

English

# ATMOS® Varioair 3



perating Instructions



# **Table of contents**



1.0 1.1 1.2 1.3 1.4	Introduction  Notes on operating instructions Intended use Function Explanation of symbols	2 2
2.0	For your safety	
3.0 3.1 3.2 3.3 3.3.1 3.3.2 3.3.3 3.3.4 3.3.5 3.4	Setting up and starting up Scope of supply Illustrations Connections Electrical connection Connecting a nystagmograph Equipotential bonding conductor connection Connection of the handle Air inlet Starting up	6 8 8 8 8
<b>4.0</b> 4.1 4.2 4.3 4.4 4.4.1 4.4.2 4.4.3	Operation	9
<b>5.0</b> 5.1 5.2 5.3	Cleaning and care  General information on cleaning and disinfection  Recommended instrument disinfectants  Recommended surface disinfectants	1′ 1′
<b>6.0</b> 6.1	Maintenance and Service Sending in the device	12
<b>7.0 8.0</b> 8.1 8.2	Accessories and spare parts Accessories Spare parts	14
9.0	Technical data	1
10.0	Disposal	16
11.0	Notes on EMC	17



#### 1.1 Notes on operating instructions

These operating instructions contain important notes on how to operate the Varioair 3, correctly and effectively. Therefore, they are intended not only for new operating personnel to be instructed in its use, but also for use as a reference manual. They help to avoid risks, and also to reduce repair costs and down-times. Furthermore, reliability and service-life of the equipment will be increased. For these reasons these operating instructions must always be kept available near the device.

Prior to first use please peruse the chapter "For your safety", in order to be prepared for any possible dangerous situations. To do this during work, would be too late.

The basic principles are:

## Judicious and careful work provides best protection against accidents!

Operational safety and readiness for use of the device depend not only on your capabilities, but also on the care and maintenance given to the Varioair 3. 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 only original spare parts are used. You will then have the warranty that operational safety, readiness for work and the value of your device will be preserved.

- The product Varioair 3 bears CE marking CE 0124 according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of Appendix I of this directive.
- The product ATMOS® Varioair 3 complies with all applicable requirements of the Directive 2011/65/EC restricting the use of certain hazardous substances in electrical and electronic equipment ("RoHS").
- The declaration of conformity and our general standard terms and conditions can be obtained on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 13485.
- Reprints also in extracts only with permission in written form by ATMOS.

## Short cuts / symbols contained in these operating instructions:

- Indicating a list
  - Subdivision of a list/activity

The recommended sequence must be followed in each case!

- Indicating particularly important advice!
  - Describing the effect of an activity

**ATMOS** 

MedizinTechnik GmbH & Co. KG Ludwig-Kegel-Straße 16 79853 Lenzkirch Germany

Phone: +49 7653 689-0

Fax:

+ 49 7653 689-190

+ 49 7653 689-393 (Service Centre)

E-mail: atmos@atmosmed.de Internet: www.atmosmed.de



#### 1.2 Intended use

Name: ATMOS® Varioair

**Main function:** Device for the stimulation of the

vestibular organ

Medical indications / application:

Stimulation of the vestibular organ

Specification of the main functions:

Stimulation of the vestibular organ with a defined flow and a fixed temperature for the functional testing. Stimulation duration: 1 sec

to 99 sec.

Application organ: Auditory canal to the drumhead

**Application time:** For the short-term application on

patients (max. 60 minutes).

Application site: In clinics and practices for ENT

doctors and phoniatricians. The therapy with the ATMOS stimulation and irrigation device may only be performed by medical trained staff.

**Contraindications:** Do not apply to an infected resp.

contaminated auditory canal or to a

perforated eardrum.

The product is: active

Sterility: Not necessary

Single-use product No single use product

/ reprocessing:

#### 1.3 Function

- After activating the main switch, the optical indicators are tested.
- The device then enters the standby mode in which the heating and the pump are switched off.
- Possibility to switch to the stimulation mode for stimulating the vestibular organ. The Varioair 3 is equipped with a timer for preselecting the stimulation duration.

