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LOJER BOBATHLIEGE 2-TLG

ANLEITUNG

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LOJER® For easy care

Lojer Bobath X Mat Tables

Models 4020XB, 4010XB

Instructions for use

ID: DX011285, rev. 2 / 01.12.2023 (en)

CE

TEHTY SUOMESSA
MADE IN FINLAND

Contents

⚠ Read these instructions carefully. Follow all warnings and instructions marked on the product

Lojer Group is leading producers of medical furniture and physiotherapy equipment in Nordic Countries. We design and manufacture medical and treatment furniture to be used by health care professionals in various operating environments. Lojer has committed to develop and manufacture these devices in a sustainable manner in order to provide best possible care for the patient today and in the future.

1 Lojer Bobath X Mat Tables

Lojer Bobath X Mat Tables are mat treatment tables for wide range of physiotherapy and treatment. Wide frame makes tables sturdy and maximum Safe Working Load (SWL) is 400 kg. Lojer Bobath-series include models 4010XB and 4020XB.

This document gives instructions for operating and maintaining the device. Please familiarize yourself with these instructions before using the device. Use the device only as described and for the specified applications. Store these instructions in an appropriate way, making sure that the instructions are available to all possible users throughout the life of the device.

⚠	To avoid injury, follow the instructions given in this document
⚠	To ensure safe use and not invalidate your warranty, use the product only as described in these instructions.

1.1 Intended purpose

Lojer Bobath X Mat Tables are active, non-invasive Class I medical devices (EU Medical Device Regulation 2017/745, rule 13) for transient and short term use and intended to be used for neurological therapy and wide range of physiotherapy with continuous supervision given to the patient on the lying surface of the table. Wide lying surface allows therapist to be on the table at the same time as the patient who is being treated. Tables' adjustable mechanics are used to manipulate and position the table to allow patient support, closer treatment of a portion or the entire patient, and the ability to move the patient on and off the table safely.

Tables are intended to be used by Intended User in healthcare centers, physiotherapy clinics, massage clinics and other medical facilities in indoor conditions. Tables are not intended to be used in home environment.

1.2 User groups

The Owner or Holder is any natural or legal person who have ownership of the product. The owner is responsible for the safe use of the product and is responsible for ensuring that the product is always used safely including maintenance, cleaning and disposal. It is the responsibility of the holder to ensure that all users, including temporary staff, have received appropriate training in the use of the equipment and are familiar with the risks involved in using the equipment and the dangers of improper use.

The Intended User is a person who, by virtue of his education, experience or familiarization, is capable of operating the device, must be able to anticipate and identify risks associated with the use of the device and be able to assess the patient's clinical status, suitability to use the device and treatment risks. It is the user's responsibility to ensure that the treatment meets the requirements of all applicable local laws and regulations.

A Patient is a person who needs the device for treatment; is weak, ill, injured or needs the device otherwise to compensate functional limitations, e.g. handicapped persons.

Obligation for incident reporting: User and/or patient should report any serious incident that has occurred in relation to this device to the manufacturer (Lojer Oy) and the competent authority of the Member State in which the user and/or patient is established.

1.3 Intended clinical benefits

Indication for physiotherapy, neurological therapy or treatment is typically a need of some kind of rehabilitation. Lojer Bobath X Mat Tables provides a support for a patient when therapy is given by healthcare professional. Bobath tables are especially suitable for neurological therapy and Bobath therapy where patient's movement is required. Wide lying surface allows treatment, which is usually given on a mat, done in suitable height and position for both patient and Intended User.

1.4 Contra-indications

The device has no contra-indications

1.5 Description of parts

The sections of Lojer Bobath X Mat Tables are shown below (Figure 1).

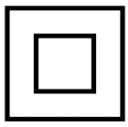
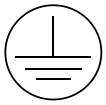
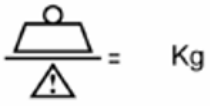
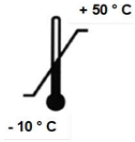
Figure 1: Lojer Bobath 4020XB and 4010XB

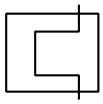
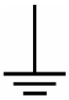
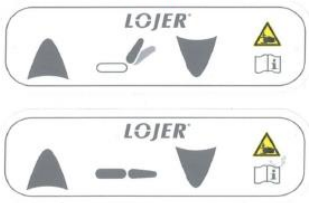
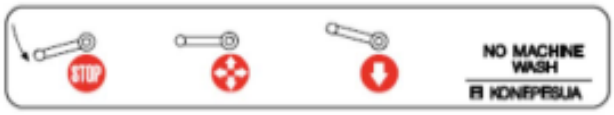
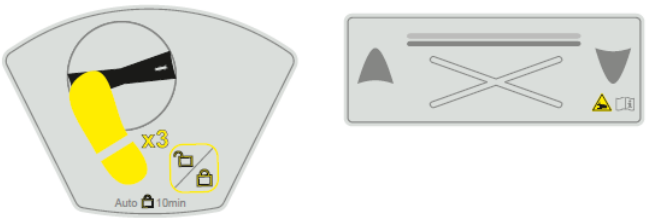
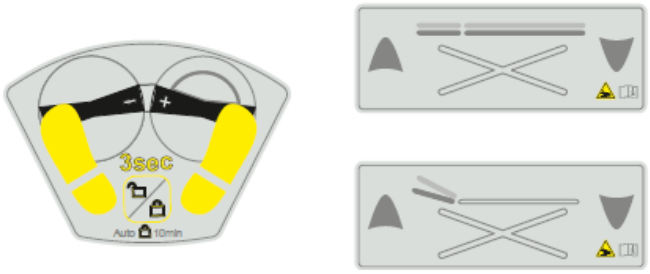
1 Leg section (4020XB)
2 Back section (4020XB)
3 Castors
4 Central locking pedal
5 Side rail (accessory)
6 Accessory rail (accessory)
7 One section lying surface (4010XB)

1.6 Symbols used on the device

Symbols used in markings of the device can be found on table below.

⚠ All the symbols on the table below are not applicable for this device, check device markings for applicable symbols!

 Warning	 Read the instructions	 Danger of squeezing
 CE-marking	 Caution / Important	 Double insulated (Class II electric appliance)
 Protective ground (Class I electric appliance)	 Ingress protection range	 This product is a medical device
 Manufacturer	 Manufacturing date	 Model number
 Serial number	 Indoor use only	 Weight of the device
 Type B Applied Part	 Safe working load (SWL)	 This side up (packaging label)
 Product marked with this symbol shall not be processed as household waste. See Recycling -Chapter.	 Fragile, handle with care (packaging label)	 Temperature limits for transportation (packaging label)

 Store in a dry place (packaging label)	 Potential equalization	 Transformer is equipped with overheating protection
 Functional ground	 Protectively isolated structure	 Battery operation
 Hand free adjustment bar for back section and height	 Central locking	
 Trendelenburg-adjustment	 Individually lockable casters	
 Foot control 4010XB		
 Foot control 4020XB		

1.7 Options and accessories

Factory installed options:

Trendelenburg

Battery

Foot control

Upholstery with face hole

Accessories:

Side rails (1-2 pcs.)

