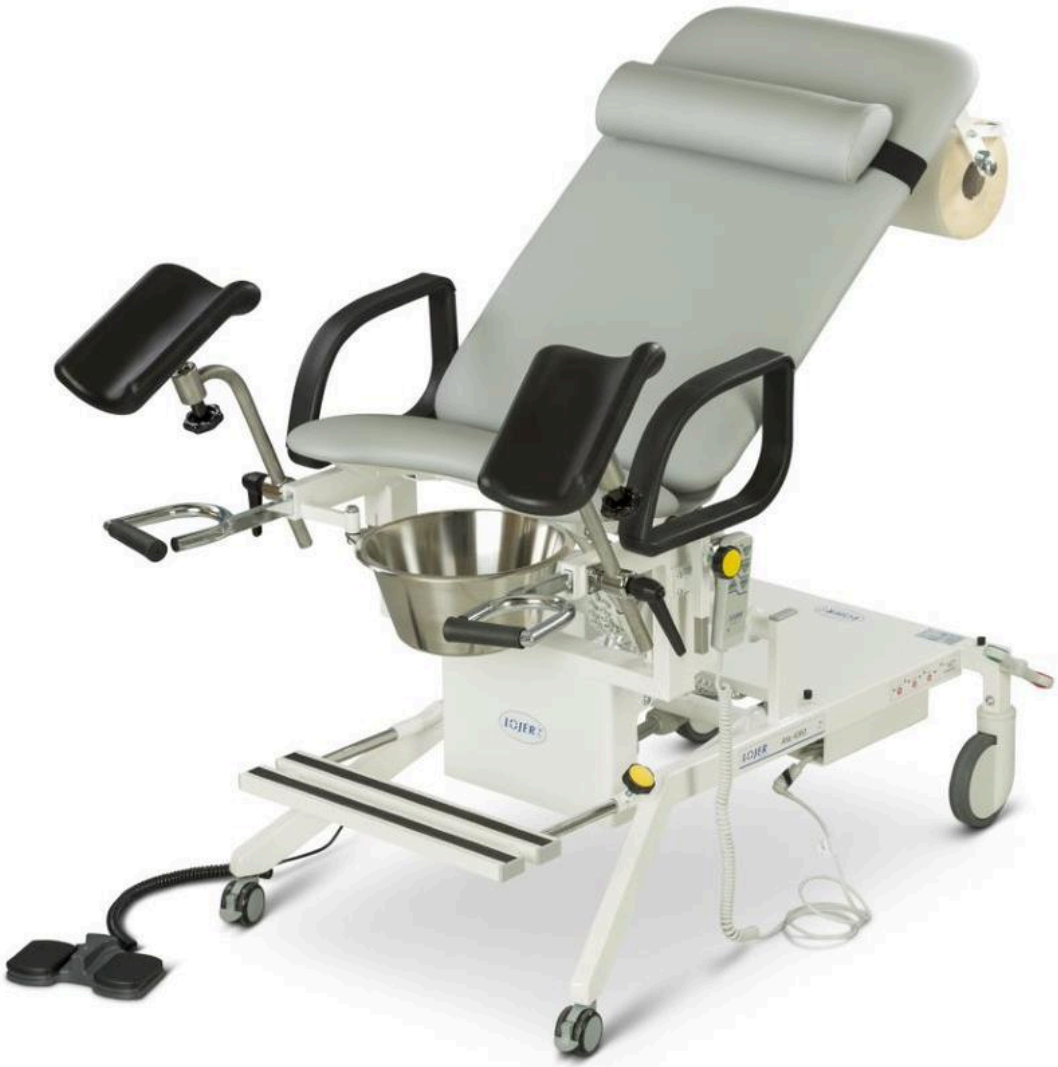
LOJER® For easy care



Lojer Afia 4060/4062
Gynaecological Examination Chair

Instruction for use

ID: DX012185, rev. 3 / 23.10.2024 (en)

CE

TEHTY SUOMESSA
MADE IN FINLAND

Contents

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

⚠ This document is a translation of the original English version. In case of conflict, the original English version applies.

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 Afia 4060 gynaecological examination chair

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

Examination chairs are intended for transient and short-term use to support a patient during medical examinations and minor procedures related to the examinations. The devices are intended to be used by the intended users in healthcare centers, hospitals or other medical facilities. The devices are not intended to be used in an operating theatre environment, nor in spaces with a very demanding hygiene level. The devices are not intended for home use.