#### 1.4 Explanation of symbols



Observe operating instructions! according to ISO /7000/0434 DIN

30600/1008 IEC 348



Follow operating instructions (blue)



Type B equipment as to IEC 417



Fuse

according to IEC 417/5016, DIN 30600/0186

°C

Temperature in degree centigrade

S

Timer adjustment in seconds



Start



Stop



Timer



Cold stimulation level



Warm stimulation level



Heating and air flow ON



Heating and air flow OFF (standby)





Control output for connecting a nystagmograph

(graphical recorder as to DIN 30600, IEC 417 5192)



Equipotential connection DIN 30600 495, ISO 417 5021



Air filter DIN 24300

## 2.0 For your safety



- The Varioair 3 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 device may only be connected to a properly installed grounded electrical outlet.
- The Varioair 3 may only be used under the supervision of skilled staff who have been authorised by ATMOS and trained in its operation (IEC 601-1 / EN 60601-1).
- The mains voltage indicated on the type plate must correspond to the values of the supply network.
- Make sure prior to every application of the equipment that it is technically safe and in proper condition. Damaged cables must be replaced immediately!
- Correct configuration in assembly of country-specific connections:
  - green / yellow: protective conductor (PE)
  - blue: neutral conductor (N)
  - black or brown: phase (L)
- The control panel must be clearly visible and accessible by the user. Ensure sufficient stability on the installation surface.
- Prior to application, the air temperature must be checked by the user (display)!
- Switch off the main switch after finishing work in practice.
- The Varioair 3 may only be operated in medicals areas, but not in areas subject to explosion hazards and not in oxygen rich environments.
- All additional equipment which is connected to the
  analogue and digital interfaces of the device must meet
  the requirements of relevant EN specifications (e.g. EN
  60950 for data processing equipment and EN 60601 for
  electrical medical equipment). In addition, configurations
  must satisfy system specification EN 60601-1-1. When
  additional equipment is connected to the signal input or
  signal output section on the device, the person carrying
  out the connection is deemed "a system configuration
  operator" and as such is responsible for meeting the
  requirements of system specification EN 60601-1-1. For
  answers to additional questions, please contact your local
  specialist supplier or the ATMOS Technical Service.

- 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.
- The validity for the certificate of conformity expires if the customer or a third party manipulates the unit, e.g. modifications of any kind, by installing non-authorized accessories, removing warning or information labels as well as using the unit for inappropriate applications.
- Please note:

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

# 3.0 Setting up and starting up



### 3.1 Scope of supply

- · Varioair 3 basic unit
- Mains cable
- Handle with tube
- · Hose tips (30 pcs.)
- · Operating Instructions

#### 3.2 Illustrations

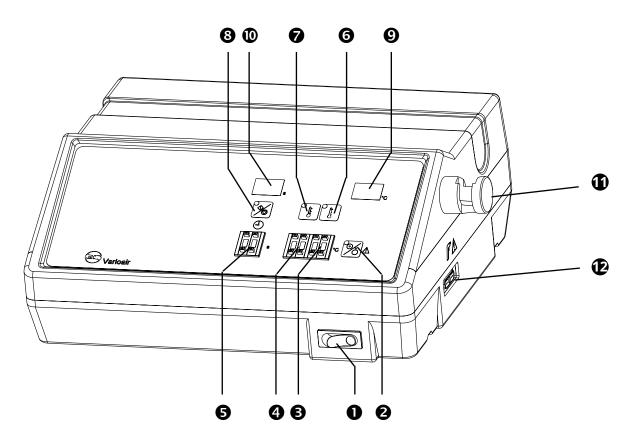


Fig. 1. Front view

- Main switch
- 2 Key switch for heating/air flow ON/OFF (standby)
- 3 Coding switch for warm-stimulation level
- 4 Coding switch for cold-stimulation level
- **5** Coding switch for stimulation time
- **6** Key switch for selecting the warm-stimulation level (e.g. 44°C)
- Key switch for selecting the cold-stimulation level (e.g. 30°C)
- 3 Key switch for start/stop of the stimulation
- **9** Temperature display (two-figure number, resolution 1°C), current value indication
- ① Display of stimulation time (two-figure number, resolution 1s)
- Support for handle
- Connection for handle

