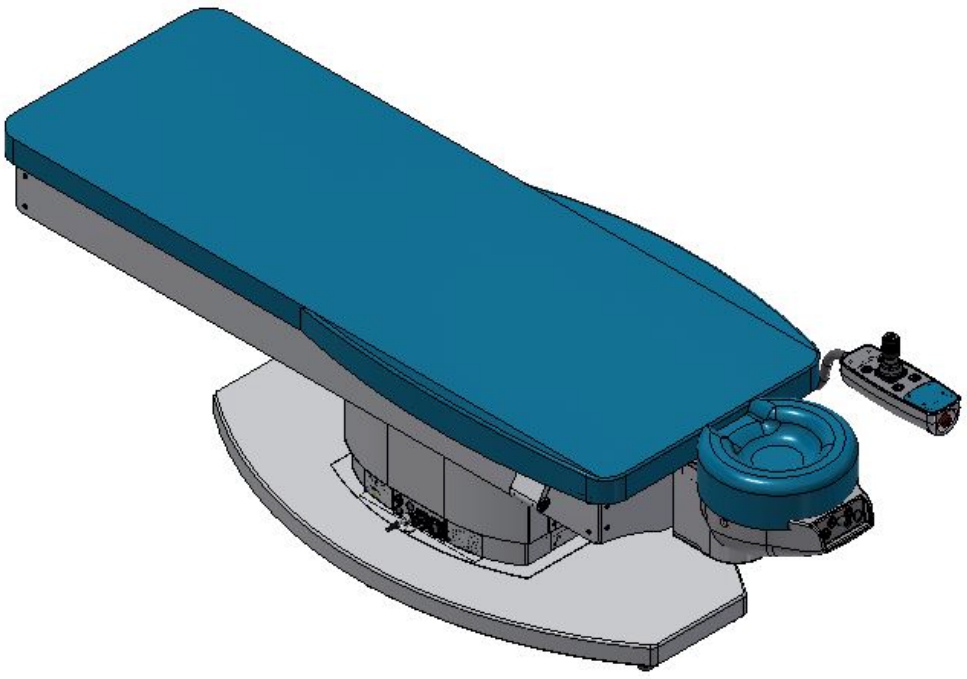
Patient Support System LSCneo



Instructions for Use

Table of contents

1. General

To safely operate and control the Patient Support System LSCneo please carefully read this user manual. Please, pay attention to all safety information pertaining to the safe operation of the Patient Support System LSCneo. Please, always keep the instructions for use on file while the product is in service.

The manufacturer reserves the right to make technical changes or modifications in accordance with advanced technical improvements. This instructions for use is not subject to an updating service.

1.1. Copyright

1.2. Safety information symbols

	Warning	Indicates a hazardous situation which may result in fatal or serious bodily injury if the appropriate safety precautions are not heeded.
	Caution	Indicates a hazardous situation which may result in minor injury if the appropriate safety precautions are not heeded. **Caution- physical damage** Indicates a hazardous situation which may result in physical damage if the appropriate safety precautions are not heeded
		This pictograph on the label indicates: Equipment Category B according to EN 60601-1

1.3. Disclaimer

	Warning	This device may only be operated in accordance with the intended use and strict adherence to the national applicable rules and regulations and the generally acceptable state of technology. User must observe the national legal requirements governing OSHA and the prevention of accidents.

Manufacturer excludes any and all liabilities in case of improper or not authorized operation, maintenance, servicing of, or alterations of the product if not authorized expressively and in writing, by manufacturer.

1.4. Manufacturer, applicable standards and CE mark

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CHRN: CHRN-AR-20001600

The device complies with the following standards and regulations for medical devices:

ISO 10993-1:2018
ISO 14971: 2019 ED 3.0
IEC 60601-2-46:2016 ED 3.0
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 60601-1:2005 + Cor1:2006 + Cor2:2007 + A1:2012 + A1:2012/Cor1:2014
IEC 62304:2006 + A1:2015

The device meets the requirements of the previous listed standards and is marked:

C US
266310

The device meets the requirements of Regulation (EU) 2017/745 and Directive 94/62/EC.

The device is marked: CE

User must observe the national legal requirements governing the prevention of accidents, Directive 89/391/EEC and Directive 2009/104/EC.

1.5. Notification to manufacturers and authorities

If an adverse event occurs or a serious incident affecting the user, patient or another person occurs in connection with this medical device, the responsible organization or person responsible must report this incident to the manufacturer or seller of the medical product. In member states of the European Union, the operator or responsible person must report serious incidents to their competent authority. In all other countries, comparable rules apply where national legislation so requires.

1.6. User instructions for safe operation and user qualifications

Before using this medical device, please carefully read and observe the safety instructions and recommendations contained in this instructions for use.

	Caution, physical damages	The device may only be installed, operated, used, and maintained by properly trained personnel or staff who have the required knowledge and experience to do so. Please, also adhere to the national qualification guidelines applicable in your country.

	Warning	Proper operation of this medical device is imperative for its safe function and operation.
	Warning	Operation of the medical device only in accordance with the intended use.
	Warning	Do not operate the medical device in explosive or hazardous environments. The medical device must not be operated, except for very minute quantities, in the presence of combustible anesthetics, or volatile solvents like alcohol, benzene or similar.
	Warning	Do not set up the medical device in humid or damp rooms. Never expose the product to sprinkling, dripping, or splashing water.
	Warning	Pay special attention to any emphasized safety instructions or information in this instruction for use.

2. Product lifetime and warranty conditions

The product lifetime is expected to be 8 years. Both, the lifetime and the warranty offered by manufacturer are conditional upon the adherence to the instructions outlined below.

Any alteration on the product that was not expressly authorized by the manufacturer, will render the warranty null and void.

	Caution Risk of operating errors	The device may only be installed, operated, used and maintained by properly trained personnel or staff who have the required knowledge and experience to do so. Please, also adhere to the national qualification guidelines applicable in your country.

	Caution General Hazards	The development, production and maintenance of these medical devices, together with associated risks, are based on an expected service life of eight years, provided the device is serviced at the specified intervals. Modifications to the product or failure to follow the manufacturer's instructions may substantially reduce the expected service life and significantly increase the risks associated with the use of this device. It is the responsibility of the institution operating this product to follow the manufacturer's instructions and judge the risks and benefits regarding the expected service life or maintenance and inspection intervals specified by the manufacturer. To ensure basic safety as no movement after error of first degree and no leakage current keep annual service intervals performed by a trained and authorized service technician. Therefore contact your distributor annually.

	Warning General hazards	This device may only be operated in accordance with the intended use and strict adherence to the national applicable rules and regulations and the generally acceptable state of technology. User must observe the national legal requirements governing OSHA and the prevention of accidents.

3. Scope of delivery

The Patient Support System LSCneo scope of delivery

Position	Qty
Patient Support System LSCneo	1
Power cord	1
Knee pad	1
Quality inspection-test report	1
Instructions for use	1
Transport lifting bars	1
Single use wrench SW 17	1

4. Intended use

The medical device is intended for use as a medical device for examinations and surgical procedures in ophthalmology on the human body. Any other use of the product is not permitted.

- This medical device is designed for a maximum load of 150 kg.
- The medical device is suitable to be used in the vicinity of the patient.
- This medical device is not suitable for the TRANSPORT of patients.
- The medical device is designed as a stationary, not a mobile device.
- This medical device is not suitable to patients unable to recline flat.

4.1. Purpose of device and essential performance

The medical device is intended as external patient support for supine position in ophthalmic applications. The essential performance (feature) of the product is the ability to position and hold a patient at a desired position within the movement capabilities of the axes (X/Y/Z) controlled by the operating controls. The movements must not continue after the discontinuation of the electronic input impulses of the controlling device nor caused by any external influences, such as electromagnetic interference radiation.

5. Set up and commissioning.

The medical device is delivered fully assembled and ready for use. Please read the instructions in the corresponding chapters of this instructions for use for the installation or connection of accessories or optional parts.

Connection or usage of high-frequency surgical equipment is not permitted. Heart defibrillators and its monitors must not be connected to the Patient Support System LSCneo. Usage of heart defibrillators in emergency cases may lead to risks. Therefore, follow the instructions for use of the heart defibrillator and in especially its safety information.

