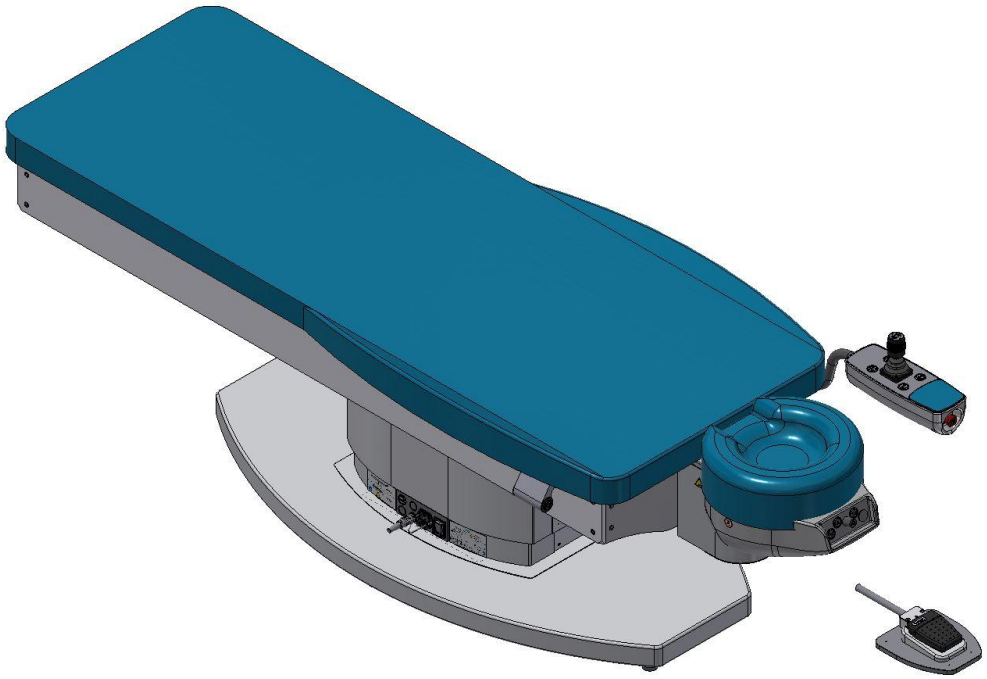
Instructions for use (IFU)

Patient Support System

LSCneo MKII



Contents

1 General

The manufacturer reserves the right to make technical changes or modifications as technology advances. There is no update service for these instructions for use.

	Action required
	The LSCneo MKII Patient Support System holds patients in a stable position during ophthalmic examinations and surgical interventions. To operate and control the LSCneo MKII Patient Support System safely, please read these instructions for use carefully. Follow all safety instructions to operate the LSCneo MKII Patient Support System safely. Retain these instructions for use for the entire service life of the product.

1.1 Copyright

1.2 Symbols used in these safety instructions

IMPORTANT	**IMPORTANT**
	Indicates possible damage to the product.
	**CAUTION**
	Indicates a potentially hazardous situation. Unless avoided, it may result in minor or moderate injury. May also be used as a warning against unsafe practices or possible damage to the equipment.
	**WARNING**
	Indicates a potentially hazardous situation. Unless avoided, it may result in death or serious injury.
	**HAZARD**
	Indicates an imminent hazardous situation. Unless avoided, it will result in death or serious injury.
	Action required

1.3 Exclusion of liability

WARNING

This device must be operated solely in accordance with its intended use, and in strict compliance with applicable national legislation and provisions, and with the generally acknowledged state of the art. Users must observe statutory national provisions on occupational safety and accident prevention.

The manufacturer excludes any liability for improper or unauthorised operation, maintenance, servicing, or modifications to the product unless expressly approved in writing by the manufacturer.

1.4 Manufacturer, applicable standards and CE marking

1.4.1 To contact the manufacturer:

AKRUS GmbH & Co. KG
Otto-Hahn-Straße 3
25337 Elmshorn
Germany

Tel.: +49 4121 7919-30 E-mail: info@akrus.de
Fax: +49 4121 7919-39 Website: www.akrus.de

1.4.2 Authorised Representative in the United Kingdom

QCS International Ltd
Suite 9, Cumbernauld Business Park
Wardpark Road
North Lanarkshire
Cumbernauld
G67 3JZ, Scotland, United Kingdom

Tel.: +44 1236 734447 E-mail: ukrp@qcsl.co.uk
Website: www.qcsl.co.uk

1.4.3 Authorised Representative in Switzerland

Medilas AG
Zürcherstrasse 39
8952 Schlieren
Switzerland

Tel.: +41 44 74740-00 E-mail: u.strasek@medilas.ch
Fax: +41 44 74740-05 Website: www.medilas.ch

CHRN: CHRN-AR-20001600

1.4.4 Standards and provisions for medical devices

The LSCneo MKII Patient Support System complies with the following standards and provisions:

ISO 10993-1:2018
ISO 14971: 2019 ED 3.0
IEC 60601-2-46:2023
IEC 63000:2016, Ed. 1.0
IEC 60601-1-2:2014/A1:2020, Ed. 4.1
CAN/CSA C22.2 No. 60601-1-2:16
CAN/CSA-C22.2 NO. 60601-1:14 incl. CAN/CSA-C22.2 NO. 62304:14
CSA C22.2 NO. 60601-2-46:18
CAN/CSA-C22.2 NO. 60601-1-6:11 + AMD1 incl. CAN/CSA-C22.2 NO. 62366:14
ANSI/AAMI ES60601-1:2005/(R)2012 AND A1:2012, C1:2009(R)2012 AND A2:2010(R)2012 (CONSOLIDATED TEXT) incl. ANSI/AAMI/IEC 62304:2006
IEC 60601-1-6:2010 + A1:2013 incl. ANSI/AAMI/IEC 62366:2007(R) 2013/A1:2013
ANSI/AAMI/IEC 60601-1-2:2014
IEC 62366:2007, IEC 62366-1:2015+COR1:2016+A1:2020
IEC 60601-1:2005 + Cor1:2006 + Cor2:2007 + A1:2012 + A1:2012/Cor1:2014+A2:2020 incl. national deviation for US, CA, JP, KR, UK
IEC 62304:2006 + A1:2015
The product complies with the requirements of the above standards and is marked as follows:

The product meets the requirements of Regulation (EU) 2017/745 and Directive 94/62/EC.
The product is marked: CE
Users must observe statutory national provisions on accident prevention, Directive 89/391/EEC and Directive 2009/104/EC.

1.4.5 Notifying the manufacturer and authorities

If an adverse event or serious incident occurs in connection with this medical device which affects the user, patient or any other person, the responsible organisation or person must report this incident to the manufacturer or distributor of the medical device. In the Member States of the European Union, the user, operator or the responsible person must report any serious incidents to the competent authority. Similar regulations apply in all other countries, where national legislation provides for this.

1.4.6 Advice for users to ensure safe operation and user qualification

Before using the LSCneo MKII Patient Support System, please read the safety instructions and recommendations in these instructions for use thoroughly and follow them closely.

CAUTION

The product must be installed, operated, used and maintained solely by suitably trained personnel or employees who have the required knowledge and experience. Please also observe the national qualification guidelines which apply in your country.

WARNING

- Correct use of this medical device is essential for its safe function and safe operation.
- The medical device must be used or operated solely for its intended use.
- Do not use or operate the medical device in explosive or hazardous environments. Do not use or operate the medical device in the presence of flammable anaesthetics or volatile solvents such as alcohol, benzene, or similar substances, unless these are present only in very small quantities.
- Do not install the medical device in damp or wet areas. Never expose the product to splashing, dripping, or spraying water.
- Pay particular attention to any highlighted safety instructions or information in these instructions for use.

1.4.7 Retaining the instructions for use & the quality test report

Please retain these instructions for use and the quality test report. Both documents are delivered with the device. It is advisable to make these documents available to any service technician if needed, as they include relevant technical information that must be accessible if a service call-out is required. If these are lost, please contact info@akrus.de to request another copy, stating the system serial number.

2 Service life & terms of guarantee

The expected service life of the product is 8 years. The service life of the product and the manufacturer's warranty depend on compliance with the instructions below. Any modification of the product that is not expressly approved by the manufacturer will invalidate the warranty.

