ATMOS MedizinTechnik

Operating Instructions

Varioair 3

English

CE 0124

GA1GB.140303.0

2023-10 Index 22

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1 Introduction

1.1 Notes on the operating instructions

These operating instructions contain important information on how to operate your product safely, appropriately and effectively.

This manual is used to train and instruct operating personnel and is also intended for use as a reference manual. This document may be reprinted, either in part or in whole, only with the written permission of ATMOS.

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

Care, period tests, regular cleaning and appropriate use are essential. They ensure the operational safety and usability of the product.

Maintenance, repairs and period tests may be carried out only by persons who have the appropriate technical knowledge and are familiar with the product. The person in question must possess the test devices and original spare parts required to take the mentioned measures.

Read chapter “2 Instructions for your safety” on page 9 before using the product for the first time. This will help you to avoid potentially dangerous situations.

This device bears the CE marking CE 0124 in accordance with the European Medical Device Regulation (MDR) 2017/745.

The product complies with all the applicable requirements of the directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).

The declarations of conformity and our general standard terms and conditions can be viewed on our website at www.atmosmed.com.

The quality management system applied at ATMOS has been certified according to the international standard EN ISO 13485.

These operating instructions apply to the following products:

Varioair 3	REF 502.1100.0

1.2 Explanation of pictograms and symbols

In the operating instructions

⚠ DANGER	Warning of a danger resulting directly in fatal or serious injury. Observe the necessary measures.
⚠ WARNING	Warning of a danger of fatal or serious injuries. Observe the necessary measures.
⚠ CAUTION	Warning of a danger of minor injuries. Observe the necessary measures.
ATTENTION	Notice of a danger of damage to the product or other objects. Observe the necessary measures.
⚠	Warning of a danger of serious or fatal injury.
ℹ	Notice of potential material damage that can be caused.
☞	Useful information on handling the device.
1.	Call for action. Proceed step by step.
»	Result of an action.
→	Move/plug in this direction.
click	Engage, check for a firm seating surface.

On the device, type plate and packaging

	Follow the operating instructions (blue)
	Observe the operating instructions
	Warning! Pay special attention
CE 0124	This product meets the relevant requirements of EU statutory ordinances.
EAC	This product meets the relevant requirements of the Eurasian Economic Union.
	Manufacturer
	Manufacturing date
	Manufacturing date Country of manufacture: Germany

REF	Article number
MD	Medical device
SN	Serial number
EAN	European article number
	Type B applied part
	Potential equalization
°C	Temperature in degrees Celsius
s	Timer setting in seconds
	Start
	Stop
	Timer
	Cold stimulation level
	Warm stimulation level
	Heating on
	Heating off (energy saving mode)
	Control output for the connection of a nystagmograph (graphical recorder in accordance with DIN 306000 495, ISO 4175021)
	Air filter, DIN 24300

1.3 Intended use

Product name: Varioair 3

Main function: Stimulation of the vestibular organ

Intended use/purpose: Stimulation of the vestibular organ

Intended users / user profile:	Physicians and medical specialists
Intended patient group:	Patients of all ages without restrictions
Medical condition to be diagnosed, treated or monitored:	Dizziness due to a disorder of the vestibular organ
Application organ:	External ear canal to the ear drum
Application time:	Temporary (< 60 min)
Application environment:	Outpatient medical facilities, e.g. ENT practices, hospital outpatient departments, medical care centres
Criteria for patient selection:	Patients with an intact, physiological ear drum and external ear canal
Indications:	Differential diagnosis of dizziness
Medical contraindication:	Pathological ear drum
Other contraindications:	Pathological external ear canal
Warnings:	N/A
The product is:	Active
Sterility / specific microbial condition:	Non sterile
Single use product / re-sterilization:	Not a disposable product. Options for re-sterilization according to the operating instructions.

