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perating Instructions

English



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General Standard Terms and Conditions



1.1 Notes on operating instructions

These operating instructions contain important notes on how to operate the ATMOS C 31 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-time. Furthermore, reliability and service-life of the equipment will be increased. For these reasons these operating instructions must always be kept available near the appliance. Prior to first use please peruse the chapter 2.0 "For your safety", in order to be prepared for any possible dangerous

situations.

The basic principles are:

Judicious and careful work provides best protection against accidents!

Operational safety and readiness for use depend not only on your capabilities, but also on **care and maintenance** given to the ATMOS C 31. For this reason regular cleaning and service work are a must. Major maintenance and repair work may be carried out only by expert personnel authorised by ATMOS. In case of repairs you should insist that original spare parts only are used. You will then have the warranty that operational safety, readiness for work and the value of your appliance will be preserved.

- These operation instructions apply for the following appliances: ATMOS C 31 SetArt. Nr. 506.7300.0 ATMOS C 31 Function ColumnA r t . N r . 506.7400.0
- Please note that these operating instructions apply for all ATMOS C 31 models and subsequently feature all options and applications. Therefore, it is possible that this document may contain descriptions not relevant for your specific appliance type.
- The product ATMOS C 31 bears CE marking CE-0124 according to the EEC guideline of the council for medical products 93/42/EEC and meets the basic requirements of annex I of this guideline.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 9001 and EN 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 written permission by ATMOS.
- Subject to alterations. Errors excepted.

Abbreviations / symbols 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.

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1.0 Introduction

1.2 Intended use

 The ENT Treatment Unit ATMOS C 31 developed and produced by ATMOS is a modular-constructed ENT work station for hospital and practice.

The ATMOS C 31 may be used only in supervised operation.

The ATMOS C 31 may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards.

Suction system:

Intended use: Removal of secretions, rinsing solutions, cerumen or to extract foreign matters; collection of the sucked material in the collection jar. The suction system is only to be used for the suction of fluids in medical ranges. Never remove explosive, inflammable or corrosive gases or fluids. Use as described in these operating instructions.

Cold-light system:

Intended use: Supply of a light source to enable the application of connected examination units containing cold-light conducting fibre. The cold-light system is only intended for operating endoscopic equipment, cold-light headlamps and microscopes.

Use as described in these operating instructions. The use of devices connected to this system acc. to the operating instructions of the respective manufacturer.

• Mirror quick heater:

Intended use: Warming up of various instruments to facilitate diagnosis and therapy or to avoid dimming. e.g. with examination mirrors. The mirror quick-heater is only intended for short-time warming up of examination instruments which mainly are made of metal, e.g. larynx mirrors or spatula. Use as described in these operating instructions.

Heated endoscope support:

Intended use: Warming up of endoscopes and flexible optics to facilitate diagnosis and to avoid dimming. The endoscope support is to be used solely for holding the endoscopes, these first having been cleaned and disinfected. Pay attention to demands stated by the respective manufacturer of optics.



Headlamp hook:

Intended use: Suspension of the headlamp when not being used. The headlamp hook is solely intended for accommodating headlamps (cold light or warm light). Use as described in these operating instructions.

 Deposit for used instruments, to be pulled out: To remove used instruments quickly out of the "clean" working area.

Compressed-air system (option):

Intended use: Atomizing of medicaments for application to the nasopharynx, politzerisation with Politzer olives or Eustachian catheters. The compressed-air system is only to be used for applying medicaments to the nasopharynx with the help of sprayers made by Messrs. ATMOS and for politzerisation with the help of Politzer olives and Politzer attachments made by Messrs. ATMOS or Eustachian catheters. Pay attention to respective literatures. Use as described in these operating instructions.

• Ear rinsing system (option):

Intended use: For irrigations of the auditory canal. The unit may not be used if the auditory canal is inflamed or contaminated. This unit is destined for short-time operation on patients.

Mirror preheater (option):

Intended use: The mirror preheater is solely intended for warming up different-sized larynx mirrors mainly made of metal. Use as described in these operating instructions.

• Further options:

The intended use of further optional systems is contained in separate operating instructions.

1.3 Function

- The ATMOS C 31 is started by activating the main switch (**0**, fig. 1, page 7).
- The exact mode of function of the standard equipment and optional functions is described in detail in chapters 4.2 bis 4.3.17.

1.0 Introduction



1.4

On / Off switch

ON (power) as to IEC 417/5007 and DIN 30600/16



OFF (power) as to IEC 417/5007and DIN 30600/16

Explanation of symbols



Pay attention to operating instructions ! as to ISO /7000/0434 DIN 30600/1008 IEC 348



Warm water system



Suction system



Compressed-air system



Cleaning in flow procedure (hose rinsing)



Cold-light system



Microscope connection (cold light)



Headlamp



Transfer of heat, in general; mirror heater

Short-time operation



Footswitch



Water temperature for ear rinsing too high

Basin rinsing



Correct water temperature for ear rinsing



Water temperature for ear rinsing too low



Button for increasing lamp intensity



Button for decreasing lamp intensity



Dangerous voltage as to IEC 417/5036, DIN 30600/131



Protective earth (ground) as to IEC 417/5019, DIN 30600/1545



Fuse as to IEC 417/5016, DIN 30600/0186



Type B equipment



Type BF equipment (only for cold light)



Alternating current

2.0 For your saftey



- The ATMOS C 31 is produced according to IEC 601/ EN 60601 and listed in the following classes:
 - VDE Class of protection 1
 - Class IIa (EEC 93/42).
- The unit may be connected only to a socket outlet with earthing contact installed according to the rules of the trade.
- The unit should not be positioned directly next to a wall, because of the ventilation openings on the rear side !
- Attention! Mirror and endoscope heaters may generate temperatures above 40°C!
- Attention with the cold-light source!
 - Because of the high energy of the light there is a large amount of heat emission at the point of the optical system. Avoid too small a distance between the tissue and the field of light emission of the light guide resp. of the endoscope, as this may cause coagulation of the patient's tissue. When using the endoscope avoid the direct contact between area of light emission and the tissue.

Attention, Fire Hazard!

Do never place the area of light emission from the light guide or from the endoscope onto heat-absorbing surfaces (dark pieces of cloth, etc.), because this will cause unacceptable high heating or even ignition of the material. Switch the light off when you do not require the light over a prolonged period of time.

- Care is to be paid in respect to light sources when working with endoscopes. Harmful heat rays are eliminated by special built-in filters: but the intensity of the light is very high. Do not look directly into the light outlets! In case of possible light failure remove the endoscope from the working area.
- The ATMOS C 31 may be used in supervised operation by qualified personnel only which has been authorised by ATMOS and which has been trained for operating the appliance (IEC 601-1/EN 60601-1).
- The mains voltage specified on the type plate must correspond with the data of the power supply system.
- Make sure prior to every application of the equipment that it is technically safe and in proper condition. Damaged leads and hoses must be replaced immediately!
- Display instruments and valves must be checked for correct function in regular intervals !
- Inspection of compressed air and vacuum display by service technician every 2 years !
- Correct configuration in assembly of country-specific connections: green/yellow: protective conductor (PE) blue: neutral conductor (N) black resp. brown: phase (L)
- This product is not re-sterilisable. 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.
- It is not allowed to use flammable substances with the device.

- Units with water consuming systems may only be switched on when the water supply is guaranteed !
- The ENT unit requires clean water (drinking-water quality) for the operation. In case the clean water cannot be provided by the water supply, a pre-filter has to be installed. The relevant country specific regulations for the instal-lation have to be considered !
- The control panel must be well visible to and in reach of the operator.
- Do not place used contaminated instruments on the ENT unit !
- The ambient conditions specified in section 9.0 "Technical specifications" must be strictly observed!
- The suction system of the ATMOS C 31 is only to be used for the suction of fluids in medical ranges. Never remove explosive, inflammable or corrosive gases or fluids.
- Switch off main switch after finishing work in practice and close water supply, if present.
- The ATMOS C 31 may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen rich environments.
- The ATMOS C 31 fully complies with the electromagnetic immunity requirements of standard IEC 601-1-2 / EN 60601-1-2 "Electromagnetic compatibility - Medical Electrical Equipment".
- The ATMOS C 31 may not be operated with units not complying with the requirements of standard EN 60601-1 "Medical Electrical Equipment" and EN 60601-1-2 "Electromagnetic compatibility (Medical Electrical Equipment)".
- 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.
- This operation manual corresponds with the construction of the unit and with the current status of safety-related standards at the time of printing. Proprietary rights are existing for all described circuits, processes, names, software programs and units.
- Please pay also attention to the safety information in following chapters.
- 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.
- When connecting several devices on one grounding receptacle, the allowed strain and leakage current have to be observed!
- Never leave the patient unattended at the treatment unit.









Service compartment 3.1.1



- Fig. 2. ATMOS C 31 Service compartment
 - Connection nipple with hose to the vacuum pump (green coding)
 - **2** Collection jar
 - Hose rinsing container (optional)Secretion hose (black coding)

 - **5** Hose for automatic collection jar
 - evacuation (optinal) (transparent coding) **6** Connecting electrodes for automatic
 - collection jar evacuation (optional)
 - Attachment for secretion hose
 - 8 Lid

3.0 Installation and starting-up



3.2 Setting up proposal



3.0 Installation and starting-up



- Fig. 3. O Socket outlets with earthing contact
 Water drainage G3/4" external thread (optional)
 - Water supply with water tap G 3/4" external thread (optional)

3.3 Connection to electrical power line

- According to the directions of VDE 0107 and VDE 0100, medically used rooms have to be equipped with a *leakage current protective circuit* (FI protective circuit) with a nominal leakage current of < 0.03 A. Installation must correspond with VDE 0107.
- The **ATMOS C 31** is connected to an earthing contact socket which is to be mounted near the unit (max. 3 m, preferably on the left side, next to the function column (see fig. 1).
- The power consumption of the **ATMOS C 31** comes to 5 A max.
- For the connection of further electrical devices, please allow for extra plugs.

(Installation of an electrically operated patient chair).



Maise in [mm] Dimensions in mm

- *Fig. 4.* **2** Water drainage G 3/4" external thread (optional)
 - Water supply G 1/2" internal thread (optional) (with water tap G 3/4" external thread)

3.4 Connection to water supply (optional)

Water supply:

Requirements:
There must be existing water pipes with a G 1/2 (internal thread)

For connecting a corresponding water or ball valve with a G 3/8 hose connection.