CAUTION

- The product must be installed, operated, used and maintained solely by suitably trained personnel or employees who have the required knowledge and experience. Please also observe the national qualification guidelines which apply in your country.
- The design, development, manufacture and maintenance of such medical devices, and any risks involved, are based on an expected service life of eight years, provided the product is serviced at the intervals specified.
- Modifications to the product, or failure to follow the manufacturer's instructions, may significantly shorten the expected service life and significantly increase the risks associated with its use.
- It is the responsibility of the institution or facility using or operating this product to follow the manufacturer's instructions, and to weigh up the risks and benefits in relation to its expected service life or the maintenance and inspection intervals specified by the manufacturer.
- To ensure basic safety, e.g. that there is no movement following a first-level fault and no leakage current, maintenance must be carried out annually by a trained, authorised service technician. Please contact your distributor every year.

WARNING

- This device must be operated solely in accordance with its intended use, and in strict compliance with applicable national legislation and provisions, and with the generally acknowledged state of the art.
- Users must observe statutory national provisions on occupational safety and accident prevention.

3 Contents at delivery

Contents at delivery of the LSCneo MKII Patient Support System:

Components	Quantity
LSCneo MKII Patient Support System	1
Power cable	1
Knee cushion	1
Quality test report	1
Instructions for use (IFU)	1
Lifting bracket for transport	1
EAZY GO chassis	1
Single-use key SW 17	1

4 Intended use and performance features

The LSCneo MKII Patient Support System is intended for use as a medical device for ophthalmic examinations and surgical interventions on the human body. Any other use of the product is prohibited:

- This medical device is designed to support a maximum weight of 150 kg.
- This medical device is suitable for use in proximity to the patient.
- This medical device is not suitable for patient TRANSPORT.
- This medical device is designed to be a stationary, not a mobile, product.
- This medical device is not suitable for patients who are unable to lie flat on their backs.

The LSCneo MKII Patient Support System is designed for use as a patient bed in ophthalmology procedures when the patient is required to lie on their back. The key performance feature (characteristic) of the product is its ability to position and hold the patient in the required position within the range of movements along the axes (X/Y/Z) controlled by the operating controls. The bed must stop moving when the electronic input pulses from the control unit stop, or in the event of external influences, e.g. electromagnetic interference.

5 Operating controls

5.1 EAZY GO chassis

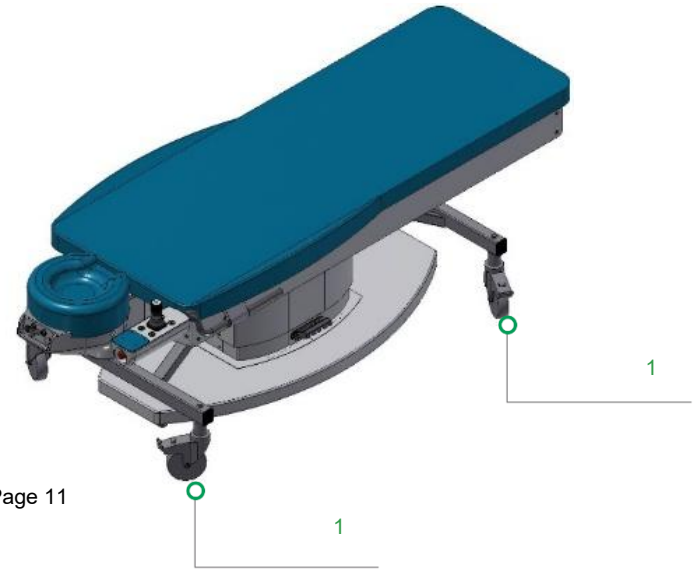


Fig.:

1. EAZY GO chassis, Page 11

5.2 Front view of operating controls

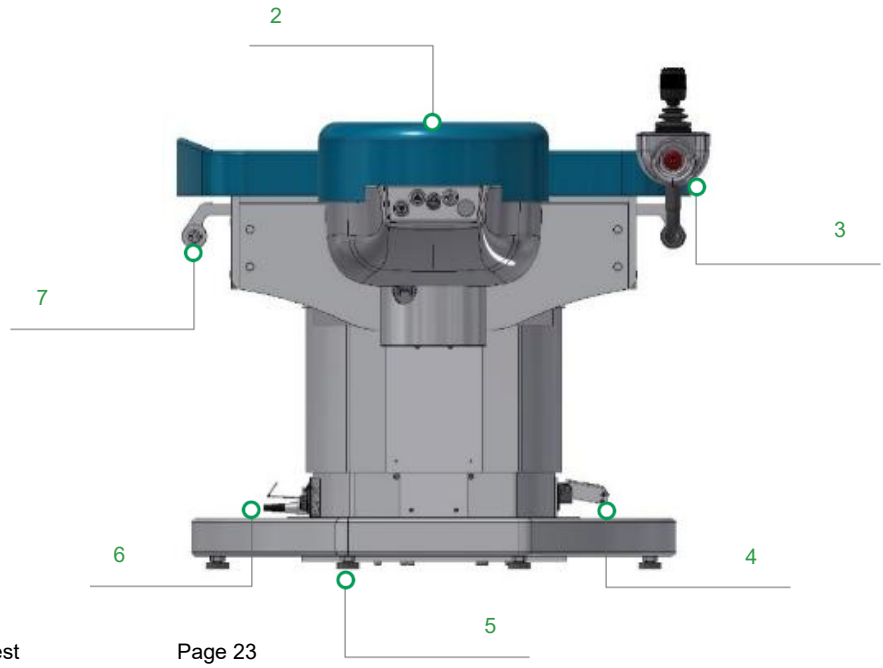


Fig.:

2. Headrest Page 23
3. Joystick panel Page 24
4. IEC sockets Page 18
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6. Power supply panel Page 17
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5.3 Power supply panel

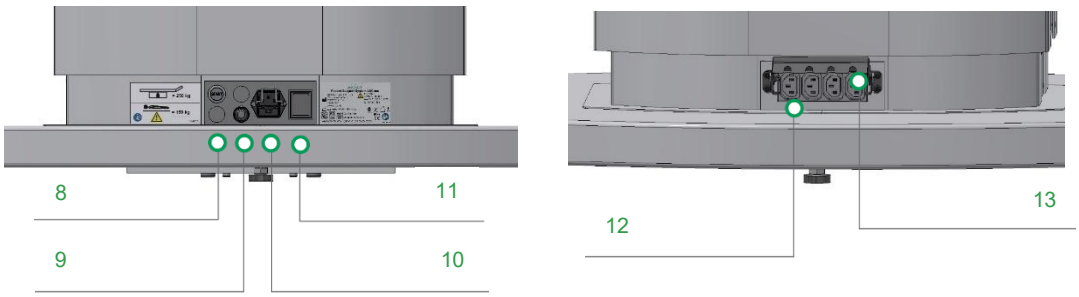

Fig.:

8.	“Start” switch	Page 20
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12.	IEC sockets	Page 18
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5.4 Headrest

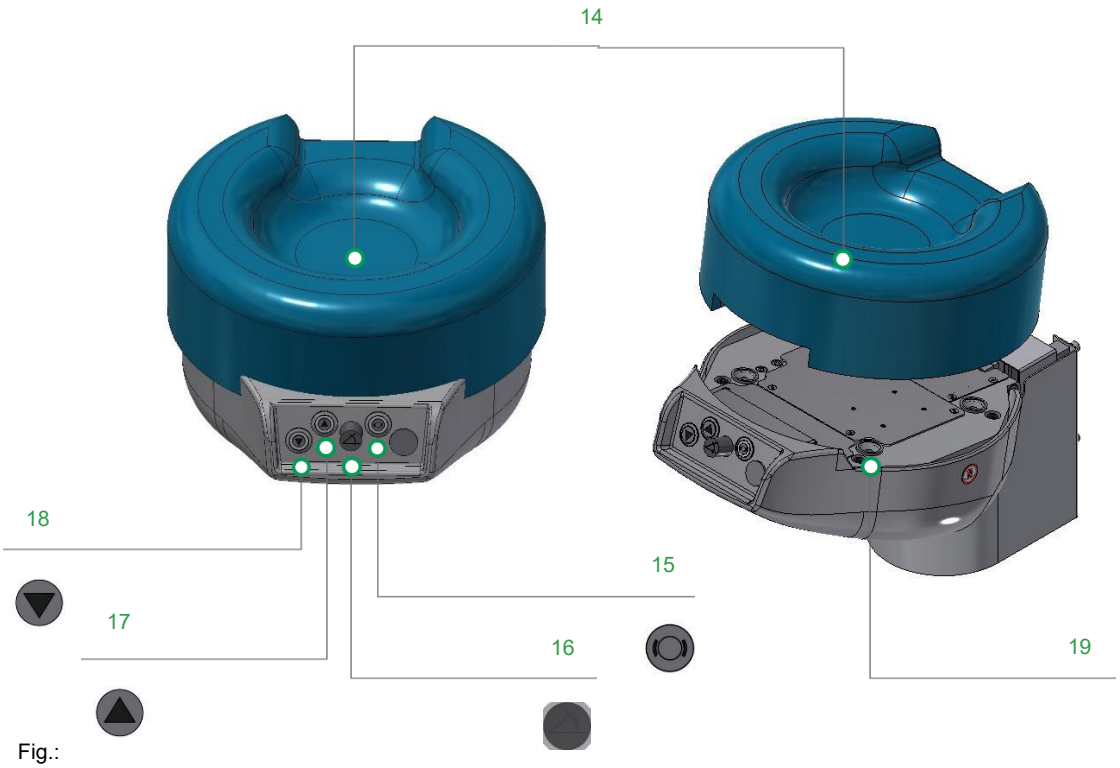

Fig.:

