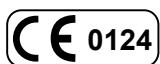


Operating Instructions

Hygrotherm Plus

English



GA1GB.140303.0

2024-01 Index 29

Table of contents

1	Introduction.....	4
1.1	Notes on the operating instructions.....	4
1.2	Explanation of pictograms and symbols.....	5
1.3	Intended use.....	6
1.4	Function.....	7
1.5	Scope of delivery.....	7
1.6	Transport and storage.....	8
2	Notes on your safety.....	9
2.1	General safety instructions.....	9
2.2	Danger to users, patients and third parties.....	9
2.3	Important notes on the maintenance of the hygiene status of warm water irrigation units.....	10
2.4	Avoiding damage to the device.....	11
3	Setting up and starting up the device.....	12
3.1	Device overview.....	12
3.1.1	Front view.....	12
3.1.2	Rear view.....	12
3.1.3	Side view.....	13
3.1.4	Irrigation handle view.....	13
3.2	Connections.....	14
3.2.1	Electrical connection.....	14
3.2.2	Equipotential bonding connection.....	14
3.2.3	Water connection.....	15
3.2.4	Connecting the irrigation handle.....	16
3.3	Starting up the device.....	16
4	Operation.....	17
4.1	Selecting the temperature level.....	17
4.2	Operating mode description.....	17
4.2.1	Thermal process to reduce the bacterial count.....	17
4.2.2	Irrigation mode.....	17
4.2.3	Energy saving mode.....	18
5	Sterilization.....	19
5.1	Safety notes on sterilization.....	19
5.1.1	General safety instructions.....	19
5.1.2	Danger for users, patients and third parties.....	19
5.1.3	Avoiding damage to the device.....	20
5.2	General information on cleaning and disinfection.....	20
5.3	Preparing and finishing the sterilization.....	21
5.4	Recommended disinfectants.....	21
5.5	Recommended surface disinfectants.....	21
5.6	Cleaning method for handle with nozzle for irrigation handle.....	22
5.6.1	Recommended disinfectants.....	23

6	Maintenance and service	24
6.1	Sending in the device.....	24
6.2	Decalcification	24
6.3	Filter replacement.....	25
6.4	Exchanging fuses.....	25
7	Troubleshooting	26
8	Accessories	27
9	Disposal	28
10	Technical data	29
11	Notes on EMC	30
12	Notes	31

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 application 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 Notes on 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 Terms and Conditions can be viewed on our website at www.atmosmed.com.

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









These operating instructions apply to the following products:

Hygrotherm plus









REF 502.1100.0








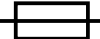






1.2 Explanation of pictograms and symbols

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.
	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.
	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
	This product meets the relevant requirements of EU statutory ordinances.
	This product meets the relevant requirements of the Eurasian Economic Union.
	Manufacturer
	Manufacturing date
	Date of manufacture Country of manufacture: Germany

	Article number
	Medical device
	Serial number
	European article number
	Type B applied part
	Potential equalization
	Temperature in degrees Celsius
	Fuse according to IEC 417/5016, DIN 30600/0186
	Heating on
	Heating off (energy saving mode)
	Connection for waste water
	Connection for water
	On/off
	Handle

1.3 Intended use

Product name:	Hygrotherm plus
Main function:	Irrigation of the external ear canal
Intended use / purpose:	Irrigation of the external ear canal
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:	Reduction in hearing due to cerumen in the ear canal

Application organ:	External ear canal to the ear drum
Application time:	Temporary (< 60 min)
Application site:	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:	Hearing loss due to impacted ear wax
Medical contraindication:	Pathological ear drum
Other contraindications:	Pathological external ear canal
Warnings:	N/A
The product is:	Active
Sterility / specific microbial condition:	Non sterile
Disposable product / re-sterilization:	Not a disposable product. Options for re-sterilization according to the operating instructions.

1.4 Function

- The thermal process to reduce the bacterial count is automatically activated by operating the main switch (see chapter "4.2.1 Thermal process to reduce the bacterial count" on page 17).
- Then automatic change to irrigation mode. Here, irrigations can be carried out with water warmed up to 37 °C and a flow rate of at least 400 ml/min.

