Exaphysio

Behandlungsliegen

Instruction for use

Stand: 09/2022
(Rev. 3.0)

Content

List of figures

List of tables

1 Foreword

Dear customer!

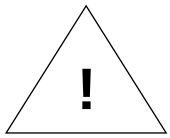
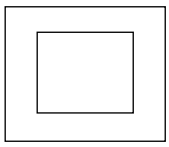
We would like to thank you for the trust you have placed in us and for purchasing our product. We have manufactured this medical product with great care.

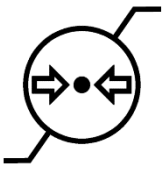
Please read the instructions for use carefully before using the product for the first time and always keep them close at hand.

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.

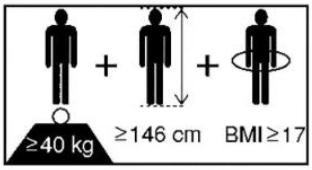
	Unique identifier of a medical device - displays a carrier containing information about a unique identifier of a medical device.
	Safe working load
	Minimum body dimensions/weights of the patient

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.

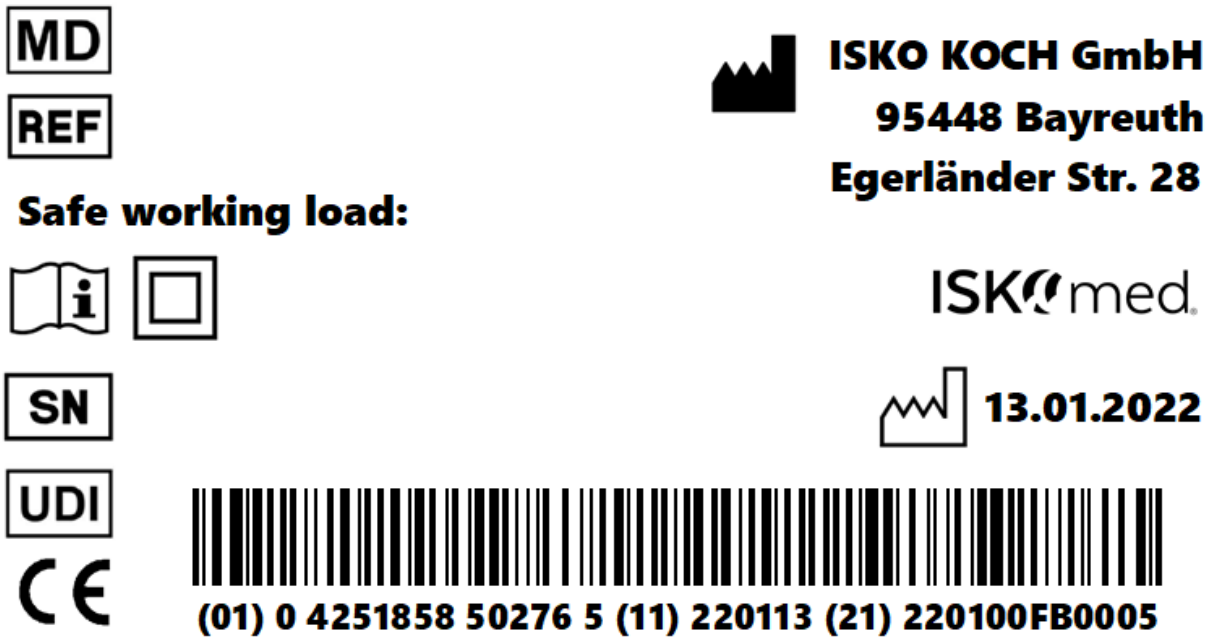


Figure 1: Exemplary type plate

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 60601-1-6	*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

- Before operating the examination couch, you should read these 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.
- Ensure that children only have access to the couch under supervision and that no children remain in the danger zone under the couch during its operation.
- The examination couch should only be set up by authorized personnel.
- Ensure a level surface when selecting a location for the treatment couch.
- The fuse protection on the installation side must not exceed 16A. Before connecting the charging device, please make sure that the voltage and frequency of your power supply correspond to the specifications on the type plate.
- Provide a suitable floor covering if the examination couch must be moved frequently.
- Connect the mains plug firmly to the mains socket. Lay the power cord on the floor. Make sure that the treatment couch (especially when moving it) does not rest on the cable with its rollers. The cable must not be routed through the mechanical parts of the table base! (risk of crushing)
- 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 treatment table and not placed on the treatment table to prevent incorrect operation which could cause damage.
- If the patient is unattended, ensure that the treatment couch is set at its lowest height to allow the easiest possible entry and exit.