1.2 User groups

The Owner or Holder is any natural person who owns 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 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 familiarity, 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 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/ Client is a person in need of treatment or therapy given by a healthcare professional.

1.3 Contra-indications

The device has no contraindications.

1.4 Description of parts

The sections of examination chair are shown below (Figure 1).
The Afia 4062 is a special model with factory-fitted accessories as standard (parts 10, 11 and 12)

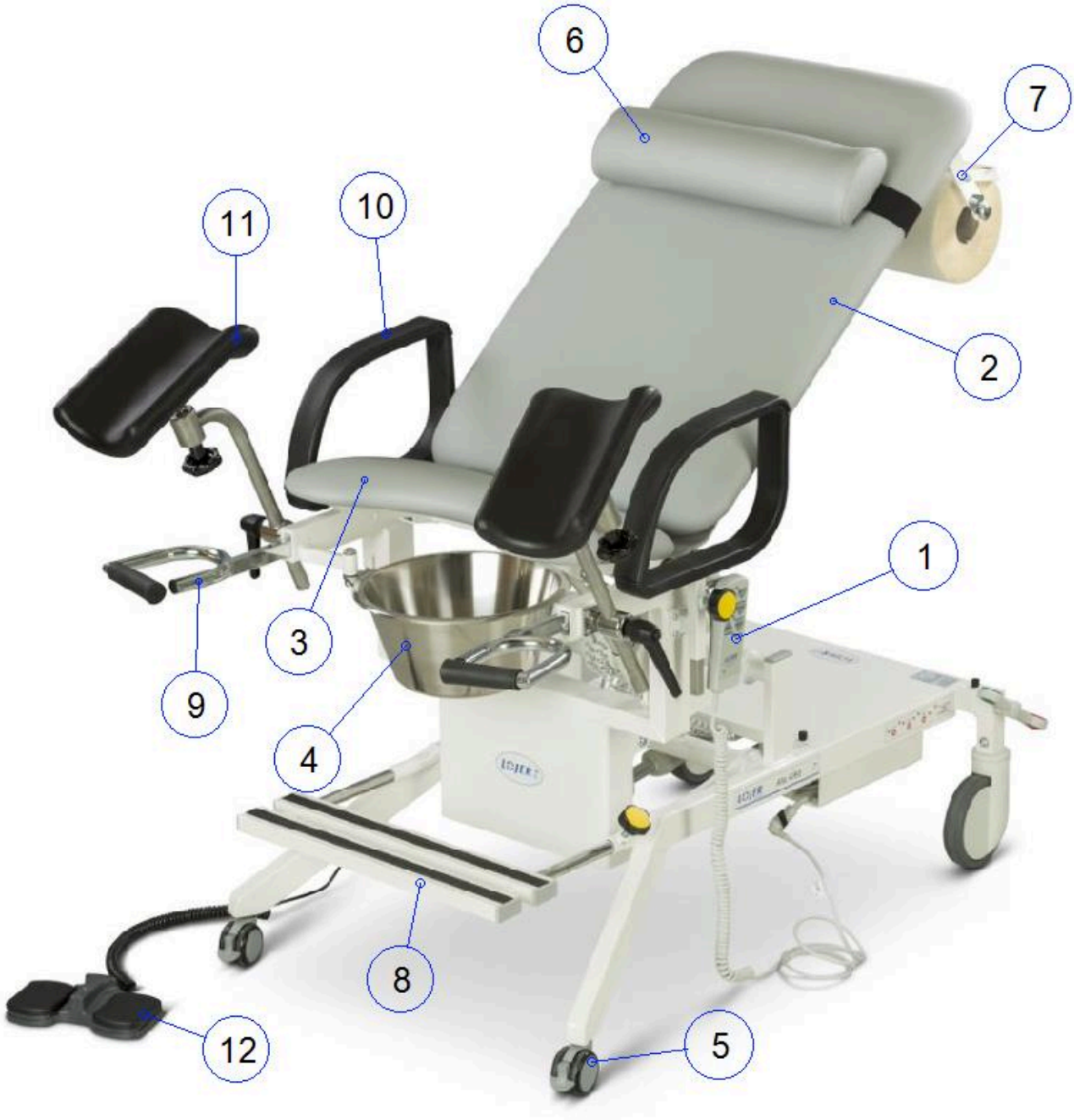
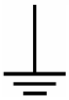
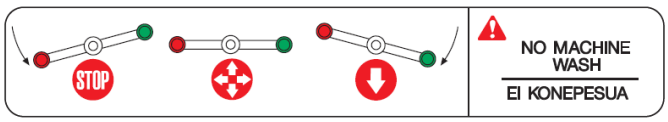


