

SURGEON CHAIR

ak 480




Instructions for use

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1 General information


	IMPORTANT
	<p>A thorough understanding of this IFU is essential for use of the SURGEON CHAIR ak 480. Please familiarise yourself with its contents, paying special attention to instructions on how to use the device safely.</p> <p>Please retain this IFU for future reference.</p>

1.1 Copyright

© The distribution and reproduction of this document, and the use or dissemination of its contents are strictly prohibited unless explicitly authorised in writing by the manufacturer. Any infringement of this shall result in payment for damages.

If a patent is granted or a utility model is registered, all rights are reserved.

1.2 Exclusion of liability

	WARNING
	<p>This device must be assembled, operated and used exclusively in accordance with its intended purpose and pursuant to country-specific regulations, generally recognised codes of practice and provisions on occupational safety and accident prevention.</p>

Any improper or unauthorised use or maintenance, or modifying the product without the manufacturer's express written agreement excludes any liability on the part of the manufacturer.

1.3 Provisions and standards

This device complies with the following Directives:

- RL 2006/42/EC
- RL 2011/65 EU

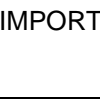


This device meets the requirements of 2006/42/EC and its implementation in Germany under the German Machinery Directive.



Users must observe all statutory provisions stipulated by accident prevention regulations.

1.4 Explanation of symbols used

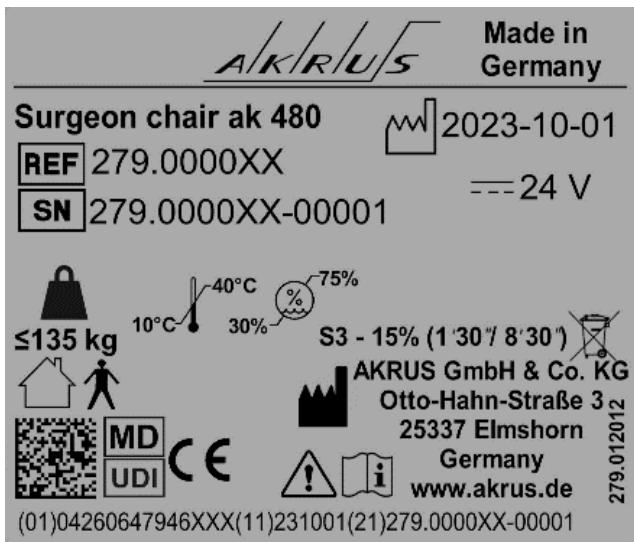
1.4.1 Instructions for use (IFU)

Please take particular care to read and comply with all of the safety precautions and information in the instructions for use.







	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.
	Indicates a required action.








1.4.2 Symbols used



Nameplate for SURGEON CHAIR ak 480




Symbol	Meaning
	Manufacturer
	Date of manufacture (YYYY-MM-DD)
	Catalogue number
	Serial number
	Label identifying the chair as a medical device
 <small>(01)04260647946000(11)210301 (21)279.012100-000000</small>	Device identification (data matrix and plain text)

Symbol	Meaning
	Indicates the maximum permitted weight the product can support.
	General warning sign
	Indicates that the product can only be used indoors
	Applied part type B, in accordance with IEC 60601-1
	Indicates that the product can only be operated by direct current from the battery supplied
S3 – 15% (1' 30" / 8' 30")	Specifying the nominal operating time S3 15% means that in any 10-minute period, the lifting column can only be operated for 1.5 minutes and must then cool down for the remaining 8.5 minutes.
	Warning: crushing hazard
	Consult instructions for use.
	CE marking – symbol indicates compliance with Machinery Directive 2006/42/EC and the Regulation on medical devices 2017/745/EC
	Disposal in the EU: do not dispose of with household waste
	Indicates permissible minimum and maximum relative humidity levels during use
	Indicates minimum and maximum temperatures to which the product can be safely exposed
	Protect from rain
	Protect from sunlight
	Indicates minimum and maximum temperatures to which the product can be safely exposed


Symbol	Meaning
	Indicates permissible minimum and maximum relative humidity levels during transport and storage
	Indicates permissible minimum and maximum atmospheric pressure during transport and storage
	Fragile: handle with care
	This way up
	Do not stack
	Do not open with a sharp blade
	Electric shock


1.5 Requirements for safe operation

Please familiarise yourself with the contents of this IFU before putting into service the device for the first time.