4 General product description

4.1 Intended purpose

The treatment couches of the BL-001-0/BL-002-0/BL-003-0 series are equipped with electric height adjustment. They are operated via hand or foot control. The drives for the adjustment functions consist of electromechanical linear motors with maintenance-free permanent lubrication. The drives are operated via an air switch, which works without electric current, but causes the actuation pneumatically. Treatment couches of the BL-001-H/BL-002-H/BL-003-H series are equipped with a hydraulic pump for adjusting the height of the couch surface. This is operated via two foot levers on the chassis.

4.2 Indication

Treatment couches are aids whose use is indicated:

- during therapeutic treatments on patients who require height adjustment of the lying surface to improve the therapy.

4.3 Contraindication

The following patients are not eligible for treatment couch use:

- In case of massive cardiovascular problems
- In case of severe dizziness, which no longer allows a safe lying on the lying surface (e.g. falling down)
- In case of severe anxiety

4.4 Equipment features

4.4.1 BL-001-0 BL-002-0 BL-003-0

The treatment couches have the following electrical functions:

- electrical height adjustment
- possibility of locking the electrical functions

Optional:

- electric headrest adjustment
- electric leg adjustment

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

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

Optional:

- Central brake system
- Roller lifting system
- Metal side rails (one or two-sided)
- Fold-up side rails (complete or head side border)
- Paper roll holder
- Nose slit in the upholstery panel
- premium swivel castors

- electric headrest adjustment
- electric leg adjustment
- headrest adjustment via gas spring

4.4.2 BL-001-H BL-002-H BL-003-H

In the ...-H variant, all electronic components are omitted. The height adjustment is realized via a hydraulic pump. Operation is by means of tread levers mounted on the left/right of the undercarriage.

Optional:

- Central brake system
- Roller lifting system
- Metal side rails (one or two-sided)
- Fold-up side rails (complete or head-side border)
- Paper roll holder
- Nose slit in the upholstery panel
- Premium swivel castors
- Headrest adjustment via gas spring

5 Assembly information

5.1 Basic information for assembly

The treatment couch should only be installed by authorized personnel. The installation-side fuse protection 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 a level standing surface when selecting the location for the treatment couch. Provide a suitable floor covering if the treatment couch must be moved frequently. Carpets, rugs and loosely laid floor coverings can be damaged or make it difficult to push.

Connect the mains plug firmly to the mains socket. When doing so, lay the power supply cable on the floor. Make sure that the treatment couch (especially when moving it) does not rest on the cable with its rollers. The cable must not be routed through the mechanics of the treatment couch base! (Danger of crushing)

Damage to the electric power line by running over or clamping can have fatal consequences.

Before moving the treatment couch or before disassembling it for transport, the power supply cable must be wound up and fastened to the device provided on the chassis.

5.2 Disassembly/assembly instructions for the lying surface

(estimated working time: 15 minutes)

1. Unscrew the existing plate (six screws)

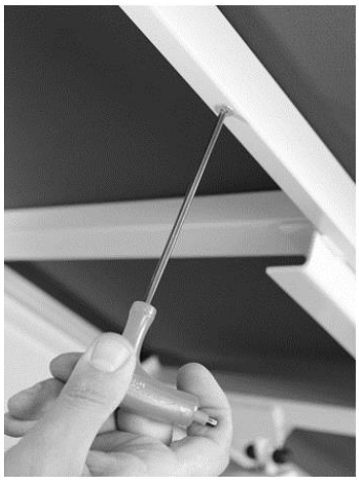


Figure 2: Unscrewing the lying surface

2. Place the new plate on the scissor mechanism

Figure 3: Lifting down the lying surface

3. Carefully screw the bolts diagonally into the thread of the new foam plate.
    a) Screw all the bolts into the plate with your finger
    b) Fasten the screws diagonally with the screwdriver

Figure 4: Screwing the lying surface

In the case of spare parts deliveries of lying surfaces, there may be deviations in the screw-on points due to the dimensional tolerance, which is why the lying surface is connected to the lying surface frame using conventional wood screws. These will be included in the scope of delivery.

