



MedizinTechnik

English

Operating Instructions

ATMOS[®] SE 6501

Function module



GA1GB.140101.0

2018-10 Index: 05



1.0	For your safety	4
1.1	Intended use	4
1.2	Safety notations	4
1.3	Safety of equipment and accessories	4
1.4	Importance of the operating instructions and training of medical personnel.....	4
1.5	Protection from the risk of electric shock	5
1.6	Ambient conditions.....	5
1.7	Maintenance	6
1.8	Risks when using the ATMOS® SE 6501	6
2.0	Description of the control element	7
3.0	Installation	9
3.1	Ambient conditions.....	9
3.2	Electrical installation	9
3.3	Installation of the accessories.....	10
4.0	Working with the ATMOS® SE 6501	11
4.1	Switching on the ATMOS® SE 6501	11
4.2	Setting the ATMOS® SE 6501	11
4.3	Aspiration	11
5.0	Special functions	12
5.1	Calling up the basic setting	12
5.2	Calling up the setting functions	12
6.0	Cleaning and disinfection	13
7.0	Technical data	14
8.0	Notes on EMC	15
9.0	Maintenance, Customer Service, Warranty, Disposal	18
9.1	Maintenance	18
9.2	Customer Service	18
9.3	Warranty	18
9.4	Disposal	19
9.5	Sending in the device.....	19

Further information, accessories, consumables and spare parts are available from:

ATMOS

MedizinTechnik GmbH & Co. KG

Ludwig-Kegel-Straße 16

79853 Lenzkirch

Germany

Phone: + 49 7653 689-0

Fax:

+ 49 7653 689-392 (National Sales)

+ 49 7653 689-391 (Export)

E-mail: atmos@atmosmed.de

Internet: <http://www.atmosmed.de>

Notes on operating instructions



These operating instructions contain important notes on how to operate the ATMOS® SE 6501 safely, correctly and effectively. Their reading helps to avoid risks, and also to reduce repair costs and down-times. This increases, amongst other things, the reliability and service-life of the device.

These operating instructions serve not only for new operating personnel to be instructed in its use, but also for use as a reference manual. Reprints (also in extracts) only with permission in written form by ATMOS.

These operating instructions must always be kept available near the device.



Care and period tests in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS® SE 6501 and are therefore a must besides regular cleaning.

Repair work and period tests may be carried out only by expert personnel authorised by ATMOS. By applying only original spare parts you will have the guarantee that operational safety, readiness for work and the value of your ATMOS® SE 6501 will be preserved.



- The product ATMOS® SE 6501 bears CE marking CE 0124 according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of Appendix I of the directive.
- The product ATMOS® SE 6501 complies with all applicable requirements of the Directive 2011/65/EC restricting the use of certain hazardous substances in electrical and electronic equipment ("RoHS").
- The declaration of conformity and our general standard terms and conditions can be obtained on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 13485.
- Prior to start-up please peruse chapter 1.0 „For your safety“, in order to be prepared for any possible dangerous situations.
- Reprints (also in extracts) only with permission in written form by ATMOS.
- Subject to Alterations, errors excepted.

These operating instructions are valid for the following devices:

ATMOS® SE 6501	600.0007.0
	533.1025.0

Please keep this document for future consultation!



1.1 Intended use

The vaporization of tissue during thermal surgical interventions produces smoke and gases.

The ATMOS® SE 6501 is a smoke evacuator system. The unit is intended for use with smoke and gas-generating medical devices such as laser surgery and electrosurgical units and cauteries.

The ATMOS® SE 6501 extracts the smoke-laden air. The air is cleaned by a high-performance filter and returned to the ambient air.

WARNING! Use of the ATMOS® SE 6501 for secretion suction in the medical field and for the extraction of combustible, explosive liquids, gases or radiating or radioactive substances is forbidden.

1.2 Safety notations

WARNING! The WARNING! safety indication refers to a risk of personal injury.

CAUTION! The CAUTION! safety indication refers to a risk of damage to property.

ATTENTION: The ATTENTION: safety indication refers to a risk which can cause equipment to become unserviceable.