Examination light

Push handles

Accessory rail 380 mm x 10 mm x 25 mm (max. 6 pc.)

Lift support

2 Introduction

2.1 Inspection upon delivery

Before the device is taken into use, check that the packaging is intact and that it has not been damaged during transportation. Please notify the transport company and the supplier of any transit damage within two (2) days of receiving the delivery.

Ensure that the delivery contains all the parts detailed in the delivery note. If there is anything missing from the delivery consignment, please contact the supplier immediately.

⚠ The device can be stored at a temperature of -10...+50 °C (-10...+40 °C with battery option). The permitted humidity is 20...90 %.

2.2 Before use

The device is intended to be used in normal, dry indoor conditions. Ensure that the temperature of the room is between +10…+40 °C (+10…+30 °C with battery option) and the humidity is within the range of 30…75 %. If there is chance that device has been exposed to temperatures below 0°C, allow it to adjust to the indoor temperature for at least 5 hours before using any of its features.

Familiarize yourself with the instructions and carry out the following before using the device:

- Make sure that all packing materials have been removed
- Make sure that the device can freely move up and down
- Place the device in the location where it will be used.
- Clean the product as instructed before use
- Connect the power plug to a socket whose supply voltage corresponds to the voltage shown on the device's type plate. Make sure that the cord runs freely outwards from the connection box.

⚠ Pay attention when lifting the table. Do not lift the table alone. The table weighs 120 kg.

Lifting points points of the table (Picture 1.1):

Picture 1.1 Lifting points

2.3 Safety instructions

For safety reasons always connect the power cord to grounded socket which should be located near the head end of the examination table.

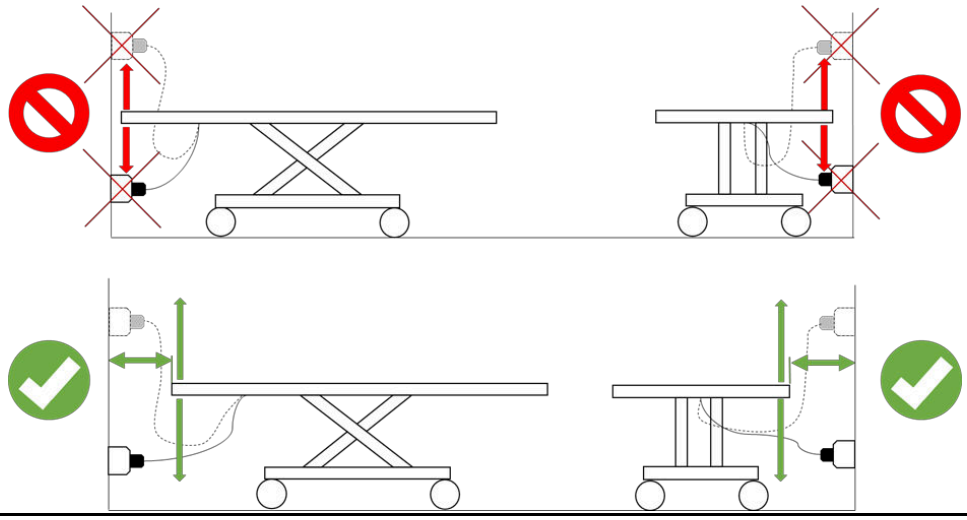
Do not bind the power cord to the device as the lifting motion can damage the cord. Ensure that the cord is easily detachable in emergency situation.

Make sure that the distance to the socket is not more than 2 meters.

Always detach the power cord before moving the device. Make sure that the cord doesn't get stuck between parts of the frame or under the castors.

If the power cord is damaged, unplug it immediately. Do not use the device and contact the service. Use only the original power cord.

Make sure that there is enough space between the socket and the device and that raising the device will not damage the plug or cord plugged into the socket.



Make sure that the patient doesn't accidentally move/touch any control device.

Make sure that the patient's limbs do not get caught in the frame of the device.

Do not place the device under any wall structures or too close to the wall.

Do not place anything under the device.

Only patient should be on the lying surface when the table is adjusted.

Make sure that there is enough space around, above and below the device for the movements. Notice that the accessories increase the need for space.

Make sure that the space around the device is safe. There should be no sharp edges or other possibly harmful objects around the table.

Do not modify the structure of the device or install parts other than those mentioned in this document.

⚠	Do not use the device or the accessory if it doesn't work properly. Contact the service.
⚠	Do not push the device on to a door sill.
⚠	Use the device according to the intended use defined by the manufacturer.
⚠	Always lock the castors before using the device.
⚠	Do not attach anything on the accessory or controls other than the intended parts.
⚠	Do not use any accessory as a lift support.
	Protective paper or patient slippery clothing may cause the tray to slide
	**WARNING!** Children, patients or people with no experience of the device or those with restricted understanding must not use the device. Children must be supervised to ensure that they do not play with the device! For safety reasons lock the device, turn the hand control away from the patient. Or unplug the power cord when the device is left unsupervised.
	**WARNING!** The safe working load (SWL) is the maximum load including the patient and possible accessories.

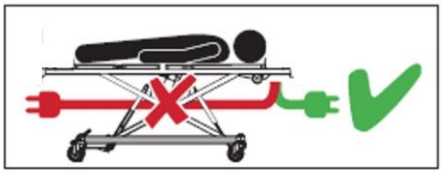
3 Using the device

1. **Note!** Do not use the electrical functions of the device non-stop for longer than the permissible two (2) minutes. Longer continuous use may cause the transformer to overheat. If you use electrical functions non-stop for two (2) minutes, keep to the operating time ratio and do not use any electrical functions for 18 minutes.

⚠ Make sure that the accessories do not hit anything when adjusting/moving the table.

⚠ Make sure the device is functional before use.

⚠ **WARNING!** Make sure that the cord doesn't get stuck between parts of the frame or under the castors.



Tables are electrically adjustable by hand control or foot control (option). The table is adjusted by pushing a button from the hand/foot control. When the adjustment bar is pushed, the table/back section lifts and when the bar is lifted, the table/back section lowers. Movement stops when the button/bar is released. In fault situation the movement can be stopped by holding down the button for opposite direction. With hands-free adjustment bar, the movement can be stopped by holding the bar on the opposite direction.

3.1 Adjustment range, hand control and foot control (option)

Adjustment range of the Bobath X Mat tables is shown below (Figure 2).

