

# Users manual

ENT Diagnostic & Treatment Unit

MODULA Europa



## Introduction

Thank you for choosing our MODULA Europa Treatment unit. Its modular design allows the unit to be used for a wide range of applications in every practice or hospital. These operating instructions contain information on operation, care and simple maintenance tasks. All the information on the following pages, relate to a MODULA unit fitted with all optional functions of equipment. Descriptions for items which are not installed are therefore non-binding.



**Caution! Before using the treatment unit, please read these operating instructions carefully.**

These operating instructions were produced by G. Heinemann Medizintechnik GmbH and have been checked for accuracy. They do not, however, claim to be complete. All information may be amended without prior notification. No part of these operating instructions may be copied or broadcasted by any method or means, whether electronic or mechanical, without the written approval of G. Heinemann Medizintechnik GmbH.

## Signs and Symbols



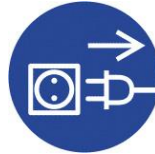
*Attention!*



*Attention! Hot!*



*Dangerous Voltage!*



*Pull plug before opening!*



*Note*



*Read user's manual!*



*Applied part  
Type B*



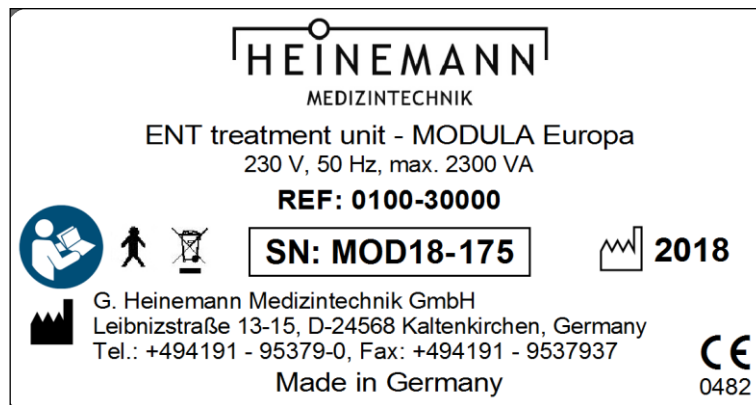
*Applied part  
Type BF*



*Do not look into  
the light source!*



*UV radiation!*



*Type label MODULA Europa*

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## 1 General Notes for Use

The MODULA ENT treatment unit may only be used by qualified persons to guarantee appropriate usage of the device. Only persons who have been instructed for correct usage of the device are allowed to use the device. Instructions may only be given by persons who were authorized by G. Heinemann Medizintechnik GmbH.

As for all highly developed technical devices, care and regular maintenance of the treatment unit is crucial. You should ensure that you are thoroughly familiar with the functions and specifications of the device.



**Caution!** Before using the device, it is essential that you thoroughly familiarize yourself with the functions of the treatment unit.



**Caution!** G. Heinemann Medizintechnik accepts no liability for the safety or proper function of the device where it has been installed, extended or repaired by persons who have not been authorized by the manufacturer or if the device is used incorrectly or other than as described in the operating instructions

### 1.1 Intendend use

The product is a Class IIa medical device as defined by Directive 93/42/EEC, active and not sterile product. The product is to be used for human medical purposes only. The product consists of a metal body and additional functions.

The treatment unit is intended for diagnosis and treatment of ENT conditions. Application organs are mouth to pharynx, auditory canal to the ear drum and the nasal cavities. Application time for ENT unit: short term use on the patient (up to 30 days), main systems: temporary application on the patient (less than 60 minutes). Application sites are clinics and practices for ENT doctors and phoniatriests. The examination and/or therapy with the ENT unit may only be executed by medically trained persons.

Operation of the unit requires a power supply and, depending on the equipment installed, water and drainage connections. Specifications for these can be found in the appendix.