1.5 Scope of delivery

Quantity	Description
1	Hygrotherm plus main device
1	Irrigation handle with connection hose
3	Jet connection for irrigation handle 80 mm
1	Splash guard for attachment to jet connection
1	Hose tips
1	Water filter, complete, 3/4" A-3/4"
1	Water supply hose
1	Waste water hose
1	Power cable
1	Operating instructions

1.6 Transport and storage

Transport the product only in a shipping box that is padded and provides 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 24.

Ambient conditions for transport and storage:

- Temperature: -20...+50 °C
- Humidity without condensation: 5...90 %
- Pressure: 700...1060 hPa

2 Notes on 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 to 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 small parts that can be swallowed include 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 24.
- 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 hazards 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.
- Check whether the device or power cable is damaged each time before using the device. 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 where you can easily disconnect it from the mains power supply at any time.
- 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 enters 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 24.
- 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 Important notes on the maintenance of the hygiene status of warm water irrigation units

To loosen cerumen in the ear canal and stimulate the organ of equilibrium, ATMOS offers the warm water unit Hygrotherm plus (37 °C).

These units heat the drinking water that comes from the household connection to the respective pre-selected temperature. At these water temperatures, there may be increased germ counts in the rinsing water which, in turn, can lead to adverse health effects in sensitive patients if the following operating instructions are not observed.

Prerequisite for starting up the device

- ❑ The water provided by the household connection must, at a minimum, meet the WHO directives or the country-specific directives for drinking water.

Connection

- Fresh water must flow through the wall connection for a period of approximately one minute before connecting the device.*
- Ensure that the installation is carried out hygienically! Disinfect the threaded connections with 70% alcohol before screwing them into place.*
- Wear disposable gloves when carrying out maintenance work on parts that conduct water.*
- Carry out the thermal cleaning process at least three times before using the device for the first time.*

* This work is carried out by an authorized ATMOS service technician.

Running operation

- Before beginning the surgical operation, switch on the unit and await the thermal cleaning process.
- After the device has been idle for a long period of time (weekend, holidays etc.), the thermal cleaning process must be awaited and repeated twice.
- We recommend switching the device off and on every two hours and not later than four hours to start thermal cleaning mode.
- Immediately replace contact parts, for example the hose tip, each time the patient is changed (to prevent retrograde contamination).
- Prior to use, spray water and check the temperature.

Service

- Pay attention to hygiene when exchanging the suspended particle filter (see Start-up). Dispose of the filter and carefully clean the filter glass. Avoid contact with contaminated parts in the process.
- Carry out thermal cleaning each time after service.
- Depending on the quality of the drinking water available, biofilm growth cannot be ruled out (despite our patented thermal process for reducing the bacterial count). We therefore recommend examining the drinking water quality at regular intervals at the drinking water connection of the devices and at the applied part in accordance with ISO 6222. If there is a significant rise in germs between the drinking water connection and the applied part, the biofilm-removing process with subsequent disinfection can be carried out.

2.4 Avoiding damage to the device

Storage and operation in an unsuitable environment.