5.3 Disassembling the treatment couch

If necessary, e.g. for transport, the treatment couch can be dismantled with little effort as described but in reverse order. The reassembly after disassembly of the treatment couch should be carried out by authorized personnel.

6 Operation

6.1 Operation of the electric movement

(Electrical adjustment for treatment couches of the BL-001-0/BL-002-0/BL-003-0 series)

Each upward or downward movement of the height adjustment is effected by pressing the respective key of the hand control or foot switch. The keys are marked with symbols according to their function.

Figure 5: 1-row hand control (1st row of keys: height adjustment)

Do not exceed the duty cycle of max. 6 min per hour!

If the couch is not used, it must be disconnected from the mains to prevent the height drives from moving in any case! This also applies to cleaning personnel. They must be instructed accordingly when cleaning the couch!

If the treatment couch has an additional electrical head section adjustment, it must be operated with the corresponding hand control shown in Figure 6.

Figure 6: 2-row hand control (1st row of buttons: headrest adjustment, 2nd row of buttons: height adjustment).

An operation of the electric height adjustment can also be realized via a foot switch. With (+) the couch will move upwards and with (-) it will move downwards. In this case, the automatic locking function must also be deactivated.

6.1.1 Automatic locking function

The treatment couch has an automatic locking function ("Auto-Lock") of the electrical height adjustment. In the idle state, the electrical height adjustment of the treatment couch is always locked, which means that it cannot be operated via the hand control. The electrical adjustment can be activated via a key combination of the switch. Here, first press the "Up" key (1) and then the "Down" key (2) of the corresponding key row of the height. A short beep indicates that the couch has been unlocked and is now ready for use. After unlocking, the couch is activated for 5 seconds. After this period, the couch is automatically locked again. The locking is also signaled by a short beep. Unlocking always takes place via the height key row.

6.2 Operating the hydraulic movement

(Hydraulic adjustment for treatment couches of the BL-001-H/BL-002-H/BL-003-H series)

The height of the lying surface can be adjusted by actuating the pump levers on the left and right of the chassis.

When the right pump lever is pressed down, the lying surface is raised.

Pressing the left pump lever down causes the cushion plate to be lowered.

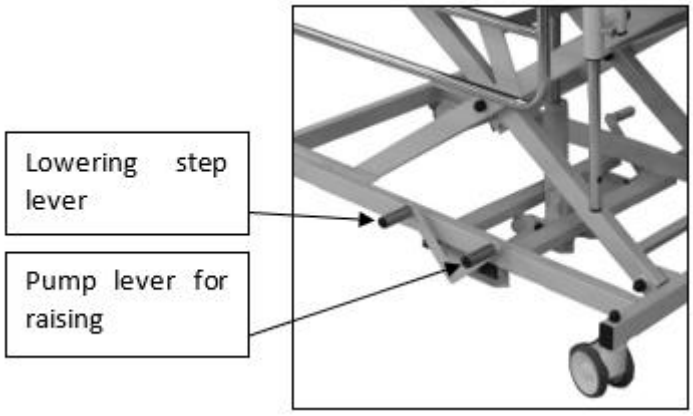


Figure 7: Operation of the step lever for hydraulic adjustment

6.3 Operating the fold-up side rail

The folding side rail can be used to provide an additional border around the lying surface. However, this border does not serve as protection against the patient falling out.

The initiation of the folding process can be achieved by releasing the catch. To do this, pull out the black latch and turn it slightly so that the bolt no longer holds the side rail. Repeat this procedure for each side. The side rail can then be folded down. To return the side rail to an upright position, proceed in reverse order.

Figure 8: Fold-up side rails

Person must not sit on the side rails under any circumstances!

6.4 Operating the metal side rails

Side rails can be used to stabilize patients on their own responsibility on the relatively narrow couches or to support positioning pillows, for example. Any risk of falling during repositioning or during treatment can also be countered with the aid of side rails.

The position of the castor plays a decisive role when lowering the side rails. Please ensure that the metal side rails do not rest on the castors (this does not apply to the standard couch - 80x200 cm dimension).