## 1.2 Indications / Contraindications

The treatment unit is for use in all transient examinations of the ear, nose and throat in hospitals or medical practices. The following table provides an overview of potential indications and contraindications:

<b>Ear Irrigation:</b>	Cleaning of the auditory canal Examination of the auditory triangle (caloric reflex test)
<b>Suction:</b>	Suction of blood (emergency, bleeding, post-surgery) Suction of exudate after surgery Suction of exudate / secretion Cleaning of the auditory canal Cleaning of the paranasal sinuses Oral suction (tonsillolith / pus)
<b>Compressed air:</b>	Application of medicine (nebulisation), also onto surfaces Politzerisation
<b>Light Sources:</b>	Illumination (endoscopy / headlight)

*Table 1: Indications*

<b>Ear Irrigation:</b>	Eardrum perforation Cholesteatoma Otitis media chronica Acute dizziness Otitis externa Tympanoplasty sugery
<b>Suction:</b>	suction of secretion (tinnitus patients)
<b>Compressed Air:</b>	Skull and brain injuries Orbit / eyeball injuries Cerebrospinal fluid fistula After tympanic surgery Sinusitis Rhinorrhea Temporal bone fracture

*Table 2: Contraindications*

## 2 Delivery and Unpacking

Please examine the treatment unit for any transportation damage and check that all items are at hand immediately on receipt. Check the enclosed delivery note. Failure to do so may result in loss of the right to replacement. Some accessories are packed inside the treatment unit.

## 2.1 Claims

Any missing parts or incorrect functionality should be reported to the supplier of the treatment unit together with the invoice, serial number and a precise description of the fault, immediately!

## 2.2 Installation



**Caution!** G. Heinemann Medizintechnik accepts no liability for the safety or proper function of the device where it has been installed, extended or repaired by persons who have not been authorized by the manufacturer!



**Caution!** The treatment unit must not be used in areas in which there is a danger of explosion.

An authorized service technician will connect and set up the treatment unit for use after delivery.

Please ensure that water and power connectors are properly installed by a plumber. Further information can be obtained from our service department.



**Caution!** Repair or replacement of the power cable may only be performed by authorized technical staff.

A water and power supply connection diagram is contained in this manual (Page 9). The dimensions for water connections given in the diagram below must be adhered to.

### Electrical connection:

- Movable multiple power distributor (multiple socket) may not be used as mains connection for the MODULA treatment unit. Every single consumer (e.g. a water separation system, a microscope or an endoscopic camera) must be contacted via a separate mains connection (grounded socket).
- Installation according to DIN VDE 0100-710 (IEC 60364-7-710): Residual current device with nominal residual current <30 mA
- Connect the MODULA treatment unit power cable to a safety socket, at a maximum of 1.5 m away from the treatment centre
- The supply circuit must be separate from other devices, such as is done with PCs.
- If the treatment centre is supplied by via an isolating transformer, then there must be insulation monitoring in the isolating transformer.
- Treatment unit connected load: 2.300 VA, the electrical connection must be able to deliver the corresponding power in accordance with DIN VDE 0100-710. Further data can be found in the instructions for use (heading: Technical data).