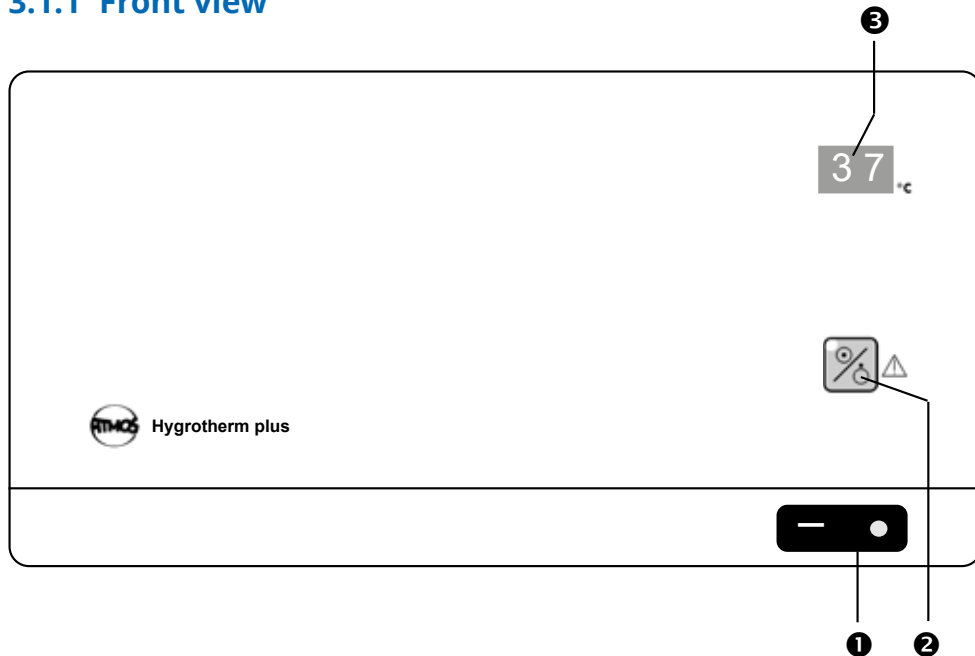
The product may become damaged.