Figure 1: Lojer Afia 4060/4062 main parts

1. Hand control
2. Back section
3. Seat section
4. Bowl
5. Castor locking
6. Neck cushion
7. Paper roll holder
8. Step support
9. Heel supports
10. Hand support (optional 4060, standard 4062)
11. Calf supports (optional 4060, standard 4062)
12. Foot control (optional 4060, standard 4062)

1.5 Symbols used on the device

Symbol	Description
CE	CE mark
IPX6	Protected against powerful water jet
	Consult instructions for use
	Type B applied part
	Transformer is equipped with overheating protection.
	Indoor use only.
	Protectively isolated structure.
	Double insulated (Class II electric appliance)
	Potential equalization
	Functional ground
	Squeezing hazard
	Important/Warning
	Warning
	Product information
	Central locking

International patent

Fragile (package label)

This side up (package label)

Store in a dry place (package label)

Temperature limits

Manufacturer

1.6 Options and accessories

Factory installed options:

Calf supports, pair
Hand supports
foot control

Accessories:

Paper cutter

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...+40 °C. The permitted humidity is 30...75%.

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 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 instucted 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.

Lifting points of the table are shown below:

Figure 1.1 Lifting points

⚠	Estimate the patient's clinical state and risks of using the device (Danger of falling, trapping and suffocation).
⚠	Risk of falling and squeezing! When using mechanical adjustments of the device and its accessories, always make sure of proper locking of the adjustments by testing with hands.
⚠	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 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.
⚠	Accessories must not be used as lift supports.
⚠	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.

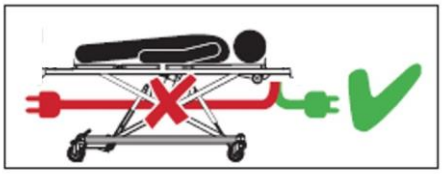
3 Using the device

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



Examination tables are electrically adjustable by hand control, foot control (option). The table is adjusted by pushing a button from the hand/foot control. Movement stops when the button is released. In fault situation the movement can be stopped by holding down the button for opposite direction.

3.1 Adjustment range and hand control

Adjustment range of the 4040X examination table is shown below (Figure 2).

- Height adjustment 59-88 cm
- Back section adjustment -7-70°
- Seat section 25°
- Trendelenburg max. 7°