- Height adjustment 40-95 cm
- Back section adjustment 0-73° (model 4020XB)
- Trendelenburg/anti (option) max. 20°

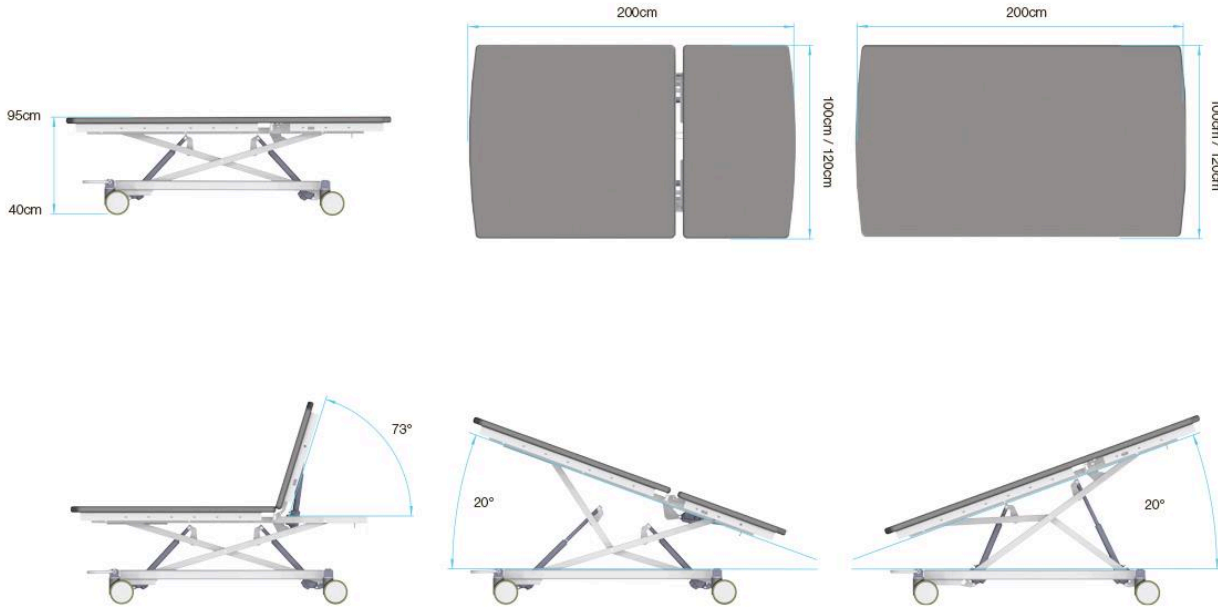


Figure 2: Adjustment range

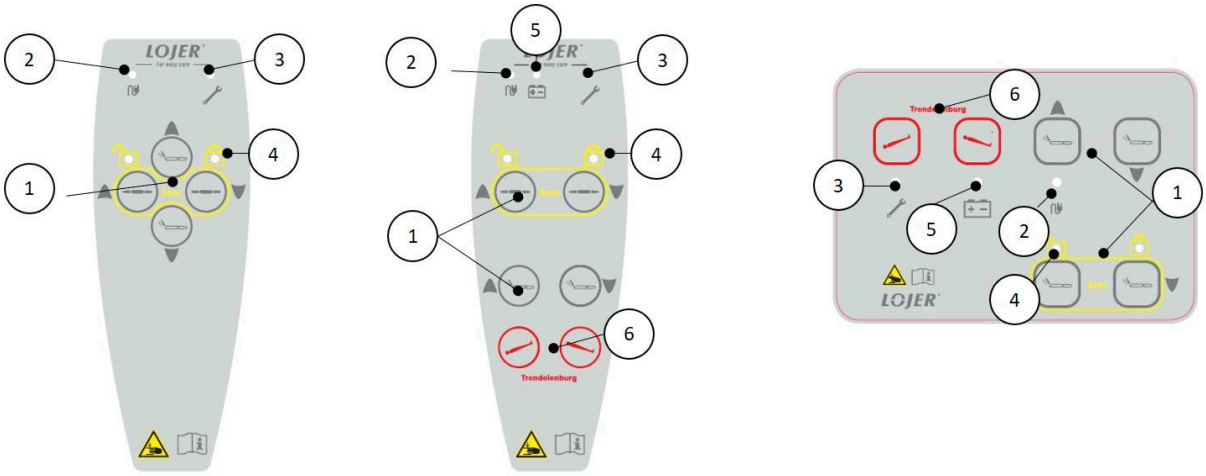


Figure 2.1: Hand controls and ICP control for 4020XB. (ICP control only with antimicrobial model)

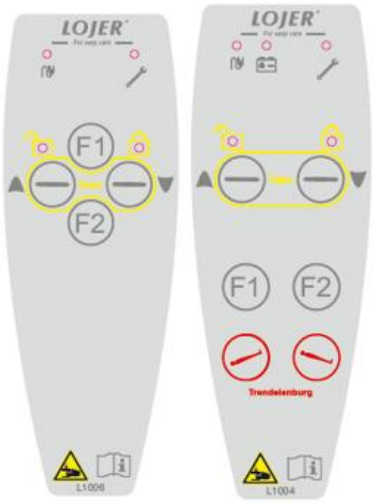


Figure 2.2: Hand controls for 4010XB

1 Height and back section adjustment (locking function marked with yellow)
2 Power cord connected (yellow led on)
3 Service needed (yellow led on)
4 Locking status indicator leds
5 Battery in use (yellow led on)
6 Trendelenburg adjustment

For 4010XB, F1 and F2 buttons are required for resetting the software.

Table can be locked by pressing height adjustment buttons simultaneously on hand control/ICP for 3 sec. (Figure 2.2). Table is opened with same buttons. Sound signal (2 beeps) is heard when the status is changed. Indicator led turns on. Table is unlocked as default.

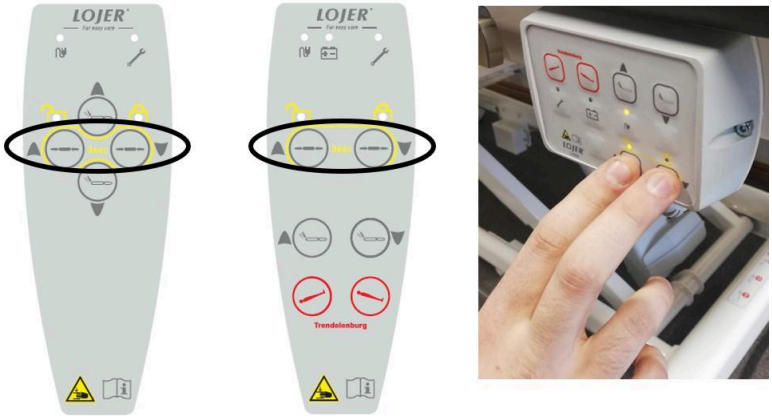


Figure 2.3: Locking buttons (marked with yellow) on hand controls and ICP (antimicrobial model)

Foot controls (option) are locked by default. They can be opened/locked by pressing +switch 3 times in1,5sec (Figure 2.4), or pressing 3sec outermost swithes (Figure 2.5). Sound signal (2 beeps) is heard when the status is changed. The hand control also locks/opens.