1.3 Safety of equipment and accessories

Compliance with safety information

Appropriate application of and compliance with the safety information makes a considerable contribution to the safety of the user, patients, and environment.

Using with other devices

ATMOS devices conform to all relevant generally recognized technical rules, as well as the valid regulations for occupational safety and accident prevention.

Contribution of medical personnel to safety

Working with medical equipment is basically associated with certain risks to medical personnel and patients. Risks cannot be entirely eliminated by design measures alone. Safety does not depend solely on the equipment but depends to a large extent on factors influenced by you. These factors are dealt with in the safety information in this chapter.

1.4 Importance of the operating instructions and training of medical personnel

Who should read these operating instructions?

These operating instructions form an important part of the safety concept of the unit.

Therefore, everyone who is concerned with

- preparing
- adjusting
- operating
- disassembling
- cleaning and disinfecting

the unit and instruments should read the operating instructions and the instructions for using the instruments.

Please pay particular attention to the safety instructions in each chapter.



Please note:

A medical insulating transformer with earth leakage monitor or any similar safety system acc. to EN 60 601-1 is required, if several devices are connected over one common power supply. The transformer must correspond to the power consumption of all the devices to be connected.

Instructions for use

WARNING! The equipment may only be used by medical professionals who have been appropriately trained in correctly operating the device under consideration of these operating instructions.

Training must be carried out only by personnel who are qualified by their knowledge and practical experience. ATMOS cannot be held liable for any damage caused by user error.

In the event of uncertainties or if you have any questions, please contact ATMOS. We are gladly prepared to give you further assistance and will be pleased to receive your suggestions concerning these operating instructions.

The ATMOS® SE 6501 may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen rich environments.

1.5 Protection from the risk of electric shock

Leakage current

The equipment conforms to the requirements of Type CF (Cardiac Float) and is protected against the effects of a defibrillator discharge.

Inspecting the equipment and accessories

WARNING! Inspect the equipment and the accessories (e.g. foot control, cable) for damage after each use. You must not use damaged equipment or damaged accessories. Exchange defective accessories. If the equipment is damaged, please contact our customer service. For your safety and that of patients, never attempt to effect repairs yourself. Any modification will invalidate liability by ATMOS.

Power cord, power outlet

WARNING! The supply voltage must match the voltage specified on the rating plate. The device may be connected to a properly installed protective contact socket. Only use the ATMOS power cord or an equivalent power cord for this purpose. The power cord must bear the national test symbol.

Power fuses

WARNING! The unit is protected with power fuses. They can be found in the fuse drawer next to the power connection of the unit. If one of these power fuses has blown, the unit may not be used on the patient again until it has been checked by a competent technician. Only spare fuses with the values indicated on the unit rating plate may be used.

Potential equalisation

If necessary, connect the potential equalization pin of the unit to the potential equalization system of the operating room using a potential equalization conductor.

1.6 Ambient conditions

Do not operate in explosion hazardous areas

WARNING! The device may only be operated in rooms used for medical purposes. Position the device in such a way that it is located outside of explosion hazardous areas. Explosion-hazardous areas may be caused by the use of flammable anaesthetics, skin cleansing products and disinfectants.

Operating conditions

ATTENTION: The device must be operated at a certain temperature and humidity. You will find the specified temperature and humidity in the Technical Data. If levels exceed or fall below the tolerances specified there, the device may fail. If other conditions have to be observed for operation of this device, you will also find them in the Technical Data.



Portable and mobile communication equipment HF

ATTENTION: Portable and mobile HF communication facilities can influence the equipment.

Transport and storage

ATTENTION: The device must be stored and transported at a certain temperature and humidity. You will find the specified temperature and humidity in the Technical Data. If levels exceed or fall below the tolerances specified there, the device may fail. If other conditions have to be observed for transport and storage of this device, you will also find them in the Technical Data.

Acclimatization

ATTENTION: If the device was stored or transported below a certain temperature, it will take a certain time to acclimatize to room temperature. You will find the specified temperature and acclimatization time in the Technical Data.

Ventilation

ATTENTION: The device must be installed in such a way that there is an unobstructed circulation of air around the housing. Installation in confined wall recesses is not permitted.