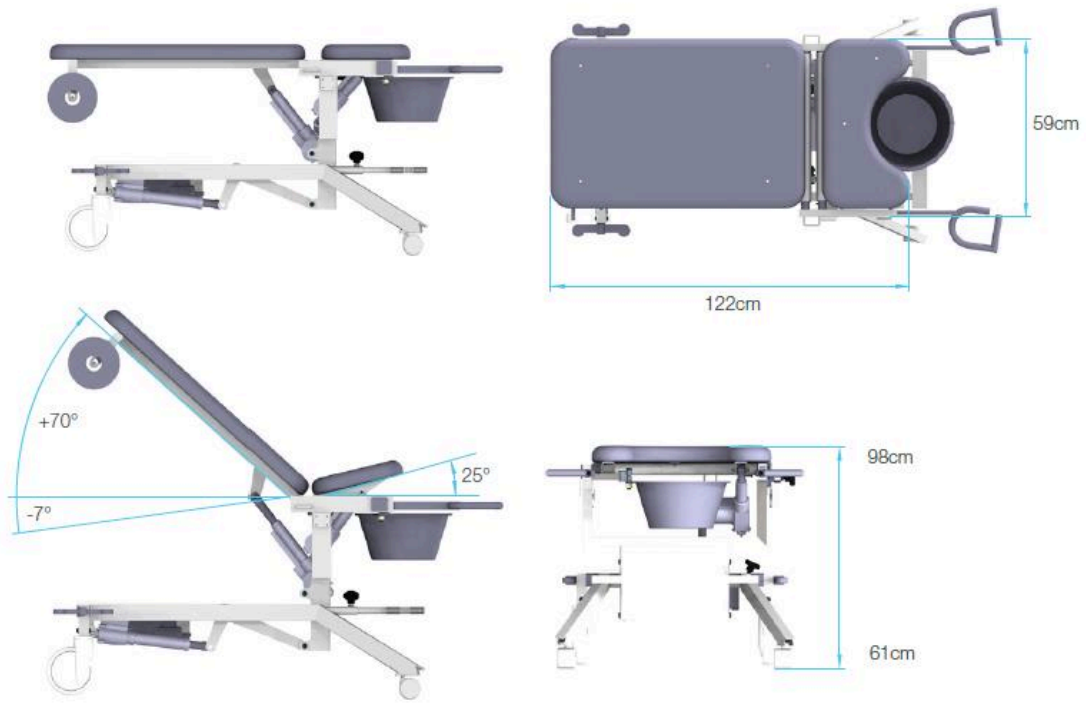
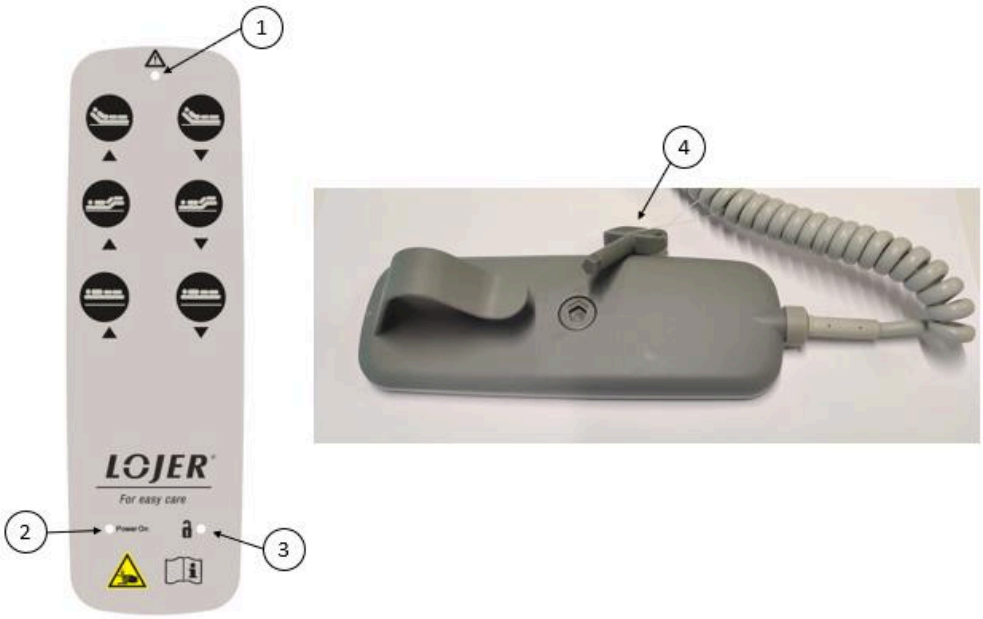


Figure 2: Adjustment ranges



1 The light is on when a button is pressed.
2 The light is on when the power is on.
3 The light is on when the lock is open. No light when locked.
3 The key to change the locking mode.

Figure 2.1: Hand control

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 power cord is not left between the structure of the table or under the casters.
⚠	Move the table only with the table top horizontally.
⚠	Patients should not be transported on the examination chair.
⚠	Always lock the wheels after transport.
⚠	Do not park the device on sloping surface. Unlocking the wheels on sloping surface can cause danger.

The examination chair has centrally lockable rear wheels. There is a pedal on each side of the chair with a green mark on one end and a red mark on the other.

Press the red end down to lock the wheels. Pressing one of the pedals is locking both. When the pedal is horizontal, the wheels are free.
To make transport easier, you can lock the rear wheel by pressing down on the green end of the pedal.

Figure 3: Pedal positions of the central locking pedal

The front wheels can be locked by pressing the locking lever down. To unlock, lift the lever.

	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 control, foot control (option). 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.

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

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.

