ATMOS
MedizinTechnik

English

Operating Instructions

AtmoSafe

CE

GA1GB.220101.0

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1.0 Introduction

1.1 Notes on Operating Instructions

- These operating instructions contain important notes on how to operate the ATMOSafe safely, correctly and effectively. Therefore, they are intended not only for new operating personnel to be instructed in its use, but also for use as a reference manual. They help to avoid risks, and also to reduce repair costs and down-times. Furthermore, reliability and service-life of the equipment will be increased. For these reasons these operating instructions must always be kept available near the device.

  Prior to first use please peruse the chapter 2.0 “For your safety”.

The basic principles are:

Judicious and careful work provides best protection against accidents!

Maintenance and repair work may be carried out only by expert personnel authorised by ATMOS. In case of repairs you should insist that only original spare parts are used. You will then have the warranty that operational safety, readiness for work and the value of your device will be preserved.

- The product ATMOafe bears CE marking CE 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 ATMOSafe 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.
- ATMOS will supply a service manual containing detailed circuit descriptions and schematics as well as information on adjustment and servicing to service organizations authorized by ATMOS.
- Reprints (also in extracts) only with permission in written form by ATMOS.

Short cuts / symbols contained in these operating instructions:

- Indicating a list
  - Subdivision of a list/activity

  The recommended sequence must be followed in each case!

☞ Indicating particularly important advice!

↳ Describing the effect of an activity

1.2 Function

- The AtmoSafe is an electrically operated medical device, cleaning the air in medically used rooms from fume and gas constituents arising from vaporising of human or animal tissue. This fume arises typically when using laser or electro-surgical devices and is consisting as a rule of water vapour, aerosol, and organic gases.
- The AtmoSafe improves the environmental conditions in the operating theatre:
  - Reduction of the dust load by removing respirable particles
  - Improvement of view
  - Removal of foul-smelling and partly toxic organic gases
  - Evacuation and filtering of hazardous bio-aerosol (filtration of viruses)
- The AtmoSafe draws in the fume-laden air through a device positioned at the surgical application part or through a separate hose, manually held near the application part. By means of a high-efficiency filter the drawn-in air is cleaned of the hazardous matter and returned again into the ambient air.
- Cleaning of the air refers to constituents like aerosol, which is being retained by means of an ULPA high-efficiency particle filter, as well as to organic gases, which, amongst other characteristics, feature a smell unpleasant for human beings, retained by a special *gas filter*.

1.3 Explanation of symbols

Caution, observe operating instructions!	Follow operating instructions! (blue)	Display: Air passage blocked
Equipment safety fuse	Foot switch	Unit must not be exposed to explosive anaesthetic gases
Potential equalisation	Filter	Anaesthetic-tested
Application part type CF, defi-protected	Start	Protected for use in explosive atmospheres
Delayed stop period	Stop	Display: Filter to be changed
Base flow	Operation flow	Alternating current

2.0 For your safety

- The AtmoSafe has been designed in accordance with IEC 601/ EN 60601. The equipment conforms to VDE Safety Class I. It must only be connected to a properly installed earthed socket.
- Before connecting the device it needs to be checked whether the requested **mains voltage** of the device matches the mains voltage of the mains power supply.

- The AtmoSafe may be used only by trained staff under supervision (IEC 601-1 / EN 60601-1).

- Following transportation at low temperatures (<0°C) the appliance must be held for up to six hours at ambient temperature before first start-up. If the AtmoSafe **is not** acclimatized, it may **not** be used.
- The suction hose must never come into direct contact with the evacuation position in order to avoid suction adherence on the tissue.

- Check device, power cable, accessories, connection cables and hoses for damage before start-up. Defect cables and hoses must be replaced immediately. Check functions of the device prior to using it!

- Disconnection from supply network only by pulling the mains plug! First the plug is to be pulled from the wall socket. Then disconnect the connection line from the device.
- Never touch plug or line with wet hands.

- Please observe the ambient conditions stated in the technical data (chapter 10.0).
- Pay attention to maximum stability of the installation surface.

- The device must only be operated in rooms designated for medical use. The AtmoSafe **is not designed to be used in an explosion-hazardous** environment. Explosion-hazardous areas may be caused by the use of flammable anaesthetics, skin cleansing products and skin disinfectants. The suction opening of the hose should not lie on the floor Evacuation of explosive endogenous gases (e.g. methane) from the intestinal tract is also prohibited.

- The foot switch must be suitable for use in areas subject to explosion hazards. Foot switches used on operation theatres must have a watertight switching element (IPX 8).

- This product is not re-sterilizable. Repeated reuse of components which are marked with a ② is forbidden. In case of repeated reuse these components lose their function and there is a high infection risk.
- The AtmoSafe may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen rich environments.

- Do not allow any liquid to get into the device or be sucked in. If liquids have penetrated the device, it may not be operated again until it has been checked by the customer service centre.

EMC✓

- The AtmoSafe meets the immunity to interference requirements of **IEC 601-1-2 / EN 60601-1-2** „Electromagnetic Compatibility – Medical Electrical Devices“.

2.0 For your safety

- ATMOS is not liable for personal injury and damage to property if
  - no original ATMOS parts are being used,
  - the advice for use in these operating instructions is not being observed,
  - assembly, new settings, alterations, extensions and repairs have been carried out by personnel not authorised by ATMOS.