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

3 Setting up and starting up the device

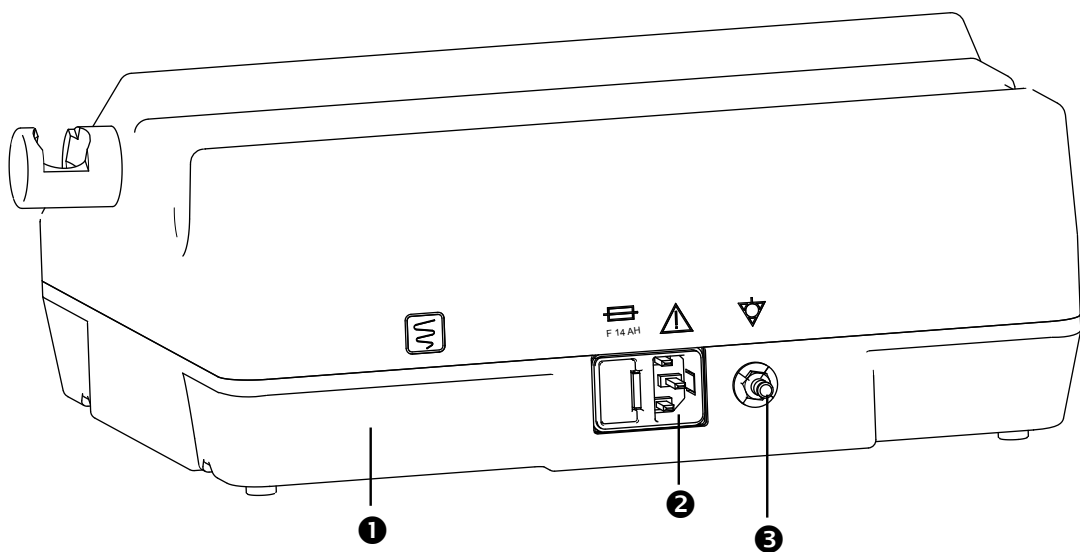
3.1 Device overview

3.1.1 Front view



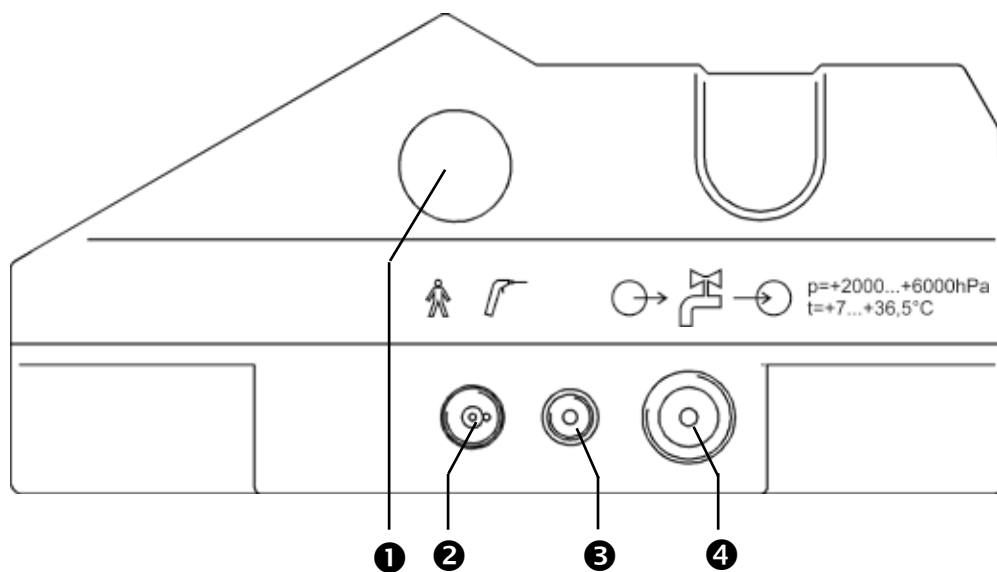
- ❶ Main switch
- ❷ Heating ON/OFF button (energy saving mode)
- ❸ Temperature display (double-digit, resolution of 1 °C), actual value display

3.1.2 Rear view



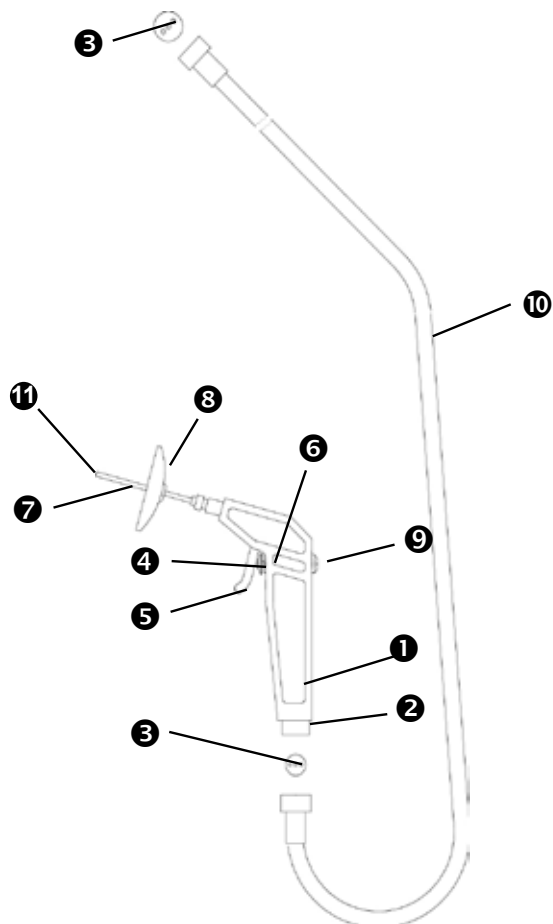
- ❶ Type plate
- ❷ Device plug with fuse compartment
- ❸ Equipotential connection

3.1.3 Side view





- ❶ Handle holder
- ❷ Connection for the double-barrelled hose
- ❸ Connection for the waste water hose
- ❹ Connection for the water supply hose

3.1.4 Irrigation handle view



- ❶ Handle
- ❷ Connection for double-barrelled hose
- ❸ Three-hole gasket
- ❹ Knurled screw
- ❺ Release lever
- ❻ Valve plunger
- ❼ Nozzle for irrigation handle
- ❽ Splash protection to be slipped onto the nozzle
- ❾ Sealing cap
- ❿ Double-barrelled hose
- ⓫ Hose tip

 The nozzle must be disinfected after each patient. The hose tips are disposable products and must be disposed of with household waste.

 The irrigation handle with connection tube and all related accessories are to be considered applied parts of the product.