Penetration of liquids

ATTENTION: The housing is not absolutely watertight. Therefore do not place the device in the immediate vicinity of tubes or tanks containing liquids.

1.7 Maintenance

WARNING! Please comply with the country-specific guidelines regarding regular testing especially for the electrical safety. ATMOS recommends a test every 24 months.

1.8 Risks when using the ATMOS® SE 6501

Supervised operation

WARNING! The ATMOS® SE 6501 may only be operated by medical staff and under supervision.

No contact with the suction site

WARNING! Never bring the suction hose into contact with the suction site. It could become attached to the tissue.

Swabs

WARNING! Position the suction device, or the instrument with suction device so that it cannot accidentally suck up swabs or the like.

Liquids

ATTENTION: Do not suck up any liquids. If there is a risk that you could suck up liquids during the operation, attach an in-line filter on the main filter. Replace the in-line filter immediately if you have sucked up any liquid.

Explosive gases

WARNING! Do not place the suction opening of the hose on the floor. Do not extract any explosive endogenous gases (e. g. methane) from the intestinal tract.

Control elements of the function module



Fig. 1.

- (1) Mains on/off switch
- (2) CF (Cardiac float)
- (3) Main filter lock
- (4) Main filter inlet

Device On / Off

The unit is defibrillator-protected.

Releases the main filter from the unit.

Connection of the suction accessories.

Control elements on the front side



Fig. 2.

- | | |
|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (5) Operation flow | Suction capacity during activation of the electrosurgical unit or after manually starting the ATMOS® SE 6501. Manual start with the <Start suction> button. |
| (6) Base flow | During work breaks, the unit operates at reduced capacity.
Suction capacity after the Run-on time has ended. |
| (7) Run-on time | The operation suction runs on for a set length of time after the electrosurgical unit is deactivated or after the <Start suction> button is released. |
| (8) Display | Shows the values of operation suction, Basic suction, Run-on time and various special functions. |
| (9) Start suction | The unit operates as long as you press the button plus the adjusted run-on time. |
| (10) Seconds symbol | Illuminates when the Run-on time is being set. |
| (11) Percent symbol | Illuminates when operation suction and Basic suction are being set. You set these on the display as a percentage of the unit's maximum capacity. |
| (12) Value higher / lower | Buttons to adjust the value in the display. |
| (13) Filter exhausted indicator | Illuminates when the filter is in the reserve range. Flashes when the filter is exhausted. |
| (14) System blocked indicator | Illuminates when the system is blocked, e. g. if you have sucked up an object. |



3.1 Ambient conditions

Do not operate in explosion hazardous areas

WARNING! The device may only be operated in rooms used for medical purposes. Position the device in such a way that it is located outside of explosion hazardous areas. Explosion-hazardous areas may be caused by the use of flammable anaesthetics, skin cleansing products and disinfectants.

Operating conditions

ATTENTION: The device must be operated at a certain temperature and humidity. You will find the specified temperature and humidity in the Technical Data. If levels exceed or fall below the tolerances specified there, the device may fail. If other conditions have to be observed for operation of this device, you will also find them in the Technical Data.

Portable and mobile communication equipment HF

ATTENTION: Portable and mobile HF communication facilities can influence the equipment.

Transport and storage

ATTENTION: The device must be stored and transported at a certain temperature and humidity. You will find the specified temperature and humidity in the Technical Data. If levels exceed or fall below the tolerances specified there, the device may fail. If other conditions have to be observed for transport and storage of this device, you will also find them in the Technical Data.

Acclimatization

ATTENTION: If the device was stored or transported below a certain temperature, it will take a certain time to acclimatize to room temperature. You will find the specified temperature and acclimatization time in the Technical Data.

Ventilation

ATTENTION: The device must be installed in such a way that there is an unobstructed circulation of air around the housing. Installation in confined wall recesses is not permitted.

Penetration of liquids

ATTENTION: The housing is not absolutely watertight. Therefore do not place the device in the immediate vicinity of tubes or tanks containing liquids.

3.2 Electrical installation

Power cord, power outlet

WARNING! The supply voltage must match the voltage specified on the rating plate. The device may be connected to a properly installed protective contact socket. Only use the ATMOS power cord or an equivalent power cord for this purpose. The power cord must bear the national test symbol.