# 3.0 Setting up and starting up



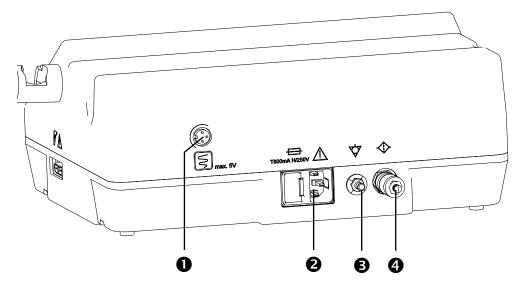
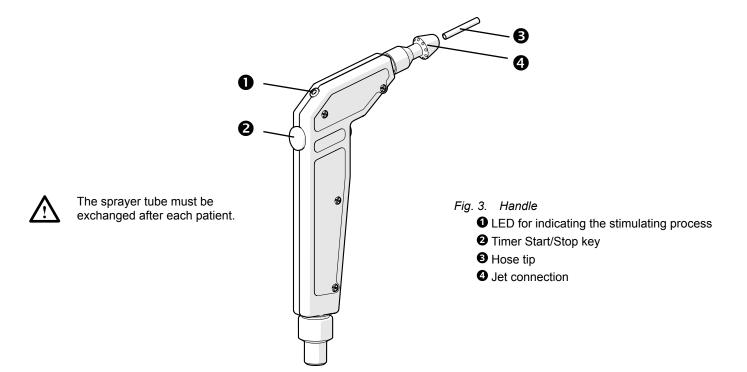


Fig. 2. Rear view

- Ocntrol output for controlling a nystagmograph
- 2 Device plug with fuse compartment
- 3 Equipotential bonding connection
- Air filter (throttle silencer)



## 3.0 Setting up and starting up



#### 3.3 Connections

#### 3.3.1 Connection to electrical power line

- Connect the mains cable to the mains supply (2, fig. 2).
- Insert the power plug in a correctly installed socket with earthing contact.

#### 3.3.2 Connecting a nystagmograph

 When controlling an ENG (electro-nystagmograph) or a CNG (computer-nystagmograph) at output (1, fig. 2), please connect only recording equipment approved by ATMOS. Connecting cable available from ATMOS (see section 8.0).

# 3.3.3 Connecting a equipotential bonding connection

Connection for potential equalization (3, fig. 2).
 Connecting cable available from ATMOS (see section 8.0).

#### 3.3.4 Connection of the handle

- Only the handle which is intended for this purpose must be used:
  - Press the special connector plug slightly onto the socket in the unit.
  - Fasten it to the housing by turning the holding screws to the right.
- Do not buckle the air tube!

#### 3.3.5 Air inlet

- · The ambient air is sucked into the unit through the filter.
- · Screw connector for the air filter.

#### 3.4 Starting up

- Insert the handle in its holder; the air outlet must point to reverse side of the unit.
- Switch on the unit (①, fig. 1).
- Automatic display test with digital numbers " 8 8 " and acoustic warning signal.
- · Automatic change into the standby mode.

## 4.0 Operation



- · Use the main switch to start the unit.
- · Readiness for operation after 1 second.
- · Completely press the hose tip onto the handle.



If the hose tip is not completely attached onto the handle, damage could be caused to the patients eardrum.

#### 4.1 Adjusting temperatures

- Two variable temperature levels (20°C 47°C) (48°C + 49°C only for testing purposes).
- The lowest achievable stimulation temperature is approx. 2°C over the ambient temperature.
- Temperate setting by coding switche (3, 4, Fig. 1).
  - left switch: for adjusting the "ten" partition
  - right switch: for adjusting the "one" partition
  - ♥ lower keys (+): Temperature increase
  - 🔖 upper keys (-): Temperature decrease
- Standard settings:
  - Level for cold stimulation: 30°C
  - Level for warm stimulation: 44°C



Avoid bending the tip of the hose within the ear/auditory canal. Otherwise the error F1 or F7 may occur.

