ATMOS MedizinTechnik

English

Operating Instructions

Variotherm plus

CE 0124

GA1GB.140302.0

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Valid for devices delivered after July 2002.

Contents

1.0 Introduction

1.1 Notes on operating instructions

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

Prior to first use, please peruse the chapter “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 Variotherm plus. For this reason, regular cleaning and service work are a must. Major maintenance and repair work may be carried out only by expert personnel authorized 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 Variotherm plus bears CE marking CE 0124 according to EU Council Directive 93/42/EEC concerning medical devices and meets the basic requirements of Annex I to this directive.
- The product Variotherm plus complies with all applicable requirements of Directive 2011/65/EU restricting 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 obtained on our website at www.atmosmed.com.
- The quality management system applied at ATMOS has been certified according to international standard EN 13485.
- Reprints—also in extracts—only with permission in written form by ATMOS.

Abbreviations/symbols contained in these operating instructions:

- Indicates a list
  - Subdivision of a list/activity

The recommended sequence must be followed in each case!

☞ Indicates particularly important advice!

↳ Describes the effect of an activity

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1.2 Intended use

Product name:	Variotherm plus
Main functions:	Stimulation of the vestibular organ Irrigation of the external auditory canal
Intended purpose:	Stimulation of the vestibular organ Irrigation of the external auditory canal
Intended users / User profile:	Doctors and medical specialists
Intended patient target group:	Patients of all ages without restrictions
Medical conditions to be diagnosed, treated or monitored:	Vertigo due to a disorder of the vestibular organ Hearing loss due to cerumen in the ear canal
Application organ:	External auditory canal to eardrum
Application period:	Transient (< 60 min)
Application environment:	Outpatient medical facilities, e.g., ENT practices, hospital outpatient departments, medical care centers
Patient selection criteria:	Patients with intact, physiological eardrum and external auditory canal
Indications:	Differential diagnostics for vertigo Hearing loss through impacted cerumen
Medical contra-indications:	Pathological eardrum
Other contra-indications:	Pathological external auditory canal
Warnings:	N/A
The product is:	active
Sterility/specific microbial status:	Non-sterile
Single use product / reprocessing:	Not a single-use product. Reprocessing according to instructions for use.

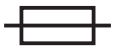
1.3 Function

- Operating the main switch on the treatment unit automatically activates the thermal process for reducing bacterial count (see section 4.5.1). Then, automatic change to energy saving mode.
- When removing the irrigation handle from its holder, automatic change to the irrigation mode. Here, the auditory canal can be rinsed with water warmed up to 37 °C and a flow of at least 400 ml/min.
- Possibility to switch to the stimulation mode for stimulating the vestibular organ with a reduced flow of water. The Variotherm plus is equipped with a timer for preselecting the stimulation duration.

1.4 Explanation of symbols


Follow operating instructions
According to ISO 7000/0434
DIN 30600/1008, IEC 348


Type B applied part


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

37 °C — Irrigation level (water at a temperature value of 37 °C)


Heating ON


Heating OFF (energy saving mode)


Control output for connecting a nystagmograph (graphical recorder as per DIN 30600, IEC 417 5192)


Equipotential connection
DIN 30600 495, ISO 417 5021


Connection for waste water


Connection for water

Low — Reduced flow (for stimulation of the vestibular organ)

High — High flow (for rinsing the auditory canal)

2.0 For your safety

- The Variotherm plus is produced according to IEC 601 / EN 60601 and listed in the following classes:
  - VDE Class of protection 1
  - Class IIa (93/42/EEC).
- WARNING: In order to avoid the danger of an electric shock, this device should only be connected to an earthed power supply.
- The device must be installed by a specialist authorized by ATMOS (see section 3.3).
- The Variotherm plus may only be used under the supervision of skilled staff who have been authorized 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)
- It is essential that the country-specific requirements for connection of medical equipment to the public drinking water supply are considered. When in doubt, please contact your local ATMOS partner.
- The control panel must be clearly visible and accessible for the user. Ensure sufficient stability of the installation surface.
- In order to safely disconnect the device from the mains power supply, the power cable must be removed from the IEC power connector of the Variotherm plus!

☞ In the thermal process for reducing bacterial count, hot water is conducted through the irrigation handle. Please do not take the handle from its holder or spray water!

☞ Metal parts can be hot!

☞ Prior to spraying, the water temperature must be checked by the user (display)!

- Switch off the main switch after finishing work in the practice and close the water valve of the water supply.
- The Variotherm plus may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and not in oxygen-rich environments.
- All additional equipment that is connected to the analog 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. If you have any questions, please contact your local specialist supplier or ATMOS Technical Service.
- The irrigation jet must not get into contact with contaminated material.
- Only use the warm water jet when a hose tip is installed!
- Take caution to avoid injury to the eardrum when inserting the water jet!
- For hygienic reasons, hose tips must be changed after each patient. This also prevents retrograde contamination of the warm water system.
- Use only for irrigation of the auditory canal!
- 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 authorized by ATMOS.
- Please note:
  A medical isolation transformer with earth leakage monitor or any similar safety system acc. to EN 60601-1 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.
- After switching on the device or at least once a week, the flow rate must be checked using a volume measuring funnel. The quantity of 500 ml/min may not be exceeded. The water jet has to be straight.

2.1 Important instructions for the maintenance of the hygiene status of warm water irrigation units

For loosening cerumen in the auditory meatus and for stimulating the vestibular organ, ATMOS offers the warm water units Hygrotherm plus (37 °C) and Variotherm plus (20 °C – 47 °C).

These units heat the drinking water that comes from the household connection to the preselected temperature. The operating instructions must be followed, or otherwise the increased number of pathogens in the rinse water can affect the health of sensitive patients.

Requirement for taking into use

❒ The water provided by the household connection must at least meet the WHO guidelines or the country-specific guidelines for drinking water.