Inspecting equipment, unit and accessories

WARNING! Inspect the equipment or the unit and the accessories (e.g. foot control, cable) for damage after each use. You must not use damaged equipment, a damaged unit or damaged accessories. Exchange defective accessories. If the equipment or unit is damaged, please contact our customer service. For your safety and that of patients, never attempt to effect repairs yourself. Any modification will invalidate liability by ATMOS MedizinTechnik GmbH & Co. KG.

Fuses

WARNING! The unit is protected with fuses. They can be found in the fuse drawer next to the power connection of the equipment. If one of these power fuses has blown, the equipment may not be used on the patient again until it has been checked by a competent technician. Only spare fuses with the values indicated on the unit rating plate may be used.

- | | |
|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1) Potential equalisation | Connect an equipotential bonding conductor and attach this to the equipotential bonding system of the room. |
| (2) Power connection | Connect the unit to a properly installed grounded outlet. Only use the ATMOS power cord or an equivalent power cord for this purpose. The power cord must bear the national test symbol. |

Installing the main filter

The main filter is secured with two polystyrene blocks as protection for transportation. Pull the main filter out of the filter shaft. Remove the polystyrene blocks.

Push the main filter into the filter shaft of the unit until it snaps into place. Take care that the filter cover is on the right side.

3.3 Installation of the accessories



Fig. 2.

Attach the air hose of the particular accessory to the inlet of the main filter.



Fig. 3.

Connect the HF connector to the electrosurgical unit if you are using an electrode handle.



Fig. 4.



Attention!

Do not suck up any liquids. If there is a risk that you could suck up liquids during the operation, attach an in-line filter on the main filter. Replace the in-line filter immediately if you have sucked up any liquid.



4.1 Switching on the ATMOS® SE 6501

Switch on the power switch. The ATMOS® SE 6501 performs a self-test. All the displays illuminate.

4.2 Setting the ATMOS® SE 6501

Operation suction, Basic suction and Run-on time are adjustable. Select the desired function.

Using the <value higher / lower> buttons you can change the value of the selected function.

You can see the value on the display. The displayed value is either a percentage or in seconds. The percentage symbol or seconds symbol illuminates. The percentage figure refers to the device's maximum output.

Setting operation suction

Operation suction is the suction capacity during activation of the laser or electrosurgical unit or after manually starting the ATMOS® SE 6501. The terms manual start and manual deactivation mean the use of the <Start suction> button. Select a value between 20 and 100 %, using the <Higher> / <Lower> buttons. 100% corresponds to a suction capacity of approx. 650 l/min.


Setting the follow-up time

The operation suction runs on for a specified length of time after the ATMOS® SE 6501 is deactivated. This period of time is the follow-up time. Select a value between 0 and 10 seconds, using the <Higher> / <Lower> buttons.


You can also let the operation suction continue running for an indefinite period after deactivation of the electrosurgical unit or after manual deactivation of the ATMOS® SE 6501. Select a period longer than 10 seconds, using the <Higher> button. The word "On" appears on the display. The permanent operation suction mode is activated.

The permanent operation suction can be switched on and off with the <Start suction> button.

4.3 Aspiration

 **WARNING!** Position the suction device, or the instrument with suction device so that it cannot accidentally suck up swabs or the like.

Press the <Start suction> button or activate the attached laser or electro surgical device. The unit operates so long as the button is pressed or the attached laser or electro surgical device is activated. Suction then continues for the duration of the set follow-up time, after which basic suction takes place for the duration of the set basic suction time.

 **WARNING!** Never bring the suction hose into contact with the suction site. It could become attached to the tissue.

ATTENTION! Do not suck up any liquids. If there is a risk that you could suck up liquids during the operation, attach an in-line filter on the main filter. Replace the in-line filter immediately if you have sucked up any liquid.