3.2 Connections

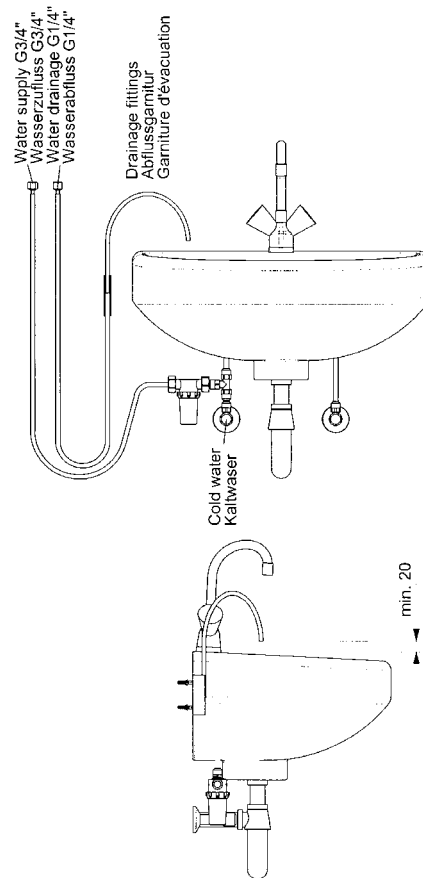
3.2.1 Electrical connection

- According to 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 mains connection.
- Insert the power plug into a correctly installed socket with earthing contact.

3.2.2 Equipotential bonding connection

- Connection for potential equalization. Connection cable available from ATMOS.

3.2.3 Water connection



Local requirements:

- Water tap with G3/4" external thread.
- Drinking water!
- Input water pressure: +2000...+6000 hPa (6 bar).
- Feed temperature: +7...+19.5 °C (recommended), but at least 0.5 °C below the desired 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, which are to be considered when connecting the device 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 device 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.
1. Connect the filter unit to the water tap by means of adapter and gasket.
 2. Insert the gaskets in the cap nuts of the water supply hose.
 3. Screw the nuts to the filter connection and the device connection.
 4. Insert the sealing rings into the cap nuts of the waste water hose.

5. Screw the nuts to the device connection and the drainage fittings.
 - ☞ There is no special calcification safety device integrated in the water system. A calcification safety device must be connected when the respective drinking water is of hardness grade 3 (14 - 21°dH resp. 2.5 - 3.8 mmol/l = hard water) and with hardness grade 4 (from 21°dH resp. from 3.8 mmol/l = very hard water).
 - ☞ Please contact your local water supplier and/or plumber.

Hardness range	Total hardness in millimol per litre	°dH	
1 (soft)	≤ 1.3	≤ 7.3	Calcification protection system 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 required
4 (very hard)	> 3.8	> 21.3	

 Please close the water tap when the device is not in use!

3.2.4 Connecting the irrigation handle

1. Insert a “three-hole gasket” into the double-barrelled hose and screw it onto the device connection.
 - ☞ Use only “three-hole gaskets” or the device will not work correctly!
2. Insert a “three-hole gasket” into the irrigation handle and screw it onto the free end of the double-barrelled hose.
3. Open the water tap. Check whether all connections are tight.

3.3 Starting up the device

1. Insert the handle into its support so that the irrigation nozzle points to the rear of the device.
2. Switch on the device.
 - » Automatic display test with digital number sequence “8 8” and acoustic warning signal.
 - » Automatic activation of the thermal process to reduce the bacterial count. Duration: 5 min.
 - » Automatic switch to irrigation mode (37 °C).
- ☞ Automatic switch to energy saving mode if irrigation mode is not used (handle is not removed from its support) within 5 minutes.

4 Operation

- ☞ Before switching on the device, make sure the handle is in its support (irrigation nozzle must point to the rear of the device).

4.1 Selecting the temperature level

After operating the main switch, automatic activation of the thermal process to reduce the bacterial count, followed by the automatic activation of the “irrigation mode” temperature level (37 °C).

4.2 Operating mode description

4.2.1 Thermal process to reduce the 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 support on the side (nozzle pointing to the rear of the device).
- » If not, a warning signal will sound (also when the handle is removed during the thermal process to reduce the bacterial count).
- » Additional display of the error code “F0” (disappears when the handle is returned).
- ☞ In the thermal process to reduce the bacterial count, hot water is ducted 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 to reduce the bacterial count, the first segment of the temperature display shows a “d” and the second segment the remaining time (in minutes).
- Afterwards, the device will cool down to 37 °C and automatically switch to irrigation mode.