Connection

❒ Fresh water must flow through the wall connection for a period of approx. 1 minute prior to the unit being connected.*

❒ Ensure that the installation is hygienically carried out! Disinfect the threaded connections with 70% alcohol before screwing them into place.*

❒ Wear disposable gloves when carrying out maintenance work on parts that come into contact with the water.*

❒ Carry out thermal cleaning at least 3 times before initial operation.*

* This work is carried out by the ATMOS service technician.

Running operation

❒ Before beginning everyday practice operations, switch on the unit and await the thermal cleaning process.

❒ After the device has been idle for a long period of time (weekend, during holidays, etc.), the thermal cleaning process must be initiated and repeated.

❒ We recommend that the device be switched off and on every 2 hours, but no later than 4 hours, to start the thermal cleaning mode.

❒ Contact parts, e.g., hose tips, must be replaced after every patient (prevention of retrograde contamination).

❒ Before every use, spray water and check the temperature.

Service

❒ Observe hygiene when changing the suspended particle filter (see commissioning) (dispose of filter and carefully clean the filter glass). Ensure that no contact is made with contaminated parts.

❒ Carry out thermal cleaning after each service.

❒ We recommend having regular germ count measurements of the water taken at the inlet and outlet of the unit. In the case of a complaint, data measurements must prove whether the contaminants are “water bacteria” or “skin bacteria.”

3.0 Setting up and starting up

3.1 Scope of supply

Quantity	
1	Variotherm plus basic unit
1	Irrigation handle
1	Double-barrelled hose
3	Jet connection short, straight (80 mm)
1	Splash guard
1	Rubber bushing for splash guard
2	Three-hole gasket
1	Hose tips for jet connection (30 pcs)
1	G3/4i-G1/4a-screwing (water tap G3/4 on filter G1/4)
1	Cap nut G3/4
1	Water filter complete
2	Gasket (f.G1/4a) 13x18x1
1	G1/4a-G3/4a-reducer (filter G1/4 on water hose G3/4)
1	Water supply hose G3/4i, L = 3 m
1	Waste water hose G1/4i, L = 3 m
2	Gasket (f. G1/4i) 10x15x1
1	Cardboard box 455 x 340 x 250 mm
1	Padding for cardboard box
1	Operating Instructions

3.2 Illustrations

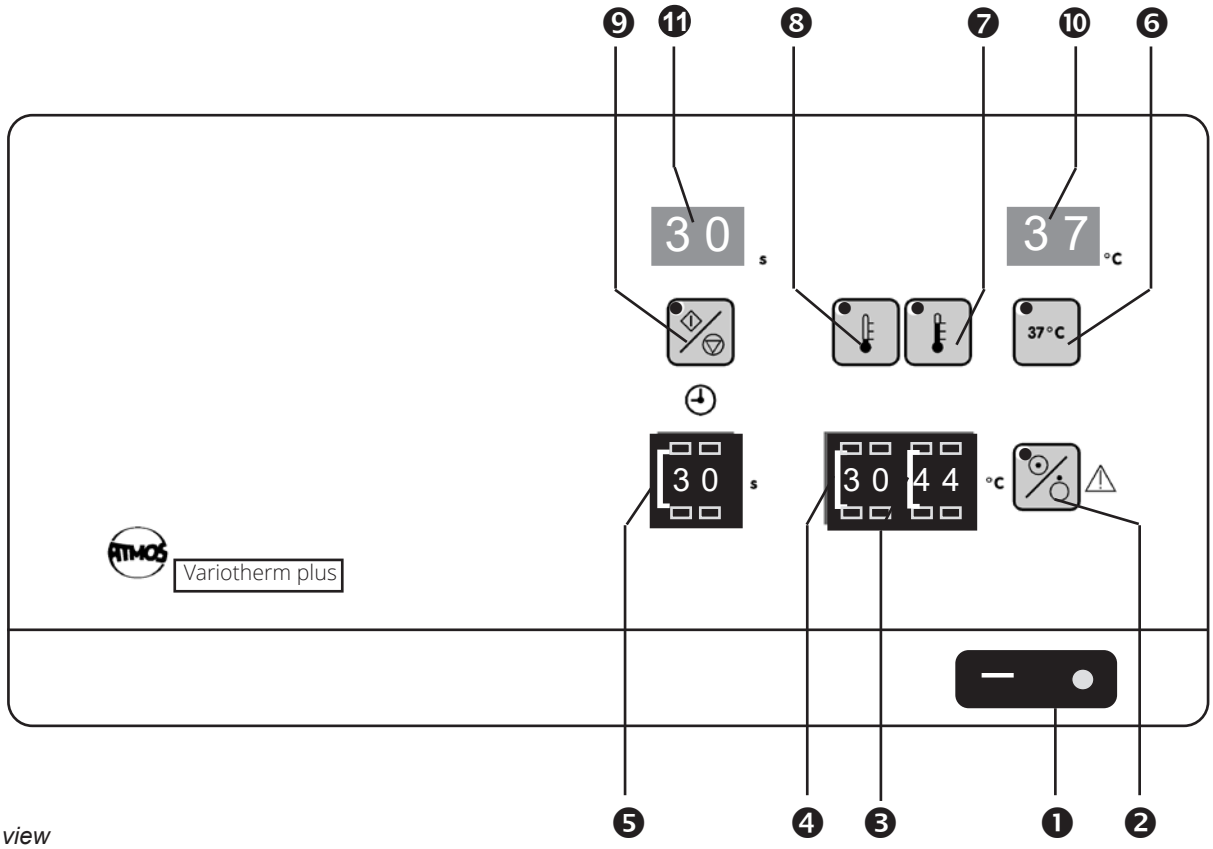


Fig. 1. Front view

❶ Main switch

❷ Key switch for heating ON/OFF (energy saving mode)

❸ Coding switch for warm stimulation level

❹ Coding switch for cold stimulation level

❺ Coding switch for stimulation time

❻ Key switch for selecting the irrigation level (37 °C)

