Exasan
Exasan Duo

Treatment couches

Instructions for use

As of: 11/2022
(Rev. 2.0)

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1 Foreword

Dear Customer

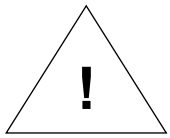
We would like to thank you for your trust and for purchasing our product. We have manufactured this medical device with great care.

Please read the instructions for use carefully before using the device for the first time and keep them within easy reach at all times.

These instructions for use cannot cover all possible applications of the device. For further information or in the event of problems that are not described in these instructions for use, or are not described in sufficient detail, please contact your specialist dealer or medical supply store.

2 General information

2.1 Symbols used

	This warning sign indicates all instructions that are important for safety. Failure to comply may result in accidents or injuries.
	Manufacturer - Indicates the manufacturer of the medical device in accordance with EU Directive 2017/745 The symbol must appear together with the name and address of the manufacturer (i.e. the person who places the medical device on the market) in the immediate vicinity of the symbol
	Conformity symbol according to 2017/745 of the Medical Devices Directive
	Medical device - Indicates the medical device provided by the manufacturer in accordance with EU Directive 2017/745
	Disposal of electrical components in accordance with legal requirements. Do not dispose of in household waste!
	Date of manufacture – indicates the date on which the medical device was manufactured.

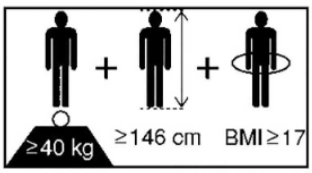
	Item number – indicates the manufacturer's item number so that the medical device can be identified.
	Serial number – indicates the manufacturer's serial number so that a specific medical device can be identified.
	Distribution partner - indicates the company that distributes the medical device locally.
	Follow the instructions for use or follow the electronic instructions for use - indicates to the user that it is necessary to follow the instructions for use.
	Unique identifier of a medical device - indicates a carrier containing information about a unique identifier of a medical device.
	Safe working load
	The product must be disposed of separately in the European Union. Disposal in normal household waste is not permitted.
	Minimum body measurements/weights of the patient

Table 1: Symbols used

2.2 Type plate

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

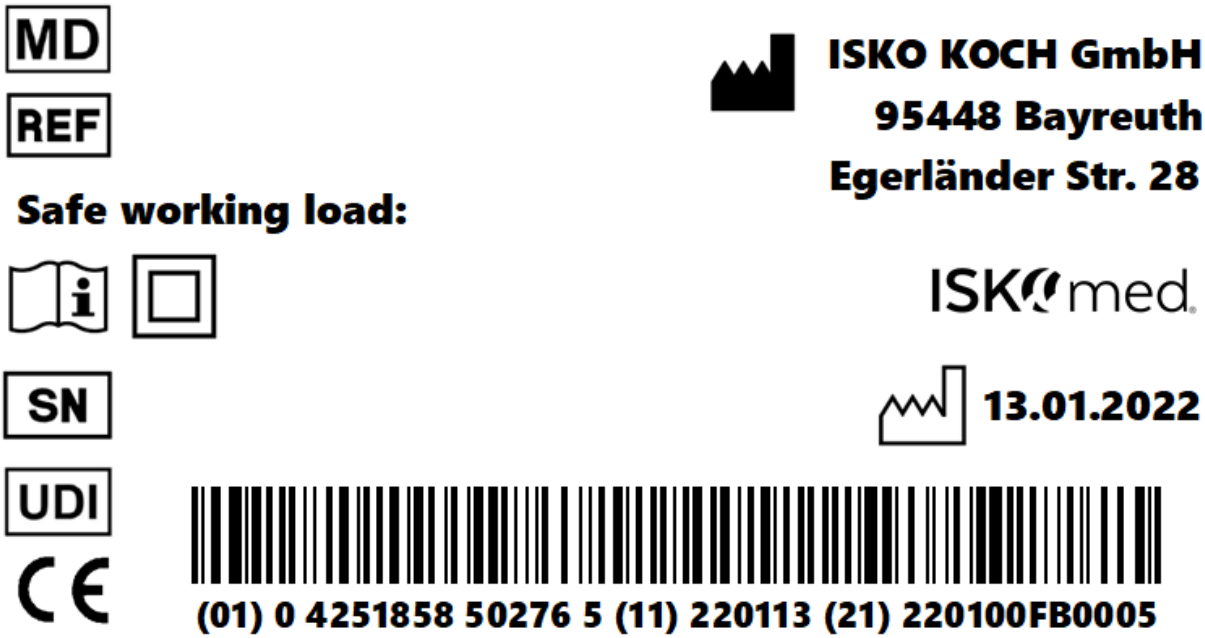


Figure 1: Example type plate

Figure 1 shows an example type plate. Please refer to the attached type plate for the exact specifications of your product.

