



MedizinTechnik

English

Operating Instructions

Hygrotherm plus





| | | |
|-------------|---|-----------|
| 1.0 | Introduction | 3 |
| 1.1 | Notes on operating instructions | 3 |
| 1.2 | Intended use | 4 |
| 1.3 | Function | 4 |
| 1.4 | Explanation of symbols | 4 |
| 2.0 | For your safety | 5 |
| 2.1 | Advice for the user for maintaining hygienic status | 6 |
| 3.0 | Setting up and starting up | 7 |
| 3.1 | Scope of supply | 7 |
| 3.2 | Illustrations..... | 8 |
| 3.3 | Connections..... | 11 |
| 3.3.1 | Electrical connection..... | 11 |
| 3.3.2 | Connecting a equipotential bonding connection . | 11 |
| 3.3.3 | Water connection | 11 |
| 3.3.4 | Connection of the irrigation handle | 12 |
| 3.4 | Starting up..... | 12 |
| 4.0 | Operation | 13 |
| 4.1 | Selecting temperature level | 13 |
| 4.2 | Description of operating modes | 13 |
| 4.2.1 | Thermal process for reducing bacterial count..... | 13 |
| 4.2.2 | Irrigation mode..... | 13 |
| 4.2.3 | Energy saving mode | 13 |
| 5.0 | Cleaning and care | 14 |
| 5.1 | General information on cleaning and disinfection | 14 |
| 5.2 | Recommended disinfectants..... | 14 |
| 5.3 | Cleaning method for handle with jet connection for water irrigation tip | 15 |
| 6.0 | Maintenance and Service | 16 |
| 6.1 | Decalcification..... | 16 |
| 6.2 | Replacement of filter..... | 16 |
| 6.3 | Sending in the device..... | 16 |
| 7.0 | Troubleshooting | 17 |
| 8.0 | Accessories and spare parts | 18 |
| 8.1 | Accessories..... | 18 |
| 8.2 | Spare parts | 18 |
| 9.0 | Technical data | 19 |
| 10.0 | Disposal | 20 |
| 11.0 | Notes on EMC | 21 |



1.1 Notes on operating instructions

These operating instructions contain important notes on how to operate the Hygrotherm plus, 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 appliance.**

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 Hygrotherm 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 authorised by ATMOS. In case of repairs you should insist that only original spare parts are used. You will then have the warranty that operational safety, readiness for work and the value of your device will be preserved.

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

Short cuts / symbols contained in these operating instructions:

- Indicating a list
 - Subdivision of a list/activity

The recommended sequence must be followed in each case!

☞ Indicating particularly important advice!

↪ Describing the effect of an activity.

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1.2 Intended use

| | |
|---|--|
| Name: | ATMOS® Hygrotherm |
| Main function: | Device for the irrigation of the auditory canal |
| Medical indications / application: | Ear irrigation, cleaning of the ear |
| Specification of the main functions: | Produces a jet of water for the ear irrigation at body temperature (37 °C) with a flow rate of 400 ml/min for the removal of cerumen. |
| Application organ: | Auditory canal to the drumhead |
| Application time: | For the short-term application on patients (max. 60 minutes). |
| Application site: | In clinics and practices for ENT doctors and phoniaticians. The therapy with the ATMOS stimulation and irrigation device may only be performed by medical trained staff. |
| Contraindications: | Do not apply to an infected resp. contaminated auditory canal or to a perforated eardrum. |
| The product is: | active |
| Sterility: | Not necessary |
| Single-use product / reprocessing: | No single use product |

1.3 Function

- Operating the main switch (❶, fig. 1) automatically activates the thermal process for reducing bacterial count (see section 4.2.1) .
- Then, automatic change into the irrigation mode. Here, irrigations with water warmed up to 37 °C and a flow of at least 400 ml/min can be effected.