14.	Headrest cushion	Page 24
15.	Swivel mechanism lock	Page 22
16.	To lower the headrest mechanically	Page 23
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18.	Headrest DOWN	Page 23
19.	Ball catch lock	Page 24

5.5 Joystick panel

Fig.:

5.6 Foot switch

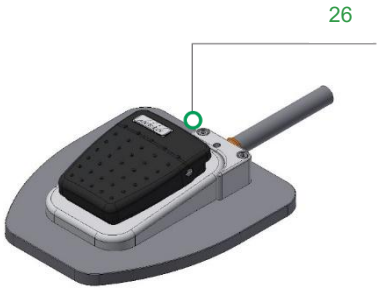


Fig.:

5.7 Bed

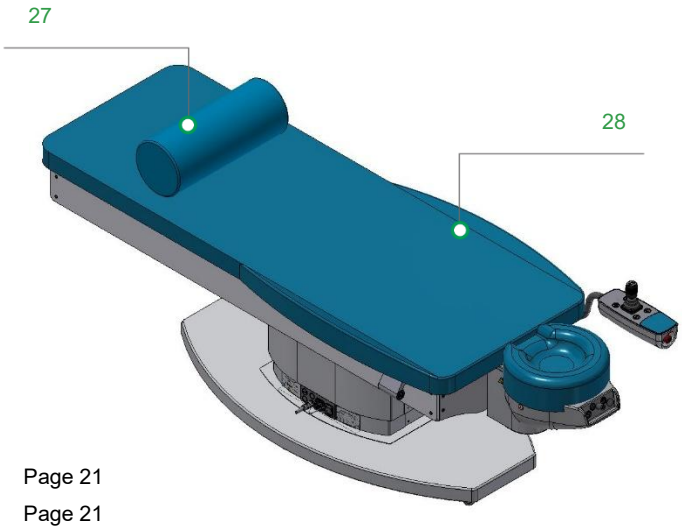


Fig.:

27. Knee support Page 21
28. Bed Page 21

6 Set-up and putting into service

6.1 Preparations for set-up

The LSCneo MKII Patient Support System is a Class I medical device and is delivered fully assembled and ready for use. Please read the instructions on installing or connecting accessories or optional parts in the relevant sections of these instructions for use.

Connecting or using radio frequency surgical devices is prohibited. Defibrillators and their monitors must not be connected to the LSCneo MKII Patient Support System. Using a defibrillator in an emergency may incur risks. Please therefore follow the instructions for use for the defibrillator, specifically the safety instructions.

Additional assembly and calibration procedures are not required, unless expressly specified by the manufacturer. Technical documentation, such as wiring diagrams, lists of parts and components, assembly instructions or other information, is available from the manufacturer upon request for qualified service personnel for the purposes of repairing parts of the medical device that the manufacturer has identified as repairable.

6.2 Moving the LSCneo MKII Patient Support System with the EAZY GO chassis

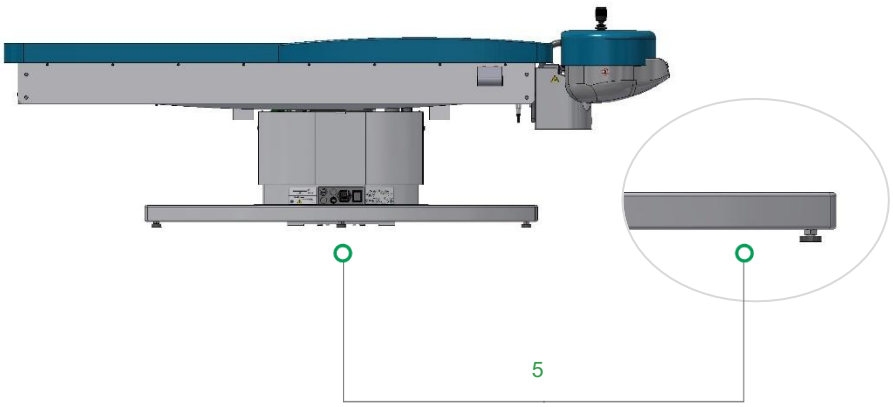
The detachable EAZY GO chassis can be used by authorised service technicians to move the LSCneo MKII Patient Support System and install it in its final position.

	CAUTION
	Move/push the LSCneo MKII Patient Support System with the foot end forwards to reduce the risk of collisions and mechanical damage to the headrest.
	WARNING
	The detachable EAZY GO chassis is NOT authorised for the TRANSPORT of any persons.

6.3 Installation and set-up

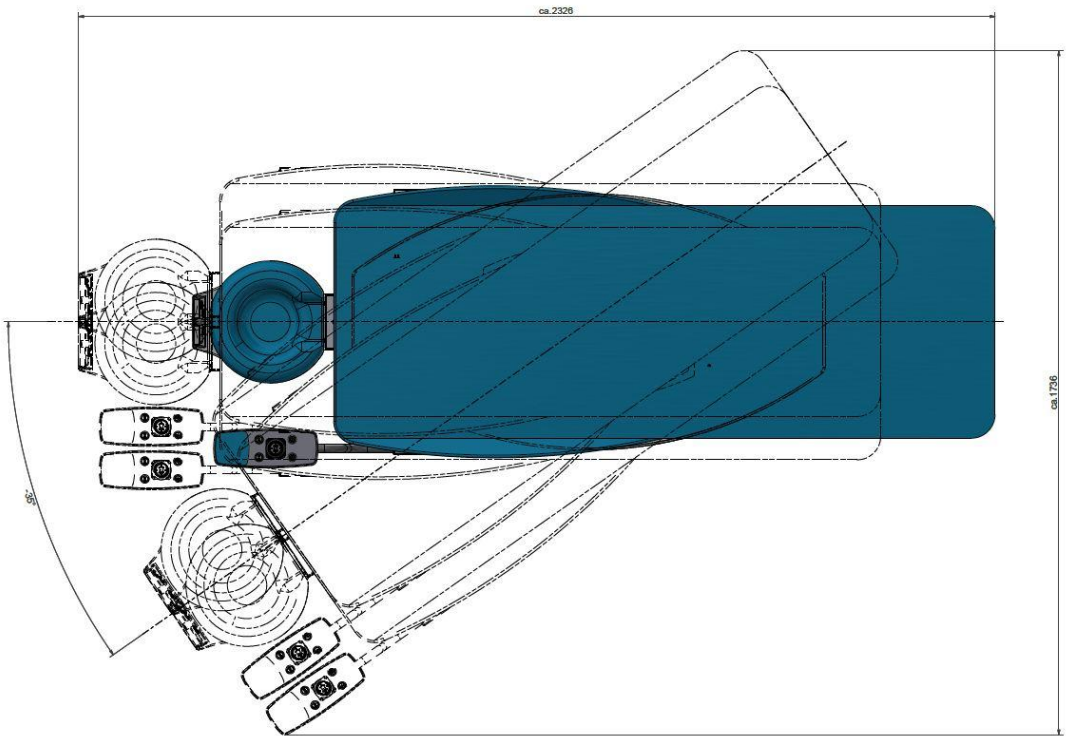
The LSCneo MKII Patient Support System must only be moved into and out of its static position by trained and qualified service personnel using the detachable EAZY GO chassis. Installation and dismantling should be carried out by two people.