❼ Key switch for selecting the warm stimulation level (e.g., 44 °C)

❽ Key switch for selecting the cold stimulation level (e.g., 30 °C)

❾ Key switch for start/stop of the stimulation

❿ Temperature display (two-figure number, increment of 1 °C), actual value indication

⓫ Display of stimulation time (two-figure number, increment of 1 s)

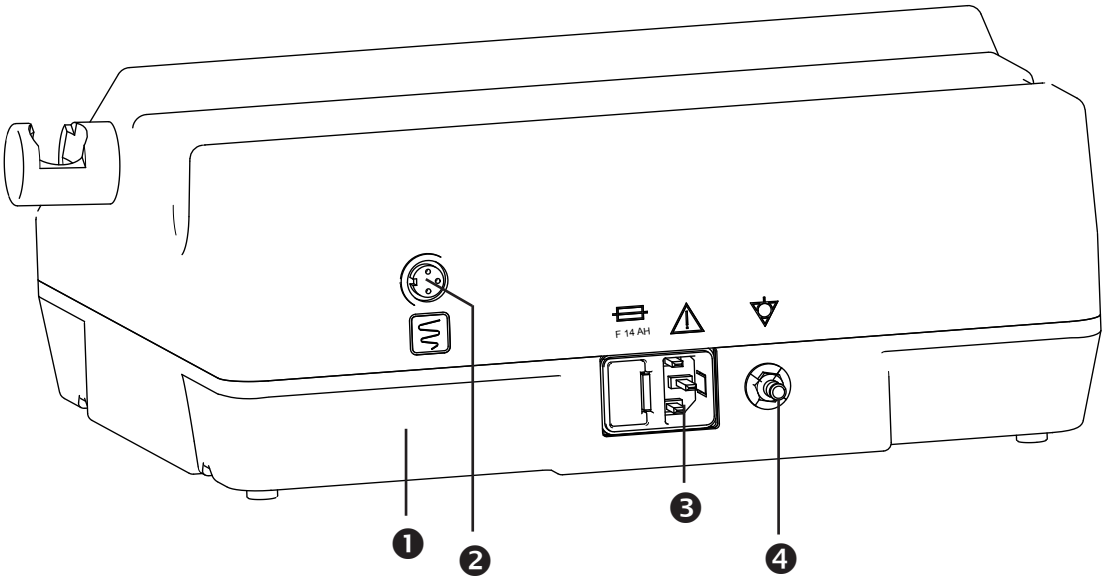


Fig. 2. Rear view

❶ Type plate
❷ Control output for controlling a nystagmograph
❸ Device socket with fuse compartment
❹ Equipotential bonding connection

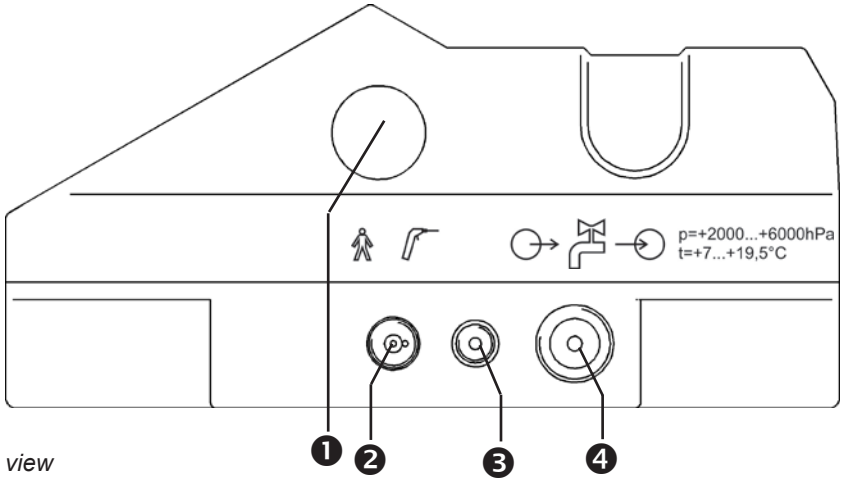
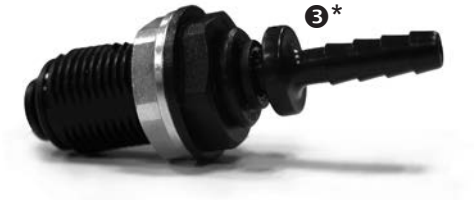
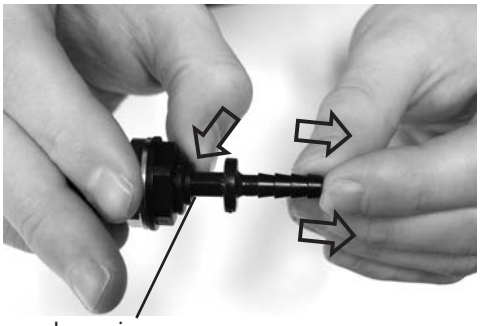


Fig. 3. Side view

❶ Holder for handle
❷ Connection for double-barrelled hose
❸ Connection for waste water hose *
❹ Connection for water supply hose





