Mobile Mammography, Biopsy and Stereotaxy Chair

ak 5010 MBS

Instructions for Use (IFU)

Contents

1 General information

	A thorough understanding of these IFU is essential for use of the ak 5010 MBS examination chair (mobile Mammography, Biopsy and Stereotaxy chair). Please familiarise yourself with the contents, paying special attention to instructions on how to use the device safely. Please retain these IFU for future reference.

1.1 Copyright

1.2 Exclusion of liability

	**WARNING** 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.

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:

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

This device meets the requirements of these directives and the medical device Regulation (EU) 2017/745.

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

1.4 Explanation of symbols used

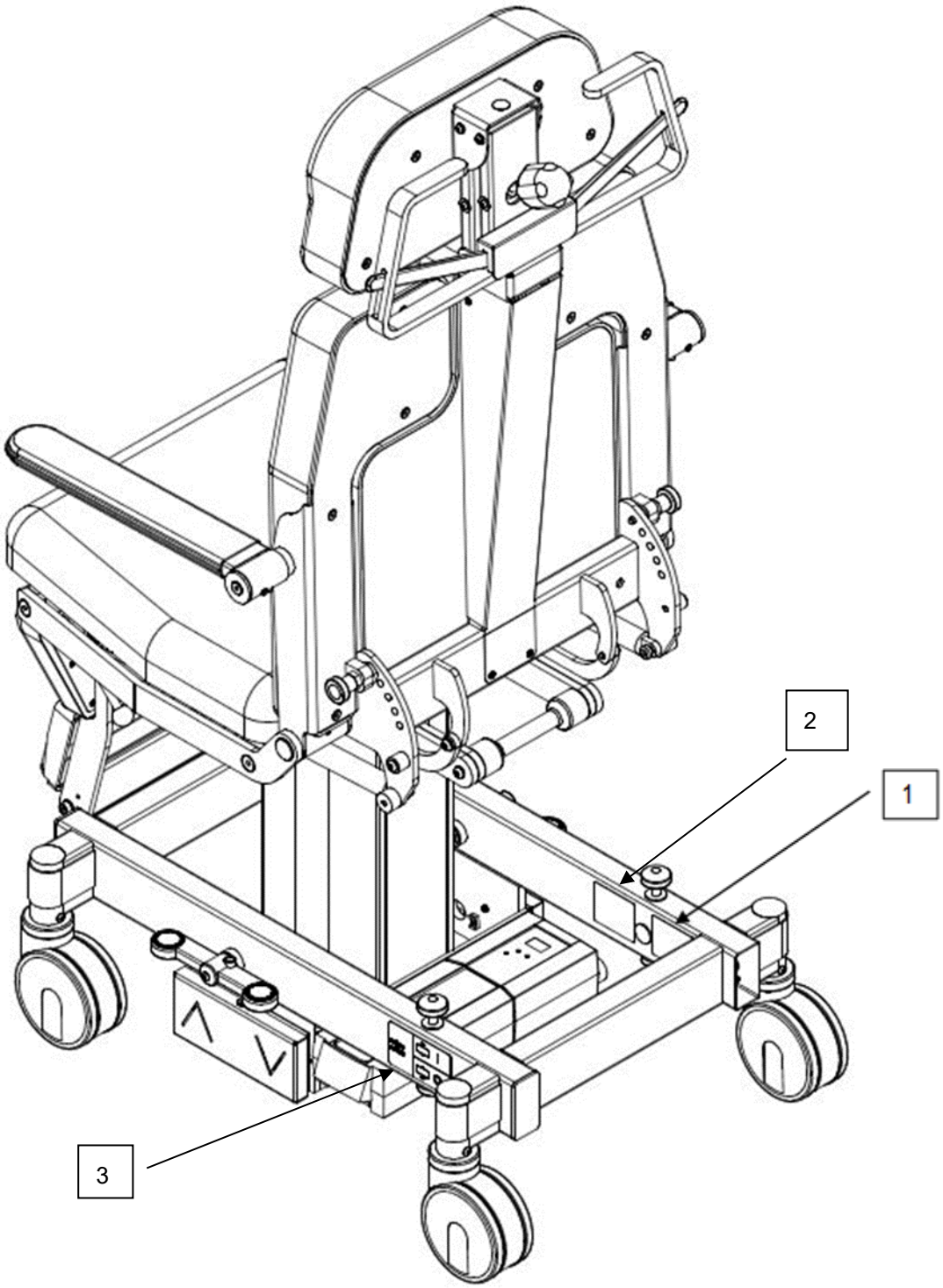
1.4.1 Instructions for use (IFU)

