Curadorm Pro

Pflegebetten

Instruction for use

Stand: 11/2022
(Rev. 2.0)

Content

List of figures

List of tables

1 Foreword

Dear customer!

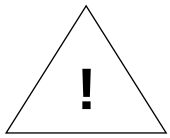
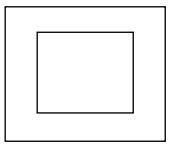
We would like to thank you for the trust you have placed in us and for purchasing our product. We have manufactured this medical product with great care.

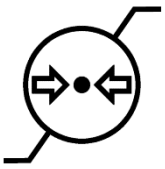
Please read the instructions for use carefully before using the product for the first time and always keep them close at hand.

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

	This warning sign indicates all instructions that are important for safety. Non-observance can lead to accidents or injuries.
	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)
	Conformity symbol according to 2017/745 of the Medical Devices Directive
	Medical Device - Shows the medical device provided by the manufacturer in accordance with EU Directives 2017/745
	Device type B according to IEC 601-1 (Special protection against electric shock)
	Device of protection class II, protective insulation

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

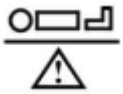
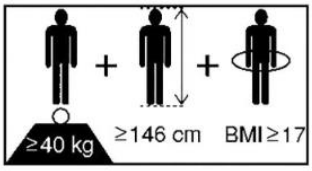
UDI	Unique identifier of a medical device - displays a carrier containing information about a unique identifier of a medical device.
	Safe working load
	Max. patient weight
	Minimum body dimensions/weights of the patient

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.

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

Table 2: Standards verification

3 Safety instructions

- You should read these instructions for use carefully before using the bed. It contains important information for the safe and reliable use of the device. Keep the instructions for use for future reference.
- Safety, reliability and performance are guaranteed if the following instructions are observed and the bed is used properly.
- The beds are suitable for home care as well as clinical use. A maximum patient weight of 135 kg must be observed.
- Ensure that children can only access the bed under supervision and that no children are in the danger zone under the bed during operation.
- 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.
- Provide 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. 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)
- When not in use, make sure that the handsets are attached to the bed and not laid down in the bed to prevent damage caused by incorrect operation.
- If the patient is unattended, ensure that the bed is set at its lowest height to make it as easy as possible to get in and out of bed.
- Ensure that children only have access to the bed under supervision and that there are no children in the danger zone under the bed during operation.

4 General product description

4.1 Intended purpose

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

4.2 Indication

For immobile patients as well as patients with restricted mobility, for example, when

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

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 bed has the following electrical functions:

Type	electr. height adjustment	electr. head adjustment	electr. knee adjustment
Curadorm Pro	**Yes**	**Yes**	**Yes**

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 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 Setting up the care bed

The bed must only be setup by authorised personnel. The installation-sided safeguard must not exceed 16A. Prior to connecting the device, please ensure that the voltage and the frequency of your power supply system correspond to the details on the name place. Ensure a level surface when choosing a location for the bed. Please make sure the floor coverings are suitable, if the bed needs to be moved frequently. Carpets, wall-to-wall carpets and loosely laid floor covers can become damages or make it more difficult to push the bed. Firmly connect the power plug to the power socket. In doing so, lay the supply cable on the flood. Ensure that the bed (particularly when pushed) is not stood on the cable with the rollers. The cable must not be guided through the mechanics of the bed base! (Risk of crushing)

The bed must only be moved or transported if the lifting motors are in the lowest position.

A damage to the electrical power cable caused by improper handling (driving over or clamped between moving parts) can have fatal consequences.

5.3 Assembly of the lying surface

Push both parts of the lying surface together and secure using the bolts and the spring cotter (arrow 1, Figure 2). The tightly screw both set screws (arrow 2, Figure 2).

The lying surface is correctly assembled, once a gap is no longer visible at the joints of the frame and both parts can no longer separated once securely fastened.