Press down ring

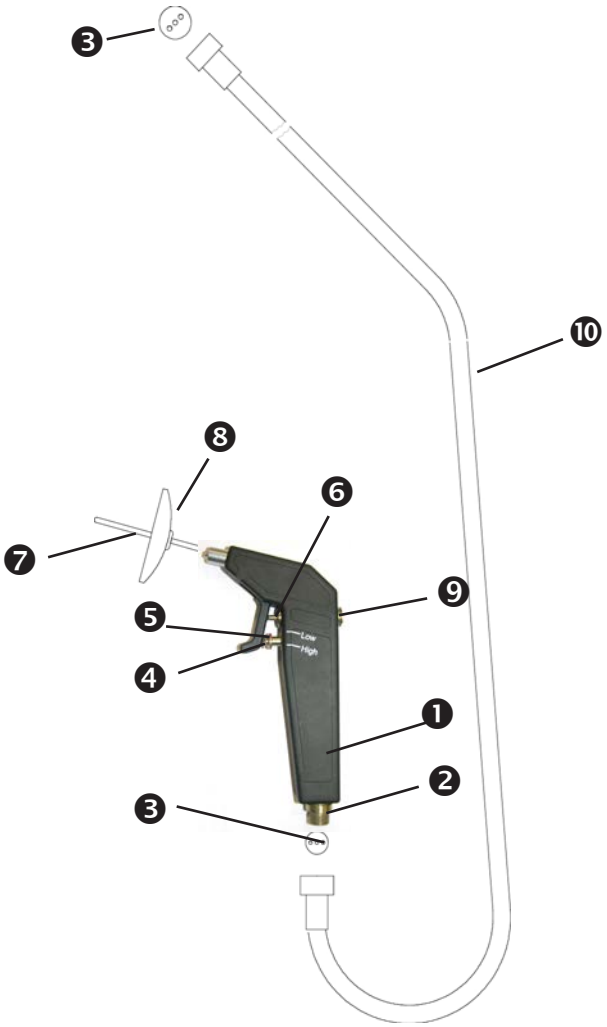


Fig. 4. Irrigation handle

❶ Handle
❷ Connection for double-barrelled hose
❸ Three-hole gasket
❹ Adjusting screw
❺ Set screw
❻ Valve plunger
❼ Jet connection
❽ Splash guard
❾ Cap
❿ Double-barrelled hose

⚠ The sprayer nozzle must be changed after each patient.

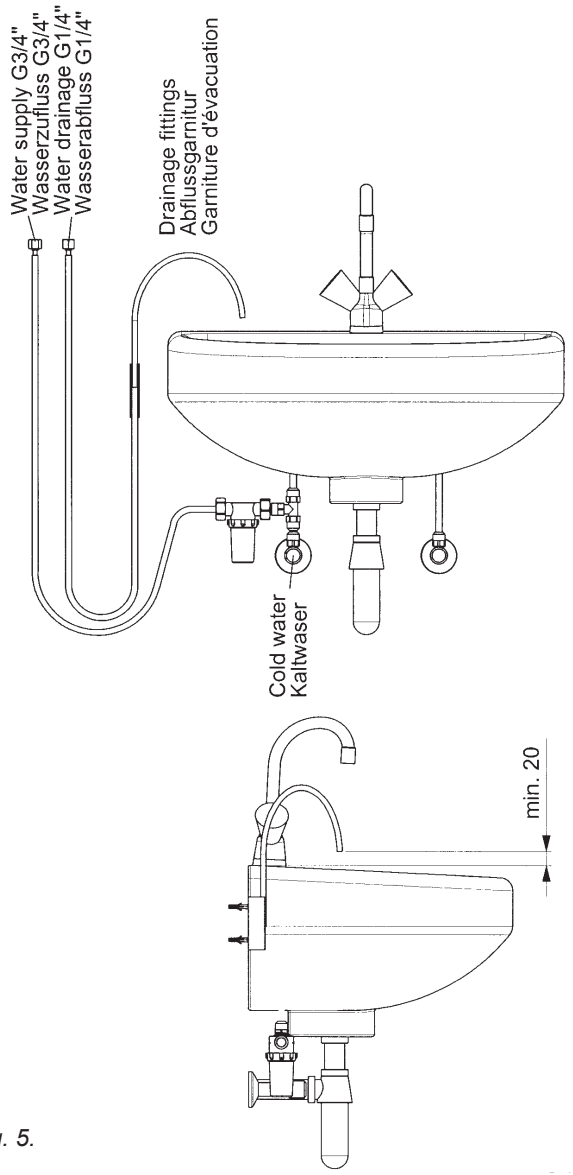


Fig. 5.

3.3 Connections

3.3.1 Electrical connection

- 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.
- Connect the power cable to the socket on the unit (❸, 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 (❷, Fig. 2), please connect only recording equipment approved by ATMOS. Connecting cable available from ATMOS (see chapter 8.0).
- At the end of the stimulation time, a trigger signal for a nystagmograph is available at the rear 3-pole DIN socket. This outlet is an electrically isolated photo transistor. The emitter connection that has to be connected to the ground line of the trigger inlet on the nystagmograph is attached to pin 3. The open-collector connection is located on pin 1 and is to be connected to the positive supply voltage (+5 V or +12 V) by means of a pull-up resistance. The maximum collector voltage of the transistor may not exceed 80 MA.

3.3.3 Equipotential bonding conductor connection

- Connection for potential equalization (❹, Fig. 2). Connecting cable available from ATMOS (see chapter 8.0).

3.3.4 Water connection

- Local requirements:
  - Water tap with G3/4" external thread.
  - Drinking water!
  - Input water pressure: +2000...+6000 hPa.
  - Feed temperature: +7...+19.5 °C (recommended), but at least 0.5 °C below the required lowest cold stimulation value.
  - Drainage fittings (REF 502.0880.0)
- Connection to water supply and waste water:
  - There are country-specific regulations for the installation to be considered when the unit is connected to the public water supply. To comply with the rules according to EN 1717, an unpressurized water separation with overflow is required.
    Therefore, ATMOS recommends installing the water separation unit ATMOS Aqua Clean (REF 502.1200.0) between the water supply and the device in order to meet the connection requirements according to EN 1717.
  - Prior to connecting the unit to the water supply, the feed line must be flushed clean by opening the water tap for a minute and allowing free flow of the tap water.
  - Connect the filter unit to the water tap by means of adaptor and gasket.
  - Insert the gaskets in the cap nuts of the water supply hose.
  - Join the nuts with the filter connection and the unit connection (❹, Fig. 3).
  - Insert the gaskets in the cap nuts of the waste water hose.
  - Join the nuts with the unit connection (❸, Fig. 3) and the drainage fittings.
  - 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 °dH or 2.5–3.8 mmol/l = hard water) and of hardness grade 4 (from 21 °dH or from 3.8 mmol/l = very hard water).
    Please contact your local water supplier and/or plumber.