#### 4.2 Selecting temperature levels

- For selecting the desired temperature level, use the respective key (6, 9, fig. 1).
  - by Display of the active level by illuminated diodes.
  - Display of the air temperature (current value) in °C.
- For switching off the heating system press the respective key (⑤, ⑥, fig. 1) of the active temperature level.
  - \$\text{LED of the temperature level goes out.}
  - ♥ Display of the air temperature (current value) in °C.

#### 4.3 Adjusting stimulation time

• By means of coding switch (9, Fig. 1).

#### 4.4 Description of operating modes

#### 4.4.1 Preparation mode

#### Purpose:

The temperature set by the user is adjustable.

#### **Properties:**

- Temperature: corresponds to the preselected cold or warm stimulation level.
- · Air flow: 5.0 l/min.

#### **Activation:**

- By operating one of the key switches for selecting a temperature level (⑤, ⑥, fig. 1) or by operating the key switch for heating/air flow ON/OFF (②, fig. 1) in the standby mode.
- If the active temperature push button is repeatedly pressed, the heating is switched off.
  - Air with a temperature that almost corresponds to the ambient air temperature is available.

#### Deactivation:

- Operating the key switch heating/air flow ON/OFF (2), fig. 1) switches the unit to the standby mode.
- Automatically switch to the standby mode when the unit is not used within a 3 minute period.



#### 4.4.2 Stimulation mode

#### Purpose:

Stimulation of the vestibular organ.

#### **Properties:**

- Temperature: corresponds to the preselected cold or warm stimulation level
- · Air flow: 5.0 l/min
- · Duration: as pre-set by the timer.

#### **Activation:**

- Initially select the type of stimulation by actuating either warm-stimulation or cold-stimulation key (⑤, ⑥, fig. 1) (see section 4.1 for pre-setting of temperature)
- · Operate the "timer-start-key" on the unit or on the handle.
- Preparation for stimulation:
  - As long as the push button is pressed, the pump remains switched off to allow the jet connection to be positioned in the auditory canal.
- When the push button is released, the thermal stimulation is performed for the time set by the user (§, fig. 1).
  - ♣ LED on handle (♠, fig. 3) lights up during thermal stimulation.
- At the end of the stimulation period a control signal for a recording unit is issued at the nystagmograph output.
- After completion of stimulation the pump is switched off.
- Repeated actuation of the "timer-start-key" during the stimulation leads to stopping timer operation.
- Second actuation of the currently active key effects deactivation of the pertaining stage.
  - ♥ Heating is switched off.
- ⋄ Stimulation with near-ambient air temperature.

Hose tip for the nozzle may not be blocked.



## 4.4.3 Standby mode

#### Purpose:

- · Reduction of energy consumption.
- · Reduction of noise level.

#### **Activation:**

- Actuation of key "heating/pump on/off" (②, fig. 1).
  - Heating is switched off.
- ♥ Pump is switched off after 2 s.
- Automatically after each stimulation process.
- Automatically when the unit is not used within a 3 minute period.

## 5.0 Cleaning and care



# 5.1 General information on cleaning and disinfection

After use, all parts which come into contact with the patient (jet connection) must be removed and disinfected! The cleaning agents and disinfectants listed in section 5.2 are all suitable.

Hose tips must be exchanged after each patient.

The handle is not autoclavable!

The surfaces of the Varioair 3 resist most of the common surface disinfectants.

#### However, do not use

- disinfectants which contain concentrated organic or inorganic acids as they could cause corrosion damage.
- disinfectants containing chloramides, phenol derivatives or anionic tensides, as these may cause stress cracks in the material used for the housing of the unit.

You may also use disinfectant sprays or disinfectant tissues for cleaning and disinfection.