1.4 Explanation of symbols



Observe operating instructions!
According to ISO /7000/0434 DIN 30600/1008 IEC 348



Type B equipment as to IEC 417



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



Temperature in degree centigrade



Heating ON



Heating OFF (energy saving mode)



Equipotential connection
DIN 30600 495, ISO 417 5021



Connection for waste water



Connection for water



- The Hygrotherm plus is produced according to IEC 601/ EN 60601 and listed in the following classes:
 - VDE Class of protection 1
 - Class IIa (EEC 93/42).
- The device may only be connected to a properly installed safety socket.
- The unit must be installed by a specialist authorized by ATMOS (see chapter 3.3).
- The Hygrotherm plus may only be used under the supervision of skilled staff who have been authorised by ATMOS and trained in its operation (IEC 601-1 / EN 60601-1).
- The mains voltage indicated on the type plate must correspond to the values of the supply network.
- Make sure prior to every application of the equipment that it is technically safe and in proper condition. Damaged cables must be replaced immediately!
- Correct configuration in assembly of country-specific connections:
 - green/yellow: protective conductor (PE)
 - blue: neutral conductor (N)
 - black or brown: phase (L)
- 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 on the installation surface.
- ☞ In the thermal process for reducing bacterial count hot water is being ducted 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 main switch after finishing work in practice and close water valve of supply.
- The ATMOS® Hygrotherm plus may be operated only in rooms used for medical purposes, but not in areas subject to explosion hazards and in oxygen rich environments.
- All additional equipment which is connected to the analogue and digital interfaces of the device must meet the requirements of relevant EN specifications (e.g. EN 60950 for data processing equipment and EN 60601 for electrical medical equipment). In addition, configurations must satisfy system specification EN 60601-1-1. When additional equipment is connected to the signal input or signal output section on the device, the person carrying out the connection is deemed „a system configuration operator“ and as such is responsible for meeting the requirements of system specification EN 60601-1-1. For answers to additional questions, please contact your local specialist supplier or the ATMOS Technical Service.
- The irrigation jet must not get into contact with contaminated material.
- Only use the warm water jet when a tube tip is installed!
- Take caution to avoid injury to the eardrum when introducing the water jet!
- For hygienic reasons jet connections must be changed after each patient. This also prevents retrograde germination of the warm water system.
- Use only for irrigation of 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 authorised by ATMOS.
- Please note:
A medical insulating transformer with earth leakage monitor or any similar safety system acc. to EN 60 601-1 is required, if several devices are connected over one common power supply. The transformer must correspond to the power consumption of all the devices to be connected.
- The flow rate has to be checked after switch on or at least once a day with a measuring cup. 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 the stimulation of the labyrinthine system, ATMOS offers the warm water units Hygrotherm plus (37°C) and Variotherm plus (20° - 47°C).

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

Requirement for taking into use

- The water which is 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 which come into contact with the water.*
- Carry out thermal cleaning at least 3 times before patient use.*

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

Running operation

- Before beginning the surgical operation, switch on the unit and await the thermal cleaning process.
- After the device had 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 and not longer than 4 hours to start the thermal cleaning mode.
- Exchange and disinfection required for contact parts such as the jet connection after each patient (prevention of retrograde germification).
- Before every use, spray water and check the temperature.

Service

- Ensure that the suspended particle filter is hygienically changed (see commissioning) (dispose of filter and carefully clean the filter glass). Ensure that no contact is made with the contaminated parts.
- Carry out thermal cleaning after each service.
- Depending on the quality of the drinking water available, a biofilm growth cannot be excluded (despite our patented thermal process for reducing bacterial count). We, therefore, recommend to test the drinking water quality in regular intervals (acc. to ISO 6222) at the drinking water connection on the unit and on the application part. In case of a significant rise of germs, a biofilm removing process with following disinfection can be carried out.



3.1 Scope of supply

Quantity

| | |
|---|--|
| 1 | Hygrotherm plus basic unit |
| 1 | Irrigation handle |
| 1 | Double-barrelled hose |
| 3 | Jet connection short, straight (80 mm) |
| 1 | Splash guard |
| 1 | Rubber bush for splash guard |
| 2 | Three-holes 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 455 x 340 x 250 mm |
| 1 | Padding for cardboard |
| 1 | Operating Instructions |