Water hardness	Millimole per liter	°dH	
1 (soft)	≤ 1.3	≤ 7.3	Calcification protection system is not required
2 (medium)	1.3 to 2.5	7.3 to 14	
3 (hard)	2.5 to 3.8	14 to 21.3	Calcification protection system is required
4 (very hard)	> 3.8	> 21.3	

⚠ Close the water tap when the unit is not in use!

3.3.5 Connection of the irrigation handle

- Insert a three-hole gasket (❸, Fig. 4) in the double barrelled hose (❿, Fig. 4) and screw it on the unit connection (❷, Fig. 3).

☞ Use only three-hole gaskets or otherwise the unit will not function correctly!

- Insert a three-hole gasket in the irrigation handle and screw it on the free end of the double-barrelled hose.
- Open the water tap. Check whether all connections are tight.

3.4 Starting up

- Insert the handle in its holder; the jet must point to reverse side of the unit.
- Switch on the unit (❶, Fig. 1).
- Automatic display test with digital numbers “8 8” and acoustic warning signal.
- Automatic activation of the thermal process will begin for reducing bacterial count. Duration: 5 min.
- Automatic change to the irrigation mode (37 °C).
- When the irrigation mode is not being used (handle is not removed from its holder), the unit changes to energy saving mode after 5 min.

4.0 Operation

Before switching on the unit, make sure that the handle is in its holder (jet must point to reverse side of the unit).

4.1 Adjusting temperatures

- Number of temperature levels: 3
  - One level fixed to 37 °C irrigation temperature
  - Two variable temperature levels
    20 °C – 47 °C
    48 °C and 49 °C only for testing purposes
- Temperature setting by coding switch (❸, ❹, 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 irrigation mode: 37 °C fixed
  - Level for cold stimulation: 30 °C
  - Level for warm stimulation: 44 °C

4.2 Selecting temperature levels

- After operating the main power switch, the automatic activation of the thermal process begins for reducing bacterial count, followed by the automatic activation of the temperature level “irrigation mode” (37 °C).
- For selecting the desired temperature level, use the respective key (❻, ❼, ❽, Fig. 1).

  ↳ Display of the active level by LEDs.

  ↳ Display of the water temperature (current value) in °C.

4.3 Adjusting stimulation time

- By means of coding switch (❺, Fig. 1).

4.4 Adjusting flow quantity

- Prior to stimulation, turn the set screw (❶, Fig. 6) to the postition "Low".
- 2 adjusting possibilities:
  - High: flow quantity for ear irrigation
  - Low: flow quantity for stimulation of the vestibular organ

Prior to ear irrigation, turn the set screw to the postition "High", push it into the handle, and then adjust it by screwing it in further.

For fine adjustment of the flow, turn the adjusting screw (❷, Fig. 6) in or out.

☞ Periodically check the water flow for the stimulation of the vestibular organ and readjust if necessary.

Fig. 6. Irrigation handle
❶ Set screw
❷ Adjusting screw

4.5 Description of operating modes

4.5.1 Thermal process for reducing bacterial count

Purpose:

Reduction of bacteria count in the warm water circuit to prevent or clear a contaminated system.

Activation:

Occurs each time the unit is switched on.

- Condition for starting the correct thermal process for reducing bacterial count:
  - The irrigation handle must be inserted in the holder on the side (jet pointing to reverse side of the unit).
  - ↳ If not, a warning signal is given (warning also sounds when the handle is removed during the thermal cleaning procedure).
  - ↳ Additionally, the error code “F0” is shown (disappears when handle is returned).

☞ In the thermal process for reducing bacterial count, hot water is conducted through the irrigation handle. Please do not take the handle from its holder or spray water!

☞ Metal parts of the irrigation handle and of the double-barrelled hose will be hot! Please do not touch metal parts during the thermal cleaning procedure!

- During the thermal process for reducing bacterial count, the temperature display shows a “d” on the first segment and the remaining time (in minutes) on the second segment.
- After cooling down to 37 °C, the unit will automatically switch to irrigation mode.

4.5.2 Irrigation mode

Purpose:

Rinsing of the auditory canal.

Properties:

- Temperature: 37 °C, permanently set.
- Position of the set screw: High (see Fig. 6, page 13).

Activation:

- Automatically after completion of thermal cleaning procedure and taking out the handle or by key (❻, Fig. 1).
- When the irrigation mode is not being used (handle remains in holder), the Variotherm plus changes to energy saving mode after 5 min.
- Reactivation of the irrigation mode by taking the handle out of the holder or activating a key on the temperature control unit.
- If the 37 °C push button is pressed repeatedly, the heating is switched off.
  - ↳ Water with feed temperature is available.

4.5.3 Stimulation mode

Purpose:

Stimulation of the vestibular organ.

Properties:

- Temperature: corresponds to the preselected cold or warm stimulation level.
- Position of the set screw: Low (see Fig. 6, page 13).
- Duration: as preset by the timer.

Activation:

- Initially select the type of stimulation by activating either the warm stimulation or cold stimulation key (❼, ❽, Fig. 1) (see section 4.1 for presetting of temperature).
  - ↳ Water with the preset temperature value flows to the handle.
- Wait for 20 seconds.
- Operate the “timer start” key.
- Preparation for stimulation:
  - Operate unit 15 seconds in holding position so that the jet can be positioned correctly in the auditory canal.

☞ During this period, the water is directed via the handle into the drain in order to guarantee optimum temperature stability; optical indication by the flashing figure in the temperature display.
Do not start stimulation by operating the release lever on the handle until you hear the audible signal!