Proper functioning of the latching fittings is a prerequisite; the proper latching of the fitting must also be monitored by the nursing staff!

Side rails on treatment couches are not suitable for restricting the mobility of persons requiring treatment.

Children in particular will try to overcome or bypass these barriers if there are grids only on the long sides of the couches.

In any case, patients should not be left on couches without competent supervision.

The treatment couch may only be moved with the metal side rails raised.

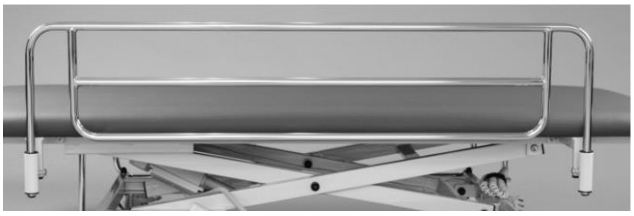


Figure 9: Metal side rails

6.5 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

6.6 Operating the central brake system

The treatment couch should always be braked at the installation site by operating the central brake system's tread levers, so that the unit is completely firm and stable. In addition to the conventional implementation of the rollers, there is also a solution via a central brake system. This can be purchased as an accessory. With the central brake system, all four rollers are braked or released by the release of a brake lever. The orientation of the brake lever indicates the state of the braking system. When the brake lever is in a horizontal position, the couch is unbraked. If the brake lever points in a direction rotated by 30°, the couch is braked.

6.7 Operating the roller lifting system

When the foot lever is actuated (foot lever is down, Figure 11 right), the castors are completely lifted off the floor, thus the couch stands completely stable and firm on its feet. The couch cannot be moved in this position. To put the couch back on the casters, release the foot lever (foot lever is up, Figure 11 left). The foot lever should not be operated in the lowest lying surface position, as it is difficult to reach the lever here.

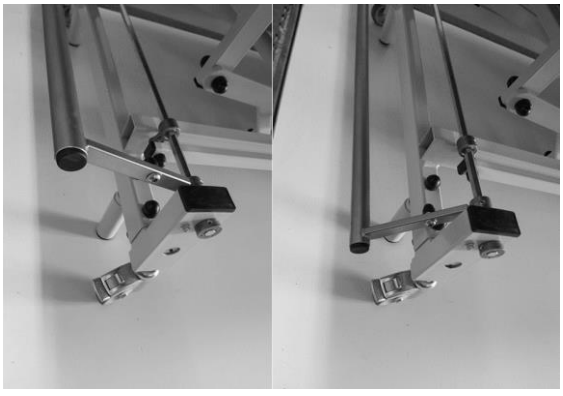


Figure 11: Operation of the roller lifting system

6.8 Operating instructions

- After assembly and before a patient uses the couch, check that all connections and the entire couch are firmly seated
- To avoid the risk of injury, no parts of the patient's body may protrude above the table surface or feet may rest on the table base while the adjustment functions are being actuated
- Make sure that the drives are functioning properly
- A treatment couch that is not fully functional must be withdrawn from use immediately

- Make sure that no objects, e.g. wastepaper basket. side table, chair, etc., are located in the treatment couch's movement range
- Before moving the treatment couch, the mains plug must be disconnected from the socket to prevent damage to the electrical system
- Make sure that the power-on time is observed. Therefore, never make long and unnecessary electrical adjustments. If the thermal fuse in the control unit has been triggered once after 6 min/h, then the control unit must be replaced by an authorized specialist!

If the couch is not used, it must be disconnected from the mains to prevent the height drives from moving in any case! This also applies to cleaning personnel. They must be instructed accordingly when cleaning the couch!

The attachment of additional equipment, such as insulin pumps, ventilation machines, etc., is prohibited if equipotential bonding has not been created beforehand.