3.2 Illustrations

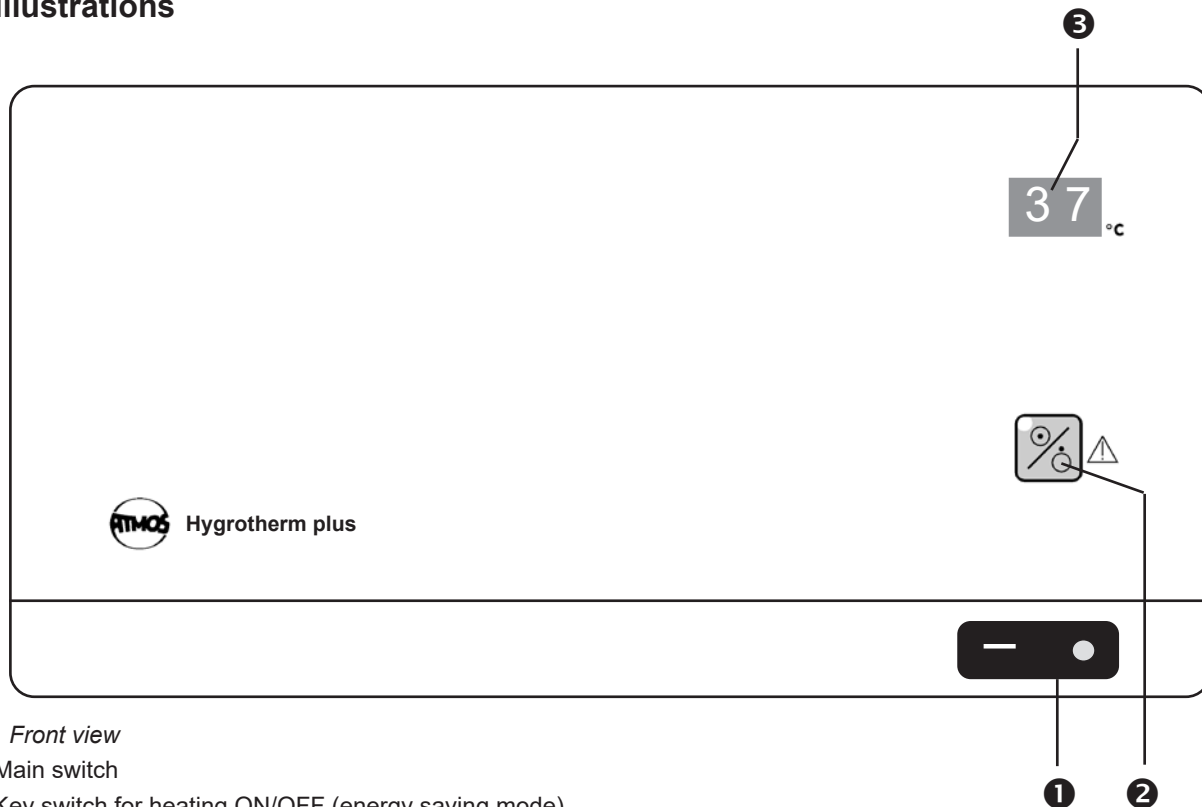


Fig. 1. Front view

- ❶ Main switch
- ❷ Key switch for heating ON/OFF (energy saving mode)
- ❸ Temperature display (two-figure number, resolution 1°C), current value indication