After 10 minutes, they will lock automatically. The hand control remains active. If you try to use foot control after automatic locking (not opened) hand control led (4) is blinking.

Figure 2.4: 4010XB

Figure 2.5: 4020XB

3.2 Castors

⚠	Make sure that the table is on the working position before starting any treatment.
⚠	Always remember to unplug the power cord before moving the device. Make sure that the cord is not left between the structure of the table or under the casters. Danger of electric shock.
⚠	Move the table only with the table top horizontally.
⚠	When transferring a patient both side rails must be used.
⚠	Anesthetized or confused patients should not be transfered on the examination table.
⚠	When moving the patient on an sloping surface, there should be 2 nurses.
⚠	Always lock the wheels after transport.
⚠	Do not park the device on sloping surface. Unlocking the wheels on sloping surface can cause danger.

Always lock all caster before using the device. Centrally lockable casters are available as a factory installed option. The locking pedal is on the leg end of the table. The casters are locked when the pedal is pressed. When the pedal is horizontally, casters are free. When the pedal is lifted, directional locking is on (Figure 3). Test the directional locking by moving the table sideways.

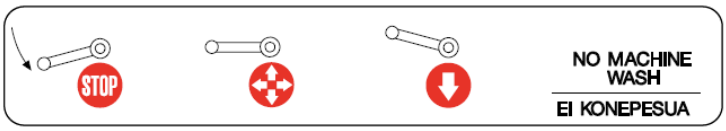


Figure 3: Pedal positions of the central locking pedal

⚠	SQUEEZING HAZARD! Make sure that nothing is or gets between the structure or under the device while using the castors or moving the table.

3.3 Height adjustment

The height of the table can be adjusted with hand/foot(option) control. Keep the hand-control in place reserved for it. (Figure 4).

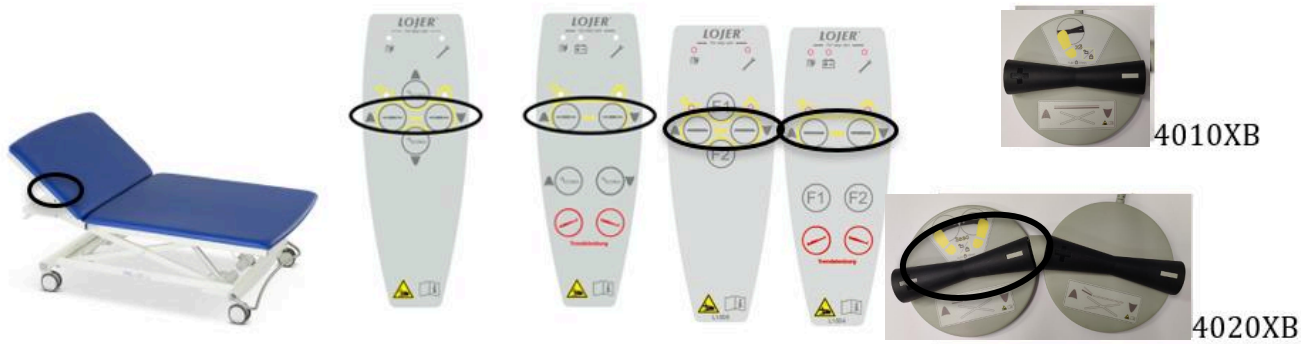


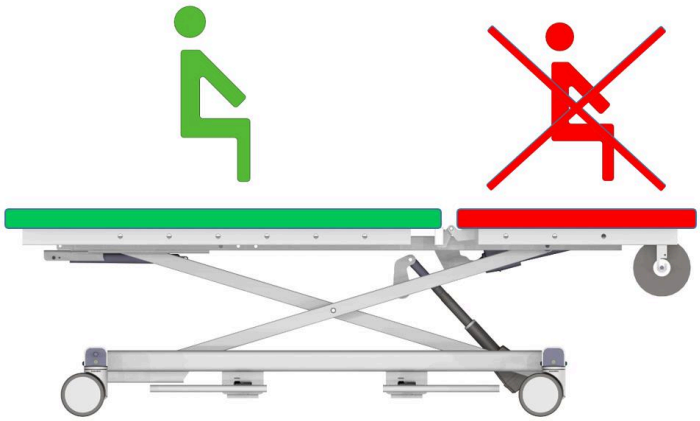
Figure 4: Height adjustment

	SQUEEZING HAZARD! Make sure that nothing is or gets between the structure or under the device during lifting/lowering.
	WARNING! Children or people with no experience of the device or those with restricted understanding must not use the device. For safety reasons use safety switch, unplug the power cord or move the hand control (battery model), when the device is left unsupervised.
	Ensure that there are no obstacles in the foot control range of movement. **Squeezing hazard caused by accidental movement of the device!**

	Examination tables have a safety feature which automatically lifts (5 cm) the table if something is between the structure (squeezing recognition).

3.4 Back section

Do not sit on the back section.



Back section can be adjusted electrically with hand/foot(option) control or with optional handsfree adjustment bar. Adjustment range is 0…73° (Figure 6).

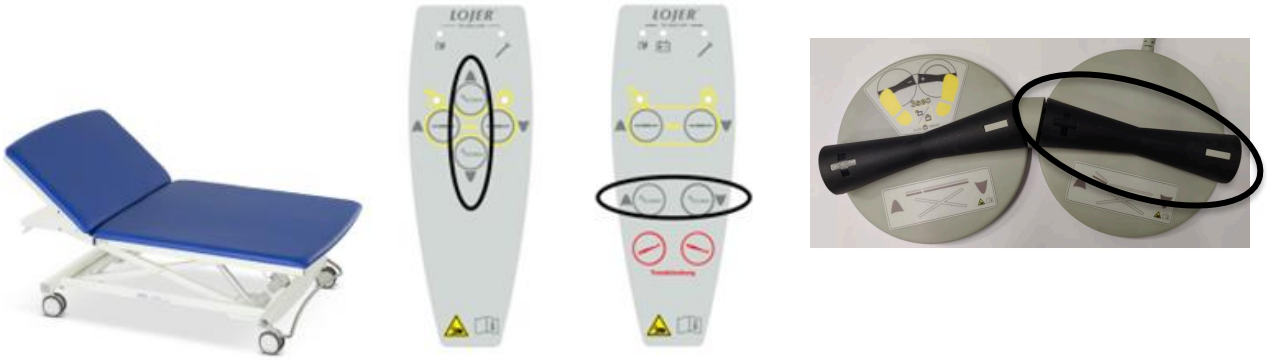


Figure 6: Back section adjustment

SQUEEZING HAZARD! Make sure that nothing is or gets between the structure or under the device during lifting/lowering

Ensure that there are no obstacles in the foot control range of movement. **Squeezing hazard caused by accidental movement of the device!**

3.5 Trendelenburg (option)

Trendelenburg angle is adjusted electrically with hand control (Figure 8). The table stops automatically at 12°. If necessary the angle can be increased up to 20° by pressing the button again. Angle adjustment starts again after 5 sec.