Sterile

- In the surgical invasive sterile area sterile parts only may be used. Hoses, application parts, as well as instruments, must be used either as sterile single-use part or sterilised multiple-use part.
- Power cables must correspond to the applicable national regulations. The suitability for medical applications must be ensured in particular.

Hospital Grade

- In case of leaks in the system the indication for suction adherence may fail.
- With very low power setting at the HF surgical device auto activation may possibly not function.
- In case of high electromagnetic and performance-related interference the sensitivity of auto activation must be reduced.
- 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.

3.0 Intended use

Name: AtmoSafe

Main functions: Smoke extraction system for use in conjunction with smoke or gas producing medical appliances, like laser and high-frequency surgical appliances, cauterises, oscillation saw, and methods like the removal of bone cement in revision endoprosthetics.

Medical indications / application: For extraction and filtering of evaporated burn-off products arising with thermal medical operations by vaporisation of tissue.

For extraction and filtering of aerosols, emitted by oscillation saws (e.g. in autopsy).

For extraction and filtering of vapours arising when two component adhesives or cement mixtures are mixed and used (e.g. in implant surgical work).

Specification of the main function: The AtmoSafe draws in the fume-laden air through a device positioned at the surgical application part or through a separate hose, manually held near the application part. By means of a high-efficiency filter the drawn-in air is cleaned of the hazardous matter and returned again into the ambient air. Cleaning of the air refers to constituents like aerosols, which is being retained by means of an ULPA high-efficiency particle filter.

Application organ: No specific application organ

Application time: Short-term use on the patient (< 30 days).

Application site: The application site is the clinical, outpatient as well as the practices area. The application of the device may only be performed by medically trained and introduced staff .

Contraindications: No application outside of the medical sector. No suction of flammable, corrosive and explosive substances.

The product is: X active □ not active

Sterility: Not necessary

Single-use product / reprocessing: The device and part of the accessories are reusable. For information on reprocessing and disinfection, please see the operating instructions.