3.4 Adjustment of table top sections

The backrest can be electrically adjusted with the hand control. The adjustment range is -7… 70 ° (Figure 6).

The Seat section of can be electrically adjusted with the hand control 0… 25 °. (Figure 6.1).

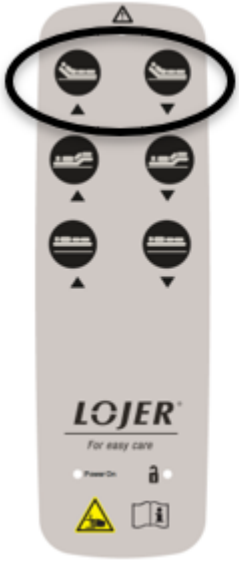


Figure 6: Backrest adjustment

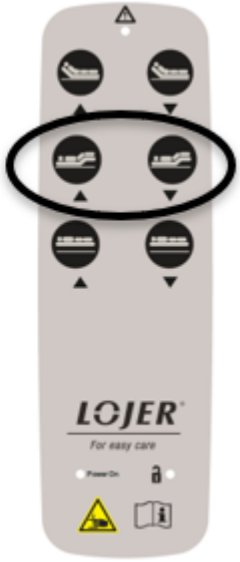


Figure 6.1: Seat section adjustment

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

3.5 Paper roll holder

The paper roll stand (50cm) is located on the top of the table (Figure 7). The shaft is locked in position on the

Figure 7: Paper roll holder

frame. Raise the shaft holding levers and release the shaft. Insert the shaft and paper roll by inserting the shaft into its slot. Paper roll cutter is an option.

3.6 Trendelenburg

The Trendelenburg angle 0-7 ° is operated electrically with the backrest adjustment (Fig. 6).

⚠	Act with caution when using Trendelenburg function.

3.7 Arm rest (accessory)

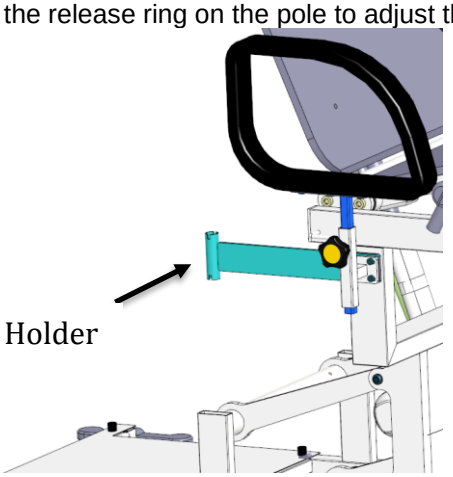
The height of the armrest can be adjusted by loosening and locking the thumbscrew again (Fig. 11). It can also be removed from its supporter.

Figure 11.

⚠	Make sure that the arm rest is properly locked.
⚠	Arm rest is meant only for supporting the arm of the patient. Do not sit or load the arm rest in any other way.

3.8 IV-pole and holder (accessory)

IV-pole is available for the examination table. However, the table must have a holder (optional).
Lift the release ring on the pole to adjust the height. Release the ring to lock the pole on the suitable height.



⚠ Make sure that the IV-pole won't hit anything when adjusting the height of the table. Remove all accessories when moving the table.

3.9 Heel supports

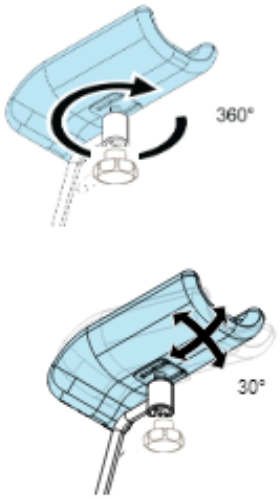
The examination table has length-adjustable heel supports.

Lift the heel support and pull it out or push in.

Lower the heel support and pull or push it lightly so that it fits into the appropriate locking hole. There are five locking holes in the heel support arm.

3.10 Calf supports (accessory)

The calf supports can be adjusted in height by loosening the lever screw. By opening the thumbscrew of the pad part, the support can be rotated 360 ° as well as tilted in all directions by 30 °.