**Water connection / water inflow:**

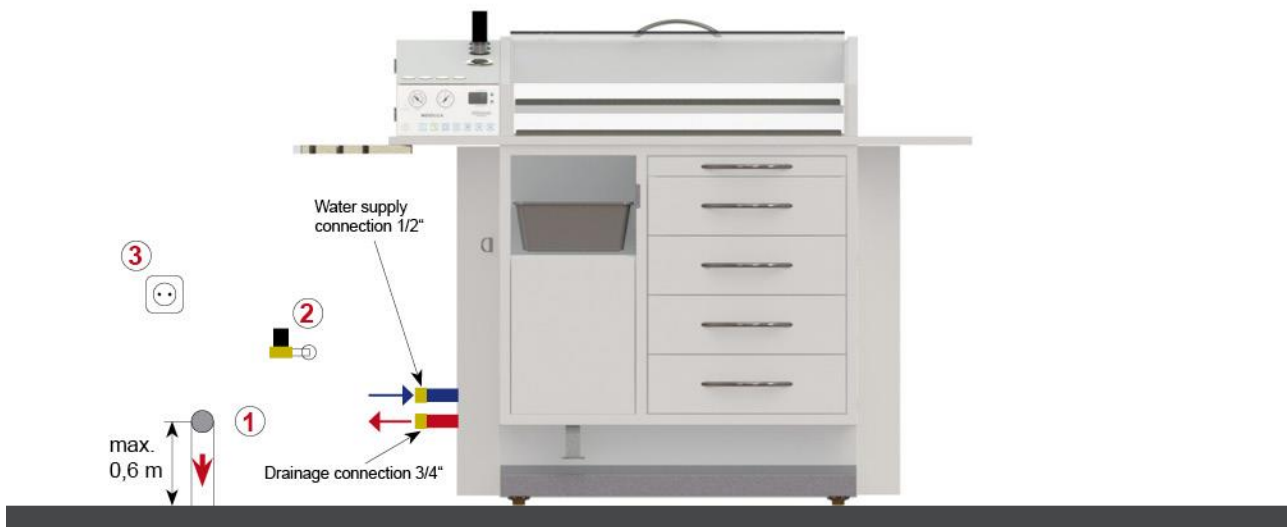
- To an easily accessible 1/2" angle valve with a 3/8" x 10 mm compression fitting or a 1/2" WAS valve with 3/4" outlet
- It must be possible to easily turn off the water flow (without tools)
- Minimum height of the water connection above the floor: 10 cm
- Distance of the water tap to the treatment unit, max.: 150 cm
- House-side required water pressure: > 3 bar and < 5 bar
- The water provided at the house connection must comply to at least the WHO international guidelines and the country-specific guidelines for drinking water.
- The country-specific connection conditions must be observed when connecting to the public sewage network.
- The connect to a suitable water separation system is recommended, to comply with the requirements of the German Drinking Water Ordinance (EN 1717).
- When the water hardness is more than 2.5 millimoles total hardness (millimoles of calcium carbonate) per litre, (> 14°dH) lime scale protection is necessary. Information about water hardness can be obtained from the local water supplier.

**Water drainage**

- Waste water drainage connection / sleeve from 32 mm - 50 mm HT alternative: 3/4" or 1" threaded connection
- Maximum height from the floor: 60 cm
- Distance of the water tap to the treatment unit, max.: 150 cm

Our service technician / medical products advisor will instruct you on operation after installing the device.





- ① Drainage: drainage pipe Ø 50 mm, max. height over ground 0.6 m
- ② Water supply: Aqua-Stop with angle valve (compression fitting) 3/8", recommended water pressure 3 - 5 bar
- ③ Power supply: 230 V, 50/60 Hz, max. 10 A

Fig. 1

### 3 Safety instructions



- The device must be directly connected to a properly installed earthed socket. The supply voltage must be conform to the voltage indicated on the type label. Rooms used for medical purposes must be equipped with residual current circuit breakers
- The power cord may only be replaced or repaired by authorized technical staff from G. Heinemann Medizintechnik GmbH or local authorized representatives
- Ensure that the device is functioning correctly and in a proper condition before each use. Any damaged cables or tubes must be replaced immediately. Malfunctions must be reported to the technical service department without delay
- Avoid spilling liquids or placing used (contaminated) instruments on the treatment unit. If your unit has a tray for discarded instruments, ensure that instruments are discarded such that no liquids enter the treatment unit. For further hygiene and care instructions, please refer to our hygiene brochure