5.1 Calling up the basic setting

Press and hold down the <Operation suction> button when you switch on the ATMOS® SE 6501. Press the <Start suction> button. Press the <Operation suction> button. The ATMOS® SE 6501 is now in the basic setting:

Basic suction setting

During work breaks, the unit operates at reduced capacity. The basic suction is the suction capacity after the run-on time. Select a value between 0 and 30%, using the <Higher> / <Lower> buttons. The base flow is switched off after a certain period of time (work's setting = 2 min). The timing for the basic setting can be adjusted in the settings menu. The basic suction time can be set between 1 and 99 seconds.

Furthermore the unlimited basic suction mode can be adjusted: Setting to "on".

Basic settings

- Operation suction: 80%
- Basic suction: 10%
- Run-on time: 2 s
- Blocked suction detection sensitivity: 5
- Suction inhibit after blocked suction detection: 0 s
- Basic suction time: 30 s
- Setting mode: On

5.2 Calling up the setting functions

Press and hold down the <Operation suction> button and the <Basic suction> button when you switch on the ATMOS® SE 6501. Press the <Start suction> button. You are now in Program 1 (P. 1) display brightness. Press the <Start suction> button again. Now you can select the display brightness using the <Higher / Lower> buttons. Press the <Start suction> button to confirm the changes. Select the next program using the <Higher> / <Lower> buttons. Press the <Operation suction> button when you have carried out all the settings.

Setting functions

- P. 1: Display brightness 1 - 10
- P. 2: Sound (On / Off) 0 - 1 (0 = off)
- P. 3: Blocked suction detection sensitivity 0 - 10 (0 = Off)
- P. 4: Suction inhibit after blocked suction detection 0 - 10 s
- P. 5: Basic suction time: 1 - 99 s (permanent = On)
- P. 6: Filter capacity 0 - 99 % (99 % = new filter, 0 % = exhausted)



Wipe-disinfection

For cleaning and disinfecting the surfaces of the unit ATMOS recommends a wipe disinfection. Use only disinfectant which complies with the relevant national standards.

Instructions for cleaning and disinfection

- WARNING!** Ensure that you disconnect the equipment or equipment cart from the power supply before starting cleaning and disinfection. Unplug the power connector!
- WARNING!** Mix the disinfectant in the concentration specified by the manufacturer.
Clean surfaces contaminated with blood before using the disinfectant, otherwise it may be less effective.
Wipe the surfaces ensuring that they are uniformly treated.
Comply with the reaction time of the disinfectant specified by the manufacturer.

For your safety


- WARNING!** Do not allow any moisture to get into the device. Drain off any ingress of liquid immediately. The equipment must be used again only when this liquid has completely evaporated.
- ATTENTION!** Do not alternate between using disinfectant solutions based on different active ingredients. A color reaction may occur with plastics.
- WARNING!** Do not clean or disinfect surfaces with combustible or explosive products. If their use cannot be avoided, combustible or explosive products must have completely evaporated before the unit is switched on.
- ATTENTION!** Do not treat surfaces with alcohol-based spray disinfectants for fast disinfection. With elastic moulded parts, keyboards and paint surfaces there is the risk of cracks. Propanol and ethanol will attack surfaces.
- ATTENTION!** If alcoholic disinfectants are used on units with foil keyboards, this may take off the anti-glare finish. The user surfaces still remain fully functional without presenting any risk.

Surface disinfectants

Disinfectant	Ingredients	(in 100g)	Manufacturer
Dismozon pur (Granulate) End of product 12/2014	Magnesium monoperoxyphthalate hexahydrate	80 g	Bode Chemie, Hamburg
Dismozon plus (Granulate)	Magnesium monoperoxyphthalate hexahydrate	95.8 g	Bode Chemie, Hamburg
Green & Clean SK (Application concentrate)	Alkyl dimethyl benzyl ammonium chloride Dialkyl-dimethyl-ammonium chloride	< 1 g	Metasys, Rum (Austria)