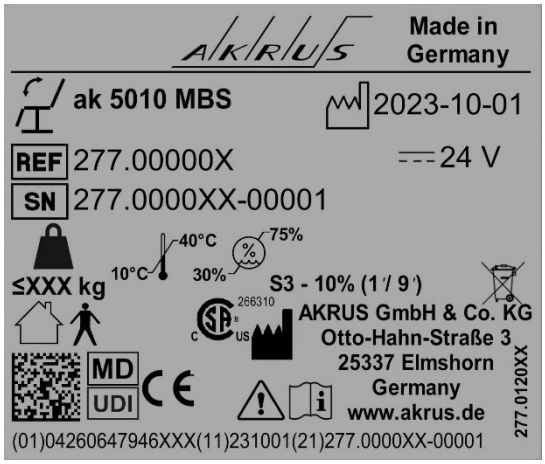
Please take particular care to read and comply with all of the safety precautions and information in the instructions for use.

	**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.
	Action required

1.4.2 Symbols used



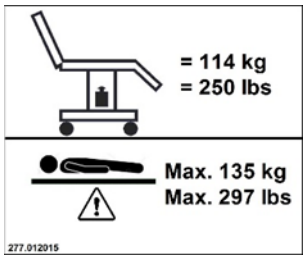


(1) Product label for ak 5010 MBS

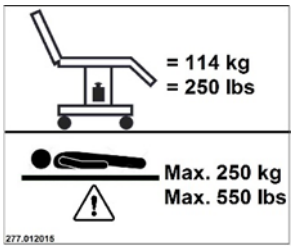
Product label for Adapter footrest MBS

Product label for Additive Back support MBS

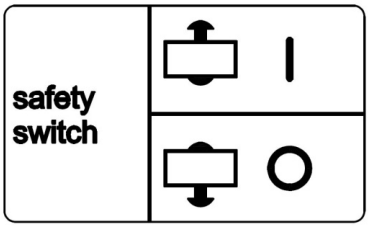
Product label for Additive Back support (viscoelastic) MBS



(2) Chair weight
Max. patient weight (135 kg, 330 lbs)



(2) Option: Chair weight
Max. patient weight (250 kg, 550 lbs)



(3) Safety switch

Safety switch: Power ON

Safety switch: Power OFF

Up Down

(4) Direction on foot lever. The arrows indicate the direction of movement.

Symbol	Meaning
	Manufacturer
	Date of manufacture (YYYY-MM-DD)
REF	Reference number
SN	Serial number
MD	Label identifying the device as a medical device
(01)04260647946000(11)210301 (21)279.012100-000000	Device identification (data matrix and plain text)
	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 accumulator supplied
S3 – 10% (1’ / 9')	Specifying the nominal operating time S3 10% means that in any 10 minute period, the lifting column can only be operated for 1 minutes and must then cool down for the remaining 9 minutes.

Symbol	Meaning
	“Do not load” prohibition sign Any load > 200N is prohibited
	Consult instructions for use.
	CE marking – symbol indicates compliance with Machinery Directive 2006/42/EC and the Medical Device Regulation 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
	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

Symbol	Meaning
	Do not open with a sharp blade

1.5 Requirements for safe operation

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

	**WARNING**
	Please check that the product is working correctly before every use.
	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.
	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 may only be opened by persons 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).

	**CAUTION**
	Risk of burns due to insufficient protective earth conduction using HF-surgical instruments, heart defibrillators and monitors of defibrillators combined with the examination chair ▪ HF-surgical instruments, heart defibrillators and monitors of defibrillators can cause burns, electric shock or explosions, which could harm the patient or user. ▪ Always follow the instructions for use of the heart defibrillator and HF-surgical instruments in especially its safety information.

	**IMPORTANT**
	Users require no training to operate the product.
	This product should only be operated by trained or authorised personnel.
	The product must not be used or stored in damp rooms, and under no circumstances in rooms with dripping, splashing or spraying water.
	Correct use of this product is essential for its safe operation.
	The product may only be used within the scope of its intended use.
	When cleaning and maintaining the device, make sure that no water or liquids enter the connection housing. See also Section “11 Equipment care and protection against contamination”

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 must only be operated in compliance with the specifications for intended use and the environmental conditions described in the Section “Technical Data”.
	If the medical device shows signs of wear, contact the distributor to have it serviced.

