Exaflip

Behandlungsliegen

Instruction for use

Stand: 08/2022
(Rev. 2.0)

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1 Foreword

Dear customer!

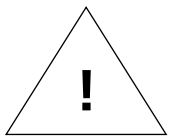
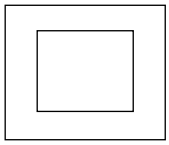
We would like to thank you for the trust you have placed in us and for purchasing our product. We have manufactured this medical product with great care.

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

	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.

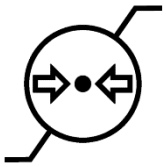
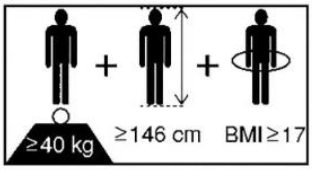
	Serial number - displays the manufacturer's serial number so that a specific medical device can be identified.
	Distributor - indicates the company that distributes the medical device at the location.
	Temperature Limit - indicates the temperature limits to which the medical device can be safely exposed.
	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.

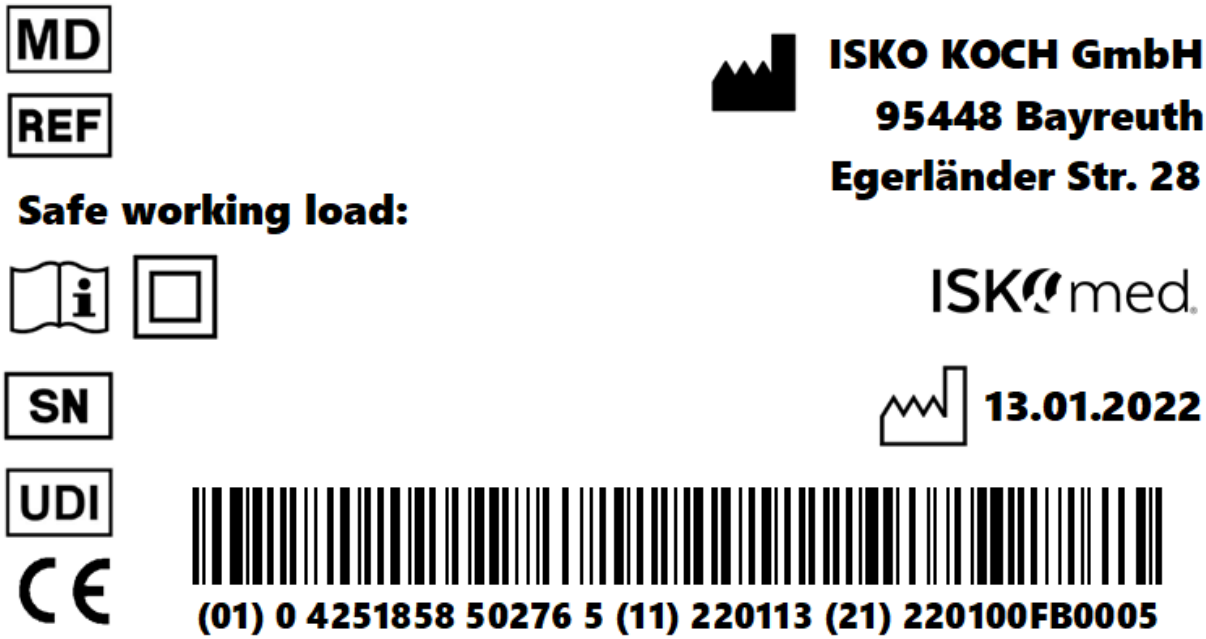


Figure 1: Exemplary type plate

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.
- A maximum safe working load of 135 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.
- 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 wall couch is a medical device which - similar to a treatment couch - can be used to support therapy by the nurse, doctor or therapist. The folding mechanism is supported by one or two gas springs.

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 safe lying on the couch surface (e.g. falling down)
- In case of severe anxiety

5 Assembly information

5.1 Basic information for assembly

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

Before connecting the device, please make sure that the voltage and frequency of your power supply correspond to the specifications on the type plate.

Make sure that the wall surface is level when mounting the examination couch.

There is a risk of entrapment when folding the couch surface up or down. Please ensure that children who are playing do not have access to the couch.

5.2 Positioning for assembly

5.2.1 WL-002

The top edge of the mounting rail is to be marked 1.5 cm above the ordered plate height.

Make a secure screw connection with the supporting wall. In doing so, use all available holding points (holes) for the mounting.

Check the stability of the selected wall beforehand. The screws and dowels are not included in the scope of delivery and depend on the wall structure. After installation, you must load the table once with twice the expected working load in order to determine any weak points in the retaining elements.

In the case of treatment couches with feet, these must be adjusted to the correct height after wall mounting. You can define the height positioning of the wall couch. We recommend a lying surface height in the range of 66 - 86 cm (measured from the floor to the upper edge of the lying surface). The support feet must always be adjusted to the installation height so that the wall couch has a firm support surface.