4.1 Illustrations

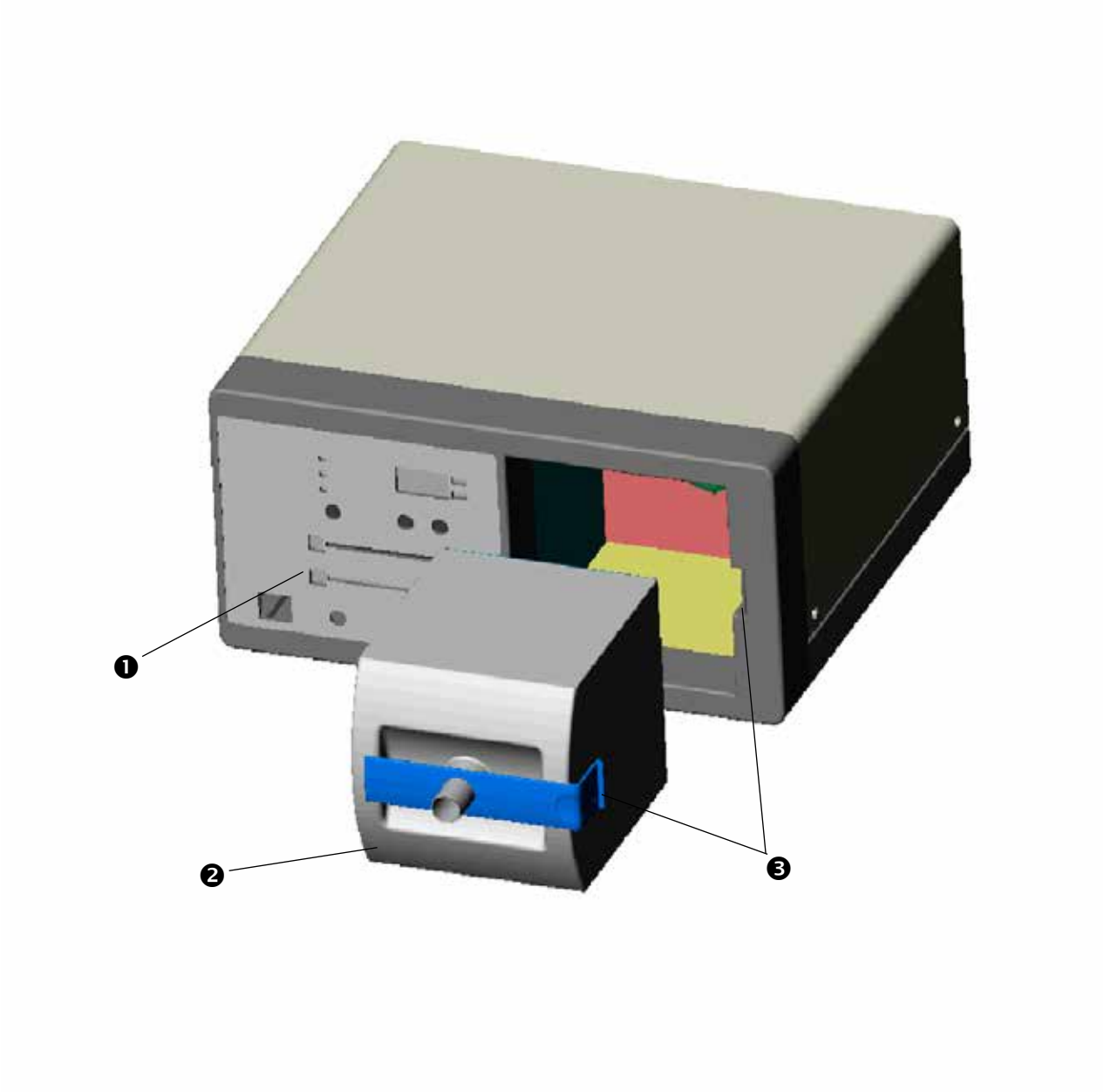


Fig. 1. AtmoSafe Overall view

- ❶ Operator panel
- ❷ Mains filter
- ❸ Filter locking

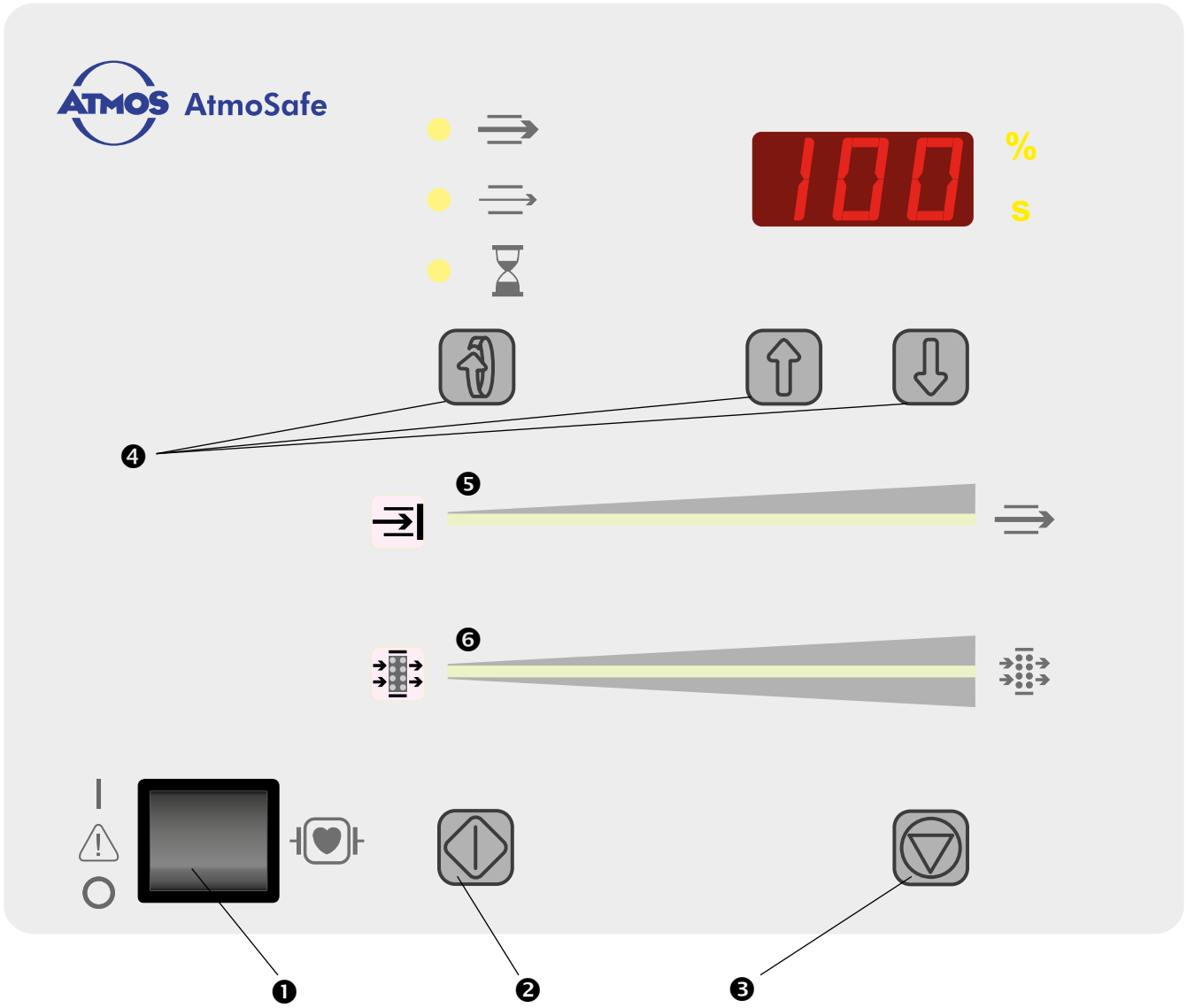


Fig. 2. Display and control elements

- ❶ ON/OFF switch
- ❷ Start button manual
- ❸ Stop button manuel
- ❹ Presetting buttons
- ❺ Air flow display
- ❻ Filter capacity display