3 Contents at delivery

The ak 5010 MBS is delivered with the following items:

Item	Number
ak 5010 MBS	1
Charger and power cable	1
Accumulator	1
Quality test report	1
Instructions for use (IFU)	1
Any accessories ordered	---

4 Intended purpose

Mammography chairs are designed to position and support patients for examinations before and during a mammography or stereotactic breast biopsy.

The key purpose (not a performance feature) of ak 5010 MBS is the ability, using operating controls, to move a patient in a controlled manner into a position within the possible range of movement. Movement must stop when the operating command ends and not be initiated by external influences such as electromagnetic interference (proof of immunity test, in accordance with IEC 60601-1-2 EMC).

5 Intended use

- Use in doctors' surgeries and other medical facilities
- The product is suitable for use in immediate proximity to patients.
- The ak 5010 MBS is designed for a maximum patient weight of 135 kg (300 lbs). A 250 kg (550 lbs) version is also available (with a reinforced lift).
- The head rest is designed for a maximum weight of 20 kg (44 lbs).
- The ak 5010 MBS is only used for patients treated with local anaesthetic.
- The ak 5010 MBS is intended for examinations on human patients.
- Any use other than the stated intended purpose is prohibited; the product must be used for its intended purpose.
- The ak 5010 MBS may only be operated with the accumulator supplied with the device. The accumulator must be removed from the device for charging with the charger supplied with the device.

	**WARNING**
	The ak 5010 MBS is designed for a maximum patient weight of 135 kg (300 lbs). A 250 kg (550 lbs) version is also available (with a reinforced lift).

	**CAUTION**
	The head rest is designed for a maximum weight of 20 kg (44 lbs).
	The ak 5010 MBS is only used for patients treated with local anaesthetic.

6 Putting into service

The medical device is delivered fully assembled. If delivery includes optional parts or accessories, please refer to the Sections below or 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 safely operate this medical device.

7 Checks before use

	**WARNING**
	Before every use, it is essential to check that the ak 5010 MBS is fully functional.
	Be sure to activate the safety switch during the examination to prevent any unwanted upwards or downwards movement of the chair.
	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

	**CAUTION**
	The medical device is only free from electric current when the accumulator is removed.
	The exact position of the accumulator or the accumulator charger is described in the relevant Sections of these IFU (see Sections 9.1 and 9.4). Only the power cable supplied or one specified by the manufacturer can be used to connect the charger to mains electricity.

9 Description of the device

9.1 Accumulator

The electric motor in the ak 5010 MBS is powered by a rechargeable accumulator. The accumulator has a capacity of approx. 40 operations per charging cycle when used with a typical load profile.

	**CAUTION**
	Keeping a spare, charged accumulator is recommended.
	Please handle the accumulator with care and caution. Incorrect handling, as described below, can significantly damage or even destroy the accumulator: • Total discharge (upwards and downwards movements are noticeably slower or chair does not move). • Drops (even from low heights) • Short-circuiting the terminals

To dispose of the accumulator see Section “Disposal”.

9.2 Accumulator, recharge intervals

	**CAUTION**
	The accumulator 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 accumulator cannot be damaged by overcharging, so does not need to be removed from the charging unit once fully charged.

9.3 Charger

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

The charger must always be positioned so that the power plug is easily accessible in order to disconnect it from the power supply.

The charger is equipped with a self-detecting power supply and is suitable for voltages from 100 volts to 240 volts at 50 Hz to 60 Hz. A green LED indicates it is ready to charge.

Charging can take up to 5 hours and is indicated by a yellow LED. When charging is complete, this LED turns off. The accumulator cannot be damaged by overcharging, so it does not need to be removed from the charging unit when charging is complete.

Charger and power cable

ON = indicator light ON

CHARGE = indicator light CHARGE

Vertical mounting

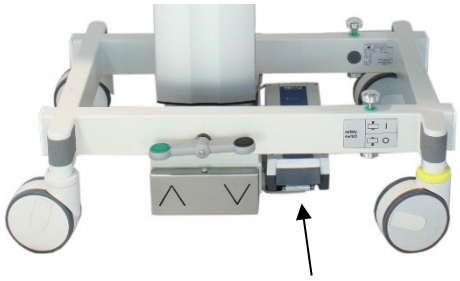
of the charger and accumulator

	CAUTION
	In the cases below, the accumulator 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 accumulator is empty soon after charging (4) the accumulator is not fully charged after even a long charging time (> 4h). If any of the above occur, please replace the old accumulator with a new accumulator. Please contact your local AKRUS GmbH & Co. KG authorised distributor.
	The accumulator is only fully charged when the CHARGE LED goes off after completion of charging.