Figure 2 shows the mounting points with the wall via the red arrows. These may differ slightly depending on the model.

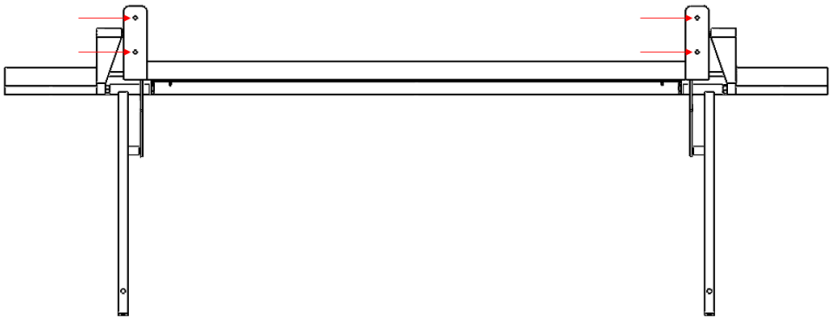


Figure 2: Wall mounting point of the wall couch WL-002-0

5.2.2 WL-012 wall couch with grid adjustment

The top edge of the mounting rail is to be marked 1.5 cm above the ordered pad plate height.

Make a secure screw connection with the supporting wall. In doing so, use all available holding points (holes) for the mounting.

Check the stability of the selected wall beforehand. The screws and dowels are not included in the scope of delivery and depend on the wall structure. After installation, you must load the table once with twice the expected working load in order to determine any weak points in the retaining elements.

In the case of treatment couches with feet and grid adjustment, these must be set to the correct height after wall mounting. You can define the height positioning of the wall couch. We recommend a lying surface height in the range of 66 cm floor height at the lowest grid position. You also have the option of adjusting the couch upwards in 5 cm increments using four additional locking points. This results in an adjustment range of 66-86 cm (measured from the floor to the upper edge of the lying surface). A decisive factor in the grid adjustment is the use of shims at the screw connection points with the wall (see Figure 3). This ensures sufficient distance, which enables optimal operation of the grid adjustment.

Figure 3: Shims as support for wall mounting

5.2.3 WL-003

The lifting mechanism must rest on the floor with the lower frame. A large part of the load is thus transferred to the floor via the frame. The fastening points on the wall must together take on approx. 2500 N tensile force (approx. 250 kg), which is no problem if the wall conditions are solid and standard screws of the appropriate thickness are used. Please avoid screwing too tightly (overstretching the screw). And use screws that are adapted in diameter to the holes. In case of lightweight walls, we recommend through-threaded rods with correspondingly large counter plates or the use of a couch type with swiveling front feet - then without electric height adjustment.

We recommend that after assembly, for test purposes, you load the complete unit with approximately double the user load (> 200 kg).

Figure 4 shows the mounting points with the wall via the red arrows. These may differ slightly depending on the model.

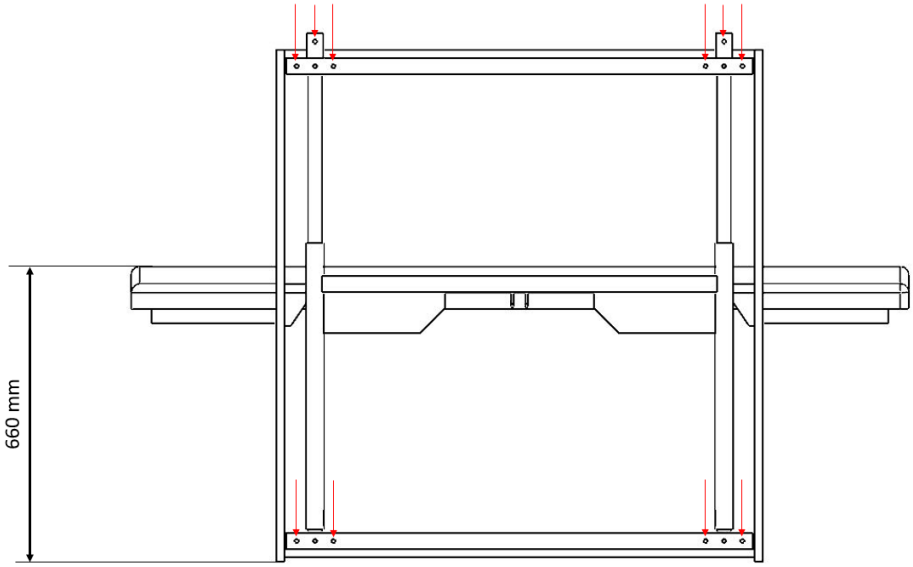


Figure 4: Wall mounting point of the wall couch WL-003-0

6 Operation

6.1 Operating the functions

(for wall couch WL-003-0)

The electric height adjustment can be locked via the hand switch. In addition, the hand switch has a magnet, which allows ideal stowage on the wall couch.

The couch has an electric adjustment range of 66 - 106 cm.