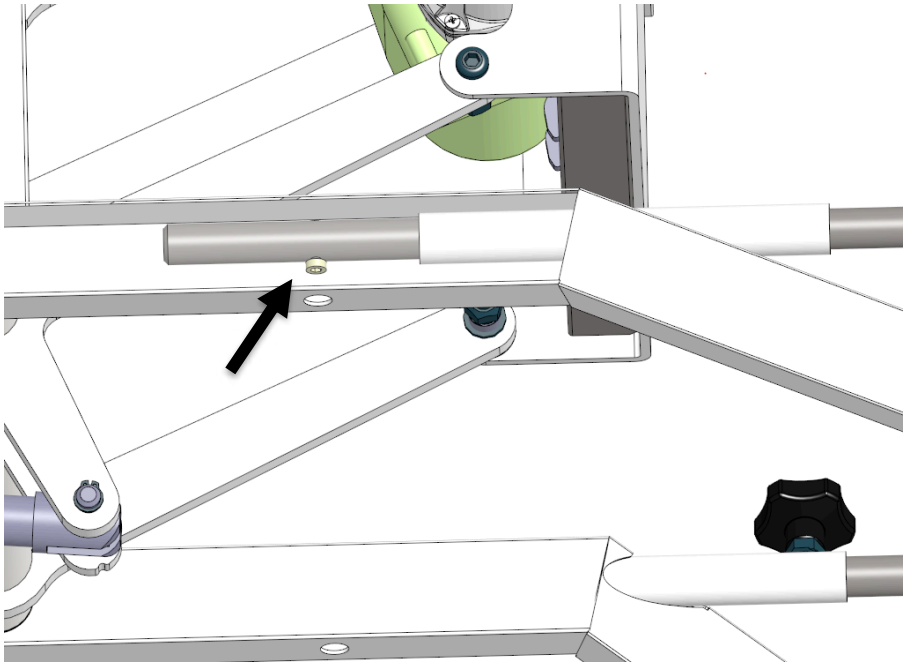
⚠ Make sure the calf support is properly locked.

3.11 Foot plate

You can adjust the foot plate lengthwise by slightly loosening the adjusting screw in the frame tube and moving the footboard to the desired position. Finally, tighten the adjusting screw.

⚠ Make sure the foot plate is properly locked.

Removing the footboard from the table requires the removal of the stop screw. If a footboard is used, the screw must be in place.



4 Cleaning and disinfecting

	Before starting cleaning or servicing, make sure that the power cord is disconnected and that the device's functions have been locked. Check by testing the functions.
	Do not machine wash or use water spray for cleaning. Do not clean in high temperature or air humidity by using e.g. steam or hot water.
	All surfaces must be allowed to dry after cleaning or disinfecting before using the device or its accessories.
	Clean the product as instructed before use.
	Do not use any unsuitable cleaners or disinfectants for cleaning and disinfecting the device. See the instructions below. Follow the respective manufacturer's instructions.
	Allow the surface of electrical components to cool off before carrying out maintenance or cleaning procedures.
	Avoid moisture entering the connection points. Excessive moisture can cause liquid pooling and damage the device.
	Avoid contact with non-colorfast materials (e.g. jeans or other textiles). This kind of discoloration is excluded from any guarantee.

4.1 Cleaning

Clean the device aseptically following the work order: From top to bottom and from cleanest to dirtiest. Take into account the following things when cleaning the device:

- The device cannot be machine washed.
- Clean stains and visible dirt as soon as possible.
  - ➔ Blood and secretion stains should be removed immediately after they appear.
  - ➔ Some substances used in care work may cause permanent stains.
- Make sure that the power cord is disconnected and that the device’s functions have been locked.
- To guarantee successful cleaning, if necessary, remove the accessories of the device.
  - ➔ Remember to clean the accessories before reattaching or storing them.
- The surfaces should always be cleaned before disinfection.
  - ➔ Follow the cleaning instructions given by the detergent manufacturers.
- In order to keep the surfaces in good condition, clean the device regularly.
  - ➔ Always clean the device between patients.
  - ➔ Take into consideration facility-specific cleaning and disinfecting instructions when cleaning the device.
- Any surface should not be subject to long-term exposure by any type of liquids.

4.1.1 Frame and other hard surfaces

- Clean all surfaces with a damp (micro)fiber cloth and a mild detergent solution (neutral pH 6–8 or weakly alkaline pH 8–10). Pay special attention to thorough cleaning of contact surfaces.
  - ➔ Do not use e.g. any solvents, abrasive cleanings agents or scouring pads as they can damage the surfaces.