- Carrying out the thermostimulation via the set screw on the handle (❺, Fig. 4).
- At the end of the stimulation period, a control signal for a recording unit is issued at the nystagmograph output.
- After stimulation is completed, the unit remains in a holding position for 15 seconds so that the handle may be removed from the auditory canal.
  - ↳ During this time, water flows into the drain; again, an optical indication is made by flashing temperature value.
- Repeated activation of the “timer start” key stops timer operation.
- Second activation of the currently active key deactivates the corresponding level.
  - ↳ Heating is switched off completely.
  - ↳ Stimulation with cold water (feed temperature).

4.5.4 Energy saving mode

Purpose:

Reduction of energy consumption.

Activation:

- Activation of key “heating on/off” (❷, Fig. 1).
  - ↳ Heating is switched off.
- After five minutes of non-use of the unit.

5.0 Cleaning and care

5.1 General information on cleaning and disinfection

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

The hose tips must be changed after each use.

The surfaces of the Variotherm plus resist most common surface disinfectants.

However, do not use

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

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

☞ Set 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 5.2 are all suitable.

☞ Spilled liquid must immediately be wiped dry.

☞ Always observe the instructions for use by the manufacturer of the disinfectants, including all concentration specifications.

☞ The described actions relating to cleaning and disinfection or sterilization do not substitute the relevant instructions which must be adhered to prior to operation.

5.2 Recommended disinfectants

Manual disinfection of instruments

Disinfectant	Ingredients	in 100 g	Manufacturer
Korsolex basic (Application concentrate)	glutaral (ethylenedioxy)dimethanol surfactants, salts, corrosion inhibitors	15.2 g 19.7 g	Bode Chemie, Hamburg
Sekusept aktiv (Application concentrate)	sodiumpercarbonate, phosphonates nonionic surfactants		Ecolab, Düsseldorf
Gigasept FF new (Application concentrate)	succindialdehyde dimethoxytetrahydrofurane corrosion inhibitors nonionic surfactants and perfumes	11.0 g 3.0 g	Schülke & Mayr, Norderstedt

Automatic disinfection of instruments

Disinfectant	Ingredients	in 100 g	Manufacturer
Neodisher MediClean forte (Application concentrate)	NTA nonionic surfactants enzymes preserving agents	5–15 g < 5 g	Dr. Weigert, Hamburg

Surfaces

Disinfectant	Ingredients	in 100 g	Manufacturer
Dismozon pur (Granulate) End of product 12/2014	magnesium monoperoxyphthalate hexahydrate	80 g	Bode Chemie, Hamburg
Dismozon plus (Granulate)	magnesium monoperoxyphthalate hexahydrate	95.8 g	Bode Chemie, Hamburg
Green & Clean SK (Application concentrate)	Alkyl dimethyl benzyl ammonium chloride Dialkyldimethylammoniumchloride Alkyl dimethyl ethyl benzyl ammonium chloride	< 1 g	Metasys, Rum (Austria)
Perform	Pentapotassium bis(peroxymonosulphate)-bis(sulphate)	45.0 g	Schülke & Mayr, Norderstedt

When using disinfectants containing aldehyde and amine on the same object, color changes may occur.

5.3 Cleaning method for handle with jet connection for water irrigation tip

The ATMOS devices Variotherm plus and Hygrotherm plus are properly used with disposable hose tips. These hose tips must be disposed of after each application to the patient.

When using the hose tips, ATMOS recommends reprocessing according to the cleaning and disinfection plan below.

	What	How			Details	When				Who
	Parts to be reprocessed	C Cleaning	D Disinfection	S Sterilization		After each application	Daily	Weekly	Monthly	Qualified and trained staff who are familiar with reprocessing (please fill in the responsible person -> use a water-based overhead marker)
	**Ear irrigation / Thermal nystagmus stimulation**									
	Handle	X	X[3]		Wipe cleaning and disinfection		X			
	Jet connection	X	X[2,4,5,6]		Cleaning and disinfection (manual or automatic)		X			
	Splash guard	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)		X			
	Hose tip (disposable)				Change after each application	X				
	Rinsing attachment	X	X[2,4,5]		Cleaning and disinfection (manual or automatic)	X				
	Hygiene filter				See operating instructions for hygiene filter				X	

Recommended disinfectants

[3] Surface disinfection for coated surfaces:

- Green & Clean SK (ATMOS)
- Dismozon® plus (Bode Chemie)
- Kohrsolin® FF (Bode Chemie)
- Perform® (Schülke & Mayr)
- Terralin® Protect (Schülke & Mayr)

Other surfaces:

- Dismozon® plus (Bode Chemie)
- Kohrsolin® FF (Bode Chemie)
- Bacillocid® rasant (Bode Chemie)
- Mikrobac® forte (Bode Chemie)
- Perform® (Schülke & Mayr)
- Terralin® Protect (Schülke & Mayr)
- Surface disinfectant FD 312 (Dürr Dental)
- Quick disinfection B 30 (Orochemie)

[4] Manual disinfection of instruments:

- Korsolex® AF (Bode Chemie)
- Korsolex® basic (Bode Chemie)
- Korsolex® plus (Bode Chemie)
- Korsolex® extra (Bode Chemie)
- neodisher® Septo MED (Dr. Weigert)
- neodisher® Septo 3000 (Dr. Weigert)
- Sekusept® PLUS (Ecolab)
- Sekusept® aktiv (Ecolab)
- Gigasept® Instru AF (Schülke & Mayr)
- Gigazyme® (Schülke & Mayr)
- Gigasept FF neu (Schülke & Mayr)

[5] Automatic disinfection of instruments:

- Dismoclean® 21 clean (Bode Chemie)
- Dismoclean® 24 Vario (Bode Chemie)
- Dismoclean® 28 alka one (Bode Chemie)
- Dismoclean® twin basic/twin zyme (Bode Chemie)
- neodisher® FA (Dr. Weigert)
- neodisher® FA forte (Dr. Weigert)
- neodisher® MediClean forte (Dr. Weigert)
- Thermosept® alka clean forte (Schülke & Mayr)
- Thermosept® RKN-zym (Schülke & Mayr)

For concentrations, contact time, temperature and material compatibility, please see the relevant information from the manufacturer.