Additional assembly and calibration procedures are not required, if not expressly indicated by manufacturer. Technical documentation like wiring diagrams, part and subassembly lists, assembly instructions or other information are available upon request from the manufacturer to qualified service personnel for the purpose of the repair of such parts of the medical devices, which manufacturer has identified to be repairable.

6. Electric connections

The power connection inlet socket for the power cord is shown and described in this instructions for use.

	Caution	Use only the power cord provided with this device.
	Warning General hazard	To disconnect the device from power supply, pull the mains plug The device must be set up such, that the power cord can be pulled out immediately and without additional tools.
	Warning Electrical shock	Do not use extension cords or mobile multi outlet power strips for the device. The electric installation must meet the requirements of IEC 60364-7-710 or the applicable national regulations. This includes the presence of an earth leakage circuit breaker (ELCB). To mitigate the hazard of an electric shock, the device must be connected to a power source featuring a ground wire. Make sure, the power plug meets the requirements and is approved for the local power source. Any replacement for the provided power cord must meet the specifications outlined below: • Protective ground wire resistance of power cord 0.1 Ohm max. •Locally approved power cord for medical devices. • Plug on the device C19 according to IEC 60320 • Cross section minimum 1.5 mm2/AWG 16
	Warning Fire hazard	Do not operate the device in an environment with explosive gases (i. e. combustible mixtures of anesthesia- cleaning or disinfection substances with air, oxygen, or nitrous oxide [N2O]). The electric installation must meet the requirements of IEC 60364-7-710. When selecting the over current fuse, carefully read the information about current consumption (power draw) on the label

7. Product description and controls

7.1. Connections

7.1.1. Power connection

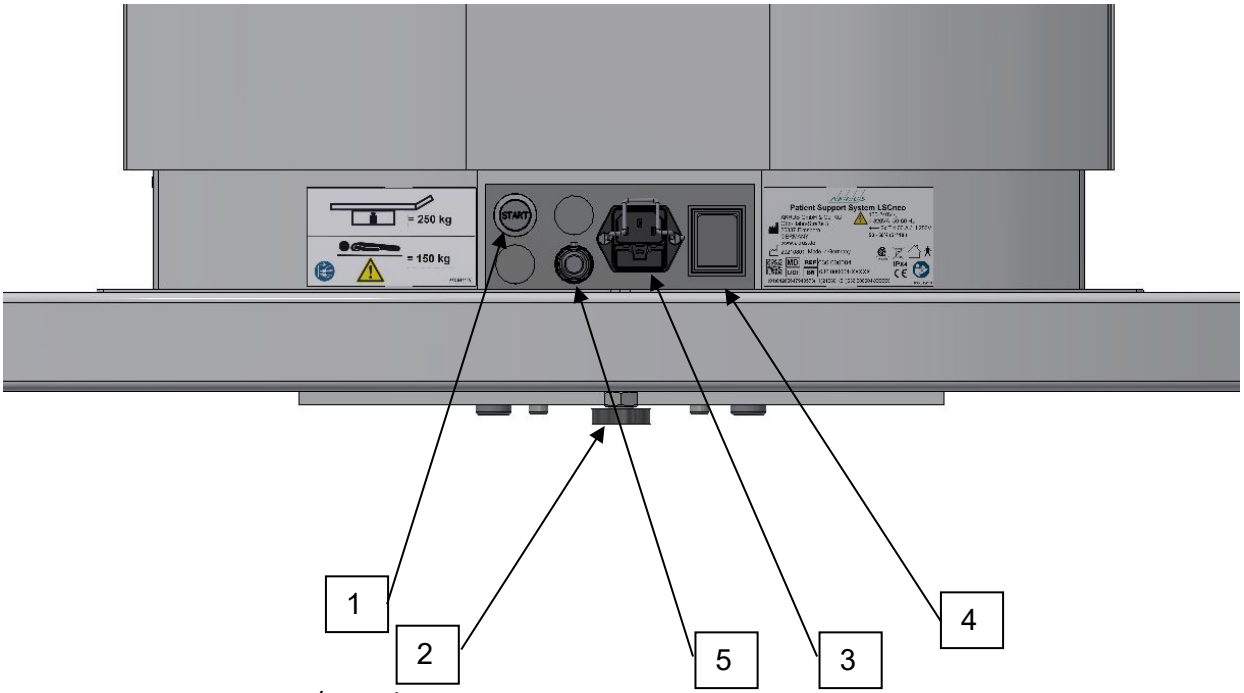
Use the IEC cable to connect the Patient Support System LSCneo [3] to line power. The fuse is included in the power inlet socket. The wide range SMPS unit is capable to accept any voltage between ~100-240VAC.

Reliant Safety grounding required (PE) use only Power cord sets released by manufacturer (Akrus, Patient Support System LSCneo, List of critical components)

US/CAN: Grounding related to HOSPITAL GRADE required.

7.1.2. On / Off and start switches

Line power connection to the Patient Support System LSCneo and the power feed to the outlet sockets is controlled by the green illuminated main switch [4]. The PCB motherboard is activated by the start button [1]. Press and hold the start switch for at least 2 seconds.



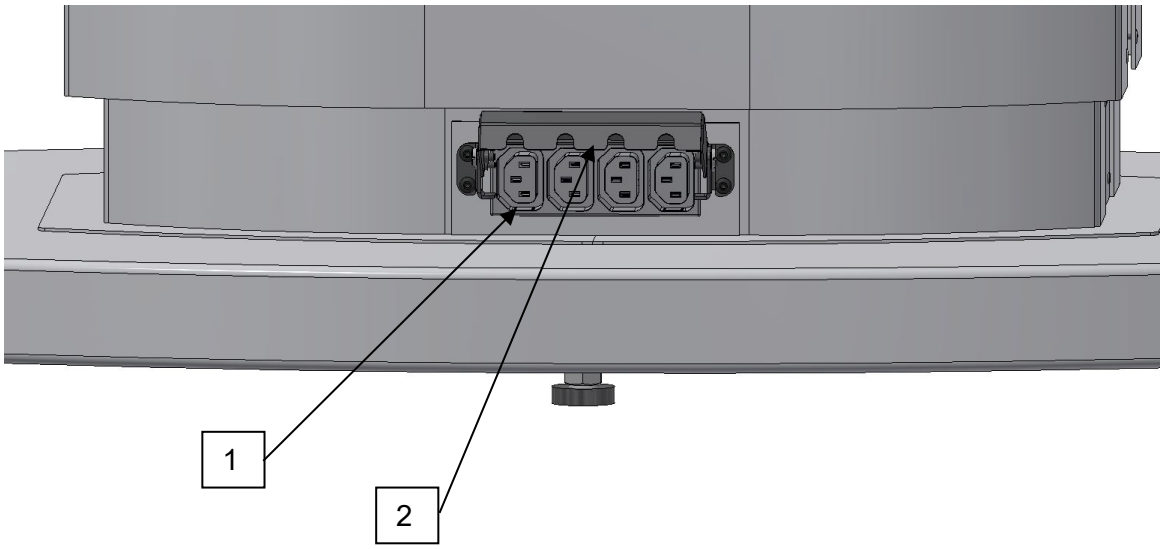
Connectors / Switches

1-Start button
2- Stud
3- Power inlet unit with fuse socket
4- Main switch (I = power ON, O = power Off)
5- Bridging plug must not be removed otherwise no function of Patient Support System LSCneo possible

7.1.3. Power outlet sockets

4 IEC power outlet sockets are located at the lower part of the central column, covered by a pull-out guard. Do not exceed an accumulated power draw of 2.5A. The outlet voltage on the sockets is the same as the line voltage.