Battery is always included with Trendelenburg option.

⚠	Act with caution when using Trendelenburg function.

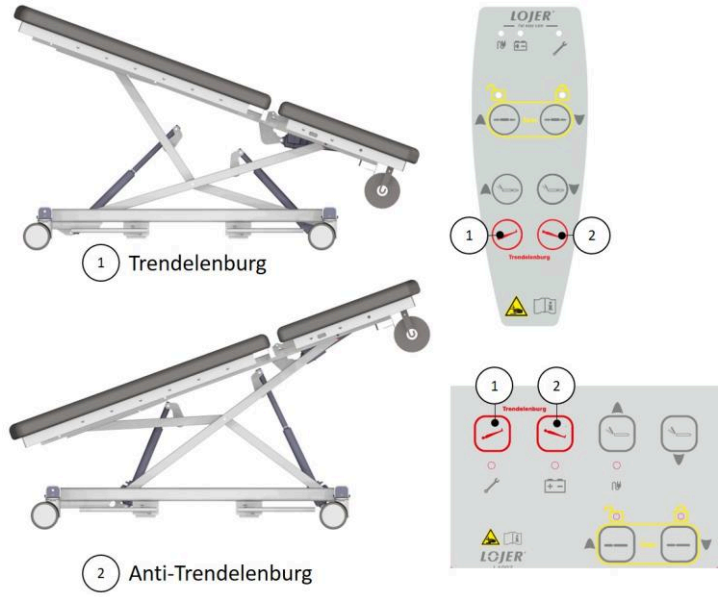


Figure 8: Trendelenburg/Anti-Trendelenburg

3.6 Battery (option)

Table can be equipped with battery (battery is always included with Trendelenburg option). Battery is only to be used temporarily e.g. during power loss. Battery indicator led (Figure 2.1 (5)) is on when the device is on battery use. When charging, indicator leds flash slow (Figure 2.1 (2&5). The device should be connected to mains, when the battery indicator led flashes and sound signal is heard during adjustments.

⚠	Notice that the device with battery the electrical functions of the table work even when the power cord is unplugged. Use the locking function of the table to ensure safety.
⚠	Always lock the table during transportation if table is equipped with battery.

3.7 Side rails (accessory)

Side rail(s) are available as an accessory. Release locking of the rail by pulling the knob (Figure 12 (1)) and turn the rail down/up. The rail can be removed by opening the screws (2 psc) (Figure 12 (2)).

Figure 12: Side rail

3.8 Pushing handles (accessory)

Pushing handles can be installed foot end of the table (Figure 14). Install the handle in place and tighten the screw.

Figure 14: Pushing handles

3.9 Lift support (accessory)

⚠	Risk of squeezing! Danger of squeezing when the lift support is in place and the back section is adjusted.
⚠	Never turn the handle of the lift support inwards to the device.
⚠	When setting the lift support in place, make sure that the lift support is locked and does not get to rotate.

⚠	Check the frame fastening and the functionality of the lift support regularly.
⚠	Do not attach anything to the lift support.

The lift support can be installed to the side of the table with two screws. With 4010XB the lift support can be installed to all available points. With 4020XB the lift support can be installed to the leg section of the table (Figure 15). The lift support locks in three different positions: handle facing away from the table, handle facing the foot end or handle facing the head end.

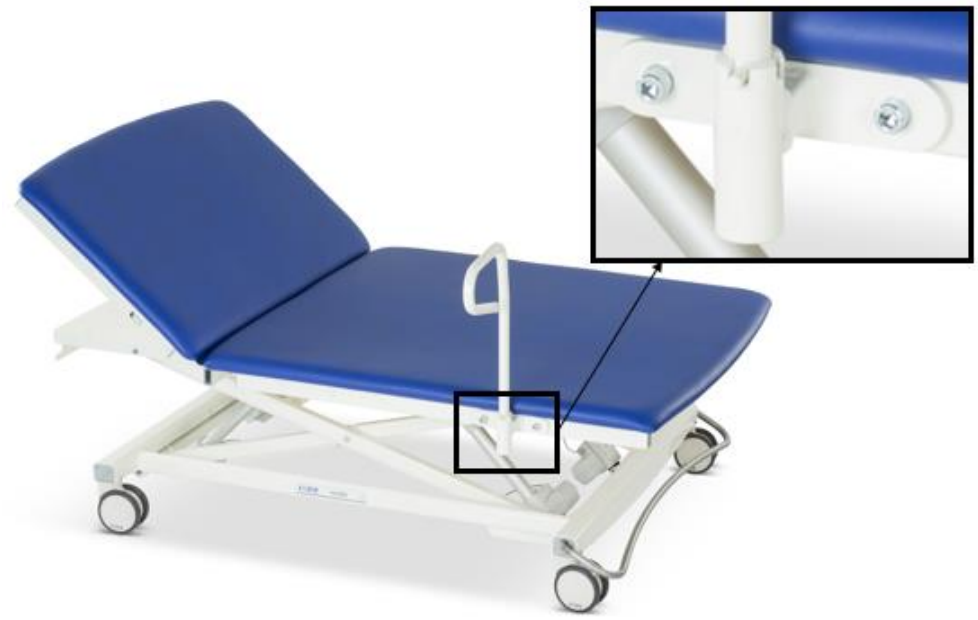


Figure 15: Lift support

4 Cleaning and disinfecting

Before cleaning remove all accessories and unplug the power cord. Clean stains as soon as possible.

In order to keep the surfaces in good condition do the cleaning regularly. Do cleaning/disinfectant always between patients. Do more thorough cleaning once a month. Follow the cleaning/disinfecting instructions given by the respective facility.

Metal – and plastic surfaces Clean the metal and plastic surfaces and the hand controls with a damp cloth and weak alkaline cleaning fluid. Use small brush for corners and other difficult spots. Rinse with clean water and dry carefully after cleaning. Do not use excessive fluids. Use disinfectant (alcohol or chlorine) and follow the disinfectant manufacturer's instructions for use. Let dry by evaporation in room temperature.

Plastic surfaces (ABS, HDPE, PP) are highly resistant to chemicals. Plastic is resistant to bleaching agents (alkaline compounds), dilute organic or inorganic acids. Also solvents and cleaning agents may be used.

Plastic surfaces may get damaged if aromatic hydrocarbons (benzene and its derivates), ketones, ethers, esters and chlorinated hydrogarbons are used. Plastic might also deteriorate if it is exposed to various chemicals at the same time.

Stainless steel surfaces are highly resistant to chemicals. Use for mild detergent solution for cleaning. Ammonia and most of the solvents can be used to remove difficult stains. Avoid chlorine-based solutions.