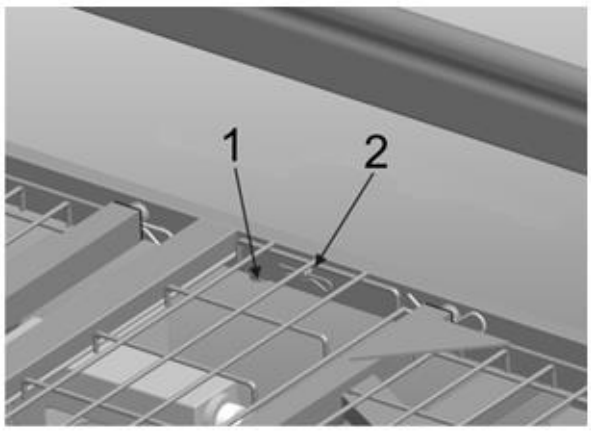


Figure 2: Assembly of the lying surface

Tighten the set screws!

The entire lying surface can then 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.

5.4 Assembly of the wooden surround

Push the head- and the footboard (7) into the locations on the lying surface (1) and screw tight.

Slide the sliding blocks (6) into the slide bar of the head- and foot board (7) incl. the distance piece (8) as shown and secure with the clamping plate and the knurled screw (5).

Insert the laths (2) with mounted end caps (4) of the side rails at the foot end. (Laths in the lowest position)

Insert the sliding blocks (6) into the lath holes at the head end as illustrated, then slide them into the slide bar at the headboard incl. the distance piece (8) and secure with the knurled screw and the clamp (5). (c.f. Figure 3)

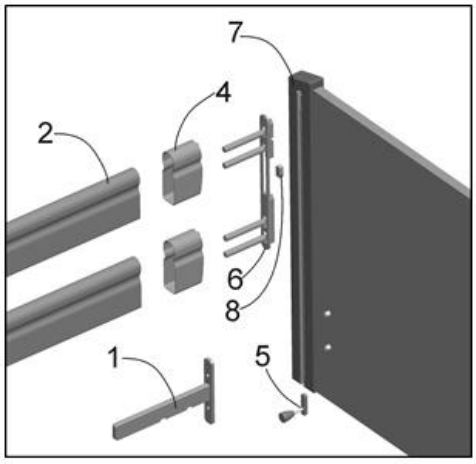


Figure 3: Assembly of the wooden surround

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

5.5 Disassembly of the care bed

If necessary, e.g. for transport, the care beds can be dismantled with little effort as described but in reverse order. After disassembling the bed, it should be reassembled by authorized personnel.

6 Operation

6.1 Operating the side rails

Putting up the wooden side rails:

Pull the upper side bar upwards until it audibly snaps into place in the locking mechanism.

Lowering the wooden side rails:

Raise the upper side bar so that the release button can be pressed, keep the release button pressed and lower the side bars.

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.

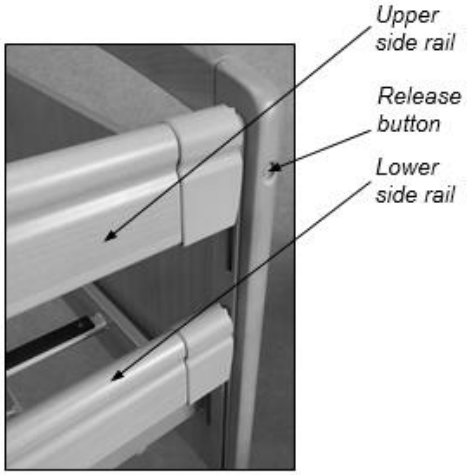


Figure 4: Description side rails and release button

If a patient is left unattended with the side rails in the upper position then, to minimise the risk of falling, the bed is to be set at the lowest position!

Only the original side rails provided may be used! The height between the upper edge of the unladen mattress and the upper edge of the side rails must, in all events, be 22 cm!

The side rails can only fulfil the protective function when the head and foot sections are lowered!

6.2 Operating the functions

Curadorm Pro 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 & comfort functions. The comfort function allows the back-rest and leg-rest to be operated simultaneously using just one button.

Each function can be switched on or off individually with the metal key.