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

6.2 Tilting process

Only initiate the tilting process of the cushion plate when the wall couch is unloaded.

To fold down the wall couch, the ring catch on the stainless steel tube must be pulled outward. The folding down function of the wall couch is unlocked by pulling and holding the locking ring. The lying surface can only be folded down with the safety pin pulled out. (see Figure 5)

Figure 6 and Figure 7 show examples of a WL-003-0 wall couch in the folded-up and folded-down state.

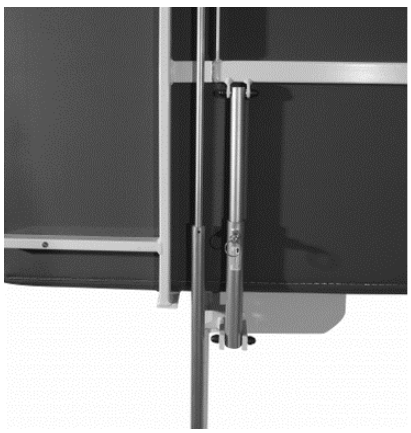


Figure 5: Stainless steel gas spring protection tube with pull ring catcher

Figure 6: Wall couch folded upwards

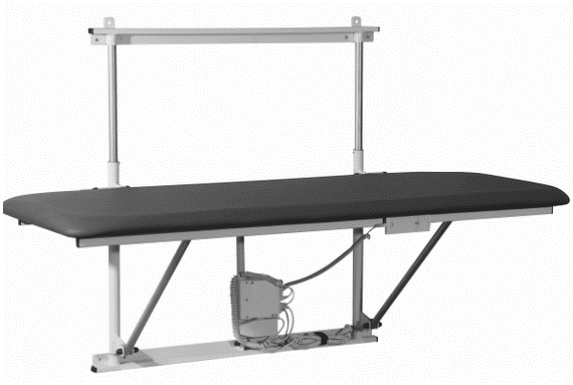


Figure 7: Wall couch folded downwards

6.3 Side rails

(optional)

The side rail can be folded upwards in any height position. To do this, the side rail is folded vertically in the direction of the arrow until it locks into place. (cf. Figure 8)

Figure 8: Operation of the side rails

The side rail can then be pulled up vertically until it snaps into place again.

To fold back the side rail, both pull catches (pos. 1) must first be unlocked by pulling so that the side rail can be pushed down.

The entire side rail can then be folded back diagonally by pulling the release cord (Pos. 2). (cf. Figure 9)

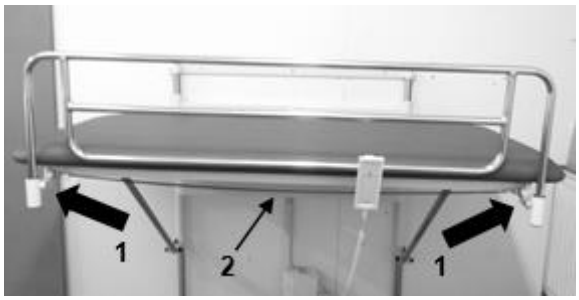


Figure 9: Side rail in latched end position

6.4 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

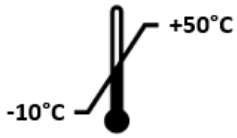
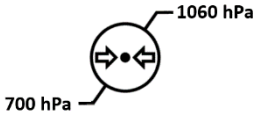
Temperature range	min. -10 °C max. +50 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 3: Storage conditions

7.2 Operating conditions

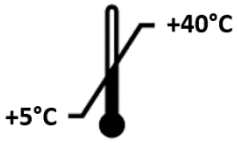
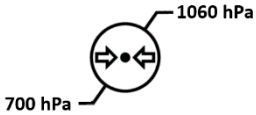
Temperature range	min. +5 °C max. +40 °C	
Relative humidity	min. 20 % max. 80 %	
Air pressure (at altitude ≤ 3000 m)	min. 700 hPa max. 1060 hPa	

Table 4: Operating conditions

8 Technical data

(Subject to change without notice!)

Description	WL-002-0	WL-012-0	WL-003-0
Rated voltage	-		230V~/ 50Hz
Rated power	-		70 VA
Device type B according to IEC 60601-1	-		
Protection class			
IP protection class			IPX4
Duty cycle ED 10%			maximum 6 minutes/hour
Maximum load/patient weight	135 kg		
Dimensions of the lying surface (standard)	75 cm x 180 cm		
Total mass of the treatment couch	45 kg	50 kg	ca. 65 Kg
Height adjustment cushion plate	0 cm	20 cm	40 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	A motor does not respond to switch actuation	Check plug connection between motor cable and control. Check cable connections for pinch points. Check power cable connection..
2	Height adjustment starts and stops immediately	Reduce overload i.e. applied weight;

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 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).
- 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 wall couches complies with the basic requirements of the EC Directive for

Medical devices 2017/745, Annex II

ISKO KOCH GmbH

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95448 Bayreuth

CE