Painted or chromed metal surfaces can be cleaned with mild detergent. They are also highly resistant to chemicals. Do not use harsh abrasive powders on these surfaces.

⚠	All surfaces must be dry before connecting to mains and using the device.
⚠	For safety reasons before cleaning unplug the power cord.
⚠	Do not use water spray (shower, high-pressure water guns) for cleaning.
⚠	Do not clean in high temperature and air humidity. Do not expose the device to excessive moisture which can result in liquid pooling.
⚠	Do not use solvents or petrol for cleaning. Do not use acids for cleaning.
⚠	Disinfecting wears out the surfaces. After disinfecting clean the surfaces with clean, damp cloth. Dilute the disinfectant according to the manufacturer's instructions.
⚠	Please follow the instructions of the respective manufacturer when using common cleaners.
⚠	Do not use oil or grease-based solutions.
⚠	Do not use chemical or dry cleaning on the material.
⚠	The material is not resistant to solvents, chlorides, washing/polishing agents or aerosol sprays.
⚠	Colorings (by jeans or other textiles) are excluded from any guarantee.

For hygienic reasons cover the upholstery with protective cloth or paper. Remove any stains as quickly as possible with lukewarm water and a damp cloth. Microfiber cloth is recommended for this purpose. In case of heavy soiling, use a mild cleaning agent and soft brush. Recommendable cleaning agent: Lojer Desiplint (1:10), which is effective against bacteria without drying the upholstery material. Repeat the cleaning procedure if necessary. (Composition of Lojer Desiplint: Chlorhexidine digluconate 0,1 – 0,2 %, water 99,8 %.)

5 Maintenance

⚠	Always unplug the power cord before service. Make sure that the functions are switched off.
⚠	Read the instructions carefully.
⚠	Only trained and manufacturer authorized person may carry out service and repair. Maintenance carried out by an unauthorized person may cause injury or damage to the device which the manufacturer is not responsible for.
⚠	Use only original spare parts approved by the manufacturer.
⚠	Make sure that the device is operating correctly after all maintenance measures.
⚠	Do not use the device or the accessory if it doesn't work properly. If the device has batteries, unplug the power cord and use the safety switch. Contact the service.
⚠	All service and repair operations must be documented.
⚠	Check the condition of the power cord before using the device.

5.1 Biannual measures

The professional user is responsible for executing biannual measures.

Check the condition and functioning of following parts at least every six months.

- Power cord and its fastening.
- The wiring of the motors.
- Controls and their wiring.
- The fastening of the accessories.
- The fastening of the castors. Proper functioning of the locking.
- Go through all adjustment and make sure that the table is working correctly.

Stop using the device if you notice any defects e.g. the device is making noise or functioning in sufficiently. Contact the service. Only authorized personnel can open or change the actuator/control unit.

⚠	If some part of the device is damaged, detach the power cord and stop using the device. Contact the service.
⚠	Make sure that the all parts are properly placed after any maintenance measures. Check all functions.

5.2 Annual measures

Check and lubricate the following parts once a year or more often if necessary. Use e.g. Wurth HHS 2000

- Joints
- Bearings
- Fastening points of the actuators

5.3 Troubleshooting

If the table doesn’t work properly, first unplug the power cord.

Indication	Defect	Action
Table stays locked.	Software error. Defective control. Defective control box.	Unplug the power cord, wait for the indicator LEDs to turn off (~10 sec.) and plug the cable back. Table should be unlocked. Contact the service.
Battery operation: Battery indicator LED flashes	Battery charge decreased.	Observe the operation of the table and prepare to charge the battery.
Battery operation: Battery indicator LED flashes and sound signal is heard when the table is adjusted.	Battery charge critically low	Immediately connect the power cord to mains socket.
Table doesn’t move, locking indicator LEDs flash and sound signal is heard when buttons are pressed.	Table has lost the sensor information.	Position Lost, table needs to be initialized: Drive the table up. The initialization is complete if no sound signal is heard and the LEDs are not flashing.
Table doesn’t move, LEDs on the top of hand control are flashing	Fatal error	Fatal error reset is needed by pushing Back up and Back down buttons (F1 and F2 4010XB) simultaneously 5 seconds. After fatal error reset, initialize the table.
One of the actuators doesn’t work	The wiring is damaged or loose	Check the fastening and the condition of the wirings.
	Defective control or hands-free adjustment bar.	Check the control operation by testing with similar working control. Change the control if necessary. Contact the service.
	Defective actuator.	Contact the service.
	Defective control box.	Contact the service.
Any of the actuators don’t work.	Defective control or hands-free adjustment bar.	Check the control operation by testing with similar working control. Change the control if necessary.
	No power.	Check that the power cord is properly plugged.
	Defective power cord.	Check the cord and contact service.
	Table is locked.	Unlock the table by pressing both height adjustment button simultaneously for 3 seconds. Foot control is locked by default and auto locks in 10 min.

Device is making noise.	The lubrication of the joints has worn out.	Lubricate the joints and actuator fastening points.
	The actuator is worn out or overloaded.	The actuator might stop working. Contact the service.

In order to change the actuators, controls or control box and ordering other spare parts contact the Lojer Service. Before contacting make a description of the problem and find out the following information from the type plate of the device:

- Name, model and the serial number of the device
- Date of purchase

5.4 Preventive maintenance

The electrical characteristics and normal operation of the device should be performed according to the EN 62353 standard. In order to maintain the performance of the device, tests should be executed at least every 3 years. Electrical equipment should be inspected by an approved service technician or some other party approved for servicing medical devices.

EN 62353 applies to testing of medical electrical equipment during maintenance, inspection and servicing to assess the safety of the devices. Tests should be performed by qualified personnel. Qualification should include training, knowledge and experience with the relevant test procedures, technologies and regulations. The personnel assessing the safety should be able to recognize possible consequences and risks related to non-conforming devices.

⚠	Tests performed by non-qualified personnel might cause injury or damage to the device which the manufacturer is not responsible for.