The LSCneo MKII Patient Support System features six adjustable feet for excellent stability. The adjustable feet can be adjusted using the 17 mm open-end wrench delivered with the device to compensate for uneven flooring. The system must be level at all times.



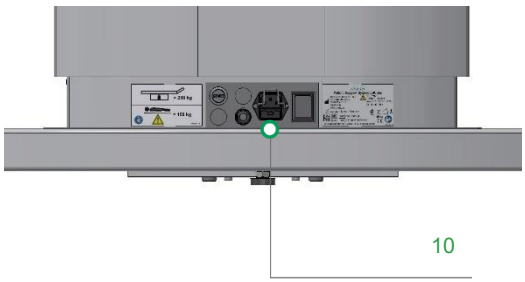
6.3.1 Aligning the system with a laser device

The bed of the LSCneo MKII Patient Support System is locked into end positions of 0° to -35°. 0° means that the bed has been pivoted inwards and swivelled parallel to the pedestal. –35° CCW means that the bed has been pivoted outwards and is at an angle of 35° to the right of the system's centre line. Any laser system must be aligned according to these specifications. Further information on setting up the system can be found in the installation instructions. Installation is carried out by service technicians.



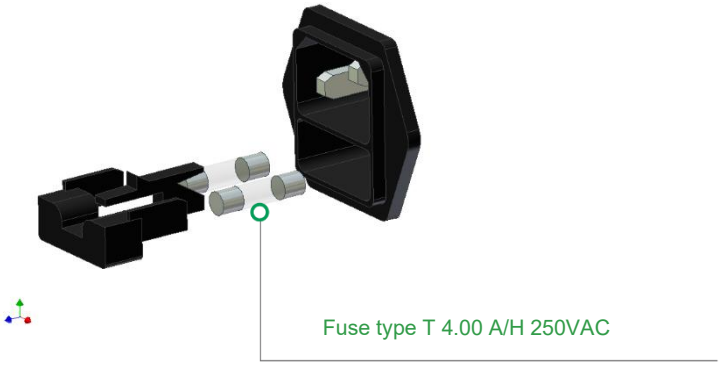
6.4 Power supply

Use the IEC power cable provided to connect the LSCneo MKII Patient Support System to mains electricity and connect it to the mains electricity socket [10]. The mains electricity socket has a fuse and cable grip. The switching power supply unit is compatible with voltages of ~100–240 VAC. Reliable safety earthing (PE) is required. Only use power cables approved by the manufacturer (AKRUS, LSCneo MKII Patient Support System, List of critical components) US/CAN: Earthing SUITABLE FOR HOSPITALS is required.



6.4.1 Power supply fuse protection

The mains electricity socket [10] has two built-in fuses to protect the flow of electricity inside the system. Only qualified technical personnel are permitted to replace these fuses.

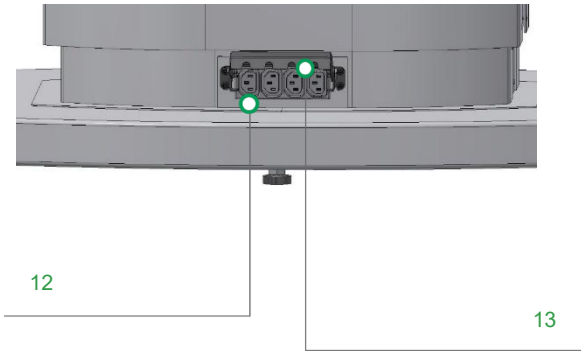


WARNING

- Make sure the power cable is unplugged before replacing the fuses. Only use the fuse type specified: 100–240 VAC mains voltage (2 x T 4.00 A/H 250 VAC)
- If the fuse blows again after it has been replaced, there is a serious problem with the electrical system. Phone the Service Department.

6.4.2 Power supply for additional devices via IEC connection

On the lower part of the centre column (on the right when looking towards the foot end) there are four IEC sockets [12] which are covered by the “Cable grip, folding” [13]. Total current consumption must not exceed 2.5 A. The output voltage at the sockets is the same as mains voltage.



	Action required
	Connecting any type of electrical device to one of these sockets means the LSCneo MKII Patient Support System is operating as a medical electrical system. The safety rating for the LSCneo MKII Patient Support System then no longer applies. All safety-related standards must be assessed by the responsible (subsequent) organisation, in accordance with IEC 60601-1 3rd edition or later, IEC 60950, or the subsequent standard IEC 62368-1.

6.4.3 Safety instructions for the power supply

The socket for the power cable is pictured and described in these instructions for use.

CAUTION

Only use the power cable supplied with this product.

WARNING

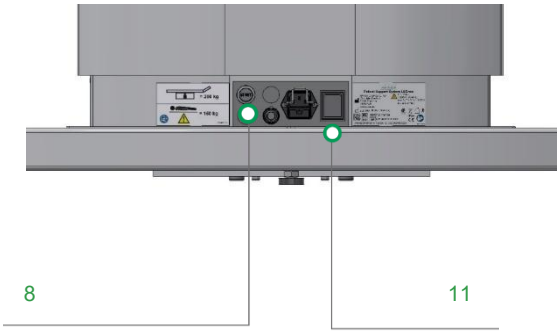
- Unplug the power plug to disconnect the device from the power supply.
- The device must be installed so that the power cable can be unplugged immediately, without any additional tools.
- Do not use extension cables or mobile multiple socket strips with the product.
- The electrical installation must comply with the requirements of IEC 60364-7-710 or applicable national provisions. This includes the presence of a ground fault circuit interrupter (GFCI).
- To reduce the risk of electric shock, the device must be connected to a power source with an earthing cable.
- Ensure that the power plug complies with requirements and is approved for the local power supply. Any power cable used to replace the power cable provided must meet the specifications below:
  - Protective conductor resistance of the power cable of max. 0.1 Ohm
  - Locally approved power cable for medical devices
  - Power plug on the device C19, in accordance with IEC 60320
  - Minimum diameter of 1.5 mm^2/AWG 16
- Do not operate the product in an environment containing explosive gases (e.g. flammable mixtures of anaesthetics, cleaning agents or disinfectants with air, oxygen, or nitrous oxide [N_2O]).
- The electrical installation must comply with the requirements of IEC 60364-7-710.
- When selecting overload protection, read the power consumption (current consumption) information on the label carefully.

7 Using the LSCneo MKII Patient Support System

7.1 Switching on and off

The mains electricity supply for the LSCneo MKII Patient Support System and the power supply to the IEC power supplies are controlled via the “main switch” [11]. Switching the device on is a two-step process. Step 1: Switch the “main switch” to I = Power ON, to supply power to the system. Step 2: Press “Start” [8] to activate the main board, i.e. to switch on the whole system. The system’s automatic start-up sequence follows. Step 7.2 must be performed to put the system into service.

The LSCneo MKII Patient Support System can be switched off when the bed is pivoted in- or outwards. It is helpful to move the bed along the Z-axis (up and down) to its lowest end position, see 7.4.2.2. Automatic DOWN movement. The main switch should then be set to 0 = Power OFF.



7.2 System initialisation before use

Once you have turned the main switch [11] to I = Power ON and pressed the “Start” button [8], the main switch lights up green to confirm there is a power supply. The system’s motors have to detect which position they are in. This happens within the system during initialisation, which always runs when the LSCneo MKII Patient Support System is disconnected from the power supply. Please proceed as follows:

After pressing the “Start” button, wait 8–10 seconds until the LED on the “Initialisation & Auto-Down” button [22] on the joystick panel begins to flash slowly. Now press the “Initialisation & Auto-Down” button. The system will run a short initialisation process of approx. 4 seconds. During this process, the LED on the button will flash quickly.

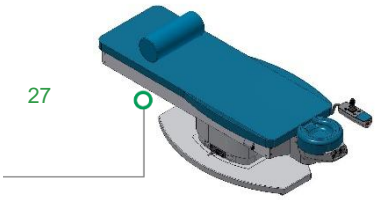
The white LED light on the “Initialisation & Auto-Down” button will stop flashing and remain steady to indicate successful initialisation. The LSCneo MKII Patient Support System is ready to use.