	HAZARD
	Please check that the product is working correctly before every use.
	WARNING
	The medical device may only be installed, operated and maintained by personnel who have received detailed training and have the necessary knowledge and experience. Please also refer to the national qualification guidelines which apply in your country.
	The product must not be used in potentially explosive atmospheres. The product must not be used with volatile anaesthetics or volatile anaesthetics with oxidants.
	CAUTION
	Modifications authorised by the manufacturer may only be carried out by personnel authorised by the manufacturer. Any modifications not mandated or authorised by the manufacturer may cause malfunctions and expose personnel to hazards.
	Servicing and repairs to this product may only be carried out by personnel authorised by the manufacturer.
	The product must not be used as a holder for surgical equipment (e.g. surgical instruments, clothing, IV bags or other items).
IMPORTANT	IMPORTANT
	Users require no training to operate the product.
	The product must not be used or stored in damp rooms, and under no circumstances in rooms with dripping, splashing or spraying water.
	The product may only be opened by persons authorised by the manufacturer.

2 Product lifetime and warranty

	WARNING
	Hazards due to operating errors
	The medical device may only be installed, operated and maintained by personnel who have received detailed training and have the necessary knowledge and experience. Please also refer to national qualification guidelines.

	CAUTION
	General hazards
	The expected lifetime of the product is 8 years. Product lifetime and the manufacturer's warranty are subject to compliance with all stated conditions and regulations.
	In consideration of the potential associated risks, the medical device has been developed and produced with the assumption that the product will have a useful life of 8 years. Modifications to the product, or failure to comply with the manufacturer's specifications may significantly reduce the product's expected lifetime, or significantly increase the risks of using the product.
	It is the responsibility of the operator (institution) to follow the manufacturer's instructions and to assess the risk/benefit ratio taking into account the product lifetime that has elapsed. When disposing of the product, e.g. at the end of its useful life, please do so in compliance with the requirements in Section 14 Disposal.
	This product may only be operated in compliance with the specifications for its intended use. If the medical device shows signs of wear, contact the distributor to have it serviced.

3 Contents at delivery

The SURGEON CHAIR ak 480 is delivered with the following items:


Item	Number
SURGEON CHAIR ak 480	1
Charging station and power cable	1
Battery	1
Quality test report	1
Instructions for use (IFU)	1

4 Intended purpose

The SURGEON CHAIR ak 480 is a chair that provides support for medical work carried out while seated. This excludes surgical interventions in the field of cardiology.

5 Intended use

- Use in operating theatres
- The product is suitable for use in immediate proximity to patients
- The SURGEON CHAIR ak 480 is designed to support a maximum weight of 135 kg
- The SURGEON CHAIR ak 480 is not certified for transporting people
- Any use other than the stated intended purpose is prohibited; the product must be used for its intended purpose

	HAZARD
	The SURGEON CHAIR ak 480 can support a maximum weight of 135 kg


	CAUTION
	The SURGEON CHAIR ak 480 is not certified for transporting people

6 Putting into service


The medical device is delivered fully assembled. If the delivery includes options or accessories, please refer to the Troubleshooting Guide (available to the distributor's qualified service technicians) for instructions on how to install or attach these parts correctly.


No further assembly or calibration is required to operate this medical device.

7 Checks before use

	HAZARD
	Before every surgical procedure it is essential to check that the SURGEON CHAIR ak 480 is fully functional.
	Particular attention should be paid to ensuring that the armrests are sufficiently stable. See Section 10.7 Armrests
	If any wear and tear is visible on the medical device, it must be repaired before use. See Section 12 Maintenance and repairs.

8 Electrical connections


	WARNING
	Electric shock
	The user/third person must not touch patients while in contact with the connections for the SURGEON CHAIR ak 480.
	The medical device is only free from electric current when the battery is disconnected.

	CAUTION
	The exact position of the battery or the battery charging unit is described in the relevant sections of this IFU (see Sections 0 and 0).
	Only the power cable supplied or one specified by the manufacturer can be used to connect the charging station to mains electricity.

9 Description of the device

9.1 Battery


The electric motor in the SURGEON CHAIR ak 480 is powered by a rechargeable battery. The battery has a capacity of approx. 40 operations per charging cycle when used with a typical load profile.

	CAUTION
	Keeping a spare, charged battery is recommended.