- Use a soft brush to clean difficult stains, corners and other hard to reach places.
- Remove detergent residues or excess detergent by wiping the surfaces with a cloth dampened with clean water (follow the respective detergent manufacturer's instructions).
- Allow the surfaces to fully dry before using or storing the device.

4.1.2 Textile surfaces

- Clean all surfaces with a damp (micro)fiber cloth and a neutral detergent solution (pH 6–8).
    - ➔ Do not use e.g. any solvents, abrasive cleanings agents or scouring pads as they can damage the surfaces.
- Use a soft brush to clean difficult stains, corners and other hard to reach places.
- Remove detergent residues or excess detergent by wiping the surfaces with a cloth dampened with clean water (follow the respective detergent manufacturer's instructions).
- Dry the surfaces carefully after cleaning and ensure that they are fully dry before using or storing the device.

4.2 Disinfecting

The surfaces should always be cleaned before disinfection. Use disinfectant only if justified (e.g. to prevent the transmission of harmful microbes) as disinfection agents might change the surface structure of materials over time.

- Blood and urine stains should be removed immediately after they appear.
- Follow the disinfecting instructions given by the disinfectant manufacturers.
- Any surface should not be subject to long-term exposure by any type of liquids.

4.2.1 All surfaces

- Disinfect the surfaces with a damp (micro)fiber cloth, using disinfectants suitable for disinfecting medical devices, in accordance with the respective manufacturer's intended purpose and instructions for use.
    - ➔ For example, peroxygen or chlorine-based substances can be used to clean and disinfect secretion stains.
        - ➔ Clean and disinfect the device’s castors when they have been visibly contaminated.
- Allow the surfaces to fully dry before using or storing the device.

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.	Hand control is locked 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. Check the hand control lock mode. Contact the service.
One of the actuators doesn't work	The wiring is damaged or loose	Check the fastening and the condition of the wirings.
	Defective hand or foot control	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.	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.
	Hand control is locked	Check the hand control lock mode.
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 RESULSTS	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	400 VA
Duty cycle	2 min ON/18 min OFF
Ingress protection range	IPX6
Electric classification	Class I (functional ground), B-type applied part
Safe working load	150 kg
Width	59 cm
Length	122 cm
Weight	75 kg
Transportation temperature	-10…+40 °C, humidity 30…75%
Operating/storage temperature	+10…+40 °C humidity 30…75%
Air pressure	80…106 kPa
UDI-DI	06430021930309 (Afia 4060), 06430021930316 (Afia 4062)