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

Figure 5: Hand control

6.3 Operating the wheels

The nursing bed should always be braked at the place of installation with the help of the central brake. To do this, the foot pedal is pressed down with the foot. (see Figure 6, left) If the foot pedal is in a horizontal position (see Figure 6, right), the bed is unbraked and can be moved.

Figure 6: Example rollers 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 7)

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

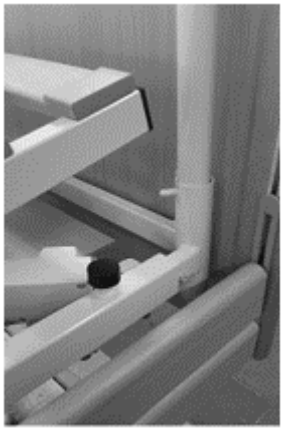


Figure 7: Patient lifting pole mount at the head end

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

Figure 8: Adjustable grab handle

6.5 Emergency lowering

As an option a battery driven emergency lowering system that bridges power failures in the main power supply is available. In addition the head section and knee bend motors are assembled with manually removable pins in order to be able to achieve a horizontal position e.g. in the event of a power failure.

Emergency lowering of the head section

At least two persons are absolutely necessary for manual lowering of the head section

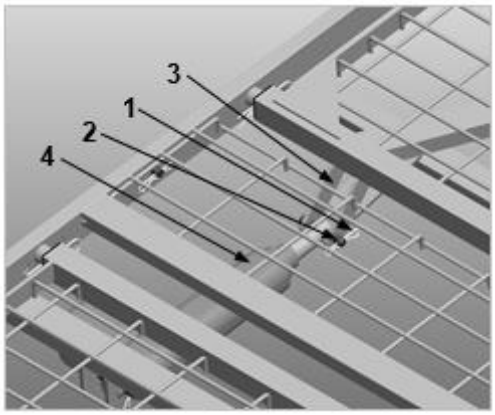


Figure 9: Emergency lowering

- Check whether the bed is stationary and braked.
- One assistant must relieve the head section by lifting it slightly, e.g. by the mattress support bracket, and holding it in this position.
- The second assistant can now pull off the cotter pin (1) on the pin (2) of the motor mounting lever (3) and remove the motor pin (2).
- The head section motor (4) can now be swiveled away downward.
- After leaving the danger area under the bed, the first assistant can now slowly and carefully lower the head section. The head section must be held firmly. Uncontrolled lowering poses a risk of injury to the patient and the assistant.

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 laid 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).

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

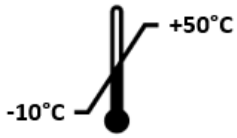
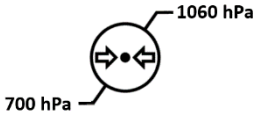
Temperature range	min. -10 °C max. +50 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 3: Storage conditions

7.2 Operating conditions

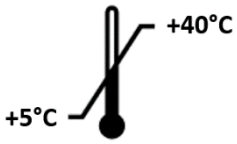
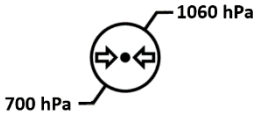
Temperature range	min. +5 °C max. +40 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 4: Operating conditions

8 Technical data

Name	**Curadorm Pro**	
Nominal voltage	**~230 V/ 240 V / 50Hz**	
Rated output	**160 VA**	
Device type B in accordance with IEC 601-1		
Protection class		
Sound power level	**63 dB(A)**	
IP protection class for drive components:		
Control unit	**IPx6**	
Hand control	**IPx4**	
Drives	**IPx4**	
Power-on time 10%	**maximal 6 min/h**	
Max. patient weight	**170 kg**	**170 kg**
Safe working load	**210 kg**	**210 kg**
Masses of the nursing bed:		
Dimensions of the lying surface	**200 x 80 cm**	**200 x 90 cm**
Height adjustment (measured without mattress)	**32 – 82 cm**	
Adjustment angle head part	**0° to 72°**	
Adjustment angle thigh part	**0° to 43°**	
Total weight	**100 kg**	**105 kg**

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

Medical devices 2017/745, Annex II

ISKO KOCH GmbH

Egerländer Str. 28

95448 Bayreuth

CE