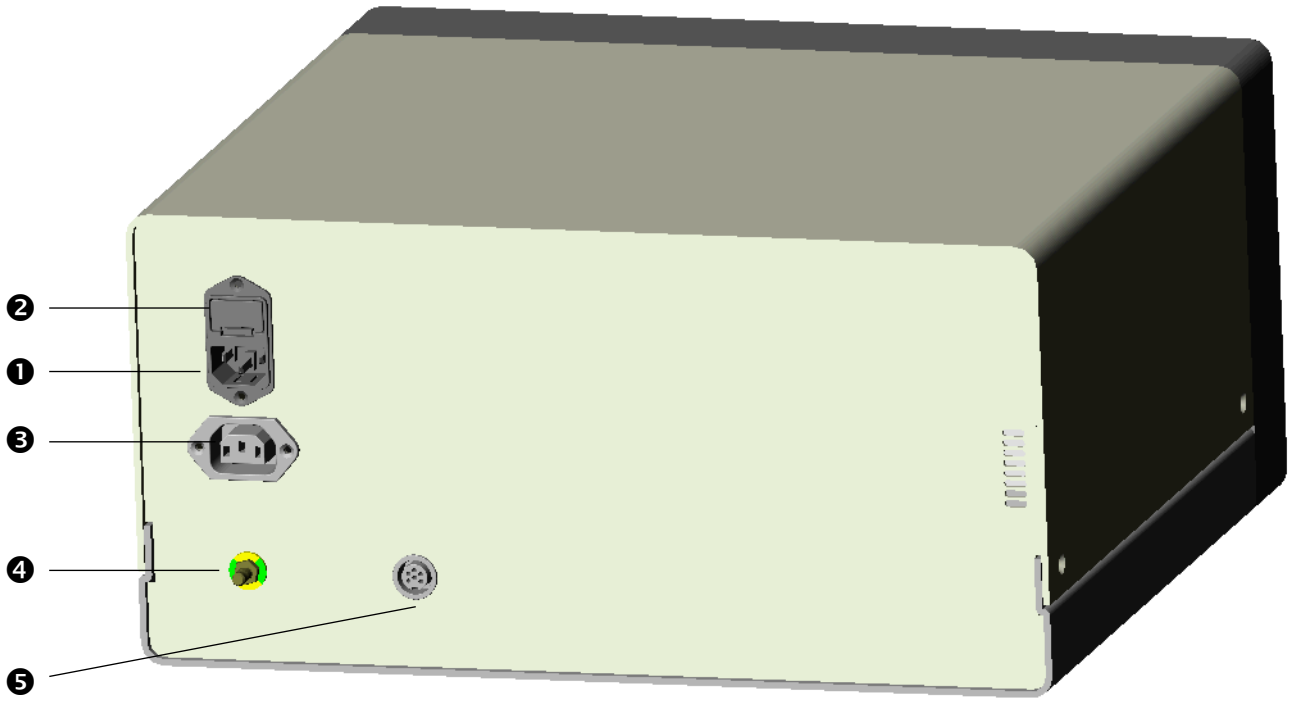


Fig. 3. AtmoSafe Rear view

- ❶ Mains supply
- ❷ Equipment safety fuse
- ❸ Non-heating apparatus mains connection for an HF surgical device
- ❹ Connection for potential equalization
- ❺ Activation input

5.1 Initial starting up

Prior to shipment each AtmoSafe is being inspected by the manufacturer for function and safety. In order to make sure that the appliance is working safely after transport and installation, the following points should be observed: The user should put the appliance into operation only if the manufacturer or the supplier

1. has carried out a functional test on the appliance at the place of operation
2. has instructed the person responsible for operating the device on how to handle the device by means of the operating instructions.

Peruse safety information in part 2.0 prior to starting up the device for the first time.

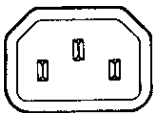
Following transportation at low temperatures (<0°C) the appliance must be held for up to six hours at ambient temperature before first start-up. When the device has not been acclimatised evacuation cannot be activated The device is protecting itself.

5.2 Assembly

The device has to be positioned on a stable base; attention must be paid to the load carrying capacity.

The base must not be soft (foamed material or similar), so that the exhaust air openings are not covered.

5.2.1 Installation together with a surgical device



The power cable of the surgical device must be fi tted with an inlet connector for non-heating apparatus according to IEC 320.

This inlet connector for non-heating apparatus is plugged into the auxillary mains socket (❸, Fig. 3) on the rear of the AtmoSafe. The AtmoSafe is now controlling the power input of the surgical device by means of the internal ISA device (Internal Synchronous Activation) and, in this way, effects auto activation. Auto activation means that the evacuation mode is switched on as soon as the thermal surgical function of the surgical device (Cut, coag,...) is activated.

Prior to first use of the surgical device auto activation must be calibrated once. How the AtmoSafe is to be adapted to the surgical device is said in Chapter 5.7.5 Calibration of auto activation.

Auto activation of the AtmoSafe works with most surgical devices in the power range 50 W...1400 W (for inst. ERBE ICC 350, ICC 50,...)

Only compatible devices may be connected to the auxiliary mains socket (❸,Fig. 3).

5.2.2 Main filter

- After having taken off the packaging and the plugs, please slide the main filter (❷, Fig. 1, p. 15) into the filter shaft of the unit until it locks. Take care that the filter cover is on the right side.

  When there is no main filter in the unit evacuation cannot be activated.

5.2.3 Hose

- After having taken off the packaging the hose (Ø 22 mm) is put with one end onto the connecting nipple of the main filter.

5.2.4 Prefilter

- Please put the prefilter onto the hose, preferably at the open hose end. The prefilter protects the hose and the main filter against coarse contamination. For more flexibility at the hose end near the field of operation, the filter can be installed between the hose and the main filter. The direction of flow must be taken care of, it is shown on the prefilter. You must use only a clean and dry filter.

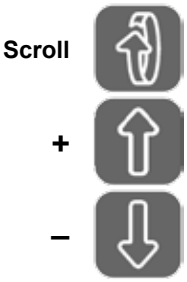
5.2.5 Check on supply voltage

- Please check whether the mains voltage data shown on the fuse drawer (❷, Fig. 3, p. 17) of the device agree with the values of the mains supply network, and then connect the AtmoSafe to the supply network.