1.4 Function

- After actuating the main switch, the optical indicators are tested.
- The device then switches to standby mode in which the heating and pump are switched off.
- Possibility to switch to stimulation mode in which the vestibular organ can be stimulated. The Varioair 3 is equipped with a timer for presetting the stimulation time.

1.5 Scope of delivery

Quantity	Description
1	Varioair 3 basic device
1	Power cable
1	Handle with supply line
30	Hose tips
1	Operating instructions

1.6 Transport and storage

Transport the product only in a shipping box that is padded and offers sufficient protection.

If you notice transport damage:

1. Document and report the transport damage.
2. Send the device to ATMOS; see chapter “6.1 Sending in the device” on page 20.

Ambient conditions for transport and storage:

- Temperature: -20...+50 °C
- Humidity without condensation: 5...90%
- Pressure: 700...1100 hPa

2 Instructions for your safety

Please read the safety instructions thoroughly and pay attention to them before using the product.

2.1 General safety instructions

Report any serious incidents that occur in connection with this product to the manufacturer and the national authority responsible for you.

2.2 Danger for users, patients and third parties

Danger of suffocation to children due to accessories!

Children can strangle themselves or choke on small parts.

- Keep children away from hoses and connection cables.
- Keep children away from small parts that can be swallowed. Examples of such swallowable small parts are, for example, the fingertip and sealing ring.

Explosion and fire hazard!

Burns and injuries are possible.

- Never operate the product in potentially explosive or oxygenated areas.
- Use only original accessories and spare parts from ATMOS. This applies in particular to the power supply unit, power cable and battery.

Avoid misuse.

Your patient can become severely injured.

- The product is permitted for use only by instructed specialist personnel under supervision.
- The product is permitted for use only by medically trained staff.
- Diagnoses may be made only by persons with the appropriate medical training.

Keep the device fully functional.

Malfunctions could cause injury to you and your patients.

- Please observe the notes on the electromagnetic compatibility (EMC) of the device.
- A function check must be performed each time before use.
- Please observe the information on period tests in chapter “6 Maintenance and service” on page 20.
- Use only original accessories and spare parts from ATMOS.
- Assembly, new settings, alterations, extensions and repairs may be carried out only by persons authorized by ATMOS.

Tripping hazard due to cables.

Injuries and fractures are possible.

- Lay connection cables properly.

Electric shock due to unsuitable mains connection, incorrect handling of the product or damaged product components

Burns, cardiac arrhythmia and even fatal injuries are possible.

- Do not operate the device if it has been dropped. In this case, clean and disinfect the device and send it to ATMOS for repairs.
- Prior to each use, check the device and power cable for damage. Do not operate the device if you notice any damage. In this case, clean and disinfect the device and send it to ATMOS for repairs.
- Disconnect the device from the mains supply before cleaning or disinfecting it.
- Disconnect the device from the mains power supply before cleaning, servicing, repairing or opening it.
- You can disconnect the device from the mains supply only by pulling the power plug.
- Position the device so that you can always easily disconnect it from the mains power supply.
- Connect the device only to a mains power supply with a protective conductor.
- Never touch the plug or power cable with wet hands.
- Use the power supply unit and power cable only in a dry environment. The environment must be non-conductive.
- Make sure no liquid enters the device. The device must no longer be used if liquid gets into it. In this case, clean and disinfect the device and send it to ATMOS for repairs.
- Use power supply units and power cables only in accordance with the operating instructions.
- Use only appropriate mains connections and extension cords.
- Never touch the device's interfaces and the patient at the same time!
- Use only original accessories and spare parts from ATMOS. This applies in particular to the power cable , power supply unit and battery.
- Please observe the information on period tests in chapter “6 Maintenance and service” on page 20.
- Assembly, new settings, alterations, extensions and repairs may be carried out only by authorized persons.
- Do not modify the device without the manufacturer’s permission.

2.3 Avoiding damage to the device

Storage and operation in an unsuitable environment.