9.4 Accumulator holder

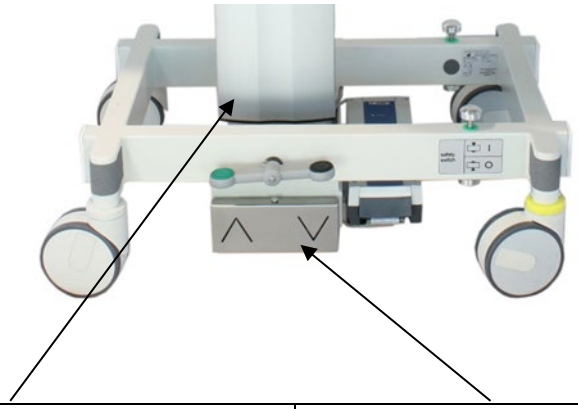
The accumulator holder is easily accessible under the frame. There is a recessed handle on the top of the accumulator. To remove the accumulator from the holder, gently pull on the recessed handle. Conversely, to insert the accumulator, push it gently into the holder until you hear a clear, sharp click. It is now locked into place.

The accumulator should be removed from the medical device's battery holder if the medical device is not to be used for an extended period of time.



Location of the accumulator holder

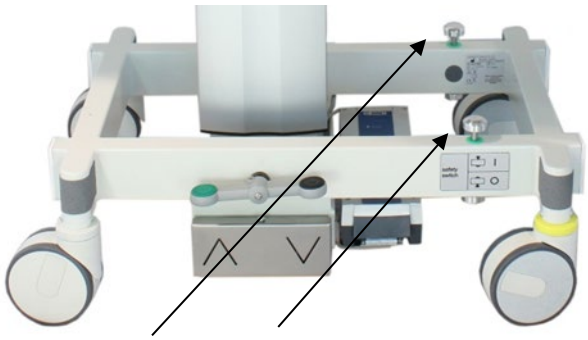
9.5 Electric lift (101-016 / 101-017) and foot-controlled switch (277.012003)



The ak 5010 MBS is powered by a low voltage motor.	To move the chair up and down, press one of the two foot-operated switches on the right or left of the ak 5010 MBS. The arrows show the direction of movement.

9.6 Safety switch

	WARNING
	Be sure to activate the safety switch during the examination to prevent any unwanted upwards or downwards movement of the ak 5010 MBS.



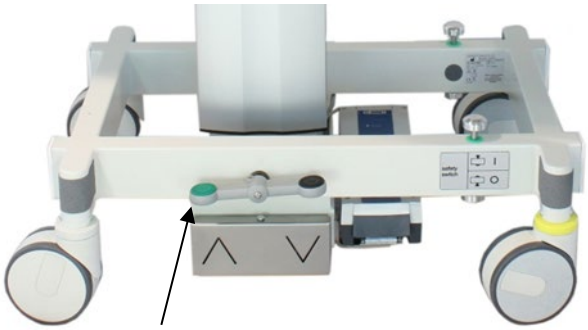
To prevent any unwanted upwards or downwards movement during treatment, the ak 5010 is fitted with two safety switches, on the right and left of the frame.

Pressing down on the mushroom-shaped switch turns off the power; to switch it on, lift the switch from below with the front of your foot.

Red circle visible: chair is locked.

Green circle visible: chair can move.

9.7 Control lever for chassis



The ak 5010 MBS features a chassis and two control levers on either side of the lower frame.

Foot lever in different positions.

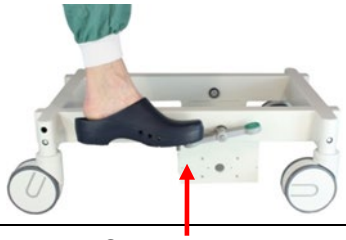
There are three possible positions.

(1) All wheels move freely and rotate (lever horizontal).
(2) All wheels move freely, and 1 wheel is locked for steering (green circle down).
(3) All wheels are braked (black circle down).

(1) All wheels move freely.