Please handle the battery with care and caution. Incorrect handling, as described below, can significantly damage or even destroy the battery:

- Total discharge
- Drops (even from low heights)
- Short-circuiting the terminals

9.2 Battery, recharge intervals

	CAUTION
	The battery should be charged approximately every 3 days by the user or maintenance staff, or daily if used intensively (> 30 uses/day). It can be charged overnight or at weekends: the battery cannot be damaged by overcharging, so does not need to be removed from the charging unit once fully charged.

9.3 Battery charging station

The charging station is wall-mounted with 2 screws. It is important to mount the charging station vertically, so that gravity holds the battery contacts securely onto the terminals on the charger.

The charging station can detect the power supply level. It is suitable for voltages from 100 volts to 240 volts at 50/60 Hz. A green LED indicates it is ready to charge.

Charging can take up to 4 hours, and is indicated by a yellow LED. When charging is complete, this LED turns off. The battery cannot be damaged by overcharging, so it does not need to be removed from the charging unit when charging is complete.



Charging station and power cable



ON = power ON
CHARGE = battery CHARGING



Vertical mounting
of charging station and battery



CAUTION

In the cases below, the battery may be faulty if the ON LED is lit and:

- (1) the CHARGE LED does not come on
- (2) the CHARGE LED flickers
- (3) the battery is empty soon after charging
- (4) the battery is not fully charged after even a long charging time (> 4h).

If any of the above occur, please replace the old battery with a new battery. Please contact your local Akrus authorised distributor.

9.4 Battery holder

The battery holder is easy to access on the back of the motor column. There is a recessed handle on the top of the battery. To remove the battery from the holder, gently pull on the recessed handle. To insert the battery, push it gently into the holder until you hear a click. It is now locked into place.




10 Using the SURGEON CHAIR ak 480


10.1 Ready for use

The SURGEON CHAIR ak 480 is always ready for use with a charged battery. It does not have a main switch. See Section 10.3 Up/down foot-controlled switch.


for how to use the foot-controlled switch.

	HAZARD
	Please check that the product is working correctly before every use.

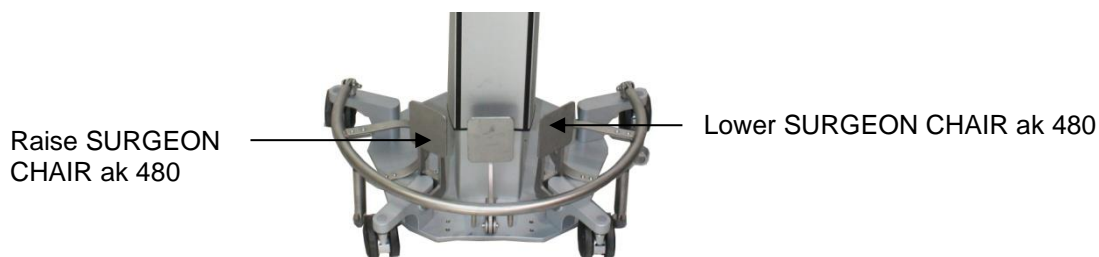
10.2 Motor operating time

	CAUTION
	The electric motors are designed for brief operation. In any 10-minute period, the lifting column can only be operated for 1.5 minutes and must then cool down for the remaining 8.5 minutes. Prolonged operation while the user is seated can cause overheating and permanent damage.

10.3 Up/down foot-controlled switch

	WARNING
	Electric shock
	Do not touch the patient while adjusting the height


Chair height is adjusted using two separate, heel-operated switches located above the foot ring. Press gently with the heel to move the chair to the desired height.



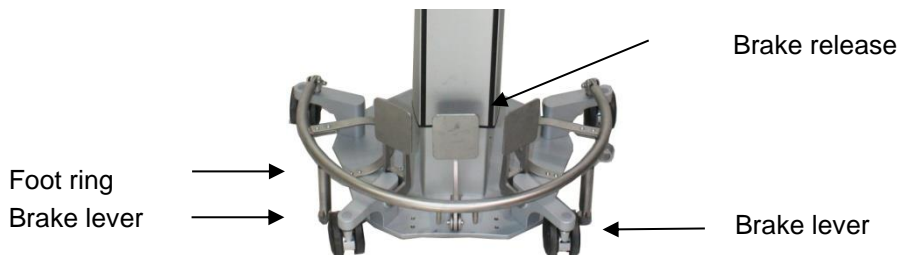
10.4 Castors and wheel brake

The SURGEON CHAIR ak 480 has 5 smooth-running double castors. The castors make manoeuvring the SURGEON CHAIR ak 480 effortless.