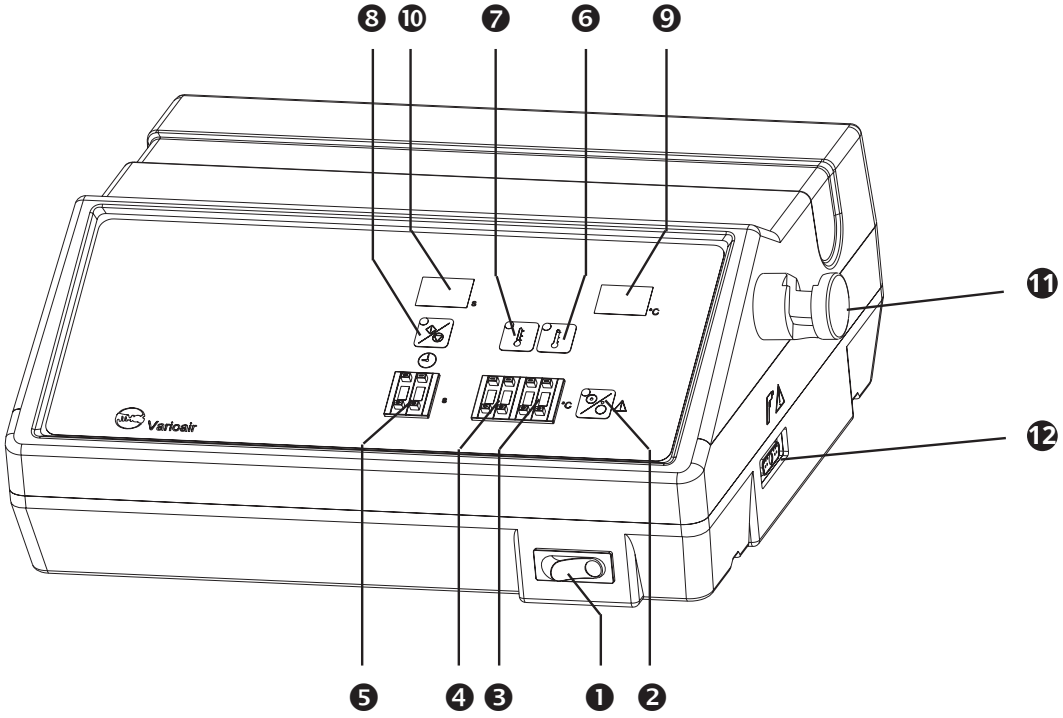
The product may become damaged.

- Please observe the ambient conditions regarding transport, storage and operation.