7.3 Position when getting onto/off the bed & patient comfort on the bed

To ensure patients can get onto and off the bed comfortably, the bed should be lowered in height (Z-axis) and towards the foot end (Y-axis). To do so, turn the joystick counter clockwise and push it towards the foot end. Both functions can be performed simultaneously. If necessary, the bed can be pivoted outwards. Please check how to use the foot switch, Page 28 7.7 Foot switch.

Alternatively, press the button “Initialisation & Auto-Down” [22]. The bed automatically moves to its lowest end position. Only then can the bed be moved towards the foot end using the joystick.

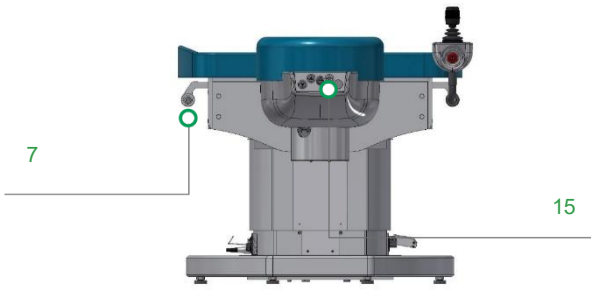
The bed is wider in the shoulder area than at the foot end. The patient can rest his or her arms comfortably. The LSCneo MKII Patient Support System comes with a freely movable knee support [27], which can be positioned behind the knees to relieve pressure on the pelvis (dimensions: length 440 mm x diameter 175 mm). To swivel the bed into the required treatment position, follow the steps on Page 22 7.4 Swivelling the bed. How to first align the patient's eye is described on Page 26 7.6.4 Automatic Settings Oculus Sinister / Oculus Dexter.



	Action required
	If the joystick is used while the system is moving under an automatic program, the automatic movement will stop immediately. Pressing the relevant button again will resume the programmed movement.

7.4 Swivelling the bed

In the LSCneo MKII patient support system with swivelling bed, the various end positions at which the swivel mechanism stops are electrically locked. To release the lock, press one of the “LOCK/UNLOCK” buttons [7] [15]. A steady light on the button LED means the bed can be swivelled. Move the bed to the desired swivel position. Once you have moved the bed to its end position, it will automatically lock, and the LEDs will switch off.



	Action required
	If a “LOCK/UNLOCK” button has been pressed but the bed is not to be swivelled, release the lock by moving the joystick from its centre position. Only swivel the bed when the corresponding control LEDs are lit to avoid damaging the swivel mechanism.
	**WARNING**
	The LSCneo MKII Patient Support System and its swivelling bed must not be loaded with an asymmetrical weight of more than 70 kg at the foot or head end when in an extended or swivelled position. There is a risk it will tip over.

7.5 Headrest

The headrest is a complex component of the LSCneo MKII Patient Support System. It has a fixed, removable head cushion that is shaped to hold the patient's head in position. Before any surgical intervention, make sure that the head is in a stable position.

The headrest has two separate adjustment mechanisms. These two mechanisms allow the headrest to be individually adjusted for each patient.

7.5.1 Electric height adjustment

The “UP” [17] and “DOWN” [18] buttons on the headrest panel control a continuous adjustable drive that moves the headrest up or down by up to 50 mm. To operate these buttons, the foot switch must be pressed down throughout the adjustment. When the foot switch is pressed down, the LEDs on the “UP” and “DOWN” buttons light up to confirm the foot switch is working.

7.5.2 Mechanical headrest tilt and emergency procedures

The protruding “Mechanical headrest tilt” [16] push button on the headrest panel releases the headrest lock and allows a ventral (forwards) tilt of +5° and a dorsal (rear) tilt of -20° from horizontal.

In the event of a power failure or other technical malfunction of the LSCneo MKII Patient Support System, the headrest can be mechanically tilted dorsally. This interrupts contact between the laser and the eye.

WARNING

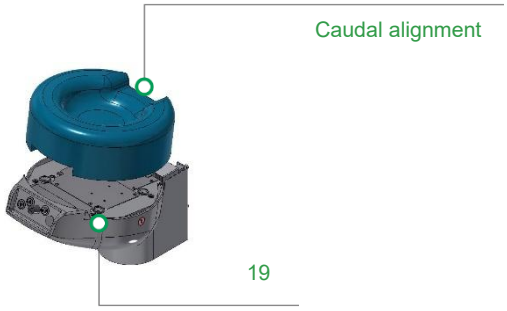
Important for all lasers that work through physical contact between the laser and the patient’s eye:

The laser must only be used when the headrest is in 0° position. Under no circumstances should the headrest be positioned below horizontal for the procedure. In an emergency, the 20° dorsal tilt breaks contact between the laser and the eye and helps to remove the patient from under the laser.

7.5.3 Removing and fitting the headrest cushion

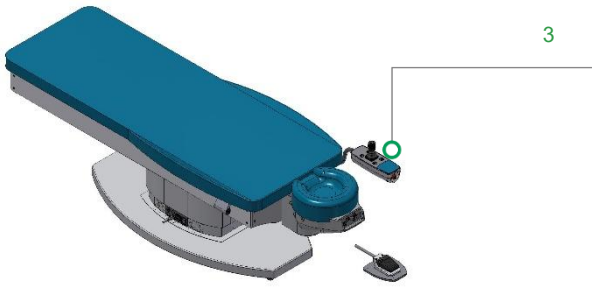
To release the headrest cushion [14], reach under the right and left sides of the headrest where it protrudes slightly, and lift the headrest cushion. The balls in the catch lock [19] will come away from their sockets with resistance.

To attach the headrest cushion, align the headrest with the open area facing caudally (towards the foot) and place the four balls of the catch lock into the corresponding sockets on the headrest. Pushing the headrest down gently will click the balls of the catch lock into the sockets. The headrest cushion is now fixed in place.



7.6 Joystick panel

The joystick panel [3] houses the controls for moving the bed. The entire joystick panel can be mounted to the right or left of the LSCneo MKII Patient Support System. It can also be moved forwards or backwards, and it can be tilted laterally inwards or outwards. These settings allow the joystick panel to be customised to suit the user's needs. When the system is delivered, the joystick panel is located to the right of the headrest, facing the foot end.



	Action required
	The joystick panel settings described may only be implemented by trained service technicians to prevent any damage to the joystick panel or its individual functions.

7.6.1 Movements the joystick can make

The joystick [20] is used to precisely control the direction and height of the bed or the patient's eye, and allows the user to make the necessary alignment with the laser. The joystick is operated by the user. The joystick responds precisely, and it can also be used to control the motor speed. Lightly pushing the joystick starts the motor moving slightly and slowly. Pushing the joystick firmly results in faster movement. The system features a soft start/stop system to prevent jerky movements.

Users must familiarise themselves with the precise joystick system of the LSCneo MKII Patient Support System before first use to be able to use its functions fully. Corresponding movements of the joystick control the movement of the bed in the Z (up and down), Y (forwards and backwards), and X (right and left) directions. Simultaneous up/down and/or sideways movements are possible.

Forwards and backwards:	Push the joystick towards the foot or head end
Right and left:	Push the joystick to the right or left
Up and down:	Twist the joystick to the right to raise the bed
	Twist the joystick to the left to lower the bed

.

	Action required
	• The joystick only works when used with the foot switch supplied, Page 28, 7.7 Foot switch. When the foot switch is pressed, the “UP” and “DOWN” LEDs on the headrest control light up simultaneously. • By pressing the “INV Reverse movement” button, Page 26 7.6.2 Reverse movement, the motors for the X (left and right) and Y movement (forwards and backwards) move the bed in the opposite direction of the joystick movement.

7.6.2 Reverse movement

By pressing the “INV Reverse movement” button,  [21] the motors for the X (left and right) and Y movement (forwards and backwards) move the bed in the opposite direction of the joystick movement. The push button LED lights up white. This function compensates for the Kepler effect under the microscope. To reset this function, briefly press the button again.

7.6.3 Automatic DOWN movement

When the eye treatment is finished, press the “Initialisation / Auto-Down” button  [22], to move the patient away from the laser. The bed moves to its lowest end position on the Z-axis (up and down). To interrupt the automatic downwards movement, push the joystick briefly in any direction. This function stops the bed from moving automatically.

This function can always be used to move the bed to its lowest end position.