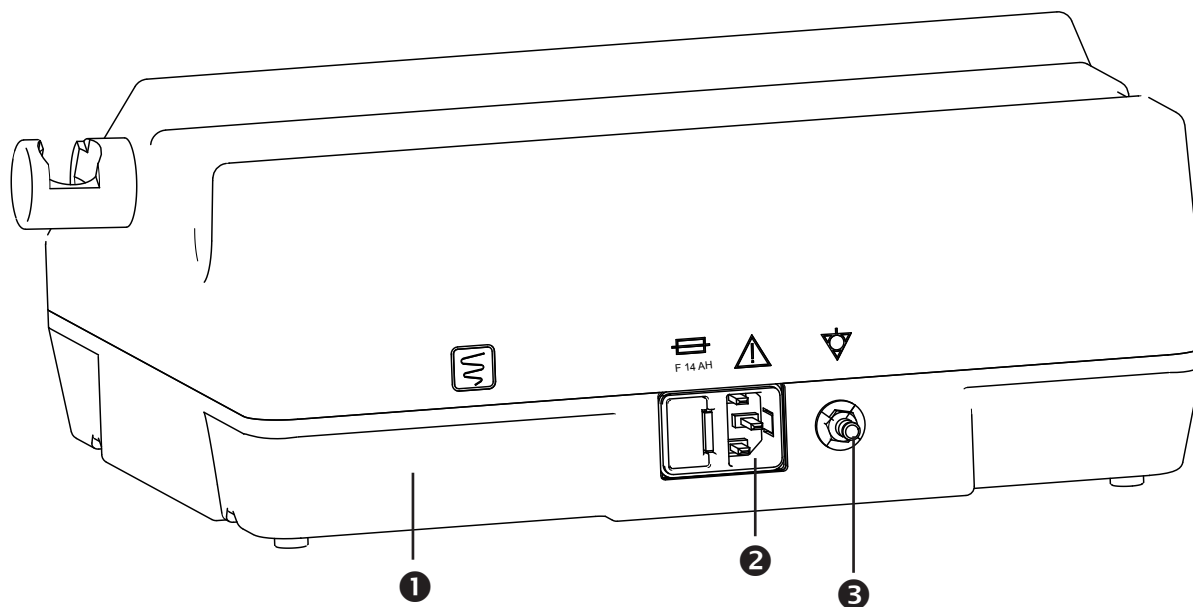


Fig. 2. Rear view

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

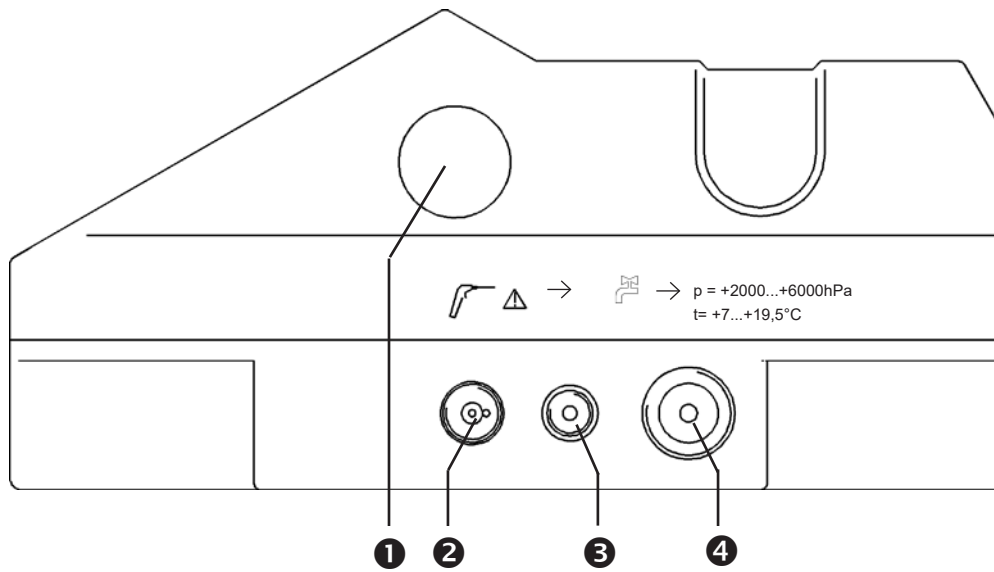
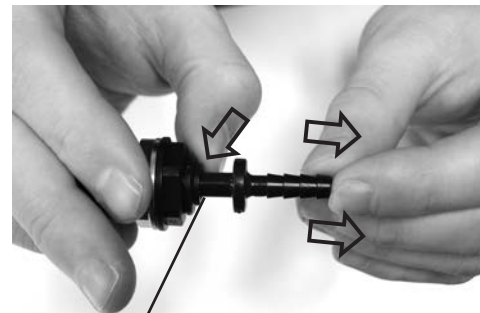