	CAUTION
	The SURGEON CHAIR ak 480 is not certified for transporting people

	CAUTION
	Danger of tipping When moving the SURGEON CHAIR ak 480 over a ridge in the floor or a door threshold ≥ 20 mm, pull the SURGEON CHAIR ak 480 by its backrest. This reduces the risk of tipping.

The SURGEON CHAIR ak 480 has one central brake. To apply the brake, gently depress the foot ring until the lock clicks into place. To release the brake, press heel gently against the centre foot plate.



10.5 Adjusting the seat

The seat can be adjusted in two practical ways:

- The seat can move forwards and backwards (Section 10.5.1)
- The seat can be horizontal or tilted by 10° (Section 10.5.2)

10.5.1 Adjusting the sliding seat (optional function)

The optional sliding seat allows the seat to be moved forwards and backwards by approx. 120 mm. The release lever is located under the seat. It is easy to operate with your lower leg and without looking down. Release the lock by pushing backwards. Once in the desired position, release the lever and the seat is locked in position.



Release lever



Seat forward and back

10.5.2 Adjusting the seat tilt angle

The seat tilt can be adjusted by approx. 10°. The tilt lever is located under the seat.



Release lever



Seat horizontal and tilted by 10°

10.6 Backrest

The backrest can be adjusted in three ways:

- Adjusting the tilt angle (Section 10.6.1)
- Adjusting the height (Section 10.6.2)
- Adjusting the lumbar support angle (Section 10.6.3)

10.6.1 Adjusting the tilt angle

The lever to adjust the backrest tilt angle is located under the seat. To allow the backrest to tilt freely, lift the lever to the highest horizontal position. To lock the backrest at a specific angle (see diagram), push the lever down to its lowest position.



Release lever



Backrest can tilt forwards and backwards

10.6.2 Adjusting the height

Use the lever at the base of the backrest to adjust backrest height.

- In horizontal position: backrest can be moved up and down
- In vertical position: backrest is locked



Release lever to adjust backrest height

10.6.3 Adjusting the lumbar support (optional function)

To adjust the angle of the lumbar support, use the adjustment screws on the back of the backrest.



Adjustment screws to adjust the angle of the lumbar support

10.7 Armrests

The SURGEON CHAIR ak 480 can be fitted with different arm rests. They can be adjusted very precisely to meet the surgeon's ergonomic needs. The armrest support brackets can be swivelled and rotated.



CAUTION

Always **lock the different armrests sufficiently tightly** after making any adjustments to prevent them from moving accidentally.



Support brackets

10.7.1 Standard armrests

Standard armrests can be adjusted in height. In addition to the support bracket swivelling, they can be swivelled around the pivot point on the mounting.



10.7.2 Multi-articulated armrests

Multi-articulated armrests allow unlimited armrest adjustments, and therefore any ergonomic position the user wishes, or needs to operate. To adjust the armrests, first release the easy-access locking handles. Use the locking handles to lock the armrests in position.

10.7.3 Adjusting longitudinal armrest position

The levers on the side of the armrests release the armrests so they can slide forwards or backwards by approx. 20 cm. Use the levers to lock the armrests in position.



Release lever



Sliding the armrest backwards and forwards

10.7.4 Tilting the armrest

Use the lever under the ball head to tilt the arm rest up or down.



Release lever



Tilting the armrest

10.7.5 Adjusting armrest height

Use the twist knob on the support bracket to adjust armrest height and to rotate it around the pivot point.




Twist knob on lower bracket



Adjusting armrest height

11 Equipment care and protection against contamination

	WARNING
	Contamination hazard
	Please follow the processing instructions to avoid the risk of contamination.

11.1 Warning notice

IMPORTANT	IMPORTANT
	Before using the chair for the first time, it must be prepared according to these instructions.
	With high-risk patients, protection against contamination is recommended to protect the product from contamination by liquids, bodily fluids or other undesirable substances.
	Use the protective equipment recommended by the cleaner/disinfectant manufacturer during processing.
	Never use solvents or abrasion (scouring). The resistance of the fabrics used against aggressive chemicals depends on numerous factors, such as: <ul style="list-style-type: none"> • Physical state of the chemicals (solid, liquid or gaseous) • Temperature • Concentration • Duration of contact In some cases, a combination of chemicals can cause damage, even if the chemicals are individually safe.
	During processing, care must be taken to ensure that no liquids get into the chair.
	It is not intended for storing instruments or other medical devices.