3 Set-up and start-up

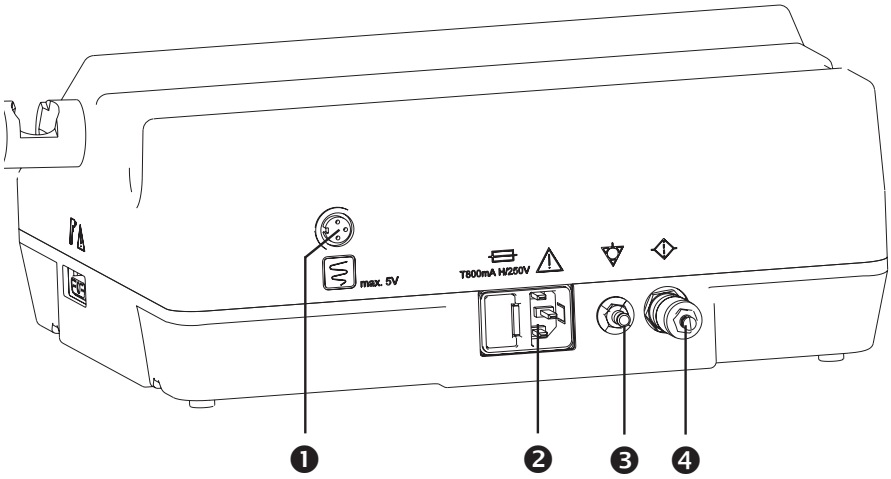
3.1 Device overview

3.1.1 Front view



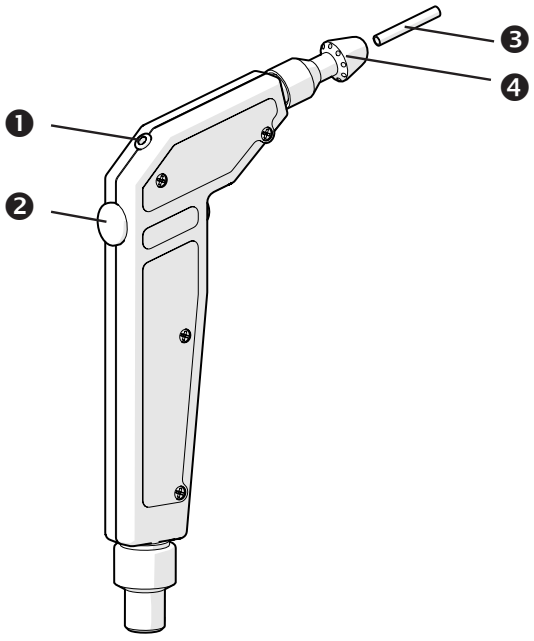
❶ Main switch
❷ Heating / Air flow ON/OFF button (standby mode)
❸ Coding switch for the warm stimulation level
❹ Coding switch for the cold stimulation level
❺ Coding switch for the stimulation time
❻ Button used to select the warm stimulation level (e.g. 44 °C)
❼ Button used to select the cold stimulation level (e.g. 30 °C)
❽ Button used to start/stop the stimulation
❾ Temperature display (double-digit, resolution of 1 °C), actual value display
❿ Stimulation time display (double-digit, resolution of 1 s)
⓫ Handle holder
⓬ Connection for the handle

3.1.2 Rear view



1. Control output used to control a nystagmograph
2. Device plug with fuse compartment
3. Equipotential connection
4. Air filter (throttle silencer)

3.1.3 Handle overview



1. LED for indicating the stimulating process
2. Timer start/stop button
3. Hose tip
4. Nozzle

⚠ The sprayer nozzle must be exchanged after each patient.

3.2 Connectors

3.2.1 Electrical connection

1. Connect the power cable to the mains connection
2. Insert the power plug in a correctly installed socket with earthing contact.

3.2.2 Connection to a nystagmograph

When controlling an ENG (electro-nystagmograph) or CNG (computer-nystagmograph) at the output, please connect only recording equipment approved by ATMOS. Power cable available from ATMOS (see chapter “8 Accessories and spare parts” on page 22).

3.2.3 Equipotential connection

- Connection for potential equalization: connection cable available from ATMOS (see chapter “8 Accessories and spare parts” on page 22).

3.2.4 Connecting the handle

Only the handle intended for this purpose may be used:

1. Press the special connector plug slightly into the jack in the device.
2. Fasten it to the housing by turning the holding screws clockwise.

☞ Do not kink the air hose!

3.2.5 Air inlet

Connection for potential equalization: power cable available from ATMOS (see chapter “8 Accessories and spare parts” on page 22).

3.3 Start-up

1. Insert the handle in its support so that the air outlet points to the back of the device.
2. Switch on the device.

» Automatic display test with digital number sequence “8 8” and acoustic warning signal.

» Automatic change to standby mode.

3. Use the main switch to switch on the device.

» Readiness for operation after 1 s.

4. Push the hose tip completely onto the handle.

⚠ If the hose tip is not completely pushed onto the handle, damage could be caused to the patient’s ear drum.

4 Operation

4.1 Setting the temperatures

Two variable temperature levels:

- 20 - 47 °C
- 48 °C + 49 °C (for test purposes only)

☞ The lowest achievable stimulation temperature is approx. 2 °C above the ambient temperature.