- Feet main switch of the device to OFF prior to cleaning and disinfection! Wipe the unit surface with a cloth moistened with a cleaning or disinfecting solution. Take care that no liquid penetrates the device. The cleaning agents and disinfectants listed in section 5.3 are all suitable.
- Always observe the instructions for use by the manufacturer of the disinfectants, including all concentration specifications.
- The described action relating to cleaning and disinfection resp. sterilisation do not substitute the relevant instructions which must be adhered to prior to operation.

#### 5.2 Recommended instrument disinfectants

Disinfectant	Ingredients	in 100 g	Manufacturer
Sekusept® PLUS	Glucoprotamin	25 g	Henkel, Düsseldorf
(concentrate)	non-ionic tensides, solvents, complexing agents		
Gigasept® FF	succindialdehyde		Schülke & Mayr,
(concentrate)	dimethoxytetrahydrofurane 3.0 g		Norderstedt
	corrosion protection components, non-ionic tensides, perfumes		
Mucozit®-T new	bis(3-aminopropyl)laurylamine	8.0 g	Merz & Co., Frankfurt /
(concentrate)	ntrate) Alkyl dimethyl benzyl ammonium chloride		Main
	Cocospropylendiam-1,5-inguanidium-acetate	7.0 g	

#### 5.3 Recommended surface disinfectants

Disinfectant	Ingredients in 100 g		Manufacturer
TERRALIN	Benzalkonium chloride		Schülke & Mayr,
(concentrate)	Phenoxypropanols	35.0 g	Norderstedt
Hexaquart® forte	benzalkonium chloride (benzyl-C12-18 20 alkyldimethylammonium, chloride)		BBraun, Melsungen
	Didecyldimethylammonium chloride	7.9 g	
	Non-ionic surfactant	5 – 15%	
	NTA	< 5 %	
Incidin Plus	Glucoprotamin	26.0 g	Henkel, Düsseldorf
(concentrate) non-ionic surfactants			
	Solvents, complexing agents		
Pursept-A	Pursept-A ethanol		Merz & Co., Frankfurt /
(Disinfectant spray or	glyoxale	0.1 g	Main
disinfectant cloths)	quaternary ammoniumchlorides	0.05 g	

When using disinfectants containing aldehyde and amine at the same object colour changes may occur.

## 6.0 Maintenance and Service



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

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

Carry out an inspection according to the manufacturer's specifications every 12 months.

#### 6.1 Sending in the device

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

# 7.0 Troubleshooting



Error in temperature display	Possible cause	Remedy
"F0"	Not used	
"F1"	maximum allowed temperature exceeded (>51°C) (if the temperature exceeds 51°C for more than 2 seconds, the pump is switched off automatically).	<ul> <li>Switch off device, cooling down for approx. 1 minute is required.</li> <li>Check, whether temperature setting is too high. If necessary, adjust desired temperature to a value of &lt;51°C by means of the coding switches.</li> <li>Inform the service staff.</li> <li>Bent hose tip within the ear/auditory canal.</li> </ul>
"F2"	-5V is missing (supply voltage on the control board)	Inform the service staff.
"F3"	Break of the safety NTC	<ul> <li>Check proper connection of the handle.</li> <li>Replace the handle.</li> <li>Inform the service staff.</li> </ul>
"F4"	Not used	
"F5"	Break of the regulating NTC	<ul> <li>Check proper connection of the handle.</li> <li>Replace the handle.</li> <li>Inform the service staff.</li> </ul>
"F6"	Not used	
"F7"	Temperature too high (>48°C)	<ul> <li>Check, whether temperature setting is too high. If necessary, adjust desired temperature to a value of &lt;48 °C by means of the coding switches.</li> <li>Inform the service staff.</li> <li>Bent hose tip within the ear/auditory canal.</li> </ul>
"F8"	Short-circuit of the regulating NTC	<ul> <li>Replace the handle</li> <li>Have temperature feeler of the regulating NTC checked by the service staff.</li> </ul>
"F9"	Not used	

Figure 16 If errors cannot be corrected with the assistance of the trouble-shooting list, please inform the service staff or send in the device for repair. Do not start any attempts to repair the unit yourself!