11.2 Processing restrictions


The SURGEON CHAIR ak 480 must be cleaned at regular intervals in line with the surface disinfection hygiene plan. The chair must be prepared before each new use.

The chair cannot be processed automatically.

The chair cannot be sterilised.


Its estimated useful life is 8 years. If early signs of wear and tear appear, stop using the chair.

11.3 Processing instructions

	WARNING
	Electric shock
	The battery must be removed before the chair is cleaned. The chair must be completely dry before the battery is reinserted.

Preparations before cleaning	Remove the battery from the SURGEON CHAIR ak 480
Cleaning	<p>For manual cleaning, use ready-to-use “Cleanisept Wipes Maxi” by manufacturer Dr. Schumacher GmbH. Please proceed as follows:</p> <ol style="list-style-type: none"> 1. Follow the instructions from manufacturer Dr. Schumacher on using personal protective equipment. 2. Clean visibly contaminated surfaces with a CLEANISEPT WIPE and remove contamination. Dispose of the wipe. 3. Wipe surfaces with CLEANISEPT WIPES until fully wetted. Allow to dry for the full contact time. 4. According to VAH, the full contact time is 1 minute. 5. Discard the used wipe and begin disinfection.
Disinfection	<p>For manual disinfection with wipes, use ready-to-use “Cleanisept Wipes Maxi” by manufacturer Dr. Schumacher GmbH. Please proceed as follows:</p> <ol style="list-style-type: none"> 1. Follow the instructions from manufacturer Dr. Schumacher on using personal protective equipment. 2. To disinfect surfaces, wipe with CLEANISEPT WIPES until fully wetted. Allow to dry for the full contact time. 3. According to VAH, the full contact time is 1 minute.
Drying	<p>Allow the chair to dry completely before use.</p> <p>Do not replace the battery until the chair is completely dry</p>
Maintenance and checks before use	<p>No maintenance is required. The product is maintenance free. See Section 12 Maintenance and repairs.</p> <p>For how to check the chair before use, see Section 7. Checks before use</p>
Packaging	None – n/a
Storage	None – n/a
Additional information	None – n/a
Manufacturer's contact details	<p>Manufacturer of Cleanisept Wipes Maxi: Dr. Schumacher GmbH Am Roggenfeld 3 34323 Malsfeld post@schumacher-online.com www.schumacher-online.com</p>

12 Maintenance and repairs

	CAUTION
	Modifications authorised by the manufacturer may only be carried out by personnel authorised by the manufacturer. Any modifications not mandated or authorised by the manufacturer may cause malfunctions and expose personnel to hazards.
	Servicing and repairs to this product may only be carried out by personnel authorised by the manufacturer.

No maintenance by the user is needed on the SURGEON CHAIR ak 480.

The following spare parts can be replaced by the user or maintenance personnel if they show signs of wear:

Description	Order no.
Bumper (2 units)	320-210
Battery unit	100-925
Charger	100-924


If repairs by the distributor's maintenance staff or service technicians are required, the Troubleshooting Guide will provide all necessary information.

13 Safety inspections

The manufacturer does not require any safety inspections of this product.

Any statutory safety inspections in different countries are based on national regulations for Class I medical devices in their currently valid version.

14 Disposal

	CAUTION
	Before disposing of the product, it must be reprocessed in accordance with Section 11.

The basis for disposing of waste in the European Union is the European Waste List. In some cases, countries and even municipalities issue their own waste regulations, which must be complied with. Outside the European Union, the relevant country-specific regulations for waste disposal must be complied with.



The battery and all electrical components (motors, control unit) must be disposed of properly as electronic waste or returned to the distributor.