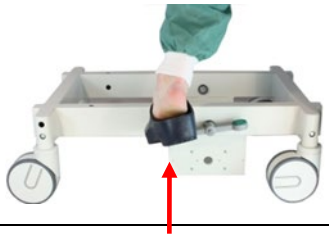
(2) One wheel locked for steering (foot rest side, top view right).

(3) All wheels are locked.



Correct use

Place your foot sideways and press firmly with the front of your foot.



Incorrect use

Placing your foot in the middle of the axle, or vertically from the side onto the lever makes it difficult push the lever strongly enough.

10 Operating the ak 5010 MBS

10.1 Ready for use

The ak 5010 MBS is always ready for use with a charged accumulator. It does not have a main switch, but a safety switch, see chapter 9.6.

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

	CAUTION
	The product must be cleaned before every use. See Section 11.

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 minute and must then cool down for the remaining 9 minutes. Prolonged operation while the user is seated can cause overheating and permanent damage.

10.2.1 Accumulator charge status (see also 9.2)

	CAUTION
	Once the accumulator is 80% discharged, the motor speed is noticeably slower. The accumulator must then be recharged in the charger. If it is further discharged through continued operation, the accumulator may be irreversibly damaged.

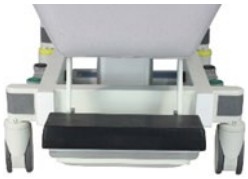
10.3 Getting into and out of the chair

A folding foot plate helps smaller patients or patients with limited mobility to get into the chair.	The minimum seat height is about 68 cm.

10.4 Foot rest adapter (277.950300)

To help smaller patients with shorter legs to sit comfortably in the chair, 1 or 2 adapter blocks can be attached to the foot rest.

	CAUTION
	These adapters are NOT designed as a step-in aid. If needed, attach the adapters after the patient is seated in the ak 5010 MBS.

			
To attach a single block: tilt the block slightly and lock it into place with the hook.		To attach a double block: first slide the two blocks over each other and then hook them in, as above.	

10.5 Adjusting the arm rests

Both arm rests fold away upwards and can be placed parallel to the back rest.

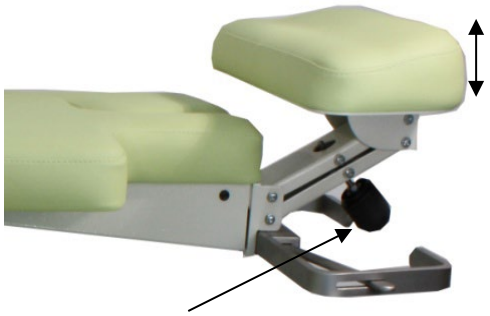
10.6 Adjusting the back rest

The back rest can be freely adjusted from a vertical to a horizontal position. Pressing one of the two spring-loaded levers behind the head rest (arrow) unlocks the mechanism and the back rest will gently move up or down.

10.7 Adjusting the head rest (277.030600 / 277.030700)

CAUTION

The adjustment mechanism can be damaged if the end positions are forcibly overtightened.



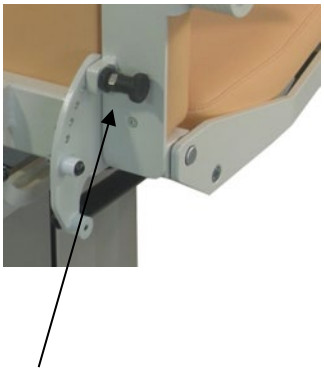
The ak 5010 chair has a continuously adjustable head rest (max. 20 kg, 44 lbs), which supports the head very comfortably when the patient is lying on their side (park bench).

The head rest is moved up and down using the twist knob (arrow).

The head rest can be moved to the left or right.

10.8 Adjusting separate sections of the back rest

The back rest has two individually adjustable sections, which allow patients to be positioned sideways (park bench).



To adjust these adjustable sections, hold the relevant part with one hand, pull out the locking pin (arrow) with the other hand and let it lock into the desired position.

10.9 Optional accessory: Lateral back rest (277.032010)

To attach the lateral back rest, put the rear arm rest in a vertical position. Slide the U-shaped plastic holders over the arm rest.

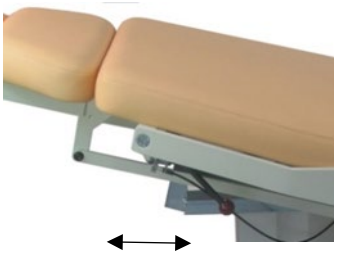
Position the patient far enough forward to ensure unhindered access to the treatment device. Then insert the locking pin into the appropriate notch.