- Please be aware of the risk of crushing injuries from moving parts!
- Do not simultaneously touch parts inside the suction bottle compartment and/or the light source compartment and the patient!
- The environmental conditions specified in chapter 11.1 must be adhered to.
- The suction of the MODULA units is intended for the aspiration of liquids in the medical field. Please note the contraindications. If you use the extraction system to remove cerumen, pay attention to the choice of the appropriate cannula, and to the noise level in the patient's ear. No explosive, flammable or corrosive gases or liquids may be extracted.
- The MODULA unit meets the standards for susceptibility to interference set out in EN 60601-1-2 (EMC of medical electrical equipment). The MODULA unit may not be used in conjunction with devices which do not conform to the standards EN 60601-1 "Medical Electric Equipment" and EN 60601-1-2 "Electromagnetic compatibility (medical electric equipment)".
- The warranty does not cover loss or damage occurring as a result of the use of third party accessories or consumables. Heinemann Medizintechnik is not liable for bodily injury or damage to property in the event that parts other than original Heinemann parts are used, in the event of failure to observe the instructions for use given in these operating instructions or if the device has been assembled, reinstalled, modified, extended or repaired by persons not authorized by G. Heinemann Medizintechnik GmbH.
- **Attention!** Due to strong light energy, increased heat emission may occur at the tip of the endoscope and/or the light source output. Avoid close proximity between human tissue and the endoscope tip, the light cable end and the cold light source output as this may lead to coagulation of tissue. Always avoid direct contact between the endoscope tip and tissue when performing endoscopy.
- **Caution! Fire Hazard!** Never place the light cable or endoscope on heat-absorbing surfaces (e.g. dark cloth) or in proximity to fabrics soaked in flammable liquids. Heat accumulation at the endoscope tip or light cable end may ignite a fire.
- **Caution when working with endoscopes connected to light sources!** Dangerous heat rays are filtered by a special integrated filter. However, light intensity is high. Do not look directly into the light output. In case of defective light source, remove the endoscope from your working area
- **Instruction for replacement of light bulbs!** Always pull the main power plug of the ENT treatment unit before replacing light bulbs! Leave enough time for cool down of light bulbs (at least 15 minutes) before replacing light bulbs! **Caution! Danger of injuries!** Light bulbs may burst when performing

light bulb replacement. Splitter may injure eyes and skin. Always wear protective glasses and clothing

- **Suction system:** When fluids or solids are vacuumed into the vacuum pump due to a failure, you must contact Heinemann Medizintechnik authorized technical staff. In this case, the suction system must be repaired by authorized technical staff, incl. replacement of vacuum pump and tubes.

## 4 Operation instructions

The treatment unit should be inspected and its proper function checked daily prior to being used with patients (tubes, cable connectors, display instruments, cleanliness, etc.)



**Proper power and water connections of the treatment units must be secured at all times!**

The unit is operated using a touch-sensitive glass surface, which covers a set of sensors. The sensors transform touches of the sensor field into a switching signal. The sensors react to touch with a short delay (in order to avoid unintended touches) and activate the relevant function. Activation of a function is confirmed with a click. After activating a function, the colour of the sensor field changes from blue to green. It remains blue for as long as the function remains active.

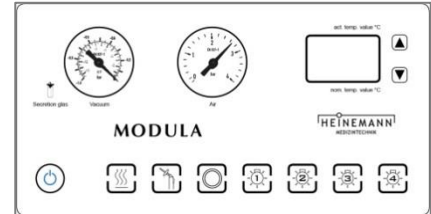


Fig. 2

### 4.1 Main power switch

Pressing the main power switch (Fig. 3) sets the treatment unit into standby mode. The Fig. 3 shows the OFF position (O) of the switch. For activating, press the rocker switch to the ON – position (I). To activate the unit, press the standby-key (Fig. 4) for approx. 3 seconds. Now the treatment unit is ready for use. This state is indicated by green illumination of the standby key and blue illumination of other function keys. Only those keys of functions which have been ordered with the unit are illuminated blue. To set the unit back in standby mode, touch the standby key for 3 seconds. Function key illumination is switched off and only the standby keys remains illuminated in blue.