- This (water tap) ball valve must be installed in such a way that when leaving the device it can be turned off without any problerm.
- The water which is provided by the household connection must at least meet the WHO guidelines or the country-specific guidelines for drinking water.
- Rinse water supply line in order to remove any con-tamination from the system.
- When clean water is available, connect delivery hose to water tap mentioned above
- Required pressure in domestic water system: >2 bar, but <5 bar.
- There are country-specific regulations for the installation to be considered when the unit is connected to the public water supply .
- A water connection with pipe ventilation is recommended!
- There is no special calcification safety device integrated in the water system. Such a system is to be connected when the respective drinking water is of hardness grade 3 (14 -21°d resp. 2.5 - 3.8 mol/m³ = hard water) but especially with hardness grade 4 (from 21°d resp. from 3.8 mol/m³ = very hard water). You may receive information on the hardness grade of your water from the water supply office.





Fig. 5. **1** Connection for wase water hose**2** Inlet connector for non-heating apparatus



Fig. 6. Collection jar lid with hose coding
green: Filter – Pump
white, transparent: Collection jar lid – Patient
black: Lid – Hose pump



3.5 Waste water drain (optional)

- Requirements:
 - Permanently installed connection fitting with G3/4" external thread.
- To adapt the ³⁄₄ draining hose to standard HT 40 a connection adapter 510.2130.0 can be ordered (510.2129.0 for HT 50)
- Connect waste water hose with unit (**0**, Fig. 5) and the G3/4" connection fitting (insert pertaining seals).

3.6 Starting-up the ATMOS C 31

- Electrical connection
 - Join the inlet connector for non-heating apparatus(2, fig.5) with the earth socket outlet using the mains cable supplied.
- Waste water connection (with optional automatic collection jar evacuation)
 - Connect the waste water connector ($\mathbf{0}$, fig.5) to the water drain ($\mathbf{2}$, fig. 5).

• Connection of suction hose

 Thread the suction hose through the hole on the side into the service compartment and push it straight onto the connector for the secretion hose (¹), fig. 6).

The transport locking screws on the unit's baseplate must be removed by skilling staff prior to starting up! To do this, the rear panel must be opened and the two front screws must be unscrewed. The pump unit is removed from the rear locking device by pulling it forwards.

• Connection of fibre-optic cable

- Plug the fibre-optic cables into the variable connections of the light source (Storz connector).
- If you require several adapter sleeves (e.g. Olympus, Pentax, Wolf, etc.), they may be interchanged as necessary (see chapter 8.2.4).
- So that the fibre-optic cables do not rest on the floor, they may be threaded through behind the handle support.

Installation and starting-up 3.0





Fig. 7a. Connecting LED



Fig. 8. CPC-Cuppling



Fig. 9. Connecting the hose for ear rinsing Connection for compressed-air hose Onnection for ear rinsing hose

- 3.6 Starting-up the ATMOS C 31 (contin.)
 - Light package LED REF 506.7550.0 (Fig. 7a) Connecting for the ATMOS LS 21 LED light source and ATMOS HL 21 LED headligt.
- Switch LED I and LED II
- Holder for ATMOS HL 21 LED headlight
- B Holder for ATMOS LS 21 LED light source
- Onnecting socket LED II
- Connecting socket LED I
- Connection of the compressed-air hose (optional) Connection of the function hose for compressed air at the side of the column.
 - Compressed-air hose is connected by means of plug connections; make sure that the plug attachment is engaged. The hose is disconnected by pressing the release slide (**0**, fig. 8) at the plug connector and by pulling out the plug attachment.
- R Push the handles into the handle support as indicated by the symbols. The photoelectric barriers will operate the wrong pump if the handles are transposed!
- Connecting the hose for ear rinsing (optional) The hose for the warm water system is screwed on the CPC coupling.
- R Different socket nipples; misplacing of the hoses is thus impossible !

Connecting the hose for ear rinsing (optional) Connect the aqua stop valve with the water tap (local connection). Open the water supply. When the main switch is set to ON and a water consuming device (basin rinsing or hose rinsing system) is used the water supply is opened by automatic opening of the magnetic valve in the aqua stop system.

P Thus, there is no pressure inside the water supply hose if no water consuming device is activated.



4.1 ATMOS C 31 - Basic unit

The ENT unit ATMOS C 31 offers optimum instrument handling whilst at the same time providing an optimum arrangement of all functions that an ENT specialist requires for his daily work in the practice.

The instrument deposit area:

At the top of the functional column there is an area designed to take medicine bottles (④, fig. 1, page 7), so that the instrument deposit area can be used to its best advantage for instruments.

There is also the facility for protective storage of less frequently used instruments and consumables in the drawers (Θ and Θ , fig. 1).

Most of the unit's surfaces are coated with a special textured lacquer that fulfills the requirements for workplace hygiene. However, as the lacquer is not resistant to all medicines and disinfectants it is imperative to wipe up splashes immediately.

4.2 Basic functions

4.2.1 Main switch

 The ATMOS C 31 is switched ON and OFF by means of the main switch (①, fig. 1, page 7).



Fig. 10. Maximum load

4.2.2 Maximum loads

- Persons must not support on the ATMOS C 31 (danger of tilting).
- Maximum load of the instrument surface: 15 kg.
- Maximum load of the writing and working surface: 10 kg.
- Maximum load of the second deposit surface (optional): 7.5 kg.

4.2.3 How to open the covering

• Open the unit covering up to the stop.





Fig. 11. Suction system

- O Suction attachment
- 2 Vacuum control
- **B** Vacuumgauge
- ON/OFF switch



4.2.4 Suction system



The hose attachment must be exchanged after each patient.

Prior to each application, proper function of the display instruments and control valves must be checked !

• Purpose:

- Suction of fluids and secretions; collecting the secretion in the collection jar.
- Automatic activation of the suction mode by taking out the suction attachment.
- Control of suction rate by means of rotary knob for vacuum control (2, fig. 11).
- Indication of set vacuum at vacuumgauge (3, fig. 11) (keep suction attachment closed by hand).
- Secretion is collected in 1.25 I jar with mechanical overflow safety and water-repellent bacterial filter.
 - Prevents ingress of secretion into the pump.
- Collection jar to be emptied when half full at the latest, see chapter 4.2.4.1!
- The suction system may be operated only with inserted bacterial filter. In case the filter is blocked it has to be exchanged. (see chapter 6.1) ! For hygienic reasons, the bacterial filter should be exchanged or cleaned **daily**.
- The suction hose must never come into direct contact with the application site. Do always use a suction catheter, suction tip, or medical suction set !
- Change the suction catheter after every patient and clean the suction hose, e.g. with the aid of the optional hose rinsing system (aspirate rinsing fluid or disinfectant solution)!
- All commercially available models of suction cannulae (Adson, Walter, Frazier, Fergusson, Plester, Yankauer, Torrington) may be attached to the silicone attachment.

4.2.4.1 Emptying the collection jar

- Detach all hose connections carefully on the lid system and take collection jar out carefully to prevent spills and contamination of the area. Dispose of secretions properly.
- Grip lid system firmly, open lid of filter housing by turning in anti-clockwise direction and remove filter. Rinse all parts thoroughly under running water. A detergent or cleaning agent may also be used if required.
- After cleaning a new filter must be inserted (smooth side down!).

See also suction accessories (chapter 8.2.1).

Fig. 12. • Bacterial filter

- 2 Secretion hose
- **B** Green coding ring: pump connection
- Black coding ring: suction hose connection





- Fig. 13. Cold-light system
 Switch for selecting the light exit
 Intensity control
 Holder for cold-light cable
 - Endoscope holder

4.2.5 Halogen cold-light system

Attention with the cold-light source!

Because of the high energy of the light there is a large amount of heat emission at the point of the optical system. Avoid too small a distance between the tissue and the field of light emission of the light guide resp. of the endoscope, as this may cause coagulation of the patient's tissue. When using the endoscope avoid the direct contact between area of light emission and the tissue.

Attention, Fire Hazard!

Do never place the area of light emission from the light guide or from the endoscope onto heat-absorbing surfaces (dark pieces of cloth, etc.), because this will cause unacceptable high heating or even ignition of the material. Switch off the light when you do not require the light over a prolonged period of time.

- The cold-light source used in the ATMOS C 31 consists of four halogen low-voltage lamps with a colour tem-perature of 3300 K. The halogen lamps are only switched on if the respective light exit is activated.
- The brightness is individually adjustable for each of the four light exits; a memory function realizes which optics are used and guarantees the availability of the previously set light performance with every use of the chosen instrument.
- The light guide connectors are installed on the right side of the function column.

The respective connections are marked with the cor-responding symbols:



Headlamp

Microscope

I

Light guide 1 Light guide 2

Starting the cold-light system

- After having operated the main switch of the ATMOS C 31
 (①, fig. 1, page 7) the cold-light source changes over to standby mode, i.e. none of the halogen lamps is switched on.
 - When removing a light guide resp. when swivelling down the microscope or removing the headlamp from its suspension the respective instrument is supplied with light. Manual selection of a light exit on the foil keyboard is, of course, possible at any time.

Operation 4.0



Fig. 14. Front foil

- +Button for activating the priority switching
- 2 –Button for deactivating the priority switching



Priority circuit:

Activating the priority circuit:

When switching on the ATMOS C 31, keep pressing the +button (**0**, fig. 14).

Deactivating the priority circuit:

When switching on the ATMOS C 31, keep pressing the -button (**2**, fig. 14).

Highest priority is allocated to endoscope 1 and lowest priority to the headlamp. Thus, an instrument with high priority (e.g. endoscope 2) is supplied with light even if another instrument with low priority (e.g. headlamp) is already used. When the endoscope is put back the light supply changes automatically to the instrument with lowest priority. Without this priority circuit the light would expire and a manual switchover to headlamp would be necessary.

- Due to their limited durability, the halogen bulbs of the R cold-light system may fail at any time during use. In case of inadvertent switching over or switching off of the individual light exits, they may at any time again be manually switched on with the buttons on the operating panel.
- R The cold-light system is designed for continuous operation in stand-alone application. However, it is possible that the thermal cut-out will be triggered and the cold light will be switched off if it is operated contrary to defined use whilst the suction and compressed-air systems are operated conisly at over-voltage at the same time. The coldlight system will be operable again following a cooling period.

4.2.6 Mirror quick heater

- Switch on the mirror quick-heater with key switch (**0**, fig.15) The mirror quick heater heats up for 10 sec. and switches off automatically afterwards.
- Supply voltage of the heating coils: 6 V/15 A.
- Hold the mirror to be heated over the burning heating coil (2, fig. 15) located beneath the round grid.
- R Prior to use of the mirror, always check its temperature (with hand etc.) !
- R Automatic switching to avoid overheating!
- R Safety cover, sleeve and heating element might be very hot. Do not touch directly after heating-up !
- Changing the heating coil, see section 6.3.