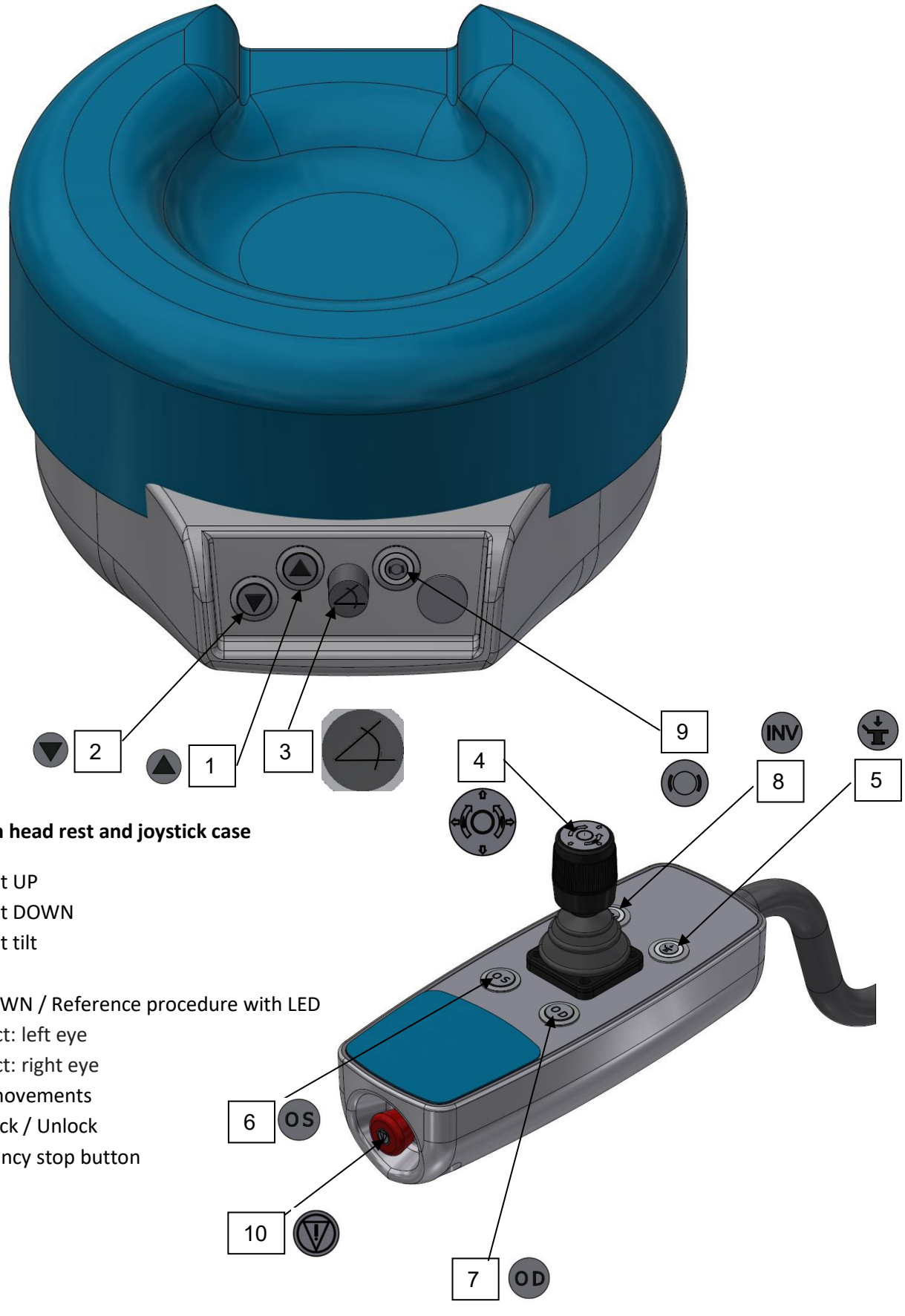
Attention: By connection any kind electrical equipment to one of these sockets the Patient Support System LSCneo changes it's state from a single medical device into a medical electrical system, see IEC 60601-1 chapter 16. The safety degree for the standalone product does no longer apply. All standards relevant to safety measures must be evaluated by the responsible (connecting) organization as IEC 60601-1 edition 3 or later, IEC 60950 or successor standard IEC 62368-1.



IEC power outlet

1-IEC sockets
2-pull out guard

7.2. Controls on head rest and Joystick case

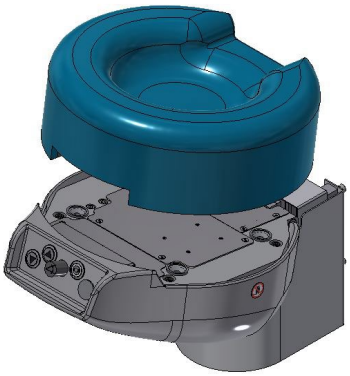


Controls on head rest and joystick case

1- Head rest UP
2- Head rest DOWN
3- Head rest tilt
4- Joystick
5- Auto-DOWN / Reference procedure with LED
6- Pre-select: left eye
7- Pre-select: right eye
8-Inverse movements
9-Swivel Lock / Unlock
10- Emergency stop button

7.2.1. Removal of head rest foam cushion

To remove the head rest cushion from the head rest, simply pull the snap lock ball heads out of the socket. To place the cushion on the head rest, apply gentle pressure to the cushion to lock the ball head snap locks into the sockets.



7.3. EAZY GO wheels (OPTION)

Authorized service technicians may use the detachable EAZY GO gear (optional) to move the Patient Support System LSCneo out of position if so required.

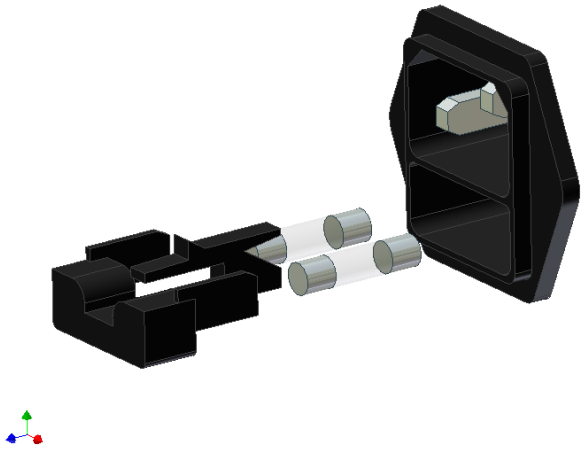
	Warning	The detachable gear is NOT approved for the TRANSPORT of people.

	Caution	Move/push the Patient Support System LSCneo with the foot end in front to mitigate the danger of any collisions and mechanical damages to the head rest.