PROTECTIVE EARTH RESISTANCE	Test is performed only for Class I equipment. All accessible conductive parts should be included into test. Measurement current should be 200 mA. The total resistance should not exceed 0,3 Ω. Detachable power cords kept ready for use should be measures as well. Their resistance should not exceed 0,1 Ω. Before testing check the earth conductors and change them if necessary. Test is performed between the protective earth connector of the mains plug and protectively earthed accessible conductive part. The measured resistance should not exceed 0,2 Ω. Test both the potential equalization point and the frame. If the device is disassembled or the protective earth conductors have been changed, protective earth resistance should be measured from various points.
LEAKAGE CURRENTS	The measuring device should be appropriate for testing leakage currents. Detach the power cord of the medical device and connect it to the measuring device. Attach the protective earth measurement lead to the point under test (change points if necessary). Attach the applied parts to the measuring device. (Note! In Class I equipment a leakage current measurement can be performed only after the protective earth testing has been passed.) Use the correct measurement method and procedures related to that. Currents to be measured:

	Equipment leakage current (current from the mains part to earth through protective conductor and accessible parts and applied parts): Class I, type B applied part 500µA. Applied part leakage current (current from the mains part and the accessible parts to applied parts of the device): Class I, type B applied part 5000µA.
EVALUATION: The evaluation of safety of the tested equipment should be performed by electrically skilled person, who has the appropriate training for the equipment under test.	
FUNCTIONAL TEST	Perform the procedures mentioned in Section 5.1 Go through all functions in order to make sure that the device is working correctly. Stop using the device if you notice any defects e.g. the device is making noise or functioning in sufficiently. Contact the service.
REPORTING OF RESULTS	All test performed should be documented. The documentation should include at minimum the identification of the testing organization, name of the person who performed the tests, identification of the equipment, details of the tests, date and the result of the functional tests and measurements.

6 Technical information

Check the information also from the type plate (Figure 15).

Operating voltage	100V-240V~50-60 Hz
Input power	450 VA
Duty cycle	2 min ON/18 min OFF
Ingress protection range	IPX6
Electric classification	Class I (functional earth) A-type applied part
Safe working load	400 kg
Width	100/120 cm
Length	200 cm
Weight	145 kg
Transportation/Storage temp	-10…+50 °C, humidity 20…90%
	-10…+40 °C, humidity 20…90% (with battery option)
Operating temperature	+10…+40 °C, humidity 30…75%
	+10…+30 °C, humidity 30…75% (with battery option)

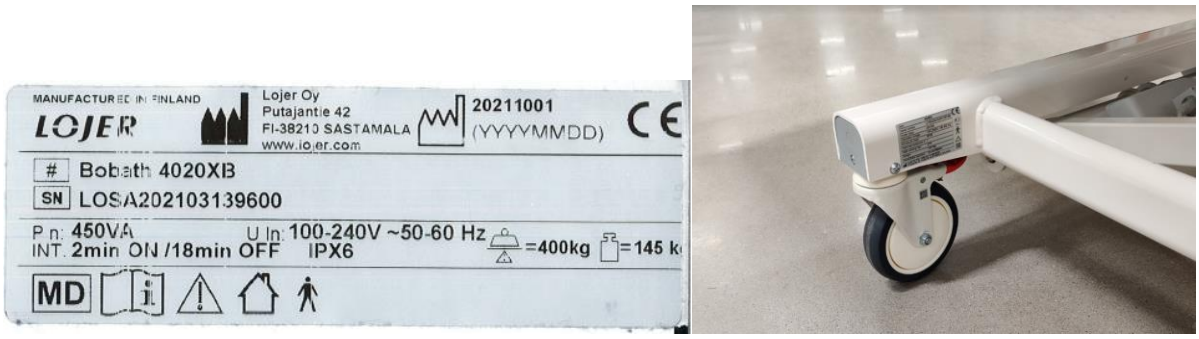
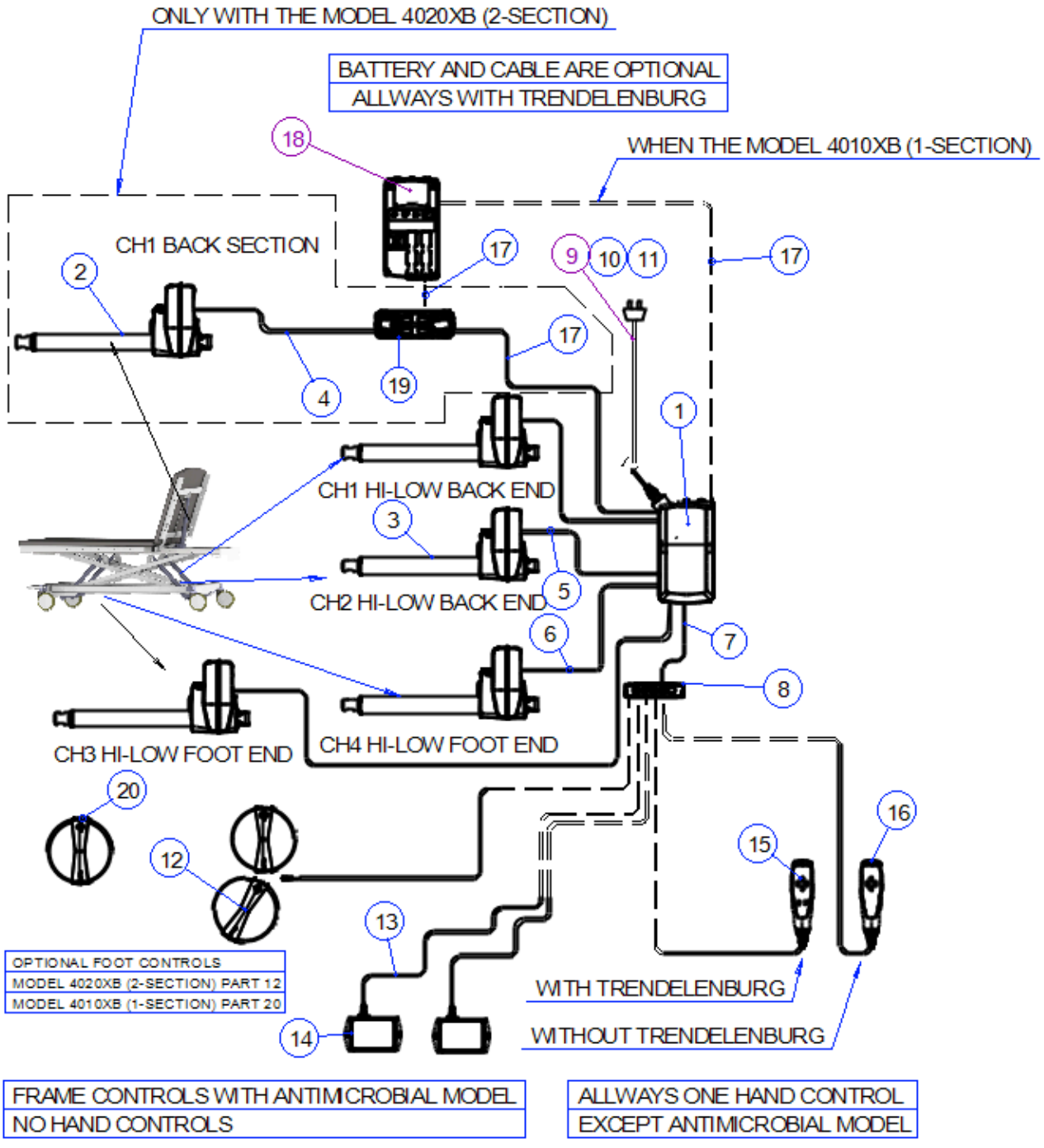