Fig. 3



**Note: Always switch the unit into standby mode before switching it off with the main power switch.**

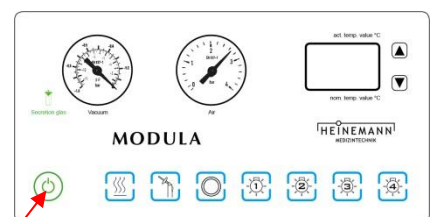


Fig. 4

### 4.2 Mirror Heater (Standard)

After touching the mirror heater key (Fig. 5), warm air is blown out of the mirror heater (Fig. 6). The mirror is heated at a distance of 3-4 cm from this opening. The mirror heater remains active for about 20 seconds before switching itself off automatically. In order to avoid accumulation of heat within the mirror heater, the fan continues to run for a further 10 seconds.

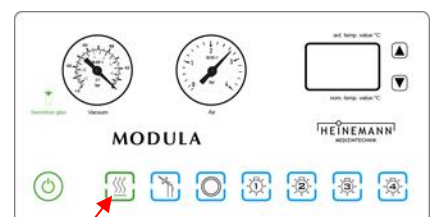


Fig. 5

Should a high temperature be detected, a safety thermostat will deactivate the mirror heater.



**Caution!** Do not place any objects or body parts directly over the opening, as the metal grid can become very hot!



Fig. 6

### 4.3 Suction System with manual emptying

Suction is automatically activated when the suction handle is picked up from the swivel arm.



**Caution!** Always use suitable suction catheters for suctioning and regulate the suction flow to prevent any risk of injury as a result of excessive pressure focused at a single point.

The end of the suction tube has an adaptor for either an ear rinsing bowl or a suction cannula (**you have to change the suction cannula after each patient!**). After completing treatment, the vacuum pump deactivates automatically when the suction tube is replaced in the suction tube holder (the 3rd holder from the left on the swivel arm). Patient secretions are suctioned into a dedicated reservoir which is located behind the side cover (Fig. 9), where they are collected until the reservoir is full.

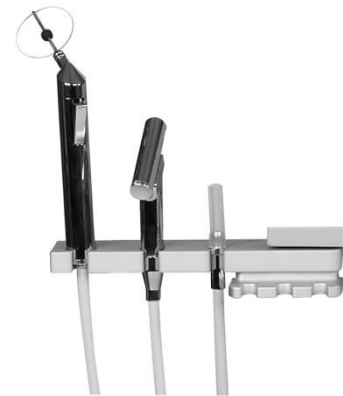


Fig. 7



**Caution!** If you use the extraction system to remove cerumen, pay attention to the choice of the appropriate cannula, and to the noise level in the patient's ear. Otherwise there is a risk of damaging the eardrum.

For reasons of hygiene, this reservoir should be emptied daily. The reservoir will otherwise continue to fill until the overflow prevention mechanism is triggered. A red warning light on the control panel indicates that the reservoir is full (Fig. 8). The reservoir must be emptied when this warning light is illuminated.

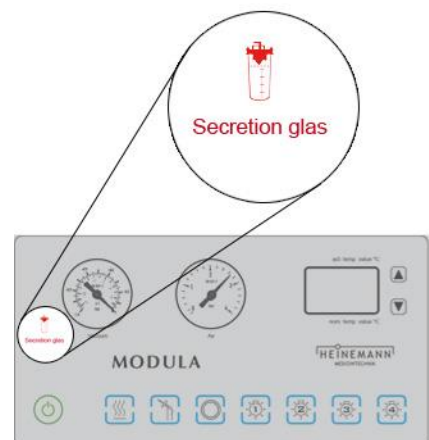


Fig. 8

Optional manual suction pressure control, allowing the required suction pressure to be controlled using a control knob or an adapted “Fingertip”, can be ordered separately.