Key

2 Heating coil





Fig. 16. • Water temperature display



Fig. 17. U Storage container for ear rinsing 37°C
Connection for irrigation handle
Irrigation handle







Fig. 18. Mirror preheater Mirror rack

4.3 Options

4.3.1 Ear rinsing system (option)

- The ear rinsing system is supplied with water by a heated (37°C) 4.5 I storage container (①, Fig. 17). This container can easily be filled, cleaned or disinfected. The pump turns on automatically only when pressure drops. Water pressure and flow quantity may be regulated with the release lever on the irrigation handle. With the switch ①, Fig 17 a, the ear irrigation system can be switched on and off.
- Switch on the ENT unit only after water has been filled in the storage container of the ear rinsing sy stem.
- Use e.g. the measuring cup (000.0583.0) to fill the storage container with water of drinking quality (at least 2 I, max. 4.5 I) and close the lid.
- The water must not be contaminated and its temperature must not exceed 37°C as it cannot be cooled down. If there is no water of drinking quality available, you may also fill in isotonic saline solution. Alternatively, you may achieve drinking water quality by filtering or boiling the water resp.by adding disinfectants.
- This system may not be used if the auditory canal is injured as there might be a risk of infection if the irrigation liquid is contaminated.
- The temperature display indicates the water temperature. It takes approx. 15 min. until 2 litres of cold tap water are heated up to 37°C. Observe the temperature display and check water temperature prior to every application. As soon as the middle lamp is lit the water has reached the desired temperature.
- Take the water handle out of its holder and spray off water until all air bubbles are removed and the level of the pump noise gets lower (repeat this procedure every time the pump noise gets loud, e.g. after long periods during which it has not been used or after the water level has dropped below the suction limit).
- Change the jet connection daily. Only use disinfected jet connections to avoid a spreading of germs. Use the hose tip to avoid damages to the tympanic membrane.
- Cleaning: Empty the storage container and the hose system every evening using the irrigation handle. The remaining fluid can, for example, be removed with the suction system.
- To avoid a contamination of the storage container please use a disinfected suction attachment.
- Disinfection: The storage container has to be disinfected once a week with a surface disinfectant (see list of recommended disinfectants in chapter 5.5).
- The hose system of the ear rinsing equipment has also to be effected disinfected once a week with a hose disinfectant.
- A measuring of the total number of germs is to be effected in regular intervals. If there is a considerable increase in germs between storage container and irrigation handle a biofilm removing procedure and a special disinfection of the hose system have to be effected by an ATMOS service technician.
- Before cleaning the storage container, switch off the unit as, otherwise, the jar might get too hot when no liquid is filled in.





Fig. 19. Service compartment

- Connecting nipple
- 2 Collection jar
- B Hose rinsing container (option)
- 4 Secretion hose
- Hose for automatic collection jar evacuation
- Connecting electrodes for automatic
- collection jar evacuation (optional)
- Connection for secretion hose



Fig. 20. Plastic quiver for cleaning and disinfecting solution (506.7015.0)

4.3.2 Mirror preheater (option)

- The mirror preheater is switched on when the main switch (**0**, fig. 1, page 7) is activated.
 - The rack (①, fig. 18) containing the mirrors is heated up to about 40°C.
- ENT unit should be switched on about 20 minutes before starting work, to ensure preheating in good time!
- Attention, high temperatures !
- Prior to use of the mirror, always check its temperature (with hand etc.) !

4.3.3 Collection jar evacuation, fully-automatic (option)

- Purpose:
 - Prevents interruption of work in practice.
 - Secretion is not held in jar over a longer period of time.
 - · Prevents contact of staff with secretion.
- Activated automatically when:
 - Reaching the upper filling limit (electrodes).
 - Returning suction attachment to holder.
- The tube cassette of the tube pump is a wear part and must be replaced at regular intervals (see chapter 6.2)!
- Pay attention to cleaning described in chapter 5.0!

4.3.4 Quiver for cleaning and disinfecting solution (option)

- Cannulae and suction hose should be rinsed through each time after use to prevent sticking and clogging up. We therefore offer an optional quiver that may be attached to the handle support (see fig. 20).
- After cleaning, cannulae may no longer be used in patients (exception: if the cleaning solution is changed after every patient).
- Particularly suitable: ATMOS special cleanse (080.0005.0).





Fig. 21. I Float switch
Hose rinsing container
Line to hose rinsing system

4.3.5 Hose rinsing system (option)

- After use, the suction system has to be rinsed by means of the hose rinsing system.
 - Insert the suction attachment into the white rinsing attachment of the hose rinsing system. Press the rinsing insert in and rinse the hose for a few seconds.
 - This procedure will prevent the hoses and suction cannulae from clogging up.
- The tank for the rinsing fluid of the hose rinsing is located in the service compartment at the front of the unit. For optimum cleaning, add the ATMOS special cleanser (Art.No. 080.0005.0) to the rinsing liquid. The tank may, optionally, be automatically filled up with fresh water. Water supply is then controlled by a level switch. A safety switch in the tank holder next to the tank prevents the filling if the tank is missing.
- Container filling of hose rinsing system: In case of extremely high humidity values, the switch sponge must be replaced in short intervals (approx. every 2 days); otherwise, correct function cannot be guaranteed.
- The suction attachment of the hose rinsing system may be contaminated. Therefore, it must be cleaned and disinfected **daily** !



Fig. 22. Kidney-shaped rinsing basin

4.3.6 Kidney-shaped rinsing basin (option)

- Purpose:
 - The basin receives the water that returns from rinsing procedures of the ear and the maxillary sinus.
- Remove the basin from its support and hold it under the ear to be rinsed.
- After use, we recommend to activate the rinsing system. To do so, press the key on the unit; a time mechanism will then start the rinsing procedure (for abt. 10 sec.).
- The rinsing basin is not suited to collect large water quantities, e. g. when evacuating a pail, as water might overrun the interior of the unit!





0 0 0 0

- Fig. 23. Compressed-air system
 - Compressed-air handle
 - 2 Holder for automatic photoelectric barrier control
 - Sprayer suspension
 - Ocmpressed-air control
 - **6** Compressed-air display



Fig. 24. Compressed-air handle with Politzer adapter **①** Compressed-air handle

- Adaptor for Politzer olive
- B Politzer olive

4.3.7 Compressed-air system (option)

- Prior to each application, proper function of the display instruments and control valves must be checked !
- Purpose:
 - a) Medicaments can be applied to the nasopha rynx.
- The pump for the compressed-air system switches on after the compressed-air handle has been removed from its holder.
- Handle is mounted on a sprayer; the top of the com-pressedair handle locks in place in the ring of the sprayer bottle.
- Available sprayers:
 with straight spraying tube for normal liquid medicaments
 - with twin tube and adjustable angular jet for oily medicaments.
- If a sprayer is used with medication the instructions of the medication manufacturers have to be observed.
- Do not use the sprayer for the storage of medication !
 Caution to be paid to avoid injury when introducing sprayer jet!

Please note, in case the ventilation opening is blocked or the sprayer head is immersed in fluids (e.g. blood, secretion, etc.) a negative pressure could occur and the fluid could flow back into the bottle.

In this case the medicine sprayer, sprayer head, flexible nozzle as well as the hose piece for the medicine sprayer must be reprocessed as described in chapter 5.0 cleaning.

- Operating the release lever.
- The medicament sprayer is supplied with air and the medicament in the sprayer bottle is atomized.
- The amount of compressed air is adjusted with regulator (4, fig. 23) in conjunction with the display (5, fig. 23).
- After use, the medicament sprayer is again inserted in its holder, the bar is pressed, the handle is removed from the sprayer and again inserted in its support.
 Compressed-air system is again switched off.
 - b) Politzerisation with Politzer olives or Eustachian
 - catheter can be carried out.
 Pump switches on after the compressed-air handle has been
- The adapter (2, fig. 24) supplied for this purpose is locked
- into the compressed-air handle.
- Politzer olive (**3**, fig. 24) is inserted in the adapter.
- The pressure for the insufflation of the Eustachian tube can be controlled by means of the manometer and the compressed-air regulator. Select an insufflation pressure adapted to the condition of the tympanic membrane. If the tympanic membranes are already pre-damaged even low pressure values might lead to injuries ! Maximum pressure may no exceed 0.2 bar !
- Activating, adjusting and regulating the compressed air and switching off the compressed-air system as described above.
- Accessories, see chapter 8.2.3.





2

0

Fig. 25. Headlamp connection **1** Jack





4.3.8 Connection for warm-light headlamp/ Nystagmus binoculars (option)

- After the switch (**0**, Fig. 26) has been turned on, the headlamp connection is ready for operation.
- The connector of the headlamp, e.g. CLAR 55 Art.No. 502.0161.0, is plugged into the jack (①, Fig. 25) (con-nection cable is included in standard delivery of this option).
- When connecting nystagmus binoculars (cable available as accessory, Art.No. 502.0141.6), the voltage is reduced automatically (4V) even if you work with low voltage.
- Care must be taken to ensure that the connection jack and the patient are not touched at the same time when plugging and unplugging the warm-light headlamp!

4.3.9 Headlamp suspension (option)

- For storing the headlamp.
- When the headlamp is suspended again, the cold-light exit is switched off automatically.





Fig. 27. Counter-mirror lamp



Fig.28. Endoscope heating
Main switch
Sleeves of the endoscope heater

4.3.10 Counter-mirror lamp (option)

- The counter-mirror lamp (fig. 27) can be mounted to the left side of the column.
- See separate operating instructions.

4.3.11 Endoscope heating (option)

- Endoscope heating is switched on when the main switch is activated.
 - ✤ Endoscopes are warmed to approx. 40°C.
- ENT unit should be switched on about 20 minutes before starting work, to ensure preheating in good time!
- The metal quivers of the endoscope holder are to be used solely for holding the endoscopes, these **first having been cleaned and disinfected.**
- The metal quivers must regularly be removed and cleaned.
 Do not fill in any liquids.





Fig. 29. Tonue patches and swab dispenser

4.3.12 Tongue patches and swab dispenser (option)

- The tongue patches and swab dispenser hygienically stores tongue patches and swabs.
- The whole dispenser may be pulled out at the front for filling or refilling (fig. 29).

4.3.13 Waste bin (option)

- The door of the waste bin (¹, fig. 1, page 7) is fitted with a "kick box" locking device. The waste bin automatically opens a little by lightly touching the door with the hand or foot.
- The kick box locks automatically on closing.

4.3.14 Microscope (option)

- Cold-light microscope on a mount which is secured to the ATMOS C 31. Light is provided via a fibre optic light conductor which is connected to an exit of the ATMOS cold-light system.
- Refer to separate operating instructions!
- © Only microscopes and accessories approved may be added to the support !