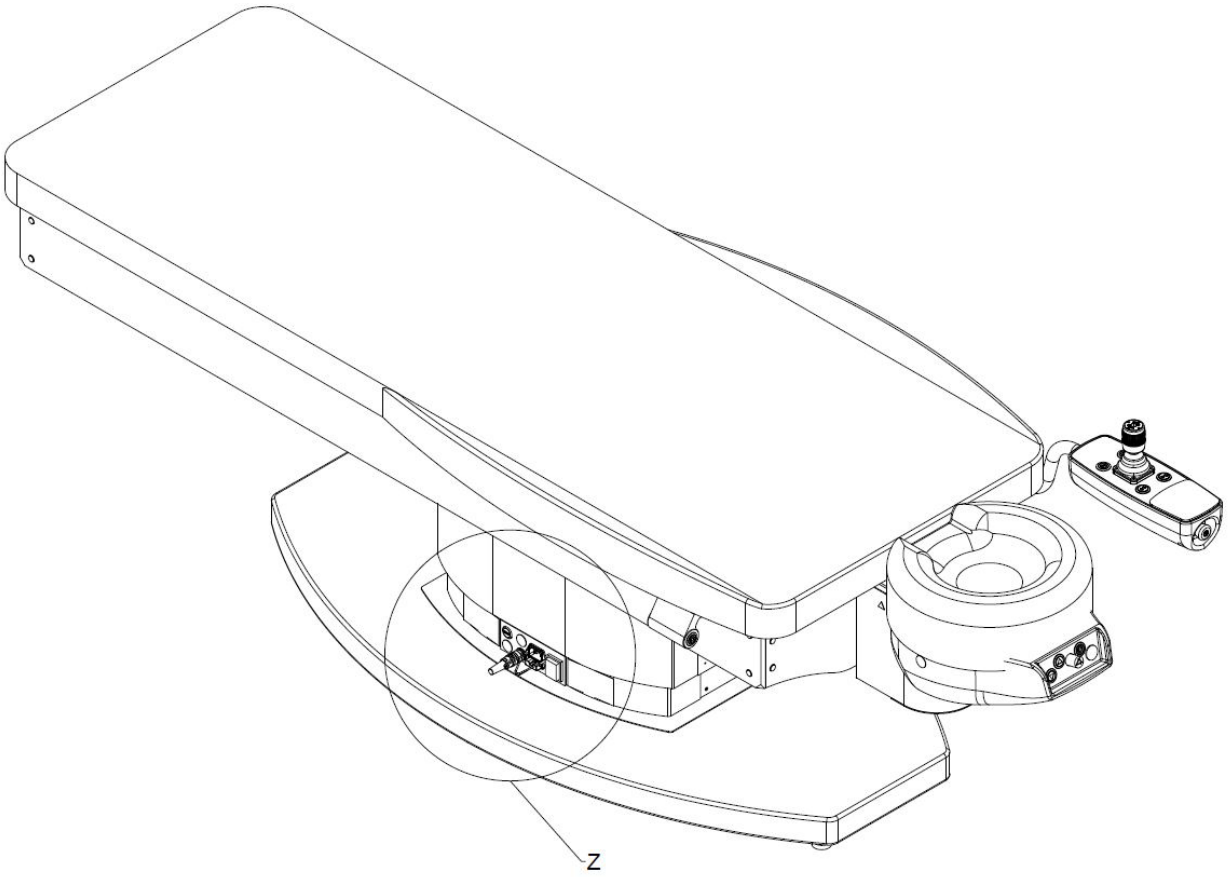
7.4. Change of fuses

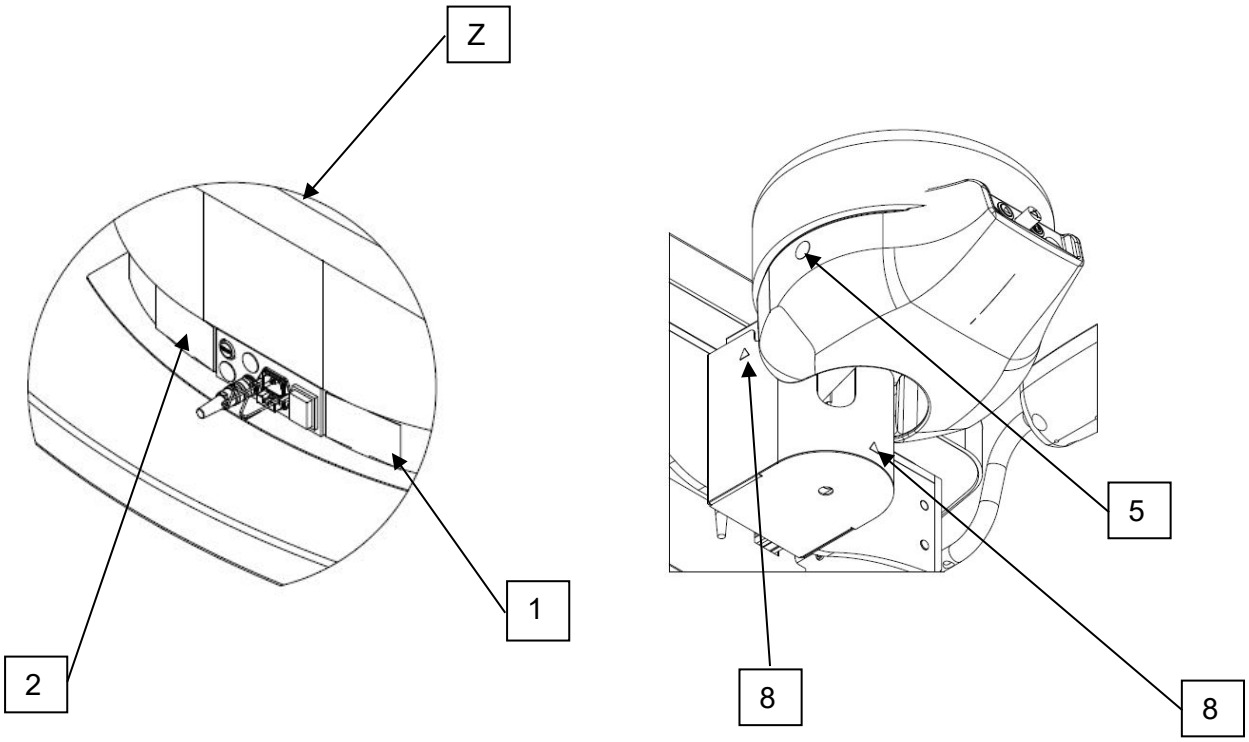
	Warning	Before changing the fuses, make sure the power cord is disconnected! Use only the fuses as indicated below. 100-240 VAC line voltage (2 X T 4.00 A/H 250VAC)

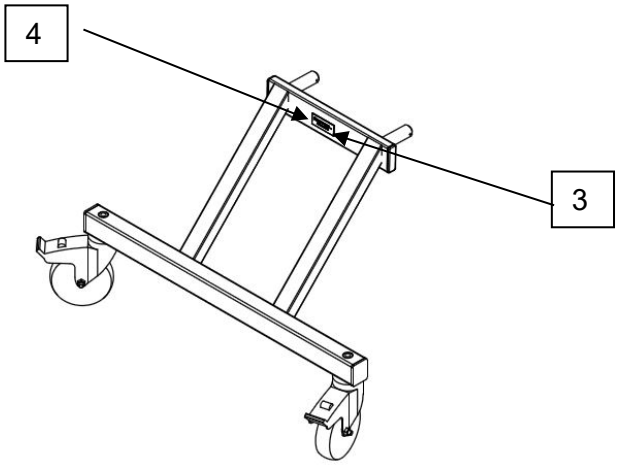
	Warning	If the new fuse burns again after the exchange, a major fault in the electrical system is present. Call service.