Important information

Wipe cleaning and disinfection: All surfaces must be wiped with a clean (disposable) wipe which is dampened with disinfectant solution; the entire surface must be wiped thoroughly and may not be dried afterwards.

[1] Please observe the manufacturer's instructions for use.

[2] Preferred: machine cleaning and disinfection in a washer disinfector

[6] Material dimensionally stable at 134 °C

- Decalcification and changing of filter (see sections 6.1, 6.2) should be carried out immediately by the user when required.

Maintenance, repairs, and periodic 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.
- Please observe the corresponding service instructions.

6.1 Decalcification

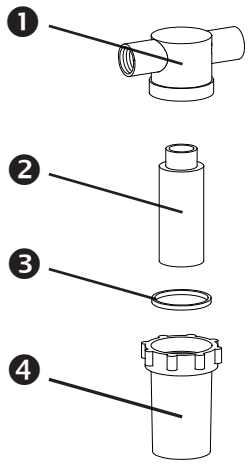
If the tap water in the area where the unit is used is known for mineral precipitation, preventive decalcification should be carried out:

- Close water tap.
- If applicable, dismantle filter when mounted vertically on water tap.
- Unscrew screwed glass of filter.
- Fill glass with approx. 100 ml of decalcifier on acetic, citric, or lactic acid basis (e.g., Citrosteril by Fresenius).
- Screw glass on again.
- Install filter vertically again, if applicable.
- Open water tap again.
- Switch on the device.
  - ↳ Decalcification takes place automatically in the thermal process for reducing bacterial count. After the unit has been in this mode for 5 minutes, the water passages have been decalcified and cleaned and also sufficiently flushed. The Variotherm plus is again fully ready for operation. When water passages are heavily calcified, a modified procedure may become necessary having a prolonged reaction period for the decalcifier.

Recommendation: Calcification safety device (REF 502.0995.0).

6.2 Replacement of filter

- When the filter cartridge is very dirty (dark color), the filter cartridge is to be changed as follows:
  - Close water supply tap.
  - Switch on unit to reduce pressure in the filter body.
  - Switch off unit after "F1" appears.
  - Unscrew plexiglass cup (❹, Fig. 7) from filter body (❶, Fig. 7) by turning counterclockwise.
  - Remove filter cartridge (❷, Fig. 7) and replace with a new one.
- The filter element must not come into contact with contaminated objects in order to prevent the ingress of germs into the water system.



❶ Filter body
❷ Filter cartridge
❸ Sealing ring
❹ Plexiglass cup

Fig. 7. Water filter

6.3 Sending in the device

- Remove and properly dispose of consumables.
- Clean and disinfect the product and accessories according to the operating instructions.
- Place any used accessories with the product.
- Fill in the form QD 434 "Delivery complaint / return shipment" and the respective **Decontamination certificate**.

☞ This form is enclosed with each delivery and can be found at www.atmosmed.com.

- The device must be well padded and packed in suitable packaging.
- Place 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

“F0”	Handle is not in its holder	• Insert handle in its holder to allow thermal process for reducing bacterial count to start (jet connection must point to the back of the unit). • Replace handle (REF 502.0963.0).
“F1”	No water (water pressure < 0.5 bar)	• Check whether the water supply delivers a pressure of at least 2 bar (did you open the water tap?). • Filter clogged?
“F2”	-5 V is missing (supply voltage on the controller board)	• Inform the service staff.
“F3”	Break of the safety NTC	• Inform the service staff.
“F4”	Safety switching does not react (49 °C comparator)	• Have the safety switching (temperature controller) checked by the service staff.
“F5”	Break of the regulating NTC	• Inform the service staff.
“F6”	Different switch settings in the handle holder	• Handle must be correctly inserted in its holder. • Otherwise, inform the service staff.
“F7”	Temperature too high (> 48 °C); display only in the stimulation and irrigation mode but not in the thermal cleaning procedure	• Check whether temperature setting is too high. If necessary, adjust desired temperature to a value of < 48 °C by means of the coding switches. • Inform the service staff.
“F8”	Short-circuit of the regulating NTC	• Have temperature feeler of the regulating NTC checked by the service staff.
“F9”	No heating performance (excess temperature switch, def. semi-conductor relay or regulator)	• Inform the service staff (internal excess temperature switch might have released).

☞ If errors cannot be corrected with the assistance of the troubleshooting 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
Calcification safety device	502.0995.0
Jet connection extra long, straight (110 mm)	508.0429.0
Rinsing connection (Teflon) for stimulating the vestibular organ	501.0355.0
Extension of supply hose G3/4a-G3/4i, L =1,5 m	501.0315.6
Waste water hose, special length, G1/4a-G1/4a (please indicate desired length)	502.0881.1
Drainage fittings as to DIN 1988	502.0880.0
Connecting cable for a nystagmograph	502.0850.0
Connecting cable for the equipotential compensation, L = 5m	008.0596.0

8.2 Spare parts

Description	REF
Variotherm plus, basic unit, 220-240 V AC, 50/60 Hz	502.0900.0
Variotherm plus, basic unit, 110-127 V AC, 50/60 Hz	502.0900.1
Irrigation handle 4+	502.0963.0
Double-barrelled hose	510.0412.0
Jet connection short, straight (80mm)	508.0427.0
Splash guard	501.0331.0
Rubber bush for splash guard	501.0331.1
Throttling nozzle 0.5 mm (150 ml/min)	502.0946.0
Throttling nozzle 0.7 mm (250 ml/min)	502.0946.1
Three-hole gasket	501.0320.0
Hose tips for jet connection (30 pcs)	502.0844.0
G3/4a-G3/4i, L =3 m	502.0768.1
Cap nut G3/4 (to be included in order)	052.0035.1
Water filter complete	502.0890.0
Filter element for water filter	502.0891.0
Gasket (for G1/4a) 13x18x1	055.0018.0
G1/4a-G3/4a-reducer (filter G1/4 on water hose G3/4)	502.0724.1
Supply hose with connection G3/4i, L = 3 m	501.0315.7
Waste water hose with connection G1/4, L = 3 m	502.0882.0
Gasket (for G1/4i) 10x15x1	055.0003.0
Power cable with protective contact socket (Germany), L = 3m	507.0859.0
Power cable with British plug BS1363A (UK), L = 2.5m	008.0762.0
Fuse F 8 A (quick-acting) 250 V breaking capacity H (1500 A)	008.0767.0
Fuse for special voltage (110-127VAC): F 15A (quick-acting) breaking capacity 10kA	008.0766.0
Front foil Variotherm plus	060.0357.0