Temperature setting by coding switch:

- Left switch: for adjusting the "ten" partition
- Right switch: for adjusting the "one" partition

☞ Lower keys (+): temperature increase

☞ Upper keys (-): temperature decrease

Default settings:

- Cold stimulation level: 30 °C
- Warm stimulation level: 44 °C

⚠ Avoid bending the hose tip within the ear / ear canal. Otherwise the error “F1” or “F7” could occur.

4.2 Selecting temperature levels

1. To select the desired temperature level, press the respective button.

» Indication of the active level by LEDs.

» Display of the air temperature (current value) in °C.

2. To switch off the heating, press the button of the active temperature level.

» LED of the temperature level goes out.

» Display of the air temperature (current value) in °C.

4.3 Setting the stimulation time

The stimulation time is set with coding switches.

4.4 Operating mode description

4.4.1 Preparation mode

Purpose:

Adjustment to the temperature set by the user.

Properties:

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

Activation:

- By pressing one of the buttons to select a temperature level or pressing the Heating / Air flow ON/OFF button in standby mode.
- The heating is switched off by repeatedly pressing the active temperature button.

» Air with approximate room temperature is available.

Deactivation:

- The device is switched to standby mode by pressing the Heating / Air flow ON/OFF button.
- Automatic switch to standby mode when the device is not used for three minutes.

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:

1. First select the stimulation type with the warm or cold stimulation button (see chapter “4.1 Setting the temperatures” on page 14).

☞ Recommended setting for Germany: 27 or 44 °C at 45 s.

2. Press the "timer start button” on the device or handle.
3. Preparation for stimulation

☞ The pump remains switched off to allow the nozzle to be positioned in the ear canal as long as the button is pressed.

4. When the button is released, the thermal stimulation is performed for the time set by the user.

» The LED on the handle is switched on during the thermal stimulation.

» At the end of the stimulation period, a control signal for a recording unit is issued at the nystagmograph control output.

5. At the end of the stimulation, the pump is switched off.
6. The timer operation is stopped by pressing the “timer start button” again during the stimulation.
7. The corresponding level is deactivated by pressing the button currently active a second time.

» The heating is switched off.

» Stimulation with virtually ambient air temperature.

⚠ The hose tip for the nozzle must not be blocked.

4.4.3 Standby mode

Purpose:

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

Activation:

1. Actuation of the “Heating / Pump on/off” button

» The heating is switched off.

» The pump is switched off after 2 s.

- Automatically after each stimulation process.
- Automatically if the device is not used for three minutes.

5 Sterilization

5.1 Safety instructions for sterilization

5.1.1 General safety instructions

We recommend that you always document all maintenance work and part replacements in writing.

It is the responsibility of the user to ensure that the required cleaning and disinfection results are achieved. Validation and routine monitoring of the procedure is usually necessary.

The sterilization may be carried out only by persons with the necessary expertise. The person in question must possess the equipment required to carry out the mentioned measures.

The nozzle, which comes into contact with the patient, must be disinfected after each use.

The hose tips must be exchanged each time after use.

The surfaces of the Varioair 3 are resistant against most surface disinfectants.

However, do not use any:

- Disinfectants that contain concentrated organic or inorganic acids because they could cause corrosion damage.
- Disinfectants containing chloramides, phenol derivatives or anionic tensides, because they may cause stress cracks in the plastic used.

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

☞ Use the main switch to switch off the device before beginning with cleaning and disinfection.

Wipe the device surface with a cloth moistened with cleaning agent or disinfectant. Make sure no liquid enters the device. All cleaning agents and disinfectants listed in chapter “5.4 Recommended disinfectants” on page 19 are suitable.

☞ Any spilled disinfectant must be immediately wiped up.

☞ Always observe the operating instructions of the manufacturer of the disinfectants, including, in particular, the concentration specifications.

☞ The described cleaning and disinfection measures do not replace the relevant instructions that apply to operation.

