

Untersuchungsliegen



Instruction for use

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(Rev. 2.0)

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1 Foreword

Dear customer!

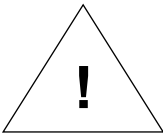





We would like to thank you for the trust you have placed in us and for purchasing our product. We have manufactured this medical product with great care.







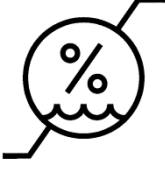
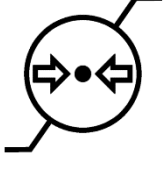

Please read the instructions for use carefully before using the product for the first time and always keep them close at hand.

Not all conceivable uses of the device can be covered in these instructions for use. For further information or in the event of problems that are not described in sufficient detail in these instructions for use, please contact your specialist dealer or medical supply store.

2 General notes

2.1 Used symbols

	<p>This warning sign indicates all instructions that are important for safety. Non-observance can lead to accidents or injuries.</p>
	<p>Manufacturer - Indicates the manufacturer of the medical device according to EU Directives 2017/745. The symbol must appear in close proximity to the symbol, together with the name and address of the manufacturer (i.e. the person who places the medical device on the market)</p>
	<p>Conformity symbol according to 2017/745 of the Medical Devices Directive</p>
	<p>Medical Device - Shows the medical device provided by the manufacturer in accordance with EU Directives 2017/745</p>
	<p>Device type B according to IEC 601-1 (Special protection against electric shock)</p>
	<p>Protection class III device, protective extra-low voltage</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
	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.

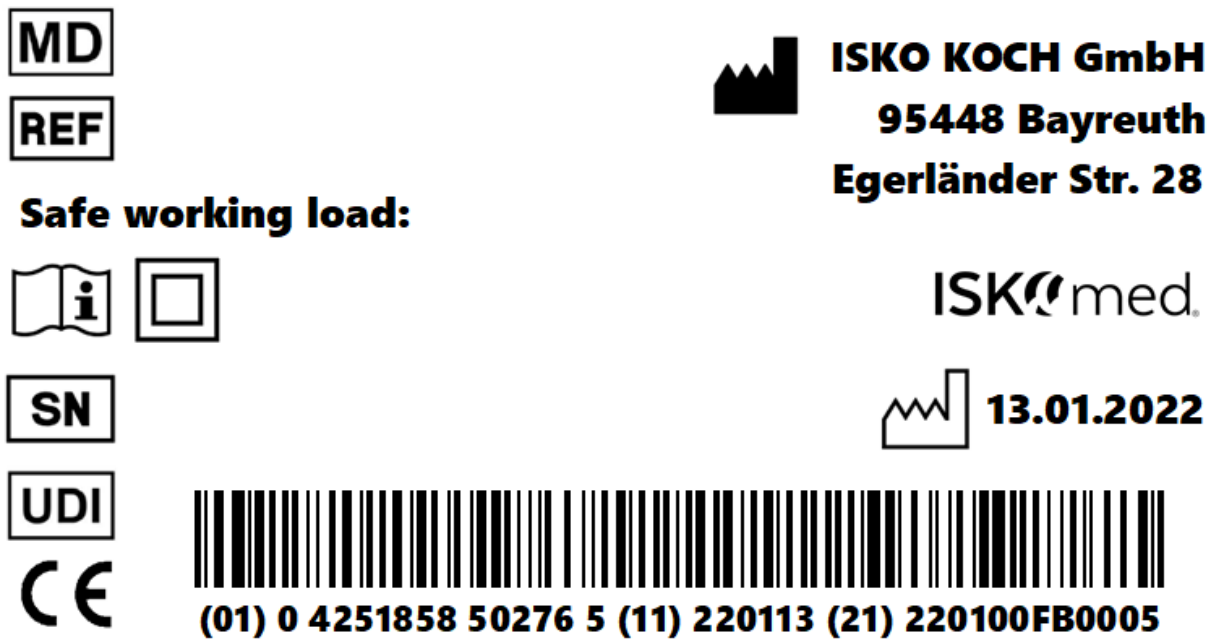


Figure 1: Exemplary type plate

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	<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 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.
- A maximum safe working load of 210 kg must be observed for this examination couch.
- 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.
- 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.
- Ensure a level standing surface when selecting the location for the examination couch
- Provide a suitable floor covering if the examination couch must be moved frequently.
- Make sure that the electrical specifications of the device correspond to the local conditions at the installation site.