2.3 Proof of compliance

The following national and international standards are used in the design and verification of the product, labelling and instructions for use.

Standard	Title	Edition
DIN EN 60601-1-6	Specification of usability	2010
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: Proof of compliance

3 Safety instructions

- Before using the treatment table, please read these instructions for use carefully. They contain 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 device is used properly.
- The couch should only be assembled by authorised personnel.
- Ensure that the surface is level when selecting a location for the treatment couch.
- Ensure that the floor covering is suitable if the treatment couch needs to be moved frequently. Carpets, carpeted floors and loose floor coverings can be damaged or make it difficult to move the couch.

4 General product description

4.1 Intended purpose

The BL-010 and BL-020 series treatment tables are intended for therapeutic applications with the patient in a lying position.

4.2 Indication

Treatment tables are medical devices whose use is indicated for:

- For therapeutic treatments on patients. The patient is usually in a lying position during treatment.

4.3 Contraindication

The following patients are not permitted to use treatment couches:

- Those with severe cardiovascular problems
- In cases of severe dizziness that makes it impossible to lie safely on the lying surface (e.g. risk of falling)
- In cases of severe anxiety

4.4 Product features

Treatment tables in the BL-010 series are equipped with a locking function for adjusting the head section of the table surface to adapt the lying position. The adjustment range is between +45° and -30°. The table has four screw-adjustable feet. The dimension of the upholstered surface is 70 x 200 cm.

Treatment tables in the BL-020 series are equipped with four screw-adjustable feet for adaptation to local conditions. The height of the lying surface can be adjusted by turning the feet in or out. The dimension of the lying surface is 80 x 200 cm.

Optional:

- Metal side rails (one or two sides)
- Paper roll holder
- Nose slot in the upholstered panel

5 Assembly information

5.1 General information on bed setup

Ensure that the surface is level when selecting a location for the treatment couch. Ensure that the floor covering is suitable if the treatment couch needs to be moved frequently. Carpets, carpeted floors and loose floor coverings can be damaged or make it difficult to move the couch.

5.2 Assembly/disassembly instructions for the lying surface

Estimated working time: 15 minutes

1. Unscrew the existing panel (six screws)

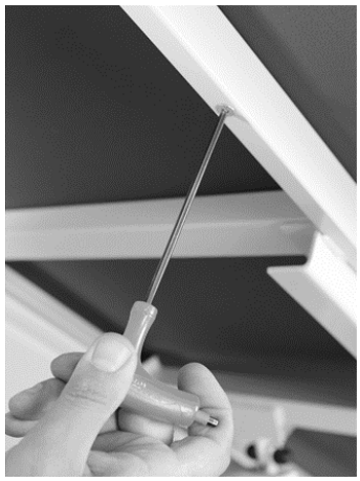


Figure 2: Unscrewing the lying surface

2. Place the new panel on the scissor mechanism

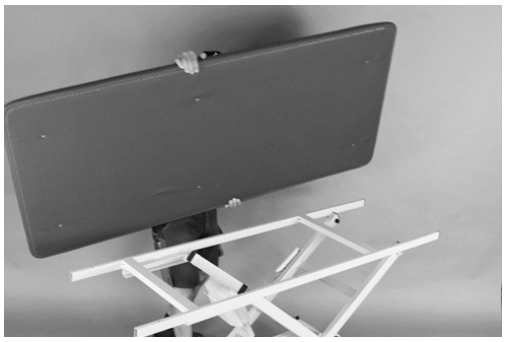


Figure 3: Lowering the lying surface

3. Carefully screw the bolts diagonally into the thread of the new foam panel.
    a. Screw all bolts into the panel by hand
    b. Tighten the screws diagonally with the screwdriver