# 8.0 Accessories and spare parts



## 8.1 Accessories

Description	REF
Power cable	507.0859.0
Handle, complete	502.1035.0
Hose tips for jet (30 pcs.)	502.0844.0

## 8.2 Spare parts

Description	REF
Device base	000.0796.0
Fuse T 800 mA / H 250V 5x20 mm	008.0081.0
Power cable	507.0859.0
Handle, complete	502.1035.0
Jet connection	502.1045.0
Hose tips for jet (30 pcs.)	502.0844.0

# 9.0 Technical data



Voltage range	100 - 240 V~ ± 10 %; 50/60 Hz		
Current consumption	max. 0.75 A		
Power consumption	max. 85 W		
Connections	Mains connection via IEC socket;control output for a nystagmograph; equipotential equalization; connection for the handle; air inlet		
Fuses	2 x T 1.6 A (f. 250 V~, 50/60 Hz)		
Stimulation time	Can be preselected by timer from 1 up to 99 sec.		
Timer indication	Indication accuracy ± 0.5 s ± ½ digit		
Air temperature	20°C - 47°C		
Lowest temperature	Approx. 2°C above room temperature		
Temperature indication	Indication accuracy ± 0.5 s ± ½ digit		
Temperature deviation	< ± 1°C		
Air flow	5.0 l/min ± 10 %		
Operating time	Short term operation: 1. Automatic shut-off after completion of stimulation. 2. Automatic shut-off after 3 minutes.		
Modes of operation	Preparation mode; stimulation mode (at temperature preselected for the cold stimulation level resp. warm stimulation level); heating off and no air flow (economy mode, standby mode)		
Protective earth conductor resistance	max. 0.1 Ω		
Earth leakage current	max. 0.5 mA		
Enclosure leakage current	max. 0.1 mA		
Patient leakage current	max. 0.1 mA		
Ambient conditions for transport/ storage	-20+50°C; 590 % humidity without condensation at air pressure 7001060 hPa		
Ambient conditions operation	+10+35°C; 2080 % humidity without condensation at air pressure 7001060 hPa		
Maximum operational altitude	≤ 3000 m (NN)		
Contamination level	Class 2		
Overvoltage category	II .		
Dimensions HxWxD	14.5 x 37 x 32 cm		
Weight	3.7 kg		
Period tests	Inspection according to the manufacturers specifications every 12 months.		
Safety class (EN 60601-1)	1		
Degree of protection	Type B ★		
Protection class	IPX0		
Further classifications according to other regulations	VDE protection class 1 (IEC 601/EN 60601)		
Classification according to Appendix IX EC Directive 93/42/EEC	Class IIa		
CE marking	CE 0124		
Applied standards	EN 60601-1: 1990 + A1:1993 + A2:1995; EN 60601-1-2: 1993 (EMV / EMC)		
GMDN code	34891		
UMDNS code	10-548		
ID No. (REF)	502.1100.0		
Canadian Classification			
Device group PNC Risk Class Description	Ear, nose, throat 77ETP 2 STIMULATOR, CALORIC (WATER)		

Issue of the technical data: 23.12.2016

# 10.0 Disposal



- Packaging material, cardboard and/or PE foam, can be fully recycled or returned to your supplier.
- The Varioair 3 does not contain any hazardous materials.
- · The housing is recyclable.
- The component parts of the Varioair 3 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.
- Used hose tips, which no longer can be disinfected, must be discarded into domestic waste immediately.

# 11.0 Notes on EMC



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

#### 11.1 Guidelines and Manufacturer's Declaration - Emissions

The ATMOS® Varioair 3 is designed for operation in the environment specified below. The customer or user of the ATMOS® Varioair 3 should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions acc.to CISPR 11	Group 1	The ATMOS® Varioair 3 uses HF energy for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions acc. to CISPR 11	Class B	
Harmonic emissions according to IEC 61000-3-2	Class A	The ATMOS® Varioair 3 is suitable for use in all establishments, including domestic and those connected directly to a public power supply network that supplies buildings used for residential
Voltage fluctuations/flicker according to IEC 61000-3-3	Corresponds	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.