4.2.2 Irrigation mode

Purpose:

Rinsing of the auditory canal.

Properties:

- Temperature: 37 °C, permanently set.
- Water flow: at least 400 ml/min, after turning open the limit screw at the release lever of the handle.

Activation:

- Automatically after completion of thermal cleaning procedure and taking out the handle.
- ☞ When irrigation mode is not used (handle remains in its support), the Hygrotherm plus switches to energy saving mode after five minutes.
- Reactivation of the irrigation mode by removing the handle or pressing a button on the temperature control unit.

4.2.3 Energy saving mode**Purpose:**

- Reduction of the energy consumption.

Activation:

- Press the "Heating on/off" button.
- » The heating is switched off.
- After five minutes of non-use of the unit.

5 Sterilization

5.1 Safety notes on 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 Hygrotherm plus resist most of the common surface disinfectants.

However, do not use any:

- Disinfectants containing concentrated organic or inorganic acids because they could cause corrosion damage.
- Disinfectants containing chloramides, phenol derivatives, or anionic surfactants 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. All cleaning agents and disinfectants listed in chapter "5.4 Recommended disinfectants" on page 21 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 Hygrotherm 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 surfactants 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
Korsolex basic (Application concentrate)	Glutaral (15.2 g), (ethylendioxy) dimethanol (19.7 g), surfactants, salts, corrosion inhibitors	Bode Chemie, Hamburg
Sekusept® PLUS (concentrate)	Glucoprotamin (25 g), non-ionic surfactants, 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

5.5 Recommended surface disinfectants

Manual disinfection of instruments

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 surfactants, 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

Automatic disinfection of instruments

Agent (manufacturer)	Active ingredients in 100 g	Manufacturer
Neodisher MediClean forte (Application concentrate)	NTA (5-15 g), non-ionic surfactants < 5 g, enzymes, preservative agents	Dr. Weigert, Hamburg

Surfaces

Agent (manufacturer)	Active ingredients in 100 g	Manufacturer
Dismozon pur (granule) End of product 12/2014	Magnesium monoperoxyphthalate hexahydrate (80 g)	Bode Chemie, Hamburg
Dismozon plus (granule)	Magnesium monoperoxyphthalate hexahydrate (95.8 g)	Bode Chemie, Hamburg
Green & Clean SK (Application concentrate)	< 1 g alkyl-dimethyl-benzyl-ammonium chloride, dialkyl-dimethyl-ammonium chloride, alkyl-dimethyl-benzyl-ammonium chloride	ATMOS, Lenzkirch
Perform	Pentapotassium bis(peroxymonosulphate)-bis(sulphate) 45.0 g	Schülke & Mayr, Norderstedt

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

5.6 Cleaning method for handle with nozzle for irrigation handle

The ATMOS devices Variotherm plus and Hygrotherm plus are used properly with (disposable) hose tips.

These hose tips must be disposed of each time after using them on a patient.

Surface	After each application	After each patient	Daily	Weekly	Every 14 days	Monthly	Pre-cleaning	Cleaning	Disinfection	Sterilization
Handle			X					X	X ³	X
Jet connection	X							X	X ^{2,4,5,6}	X
Splash protection			X					X	X ^{2,4,5}	X

5.6.1 Recommended disinfectants

3) Surface disinfection for painted surfaces:	Other surfaces:	4) Manual disinfection of instruments:	5) Mechanical disinfection of instruments:
<ul style="list-style-type: none"> • Green & Clean SK (ATMOS) • Dismozon® plus (Bode Chemie) • Kohrsolin® FF (Bode Chemie) • Perform® (Schülke & Mayr) • Terralin® Protect (Schülke & Mayr) 	<ul style="list-style-type: none"> • Dismozon® plus (Bode Chemie) • Kohrsolin® FF (Bode Chemie) • Bacillocid® rasant (Bode Chemie) • Mikrobar® forte (Bode Chemie) • Perform® (Schülke & Mayr) • Terralin® Protect (Schülke & Mayr) • Surface disinfectant FD 312 (Dürr Dental) • Quick disinfection B 30 (Orochemie) 	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • 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)
<p>For concentrations, contact time, temperature, material compatibility, please see the relevant information from the manufacturer.</p>			

Important information

Wipe cleaning and disinfection: All surfaces have to be wiped with a clean (disposable) wipe moistened with disinfectant solution. The entire surface has to be wiped thoroughly and must not be dried afterwards.