The chair offers almost unlimited positioning options, permitting all standard mammography and stereotactic procedures to be carried out. The folding back section supports the arm, while the head rest comfortably supports the head when the patient is lying on their side (park bench).

The back rest brings the patient close enough to the examination device while at the same time allowing the patient to relax.

10.10 Trendelenburg

The ak 5010 MBS allows the use of the Trendelenburg position.

	
To do so, secure the ak 5010 MBS by holding the foot rest with one hand. To unlock the mechanism, move the red lever under the seat towards the feet and lower the lying surface. To lock it into this position, pull the red lever back towards the head until it clicks into place.	

11 Equipment care and protection against contamination

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

	**CAUTION**
	The product must be cleaned before every use.

11.1 Warning notice

NOTICE	**NOTICE**
	Before using the chair for the first time, ak 5010 MBS must be prepared according to these instructions.
	For at-risk patients, patients with skin damage or to reduce possible contamination in general, we recommend covering the device with a cloth (e.g. a sterile surgical cloth).
	Use the protective equipment recommended by the cleaner/disinfectant manufacturer during reprocessing.
	Never use solvents or abrasion (scouring). The resistance of the fabrics used against aggressive chemicals depends on numerous factors, such as: • 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 reprocessing, care must be taken to ensure that no fluids get into the device.
	It is not intended for storing instruments or other medical devices.
	Allow the device to dry before use.

11.2 Reprocessing restrictions

The ak 5010 MBS must be cleaned at regular intervals in compliance with the surface disinfection hygiene plan, and at least once a day.

If there is obvious, visible contamination, or after examining patients who are obviously infectious, reprocessing should take place immediately after the examination is completed.

After every biopsy or similar treatment during which contamination with blood or tissue may occur, the ak 5010 MBS must be reprocessed.

The ak 5010 MBS cannot be reprocessed 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 Reprocessing instructions

	**WARNING**
	Electric shock
	The accumulator must be removed before the device is reprocessed. The device must be completely dry before the accumulator is reinserted.

Preparation before cleaning	Remove the accumulator from the ak 5010 MBS.
Cleaning	For manual cleaning, use ready-to-use “Cleanisept Wipes Maxi” by the manufacturer Dr. Schumacher. Please proceed as follows: 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	For manual disinfection with wipes, use ready-to-use “Cleanisept Wipes Maxi” by the manufacturer Dr. Schumacher. Please proceed as follows: 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	Allow the device to dry completely before use. Do not replace the accumulator until the chair is completely dry.
Maintenance and checks before use	None – n/a
Packaging	None – n/a
Storage	None – n/a
Additional information	None – n/a
Manufacturer’s contact details	Manufacturer of Cleanisept Wipes Maxi: Dr. Schumacher GmbH Am Roggenfeld 3 34323 Malsfeld post@schumacher-online.com www.schumacher-online.com

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.

The ak 5010 MBS does not require maintenance by the user.

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

Description	Order no.
Accumulator unit	100-925
Charger	100-924
Accessory: Adapter footrest MBS	277.950300
Accessory: Additive back support MBS	277.032010
Accessory: Additive back support (viscoel.) MBS	277-032020

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 accumulator 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
Dimensions and weight		
Total chassis length (back rest vertical)	760	mm
Total chassis width	580	mm
Chair width including attachment rails	760	mm
Seat width	580	mm
Total height (chair) with back rest upright	1440	mm
Max. length chair, back rest horizontal	1730	mm
Max. patient weight	135/250	kg
Max. patient weight	300/550	lbs
Max. static chair load	550	kg
Max. static chair load	1200	lbs
Weight (depending on options) approx.	95[1]	kg
Vertical range chair (Z axis)		
Min. seat cushion height for entry	680	mm
Hub	300	mm
Range back rest		
Vertical to horizontal	90	°
Shock position below horizontal	-15	°
Range for head rest		
Vertical in supine position	160	mm
Sideways	120	mm
Range for shoulder cut-out		
Fold down below horizontal	40	°
Chassis		
3 pos. brake system	- all wheels move freely - 1 wheel locked - all wheels locked	-
Wheel diameter	125	mm
Actuating force at end of lever ± 10 %	250	N
Electrical information		
Accumulator	24 (2.9)	Volt (Ah)
Duration of short-term motor operation (ID 10)	ED 1/9	minutes
Upholstery electric conductible (optional)		
Electrical information for charger		