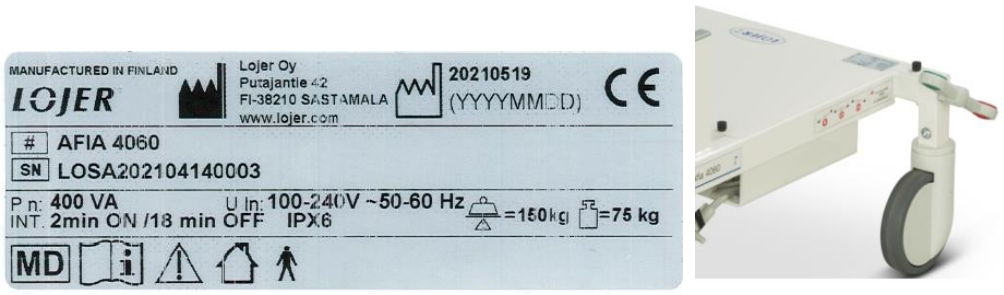
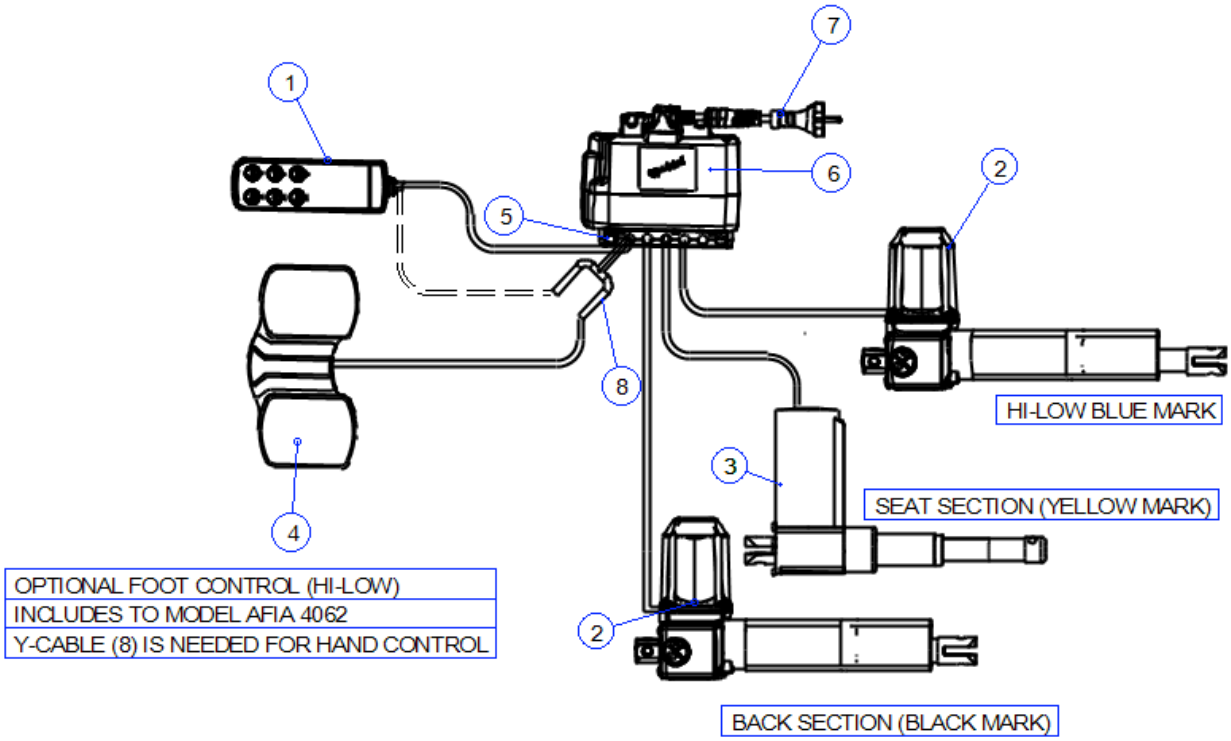


Figure 15: Type plate and its location

6.1 Circuit diagram



1	DEW_HS.04.06.06	Hand control
2	DEW_73948	back section and height motors
3	DEW_94048	Istuinosan moottori
4	DEW_75978	Foot control
5	DEW_39957	Jumper plug 13 pol
6	DEW_77183	Control unit
7	DEW_70844	Powercord
8	DEW_57559	Y-Cable for multiple controls

Other spare parts:

R260150SI	Directional wheel 150mm Integr. Tente
R260150JI	Brake wheel 150mm Integr. Tente
R26003802	Front wheel.65mm M10x15

6.2 Electromagnetic compatibility (EMC)

Medical electronic devices must be installed and used in accordance with the electromagnetic compatibility (EMC) information described in this manual.

Portable radio frequency communication devices may affect the operation of this device.

Other devices may be disturbed by EMC radiation that is even slightly above the reference value indicated in the standard. To determine whether the resulting interference is caused by this device, start and stop this device. If, as a result, interference in other devices disappears, this device is the cause of the detected interference. In such rare cases, interference may be reduced or eliminated by the following means:

- Transfer this device and other devices to a different location, move them to a different position or a different distance from each other.

⚠ 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 device, 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

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.

Guidance and manufacturer's declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	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.
RF emissions CISPR 11	Class B	Emission characteristics of this equipment make it suitable for use in industrial areas and hospitals. 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.
Harmonic emissions IEC 61000-3-2	Class A	
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 environment-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 250/300 cycles at 0°	< 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 250/300 cycles at 0°	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.
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.

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

The terms of the warranty for the product are set out in the contract documents of the purchase. Unless otherwise agreed, the general warranty terms apply (see www.lojer.com or contact our service service@lojer.com).

9 Contact information

Manufacturer
Lojer Oy
P.O. Box 54, Putajantie 42
FI-38201 Sastamala
Tel.. +35810 830 6700
Email: firstname.lastname@lojer.com
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:_____