Fig. 30. TFT Display

4.3.15 Video system (option)

- In order to make the endoscopic resp. microscopic findings visible to the patient, the ATMOS C 31 may, optionally, be supplemented with a video system, consisting of a camera with endoscopic adaptor as well as a display on the carrying arm.
- Freezing of the video image is possible with a foot switch (camera accessory).
- When transferring the video signal to further devices (video printer, video recorder, computer,...), make sure that they are approved medical products.



Fig. 31. Tulip-shaped ear rinsing bowl

4.3.16 Tulip-shaped ear rinsing bowl (option)

- Intended use: To collect the water flowing off during ear rinsing.
- The tulip-shaped bowl is added to the suction attachment of the suction system.
- As accessory, we offer a special holder for this ear rinsing bowl.

4.3.17 Holder for standard rail (option)

- Purpose: For adding disposable collection jar systems.
- The standard rail holder may be used for **one 2 or 3 I**jar.
- I Maximum load: 5 kg !

5.0 Cleaning



5.1 General information on cleaning and disinfection

- Set main switch to OFF prior to cleaning and disinfection!
- The described measures for cleaning do not re place the respective precautions for operating the unit !
- For disinfection, you may use all surface and instrument disinfectants listed on page 26.
- Always observe the concentration specifications and instructions by the respective manufacturer !
- Do <u>not use</u>
 - Disinfectants containing concentrated organic or anorganic acids or bases, since these may cause corrosion damages;
 - Disinfectants containing chloramides, phenol derivatives or anionic tensides, since these may cause stress cracks in the material used for the housing of the unit.

5.1.1 Cleaning the unit surface

- The surfaces of the ATMOS C 31 are resistent against all surface disinfectants listed on page 26.
- Wipe the unit surface with a cloth moistened with a cleaning or disinfecting solution.
- Wipe dry the device surface, the surface edges may not be wet for a longer period.

5.1.2 Cleaning "application parts"

- "Application parts" comprise: All single components or assemblies which come into contact with the patient and might get contaminated:
 collection jar,
 - secretion hose,
 - nozzles of medicament sprayers,
 - Politzer olives and adapters.
- All application parts may disinfected with instrument disinfectants (see page 26).
- All application parts which are exposed to direct contact with the patient during treatment are to be exchanged or cleaned immediately for hygienic reasons.

5.1.3 Collection jar (without autom. collection jar evacuation), bacterial filter and suction hose

- At the end of every working-day, following parts must be cleaned and disinfected:
- Collection jar with lid system and bacterial filter:
 - Pull all hose connections from the lid system and carefully remove the jar from the jar holder in order to prevent a contamination of the area around the unit (e.g. drops).
 - Properly dispose of the sucked material.
 - Take the collection jar at the lid system, open the bacterial filter cover by turning it anti-clockwise and remove the filter plate. Thoroughly rinse all parts under running water. You may, of course, add a cleanser or detergent. Afterwards disinfect all parts.
 - After cleaning and disinfection a new filter must be inserted (smooth side down!).
- Suction system and hose attachment:
- After every use, rinse out the suction system by drawing in a small amount of irrigating fluid (e.g. ATMOS Special Cleanser 080.0005.0).
 Keeps the hoses from becoming sticky or clogged.
- Suction capacity is limited by the 1.25 I collection jar. Therefore, do not use more than 1 I rinsing liquid and subsequently evacuate the jar.
- Replace The filter.

5.1.4 Collection jar and electrodes (automatic evacuation of collection jar)

- The collection jar should be removed and cleaned once every week.
 - During the cleaning of the jar the cover has to be pulled off and rinsed thoroughly under running water. Use the disinfectants mentioned in chapter 5.4 for disinfection. Before the jar is assembled again, the electrodes in the cover should be cleaned using a wet cloth.
- Mistake in polarity not possible!

5.0 Cleaning







5.1.5 Medicament sprayers

- The sprayer tube must be exchanged after each patient.
- Dismount the medicament sprayer (fig. 32, 506.5120.0; fig. 33, 506.5225.0) and thoroughly rinse all parts under running water. You may, of course, add a cleanser or detergent.
 Use water to thoroughly rinse all residues of these substances.
- Make sure that the air opening is not closed !
- When fixing the twin tube nozzle again, make sure that the mark (0,X or milling area) on the nozzle shows upwards !



Sprayer tubes are available as spare parts (see fig. 32 / fig. 33).

5.1.6 Instrument trays

- Before disinfection, thoroughly rinse the trays under running water. You may, of course, add a cleanser (deter-gent) or surface disinfectant.
 - Thoroughly rinse the trays under running water.

Melamine and anodized aluminium trays cannot be sterilised.

5.2 Endoscope quivers

• The metal quivers of the endoscope holder are to be used solely for holding the endoscopes, these first having been cleaned. The quivers are to be cleaned daily and subsequently disinfected. For doing this, the stopper at the lower end should be taken off.

5.3 Ear rinsing bowl

 The ear irrigation bowl is not autoclavable! Cleaning and disinfection (also machine cleaning) up to 93°C.

5.0 Cleaning



5.4 Recommended instrument disinfectants

Manual disinfection of instrume Disinfectant	ents Ingredients	(in 10) g)	Manufacturer
Korsolex extra (Application concentrate)	(ethylene-dioxy)dimethanol Glutaral Benzyl-C12-C18-alkyldimethyl- ammonium chloride, tensides, didecylmethylammonium chloride corrosion inhibitors	15.3 g 7.5 g 1.0 g	Bode	e Chemie, Hamburg
neodisher MediClean forte (Application concentrate)	non-ionic tensides NTA (nitrilotriacetic acid) enzymes, preservative agent	<5 g 5-15 g	Dr. V	Veigert, Hamburg

5.5 Recommended surface disinfectants

Disinfectant	Ingredients	(in 100	g)	Manufacturer
Dismozon pur (Application concentrate)	magnesium monoperoxyphthalate hexahydrate	80 g	Bode	Chemie, Hamburg
Green & Clean SK (Application concentrate)	alkyl-dimethyl-benzyl-ammonium chloride dialkyl-dimethyl-ammonium chloride-	<1 g	Metas	ys, Rum (Austria)
Perform	Pentakalium bis(peroxymonosulfate)- bis(sulfate)		Schülk	e & Mayr, Norderstedt

If using aldehyde-containing or amine-containing disinfectants at the same object, this may result in discolourations.

6.0 Maintenance and servicing

- The ATMOS C 31 is equipped with maintenance-free pumps for suction and compressed air. Nevertheless, to ensure correct functioning of the unit over a long period of time simple maintenance work which can either be done by the user himself, or, if desired, by service technicians, is necessary from time to time.
 - To guarantee correct function of the automatic rinsing and suction mechanism, switch off the ENT unit prior to changing the collection jar.
 - There is a service compartment (lower part of the function column) which contains the parts needed for the maintenance procedures. The possible maintenance procedures are described in the following chapters.
- A safety-related check of the **ATMOS C 31** is to be effected acc. to the local rules in your country. Nevertheless, we recommend a yearly check acc. to the annexed service booklet.





Fig. 34. DDS bacterial filter



Fig. 35.

- 2 Release leverl
- Tube cassette
- Orainage hose
- **6** Connecting nipple to the rear wall

6.1 Changing the bacterial filter

- Set the vacuum regulator (12), fig. 1, page 7) to "maximum" (right stop).
- As soon as the vacuumgauge shows a vacuum value >-0.3 bar, while the suction hose is open, the filter has to be replaced.
- To open the bacterial filter cover please turn it
- Remove the filter plate and insert a fresh one.
- R Make sure to clean the electrodes of the automatic collection jar evacuation !
- R Mistake in polarity not possible!
- r P If no vacuum is achieved after switching on again the suction system, check free movement of the float !

6.2 Changing the tube cassette of the tube pump

- ræ The tube cassette is located in the unit's pump compartment. It may only be replaced by qualified staff!
- The tube cassette (3, fig. 35) must regularly be changed (approx. once a year) as it may otherwise get leaky.
- Set main switch to OFF.
- Clean and disinfect the hose system to avoid splashing of the secretions.
- Loosen the two hose connections.
- Remove the tube box from the drive axle by depressing the release lever.
- Attach the new tube cassette to the drive axle and arrest it in the bayonet holder by lifting the release lever. Pull the tube cassette slightly to check for secure locking.
- Add the two connecting tubes again acc. to fig. 35. ۲
- R Pump head and cassette holder to be disinfected by means of spray disinfectant!
- R Take care to ensure that the hoses are not kinked when installing it (shorten them, if necessary)!

Maintenance and servicing 6.0





Fig. 36. Mirror quick-heater • Grid



Fig. 37. Removing the heat

Changing the heating coil of the 6.3 mirror quick-heater

- ß Grid and sleeve might get very hot. Allow them to cool down before changing the heating coil !
- Set main switch of the ENT unit to OFF (1, fig. 1, page 7).
- \dot{R} emove grid ($\mathbf{0}$, fig. 36). Pull out the heating coil ($\mathbf{0}$, fig. 37) located under the grid along with its plug connections.
- Insert a new heating coil and make sure that the three heating helices come into contact only with their ends.
- Fix the grid again and set main switch to ON.

6.0 Maintenance and servicing





Fig.38/a.



Fig. 38b.



Fig.38/c.

6.4 Changing halogen cold-light lamp

- Before opening the lamp slot, switch of the unit ! The lamp and the housing of the cold-light module are very hot after failure ! Allow them to cool down!
- The lamps of the cold light system are integrated in the function column. The light module can **completely** be extracted by opening the two locking screws. Thus, the lamps can easily be replaced.
- The lamps are horizontally inserted in a socket from which they can be removed by pulling to the centre of the module.
- The spare lamp must not be touched with bare fingers (only cut off the top of the foil (fig. 38/b), the rest of the foil remains on the lamp until it is inserted in the socket)!
- Prior to changing, check on which light exit the lamp has to be replaced !
- Do not look directly into the light exits !
- Insert the spare lamp in the socket. Then remove the foil on the lamp.
- Make sure that the lamp is inserted in horizontal position ! If lamps are inserted in inclined position or not up to the stop, the light performance is considerably diminished.
- Slide the light module in up to its stop.
- Fix the light module again with the two locking screws.

6.0 Maintenance and servicing



6.5 Changing the halogen bulb of the counter-mirror lamp

- Allow the lamp to cool down before changing it !
- Pull out the plug of the halogen counter-mirror lamp.
- The halogen bulb is located under two glass disks, which are held with a snap ring.
- To release the snap ring insert a small screwdriver under the nose of the snap ring and lift it out.
- Lift out the two glass disks.
- Remove the reflector of the halogen lamp.
- When you insert the new lamp make sure that you do not touch the reflector with your bare fingers but use a clean cloth.