☞ If the AtmoSafe is used for surgical procedures, we recommend connecting it to the equipotential bonding connection of the room via connection.

The AtmoSafe is now ready for operation.

5.3 Settings



5.3.1 Presettings general

The values for operation flow, base flow, and delay can be set individually. By using the scroll button the desired parameter to be changed can be selected. The currently set flow value is shown in the display in percent. The value can be set in % - related to the total rating of the device - by 1%-steps. The currently set delay is shown in the display in seconds. By means of the arrow buttons the value can be increased or reduced. With prolonged pressing of the corresponding arrow button or , setting speed increases, so that also larger changes can be effected quickly.

5.3.2 Base flow

Also during interruptions of work, i.e. when there is no activation signal received from the laser or the HF surgical device or from the foot switch received, the device works with reduced intensity. In order to be able to set the flow intensity of this base flow you should activate the scroll button repeatedly until the indicating light next to the base flow symbol lights up. Now, you press the arrow buttons until the desired value is obtained. This value can be set between 0 and 30 %. The base flow is switched off after a certain period of time (work's setting = 2 min). This time, i.e. the base flow time, can be set on the service level. (See also chapter 5.7 Service level).

5.3.3 Operation flow

During the surgical operation, i.e. when there is an activation signal received from the laser or from the HF surgical device or from the foot switch, the device shall extract the fumes which develop with full intensity. In order to be able to set the flow rate of this operation flow you should activate the scroll button repeatedly until the indicating light next to the operation flow symbol lights up. Now, you press the arrow buttons until the desired value is obtained.

5.3.4 Delay

In order to prevent activation and de-activation of operation flow at short intervals during the frequent interruptions between cutting and coagulation phases the flow continues for a certain period of time after the end of the cutting / coagulation procedure (i.e. after the activation signal is off). In order to be able to set the delay period of this operation flow you should activate the scroll button repeatedly until the indicating light next to the delay symbol lights up. Now, you press the arrow buttons until the desired value is obtained. Adjustments from 0...100 sec are possible as well as "0 ", i.e. unlimited delay. With the adjustment "0 the start button or a connected foot switch has following function (operated once = 'on', operated once again = 'off ').

5.4 Display elements

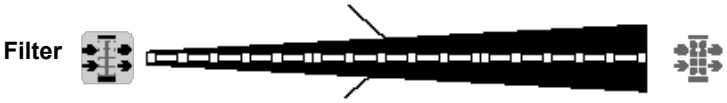
5.4.1 Flow indication

This points out the air resistance arising in the air passage (through the hose and filter system). When all the green bars are lit up, the suction resistance is low. The less bars are lit, the lower the flow. The display permits to draw conclusions, for inst. regarding the degree of blocking of the prefilter.

When the system is completely blocked, all the green bar indicators are off, and the display on the left lights up red.

5.4.2 Filter capacity

The display of filter capacity permits quick assessment of the current filter status. The more green bar indicators are lit up, the more capacity there is still left. With full exhaustion of filter capacity the green indicators are off, and the display on the left lights up red.

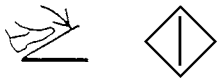


5.5 Aspiration

Please ensure that for invasive treatment the following parts are **sterile** with each new patient:

- Suction hose incl. suction jets or suction set.
- All parts extending into the operating field, in particular those near or in contact with the patient.

- Switch on the AtmoSafe by means of power switch (❶, Fig.2, p. 16).
- Please ensure that the suction hose is correctly positioned, i.e. that no sensitive parts or swabs or similar, are sucked in.



- Please activate now the flow by pressing the start button or the connected foot switch. The device will continue to work as long as the button is pressed. Thereafter, the flow will continue for the duration of the set delay period (see Chapter 5.3.4).

5.6 Options

5.6.1 Foot switch (Art. No. see accessories)

- Explosion-protected switch (AP safety) for switching flow on and off.

  - Connect the foot switch.
  - When pressing the foot switch the flow is switched on. After releasing the foot button the device will continue to work for the duration of the set delay period.
  - The function of the foot button is the same as that of the start button.

Scroll

Main switch

5.7 Service level

The service level permits the user to change certain ex work's settings.

You will reach the service level by pressing the SCROLL button (❹, Fig. 2, p. 16) and then switching on the device by means of the power switch (❶, Fig. 2, p.16). Then in the display will appear:

Basic program - Display "S 0 “

Button Description

⇧ Selection of service sub-program (plus)

⇩ Selection of service sub-program (minus)

▽ Exit form service mode

◇ Calling the corresponding sub-program

Sub-programs – overview

Display	Description
S 0	Change brightness of display
S 1	Automatic activation on / off
S 2	Suction adherence indication on / off
S 3	Change base flow period
S 4	Calibration on auto activation (automatic)
S 5	Calibration on auto activation (manual)

5.7.1 S 0 Change brightness of display

Display: 0 0 ..... 010 (Brightness value)

Button Description

⇧ Brightness +

⇩ Brightness -

▽ Return (incl. store)

Description:

Brightness can be set between 0 and 10.

5.7.2 S 1 Automatic activation on / off

Display: 1 0 (Activation off) 1 1 (Activation on)

Button Description

⇧ Activation on

⇩ Activation off

▽ Return (incl. store)

Description:

The activation by means of the integrated current sensor can be switched on and off as required

5.7.3 S 2 Suction adherence indication on / off

Display: 2 0 (Suction adherence indication off) 2 1 ((Suction adherence indication on)

Button Description

⇧ Suction adherence indication on

⇩ Suction adherence indication off

▽ Return (incl. store)

Description:

The suction adherence indication can be switched on and off as required Suction adherence indication can be switched on and off as required.