[1] Weight depends on configuration of ak 5010 MBS

Technical Data	Value	Unit
Power cable (charger)	100-240	Volt
Charging time approx.	5	h
Nominal frequency	50 – 60	Hz
Nominal current	600	mA
Fuse	T 1.25 //250	AH / V
Protection category	IP 65	
Environmental conditions during use (and during storage in unpacked condition)		
Environmental temperature	+10 - +40	°C
Relative max. humidity	30 - 75 (non-condensing)	%
Air pressure	700 – 1060	hPa
Max. meters above sea level	3000	m
Storage conditions (in original packaging)		
Environmental temperature	-10 - +50	°C
Relative max. humidity	20 to 80	%
Air pressure	700 – 1060	hPa
Transport conditions (in original packaging)		
Environmental temperature	-40 - +70	°C
Relative max. humidity	10 to 95	%
Air pressure	700 – 1060	hPa

16 Troubleshooting

Fault	Possible cause	Corrective action
Does not work at all	Accumulator empty	Charge accumulator
	Safety switch on	Unlock safety switch (see also Section 9.6)
	Accumulator seated incorrectly	Check accumulator seated correctly (see Section 9.4)
Does not work at all, charge accumulator	Accumulator 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 9.2)
	Charging unit faulty	Phone the distributor's service technician
Charging LED on charging unit does not come on	Accumulator fully charged	Phone the distributor's service technician
	Charger or accumulator 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 ak 5010 MBS is subject to particular precautionary measures regarding EMC (electromagnetic compatibility). The ak 5010 MBS is intended for use in an electromagnetic environment, as specified below.

Special precautions regarding EMC must be taken for the device and put into operation in accordance with the following requirements.

	WARNING
	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 and mobile HF communication devices can affect the ak 5010 MBS. Do not use mobile phones or other devices that do not comply with EMC class B according to CISPR 11 in the vicinity of 30 cm of the device.
	It cannot be excluded that electromagnetic interference will cause the chair to stop working.
	The ak 5010 MBS is subject to particular precautions with regard to electromagnetic compatibility (EMC). To avoid EMC interference, the ak 5010 MBS may only be installed, commissioned and maintained in the manner specified in this manual and only with the components supplied by AKRUS GmbH & Co. KG.
	The ak 5010 MBS has not been tested for electromagnetic compatibility with strong magnetic fields. The probability of malfunction due to the presence of strong magnetic fields at the point of use is low. Even so, do not place the ak 5010 MBS near sources of strong, high-frequency magnetic fields.
	The ak 5010 MBS must not be placed directly next to or stacked with other equipment. If it must be operated near or stacked with other equipment, the ak 5010 MBS must be monitored to check it is operating correctly under these circumstances.

Table 1: Information on ensuring electromagnetic compatibility

Operating environment	The ak 5010 MBS 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 ak 5010 MBS has no essential features that would lead to unacceptable risk in the event of their absence or failure.

Table 2: Results of electromagnetic emissions testing

Guidelines and manufacturer's declaration - Electromagnetic emissions		
The ak 5010 MBS is intended for use in an electromagnetic environment, as specified below. The customer or user of the ak 5010 MBS should ensure that it is used in such an environment.		
Emitted interference measurements	**Compatibility**	**Electromagnetic environment guidelines**
Contacted and radiated RF emissions according to CISPR 11	Group 1	The ak 5010 MBS only uses RF energy for its internal operation. Its RF emissions are therefore very low and are unlikely to cause interference with nearby electronic equipment.
Contacted and radiated RF emissions according to CISPR 11	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.
Emissions of harmonics according to IEC 61000-3-2	Class A	
Emissions of voltage fluctuations / flicker according to IEC 61000-3-3	Compatible	