Fig. 3. Side view

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



Press down ring

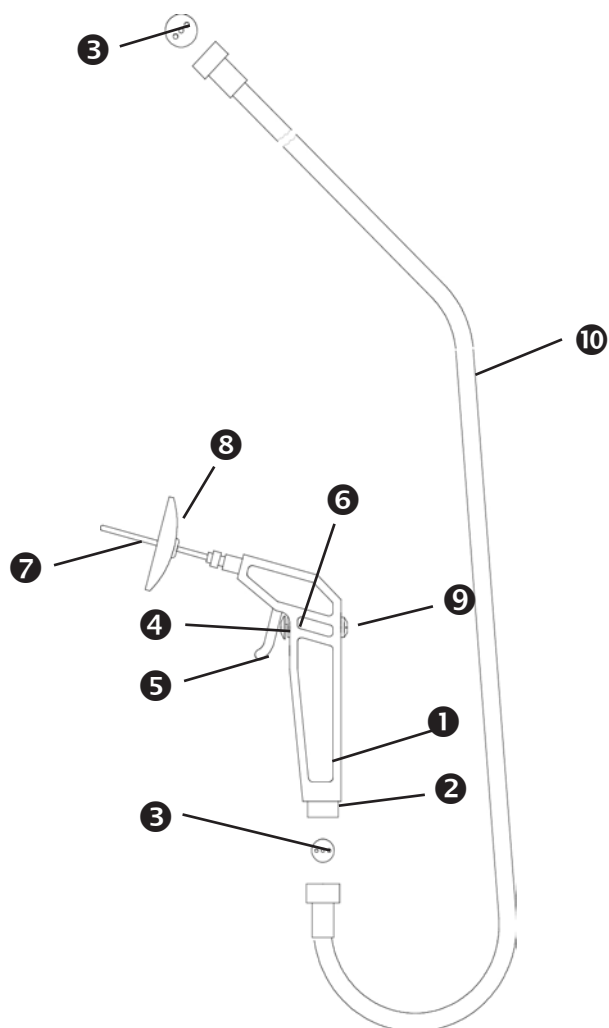



Fig. 4. Irrigation handle

- ① Handle
- ② Connection for double-barrelled hose
- ③ Three-holes gasket
- ④ Knurled screw
- ⑤ Release lever
- ⑥ Valve plunger
- ⑦ Jet connection
- ⑧ Splash guard
- ⑨ Cap
- ⑩ Double-barrelled hose

 The sprayer tube must be exchanged after each patient.

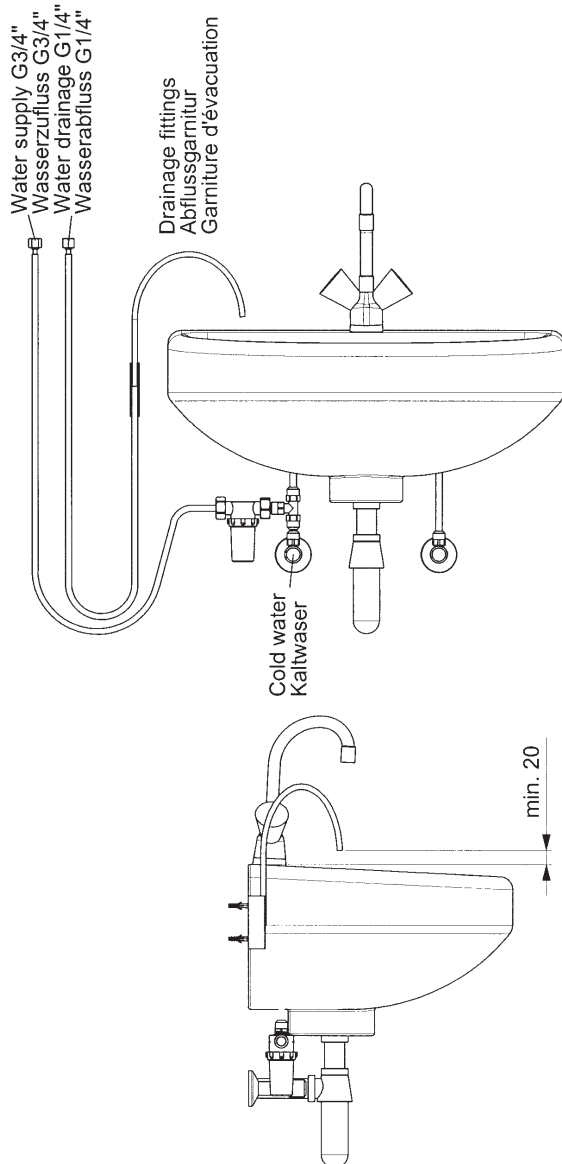


Fig. 5.