7.6.4 Oculus Sinister / Oculus Dexter – Initial alignment & automatic settings

When the bed is pivoted inwards, press the “Initialisation/Auto-down” button to align the patient’s eye for the first time. The bed is moved to its  lower end position (Z-axis). Choose the correct eye by **quickly** pressing “OS” (oculus sinister ) [25] or “OD” (oculus dexter ) [23]. Then adjust the height of the eye from bottom to top by twisting the joystick  [20]. The “OS” and “OD” buttons work independently of the foot switch, but the joystick only works when the foot switch is pressed down.

To change the eye position, follow the steps above.

The difference between the two pre-set positions for OS = oculus sinister = left eye and OD = oculus dexter = right eye is 66 mm. The following functions are available:

- The bed is **in the lower end position** & the OS or OD button is **briefly** pressed:

  The bed automatically moves towards the foot end (Y-axis) and in a transverse direction (X-axis) to the pre-set position. The bed does not move upwards.

- The bed is **not in the lower end position** & the OS or OD button (touch function) is pressed down and **held**:

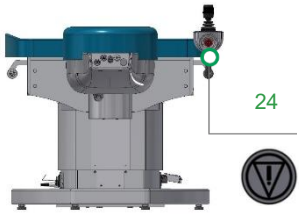
  With this function, the bed only moves in a transverse direction (X-axis) to the pre-set position. The bed remains on the same level and does not move downwards, upwards, or towards the foot end.

To use the touch button function, press and hold it down. For safety reasons, there is a slight delay before movement starts. Releasing the button stops the movement immediately.

	Action required
	The positions specified by OS/OD can be overridden using the joystick after they have reached their respective end positions. This allows for precise alignment of the eye being treated. Depending on the patient's anatomy, this may be necessary in addition to the pre-programmed settings. The additional adjustment range is +60 mm on the head side and +22 mm on each side.

7.6.5 Emergency stop function

To quickly stop the LSCneo MKII Patient Support System from moving in an emergency, there is a clearly visible red switch at the head end of the joystick housing. Pressing this “Emergency stop” switch [24] disconnects all electrical functions of the LSCneo MKII Patient Support System and the IEC power sockets from the power supply. Any movements the LSCneo MKII Patient Support System is making stop immediately when the “Emergency stop” switch is pressed.



7.6.5.1 Restarting after an emergency stop procedure

Once the emergency is over, turn the emergency stop switch [24] counter-clockwise. The main switch [11] is in position I = Power ON, the green light on the switch is off. Press and hold the “Start” button [8] for at least 2 seconds. The main switch now lights up green, indicating it is ready for operation. Run the initialisation procedure as described on Page 20, 7.2 System initialisation to restart the system.

	Action required
	If the main switch does not light up green during the LSCneo MKII Patient Support System start-up procedure, the “Emergency stop” switch may be interrupting the power flow to the system. Check the switch and return it to its original position if necessary.

7.7 Foot switch

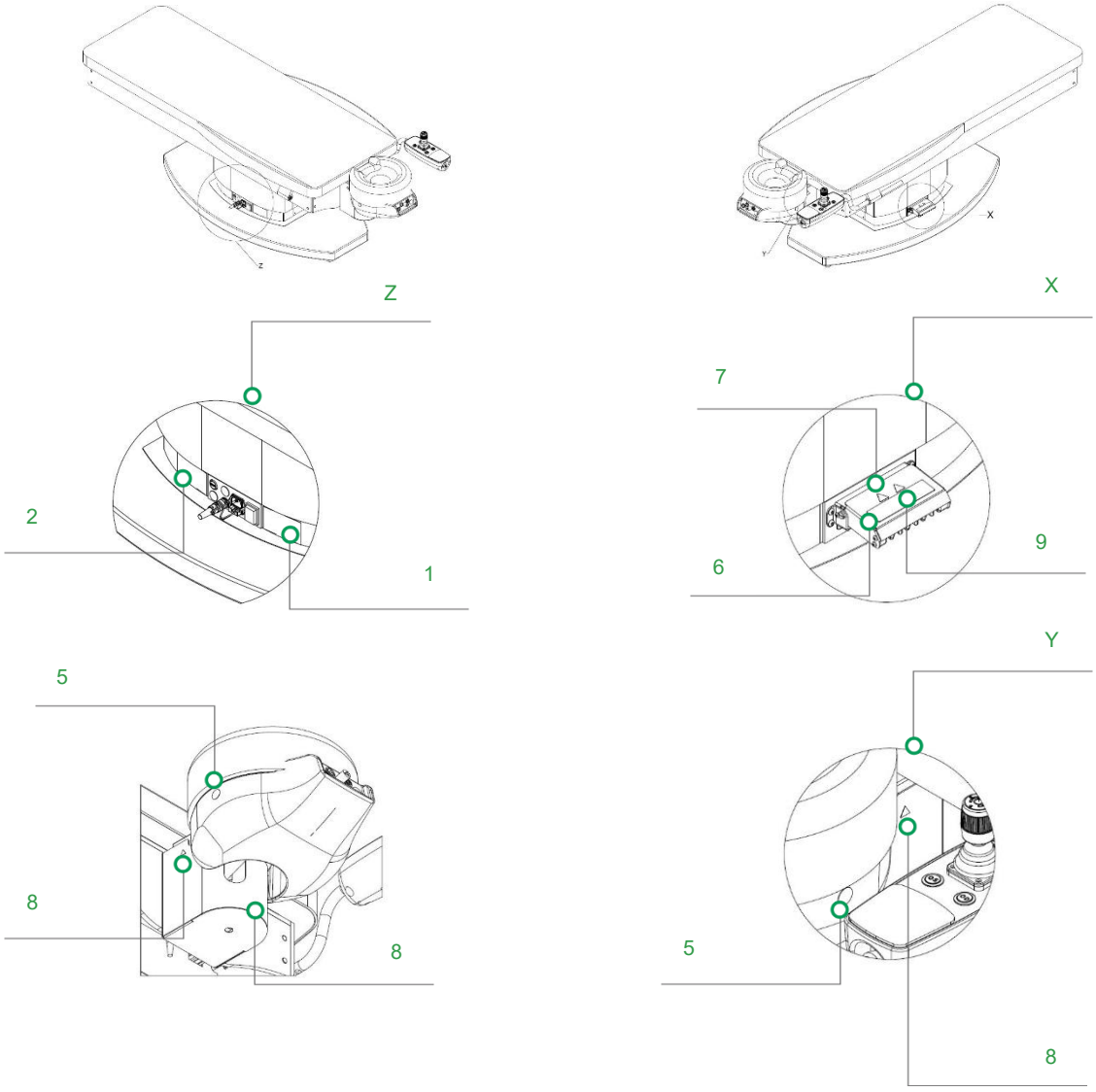
By pressing the foot switch [26] the user activates the functions of the joystick and the electronic headrest adjustment. During the patient's laser eye treatment, the user must remove their foot from the foot switch to prevent the bed from moving due to any unintentional movement of the joystick.

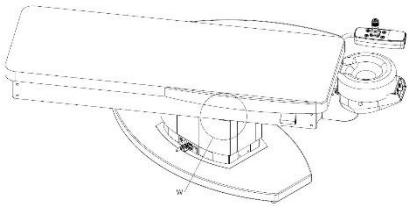
The foot switch has a sturdy base plate and a cable of approx. 2 meters in length that is resistant to mechanical stress. The cable head has a 4-pin cable connector with a screw connection, which must be screwed into the designated socket on the foot switch [9]. As space is tight, connect the cable connector first, then the power cable.

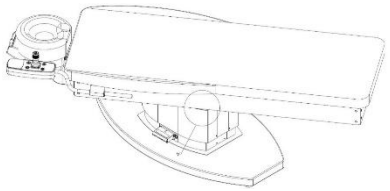
The foot switch can be positioned anywhere within the reach of the cable. When the foot switch is pressed down, the LEDs on the "Headrest UP" [17] and "Headrest DOWN" [18] push buttons light up for the user to check.