Table 3: Results of electromagnetic immunity testing

Guidelines and manufacturer's declaration - Electromagnetic immunity			
The ak 5010 MBS is intended for use in the electromagnetic environment specified below. The customer or user of the ak 5010 MBS should ensure that it is used in such an environment.			
Immunity testing	**IEC 60601 test level**	**Compatibility level**	**Electromagnetic environment - guidelines**
Electrostatic discharge (ESD) according to 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 covered with ceramic tiles. If floors are covered with synthetic material, relative humidity must be at least 30%.
Electrical fast transients/burst transients according to IEC 61000-4-4	±2 kV for power cables ±1 kV for input/output cables	±2 kV for power cables ±1 kV for input/output cables	The quality of the supply voltage should correspond to that of a typical practice or hospital environment. (for battery charger)
Surge voltages/surges according to IEC 61000-4-5	±1 kV voltage External cable - external cable ±2 kV voltage External cable - earth	±1 kV voltage External cable - external cable ±2 kV voltage External cable - earth	The quality of the supply voltage should correspond to that of a typical practice or hospital environment. (for battery charger)
Voltage dips, short interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	< 5% UT (> 95% dip in UT) for ½ period 40% UT (60% dip in UT) for 5 periods 70% UT (30% dip in UT) for 25 periods < 5% UT (> 95% dip in UT) for 5 s	< 5% UT (> 95% dip in UT) for ½ period 40% UT (60% dip in UT) for 5 periods 70% UT (30% dip in UT) for 25 periods < 5% UT (> 95% dip in UT) for 5 s	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment. (for battery charger)
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the supply frequency should be at levels typically found in a practice or hospital environment
Note: U_T is the AC mains voltage before the test level is applied.			

Table 4: Guidelines and manufacturer's declaration - Electromagnetic immunity

Guidelines and manufacturer's declaration - Electromagnetic immunity			
The ak 5010 MBS is intended for use in the electromagnetic environment specified below. The customer or user of the ak 5010 MBS should ensure that it is used in such an environment.			
Immunity testing	**IEC 60601 test level**	**Compatibility level**	**Electromagnetic environment - guidelines**
Conducted RF transients according to IEC 61000-4-6 Radiated RF transients according to IEC 61000-4-3 + Table 9	3 V effective value 150 kHz to 80 MHz 6 V at ISM frequencies 3 V/m 80 MHZ to 2.7 GHz 27 V/m (385 MHz / 18 Hz PM) 28 V/m (450 MHz / 5 kHz Hub, 1 kHz Sin. FM) 9 V/m (710/745/780 MHz / 217 Hz PM) 28 V/m (810/870/930 MHz / 18 Hz PM) 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)	3 V 6 V 3 V/m 27 V/m 28 V/m 9 V/m 28 V/m 28 V/m 9 V/m	Portable and mobile radio devices should not be used closer to the ak 5010 MBS chair or its cables than the recommended safety distance, which is calculated using the equation applicable to the transmission frequency. **Recommended safety distance** d=1.2 √P d=1.2 √P for 80 MHz to 800 MH d=2.3 √P for 800 MHz to 2.5 GHz where P is the nominal output of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended safety distance in metres (m). The field strength from fixed radio transmitters should be less than the compatibility level[b] at all frequencies as determined by an on-site survey[a]. Interference is possible in the vicinity of equipment marked with the following symbol. 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all cases. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and people.			
a. The field strengths of fixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio stations, AM and FM radio and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength where the ak 5010 MBS chair is being used exceeds the applicable compatibility levels above, the ak 5010 MBS chair should be monitored to check it is operating			

normally. If the chair is not operating normally, additional measures may be necessary, such as reorienting or relocating the ak 5010 MBS chair. b. Over the frequency range 150 kHz to 80 MHz, the field strength 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

Table 5: Recommended safety distances between portable and mobile RF telecommunications equipment and the ak 5010 MBS.

Recommended safety distances between portable and mobile RF telecommunications equipment and the ak 5010 MBS chair.			
The ak 5010 MBS is intended for use in an electromagnetic environment in which RF interference is controlled. The customer or user of the ak 5010 MBS can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the ak 5010 MBS depending on the output power of the communications equipment, as specified below.			
Nominal transmitter output W	Safety distance depending on the transmission frequency In m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	d=1.2 √P	d=1.2 √P	d=2.3 √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 nominal output is not listed in the table above, the recommended safety distance d in metres (m) can be determined using the equation that applies to the relevant column, where P is the maximum nominal output for the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all cases. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and people.			

18 Manufacturer

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19 Reporting incidents

Users must report any complaints about the product's safety, efficacy or performance to AKRUS GmbH & Co. KG (service@akrus.de) or to their local distributor.

AKRUS GmbH & Co. KG or the local distributor and the appropriate local competent authority should be notified immediately, if an examination chair has failed and may have resulted in or contributed to serious injury to a person.

20 CE marking

CE

We hereby declare that the device listed herein complies with the Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2023/1230 on machinery.

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

21 Wiring diagram