4 General product description

4.1 Intended purpose

The endoscopy couch is a medical aid developed for daily use in the examination room for endoscopic treatments. The couch allows the treated physician an optimal treatment with sufficient legroom.



4.2 Indication

The endoscopy couch is an aid whose use is indicated:

- to enable an adequate endoscopic examination

4.3 Contraindication

The following patients are not acceptable for use of the endoscopy couch:

- shock
- acute myocardial infarction
- peritonitis
- acute perforation
- fulminant colitis

4.4 Equipment features

The endoscopy couch has the following electrical functions:

- electrical height adjustment
- electrical head section adjustment (parallel to the lying surface)

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

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

This enables wireless operation of the examination couch.

The couch has solid folding grids which, on the one hand, hold the patient securely even during vigorous movements and, on the other hand, do not restrict the legroom of the seated physician when folded down.

5 Assembly information

5.1 Basic information for assembly

The examination couch should only be set up by authorized personnel.

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 surface when selecting the location for the examination couch. Provide suitable flooring if the couch must be moved frequently. Carpets, rugs and loosely laid floor coverings can be damaged or make pushing difficult

5.2 Mounting the collision protection

A collision protection is provided at the head and foot end to ensure safe operation. The head-end collision protection is already mounted on delivery. For transport reasons, the foot-side collision protection must be attached during installation. To do this, insert the collision protection into the existing longitudinal tubes of the lying surface and tighten the set screws. (cf. Figure 2)



Figure 2: Mounting the collision protection

6 Operation

6.1 Operating the functions

Each upward or downward movement of the height adjustment is triggered by pressing the rocker of the manual switch, which is mounted on the lying surface. The same applies to the head section. The buttons themselves are mounted on the left and right side of the couch respectively. (cf. Figure 3)

An ergonomic adjustment of the head section is solved via a linear drive, which enables a parallel adjustment. This type of adjustment ensures an optimal treatment position for the patient.

The electrical height adjustment must first be enabled via a key combination for safety reasons (see Chapter 6.4.1).



Figure 3: Position of the function keys



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

The height motors are equipped with synchronization software that ensures parallel stroke even if the couch is unevenly loaded.

Once a week, the couch should reach the highest or lowest point of height adjustment to allow the system to calibrate.

6.2 Operating of the side rails

The metal side rails can be released via ring catches in the erected state. The ring catches are connected to each other by a steel cable so that the two catches can be released simultaneously. After releasing the catches, the metal side rail can be turned downwards. This provides the treated clinician with an optimal space for action. (cf. Figure 4)



Figure 4: Operation of the side rails

6.3 Battery control

The charger for the Li battery should be screwed vertically to a wall in a suitable place using the special holder supplied. To charge the battery, place it on the charger with the contacts facing downwards from above. Proper power supply is indicated by the "green" LED. You can also develop your own charging concept that meets your requirements.



Figure 5: Charger

The battery must be charged for at least 8 hours before the couch is operated for the first time. Approx. 80 strokes are possible with a fully charged battery under normal conditions. After that, the battery must be charged again.

An LED lights up "yellow" when the battery is being charged. After the battery has been fully charged, this diode goes out. The charging time is approx. 8 hours if the rechargeable battery has been completely discharged.

To operate the couch, the charged battery must first be inserted into the holder under the couch surface as shown in Figure 6 so that the two contacts have a secure connection. Push the battery onto the COBO box with the contacts facing backwards via the rail under the lying surface. The COBO has an integrated emergency stop as an additional safety feature (see red pushbutton in Figure 6).

An acoustic signal sounds when using the electrical adjustments of the examination couch if the battery needs to be charged. (The control box switches off at approx. 17 V DC and sends an acoustic signal beforehand if the battery needs to be charged). When the control box is switched off, operation is no longer possible.