5.7.4 S 3 Change base flow period

Display: 300 .... 399 (Base flow period in seconds)

Button Description

⇧ Base flow period +

⇩ Base flow period -

▽ Return (incl. store)

Description:

Here the base flow period can be set. The device remains in base flow mode, as determined by this setting. Thereafter the device is switched off. With setting 99 there is no time limit for the base flow.

5.7.5 S 4 Calibration on auto activation (automatic)

Display: 499 .... 400 (Potentiometer setting in %)

Button Description

⇧ Start of calibration

▽ Termination

Following auto-calibration manual postprocessing takes place automatically (see S 7).

Description:

Prior to starting auto-calibration the corresponding surgical device must be connected and activated. The set position should be the minimum setting. The device will then search automatically for the corresponding setting value. For validation, automatic calibration is always followed by manual calibration (see S 7).

5.7.6 S 5 Calibration on auto activation (manual)

Display: 500 .... 599 (Potentiometer setting in %) All LEDs (on = activation takes place, off = no activation)

Button Description

⇧ Activation threshold + (less sensitive)

⇩ Activation threshold – (more sensitive)

▽ Return (incl. store)

Description:

Here sensitivity of automatic activation can be set. For doing this, the corresponding HF device must be connected. The setting must be done in a manner that with activated surgical device the LEDs are lit, and with non-activated surgical device the LEDs are not lit.

6.0 Cleaning and care

6.1 General information on cleaning and disinfection

- For disinfection, you may use all surface and instrument disinfectants listed on page 32.

☞ There are disinfectants which can cause discolouration of plastic parts, like the filter case, etc.; this however does not effect the function of the parts.

☞ Always observe the concentration specifications and instructions by the respective manufacturer!

6.2 Reprocessing of the hoses

☞ Please ensure that the following parts have been disinfected before treating a new patient:

- Suction hose incl. suction jets or suction set.

- Washing and disinfecting in an automatic cleaner and disinfector is also possible.
  Thermal disinfection is carried out at 93° C.

- After disinfecting the parts are to be mounted again (Chapter 5.0 “Operation”).

6.3 Cleaning and disinfecting the surface of the unit

☞ You must disconnect the mains plug before cleaning and disinfecting the unit casing.

☞ Wipe-disinfection:
Wipe the unit surface with a **cloth** moistened with a cleaning or disinfecting solution. Do not allow any liquid to get into the device. The cleaning agents and disinfectants listed in the next section are all suitable.

☞ If liquid has penetrated the unit, it may not be operated again until it has been checked by the authorised customer service centre.

☞ Do not use disinfectants containing alcohol.

Recommended instrument disinfectants

Disinfectant	**Producer**
GIGASEPT FF	Schülke & Mayr, Norderstedt
Sekusept PLUS	Henkel, Düsseldorf
Mucozit-T	Merz & Co., Frankfurt/Main

Recommended surface disinfectants

Disinfectant	**Producer**
TERRALIN	Schülke & Mayr, Norderstedt
QUATOHEX	Braun, Melsungen
Incidin Plus	Henkel, Düsseldorf
Pursept-A (Disinfection spray or disinfection cloth)	Merz & Co., Frankfurt/M.

7.0 Maintenance and Service

The base device is maintenance-free.

Filter replacement:

- As described in operating instructions, section 5.2.2 Main filter.

Preventive maintenance of evacuation system:

- Prior to every use a visual inspection of the device, hoses, main and prefilter and mains power cable must be performed.

  When using further accessories, like liquid vessel, foot switch or activation sensors, also these should be subjected to a visual check.

- Replace any damaged parts immediately.

- The unit does not require any further maintenance.

Corrective maintenance of system:

- Any changes or repairs may - with due regard to the special requirements for medical products - be carried out only by the manufacturer or by persons expressly authorised by the latter.
- Please comply with the country-specific guidelines regarding regular testing especially for the electrical safety. ATMOS recommends a test every 24 months.

Sending in the device

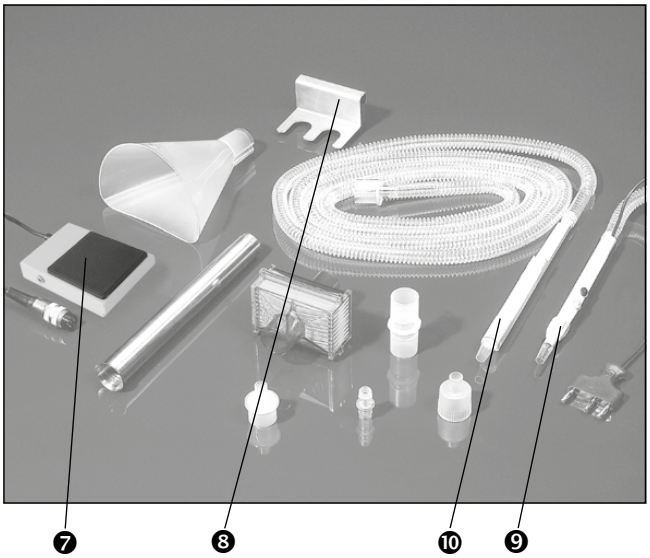
1. Remove and properly dispose of consumables.
2. Clean and disinfect the product and accessories according to the operating instructions.
3. Place used accessories with the product.
4. Fill in the form QD 434 „Delivery complaint / return shipment“ and the respective **decontamination certificate**.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