Fig. 39. Changing the rinsing container

6.6 Changing the rinsing container

- Please switch off the unit before removing the rinsing container.
- To replace the rinsing container, push it all the way up and swing it out together with the level switch. The container must be lifted over the edge of the holder.
- The container can then be withdrawn obliquely down-wards and outwards.
- To insert the container, swing the level switch upwards. The container is pushed obliquely upwards to the stop, swung over the edge of the holder and pushed down into the insert (see fig. 39).





7.1 Electrical protection

• The supply line voltage reaches the individual com-ponents via the main switch (**1**, fig. 1, page 7). The power supply is secured by means of melting fuses on the rear of the unit (fig. 40).

Fig. 40. • Fuse support

Before contacting the ATMOS Service, please check your unit acc. to the following charts.

7.2 Power supply



7.0 Trouble-shooting





7.0 Trouble-shooting

ATMOS

7.5 ATMOS cold light



7.6 Compressed-air system



7.0 Trouble-shooting

7.7 Warm-light source



7.8 Counter-mirror lamp



7.9 Automatic collection jar evacuation



7.10 Automatic hose rinsing



• inform service technician
7.0 Trouble-shooting

7.11 Kidney-shaped rinsing basin



- If, nevertheless, the errors cannot be removed inform the ATMOS service staff. Do not start any attempts to repair the unit yourself !
- Pay also attention to corresponding chapters in separate operating instructions !

8.1 Consumable supplies

8.1.1 Consumable supplies for suction system

DDS bacterial filter, 10 pcs, 50 pcs, 100 pcs.	
ATMOS special cleanser for hose rinsing, 500 ml	

8.1.2 Consumable supplies for automatic collection jar evacuation

Tube cassette for tube pump	126.0
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8.1.3 Consumable supplies for optics / light

Halogen bulb, 15 V/150 W	
Spare bulb for CLAR 55	
Spare bulb for nystagmus binoculars	
Spare bulb for counter-mirror lamp	

8.1.4 Consumable supplies for water system

Hose tips, 30 pcs., minimum quantity: 2 packs	
Collector sieve for rinsing basin, minimum quantity: 10 pcs	
Spare filter 100 µm	
Filter support (spare)	
Jet connection, short, straight (80mm)	
Splash protection	

8.1.5 Consumable supplies for rinsing basin

Collector sieve for rinsing basin, minimum quantity: 10 pcs	
Sieve holder	

8.1.6 Further consumable supplies

Tongue patches, packet with 6 pcs	
Cotton roll	
Waste bags, 50 pcs.	
Paper for instrument intermediate-deposit, 250 sheets	

8.2 **Accessories and Spare Parts**

8.2.1 Suction

Accessories:

Suction cannulae (see list, page 13)

Spare parts:

Spare parts:	Article-No.
Collection jar 1.25 I	000.0544.0
Bacterial filter cover	
Sealing ring for bacterial filter	
Collection jar lid	
Sealing ring for collection jar lid	
Sleeve of overflow safety	
Float	
Suction hose, silicone, black, intern. diam. 8mm, extern. diam. 12mm, per meter	006.0025.0

8.2.2 Mirror quick-heater

Spare part:	Article-No.
Heating coil	508.0053.0

8.2.3 Compressed air

Accessories:	Article-No.
Holder for ear speculae / Politzer olives	
Politzer olives, Teflon, universal size	
Politzer olives, Teflon, for children	
Sprayer attachment, straight	
Twin tube with nozzle	
Sprayer complete, for oily medicaments	
Sprayer complete, straight	
Spare parts:	Article-No.
Compressed-air handle II	
Glass for sprayer	000.0577.0
Attachment for Politzer olives	
Twin tube nozzle	
O-Ring	
Spring clip with roll	
Sprayer head	
Hose, Rilsan	
Medicament glass	
External tube, straight, complete	
O-Ring	
Sprayer head II	

See also illustrations on page 25!

8.2.4 Optics / Light

Accessories:	Article-No.
Laryngoscope 70°, 10 mm without light guide - can be autoclaved - working length: 195 mm	950.0151.0
Laryngoscope 90°, 10 mm without light guide - can be autoclaved - working length: 195 mm	950.0177.0
4 mm wide-angle optical system, 0°, L = 50 mm, can be autoclaved	
4 mm wide-angle optical system, 30°, L = 50 mm, can be autoclaved	
4 mm wide-angle optical system, 0°, L = 180 mm, can be autoclaved	
4 mm wide-angle optical system, 30°, L = 180 mm, can be autoclaved	
4 mm wide-angle optical system, 70°, L = 180 mm, can be autoclaved	
2,7 mm optical system, 0°, L = 145 mm, can be autoclaved	
2,7 mm optical system, 30°, L = 145 mm, can be autoclaved	
Naso-pharyngoscope Ø 3.4 mm, L = 300 mm, with removable light guide cable - Direction of view: 0° - Angle of field of view: 95° - Depth of focus: 1 - 50 mm - Angle: 120° / 180° - Light guide cable: Ø 4.8 mm, 1800 mm, Storz connection with leakage testing device and transport case	
Fibre optic cable, length: 1.8 m, 90° Storz angular connection Headlamp CLAR 73, fibre optic cable 2.3 m, Storz, with angular connection	
Headlamp, light model, fibre optic cable, straight connection	502.0515.5
Headlamp acc. to Binner, Wolf, fibre optic cable	
Headlamp CLAR 55, warm light.	
Connecting cable for headlamp CLAR 55	
Nystagmus binoculars acc. to Dr. Blessing	
Connecting cable for headlamp CLAR 55.	
Teflon element for endoscopes, diameter 2.8 mm - 4 mm	
Tank for flexible endoscopes (ATMOS, Olympus)	
Tank for flexible endoscopes (Storz)	
Adaptor sleeve for Storz connection	
Adaptor sleeve for Olympus connection	
Adaptor sleeve for Pentax connection	
Adaptor sleeve for Wolf connection	
·	

8.2.5 Further Accessories and Spare Parts

Article-No. Instrument tray set, aluminium-anodized, consisting of 2 large and 2 small trays, Instrument tray set, stainless steel, consisting of 2 large and 2 small trays, Connecting cable for potential balance (5 m)008.0596.0 Instrument tray, melamine, 190 x 150 mm......000.0746.0 Instrument tray, melamine, 300 x 190 mm......000.0747.0

8.3 Options

8.3.1 Options, general

International power pack: 100V~ – 240V~ ± 10 %, 50/60 Hz	
Instrument deposit on additional plane, full pull-out with ball guidings	
3-fold endoscope holder, heated, incl. metal quiver	
Connection for headlamp / Nystagmus binoculars	
Headlamp suspension with automatic switching function of the light source	
Tongue patches and cotton swab dispenser, combined, to be integrated into Unit Cabinet	
or Instrument Cabinet with single sub-construction	
Cotton swab dispenser in open storage space, in case of 2 Base Cabinets	
Mirror preheater, for approx. 70 mirrors	
Counter-mirror lamp	

8.3.2 Optional Suction System

Suction system for higher air-flow rate of 55 l/min, -98 kPa	
Collection jar evacuation, fully-automatic	

8.3.3 Optional Compressed Air

Compressed-air system complete with 3 medicament sprayers,	
1 Politzer adaptor and sprayer holder)7.0

8.3.4 Optional Water System

Rinsing basin, kidney-shaped, removable, on swivel arm Automatic hose rinsing system, consisting of:	
Rinsing attachment for cleaning cannulae, suction attachment and suction hose with automatic	
refilling of the supply container in the service compartment. Rinsing attachment, Teflon, for quick change in case of contamination	
Water system, necessary for options "Rinsing basin" and "Automatic hose rinsing system", consisting among others of supply hose with aquastop valve, pressure reducer, water filter, waste water hose (3m)	506.7006.0
Water prefilter for ENT Units, can be flushed out	
Decalcifier	
Covering hose for supply and waste water hode and power line, light-grey, in meters	005.0029.0
Hose end grommet for covering hose	005.0030.0
Measuring cup for filling the storage container	000.0583.0

8.3.5 Optional Power Source LCS 100

8.3.6 Optional HF-Electrosurgery Unit

Portable Erbotom ICC 50, mono- and bicoagulator	
Monopolar set, comprising: needle electrode, ball electrode, electrode handle with 2 keys, silicone neutral electrode 17 x 11 cm, incl. rubber bandage, cable for neutral electrode	
Bipolar set, comprising: single pedal switch, bipolar forceps (bayonet), connecting cable	
Biplar coagulation electrode, acc. to Binner	

8.3.7 Optional Diagnostic Otoscope

ENT instrument set: diagnostic otoscope with 1 set = 6 pcs. ear speculae for permanent service; 10 disposable ear speculae diameter 4 mm; straight bulb support with laryngeal mirror; tongue depressor; connector for fluorescent examinations and protective cap; nose expander; 1 of each spare bulb	
Heine Loading unit NicaTron NT 200, desk-top unit, without handles	
Battery handle 3.5 V	
Spare battery	507.0405.1

8.3.8 Optional Microscopy

8.3.9 Optional Camera System

- Control unit with 1-chip-camera, PAL system
- Integrated image memory for 2 freeze frames
- Y/C-cable, FBAS cable, mains supply cable
- Dimensions (WxHxD): 90 x 160 x 350 mm
- Application class BF

9.0 Technical Specifications



Voltage	230 V~ ± 10 % 50/60 Hz Special voltage (optional): 110 V~ ± 10 % ; 127 V~ ± 10 %				
Current input	50/60 Hz max. 5 A (230 V~) max. 10 A (110 / 127 V~)				
Supply	Fixed connection, power cable: 5 m				
Power consumption	max. 1150 W				
Air flow rate of pump	40 l pump: 40 l/min \pm 10 % (free flow), vacuum: 90 % of ambient pressure; 55 l pump: 55 l/min \pm 10 % (free flow), vacuum: 97 % of ambient pressure; collection jar 1,25 l TPX				
Cold-light system	4-channels-cold light; processor-controlled, halogen pin socket lamp 24V/150 W durability: 300 h				
Ear rinsing system	Water temperature adjustment, $37^{\circ}C \pm 2^{\circ}C$, filling quantity 4.5 l, flow approx. 450 ml/min				
Optional compressed-air system	21 l/min ± 10 % (free flow), pressure 2200 hPa				
Operating time	Continuous operation				
Fuses	T 6,3 A (f. 230 V~, 50/60 Hz), T 12 A (f. 110 V~, 127 V~, 50/60 Hz)				
Protective earth conductor resistance Earth leakage current Enclosure leakage current Patient leakage current	max. 0,1 Ω max. 0,5 mA max. 0,1 mA max. 0,1 mA				
Ambient conditions Transport/storage	-10+50°C; 3095 % humidity without condensing air pressure 5001060 hPa				
Operation	+10+35°C; 3095 % humidity without condensing air pressure 7001060 hPa				
Dimensions HxWxD	Column with 1 Base Cabinet 93 x 47 x 55 cm with 2 Base Cabinets 93 x 128 x 60 cm				
Weight (basic unit)	Columnmax. 60 kg (with all options)with 1 Base Cabinetmax. 70 kgwith 2 Base Cabinetsmax. 80 kg				
Protection class (EN 60601-1)	•				
Degree of protection	Type B equipment				
	Type BF equipment (only for cold light)				
Protection category	IPX0				
Classification acc. to Annex IX EEC directions 93/42/EEC	lla				
CE marking	CE 0124				
Rules applies	EN 60601-1: 1990 + A1:1993 + A2:1995; EN 60601-1-2: 1993 (EMV / EMC); EN ISO 10079-1: 1996; EN 60601-2-18: 1996				
UMDNS-Code	11-585				
GMDN-Code	11585				
Reference-No.	506.7300.0506.7300.5506.7400.0506.7400.5				
Canadian Classification Device group PNC Risk Class Description	General & Plastic Surgery 79QBU 2 ASPIRATOR, SURGICAL				

10.0 Disposal

- The ATMOS C 31 does not contain any hazardous goods.
- The material PUR of the housing can be recycled completely.
- The component parts of the ATMOS C 31 must be disposed of correctly and the materials are to be separated carefully.
- The electronics circuit boards must be fed into the appropriate recycling process.