3.3 Connections

3.3.1 Connection to electrical power line

- According to the directions of VDE 0107 and VDE 0100, medically used rooms have to be equipped with a leakage current protective circuit (FI protective circuit) with a nominal leakage current of < 0.03 A. Installation must correspond with VDE 0107.
- Connect the power cable to the mains supply (⊕, fig. 2).
- Insert the power plug in a correctly installed socket with earthing contact.

3.3.2 Connecting a equipotential bonding connection

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

3.3.3 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 (Art.Nr. 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 to install 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 (⊕, fig. 3).
 - Insert the gaskets in the cap nuts of the waste water hose.
 - Join the nuts with the unit connection (⊕, 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°d resp. 2.5 - 3.8 mmol/l = hard water) and with hardness grade 4 (from 21°d resp. from 3.8 mmol/l = very hard water). Please contact your local water supplier and / or plumber.

| Water hardness | Millimol per litre | °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!



3.3.4 Connection of the irrigation handle

- Insert a "three-holes gasket" (⑩, fig. 4) in the double-barrelled hose and screw it (⑨, fig. 4) on the unit connection (⑧, fig. 3).
- ☞ Use only "three-holes gaskets" or the unit will not function correctly!
- Insert a "three-holes 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 (①, 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 into the irrigation mode (37°C).
- When the irrigation mode is not used (handle is not removed from its support) the unit change into the energy saving mode after 5 min.



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 Selecting temperature level

- 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).

4.2 Description of operating modes

4.2.1 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 being 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 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 into 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 (⑤, fig. 4).

Activation:

- Automatically after completion of thermal cleaning procedure and taking out the handle.
- When the irrigation mode is not used (handle remains in holder) the Hygrotherm plus changes into the 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.

4.2.3 Energy saving mode

Purpose:

Reduction of energy consumption.

Activation:

- Actuation of key "heating on/off" (②, fig. 1).
 - ↳ Heating is switched off.
- After five minutes of non-use of the unit.



5.1 General information on cleaning and disinfection

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

The hose tips must be exchanged after each use.

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

However, do not use

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

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

- ☞ 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 dry wiped.
- ☞ Always observe the instructions for use by the manufacturer of the disinfectants, including all concentration specifications.
- ☞ The described action relating to cleaning and disinfection resp. sterilisation do not substitute the relevant instructions which must be adhered to prior to operation.

5.2 Recommended 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 non-ionic surfactants | | Ecolab, Düsseldorf |
| Gigasept FF new (Application concentrate) | succindialdehyde dimethoxytetrahydrofurane corrosion inhibitors non-ionic 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 non-ionic surfactants enzymes preserving agents | 5-15 g < 5g | 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 at the same object colour changes may occur.



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

The ATMOS appliances Variotherm and ATMOS Hygrotherm are used, according to the rules, with disposable hose tips (disposables). These tips must be disposed off after each application to the patient.

When using the hose tips ATMOS recommends a reprocessing in line with the below cleaning and disinfection plan.

| | 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 | | | | | | | | | | |
|  | Ear irrigation bowl | X | X ^{2,4,5} | | Cleaning and disinfection (manual or automatic) | X | | | | |
|  | 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) | | | | Exchange 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 | |
|  | Rinsing lid with rinsing hose | X | X ^{2,4,5} | | Cleaning and disinfection (manual or automatic) | | X | | | |
|  | Rinsing bottle | X | X ^{2,4,5,6} | | Cleaning and disinfection (manual or automatic); cleaning in the dishwasher with the glass care programme | | 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, material compatibility, please see the relevant information from the manufacturer.

Important information

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

¹⁾ Please observe the manufacturer's operating instructions.

²⁾ Preferred: machine cleaning and disinfection in the 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 period tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures the person must have the necessary test devices and original spare parts.

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

- At least every 12 months a repeat test of the electrical safety should be performed according to IEC 62353. ATMOS recommends an inspection according to the manufacturer's specifications.

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 at water tap.
- Unscrew screwed glass of filter.
- Fill screwed glass with approx. 100 ml of decalcifier on acetic / citric, or lactic acid base (for inst. 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 Hygrotherm plus is again fully ready for operation. When water passages are heavily calcified, a modified procedure may become necessary, with a prolonged reaction period for the decalcifier.