15 Technical data

Technical data	Value	Unit
Base area W x D	620 x 680	mm
Net weight of SURGEON CHAIR ak 480	45-54 ¹	kg
Diameter of double castors	75	mm
Range for adjusting height	550 - 710	mm
Seat area	420 x 420	mm
Cushion thickness	80	mm
Range for adjusting armrest height	140-290	mm
Max. user weight	135	kg
Electrical information		
Battery	24 (2.9)	Volt (Ah)
Mains electricity (charging station)	100-240	Volt
Charging time approx.	4	h
Nominal frequency	50 – 60	Hz
Nominal current	400	mA
Fuse	T 1.25 //250	AH / V
Permitted operation time for lifting column (in any 10-minute period)	Time in use: 1.5 Cooling time: 8.5	minutes
Special conditions for storage and/or use		
Environmental temperature	+10 - +40	°C
Relative max. humidity	10 to 95	%
Air pressure	700 – 1060	hPa
Environmental conditions during use		
Environmental temperature	+10 - +40	°C
Relative max. humidity	50	%
Air pressure	700 – 1060	hPa

¹ Weight depends on SURGEON CHAIR ak 480 configuration

16 Troubleshooting

Fault	Possible cause	Corrective action
Does not work at all	Battery empty	Charge battery
	Battery seated incorrectly	Check battery seated correctly (see Section 0)
Does not work at all, charge battery	Battery faulty	Phone the distributor's service technician
Some functions fail e.g. chair rises but does not lower	Switch may be faulty	Phone the distributor's service technician
"ON" LED on charging unit does not come on	Power cable not plugged in	Check power cable (see Section 0)
	Charging unit faulty	Phone the distributor's service technician
Charging LED on charging unit does not come on	Battery fully charged	Phone the distributor's service technician
	Charger or battery faulty	Phone the distributor's service technician
Mechanical damage	External causes	Phone the distributor's service technician

17 Electromagnetic compatibility

Like all electrical medical devices, the SURGEON CHAIR ak 480 is subject to particular precautionary measures regarding EMC (electromagnetic compatibility). The SURGEON CHAIR ak 480 is intended for use in an electromagnetic environment, as specified below.


	WARNING
	Avoid using this equipment in close proximity to other equipment or stacking it with other equipment as this could result in faulty operation. If the chair must be used in these ways, the stool and the other devices should be monitored to ensure that they are working properly.
	The use of accessories, transformers or cables other than those specified or provided by the equipment manufacturer may result in increased electromagnetic emissions or reduced electromagnetic immunity for the equipment and result in faulty operation.
	Portable RF communication devices (radio equipment) (including accessories, e.g. antenna cables and external antennas) should not be used within 30 cm (12 inches) of the parts and cables specified by the manufacturer for the SURGEON CHAIR ak 480. Failure to comply may reduce the performance of the device.

Table 1: Information on ensuring electromagnetic compatibility

Operating environment	The SURGEON CHAIR ak 480 is intended for use by qualified personnel in doctors' surgeries or hospitals. It is not intended for use near live HF surgical instruments or in HF shielded rooms for magnetic resonance imaging where there is high-intensity EM interference.
Features	The SURGEON CHAIR ak 480 has no essential features that would lead to unacceptable risk in the event of their absence or failure.

Table 2: Results of electromagnetic compatibility testing

Test	Testing accuracy	Result
Electromagnetic discharge under EN 61000-4-2	B	Passed
Radiated, high-frequency fields, according to EN 61000-4-3	A	Passed
Interference from transients, bursts, according to EN 61000-4-4	B	Passed
High-energy overvoltage pulses; asymmetric and symmetric, according to EN 61000-4-5	B	Passed
Conducted high-frequency currents, asymmetric, according to EN 61000-4-6	A	Passed
Mains voltage drops, according to EN 61000-4-11	A/B	Passed
Mains voltage interruptions, according to EN 61000-4-11	C	Passed
Magnetic fields, according to EN 61000-4-8	A	Passed
Interference voltage on cables	-	Not tested, as the device uses no external cables
Interference field strength, according to EN 55011	Group 1, Class B	Passed

18 Manufacturer



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Tel. +49 4121 7919-30

Fax +49 4121 7919-39

Email: info@akrus.de

Website: www.akrus.de

19 Reporting incidents

Users must report any complaints about the product relating to the safety, efficacy or performance of the product to Akrus (info@akrus.com) or their local distributor.

If a SURGEON CHAIR ak 480 has failed, and may have resulted in or contributed to serious injury to a surgeon, Akrus or the local distributor and the appropriate local authority should be notified immediately.