This document is subject to change without notice.

11.0 Hygiene Plan





Cleaning and disinfection plan ATMOS C 21 / ATMOS C 31



	How		What How		When				Who
Reusable parts	C Cleaning	D Disinfection	S Sterilisation	Recommendations	After each procedure	Daily	Weekly	Monthly	Qualified and trained staff who are familiar with reprocessing. (Please fill in the responsible person -> use a water-based overhead marker)
Secretion canis	ster								
Bacterial filter cover	х	X ²⁾⁴⁾⁵⁾		Manual or automatic cleaning and disinfection		Х			
Bacterial filter plate with				Exchange daily or when blockedl		Х			
blue marking (disposable) Sealing ring for bacterial filter	х	X ²⁾⁴⁾⁵⁾		Manual or automatic cleaning and disinfection		Х			
Insert of collection jar lid	х	X ²⁾⁴⁾⁵⁾		Manual or automatic cleaning and disinfection		Х			
Gasket	х	X ²⁾⁴⁾⁵⁾		Manual or automatic cleaning and disinfection		х			
Sleeve of overflow safety	х	X ²⁾⁴⁾⁵⁾		Manual or automatic cleaning and disinfection		Х			
Float, closed side must up	х	x		Manual or automatic cleaning and disinfection		х			
Secretion collection	х	X2)4)5)		Empty when the jar is full; at least daily;		х			
jar Disposable jar				manual or automatic cleaning and disinfection Exchange and disposal of full jar		х			
system						~			
Hose rinsing sy	/stem								
Suction nozzle for hose rinsing	х	X ³⁾		Wipe cleaning and disinfection		Х			
	Х	X ²⁾⁴⁾⁵⁾⁶⁾		Manual or automatic cleaning and disinfection		Х			
Silicone attachment piece				Exchange of Silicone attachment				Х	
Suction nipple with	Х			Manual cleaning and disinfection after each patient; rinse with hose disinfectant	х				
suction hose (reusable)	Х	X ²⁾⁴⁾⁵⁾⁶⁾		Manual or automatic cleaning and disinfection		Х			
Secretion suction hose	х			Rinse the secretion hose with the hose irrigation system after each procedure	X				
(disposable)		X ²⁾⁴⁾⁵⁾⁶⁾		Exchange or disinfection monthly				Х	
Storage container for hose rinsing system	Х	X ²⁾⁴⁾⁵⁾⁶⁾		Cleaning with a brush; automatic cleaning and disinfec- tion)			х		
Ear irrigation /	Therma	al nysta	gmus si	timulation					
Ear irrigation bowl	х	X ²⁾⁴⁾⁵⁾		Manual or automatic cleaning and disinfection		х			
Ear irrigation bowl Handle	x x	X ²⁾⁴⁾⁵⁾ X ³⁾		Manual or automatic cleaning and disinfection Wipe cleaning and wipe disinfection		X X			
-				-					
Handle	Х	X ³⁾		Wipe cleaning and wipe disinfection		х			
Handle Jet connection	X X	X ³⁾ X ²⁾⁴⁾⁵⁾⁶⁾		Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection	X	x x			
Handle Jet connection Splash protection	X X	X ³⁾ X ²⁾⁴⁾⁵⁾⁶⁾		Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection Manual or automatic cleaning and disinfection	X	x x			
Handle Jet connection Splash protection Hose tip (disposable) Hygiene filter	X X	X ³⁾ X ²⁾⁴⁾⁵⁾⁶⁾		Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection Manual or automatic cleaning and disinfection Exchange after each application	X	x x		X	
Handle Jet connection Splash protection Hose tip (disposable)	X X X	X ³⁾ X ²⁾⁴⁾⁵⁾⁶⁾ X ²⁾⁴⁾⁵⁾		Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection Manual or automatic cleaning and disinfection Exchange after each application See operating instructions for hygiene filter	X	X X X	x	X	
Handle Jet connection Splash protection Hose tip (disposable) Hygiene filter	X X X X	X ³) X ² (4)5)5) X ² (4)5) X ³) X	tzer	Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection Manual or automatic cleaning and disinfection Exchange after each application See operating instructions for hygiene filter Empty, dry, wipe, disinfect	×	X X X			
Handle Jet connection Splash protection Hose tip (disposable) Hygiene filter Ear irrigation system Medication neb Handle for	X X X X	X ³) X ² (4)5)5) X ² (4)5) X ³) X	tzer	Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection Manual or automatic cleaning and disinfection Exchange after each application See operating instructions for hygiene filter Empty, dry, wipe, disinfect	×	X X X	x	×	
Handle Jet connection Splash protection Hose tip (disposable) Hygiene filter Ear irrigation system Medication neb	× × × ×	X ³⁾ X ²¹⁴⁽⁵⁾⁶⁾ X ²¹⁴⁽⁵⁾ X ³¹ X Don / Poli	tzer	Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection Manual or automatic cleaning and disinfection Exchange after each application See operating instructions for hygiene filter Empty, dry, wipe, disinfect Rinse weekly with Bilpron (REF 510.2049.0)	x	x x x	x	X	
Handle Jet connection Splash protection Hose tip (disposable) Hygiene filter Ear irrigation system Medication neb Handle for	x x x x vulisatio	X ³⁾ X ²¹⁴⁽⁵⁾⁶⁾ X ²¹⁴⁽⁵⁾ X ³¹ X Don / Poli	tzer	Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection Manual or automatic cleaning and disinfection Exchange after each application See operating instructions for hygiene filter Empty, dry, wipe, disinfect Rinse weekly with Bilpron (REF 510.2049.0) Manual cleaning and disinfection		x x x	x	x	
Handle Jet connection Splash protection Hose tip (disposable) Hygiene filter Ear irrigation system Medication neb Handle for compressed air Sprayer jet	x x x x vulisatio	X ³⁾ X ^{2/4(5)(6)} X ^{2/4(8)} X ³⁾ X Don / Poli	tzer	Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection Manual or automatic cleaning and disinfection Exchange after each application See operating instructions for hygiene filter Empty, dry, wipe, disinfect Rinse weekly with Bilpron (REF 510.2049.0) Manual cleaning and disinfection Clean after every procedure Manual or automatic cleaning and disinfection		x x x x x	x	X	
Handle Jet connection Splash protection Hose tip (disposable) Hygiene filter Ear irrigation system Medication neb Handle for compressed air	x x x x oulisatio	X ³⁾ X ^{2 4(5)6)} X ^{2 4(5)} X ³⁾ X Dn / Poli X ³⁾ X ³⁾	tzer	Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection Manual or automatic cleaning and disinfection Exchange after each application See operating instructions for hygiene filter Empty, dry, wipe, disinfect Rinse weekly with Bilpron (REF 510.2049.0) Manual cleaning and disinfection Clean after every procedure Manual or automatic cleaning and disinfection Multiple rinsing of the sprayer head with water Weekly exchange of the hose or when changing the		x x x x x		X	
Handle Jet connection Splash protection Hose tip (disposable) Hygiene filter Ear irrigation system Medication neb Handle for compressed air Sprayer jet Sprayer head Hose at sprayer head	x x x x yulisatio	X ³⁾ X ²¹⁴⁽⁵⁾⁶⁾ X ²¹⁴⁽⁵⁾ X ³⁾ X X Don / Poli X ³⁾ X ²¹⁴⁽⁵⁾⁶⁾ X ²¹⁴⁽⁵⁾⁶⁾	tzer	Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection Manual or automatic cleaning and disinfection Exchange after each application See operating instructions for hygiene filter Empty, dry, wipe, disinfect Rinse weekly with Bilpron (REF 510.2049.0) Manual cleaning and disinfection Clean after every procedure Manual or automatic cleaning and disinfection Multiple rinsing of the sprayer head with water Weekly exchange of the hose or when changing the medication Cleaning and disinfection (manual or automatic)		x x x x x	x	X	
Handle Jet connection Splash protection Hose tip (disposable) Hygiene filter Ear irrigation system Medication neb Handle for compressed air Sprayer jet Sprayer head	x x x x vulisatio	X ³⁾ X ²¹⁴⁽⁵⁾⁶⁾ X ²¹⁴⁽⁵⁾ X ³⁾ X Dn / Poli X ³⁾ X ²¹⁴⁽⁵⁾⁶⁾ X ²¹⁴⁽⁵⁾ X ²¹⁴⁽⁵⁾	tzer	Wipe cleaning and wipe disinfection Manual or automatic cleaning and disinfection Manual or automatic cleaning and disinfection Exchange after each application See operating instructions for hygiene filter Empty, dry, wipe, disinfect Rinse weekly with Bilpron (REF 510.2049.0) Manual cleaning and disinfection Clean after every procedure Manual or automatic cleaning and disinfection Multiple rinsing of the sprayer head with water Weekly exchange of the hose or when changing the medication		x x x x x	x	X	