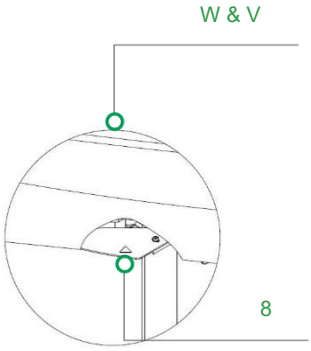
8 Safety instructions and information labels

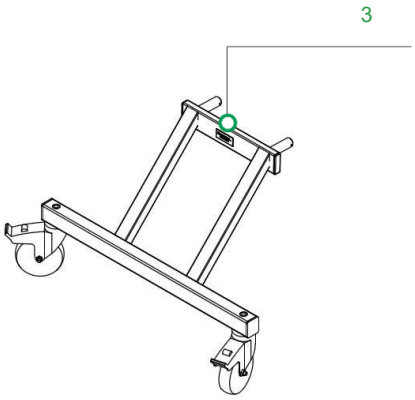
8.1 Place of operation for safety instructions and information labels



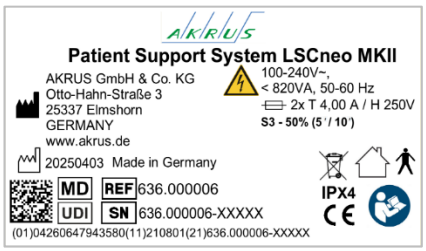


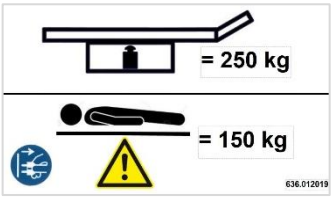
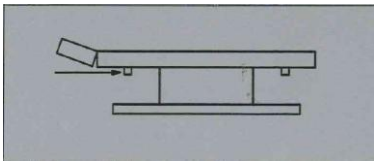
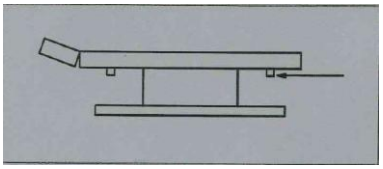
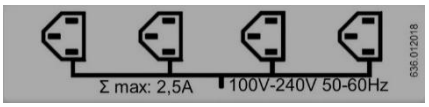



W & V
8


3

8.2 Key to safety instructions and information labels

No.	Product marking or label	Symbol	Symbol description
1			Manufacturer
			Date of manufacture
		CE	CE marking
			Applied part of Type B in accordance with IEC 60601-1
		~	A.C. voltage
		IPX4	Protection class of the housing (protected against splashing water)
			Only for indoor use
			Do not dispose of with household waste
			Fuses
		REF	Order number (catalogue/part)
		SN	Serial number
		MD	Identifies the product as a “medical device”
		UDI	Identifies the Unique Device Identifier on the label
			Unique Product Identifier (as a Data Matrix and human readable) (01)04260647943573(11)210801(21)XXXXXXX
			Label “Read instructions for use”
			Warning: Electrical voltage
		S3-50% (5´/10´)	S3 = Periodic intermittent operation. Relative duty cycle of electric motors of max. 5 minutes activation time and min. 10 minutes deactivation time
		CH REP	Authorised representative for Switzerland

No.	Symbol	Symbol description
		Weight of the LSCneo MKII Patient Support System
2		Max. patient weight  Information Pull out “power supply cable”  Use with care to prevent harm to patients, users or damage to the product.
3		Position marking for the chassis - head end
4		Position marking for the chassis - foot end
5		Prohibition sign “Do not exceed maximum load” DIN 4844-2001 Load > 200 N is prohibited.
6		Power socket symbol Use results in additional safety assessments
7		Warning: Electrical voltage
8		Warning: Hand crushing hazard
9		Caution, handle with care

9 Cleaning and protection from contamination

WARNING

Pull out the power plug before cleaning or carrying out maintenance.

- Protection from contamination
  - When in use, covering the product with a non-sterile, impermeable, disposable sheet is recommended to protect it from contamination by liquids, bodily fluids or other undesirable substances.
- The surfaces are resistant to all common wipe or spray disinfectants for medical devices. Appropriate alcohol-based disinfectants must not exceed the concentrations specified for the following components: Propanol: 35% / Ethanol: 25%
- Do not try to sterilise the product.
- Only clean the exterior surfaces of the product with a damp cloth. If there is heavy soiling, do **not** use abrasive or harsh cleaning materials, use regular cleaning products or detergent. Do not use ether, acetone, or concentrated acids.
- Ensure that no water or cleaning agents get inside the product.
- Use a damp cloth and/or a commercially available upholstery spray to clean the upholstered surfaces.
- Allow the product to dry sufficiently before using it again.

10 Maintenance

All functions used by the user are maintenance-free. There is therefore no need for users of the Patient Support Systems LSCneo MKII to carry out any maintenance.

The system must be serviced at regular intervals by a trained service technician. Contact the service technician through your distributor at least once a year or as required by local statutory provisions.

11 Product safety testing

The user is not required to carry out product safety testing. However, the user must comply with applicable national provisions regarding the testing requirements for Class I medical devices as electrical medical devices.

12 Disposing of the product

To comply with applicable EU regulations and national legislation at the time of delivery, the product shown on the delivery note must not be disposed of as normal household waste or via municipal waste disposal services.

Please contact your local distributor or the manufacturer for further information on how to dispose of the device. Please also refer to the manufacturer's current advice on the website. If the product or parts of the product are resold, the seller must inform the buyer that the product must be disposed of in accordance with statutory national legislation.

13 Technical data

Order number	636.000006
Range of main Z motor (up/down)	140 mm
Min. height of cushion top	560 mm ± 35 mm
Max. height of cushion top	675 mm ± 20 mm
Total length	2040 mm ± 20 mm
Cushion length	1690 mm ± 10 mm
Max. width	700 mm ± 40 mm
Max. patient weight	150 kg
Speed of main Z motor up/down	10 mm/s (±5 mm) up 12 mm/s (±5 mm) down
Range of headrest Z motor (up/down)	50 mm
Speed of headrest Z motor	12 mm/s (±5 mm)
Range (X) left/right	110 mm
Range (X) from centre line of bed	55 mm to the left/right
Speed of X motor (left/right)	12 mm/s (±5 mm)
Range (Y) forwards/backwards	290 mm
Speed of Y motor (forwards/backwards)	12 mm/s (±5 mm)
OS/OD	
Range (X) from centre line in automatic mode	33 mm right/left
Range (X) from centre line, plus with joystick	+22 mm right/left
Range (Y) backwards in automatic mode	230 mm
Range (Y) backwards, plus with joystick	+60 mm
Relative duty cycle of electric motors	S3 – 50%
Maximum activation time:	5 minutes
Minimum deactivation time:	10 minutes
Electrical data	
Electrical protection class for the device	I
Voltage (standard)	100–240 VAC (±10%)
Rated frequency	50–60 Hz
Current consumption (standby)	100 VA
Current consumption incl. power sockets (max.)	820 VA
Power sockets	4 x IEC (Current consumption max. ∑2.5 A)
Standby power, LSCneo MKII Patient Support System only	100 VA
Fuse F1	2 x T 4.00 A/H 250 V
IP code	IPX4
Weight	approx. 250 kg

Temperature during intended use	+15°C / +35°C
Humidity during intended use	0–50%
Atmospheric pressure during intended use/transport/storage	700–1060h Pa
Temperature during transport	-10° / +50°C
Humidity during transport	0–95%
Temperature during storage	10°C/+50°C
Humidity during storage	0–95%

14 Troubleshooting

Fault / malfunction	Possible cause	Corrective measure	Page
Does not work at all Main switch does **not** light up	Power cable not connected	Connect power cable	12, 17
	Main switch is not switched on	Switch on main switch, check that the green light on the switch lights up	20
	Main switch is switched on	Restart after pressing the emergency stop switch	20
	Power failure in the main circuit	Phone the Service Department	8
	Faulty fuse	Change the fuse	17
Does not function Power light is on	No response or standby mode indicator off after switching on	Turn main switch to 0 = Power OFF, wait 30 seconds. Turn main switch to I = Power ON, run initialisation	20
	Reference process/initialisation not run or not completed	Start and run reference process/initialisation	20
	LSCneo MKII Patient Support System is not positioned in an active operating position.	Move the LSCneo MKII Patient Support System into an active operating position and lock into position.	22
Other electrical or mechanical malfunctions		Phone the service technician	8
Foot switch not working	Foot switch not connected	Connect foot switch cable	12,28
Foot switch indicator light does not come on when the foot switch is pressed	Foot switch not connected	Connect foot switch cable	12,28
Foot switch indicator light does not come on when the foot switch is pressed	Foot switch electronics defective	Phone the service technician	8

15 Electromagnetic compatibility (EMC)

WARNING

Electromagnetic compatibility

CAUTION – ELECTROMAGNETIC INTERFERENCE HAZARD

The following EMC precautions and operating requirements apply. The LSCneo MKII Patient Support System is not intended for use in close proximity to radio frequency surgical equipment. The use of accessories, transformers or cables other than those specified in these instructions for use or sold by AKRUS as spare parts may result in increased emissions or reduced immunity for the device.