- ¹⁾ Please observe the manufacturer's operating instructions.
- ²⁾ Preferred: mechanical cleaning and disinfection in the washer disinfector
- ⁶⁾ Material dimensionally stable at 134 °C

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.
- ☞ The device should be decalcified and filters exchanged (see chapters 6.2 and 6.3) immediately by the user whenever necessary.

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 can be found 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.

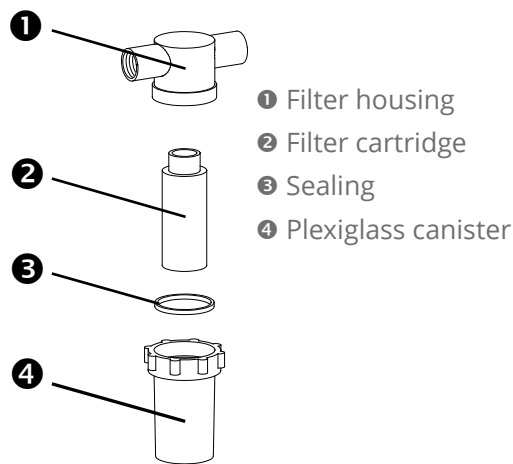
6.2 Decalcification

Preventive decalcification should be carried out if the tap water is known for mineral precipitation in the area where the device is used:

1. Close the water tap.
2. If necessary, dismantle the filter from the water tap in the event of vertical installation.
3. Unscrew the filter glass.
4. Fill the glass with approximately 100 ml of decalcifier based on vinegar, lemon or lactic acid (e.g. Citrosteril from Fresenius).
5. Screw the glass back on again.
6. Install the filter in a vertical position again, if necessary.
7. Re-open the water tap.
8. Switch on the device.
- » Decalcification takes place automatically in the thermal process for reducing bacterial count. After operating the device in this mode for five minutes, the water passages have been decalcified and cleaned and also sufficiently flushed. The Hygrotherm plus is now fully ready for operation again. When water passages are heavily calcified, a modified procedure may become necessary, with a prolonged reaction period for the decalcifier.

6.3 Filter replacement

- When the filter cartridge is very dirty (dark colour), exchange the filter cartridge as follows:
 - Close the water supply tap.
 - Briefly switch on the unit to reduce pressure in the filter housing.
 - Switch off the device when "F1" appears.
 - Unscrew the plexiglass canister anti-clockwise off the filter housing.
 - Remove the filter cartridge and replace it with a new one (REF 502.0891.0).
- The filter cartridge must not come into contact with contaminated objects to prevent the ingress of germs in the water system.



6.4 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 (F 8 A, 250V).
5. Mount the fuse holder.
6. Connect the device to the mains supply.