#### 11.2 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS® Varioair 3 is designed for operation in the electromagnetic environment specified below. The customer or user of the ATMOS® Varioair 3 should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) according to IEC 61000-4-2		± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramics tile. If floors are synthetic, the relative humidity should be at least 30 %.
EFT IEC 61000-4-4		± 2 kV Mains ± 1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000- 4-5		1 kV Common 2 kV Differential	Mains power quality should be that of a typical commercial or hospital environment.
Magnetic field at power frequency 50/60 Hz acc. to IEC 61000-4-8		3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

# 11.0 Notes on EMC

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips / Dropout IEC 61000-4-11		$< 5 \% U_{T}$ $(> 95 \% \text{ Dip of the } U_{T})$ for 0.5 Cycle $40 \% U_{T}$ $(60\% \text{ Dip of the } U_{T})$ For 5 cycles $70\% U_{T}$ $(30 \% \text{ Dip of the } U_{T})$ For 25 cycles $< 5 \% U_{T}$ $(> 95 \% \text{ Dip of the } U_{T})$ for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS® Varioair 3 requires continued operation upon the occurrence of disruptions in the energy supply, the ATMOS® Varioair 3 should make use of an uninterruptible power supply or a battery.
NOTE $U_T$ is the m	ains alternating current prior	to application of the test le	vels.

## 11.3 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS® Varioair 3 is designed for operation in the electromagnetic environment specified below. The customer or user of the ATMOS® Varioair 3 should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V <sub>eff</sub> 150 kHz to 80 MHz	[3 ] V	Portable and mobile radio equipment should be used no closer to the ATMOS® Varioair 3, including cables, than the recommended distance calculated according to that
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[3 ] V/m	which applies to the transmission frequency.  Recommended distances:
			$d = [1,2] \ \sqrt{P}$ $d = [1,2] \ \sqrt{P}$ $d = [2,3] \ \sqrt{P}$
			where "P" is the max. power in watts (W) and d is the recommended separation distance in meters (m).
			Field strengths from fixed transmitters, as determined by an electromagnetic site (a) survey, should be less than the compliance level (b).
			Interference may occur in the vicinity of equipment containing following symbol:
			(( <u>`</u> ))

## 11.0 Notes on EMC

#### NOTE 1

With 80 MHz and 800 MHz the higher frequency range applies.

#### NOTE 2

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

а

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 field strength measured at the site where the ATMOS® Varioair 3 is used exceeds the compliance level above, the ATMOS® Varioair 3 must be observed to demonstrate proper function. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ATMOS® Varioair 3.

b

Within the frequency range of 150 kHz to 80 MHz the field strength should be below 3 V/m.

# 11.4 Recommended separations between portable and mobile RF Communications equipment and the ATMOS® Varioair 3

The ATMOS® Varioair 3 is intended for use in an electromagnetic environment in which HF disturbances are controlled. The customer or user of the ATMOS® Varioair 3 can thereby help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communication equipment (transmitters) and the ATMOS® Varioair 3 - depending on the output of the communication device as indicated below.

	Safety distance, depending on transmit-frequency m			
Nominal output of the transmitter W	150 kHz to 80 MHz d = [1,2] √P	80 MHz to 800 MHz d = [ 1,2] √P	800 MHz to 2.5 GHz d = [2,3] √P	
0.01	0.12	0.12	0.23	
0.1	0.46	0.46	0.9	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

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

#### NOTE '

With 80 MHz and 800 MHz the higher frequency range applies.

#### NOTE 2

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



ATMOS MedizinTechnik GmbH & Co. KG Ludwig-Kegel-Straße 16 79853 Lenzkirch / Germany Phone: +49 7653 689-0 atmos@atmosmed.de