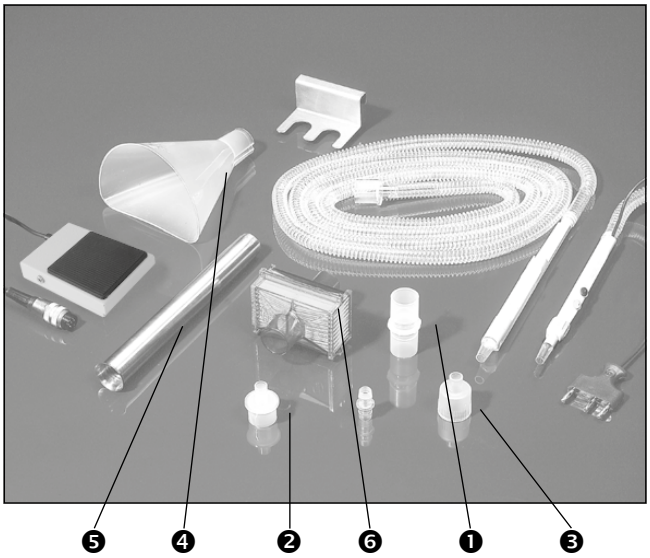
8.0 Troubleshooting

The AtmoSafe was subjected to a thorough quality control in the factory. If however any problems should occur, you can possibly eliminate these personally, if observing the following notes.

Error indication	*Possible cause*	*Remedy*
• Device does not start	- Power plug is fitted badly	- Check connection at wall socket
	- No mains voltage	- Check main fuse
	- Defect fuse	- Have fuse replaced by service
• Insufficient flow	- Leaks in hose lines	- Check hose lines for firm seating
	- Main filter is blocked	- Replace main filter
	- Prefilter is blocked	- Replace prefilter
• Display **E 01**	- Calibration defect of intern pressure sensor	- Service must carry out calibration on site
• Display **E 02**	- Excess temperature (>69°C) or sub temperature (<0°C)	- Switch off device and wait until temperature inside the device returns to normal
• Display **E 03**	- Data fault on main board	- Switch device off and on again. Should now suction adherence indication no longer work, customer service must carry out calibration on site.
• Display **E 04**	- Blower does not work	- Switch device off and on again. With renewed defect inform service.

9.0 Accessories and spare parts





9.1 Accessories

Operating instructions GA1GB.220101.0

Connection line for electric equipotential bonding (possibly only in operating theatre) 008.0596.0

❼ Foot switch for AtmoSafe, suitable for use in Zone M (not for operating theatre), explosion-protected, IPX 1 ..... 445.0061.0

OP foot switch for AtmoSafe, suitable for use in Zone M, explosion-protected, IPX 8 ..... 445.0068.0

Standard rail set 25 x 10 mm / 315 mm for lateral mounting to AtmoSafe 445.0064.0

❽ Hose holder for insertion into standard rails (25 x 10 mm or 30 x 10 mm), for air hoses with Ø 22 mm 445.0066.0

❾ Surgical handle, with integrated suction channel, with standard international plug-connection HF surgical devices, incl. air hose 10 mm, 2.5 m, ESU cable length 3 m 445.0062.0

❿ Fume evacuation handle of clip-on type, for adaption of mono-polar standard surgical handle, incl. air hose Ø 10 mm and length 2.5 m 445.0063.0

Air hose Ø 10 mm, of various lengths ..... On request

Articulated arm with 3 joints for attaching to normal standard rails (25 x 10 mm), extended length approx. 1.3 m, with 5 hose holders for hose with Ø 22 mm 445.0060.0

9.2 Spare parts

AtmoSafe compl. base package 445.0000.0

Air hose, Ø 22 mm (W), 2.10 m, for single-use, of E.V.A. 005.0200.0

Air hose Ø 22 mm, L = 2.70 m made of Hytrel, connecting sockets made of silicone temperature-resistant up to 200 °C 005.0201.0

Air hose Ø 22 mm, L = 2.10 m temperature-resistant up to 200 °C 005.0203.0

Air hose, internal Ø = 10 mm, L = 1.8 m, temperature-resistant up to 200 °C, made of hytrel, connecting sockets made of silicone 005.0204.0

❶ Connection hose straight, Ø 22 mm (M) to Ø 22 mm (M) 000.0683.0

❷ Connection hose straight, Ø 22 mm (M) to Ø 10 mm (M) 000.0689.0

❸ Connection hose straight, Ø 22 mm (F) to Ø 10 mm (M) 000.0688.0

❹ Funnel, flat on one side, of PP, with connection in Ø 22 mm (F) 000.0687.0

❺ Suction tube, plastic, with ISO cone 22 mm (M) for suction hose Ø 22 mm (F) 445.0055.0

❻ Prefilter, in-line, (HEPA), with ISO connections in Ø 22 mm (M/F) 445.0044.0

Main filter unit for AtmoSafe, multi-stage gas filter + ULPA particle filter, micro-biocidal-coated compatible with the environment 445.0040.0