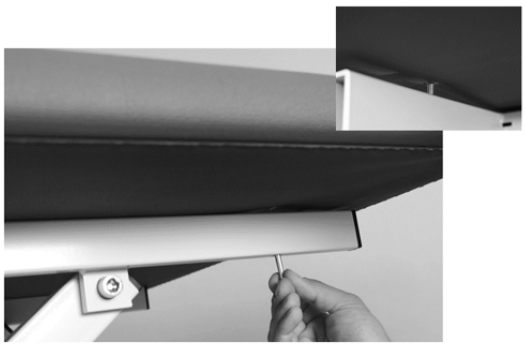


Figure 4: Screwing the lying surface in place

When replacing lying surfaces, the screw attachment points may vary due to dimensional tolerances, which is why the lying surface is connected to the lying surface frame using conventional wood screws. These are included in the scope of delivery.

5.3 Disassembly procedure for the treatment couch

If necessary, e.g. for transport, the treatment tables can be disassembled with little effort as described, but in reverse order. The disassembly procedure for the treatment table should be carried out by authorised personnel after disassembly.

6 Operation

6.1 Instructions for use

- After the assembly procedure and before a patient uses the treatment couch, check that all connections and the entire couch are secure.
- A treatment couch that is not fully functional must be taken out of service immediately.
- Ensure that there are no objects, such as waste bins, side tables, chairs, etc., in the movement area of the treatment couch.

6.2 Operation of the metal side rail

Side rails can be used to stabilise patients who are capable of moving independently on the relatively narrow

or to support positioning cushions, for example.

Side rails can also be used to counteract any risk of falling during transfer or treatment.

The position of the roller 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 – dimensions 80x200 cm).

The locking fittings must be in perfect working order; the

proper engagement of the fittings must be monitored by nursing staff!

Side rails on treatment couches are not suitable for restricting mobility

of persons requiring treatment.

Children in particular will try to climb over if the rails are only on the long sides of the lie down, to overcome or circumvent these barriers.

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

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

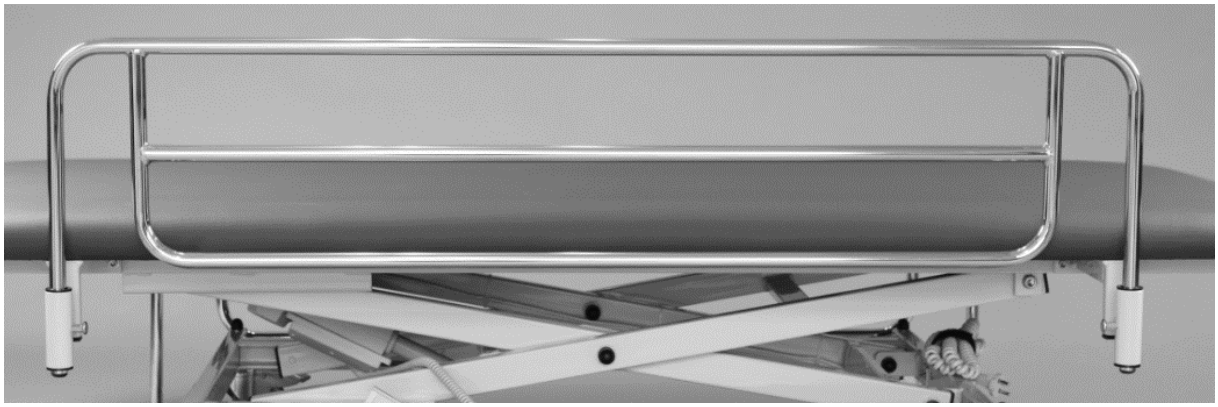


Figure 5: Metal side rails

6.3 Instructions for use

- After the assembly procedure and before a patient uses the treatment couch, check that all connections and the entire couch are secure.
- A treatment couch that is not fully functional must be taken out of service immediately.

7 Technical specifications

(Subject to change without notice!)

Designation	**BL-010**	**BL-020**
Safe working load	170 kg	170 kg
Dimensions of the lying surface (maximum)	70 cm x 200 cm	80 cm x 200 cm
Total weight	approx. 87 kg	approx. 87 kg
Head section angle adjustment range	+45° to -30	-

Table 3: Technical specifications

Repairs may only be carried out by ISKO specialists or by persons authorised and trained by ISKO with comprehensive product knowledge. Failure to comply with this provision will result in the rejection of any warranty and liability claims.