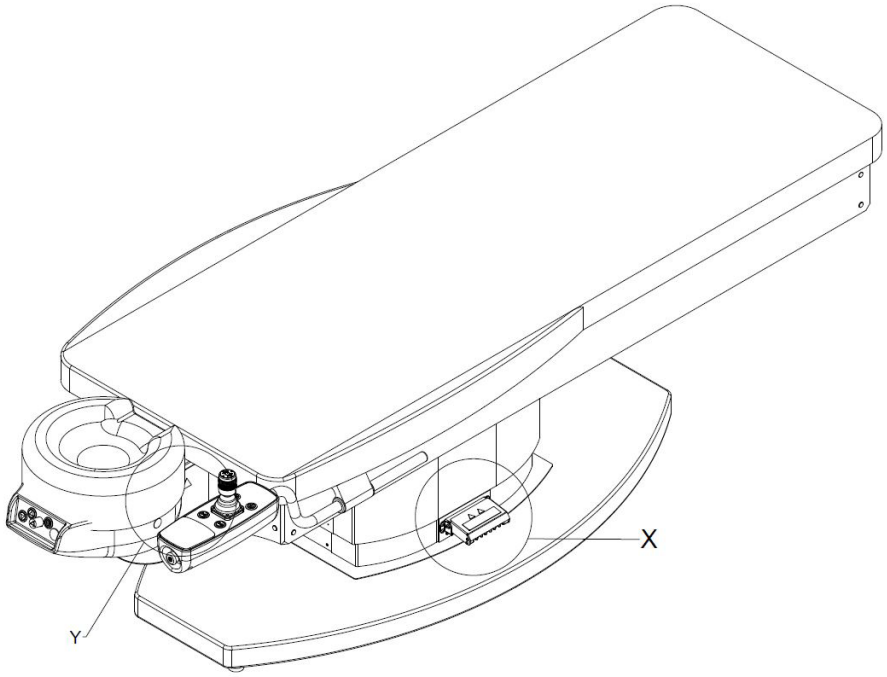


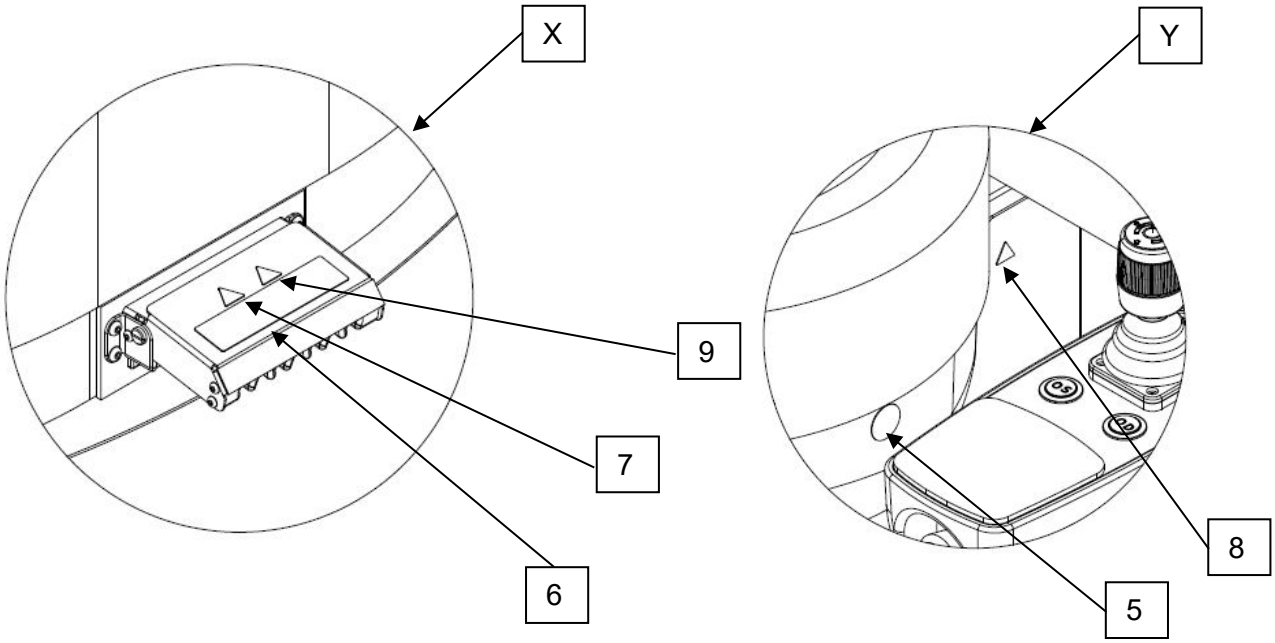
7.5. Safety information and informative labels on the Patient Support System LSCneo






4
3


X
Y


X
Y
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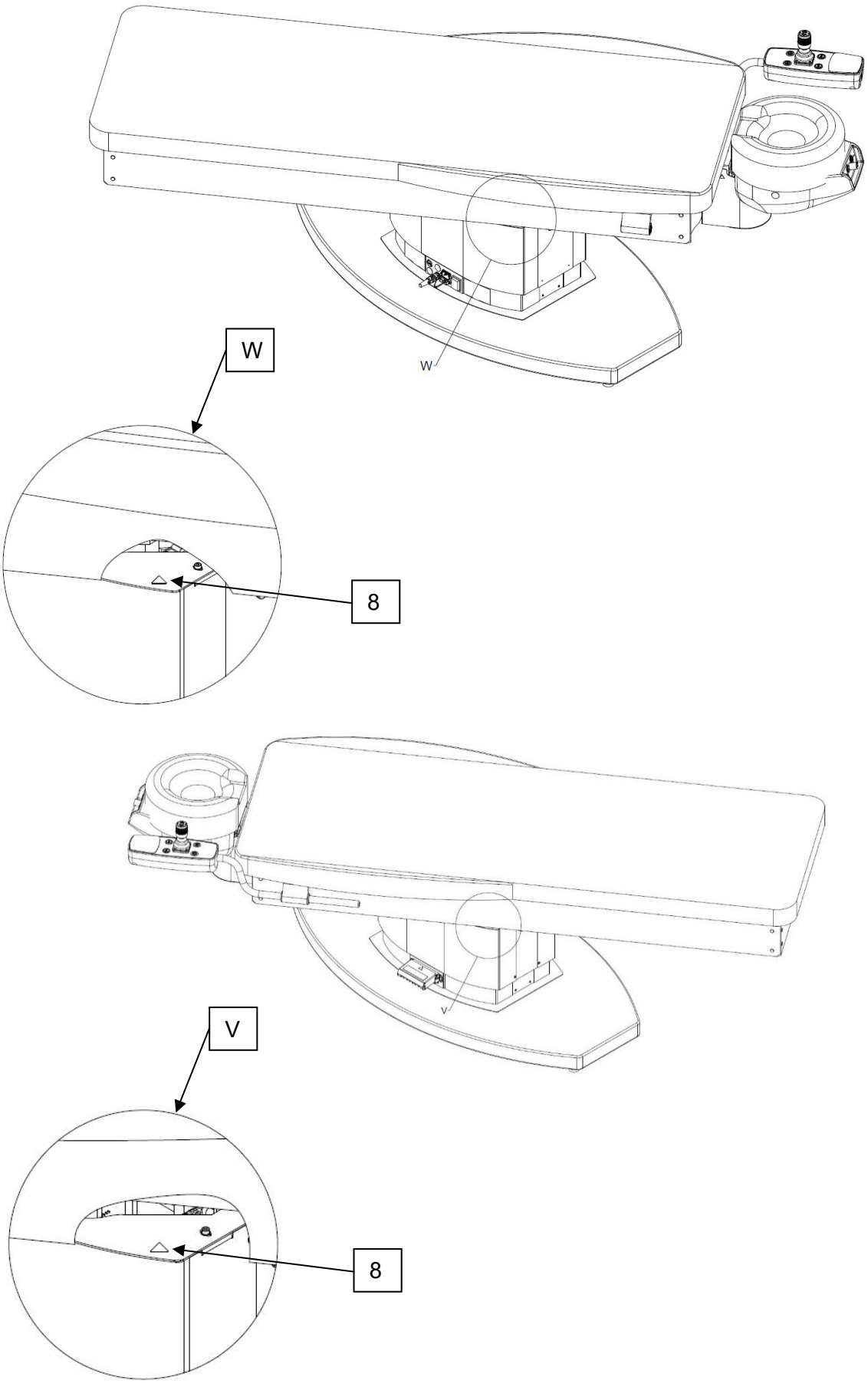
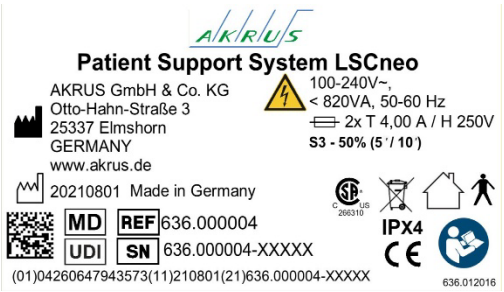
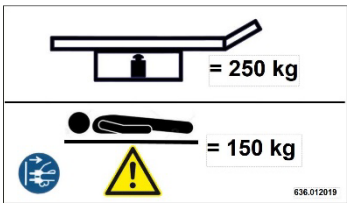
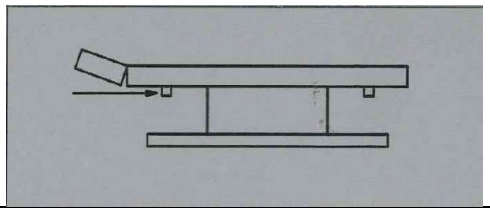
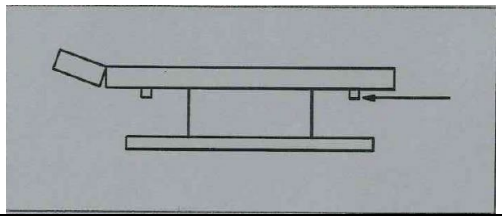
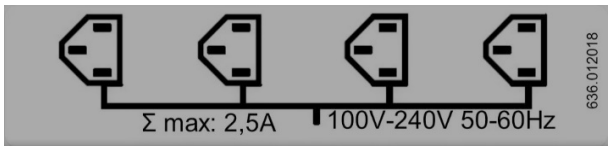

W
W
8
V
V
8

1	Product Label  	Manufacturer Date of manufacturing EU - Conformity label Application Type B in accordance with IEC 60601-1 AC voltage IPX4 Protection classification of housing (protected against splashing of water) use only indoors not general household waste fuses REF Reference number (catalog / part) SN Serial number MD Identifies product as a “Medical Device” UDI Identifies on the label the unique device identification code unique device identification code (Data Matrix and human read able) (01)04260647943573(11)210801(21)XXXXXXX Label “Read instructions for use“ Warning electrical hazard **S3 - 50% (5 ' / 10 ')** S3 = periodic intermittent duty. Duty cycle of electric motors meaning maximum 5 minutes activation time and minimum 10 minutes de-activation time CH REP Swiss authorized representative Certification mark: Indicates that the product was tested and has met the certification requirements for electrical, plumbing and/or mechanical products. File number 266310

2		Weight of Patient Support System LSCneo _____ Max. weight of patient  Information label “Disconnect main power plug “  Use with caution to prevent harm to patient, user or device
3		Position marking for gear position head end
4		Position marking for gear position foot end
5		Prohibition sign “Do not place any load exceeding load limitations “ DIN 4844-2001 Load placement > 200N is prohibited
6		Symbol Power outlet sockets Use leads to additional safety evaluations, see 7.1.3 of this instructions for use
7		Warning electrical hazard
8		Warning hand can be insured by squeezing
9		Caution handle with care

8. Operation of Patient Support System LSCneo

8.1. Set up and (re-)positioning of Patient Support System LSCneo

Use the alignment fixture to line up the Patient Support System LSCneo with the laser. Only trained and qualified service personnel is allowed to move the Patient Support System LSCneo in and out of position by using the detachable EAZY GO gear (optional) to move the Patient Support System LSCneo.

