10%	maximum 6 min/h			
Max. patient weight	135 kg			
Safe working load	175 kg			
Dimensions of the nursing bed:				
Total weight including patient lift and wooden parts	107 kg	112 kg	117 kg	
Dimensions of lying area	200 x 90 cm	200 x 100 cm	200 x 120 cm	
Height adjustment (measured without mattress)	33 – 83 cm	40 – 90 cm		
Adjustment angle head rest	0° to 83°	0° to 72°		

Adjustment angle thigh support	0° to 47°	0° to 55°
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Table 5: Technical data

The company reserves the right to make technical changes without notice.

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 harmless 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 (excl. Mattress).

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.

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 Maintenance

14.1 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.

14.2 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.

14.3 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)

Fax: +49(0)921/150845-45

E-Mail: info@isko-koch.de

14.4 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.

15 Guidance on safe working load

The Safe Working Load MUST NEVER be taken as the maximum user weight.

In common with other manufacturers we quote a Safe Working Load of each of our beds. When a bed is tested, a static load is evenly distributed over the whole surface of the bed. Remember when a bed is in use that the load is rarely static or evenly distributed. Should a visitor, for example, sit down heavily on one side of the bed then the shock load at that point will be extreme, the load will be uneven & the total combined weight may EXCEED the Safe Working Load. The SWL must take account not only of the weight of the user but also the weight of the mattress, bed linen & other items loaded on the bed

eg. Air pump for an air driven mattress.

You should also take account of any likely weight gain by the user in future

Typically, a mattress could weigh 20kg; an air driven system could be as much as 30kg; a couple of pillows 3kg; bed linen around 12kg – the total of such items, together with anything else placed on the bed, PLUS the weight of the user must NEVER exceed the Safe Working Load.

Neither ISKO KOCH, nor its employees, can accept responsibility for any issue arising from overloading a bed. Should damage result from such actions then any necessary repairs will not be covered under warranty.

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 Curadorm Comfort beds complies with the basic requirements of the EC Directive for

Medical devices 2017/745, Annex II



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