8 Materials used

The treatment table is manufactured as a welded steel tube construction. The surfaces are powder-coated or electro-galvanised. The surfaces of this product are harmless to the skin from a health perspective.

9 Service and care

All household cleaners without ammonia and abrasives may be used to clean the tube components, 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 blast cleaning of the lounger is not permitted. All pivot points of the moving parts, including the pivot eyes on the adjustment unit, are equipped with maintenance-free plain bearings and must not be oiled or greased.

10 Service life of the product

The expected service life is 7 years. Lack of maintenance and excessive use of the product can significantly reduce its service life.

11 Disinfection

- To ensure that the examination couch functions properly, every 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 pose a risk.
- Depending on the degree of soiling, we recommend cleaning the couch with a damp cloth or similar.
- Disinfectants in their specified concentration can be used for wipe and spray disinfection. (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 pads must not be used.

11.1 Specifications for cleaning agents and disinfectants:

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

Under no circumstances should soap or detergent substances be added to the disinfectant. Alcohol-based agents pose a risk of explosion and fire when used over large areas.

The use of unsuitable cleaning agents and disinfectants may cause damage to the surface coating, for which ISKO KOCH GmbH cannot be held liable.

Modifications, new settings and repairs to the couch that cannot be remedied in accordance with the above instructions may only be carried out by the manufacturer directly or by a workshop authorised by the manufacturer.

12 Maintenance

12.1 Legal basis

The Medical Device Regulation (EU) 2017/745 (MDR) and national laws and regulations require operators of medical devices to ensure that the medical device remains in a safe operating condition throughout its entire service life.

12.2 Maintenance intervals

As required by the German Medical Devices Operator Ordinance (MPBetreibV) §4 (Maintenance), a thorough visual inspection (1) and a functional test (2) must be carried out after no more than two years of operation of the medical device.

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

- Ensure all screws are securely fastened
- Mobility of the pivot points
- Check the power cord for crushing or shearing points
- Check the strain relief of the power cord

During the functional test, particular attention should be paid to the following points:

- Mobility and function of the side rails
- Mobility of the release mechanisms

Functional tests may only be carried out by ISKO specialists or by persons authorised and trained by ISKO with comprehensive product knowledge.

12.3 Spare parts

All spare parts for this medical device are available from ISKO KOCH GmbH, quoting the serial number, order number and item number (these can be found on the type plate attached to the medical device).

To ensure that functional safety and any warranty claims remain valid, only ISKO KOCH GmbH original spare parts may be used as spare parts.

ISKO KOCH GmbH

Egerländer Straße 28

95448 Bayreuth

Tel.: +49(0)921/150845-0 (Monday – Thursday 8:00 a.m. – 5:00 p.m. & Friday 8:00 a.m. – 4:00 p.m.)

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

Email info@isko-koch.de

12.4 Information on documentation

According to the German Medical Devices Operator Ordinance (MPBetreibV) and the Medical Device Regulation (EU) 2017/745 (MDR), there is a documentation requirement for:

- Maintenance
- Incidents/near misses

13 Disposal

13.1 Disposal of the device

The device and any accessories should be disposed of in an environmentally friendly manner and in accordance with legal requirements. Please comply with the applicable **waste separation regulations!** If you have any questions, please contact your local authority or waste disposal company.

13.2 Disposal of electrical components

*if electrical components are contained in the medical device

In accordance with Directive 2012/19/EU – WEEE2, this medical device is classified as an electrical device. All electrical components are free of unauthorised substances classified as harmful in accordance with the 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).

13.3 Disposal of packaging

The EU Waste Framework Directive 2008/98/EC is decisive for the handling of packaging disposal. Reusable materials must be recycled in accordance with national regulations.

14 EC Declaration of Conformity

As the manufacturer, we declare under our sole responsibility that our treatment tables meet the essential requirements of the EC Directive for

Medical Devices Regulation 2017/745, Annex II.

ISKO KOCH GmbH

Egerländer Str. 28

95448 Bayreuth

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