Any cables from additional devices must not be routed through the mechanics of the treatment couch substructure! (danger of crushing)

7 Ambient conditions

7.1 Storage conditions

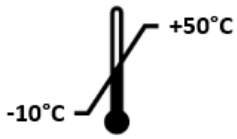
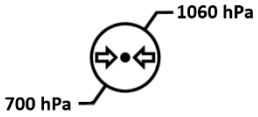
Temperature range	min. -10 °C max. +50 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 3: Storage conditions

7.2 Operating conditions

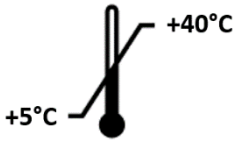
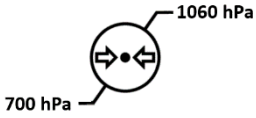
Temperature range	min. +5 °C max. +40 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 4: Operating conditions

8 Technical data

(Subject to change without notice!)

Designation	**BL-001(2)-H**	**BL-003-H**	**BL-001(2)-0**	**BL-003-0**	**BL-003-XS**	**BL-002-102**	**BL-003-S**
Rated voltage			230V~/ 50/60Hz				
Rated power			192 VA				
Device type B according to IEC 601-1							
Protection class							
IP Schutzklasse für Antriebskomponenten							
Control box			IPX4				
Actuators			IPX4				
Hand control			IPX4				
Foot switch			IP X6				
Sound power level			50 dB(A)				
Duty cycle ED 10%			maximum 6 minutes/hour				
Height adjustment	49 cm - 94 cm	49 cm-94	44 cm - 95 cm	45 cm - 83 cm		44 cm – 95 cm	
Safe working load	210 kg	260 kg	210 kg	300 kg		210 kg	260 kg
Dimensions of the lying surface (maximum)	90 cm x 200 cm	120 cm x 220	90 cm x 200 cm	120 cm x 220 cm	110 x 200 cm	80 cm x 200 cm	120 cm x 220 cm
Total mass	ca. 87 kg	ca. 96	ca. 65 kg	ca. 95 kg	Ca. 90 kg	ca. 75 kg	ca. 95 kg
Height adjustment Stroke length	40 cm	40 cm	41 cm	38 cm	38 cm	41 cm	41 cm

Table 5: Technical data

Repairs may only be carried out by ISKO specialist 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 claim 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 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 couch 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

The expected service life in professional nursing home operation is 7 years. Lack of maintenance and excessive stress on the product can significantly reduce the service life.

12 Disinfection

- In order to ensure that the couch functions properly, each ISKO couch should be cleaned, disinfected and checked after each use so that it can be used again immediately.
- Improper cleaning/disinfection of the couch can cause hazards.
- Depending on the degree of soiling, we recommend cleaning the couch 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	Motor switches off independently and shows no reaction when the switch is actuated	Operating time too long, wait 20 minutes for the drive to cool down
2	One motor or even none of the motors responds to the manual switch operation	Check the plug connection of the power supply cable. Check plug connection between handset and control box. Check plug connection between motor cables and control box.
3	Beep from the control box → A drive has lost its position	Reset/Initialization Press and hold down the keys for the height adjustment simultaneously (really simultaneously) and together until the height drive has initialized completely. The height drive retracts during initialization

Table 6: Operational faults and solutions

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

14 Recommended accessories

Article description	Order number
Foot switch lying on the floor (1 piece)	BL-101-0
Foot switch mounted on both sides of the trolley	BL-102-0
Roller lifting system	BL-501-0
1 metal side rail 145 cm, chrome-plated incl. brackets	BL-202-0
Metal side rails 145 cm, chrome-plated incl. brackets (1 pair)	BL-201-0
Paper roll holder for roll diameter max. 40 cm (delivery without paper roll)	BL-151-0
Nose slit in the upholstery panel incl. cover in the upholstery panel cover color	BL-306-1
Headrest adjustment with gas spring instead of detent adjusters	BL-311-0
Head section adjustment electrically with linear drive instead of detent adjusters	BL-312-0
Nose slit in headboard incl. cover	BL-306-0
Footrest adjustment mechanical with detent adjusters (up to approx. +30°)	BL-999-3
Swivel castor Premium (4 pieces)	BL-002-1W

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
- Checking the strain relief of the power supply cable

(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 (without patient) until they switch off by themselves. (Limit switches in the motors must switch off with an audible click).
- Mobility and function of the side rails
- Mobility of the triggers
- Check of the switches

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)

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

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

16 Disposal

16.1 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.

16.2 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).

16.3 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.

17 Declaration of Conformity

As the manufacturer, we declare under our sole responsibility that our treatment couches 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