6.2 Replacement of filter

- When the filter cartridge is very dirty (dark colour) the filter cartridge is to be exchanged as follows:
 - Close water tap of supply.
 - Switch on unit to reduce pressure in the filter body.
 - Switch off unit after appearance of "F 1".
 - Unscrew Plexiglass cup (4, fig. 6) from filter body (1, fig. 6) by turning anti-clockwise.
 - Extract filter cartridge (2, fig. 6) and replace by new one (Art.No. 502.0891.0).
- The filter element must not come into contact with contaminated objects in order to prevent the ingress of germs into the water system.

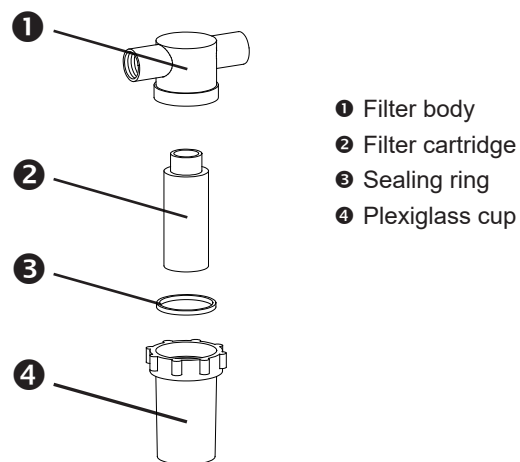


Fig. 6. Water filter

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 used accessories with the product.
- Fill in the form QD 434 „Delivery complaint / return shipment“ and the respective **decontamination certificate**.
- ☞ This form is enclosed to each delivery and can be found at www.atmosmed.com.
- The device must be well padded and packed in suitable packaging.
- Place the form QD 434 „Delivery complaint / return shipment“ and the respective **decontamination certificate** in an envelope.
- Affix the envelope to the outside of the package.
- Send the product to ATMOS or to your dealer.

Error in temperature display

| | | |
|------|---|---|
| "F0" | Handle is not in its support | <ul style="list-style-type: none"> • Insert handle in its support to allow thermal process for reducing bacterial count to start (jet connection must point to the back of the unit). • Replace handle (Art.No. 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 is missing (supply voltage on the control board) | <ul style="list-style-type: none"> • Inform the service staff. |
| "F3" | Break of the safety NTC | <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" | Break 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 the stimulation and irrigation mode but not in the thermal cleaning procedure | <ul style="list-style-type: none"> • If error does not disappear after a short moment inform service staff. |
| "F8" | Short-circuit of the regulating NTC | <ul style="list-style-type: none"> • 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) | <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 start any attempts to repair the unit yourself!



8.1 Accessories


| Description | REF |
|---|------------|
| Jet connection extra long, straight (110 mm) | 508.0429.0 |
| Extension of supply hose G3/4a-G3/4i, L =1,5 m..... | 501.0315.6 |
| Drainage fittings as to DIN 1988 | 502.0880.0 |
| Connecting cable for the equipotential compensation, L = 5m | 008.0596.0 |

8.2 Spare parts

| Description | REF |
|---|------------|
| Hygrotherm plus, basic unit, 220-240 V AC, 50/60 Hz..... | 502.0901.0 |
| Hygrotherm plus, basic unit, 110-127 V AC, 50/60 Hz..... | 502.0901.1 |
| 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 |
| Three-holes 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 |
| 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 Hygrotherm plus | 060.0362.0 |