5.1.2 Danger for users, patients and third parties

Risk of infection due to unsuitable accessories.

Deadly diseases may be transmitted.

- Always wear your own personal protective gear. The protective gear for all steps during which the product components are still contaminated consists of protective gloves, protective clothing, goggles and mouth and nose protection.
- Use only accessories that are easy to sterilize or are disposable products.

Risk of infection due to unsuitable sterilization.

Deadly diseases may be transmitted.

- Make sure all areas of the accessories are easy to access.
- Use only suitable load carriers for mechanical sterilization. This applies especially to accessories that contain hollow spaces and lumens that are difficult to reach.
- Make sure no air bubbles form in the hollow spaces and lumens of accessories when placing them in sterilization solutions.

5.1.3 Avoiding damage to the device

Damage to the device due to cleaning with fixatives.

Stains cannot be permanently removed.

- Do not use aldehydes before and during cleaning.
- Do not expose the product to temperatures above 40 °C / 104 °F before or during cleaning.

Unsuitable cleaning agents and disinfectants.

The product can become damaged.

- Do not use any process chemicals that contain the following ingredients **for plastic parts**:
  - Chloramides or phenol derivatives
- Do not use any process chemicals containing the following ingredients **for stainless steel**:
  - Organic or inorganic bases
  - Alkaline solutions

Incorrect mechanical cleaning and disinfection.

Corrosion due to moisture.

- Remove the products immediately at the end of the program.

5.2 General information on cleaning and disinfection

The nozzle, which comes into contact with the patient, must be disinfected each time after use.

☞ **The hose tips must be exchanged each time after use.**

The surfaces of the Varioair 3 are resistant against most surface disinfectants.

However, do not use any:

- Disinfectants that contain concentrated organic or inorganic acids, because they could cause corrosion damage.
- Disinfectants containing chloramides, phenol derivatives or anionic tensides, because they could cause stress cracks in the plastics used.

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

☞ Use the main switch to switch off the device before beginning with cleaning and disinfection.

Wipe the device surface with a cloth moistened with cleaning agent or disinfectant. Make sure no liquid enters the device.

- ☞ Any spilled disinfectant must be immediately wiped up.
- ☞ Always observe the operating instructions of the manufacturer of the disinfectants, including, in particular, the concentration specifications.
- ☞ The described cleaning and disinfection measures do not replace the relevant instructions that apply to operation.

5.3 Preparing and finishing the sterilization

Prior to sterilization

1. Disassemble the product for sterilization into its individual parts

After the sterilization process

1. Perform a function check.

5.4 Recommended disinfectants

Agent (manufacturer)	Active ingredients in 100 g	Manufacturer
Sekusept® PLUS (concentrate)	Glucoprotamin 25 g, non-ionic tensides, solvents, complexing agents	Henkel, Düsseldorf
Gigasept® FF (concentrate)	Succindialdehyde 11.0 g, dimethoxytetrahydrofurane 3.0 g, corrosion protection components, non-ionic surfactants and perfumes	Schülke & Mayr, Norderstedt
Mucozit®-T new (concentrate)	Bis(3-aminopropyl)laurylamine 8.0 g, alkyldimethyl benzyl ammonium chloride 19.0 g, cocospropylendiamin-1,5-inguanidinium-acetate 7.0 g	Merz & Co., Frankfurt/Main

5.5 Recommended surface disinfectants

Agent (manufacturer)	Active ingredients in 100 g	Manufacturer
TERRALIN (concentrate)	Benzalkonium chloride 20.0 g, phenoxypropanols 35.0 g	Schülke & Mayr, Norderstedt
Hexaquart® forte	Benzyl-C12-16-alkyldimethyl, chlorides 20 g, didecyl dimethyl ammonium chloride 7.9 g, non-ionic surfactants 5 – 15% NTA < 5%	BBraun, Melsungen
Incidin Plus (concentrate)	Glucoprotamin 26.0 g, non-ionic tensides, solvents, complexing agents	Henkel, Düsseldorf
Pursept-A (disinfectant spray or disinfectant tissues)	Ethanol 38.9 g, glyoxale 0.1 g, QAV 0.05 g	Merz & Co., Frankfurt/Main

- ☞ Colour changes may occur if disinfectants containing aldehyde and amine are used on the same object.