NOTE:

If electrical power is used to set up or remove the castors, the joystick for up – down movement is only available in the 35° CCW out position.

Make sure, all 6 studs have firm ground contact, and the Patient Support System LSCneo is not rocking on the floor. If necessary, unlock and adjust the studs with the 17 mm wrench provided with the product. (Wrench is placed inside the plastic pocket with this instructions for use). Secure the lock nuts when Patient Support System LSCneo is level and stable.

8.2. Switch ON and reference procedure.

To switch ON the Patient Support System LSCneo and connect the power outlet sockets to line power under normal conditions and after a temporarily loss of power proceed as below. For restart after the emergency button activation, refer to [8.6]

Switch on the main switch [4] first and check for the green light. If the green light does not come on, line power is not present. With the green light on, press and hold the start button [1] for approximately 2 seconds.

After pressing the start button, wait for 8-10 seconds until the LED on auto DOWN button starts flashing slowly. Press the auto DOWN button and the Patient Support System LSCneo will perform a short reference procedure of approx. 4 seconds. During the reference procedure the LED on the button will start flashing faster.

The steady green LED indicates the successful completion of the reference procedure.

The Patient Support System LSCneo is now ready for service.

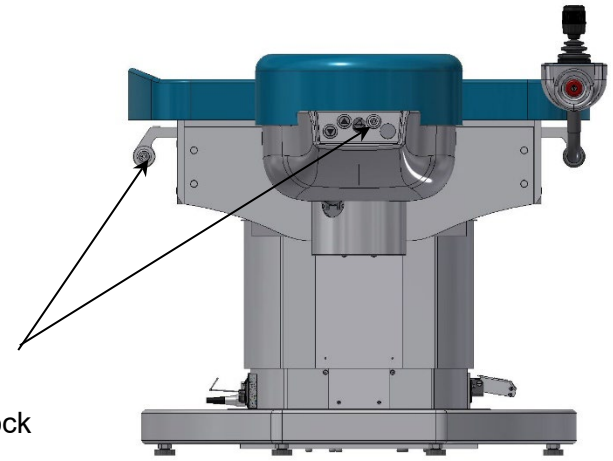
8.3. Rotation of the top

	Warning	Patient Support System LSCneo featuring a swiveling top may not be loaded in the extended position with an asymmetrical weight in excess of 70 kg at the foot or head end. Danger of tipping.

Patient Support System LSCneo featuring a swiveling top, the various stop positions are securely locked by lock bolt driven by an electric actuator. To unlock the bolt press any of the LOCK / UNLOCK buttons and swivel the top to the desired position. The LED on the button will indicate when the top is ready to move (LED on).

Note:
If any of the LOCK/UNLOCK buttons has been pressed in error, briefly push the joystick out of center position to reengage the locking mechanism.

Version: head rest and separate joystick box

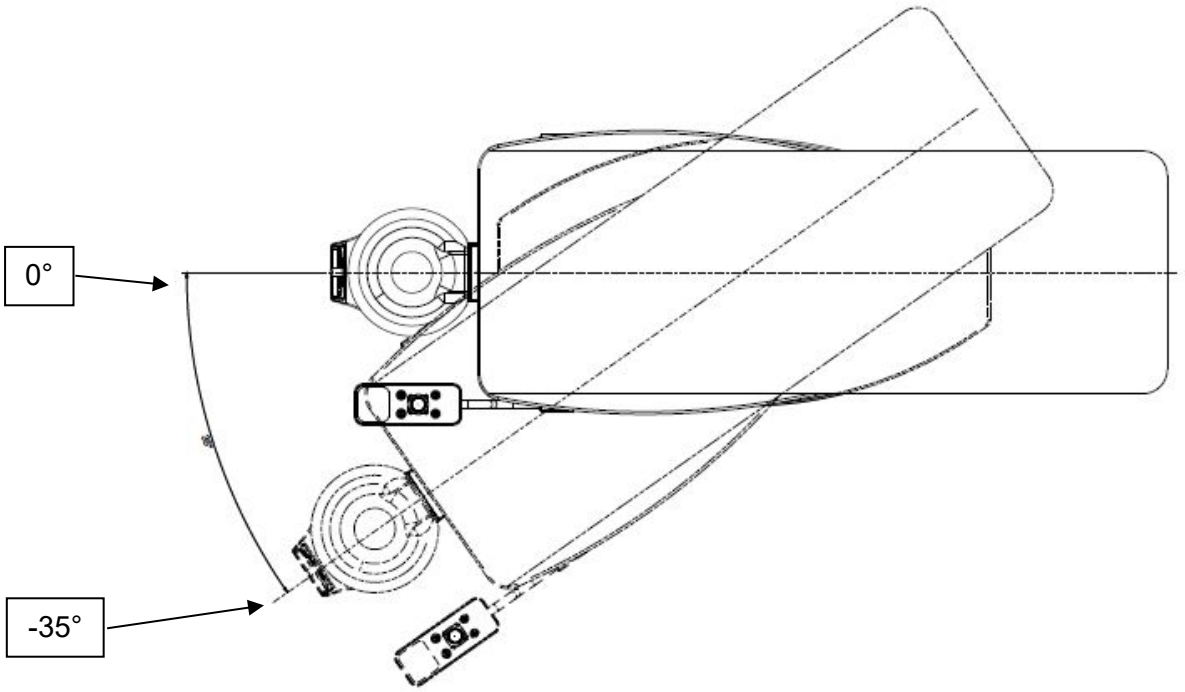


Push buttons:
Rotation Lock / Unlock

8.3.1. Patient Support System LSCneo operated with a laser unit.

The Patient Support System LSCneo is lockable in the following positions: 0° and 35°.

Version: 0°- 35° CCW (0° -> -minus 35°)



8.4. Adjustments of head rest

The headrest features two adjustment mechanisms, which are independent from each other. Both mechanisms allow setting up the headrest to support each patient individually.

8.4.1. Electric height adjustment

An infinitely variable actuator, controlled by two buttons located in the headrest panel, moves the headrest 50 mm up or down.

8.4.2. Mechanical head rest tilt ventral / dorsal and laser application

A push button, located on the headrest panel, releases a mechanical lock at the headrest allowing a ventral tilt of + 5° and dorsal tilt of – 20° from horizontal.

	Warning	Important for all lasers working with physical contact between the laser and patient's eye. Use of laser only in 0° position of Patient Support System LSCneo permitted. Never set up the head rest below the horizontal line for the procedure. In case of an emergency the 20° dorsal tilt will break the contact between the laser and the eye and assist to retrieve the patient from under the laser.

8.4.3. Emergency procedures, power failure or other technical failures.

Tilt head rest towards dorsal mechanically and break the contact between laser and eye. This way, the patient can escape from the laser by a mechanical feature in case of power failure.

8.5. Joystick

8.5.1. Joystick and electric head rest controls availability

On this model the joystick is available as described below.

Patient Support System LSCneo in center position, 0° lined up with base	**NO** joystick and electric head rest control functions available
Patient Support System LSCneo swivel out 35° CCW	**ALL** joystick and electric head rest control functions available

8.5.2. Handling of Analog joysticks

The analogue joystick features extremely precise speed and positioning control for all three axes. For high precision speed and directional control, it is important to move the joystick very slowly and evenly.