9.0 Technical data



| | |
|--|---|
| Voltage range | 220 - 240 V~ ± 10 %; 50/60 Hz |
| Special voltage | 100 - 127 V~ ± 10 %; 50/60 Hz |
| Current consumption | 6.8 A (220 - 240 V~); 14.8 A (100 - 127 V~) |
| Power consumption | 1500 W |
| Modes of operation | <ul style="list-style-type: none"> • Thermal process for reducing bacterial count • Irrigation mode (water flow 0-450 ml/min at 37°C) • Heating OFF (energy saving mode) |
| Water temperature | 37°C |
| Temperature indication | Indication accuracy ± 0.5 s ± ½ digit |
| 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 |
| Fuses | F 8 A (f. 220 - 240 V~); F 15 A (f. 110 - 127 V~) |
| Protective earth conductor resistance | max. 0,1 Ω |
| Earth leakage current | max. 0.5 mA |
| Enclosure leakage current | max. 0.1 mA |
| Patient leakage current | max. 0.1 mA |
| Ambient conditions | -20...+50°C |
| Transport / storage | 5...90 % air humidity without condensation at an air pressure of 700...1060 hPa |
| Operation | +10...+35°C 20...80 % air humidity without condensation at an air pressure of 700...1060 hPa |
| Dimensions HxWxD | 14.5 x 37 x 32 cm |
| Weight | approx. 5.5 kg |
| Period tests | Repeat test of the electrical safety every 12 months. Recommended: inspection according to the manufacturer's specifications. |
| Safety class (EN 60601-1) | I |
| Degree of protection | Type B  |
| Protection class | IPX0 |
| Classification according to Appendix IX EC Directive 93/42/EEC | Ila |
| CE marking | CE 0124 |
| Applied standards | EN 60601-1: 1990 + A1:1993 + A2:1995 EN 60601-1-2: 1993 (EMV / EMC) |
| UMDNS code | 12-305 |
| GMDN code | 35152 |
| Reference-No | 502.0901.0 |
| Canadian Classification | |
| Device group | Ear, nose, throat |
| PNC | 77ETP |
| Risk Class | 2 |
| Description | STIMULATOR, CALORIC (WATER) |



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



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

11.1 Guidelines and Manufacturer's Declaration - Emissions

The ATMOS Hygrotherm plus is designed for operation in the environment specified below. The customer or user of the ATMOS Hygrotherm 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 ATMOS Hygrotherm 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 ATMOS Hygrotherm 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 ATMOS Hygrotherm plus is designed for operation in the electromagnetic environment specified below. The customer or user of the ATMOS Hygrotherm 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 | <p>< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle</p> <p>40 % U_T (60% Dip of the U_T) For 5 cycles</p> <p>70% U_T (30 % Dip of the U_T) For 25 cycles</p> <p>< 5 % U_T (>95 % Dip of the U_T) for 5 s</p> | <p>< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle</p> <p>40 % U_T (60% Dip of the U_T) For 5 cycles</p> <p>70% U_T (30 % Dip of the U_T) For 25 cycles</p> <p>< 5 % U_T (>95 % Dip of the U_T) for 5 s</p> | <p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS® Hygrotherm plus requires continued operation upon the occurrence of disruptions in the energy supply, the ATMOS® Hygrotherm plus should make use of an uninterruptible power supply or a battery.</p> |
| NOTE U _T is the mains alternating current prior to application of the test levels. | | | |

11.3 Guidelines and Manufacturer's Declaration - Immunity

The ATMOS® Hygrotherm plus is designed for operation in the electromagnetic environment specified below. The customer or user of the ATMOS Hygrotherm 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 | <p>Portable and mobile radio equipment should be used no closer to the ATMOS Hygrotherm plus, including cables, than the recommended distance calculated according to that which applies to the transmission frequency.</p> <p>Recommended distances: $d = (3.5 / V1) * \sqrt{P}$ $d = (3.5 / E1) * \sqrt{P}$ 80-800 MHz $d = (7 / E1) * \sqrt{P}$ 0.8-2.5 GHz</p> <p>where „P“ is the max. power in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site (a) survey, should be less than the compliance level (b). Interference may occur in the vicinity of equipment containing following symbol:</p>  |
| Radiated HF disturbances acc. to IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | |



NOTE 1 By 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 ATMOS® Hygrotherm plus is used exceeds the compliance level above, the ATMOS® Hygrotherm plus must be observed to demonstrate proper function. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ATMOS® Hygrotherm 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 ATMOS® Hygrotherm plus

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

| Nominal output of the transmitter W | Safety distance, depending on transmit-frequency m | | |
|--|--|---|--|
| | 150 kHz to 80 MHz $d = [3,5 / 3] \sqrt{P}$ | 80 MHz to 800 MHz $d = [3.5 / 3] \sqrt{P}$ | 800 MHz to 2.5 GHz $d = [7.0 / 3] \sqrt{P}$ |
| 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.



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