11.0 Hygiene Plan



	What		How				Wł	Ien		Who
	VVIIat	-			Recommendations	After each procedure				Qualified and tr staff who are fa with reprocess
	Reusable parts	C Cleaning	D Disinfection	S Sterilisation			Daily	Weekly	Monthly	(Please fill in responsable pe -> use a water-l overhead mar
RI	Endoscope ma	nagem	ent							
	Plastic quiver	х	X ²⁾⁴⁾⁵⁾		Cleaning with a brush; disinfect afterwards		х			
	Metal quiver	х	X ²⁾⁴⁾⁵⁾⁶⁾		Cleaning with a brush; disinfect afterwards (manual or automatic)		х			
	Protective sleeve (teflon	x	X ²⁾⁴⁾⁵⁾		Manual or automatic cleaning and disinfection		х			
	element for metal quiver)	nageme	ent							
>					Immerse instruments into solution immediately after					
	ENT instruments	х	X ²⁾⁴⁾⁵⁾	х	use, fully wetting is required, air must be removed from any cavities, after the contact time instruments must be rinsed with water, has to be dried and sterilised after- wards. Please also observe the ATMOS operating instructions for ENT instruments.					
_	Instrument bowl with cover	х	X ²⁾⁴⁾⁵⁾		Cleaning with a brush; disinfect afterwards (manual or automatic)		х			
ø					disinfect anerwards (manuar of automatic)					
	Visualisation									
_	ATMOS Cam 21 / 31	Х	X ³⁾		Wipe cleaning and wipe disinfection	х				
-	ATMOS Strobo 21 LED	X	X ³⁾	241	Wipe cleaning and wipe disinfection		Х			
-	Flexible scope	X ¹⁾	X ¹⁾	X ¹⁾	Immediate pre-cleaning after the procedure	X				
-	Rigid scope	X ¹⁾	X ¹⁾	X ¹⁾	Immediate pre-cleaning after the procedure	X				
	Laryngoscope	X ¹⁾	X ¹⁾	X ¹⁾	Immediate pre-cleaning after the procedure	X				
-	Light conductor Light source	X	X ³⁾		Wipe cleaning and wipe disinfection Wipe cleaning and wipe disinfection	_	X X			
_	Microscope	X	X ³⁾		Wipe cleaning and wipe disinfection		X			
_	Headlight	X	X ³⁾		Wipe cleaning and wipe disinfection		X			
	Radio frequend	cy surge	ery							
/	ATMOS RS 221	Х	X ³⁾		Wipe cleaning and wipe disinfection		х			
-	(surface) Ergonomic handles	X	X1)2)4)5)	X ¹⁾	Wipe cleaning and wipe disinfection	X				
-	Bipolar tweezers	X	X1)2)4)5)	X ¹⁾	Immediate pre-cleaning after the procedure or dispose					
F	Bipolar electrode	Х	X1)2)4)5)	X ¹⁾	in wet disposal tray; use of enzymatic detergents, cleaning and disinfection (manual or automatic)	Х				
	Bipolar electrode cable	Х	X ¹⁾²⁾⁴⁾⁵⁾	X ¹⁾	Immediate pre-cleaning after the procedure or dispose	of X				
	Neutral electrode	Х	X ¹⁾²⁾⁴⁾⁵⁾	X ¹⁾	in wet disposal tray; use of enzymatic detergents, cleaning and disinfection (manual or automatic)	Х				
-	Neutral electrode cable	X	X ¹⁾²⁾⁴⁾⁵⁾	X ¹⁾	Immediate pre-cleaning after the procedure or dispose in wet disposal tray; use of enzymatic detergents,					
	ENT electrodes	Х	X1,2,4,5)	Χ.,	cleaning and disinfection (manual or automatic)	X				
	Surfaces									
	Housing	Х	X ³⁾		Wipe cleaning and wipe disinfection		Х			
	Roller shutter	Х	X ³⁾		Wipe cleaning and wipe disinfection		Х			
	Drawers	Х	X ³⁾		Wipe cleaning and wipe disinfection		Х			
_	Writing leaf	Х	X ³⁾		Wipe cleaning and wipe disinfection		Х			
	Instrument deposit	X	X ³⁾		Wipe cleaning and wipe disinfection		X			
-	Mirror pre-heater Tongue patches and	Х	X ³⁾		Wipe cleaning and wipe disinfection Wipe cleaning and wipe disinfection,		Х			
-	swab dispenser	X	X ³⁾		every day or when refiling Wipe cleaning and wipe disinfection,		X			
	Waste disposal	Х	X ³⁾		every day or when emptying the container		Х			
	Instrument tray	Х	X ³⁾		Wipe cleaning and wipe disinfection, daily or when replacing with new instruments		Х			
disinfection disurfaces:	I disinfectants Green & Clean Si Cavi Wipes (Kerr) Dismozon [®] Pur (B Kohrsolin [®] FF (Bc Perform [®] (Schülk	(USA) ode Chemie) de Chemie) e & Mayr)		Wipe cleanin able) wipe w	g and wipe disinfection: All surfaces have to be wiped with a clean (dispos- hich is damped with disinfectant solution; the entire surface has to be wiped d may not be dried afterwards.	to the Medical and the recom Definition of the of the Robert K	Devices An mendation e required toch Institu	ct, the Med s of the Ro reprocessi ite: "Requir	ical Device bert Koch ng steps re ements fo	esult from the recommen r the reprocessing of me
irfaces:	 Terralin[®] Protect (Dismozon[®] pur (Kohrsbin[®] FF (Bc Bacillocid[®] rasant) Mikrobac[®] forte (E Perform[®] (Schülk Terralin[®] Protect (Surface disinfecti 	Schülke & Mayr) ode Chemie) de Chemie) (Bode Chemie) ode Chemie) e & Mayr)	ntal)	¹⁾ Please obs ²⁾ Alternative	erve the manufacturer's operating instructions. to manual cleaning und disinfection: Wash-Disinfector 78°C / 172°F mensionally stable at 134°C	products". The semicritical and and disinfection additional repro All the recomm ants (VAH/RKI C 21 / C 31. AT	medical pr d critical. T n plan are ocessing m ended disi) and have 'MOS Med ng concent	roducts we he reproce a recomme neasures a infectants v e been test lizinTechnil	re categor ssing mea indation of re at the o which are s ed on their c cannot b	ised in the risk groups un sures mentioned in this : ATMOS MedizinTechnik perator's discretion. stated herein are listed d suitability of use on the e hold liable for any dam tants or by the applicatio

and distribution para are a recommendation of A MuCS Medican learnin. Any and distribution para are a recommendation of A MuCS Medican learnin. Any ALI the recommended distribution which are stated herein are listed distribu-tions (VAH/RK) and have been tested on their suitability of use on the ATMOS 2 1 / C 31. ATMOS Medican Technic annot be hold listed for any damage caused by wrong concentration of the distribution of the distribu-tion distribution of the distribution of the distribution of the distribu-tion distribution of the distribution of the distribution of the distribu-tion distribution of the distribution of the distribution for the reprocessing of the reusable instruments and material may only be performed at alcolities which have an edemaily certified QM Management acc. to DIN EN ISO 13465. In Medical Devices Act, ISCs, the RK directives, BGR 250 and TRBA 250 always have to be considered.



Please see the manufacturer's instructions for concentration, contact time, temperature and the compatibility of materials. 46

Wrong concentration of disinfectants may lead to damage!

12.0 Notes on EMC



- 0
- 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 ATMOS C 31 is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C 31 should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The ATMOS C 31 uses RF energy only for its inter- nal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The ATMOS C 31 is suitable for use in all esta- blishments, including domestic, and those directly
Harmonics IEC 61000-3-2	Class B	connected to the public low-voltage power supply
Flicker IEC 61000-3-3	is conform	network that supplies buildings used for domestic purposes.



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.

12.2 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS C 31 is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C 31 should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramis tile. If floors are synthe- tic, the relative humidity should be at least 30%.
EFT 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.
Power Frequency 50/60 Hz Magnetic field IEC 61000-4-8	3 A/m	Inapplicable	Power frequency magnetic fields should be that of a typical com- mercial or hospital environment.



Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environ- ment - Guidance
Voltage Dips / Dropout IEC 61000-4-11	(> 95 % Dip of the U _T) for 0.5 Cycle	< 5 % U _T (> 95 % Einbruch der U _T) für 0,5 Periode	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS C 31 demands
	40 % U _T (60% Dip of the U _T) for 5 Cycles	40 % U _τ (60% Einbruch der U _τ) für 5 Perioden	continued function even in case of interruptions of the energy supply, it is recommended to supply the ATMOS C 31 from an uninterrup-
	70% U_{τ} (30 % Dip of the U_{τ}) for 25 Cycles	70% U_{τ} (30 % Einbruch der U_{τ}) für 25 Perioden	tible current supply or a battery.
	< 5 % U_{T} (>95 % Dip of the U_{T}) for 5 s	< 5 % U_{T} (>95 % Einbruch der U_{T}) für 5 s	
NOTE U_{T} is the m	ains alternating current prior	to application of the test le	vels.

12.3 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS C 31 is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C 31 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 Radiated RF IEC 61000-4-3	Test Level 3 V _{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile communications equipment should be separated from the ATMOS C 31 incl. the cables by no less than the distances calculated/listed below. Recommended distances: $d = (3,5 / V1) * \sqrt{(P)}$ $d = (3,5 / E1) * \sqrt{(P)} 80-800 \text{ MHz}$ $d = (7 / E1) * \sqrt{(P)} 0,8-2,5 \text{ GHz}$
			 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 (<i>a</i>) survey, should be less than the compliance level (<i>b</i>). Interference may occur in the vicinity of equipment containing following symbol.



NOTE 1 With 80 MHz and 800 MHz the higher frequency range applies.
NOTE 2 These guidelines might not be applicable in any case. The propagation of electromagnetic sizes 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 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 ATMOS C 31 is used exceeds the above compliance level, the ATMOS C 31 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 Within the frequency range of 150 kHz to 80 MHz the field strength is to be below 3 V/m.

12.4 Recommended separations between portable and mobile RF Communications equipment and the ATMOS C 31

The ATMOS C 31 is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ATMOS C 31 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the ATMOS C 31 as stated below, according to the maximum output power of the communications equipment.

	Separation distance, depending on transmit-frequency m		
Nominal output of the transmitter	150 kHz bis 80 MHz	80 MHz bis 800 MHz	800 MHz bis 2,5 GHz
	d = [3,5/3] √P	d = [3,5 / 3] √ P	d = [7,0/3] √ P
W			
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 isn't indicated in the above table, the recommended separation 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 With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines are not applicable in any case. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.