7.0 Technical data



Voltage	230 V~ ±10 %; 50/60 Hz Special voltage: 100 V~ ±10 %; 50/60 Hz 115 V~ ±10 %; 50/60 Hz 127 V~ ±10 %; 50/60 Hz
Current consumption	Start-up max. 2.6 A (230 V~) Operation (100 %) 1,4 A (230 V~)
Power consumption	Start-up max. 600 W Operation (100 %) 330 W
Fuse	T 3,15 A/H (f. 230 V~)
Other safety equipment	Connection for potential equalization
Device-suction capacity	Controlled 640 l/min +/-20
Blower-suction capacity	Free flow blower 1600 l/min
Operating time	Continuous operation possible by: 100 % suction capacity and max. 30 °C and max. 253 V and 10 mm suction hose with handle
Mains filter	Particle retention 99,9995 % ULPA U-15 Service-life min. 35 h (depending on flow)
Ambient conditions for transport/storage	
• Temperature	-40...+70 °C
• Humidity without condensation	10...95 %
• Air pressure	700...1060 hPa
Ambient conditions for operation	
• Temperature	+10...+40 °C
• Humidity without condensation	15...80 %
• Air pressure	700...1060 hPa
Maximum operational altitude	≤ 3000 m (NN)
Contamination level	Class 2
Overvoltage category	II
Dimensions HxWxD	261 x 205 x 407 mm
Weight	11.2 kg (without main filter)
Period tests	Recommended: Testing every 24 months
Protection class (EN 60601-1)	I
Degree of protection	Application parts type CF 
Type of protection	IP X0
Classification according to Appendix IX EC Directive 93/42/EEC	Class 1
GMDN code	37861
UMDNS code	11-814

Issue of technical data: 20.10.2017



Where EMC is concerned, medical electrical equipment is subject to special safety measures and must be installed and commissioned according to the EMC instructions stated herein.

ATTENTION! The use of internal cables other than those specified in the Service Manual may result in increased emissions or decreased immunity of the equipment.

⚠ Attention! The equipment should not be used adjacent to or stacked with equipment, other than with that which is intended for this purpose. If adjacent or stacked use is necessary, the entire system should be observed to verify normal operation in the configuration in which it will be used.

Guidelines and Manufacturer's Declaration - Immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment - Guidance
RF Emission acc.to CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and it is unlikely that nearby electronic devices will be affected.
RF Emission acc.to CISPR 11	Class B	The device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker according to IEC 61000-3-3	complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.			
Immunity test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be made of wood or concrete or tiled with ceramic tiles. If floors are non-conductive synthetic, the relative humidity should be at least 30 %.
Fast electrical transient/burst IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains ± 1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.



Guidance and manufacturer's declaration - electromagnetic immunity			
Surges IEC 61000-4-5	1 kV Common 2 kV Differential	1 kV Common 2 kV Differential	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips / Dropout IEC 61000-4-11	<5% U_T (>95% Dip of the U_T) for 0.5 Cycles 40% U_T (60% Dip of the U_T) for 5 Cycles 70% U_T (30% Dip of the U_T) for 25 Cycles <5% U_T (>95% Dip of the U_T) for 5 seconds	<5% U_T (>95% Dip of the U_T) for 0.5 Cycles 40% U_T (60% Dip of the U_T) for 5 Cycles 70% U_T (30% Dip of the U_T) for 25 Cycles <5% U_T (>95% Dip of the U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued function during interruptions of the energy supply, it is recommended to supply the device from an uninterruptible power supply or a battery.
Magnetic field at power frequency 50/60 Hz acc. to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level.

Guidelines and Manufacturer's Declaration - Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.			
Immunity test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile HF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance. The separation distance is calculated from various equations depending on the frequency of the portable and mobile HF communications equipment:
			Recommended distances
conducted interference according to IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Equation 1) $d=1.2 P^{1/2}$
Radiated RF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	3 V/m	Equation 2) $d=1.2 P^{1/2}$
	3 V/m 800 MHz to 2.5 GHz	3 V/m	Equation 3) $d=2.3 P^{1/2}$



Guidance and manufacturer's declaration - electromagnetic immunity

P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. d is the recommended separation distance in metres (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey a) should be less than the compliance level in each frequency range b). Interference may occur in the vicinity of equipment marked with the following symbol:



NOTE 1: At 80 MHz equation 2) applies. At 800 MHz equation 3) applies.

NOTE 2: These guidelines may not be applicable in all situations. The propagation of electromagnetic waves is influenced by absorptions and reflections of buildings, objects and people.

a) The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predetermined exactly. To assess the electromagnetic environment due to fixed HF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

B) Over the frequency range of 150 kHz to 80 MHz, field strengths should be lower than 3 V/m.