Figure 6: COBO with connected battery

The COBO and the battery are located in the foot area below the lying surface. (see Figure 6)



Figure 7: Battery

Capacity	4,5 Ah
Weight	1,4 kg
Cycles per charge (strokes/downstrokes at max. working load)	Ca. 80
Charging time (at full discharge)	Ca. 8 h

Table 3: Technical specification battery

6.4 Locking function

6.4.1 Automatic locking function

The examination couch has an automatic locking function ("Auto-Lock") of the electrical height adjustment. In the idle state, the electrical height adjustment of the couch is always locked, consequently no operation is possible via the switches mounted on the couch surface. The electric height adjustment can be activated via a key combination of the switch. Here, the "Up" key must be pressed first, followed by the "Down" key. 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.



Figure 8: Position of the function keys for electrical height and head section adjustment

6.4.2 Manual locking function

The endoscopy couches are equipped with a safety shut-off system - a locking box. The integrated locking knob allows the user to lock or unlock the electrical functions directly at the box. The lock-off box is located underneath the couch surface.



Figure 9: Locking box

6.5 Operating the brake castors

The couch should always be braked at the place of installation with the help of the castor lock. Figure 10 shows the couch in braked condition. The four castors are braked simultaneously when the lever is actuated. If you want to move the couch in the room, bring the step levers into a horizontal position.



Figure 10: Central brake system state (braked state)

6.6 Operating instructions

- After the couch has been assembled and before it is used by a patient, check that all connections and the whole couch itself are firmly secured.
- Check that all drives are working faultlessly.
- If the couch 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 couch.
- 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 couch underframe when operating the adjustment functions.
- 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 couch! (Danger of crushing)

7 Ambient conditions

7.1 Storage conditions

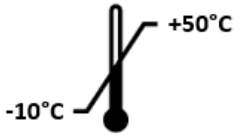

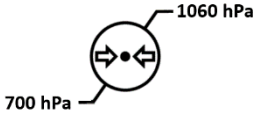
Temperature range	min. -10 °C max. +50 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 4: Storage conditions

7.2 Operating conditions

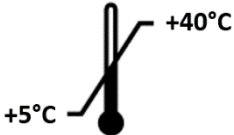

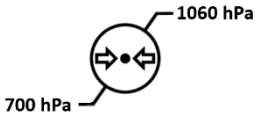
Temperature range	min. +5 °C max. +40 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 5: Operating conditions

8 Technical data

(Subject to change without notice!)



Designation	Type BL-585-1
Rated voltage	~24 V DC, capacity 2x 4.5 Ah (two battery modules are included in delivery)
Rated power	170 VA
Device type B according to IEC 60601-1	
Protection class	
Sound power level	63 dB(A)
IP protection class for drive components:	
Control unit	IPX6
Hand control	IPX6
Actuators	
Lifting column	IPX6
Head acuator	IPX4
Duty cycle ED 10%	maximum 6 minutes/hour
Safe working load	210 kg
Dimensions of the lying surface	200x70 cm
Masses of the examination couch	
Total mass	109 kg
Height adjustment	from 55cm to 95cm
Height adjustment of the head section	0cm to 11cm

Table 6: 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	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.
2	A motor does not respond to the switch actuation	Check plug connection between the motor cable and control box. Check plug connection between the hand control and control box.
3	Height adjustment does not start (couch is slightly slanted). A signal tone can be heard when the switch is actuated.	To reset the couch, press the up and down keys of the hand control simultaneously (really simultaneously!!) and keep them pressed until the interrupted signal tone stops (approx. 10 sec.). Then press the up or down key of the hand control alternately until the height adjustment of the respective column can no longer be moved (for 2 seconds). Repeat this process until the couch has reached its highest height position.
4	Height adjustment starts and stops immediately	Reduce overload i.e. applied weight;

Table 7: 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 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

(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).
- Functionality of the brakes
- 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.

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

15 Disposal

15.1 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.



15.2 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).

15.3 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.

16 Declaration of Conformity

As the manufacturer, we declare under our sole responsibility that our endoscopy 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