Control of Z, Y and X axes

Vertical, horizontal, and fwd / bwd movements of the Patient Support System LSCneo are controlled by corresponding movements on the Joystick. Simultaneous movements in different directions are available. The very soft acceleration and slow down features of the electrical motors allow a very precise positioning of the patient.

Note:

The **“tap technique”** used on digital Joysticks is **counterproductive for analog Joysticks** and impedes the optimal functions and superior features of an analogue joystick. Practice to familiarize yourself with an analog joystick to fully utilize the superior features.

8.5.3. Control of Z, Y and X axis

The Z, Y and X movements are controlled by corresponding movements on the joystick. To move the Patient Support System LSCneo up/down, twist the joystick cw/ccw. Simultaneous up/down and/or sideways movements are possible. The actuators feature a soft start stop function, which allows a very precise positioning of the patient.

8.5.4. Automatic Movements

8.5.4.1. Auto DOWN Movement

Upon completion of the procedure, press the auto down (homing) button to drive the patient to the egress position. To interrupt the Auto Down travel (emergency stop), simply just briefly push the joystick to any direction.

8.5.4.2. Preselect OS /OD

The buttons OS / OD (Chapter 7.2, figure pos.6+7) are located on the joystick panel and are clearly marked. The following features are available:

Patient Support System LSCneo is located at the lowest down (vertical) position.

- press button **briefly**; Patient Support System LSCneo will travel simultaneously in its longitudinal (Y) and across (X) direction to a preprogrammed position.

Patient Support System LSCneo is **not** located at the lowest down (vertical) level.

- press **and hold** button, Patient Support System LSCneo will travel simultaneously in its longitudinal (Y) and across (X) direction to a preprogrammed position

8.5.5. Inverse function INV

Pressing this button (Chapter 7.2, Figure pos. 8) will cause the motors for X and Y movements to travel to the opposite direction from joystick deflection. This feature will compensate the Kepler effect under a microscope.

To reset this function, just briefly depress the button again.

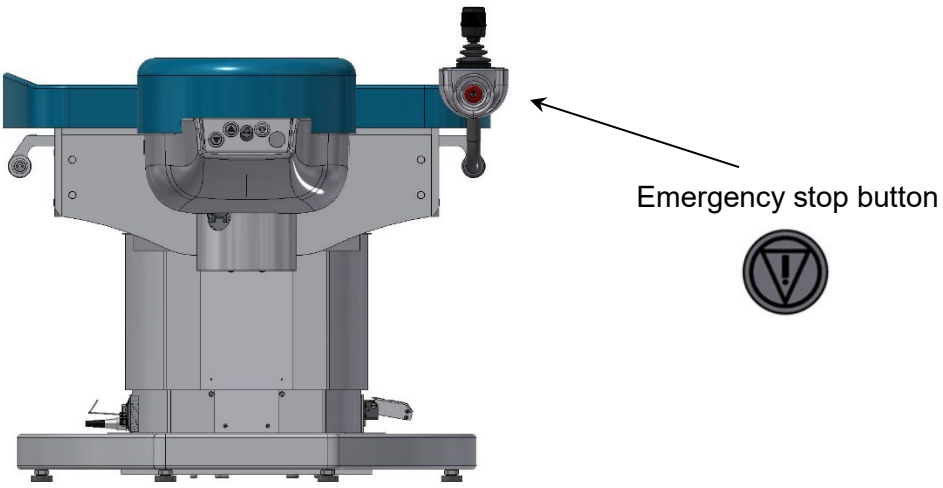
8.6. Emergency stop button and restart procedure.

In case of any emergency situation a red emergency stop button is located at the head end of the joystick case. Pressing the emergency button will disconnect all electrical functions of the Patient Support System LSCneo and the IEC power outlets. All movements of the Patient Support System LSCneo will stop immediately.

After rectifying the cause of the emergency situation reset the emergency button with a clockwise twist.

Restart procedure.

The main switch is still in the ON position, but the green light is not on. That is so by design. Leave the main switch in the ON position. After pressing the start button for a minimum of 2 seconds, the green light on the main switch will come on. Now perform the reference procedure [refer to 8.2].



8.7. Switching off procedure

To switch off the device press a rotation lock release button (8.3) and rotate the bed upper section into the (minus) -35° position. After locking in that position press the main switch. The light on the switch will go out and the Patient Support System LSCneo is switched off now.

8.8. Final test protocol

The final test report is not part of the list of deliverables because it remains with the service technician. Please, note the serial number and contact the manufacturer:

info@akrus.de

9. Cleaning and contamination protection

	Warning	Before any cleaning or maintenance work, disconnect the power cord.

- Contamination protection
  To protect the product against contamination by liquids, body liquids or other unwanted substances it is recommended to, while in use, cover the product with a nonsterile disposable impermeable cover sheet.
- Surfaces are resistant to all commonly used surface wipe off or spray disinfectants used for medical devices. Any appropriate alcohol-based disinfectant must not exceed the concentrations given for the following ingredients. Propanol=35% // Ethanol=25%.
- Do not attempt to sterilize the product.
- Clean only the external surfaces of the equipment using a damp cloth. In case of heavy stains do **not** use abrasive or aggressive materials other than common cleansers or detergents. Do not use ether, acetone, or concentrated acids.
- Make sure no water or cleaning detergents get inside of the equipment.
- To clean the upholstery surfaces, use a damp cloth and/or commonly used upholstery spray.
- Before resuming operation, allow sufficient time to dry.

10. Maintenance

The device is maintenance-free to the users.

Product is subject to the regular service intervals by a trained field technician. Refer to the current maintenance report. Contact your distributor's service technician at least annually or according to national legislations.

11. Product safety inspection

A product safety inspection is not required by manufacturer. However, user must adhere to any current national regulations governing the inspection requirements for medical devices of class I as medical electrical equipment.

12. Disposal of device

To be compliant with the current EU regulations and national regulatory requirements at the time of delivery, the product, specified on the bill of delivery, may not be disposed of as regular household waste or through the community waste disposal services.

For further information concerning the disposal of the device, please contact your local distributor or the manufacturer. Please also refer to the current internet publications of the manufacturer. In case of reselling the product or parts of the product, seller must inform the buyer about the fact, that the product must be disposed of in accordance with national regulatory requirements.

13. Technical data

Length over all	2040mm +/-20mm
Length upholstery	1690mm +/- 10mm
Width max.	700 mm ± 40 mm
Patient weight max.	150 kg

	636.000004
Range Z Main Motor (up/down)	115mm
Height min. Top upholstery	560+/-35 mm
Height max. Top upholstery (incl. head rest)	675 +/-20mm

Z Main motor up- down speed.	10.0 mm/s (±5mm) up 12.0 mm/s (±5mm) down
Range Z motor head rest (up / down)	50 mm
Z motor head rest speed.	12.0 mm/s (±5mm)
Range (X) left right (from center line)	110 mm / 55 mm left/right from centerline
Speed X motor (le / ri)	12.0 mm/s (±5mm)
Range (Y) fwd - bwd	290 mm
Speed Y motor (fwd-bwd)	12.0 mm/s (±5mm)
Duty cycle of electric motors	S3 - 50% maximum activation time: 5 minutes minimum de-activation time: 10 minutes

Electrical Data

Device electric safety class	I
Circuit voltage (std.)	100-240 VAC (±10%)
Nominal frequency	50Hz-60Hz
Power draw (stand by)	100 VA
Power draw incl. power outlets (max)	820 VA
Power outlets	4 X IEC (power draw max ∑ 2.5 A)
Standby power, bed only	100VA
Fuse F1	2 X T 4.00 A/H 250 V
Ingress Protection code	IPX4
Weight	approx. 250 kg
Temperature intended use	+15° / +35°C
Humidity intended use	0 - 50%
Ambient air pressure intended use /transport /storage	700 – 1060 hPa
Temperature Transport	-10°/ +50°C
Humidity transport	0 - 95 %
Temperature storage	-10°/ +50°C
Humidity storage	0 - 95 %

14. Trouble shooting

Fault / Malfunction	Possible cause	Corrective action
No function at all Main switch **not** illuminated	Power cord not connected	Connect power cord
	Main switch not ON	Main switch ON, watch for green light on switch
	Main switch ON	Restart after emergency button activation. [ref. to 8.6]
	Power failure in main circuit	Call service
	Defect fuse	Change fuse (ref. to 7.4)
No function Power on light illuminated	No reaction or indication of ready mode after switching ON	Switch OFF, wait for 30 seconds, switch ON again and wait for completion of booting procedure (ref. to8.2)
	Reference procedure not performed or not completed	Start and complete reference procedure (ref to 8.2)
	Patient Support System LSCneo is not positioned in a defined “active work” position.	Move Patient Support System LSCneo and lock into a defined „active work” position.
Other electrical or mechanical malfunctions		Call service technician

15. Electromagnetic compatibility EMC

Electromagnetic compatibility

CAUTION - RISK OF ELECTROMAGNETIC INTERFERENCE RADIATION

The following EMC precautions and operating requirements do apply.