6 Maintenance and service

Maintenance, repairs and period tests may be carried out only by persons who have the appropriate technical knowledge and are familiar with the product. The person in question must possess the test devices and original spare parts required to take the mentioned measures.

ATMOS recommend commissioning an authorized ATMOS service partner. This will ensure that the repairs and tests are carried out appropriately, original spare parts are used and any warranty claims remain unaffected.

- Carry out an inspection according to the manufacturer's specifications every 12 months.
- Please observe the corresponding service instructions.

6.1 Sending in the device

1. Remove all consumables and dispose of them properly.
2. Clean and disinfect the product and accessories in accordance with the operating instructions.
3. Enclose any used accessories with the product.
4. Fill in the QD 434 form "Delivery Complaint / Return Shipment" and the corresponding **decontamination certificate**.

☞ This form is enclosed with the product and is provided at www.atmosmed.com.

5. The device must be well padded and packed in suitable packaging.
6. Place the QD 434 form "Delivery Complaint / Return Shipment" and the corresponding **decontamination certificate** in an envelope.
7. Affix the envelope to the outside of the package.
8. Send the product to ATMOS or your dealer.

6.2 Exchanging fuses

1. Switch off the device.
2. Remove the power cable from the device.
3. Disconnect the fuse holder from the mains supply.
4. Replace both fuses T 1.6 A (f. 250 V~, 50/60 Hz).
5. Attach the fuse holder.
6. Connect the device to the mains supply.

7 Troubleshooting

Error on the temperature display

	Potential cause	Remedy
"F0"	Not used	
"F1"	Maximum permitted temperature too high (> 51 °C). The pump is automatically switched off if the temperature exceeds 51 °C for more than two seconds).	• Switch off the device and wait approximately one minute for the device to cool down • Check whether the temperature setting is not too high. If necessary, set the target temperature to a value of above 51 °C on the coding switches. • Inform the service technician. • Bent hose tip within the ear / ear canal
"F2"	-5 V missing (supply voltage on the controller board)	• Inform the service technician
"F3"	Safety NTC breakage	• Check whether the handle was connected correctly. • Replace the handle • Inform the service technician
"F4"	Not used	
"F5"	Breakage of the regulating NTC	• Check whether the handle was connected correctly. • Replace the handle • Inform the service technician
"F6"	Not used	
"F7"	Temperature too high (> 48 °C)	• Check whether the temperature setting is not too high. If necessary, set the target temperature on the coding switches to a value below 48 °C. • Inform the service technician • Bent hose tip within the ear / ear canal
"F8"	Short-circuit of the regulating NTC	• Replace the handle. • Have the temperature sensor of the regulating NTC checked by a service technician
"F9"	Not used	

☞ If the errors cannot be corrected with the assistance of this table, please inform the service staff or send in the device for repairs. Do not try to repair the device yourself!

8 Accessories and spare parts

8.1 Accessories

Description	REF
Power cable	507.0859.0
Handle, complete	502.1035.0
Hose tip for nozzle (30x)	502.0844.0

8.2 Spare parts

Description	REF
Device base	000.0796.0
Fuse T 800 mA / H / 250 V, 5 x 20 mm	008.0081.0
Power cable	507.0859.0
Handle, complete	502.1035.0
Nozzle	502.1045.0
Hose tip for nozzle (30x)	502.0844.0

9 Disposal

- The packaging cardboard and/or PE foam can be fully recycled or returned to your supplier for further use.
- The Varioair does not contain any hazardous materials.
- The housing material is fully recyclable.
- The component parts of the Varioair must be disposed of properly and the materials separated carefully.
- The electronic circuit boards must be submitted to the appropriate recycling process.
- Used hose tips, which can no longer be disinfected, must be immediately discarded into the domestic waste.