Do not use portable or mobile RF communications equipment, as they may adversely affect the LSCneo MKII Patient Support System. Do not use mobile phones or other products that do not comply with EMC Class B CISPR 11 in proximity to the device.

It cannot be ruled out that adverse electromagnetic interference may lead to the interruption or failure of the functions of the LSCneo MKII Patient Support System.

The LSCneo MKII Patient Support System requires special precautions regarding electromagnetic compatibility (EMC). To avoid problems with EMC, only operate the LSCneo MKII Patient Support System in accordance with these instructions for use. Only use original spare parts and components supplied by AKRUS. Installation, commissioning, and maintenance must be carried out by an authorised service technician, and in accordance with the maintenance manual.

Avoid using this device in proximity to other devices or stacking it with other devices as this may result in malfunctions. If using it under these circumstances is unavoidable, monitor the device and the other devices to ensure that they are functioning normally.

Guidelines and manufacturer's declaration on electromagnetic interference		
The LSCneo MKII Patient Support System is intended for use in an electromagnetic environment like the one specified below. The client or user of the LSCneo MKII Patient Support System should ensure that it is used in such an environment. Any loss of essential performance features should not create a hazard because of the essential performance features; however, basic safety is always provided. This means movement stops after a first-level fault. This represents essential performance according to IEC 60601-2-46.		
Immunity measurements	**Compliance**	**Guidelines on electromagnetic environments**
Harmonic currents IEC 61000-3-2	Class A	The LSCneo MKII Patient Support System is suitable for use in all areas, including residential areas and facilities directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker IEC 61000-3-3	Complies	
Conducted RF emissions CISPR 11	Group 1 Class A	Due to its emission characteristics, the device is suitable for use in industrial environments and hospitals (CISPR 11 Class A). If the device is used in a residential environment (which normally requires CISPR 11 Class B), it may not provide adequate protection against radio frequency communication services. In this case, the user may need to take protective measures, such as repositioning or realigning the device.
Radiated RF emissions CISPR 11	Group 1 Class A	

Guidelines and manufacturer's declaration on electromagnetic immunity

The LSCneo MKII Patient Support System is intended for use in an electromagnetic environment like the one specified below. The user of the LSCneo MKII Patient Support System should ensure that it is used in such an environment.
Any loss of essential performance features should not create a hazard because of the essential performance features; however, basic safety is always provided. This means movement stops after a first-level fault. This represents essential performance according to IEC 60601-2-46.

Immunity testing	**Immunity test level according to IEC 60601**	**Compliance level**	**Guidelines on electromagnetic environments**
Electrostatic discharge (ESD) in accordance with IEC 61000-4-2	± 8 kV Contact discharge ± 15 kV Air discharge	± 8 kV Contact discharge ± 15 kV Air discharge	Floors should be made of wood, concrete, or ceramic tiles. If floors are synthetic, the relative humidity should be at least 30%.
Rapid transient electrical interference/bursts In accordance with IEC 61000-4-4	± 2 kV for mains power lines ± 1 kV for input and output lines	± 2 kV for mains power lines ± 1 kV for input and output lines	The quality of the mains power supply should be that of a typical commercial or hospital environment.
Surge voltage/surge in accordance with IEC 61000-4-5	± 1 kV contact voltage ± 2 kV common-mode interference	± 1 kV contact voltage ± 2 kV common-mode interference	The quality of the mains power supply should be that of a typical commercial or hospital environment.
Voltage drops, short interruptions and supply voltage fluctuations, in accordance with IEC 61000-4-11	< 5% UT (> 95% dip in UT) over 0.5 cycles 40% UT (60% dip in UT) over 5 cycles 70% UT (30% dip in UT) over 25 cycles < 5% UT (> 95% dip in UT) for 5 seconds	< 5% UT (> 95% dip in UT) over 0.5 cycles 40% UT (60% dip in UT) over 5 cycles 70% UT (30% dip in UT) over 25 cycles < 5% UT (> 95% dip in UT) for 5 seconds	The quality of the mains power supply should be that of a typical commercial or hospital environment.
Magnetic field with power frequencies (50/60 Hz), in accordance with IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at the power supply frequency should be at levels typically found in a commercial or hospital environment.

UT is mains AC voltage before the test rule is applied.

Guidelines and manufacturer's declaration on electromagnetic immunity

The bed is intended for use in an electromagnetic environment, as specified below. The client or user of the bed should ensure that it is used in such an environment.
Any loss of essential performance features should not create a hazard because of the essential performance features; however, basic safety is always provided. This means movement stops after a first-level fault. This represents essential performance according to IEC 60601-2-46.

Immunity testing	**Immunity test level according to IEC 60601**	**Compliance level**	**Guidelines on electromagnetic environments**
Conducted RF interference, in accordance with IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile communications equipment should be used no closer to any part of the LSCneo MKII Patient Support System, including its cables, than the recommended electrical clearance calculated using the correct equation for the transmitter frequency. **Recommended electrical clearance** $d = 1,2\ \sqrt{P}$
Radiated RF interference, in accordance with IEC 61000-4-3 + Table 9	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d = 1,2\ \sqrt{P}$ MHz to 800 MHz $d = 2,3\ \sqrt{P}$ for 800 MHz to 2.5 GHz
	27 V/m (385 MHz/18 Hz PM)	27 V/m	where P is the maximum rated power output of the transmitter in watts (W) according to its manufacturer, and d is the recommended electrical clearance in meters (m).
	28 V/m (450 MHz/5 kHz Hub, 1 kHz Sin. FM)	28 V/m	The field strengths from fixed RF transmitters as determined by an electromagnetic site survey [a] should be below the compliance levels for each frequency range. [b]
	9 V/m (710/745/780 MHz/217 Hz PM)		
	28 V/m (810/870/930 MHz/18 Hz PM)	9 V/m	Interference may occur in proximity to devices marked with this pictogram:
	28 V/m (1.72/1.845/1.97 /2.45 GHz/ 217 Hz PM)		
	9 V/m (5.24/5.5/5.785 GHz/217 Hz PM)	28 V/m	
		28 V/m	
		9 V/m	

IMPORTANT

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. The propagation of electromagnetic waves is also affected by absorption and reflection by buildings, objects, and people.

Guidelines and manufacturer's declaration on electromagnetic immunity			
Field strengths from fixed transmitters, such as base stations for radio (mobile/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts can theoretically be accurately predicted. To assess the electromagnetic environment regarding fixed RF transmitters, an electromagnetic site survey should be considered. If the field strength recorded in the location where the device is used exceeds the RF compliance level stated above, the patient should be observed while lying down to monitor for normal operation. If interference occurs during normal operation, additional measures may be necessary, such as realigning or relocating the Patient Support System LSCneo MKII. Above the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.			
Not sensitive to magnetic near-fields in the frequency range of 9 kHz to 13.56 kHz IEC 61000-4-39	30 kHz– Test level: 8 A/– Modulation: CW 134.2 kHz – Test level: 65 A/m – Modulation: PM 2.1 kHz 13.56 MHz– Test level: 7.5 A/m – Modulation: PM 50 kHz	Unchanged	Not relevant

Recommended electrical clearance between portable or mobile RF communications equipment and the LSCneo MKII Patient Support System

The LSCneo MKII Patient Support System is intended for use in an electromagnetic environment where RF interference is controlled. The client or user of the LSCneo MKII Patient Support System can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LSCneo MKII Patient Support System, as recommended below, according to the maximum output power of the communications equipment.

Transmitter power in W	Electrical clearance, dependent on transmitter frequency m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1,2\sqrt{P}$	$d = 1,2\sqrt{P}$	$d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

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

IMPORTANT

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. The propagation of electromagnetic waves is also affected by absorption and reflection by buildings, objects, and people.

16 Overview of the power supply cable

The following power supply cables are 3 metres long and are approved according to the relevant standards:

Order number	Use in country/region
636.012070	Power cable “US”
636.012071	Power cable “UK”
636.012072	Power cable “Switzerland”
636.012073	Power cable “Brazil”
636.012074	Power cable “China”
636.012075	Power cable “EU”
636.012076	Power cable “India”
636.012077	Power cable “ISR”

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