Figure 16: Type plate and its location

6.1 Circuit diagram



	Code	Description	Kpl
1	R284CO7	Control Box CO71	1
2	R284LA40XL1	Back section actuator	1
3	R284LA40XL2	Lifting actuator	4
4	R284LA40-CA30X	Actuator cable	1
5	R28400914948	Actuator cable 2500mm	3
6	R28400914681	Actuator cable 1575mm	1
7	R284AKL1	Adapter cable	1
8	R284MJB006	Adapteri MJB006 turvanosto	1
9	R284SLM912261	Power cord (EU plug)	1
10	R284CAB90027	Power cord (UK plug)	1
11	R284CAB90033	Power cord (US plug)	1
12	R284FS32	Foot control 4020XB 2-section	1
13	R284ACOMM	Cable with spiral	2
14	R284ACCA	Ohjain ACC 4040XL	2
15	R284HB34	Hand control with trendelenburg	1
16	R284HB34VF	Hand control without trendelenburg	1
17	R2841019W	Battery cable	1
18	R284BA19	Battery Lead Acid	1
19	R284PJ2	Junction box PJ2	1
20	R284FS31	Foot control 4010XB 1-section	1

Other spare parts:

H3663A1503FN	centrally lockable castor Ø150mm directional wheel
H3663A1502FT	centrally lockable castor Ø150mm

6.2 Electromagnetic compatibility (EMC)

Medical electronic devices should be installed and used in accordance with the electromagnetic compatibility (EMC) information in this guidance.

Other devices may interference even a slightly standard guidelines exceeding electromagnetic radiation values. To check, if this bed is causing interference, stop use of this device by disconnecting it from mains and check if it will make difference in other equipment. If malfunction in other device ends, this device may cause noticed problems. This rare and unusual behavior can be reduced or eliminated by following methods:

- Change position, distance or relocate compared to another equipment.
- Ensure that used devices are suitable for existing enviroment.

⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Bobath X Mat Table, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

6.2.1 Electromagnetic emission

Medical device (Lojer Bobath X Mat Table) is intended for use in the electromagnetic environment specified below. The customer or the user of the medical device should assure that it is used in such an environment.

Portable devices which are using radiofrequency can affect use of this equipment

Guidance and manufacturer's declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1, Class A	Medical device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	Device is directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

6.2.2 Electromagnetic immunity

This product is intended for use in electromagnetic environments that are specified below. The user should ensure that the product is used in an appropriate environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic enviroment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, 15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines; 100 kHz frequency ±1 kV for input/output lines; 100 kHz frequency	±2 kV for power supply lines; 100 kHz frequency ±1 kV for input/output lines; 100 kHz frequency	Mains power quality should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV (line to line) ±2 kV (line to earth)	±1 kV (line to line) ±2 kV (line to earth)	Mains power quality should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 0% U(T) for 0,5 cycle at 45° phase angles 0% U(T) for 1 cycle at 0° 70% U(T) for 25/30 cycles at 0° < 5% U(T) for	< 0% U(T) for 0,5 cycle at 45° phase angles 0% U(T) for 1 cycle at 0° 70% U(T) for 25/30 cycles at 0° < 5% U(T) for	Mains power quality should be at levels characteristic of a typical location in a typical commercial or hospital environment. If uninterrupted use during power failure is required, the device should be equipped with battery. U(T) is the (AC) mains voltage before the testing level is applied.

	250/300 cycles at 0°	250/300 cycles at 0°	
Magnetic field at supply frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at mains frequency should corresponds to the typical values present in commercial and hospital environment.
Conducted radio frequency IEC 61000-4-6 Radiated radio frequency IEC 61000-4-3	3V 150 kHz - 80 Mhz 6V ISM frequency range 3 V/m 80 Mhz - 2,7 Ghz 385 Mhz – 5785 Mhz test definitions related to immunity to wireless communication devices using radio frequency (reference: Table 9, IEC 60601-1-2:2014	3V 150 kHz - 80 Mhz 6V ISM frequency range 3 V/m 80 Mhz - 2,7 Ghz 385 Mhz – 5785 Mhz test definitions related to immunity to wireless communication devices using radio frequency (reference: Table 9, IEC 60601-1-2:2014)	Portable and mobile RF communications equipment should not be used closer to any part of the medical device, including cables, than the recommended distances calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2700 MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic survey a, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances between portable and mobile communication equipment and the medical device

The medical device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the medical device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the medical device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.7GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitter rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1. At 80MHz and 800MHz the higher frequency range applies.

Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⚠ The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

6.3 Standards

The device is in conformity with requirements of the EU Medical Device Regulation 2017/745. The device is marked with CE marking. The device is classified as Class I medical device.

7 Recycling

Most of the materials used in the device are recyclable. When the device is no longer usable, it should be disassembled and recycled properly. Recycling should be done by a specialist company, and parts of the equipment should not be disposed of with unsorted landfill waste.

Pre-treatment and storage

If the device has a battery, it should be removed after use (Note: Also remove the hand controller batteries).

Oils must be removed from the hydraulic system and dispose these oils in an appropriate waste processing plant.

The gas spring must be depressurized and the oils removed before being collected to metal waste.

Disassembly of the product into components

Disassemble the product into components, and sort different materials before recycling:

METAL WASTE: frame, screws, nails, hinges, springs, etc.

ENERGY WASTE (combustible waste): solid wood and other wood-based materials, particle board, etc., which are not forbidden to burn (PVC must not be disposed of by burning, because the burning process produces highly toxic fumes).

SER WASTE (electrical and electronic waste): hand controller, all wires, motors, etc.

MIXED WASTE: plastic parts (wheels), upholstery and other parts where materials cannot be separated. PVC waste is sent separately to a waste center or to a sorting station. PVC plastic is known from the sign below, material number 03.

The pre-treated and sorted materials are delivered to special collection points. Always follow regional and collection point specific instructions. Recycling can significantly reduce soil waste.

8 Limited International Warranty

Lojer warrants, subject to the terms of the limited warranty, that the Equipment is free from defects in material and workmanship, when subjected to normal, proper and intended usage by properly trained personnel, for a period of 24 months. For the steel structure the warranty period is 10 years. Warranty period for accessories and wearing components, either bundled in the original packaging or purchased separately, such as, spare parts, replacement parts, batteries, mattresses shall be 12 months from the date of shipment.

The guarantee will become void if regular preventive maintenance according to user/service instructions has not been performed by trained medical service personnel.

Download full warranty terms from www.lojer.com or ask from Lojer Service service@lojer.com.

9 Contact information

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info@lojer.com
www.lojer.com

Service
Tel. +35810 830 6750
Email: service@lojer.com

Your local Lojer dealer, see www.lojer.com/distributors

Model: _____

Serial number: _____

Date of purchase: _____

Your local Lojer dealer:_____

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