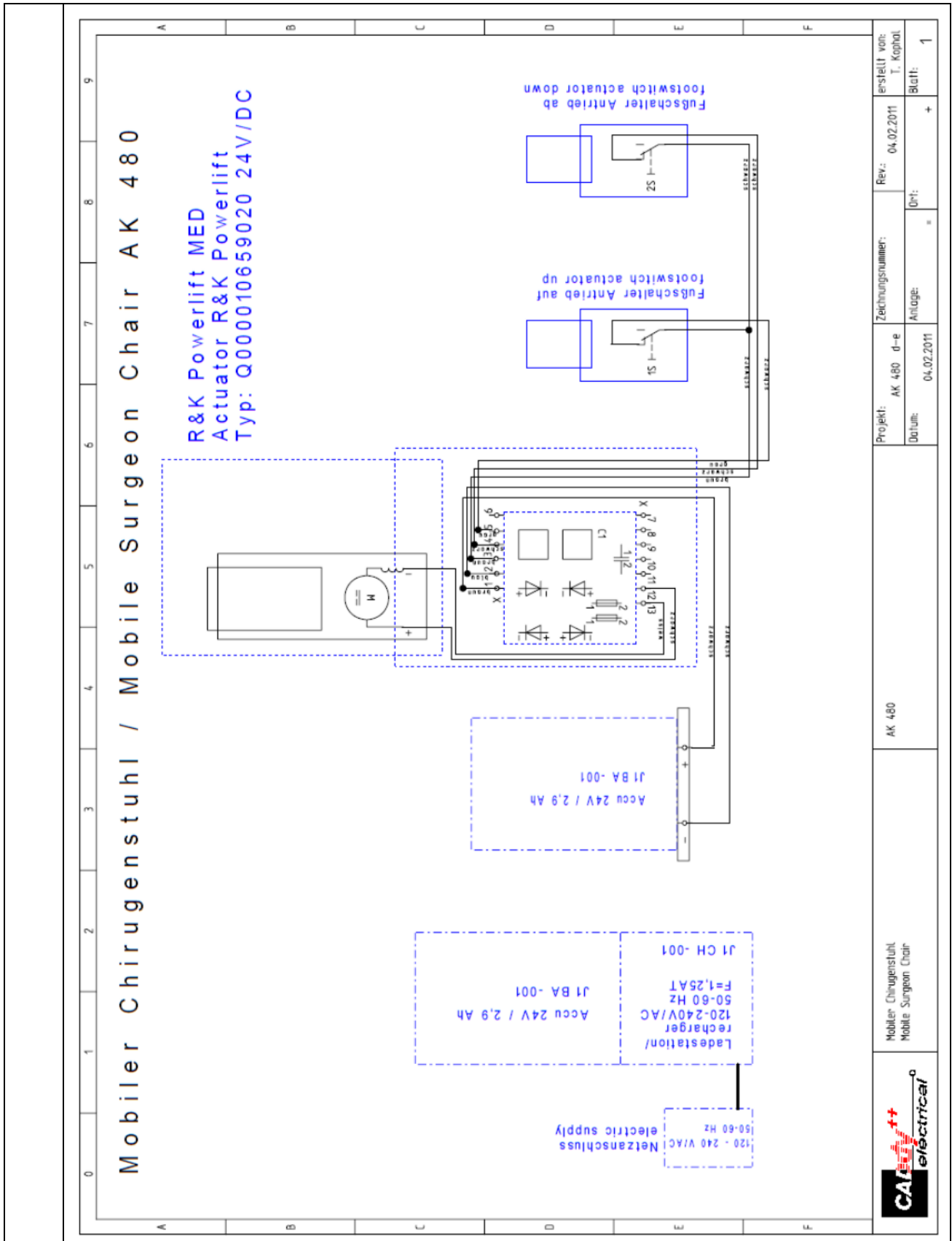
20 CE marking



We hereby declare that the device listed herein complies with Machinery Directive 2006/42/EC and the Regulation on medical devices 2017/745/EC.

Users must observe statutory national provisions on accident prevention, Directive 89/391/EEC and Directive 2009/104/EC.

21 Wiring diagram



Projekt: AK 480 d-e	Zeichnungsnummer: 04.02.2011	Rev.: 04.02.2011	erstellt von: T. Kaphal
Datum: 04.02.2011	Anlage: =	Ort: +	Blatt: 1
Mobile Surgeon Chair Mobile Surgeon Chair	AK 480		