EG - KONFORMITÄTSERKLÄRUNG **EC - DECLARATION OF CONFORMITY** DECLARATION DE CONFORMITE CE

Wir / We / Nous ATMOS MedizinTechnik GmbH & Co. KG Ludwig-Kegel-Straße 16 79853 Lenzkirch/Germany Tel. +49 7653 689-0

erklären in alleiniger Verantwortung, dass das Medizinprodukt / declare under our sole responsibility that the medical device / déclarons sous notre pleine et entière responsabilité que le produit médical

Klassifizierung / Classification / Classification : II a

Name / name / Nom:



ATMOS C 31	Economy	/REF 506.7510.0
		/ setREF 506.7350.0

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG entspricht. / meets all applicable requirements of the Directive 93/42/EEC / répond à toutes les exigences applicables de la directive 93/42/CEE

Name, Adresse und Kennnummer der Benannten Stelle: Name, address and identification number of Notified Body: Nom, Adresse et Numéro d'identification de l'organisme notifié :



DEKRA Certification GmbH, Handwerkstraße 15, D-70565 Stuttgart

Konformitätsbewertungsverfahren:

Conformity assessment procedure:

Procédé d'évaluation de conformité :

Richtlinie 93/42/EWG Anhang II des Rates über Medizinprodukte vom 14. Juni 1993, zuletzt geändert am 5. September 2007 / Directive 93/42/EEC Annex II on medical products, passed by the commission on 14th June 1993, last amended on 5th September 2007 / Directive 93/42/CEE, Annexe II du Conseil sur les produits médicaux, passée en commission le 14 juin 1993, dernière modification le 5 septembre 2007.

Gültig bis auf weitere Änderungen am Produkt bis 29. März 2015. Valid till further changes on the product until March 29th 2015. Valide jusqu'à modification du produit, jusqu'au 29 mars 2015.

Lenzkirch, den 11.06.2013 Place and date of issue

Frank Greiser Geschäftsführer / Managing Director / Directeur



i.V. Steffi Focke Sicherheitsbeauftragter / Safety Inspector / Chargée de la Sécurité



1. General:

Our General Standard Terms and Conditions apply exclusively. Client's terms and conditions which are contrary to or deviate from our General Standard Terms and Conditions are not recognised unless their validity is explicitly confirmed in writing. Our General Standard Terms and Conditions also apply even if we deliver to clients without reservation, in the knowledge of the client's contrary terms and conditions. Our General Standard Terms and Conditions also apply to all future business with that client.

2. Proposal - Order Confirmation

Our proposals are subject to change without notice unless otherwise stated in our order confirmation. Each order is only accepted by us following our written order confirmation.

3. Orders

Every order requires an exact description of all of our product's details. We assume no liability for errors and damage caused by inaccurate or incomplete ordering details.

4. Prices

Unless otherwise stated in the order confirmation, our prices in the order confirmation are ex factory prices and exclude packaging and value added tax. Packaging is charged separately at cost price in the invoice. Value added tax is charged separately in the invoice according to the legal rate on the invoice date. We reserve the right to change prices appropriately should price reductions or increases, especially due to wage settlements, changes in the price of materials or currency fluctuations, be incurred. Proof of such changes will be provided for the client on request.

5. Payment Conditions - Balancing

Unless otherwise stated in the order confirmation, our invoices are payable with a 3% discount within 10 days (except for repair and assembly services) or within 21 days from the invoice date net cash; money receipts is decisive for complying with this term. We are entitled to charge interest after the due date at a rate 2% above the relevant basic interest rate of the German Federal Bank. Should the client have payment arrears, we are entitled to charge interest on arrears at a rate 5% above the relevant basic interest rate of the German Federal Bank. Should we be able to prove higher damages due to arrears, we are also entitled to claim these. The client only has the right to balance invoices against its own claims should such claims be confirmed in a court of law or recognised by us. The client does not have the right of retention due to disputed counterclaims.

6. Delivery Periods

Fulfilment of our delivery duties requires the punctual and proper fulfilment of the client's duties. The right to defense on the grounds of an unfulfilled contract is reserved. Should the client default in accepting the goods delivery or breach other cooperation duties, we are entitled either to withdraw from the contract or claim compensation for any increased costs incurred up to that time without setting a further deadline. The right to make further claims is reserved. Furthermore, in such cases, the risk of coin-cidental destruction or a coincidental deterioration in the quality of the delivered goods is transferred to the client in the case of default in accepting such goods or payment arrears. Acts of God or stoppages (due to insufficient supplies of material, industrial disputes etc.) entitle us either to demand an appropriate extension of delivery periods or to partly or entirely dissolve the delivery contract. This does not give the client the right to claim damages. We have fulfilled delivery periods if the delivery goods have left our factory or the client has been informed of the goods' readiness for delivery within such delivery periods. Delivery periods stipulated by the client are not recognised by us unless they form part of our order confirmation. We adhere to legal terms and conditions in cases where, as a result of an undue delay in the delivery for which we are liable, the client is entitled to claim that his interests in a continued fulfilment of the contract have ceased. We also adhere to legal terms and conditions should a delay in delivery be caused by deliberate or grossly negligent action by us or our representatives for which we are responsible. We are also responsible for such actions by our representatives or agents. Should the delivery delay not be caused by our deliberate infringement of contractual duties for which we are responsible, our liability is limited to damage which is regarded as typical for that case. We are liable according to the legal terms and conditions if and in so far as the delivery delay for which we are responsible is caused by an infringement of a substantial contractual duty. In such cases, our liability is also limited to damage which is regarded as typical for that

case. Should the delivery delay be caused by a culpable infringement of non-substantial contractual duties, our client is also entitled to claim a one-off damage compen-sation worth 3 percentage points of the delivery value of the goods for each week's delay, up to a maximum which is no higher than 15 percentage points of the delivery value of the goods

7. Delivery - Familiarisation

In the case of the delivery of devices for the medico-technical industry which require assembly and/or familiarisation for the final customer using specialist trade personnel (such as Ear, Nose and Throat Apparatus and Suction Units), we reserve the right to deliver the goods exclusively to the relevant specialist traders. Should the trader not carry out assembly and/or familiarisation for the final customer, this is carried out by us. In such cases, we reserve the right to charge the client for the additionally created costs. Our specialist traders operate a recording system so that, if necessary, our products can be traced to the final customer. The specialist trader undertakes to immediately report to us all events and risks which must be reported in connection with our products.

8. Passage of Risk - Packaging

Unless otherwise stated in our order confirmation, delivery is agreed ex factory. The risk of the goods 'damage or loss is therefore transferred to the client as soon as the goods leave the factory or the client is in default of acceptance of the goods. This also applies to cases where we confirm prepaid carriage. Transport packaging and all other packaging according to the packaging regulations is not returnable. Our client is responsible for disposing the packaging at its own cost. Our deliveries are insured by us at the client's expense unless explicitly otherwise agreed. No insurance is arranged in the case of goods which are collected by our clients. In the case of transport damage, claims are only handled if the client receives confirmation of any damage, reduced weight or loss by the shipping company before accepting the delivery.

9. Warranty

The client is responsible for examining the delivered goods immediately after receiving them to determine any eventual deficiencies or delivery errors, and to report these immediately. Should the client fulfil this examining and reporting responsibility, and should payment conditions be fulfilled, we shall be liable to the client within the score of legal regulations. Our period of warranty shall in all cases be two years. Our client can make use of the warranty as follows, so long as he can provide first buyer proof (in the form of an invoice or delivery note) and provided that the product still has the original, unchanged serial number:

 a. We choose whether to fulfil our guarantee by providing repair services free of charge - either on the client's premises or in our factory
 or replacing the product. We can also provide these guarantee services through an authorised company;

b. Should a product be returned to us, the client agrees to send the product in its original or similar packaging, offering the same protection as the original packaging, to our address or any address notified by us.

c. Our guarantee ceases to apply if changes of any kind have been made to our product, unless such changes have been made by us or a company authorised by us, or have been previously agreed upon in writing by us. Our guarantee also ceases to apply if third parties have carried out repairs to our products or replaced parts thereof. This applies regardless of the fact whether these measures individually or collectively led to a deficiency of the product;

d. We accept no responsibility for damage defects caused by

- operational wear and tear;

- incorrect installation or incorrect or insufficient maintenance;

 incorrect operation of the product (in contradiction to the operating instructions delivered with the product); - improper use or operating faults; inappropriate or negligent handling and care, especially with respect to dirt, lime, suction of fluids, inappropriate cleaning and sterilisation; - using accessories and/or replacement parts which are not explicitly approved;

 incorrect assembly and/or initial operation by the client or third parties; - the client's negligence in handling the product; - unacceptable operating conditions, such as humidity, temperatures, the power supply, vibrations.

 accidents, acts of God, especially lightening, water, fire, public unrest and insufficient ventilation. We are not liable for damage to other objects apart from our product itself, except in the case of any deliberate or grossly negligent actions by us or our representatives or agents. Should no deliberate breach of contract be claimed, our liability is limited to damage which is regarded as typical for that case. This also applies in the case of our culpable infringement of substantial contractual duties The indispensable conditions of German Liability Law remain unaffected thereby.

- For second-hand equipment, the period of warranty shall be reduced to a period of twelve months.

10. Reservation of Ownership

We retain ownership of our goods until the receipt of all payments arising from the business relationship, including all demands arising from installation orders, subsequent orders, repairs, accessory deliveries and replacement orders. Should we have agreed upon payment on the basis of cheque and bill transactions, the ownership reservation applies until the cheque received by us has been paid in, and does not expire through our credit upon receiving the client's cheque. In the case of a breach of contract by the client, especially payment arrears, we are entitled to repossess our goods. Repossession of our goods repre-sents a withdrawal from the contract, unless explicitly declared in writing by us. We have the right to utilise the product after its repossession, whilst the income form such use is balanced against the client's arrears, after deducting appropriate utilisation costs. The client is responsible for handling the goods with care. Should maintenance and inspection work be necessary, the client must carry these out punctually at his own cost. Our client is entitled to sell the goods he has bought from us in a proper sale transaction. However, he must immediately assign all outstanding claims to the value of the final invoice sum (including value added tax) of our claims to his customers or third parties. The client is entitled to collect this claim even after such assignment. Our right to collect the claim ourselves remains unaffected thereby.We undertake to release the securities to which we are entitled if requested to do so by the client should the realisable value of the our securities be more than 10 percentage points higher than the outstanding claims. We reserve the right to choose the securities to be released.

11. Plans and Illustrations

We retain ownership of and copyrights to all plans, illustrations, calculations and other documents which are attached to our proposals. The client must receive explicit written permission before passing these on to third parties. Imitating our legally patented products is forbidden and will be prosecuted.

12. Jurisdiction and Place of Performance

Our central office is the place of performance for all disputes in connection with these General Standard Terms and Conditions and the contracts closed with clients under them. This jurisdiction excludes other jurisdiction relating to persons or subject-matter. Furthermore, our client is not entitled to bring charges against us in another court should he file counter-charges, carry out counterbalancing or declare retention. We, however, are entitled to bring charges against our client at their general place of jurisdiction or at another relevant court recognised by German or foreign law.Unless otherwise stated in the order confirmation, our central office is the place of performance.

Lenzkirch, September 2008 ATMOS MedizinTechnik GmbH & Co. KG 79853 Lenzkirch/Germany