7 Troubleshooting

Error on the temperature display

	Potential cause	Remedy
"F0"	Handle is not in its support	<ul style="list-style-type: none"> • Insert the handle back in its support to allow the thermal process for reducing the bacterial count to start (nozzle must point to the rear of the device). • Replace the handle (REF 502.0963.0).
"F1"	No water (water pressure < 0,5 bar)	<ul style="list-style-type: none"> • Check whether the water supply delivers a pressure of at least 2 bar (did you open the water tap?). • Filter clogged?
"F2"	-5 V missing (supply voltage on the controller board)	<ul style="list-style-type: none"> • Inform the service staff.
"F3"	Safety NTC breakage	<ul style="list-style-type: none"> • Inform the service staff.
"F4"	Safety switching does not react (49 °C comparator)	<ul style="list-style-type: none"> • Have the safety switching (temperature controller) checked by the service staff.
"F5"	Breakage of the regulating NTC	<ul style="list-style-type: none"> • Inform the service staff.
"F6"	Different switch settings in the handle holder	<ul style="list-style-type: none"> • Handle must be correctly inserted in its support. • Otherwise inform the service staff.
"F7"	Temperature too high (> 48 °C), display only in stimulation and irrigation mode, but not during the thermal cleaning procedure	<ul style="list-style-type: none"> • Inform the service technician if this message does not disappear after a short moment.
"F8"	Short-circuit of the regulating NTC	<ul style="list-style-type: none"> • The temperature probe from the regulating NTC must be checked by a service technician.
"F9"	No heating performance (excess temperature switch), def. Semiconductor relay or regulator)	<ul style="list-style-type: none"> • Inform the service staff (internal excess temperature switch might have released).

☞ 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 try to repair the device yourself!


8 Accessories

Description	REF
Water pre-filter, backwashable (ENT units)	502.0990.0
Water filter, complete, 3/4" A-3/4"l	530.2085.0
Nozzle for irrigation handle, 80 mm	508.0427.0
Nozzle for irrigation handle, 110 mm	508.0429.0
Hose tips	502.0844.0
Splash protection to be slipped on nozzle	501.0331.0
ATMOS Aqua clean (stimulation and irrigation devices)	502.1200.0

9 Disposal

- The packaging cardboard and/or PE foam can be fully recycled or returned to your supplier for further use.
- The Hygrotherm plus does not contain any hazardous materials.
- The housing material is fully recyclable.
- The component parts of the Hygrotherm plus must be disposed of correctly and the materials separated carefully.
- The electronic circuit boards must be submitted to the appropriate recycling process.
- Hose tips are disposable products and must be disposed of with the household waste after use.

10 Technical data

Voltage	220 – 240 V~ ± 10%; 50/60 Hz
Current consumption	6.8 A
Power consumption	1500 VA
Fuses	F 8 A / 250 V AC
Operating modes	<ul style="list-style-type: none"> • Thermal process for reducing bacterial count • Irrigation mode • Heating off (energy saving mode)
Water temperature	37 °C ± 0.5 °C
Temperature indication	Indication accuracy ± 0.5 s ± ½ digit
Flow rate	400 ml/min ± 10 %
Feed temperature of the water	+7...+36.5 °C
Water quality	Drinking water
Operating pressure	At least: +2000 hPa (2 bar); max: +6000 hPa (6 bar)
Connections	<ul style="list-style-type: none"> • Power connection via IEC socket • Equipotential equalization • Water supply G ¾" external thread • Water drainage G ¼" external thread • Connection for double-barrelled hose
Operating time	Continuous operation
Protective earth conductor resistance	Max. 0.1 Ω
Earth leakage current	Max. 0.5 mA
Housing leakage current	Max. 0.1 mA
Patient leakage current	Max. 0.1 mA
Ambient conditions	-20...+50°C
Transport/storage	5...90% air humidity without condensation; air pressure of 700...1060 hPa
Ambient conditions	+10...+35°C
Operation	20...80 % air humidity without condensation; air pressure of 700...1060 hPa
Maximum operational altitude	≤ 3000 m (sea level)
Dimensions HxWxD	14.5 x 37 x 32 cm
Weight	5.5 kg
Period tests	Inspection every 12 months according to the manufacturers specifications *(Germany: safety check according to Medical Device Operator Ordinance).
Protection class (EN 60601-1)	I
Degree of protection	Type B 
Type of protection	IP X0
CE mark	CE 0124
ID no. (REF)	502.1100.0

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11 Notes on EMC

- 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 Hygrotherm plus 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 Variotherm plus 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 Variotherm plus has the following removable components, which can be replaced by the operating company:

Type	REF	Max. cable length
Mains power unit	011.1363.0	1.2 m
Power cable	507.0859.0	3.0 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) should be used no closer than 30 cm* to the parts or lines of the Variotherm plus marked by the manufacturer. Otherwise, this could result in degradation of the performance 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



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