10.0 Technical data

Mains voltage (incl. tolerance)	AtmoSafe WORLD: 100...230VAC ± 10% (total range 90...253VAC) can be arranged by user / installer by inserting the correct fuse drawer AtmoSafe EUROPE: 230 V ± 10 %
Mains frequencies (incl. tolerance)	50...60 Hz +/-1%
Mains supply	Device inlet connector for non-heating apparatus
Auxiliary-mains power socket (IEC 320)	120 V / 9.7 A - 230 V / 6.3 A
Power consumption	Max. 400 W
Blower air flow (free-flow)	1600 l/min
Device air flow	650 l/min electronically controlled
Activation	Automatic activation, front-panel button, signal at activation input, optionally by foot switch
Operation mode	Suitable for continuous operation
Protective measures (Fuses,...)	The power pack is fitted with fusible cutouts 5 x 20. The motor of the blower is thermally protected.
Fuse (Breaking capacity H)	100 V: T4A (125 V) / 120 V: T4A (125 V) / 230V: 3.15A (250 V)
Acclimatisation rules	(Prior to start-up): 6 h acclimatisation after transport at low temperature
Maintenance	The base device is maintenance-free. Filter change and change of single-use articles (by user).
Designed freedom from maintenance	>10 Years (20,000h) (blower, bearings, rubber parts, etc.)
Corrective maintenance	(Acc. to DIN 31051 Measures for restoring the desired condition): Corrective maintenance by ATMOS or by customer service authorised by ATMOS in accordance with the country-specific regulations (in Germany DIN VDE 0751).
Period tests	Recommended: Testing every 24 months.
Ambient conditions	(In operation and in transport / storage):
Ambient temperatures	In operation: +10 ... +40°C / in transport and storage: - 40 ... +70°C
Air humidity	5...95 % (without condensation)
Air pressure	+ 700...1060 hPa
Weight	14 kg
Dimensions (H x W x D)	H 210 mm x W 368 mm x D 410 mm
Noise level	Max. 52 dB(A)@1 m (as per ISO 7779)
Interfaces	(Input and output) suction hose connection 7/8”(22 mm), equipotential bonding, activation input, mains connection
Protection class	I
MPG Class	Class I
Applied part	CF  defibrillator-protected
Mains filter	ULPA, retention = 99.9999 % @ 0.01µm

11.0 Disposal

Disposal of base device:

- Packaging consisting of cardboard and foamed polystyrene can be fully recycled or returned to your supplier.
- The AtmoSafe does not contain any hazardous materials.
- The housing is recyclable.
- The components of the product can be disposed like normal electronic scrap Recyclable materials should be, as far as possible and reasonable, delivered separately to a recycling organisation.

Disposal of accessories:

- The main filter and other accessories are biologically contaminated material and have to be disposed of by specialist firms in compliance with given regulation.

12.0 Notes on EMC

- Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.
- Portable and mobile HF communication facilities can influence medical electrical equipment.
- The use of other accessories, other converters and cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.

12.1 Guidelines and Manufacturer's Declaration - Emissions

The AtmoSafe is intended for use in the electromagnetic environment specified below. The customer or user of the AtmoSafe should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions acc.to CISPR 11	Group 1	The AtmoSafe uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions acc. to CISPR 11	Class B	The AtmoSafe 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.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker according to IEC 61000-3-3	Corresponds	

The device may not be used directly next to other devices or piled up with other devices. If operation next to or piled with other devices is necessary, please watch the device to check its intended operation in this arrangement.

11.2 Guidelines and Manufacturer's Declaration - Immunity

The AtmoSafe 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 wood, concrete, or ceramic tile. If floors are 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 Inapplicable	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	1 kV Differential 1 kV Common	2 kV Differential 1 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
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.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
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 sec	< 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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AtmoSafe demands continued function even in case of interruptions of the energy supply, it is recommended to supply the Atmosafe from an uninterruptible current supply or a battery.
NOTE U_T is the mains alternating current prior to application of the test levels.			

12.3 Guidelines and Manufacturer's Declaration - Immunity

The AtmoSafe 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
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	Portable and mobile communications equipment should be separated from the AtmoSafe incl. the cables by no less than the distances calculated/listed below. **Recommended distances:** d = (3.5 / V1) * √(P) d = (3.5 / E1) * √(P) 80-800 MHz d = (7 / E1) * √(P) 0.8-2.5 GHz where „P“ is the max. power in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site (a) survey, should be less than the compliance level (b). Interference may occur in the vicinity of equipment containing following symbol: 
Radiated HF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 By 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines might not be applicable in all cases. The emanation of electromagnetic waves is affected by absorption and reflection 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 predestined exactly. To determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the AtmoSafe is used exceeds the above compliance level, the AtmoSafe is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures might be necessary, e. g. a changed arrangement or another location for the device.

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

12.4 Recommended safety distance between portable and mobile RF Communications equipment and the AtmoSafe

The AtmoSafe is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the AtmoSafe can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the AtmoSafe as recommended below, according to the maximum output power of the communications equipment.

	Safety distance, depending on transmit-frequency m		
Nominal output of the transmitter W	**150 kHz to 80 MHz** **d =** [3.5 / 3] √**P**	**80 MHz to 800 MHz** **d =** [3.5 / 3] √**P**	**800 MHz to 2.5 GHz** **d =** [7.0 / 3] √**P**
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.2	1.2	2.4
10	3.69	3.69	7.38
100	11.66	11.66	23.32

For transmitters for which the maximum nominal output is not indicated in the above table, the recommended safety distance d in meters (m) can be determined using the equation belonging to the respective column whereas P is the maximum nominal output of the transmitter in watts (W) acc. to manufacturer´s specification.

NOTE 1 By 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines might not be applicable in all cases. The emanation of electromagnetic waves is affected by absorption and reflection of buildings, objects and people.

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