The Patient Support System LSCneo is not intended to be used next to HF-surgical equipment.

The use of accessories, transducers and cables that are not specified in these instructions or sold by Akrus as spare parts, may cause increased emissions or decreased immunity of the unit.

Do not use portable or mobile RF communications equipment, they may have a negative effect to the Patient Support System LSCneo. Do not use cell phones or other devices that do not comply with the EMC class B CISPR 11 in the near vicinity of the device.

It cannot be excluded that an adverse electromagnetic interference radiation may cause an interruption or abort of the Patient Support System LSCneo's functions.

Specific electromagnetic compatibility (EMC) precautions apply to the Patient Support System LSCneo. To avoid any EMC problems, do only operate the Patient Support System LSCneo in accordance with this user manual. Use only original spare parts and components supplied by Akrus. For installation, commissioning and service an authorized service technician must follow the service manual.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it may 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.

Guidance and manufacturer's declaration - electromagnetic interference		
The Patient Support System LSCneo is intended for use in the electromagnetic environment specified below. The customer or the user of that Patient Support System LSCneo should ensure that it is used in such an environment. No hazards due to loss of essential performance can be expected due to no essential performance being given, but basic safety is always fulfilled. Meaning no movement after error of first degree. This represents essential performance under IEC 60601-2-46.		
Emitted interference measurements	**accordance**	**Electromagnetic environment - guidance**
Emissions harmonics IEC 61000-3-2	class A	The Patient Support System LSCneo is suitable for use in all areas, including those in the residential area and those that are directly connected to the public supply network that supplies buildings used for residential purposes.
Emission of voltage fluctuation/flicker IEC 61000-3-3	Right match	

Contacted RF emissions CISPR 11	Group 1 class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Radiated RF emissions CISPR 11	Group 1 class A	

Guidance and manufacturer's declaration - electromagnetic immunity

The Patient Support System LSCneo is intended for use in the electromagnetic environment specified below. The user of the Patient Support System LSCneo should ensure that it is used in such an environment.
No hazards due to loss of essential performance can be expected due to no essential performance being given, but basic safety is always fulfilled. Meaning no movement after error of first degree. This represents essential performance under IEC 60601-2-46.

immunity tests	**IEC 60601 test level**	**level Conformity level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) 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 or concrete or ceramic tiles. If are floors with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical interference sizes/burst to IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output lines	The quality of the supply voltage should be that of a typical commercial or hospital environment.
Surges / surging according to IEC 61000-4-5	±1 kV outer conductor outer conductor ±2 kV voltage phase conductor Earth	±1 kV outer conductor outer conductor ±2 kV voltage phase conductor Earth	The quality of the supply voltage should be that of a typical commercial or hospital environment.
Voltage-breaks, short-time interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	< 5% UT (> 95% voltage drop in UT) for ½ period 40% UT (60% voltage drop in UT) for 5 periods 70% UT (30% voltage drop in UT) for 25 periods < 5% UT (> 95% voltage drop in	< 5% UT (> 95% voltage drop in UT) for ½ period 40% UT (60% voltage drop in UT) for 5 periods 70% UT (30% voltage drop in UT) for 25 periods < 5% UT (> 95% voltage drop in	The quality of the supply voltage should be that of a typical commercial or hospital environment.
The frequency of mains (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should comply with the typical values, as they are found in the commercial and hospital environment.

Note: UT is the A.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity			
The patient reclining is intended for use in the electromagnetic environment specified below. The customer or the user of the patient couch should ensure that it is used in such an environment. No hazards due to loss of essential performance can be expected due to no essential performance being given, but basic safety is always fulfilled. Meaning no movement after error of first degree. This represents essential performance under IEC 60601-2-46.			
immunity tests	**IEC 60601 test level**	**level Conformity level**	**Electromagnetic environment - guidance**
Conducted RF interference sizes according to IEC 61000-4-6	3 V RMS 150 kHz to 80 MHz	3 V	Portable and mobile radio equipment should be used in any lower distance to the Patient Support System LSCneo including cables than the recommended separation distance calculated from the equation applicable to the frequency. **Recommended protective distance** $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ for 80 MHz to 800 MH $d = 2,3 \sqrt{P}$ for 800 MHz to 2.5 GHz where P is the power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). The field strength of stationary radio transmitters should be in accordance with a site survey[a], less than the compliance level in each frequency range. [b] Errors are possible in the vicinity of devices that carry the following figurative sign. 
Radiated HF disturbances according to IEC 61000-4-3	3V / m 80 MHZ to 2.7 GHz	3 V/m	
+ Table 9	27 V/m (385 MHz / 18 Hz PM)	27 V/m	
	28 V/m (450 MHz / 5 kHz Hub, 1 kHz Sin. FM)	28 V/m	
	9 V/m (710/745/780 MHz / 217 Hz PM)	9 V/m	
	28 V/m (810/870/930 MHz / 18 Hz PM)	28 V/m	
	28 V/m (1,72/1,845/1, 97/2,45 GHz / 217 Hz PM)	28 V/m	
	9 V/m (5,24/5,5/5,785 GHz / 217 Hz PM)	9 V/m	

Annotation 1: At 80 MHz and 800 MHz, the higher frequency range applies. Annotation 2: These guidelines may be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection of from structures, objects and people.			
a. The Field strengths of from fixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio, AM and FM radio - and television, can be predicted theoretically with accuracy. To assess the electromagnetic environment due to the stationary transmitters, a study of electromagnetic phenomena of the site should be considered. If the measured field strength in the location at which the Patient Support System LSCneo is used, exceeds the compliance level, the patient lying should be observed to demonstrate the intended function. If abnormal performance is observed, additional measures may be required such as a modified alignment or relocating the Patient Support System LSCneo. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V / m.			
Imunnity to proximity magnetic field in the frequency range 9kHz – 13.56kHz IEC 61000-4-39	30 kHz - Testlevel: 8 A/m - Modulation: CW 134.2 kHz - Testlevel: 65 A/m - Modulation: PM 2.1 kHz 13.56 MHz - Testlevel: 7.5 A/m - Modulation: PM 50 kHz	unchanged	Not applicable

Recommended separation distances between portable and mobile RF communications equipment and the Patient Support System LSCneo

The Patient Support System LSCneo is intended for use in an electromagnetic environment in which the RF disturbances are controlled. The customer or the user of the Patient Support System LSCneo this can help prevent electromagnetic interference by communications equipment (transmitters) and the Patient Support System LSCneo - depending on the output power of the communications equipment, as shown below specified - maintaining a minimum distance between portable and mobile HF devices.

Power of transmitter W	Protection distance, depending on the frequency of transmitter 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 whose maximum power rating in the table above is not specified, the recommended separation distance can be determined d in meters (m) using the equation, which belongs to the respective column, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

Annotation 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Annotation 2: These guidelines may be applicable in all cases. The spread electromagnetic-damn size is affected by absorption and reflection of from structures, objects and people.

15.1. Synopsis of power supply cables

The following power supply cables are approved in accordance with the relevant standards:

Part No. (Akrus)	Use in country/ area
636.012070	Power supply cable "US"
636.012071	Power supply cable "UK"
636.012072	Power supply cable "Swiss"
636.012073	Power supply cable "Brasil"
636.012074	Power supply cable "Chinese"
636.012075	Power supply cable "EU"
636.012076	Power supply cable "India"
636.012077	Power supply cable "ISR"