Recommended safety distance between portable and mobile RF Communications equipment

The device is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference. This can be achieved by maintaining the minimum distance recommended below between the communications equipment (transmitters) and the equipment. The minimum distance depends on the maximum output power and the frequency of the communications equipment.

Power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2 P^{1/2}$	80 kHz to 800 MHz $d=1.2 P^{1/2}$	800 MHz to 2.5 GHz $d=2.3 P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance can be determined using the equation applicable to the frequency of the transmitter. P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the frequency bands between 80 MHz and 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 2: These guidelines may not be applicable in all situations. The propagation of electromagnetic waves is influenced by absorptions and reflections of buildings, objects and people.

9.0 Maintenance, Customer Service, Warranty, Disposal

9.1 Maintenance

Maintenance, repairs and period tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures the person must have the necessary test devices and original spare parts.

ATMOS recommends: Work should be carried out by an authorized ATMOS service partner. This ensures that repairs and testing are carried out professionally, original spare parts are used and warranty claims remain unaffected.

Period tests

Please comply with the country-specific guidelines regarding regular testing especially for the electrical safety. ATMOS recommends a test every 24 months.

9.2 Customer Service

If you are interested in a maintenance contract, please contact ATMOS or an authorized distributor.

Do you have any questions concerning the equipment or operating instructions? Would you like scientific publications from ATMOS? If so, contact an ATMOS employee or your local branch office. We are gladly prepared to provide further assistance.

9.3 Warranty

- Inspect the equipment or unit for deficiencies and transport damage immediately on receipt. Claims for compensation for such deficiencies can be accepted only when the seller or transporter is notified without delay. A damage report must be compiled.
- The warranty period is 3 years from the date of delivery. A claim under warranty is valid only on presentation of a correctly completed warranty card.
- The scope of the warranty covers cost-free repair of ATMOS equipment provided that the damage was caused by a material or manufacturing deficiency. Other claims, in particular claims for compensation, are excluded.
- The repair must be carried out only by ATMOS or by persons who have been expressly authorized by ATMOS. Claims under warranty are void if improper modifications or repairs have been undertaken.
- The warranty is neither extended nor renewed by services under warranty.

9.4 Disposal

- The ATMOS® SE 6501 does not contain any hazardous goods.
- The housing is recyclable.
- Device and accessories must be decontaminated prior to disposal.
- Pay attention to a careful separation of the different materials.
- Please observe national disposal regulations (e.g. waste incineration).



Disposal within the EC

The device described above is a high-quality medical product with a long service life. After its life cycle it must be disposed of professionally. According to the EC directives (WEEE and RoHS) the device may not be disposed of in domestic waste. Please observe existing national laws and rules for disposal of old devices in the respective country.

Disposal within the Federal Republic of Germany

In the Federal Republic of Germany the law for electrical devices (ElektroG) regulates the disposal of electrical devices. In order to guarantee a proper disposal of your old device, please either pass on your old device to your specialised dealer or send it directly to ATMOS MedizinTechnik for a professional disposal.

Before disposal respectively before transport all parts, which came into contact with the patient must be thoroughly cleaned, disinfected. The device surface must be disinfected.

9.5 Sending in the device

- Remove and properly dispose of consumables.
- Clean and disinfect the product and accessories according to the operating instructions.
- Place used accessories with the product.
- Fill in the form QD 434 „Delivery complaint / return shipment“ and the respective decontamination certificate.
- ☞ This form is enclosed with each delivery and can be found at www.atmosmed.com.
- The device must be well padded and packed in suitable packaging.
- Place the form QD 434 „Delivery complaint / return shipment“ and the respective **decontamination certificate** in an envelope.
- Affix the envelope to the outside of the package.
- Send the product to ATMOS or to your dealer.



MedizinTechnik

ATMOS MedizinTechnik GmbH & Co. KG

Ludwig-Kegel-Straße 16

79853 Lenzkirch / Germany

Phone: +49 7653 689-0

atmos@atmosmed.de

www.atmosmed.com