10 Technical data

Voltage	220 - 240 V~ ± 10%; 50/60 Hz
Current consumption	Max. 0.75 A
Power consumption	Max. 85 W
Connectors	Mains connection via IEC socket; control output for a nystagmograph; equipotential equalization; connection for the handle; air inlet
Fuses	2x T 1.6 A (f. 250 V~, 50/60 Hz)
Stimulation time	Adjustable from 1 to 99 s with timer.
Timer indication	Indication accuracy ± 0.5 s ± ½ digit
Air temperature	20 – 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: • Automatic switch-off after stimulation • Automatic switch-off after 3 minutes.
Operating modes	Preparation mode; stimulation mode (at temperature preselected for cold or warm stimulation level); heating off and no air flow (economy mode, standby mode).
Protective earth conductor resistance Earth leakage current Housing leakage current Patient leakage current	Max. 0.1 Ω Max. 5 mA Max. 0.1 mA Max. 0.1 mA
Ambient conditions Transport/storage	-20...+50 °C 5...90% air humidity without condensation; air pressure of 700...1060 hPa
Ambient conditions Operation	+10...+35 °C 20...80% air humidity without condensation; air pressure of 700...1060 hPa
Maximum operational altitude	≤ 3000 m (sea level)
Contamination level	Class 2
Dimensions H x W x D	14.5 x 37 x 32 cm
Weight	Approx. 3.7 kg
Period tests	Inspection every 12 months according to the manufacturers specifications *(Germany: safety check according to Medical Device Operator Ordinance).
Overvoltage category	II

Protection class (EN 60601-1)	I
Degree of protection	Type B
Type of protection	IP X0
Further classifications according to other regulations	VDE protection class 1 (IEC 601/EN 60601)
CE marking	CE 0124
ID no. (REF)	502.1100.0

Technical data last updated: 11th February 2021

11 EMC instructions

☞ Medical electrical devices are subject to special precautions with regard to EMC and must be installed according to the following EMC instructions.

Guidelines and manufacturer's declaration – Ambient conditions

The ATMOS Varioair is suitable for operation in the following environments:

- In professional healthcare facilities, such as medical practices, clinics, first aid facilities, and operating theatres.

The following environments are not suitable:

- Special environments such as factory or military facilities and medical areas near HF surgical devices, short-wave therapy equipment or within an HF-shielded room of a magnetic resonance imaging system.

The customer or user of the Varioair must ensure that the device is used in a prescribed environment.

Guidelines and manufacturer's declaration – Key features

☞ Please observe the respective technical data in this manual. The key features are fully usable even in the presence of electromagnetic disturbances.

Guidelines and manufacturer's declaration – Removable components that can be replaced by the operating company

The Varioair has the following removable components, which can be replaced by the operating company:

Type	REF	Max. cable length
Connection cable for a nystagmograph	502.0850.0	
Connection cable for the equipotential equalization	008.0596.0	5 m

Guidelines and manufacturer's declaration – Warnings

⚠ WARNING

The use of electrical components and accessories other than those specified or provided by the manufacturer can cause increased electromagnetic interference or reduced immunity to electromagnetic interference, resulting in faulty operation of the device.

⚠ WARNING

Portable RF communications equipment (e.g. radios, antenna cables) must not be used any closer than 30 cm* to any parts of the Varioair, including cables, specified by the manufacturer. This could otherwise result in the degradation of the key features of the device.

☞ *The distance may be reduced at higher immunity test levels.

⚠ WARNING

Avoid placing the device on top of or next to another device. This could result in incorrect operation. If this is unavoidable, the proper functioning of the device must be monitored regularly. Please switch off any nearby devices that are not in use, if possible.

12 Notes

MedizinTechnik

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