9.0 Technical data

Voltage	220 - 240 V~ ± 10 %; 50/60 Hz
Special voltage	100 - 127 V~ ± 10 %; 50/60 Hz
Current consumption	max. 6.8 A (220 - 240 V~); 14.8 A (100- 127 V~)
Power consumption	max. 1500 W
Connections	Power connection via IEC socket; control output for a nystagmograph; equipotential equalization; water supply G 3/4" external thread; water drainage G 1/4" external thread; connection for double-barrelled hose
Fuses	F 8 A (f. 220 - 240 V~); F 15 A (f. 110 - 127 V~)
Stimulation time	Adjustable by timer from 1 up to 99 sec.
Timer indication	Indication accuracy ± 0.5 s ± ½ digit
Water temperature	20°C - 47°C
Temperature indication	Indication accuracy ± 0.6°C ± ½ digit (can only be guarantee with unchanged ambient conditions)
Feed temperature of the water	+7...+19.5 °C
Water quality	Drinking water
Water flow in the irrigation mode (high flow)	450 ml/min: Standard unit and variant 250/450 ml/min 400 ml/min: Variant 400/400 ml/min 500 ml/min: Variant 500/500 ml/min
Water flow in the stimulation mode (low flow)	150 ml/min: Standard unit 150/450 ml/min (adjustable) 250 ml/min: Variant 250/400 ml/min (adjustable) 400 ml/min: Variant 400/400 ml/min (adjustable) 500 ml/min: Variant 500/500 ml/min (adjustable)
Operating time	Continuous operation
Operating pressure	At least: +2000 hPa (2 bar); max.: +6000 hPa (6 bar)
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	-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 (NN)
Contamination level	Class 2
Overvoltage category	II
Dimensions HxWxD	14.5 x 37 x 31.5 cm
Weight	Approx. 5,5 kg
Period tests	Inspection according to the manufacturers specifications every 12 months.
Safety class (EN 60601-1)	I
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

9.0 Technical data

GMDN code	34891
UMDNS code	10-548
ID No. (REF)	502.0900.0

Issue of the technical data: 2017-01-27

10.0 Disposal

- Packaging material, cardboard, and/or PE foam can be fully recycled or returned to your supplier.
- The Variotherm plus does not contain any hazardous materials.
- The housing is fully recyclable.
- The component parts of the Variotherm plus 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 that 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 the following EMC notes.
- Portable and mobile RF communication facilities can influence medical electrical equipment.
- The use of other accessories, 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 Variotherm plus is designed for operation in the environment specified below. The customer or user of the Variotherm plus 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 Variotherm plus uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions according to CISPR 11	Class B	The Variotherm plus 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 purposes.
Harmonic emissions according to IEC 61000-3-2	Class B	
Voltage fluctuations/flicker according to IEC 61000-3-3	Corresponds	

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

11.2 Guidelines and Manufacturer's Declaration – Immunity

The Variotherm plus is designed for operation in the electromagnetic environment specified below. The customer or user of the Variotherm plus should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be made of wood or concrete or tiled with ceramic tiles. If floors are synthetic, 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.
Magnetic field at power frequency 50/60 Hz acc. to IEC 61000-4-8	3 A/m	Inapplicable	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage Dips / Dropout IEC 61000-4-11	< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle 40 % U_T (60 % Dip of the U_T) For 5 cycles 70 % U_T (30 % Dip of the U_T) For 25 cycles < 5 % U_T (> 95 % Dip of the U_T) for 5 s	< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle 40 % U_T (60 % Dip of the U_T) For 5 cycles 70 % U_T (30 % Dip of the U_T) For 25 cycles < 5 % U_T (> 95 % Dip of the U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Variotherm plus requires continued operation upon the occurrence of disruptions in the energy supply, the Variotherm plus should make use of an uninterruptible power supply or a battery.
NOTE U_T is the mains alternating current prior to application of the test levels.			

11.3 Guidelines and Manufacturer's Declaration – Immunity

The Variotherm plus is designed for operation in the electromagnetic environment specified below. The customer or user of the Variotherm plus should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted disturbances acc. to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V	Portable and mobile radio equipment should be used no closer to the Variotherm plus, including cables, than the recommended distance calculated according to that which applies to the transmission frequency. Recommended distances: d = (3.5 / V1) * √(P) d = (3.5 / E1) * √(P) 80-800 MHz d = (7 / E1) * √(P) 0.8-2.5 GHz where „P“ is the max. power in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site (a) survey, should be less than the compliance level (b). Interference may occur in the vicinity of equipment containing following symbol: 
Radiated HF disturbances acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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.

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

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 Variotherm plus

The Variotherm plus is intended for use in an electromagnetic environment in which HF disturbances are controlled. The customer or user of the Variotherm plus can thereby help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Variotherm plus – 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 = [3,5 / 3] √P**	**80 MHz to 800 MHz d = [3.5 / 3] √P**	**800 MHz to 2.5 GHz d = [7.0 / 3] √P**
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.2	1.2	2.4
10	3.69	3.69	7.38
100	11.66	11.66	23.32

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

NOTE 1

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.

12.0 For your notes

12.0 For your notes

MedizinTechnik

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