**Caution!** The contents of the suction reservoir may be contaminated.



Fig. 9

#### 4.4 Suction System with automatic emptying „Sekretomatik“ (option)

Suction is automatically activated when the suction handle is picked up from the swivel arm.



**Caution!** Always use suitable suction catheters for suctioning and regulate the suction flow to prevent any risk of injury as a result of excessive pressure focused at a single point.

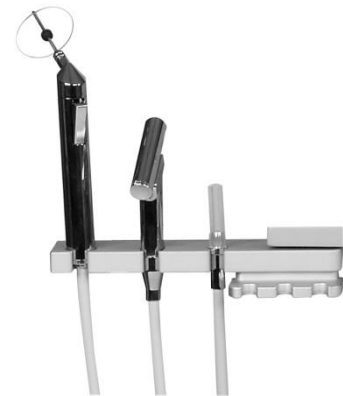


Fig. 10

The end of the suction tube has an adaptor for either an ear rinsing bowl or a suction cannula (**you have to change the suction cannula after each patient!**). After completing treatment, the vacuum pump deactivates automatically when the suction tube is replaced in the suction tube holder (the 3rd holder from the left on the swivel arm).

After the suction tube is placed in the swivel arm, the „Sekretomatik“ function is automatically activated. The suction bottle (secretion glas) is automatically emptied through the drainage tube (approx. 9 seconds). After it is emptied, the suction bottle is automatically rinsed with water (approx. 6 seconds). A small amount of water remains in the suction bottle to prevent adhesion of residues. If the suction bottle cannot be emptied due to a defect, suction system is automatically deactivated and indicates the failure with a blinking red LED (Fig. 11). Please check the suction bottle (open side cover, Fig. 12) and empty the suction bottle manually. If the defect occurs again, please contact Heinemann Medizintechnik authorized technical staff.

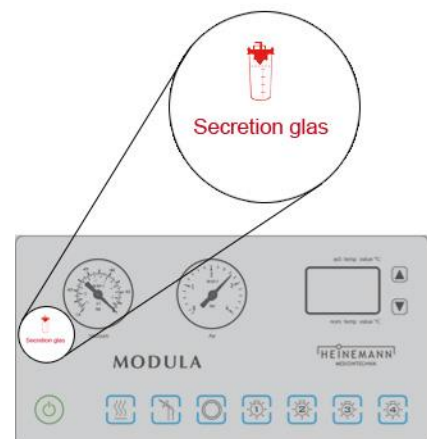


Fig. 11

Optional manual suction pressure control, allowing the required suction pressure to be controlled using a control knob.



**Caution!** If you use the extraction system to remove cerumen, pay attention to the choice of the appropriate cannula, and to the noise level in the patient's ear. Otherwise there is a risk of damaging the eardrum.



Fig. 12

#### 4.5 Tube rinsing system (option)

In order to prevent accumulation of secretion and blockages in the suction system, we recommend using the optional tube rinsing system. The tube rinsing system (Fig. 13) is activated when the suction tube is pressed onto the tube rinsing nozzle with the silicone tube (**important!**) attached. The automatic tube rinsing system starts after 0.5 s and continues for 3 s. (an error will be registered if the rinsing nozzle is activated before the suction unit. The 'Suction reservoir full' light on the control panel will flash alternately red and green. The tube rinsing system will in this case be deactivated). This can be repeated, but should not be repeated more than three times, as the collecting reservoir will quickly become full.



Fig. 13



**Note!** We recommend using the tube rinsing system at least daily.

#### 4.6 Tube rinsing system with disinfection solution (option)

In addition to the standard tube rinsing system (using water), it is also possible to install a disinfectant container for a disinfectant rinse.

The tube rinsing system (Fig. 14) is activated when the suction tube is pressed onto the tube rinse nozzle with the silicone tube (**important!**) attached. The automatic tube rinsing system starts after 0.5 s. The suction tube is rinsed with disinfectant (50 ml from the disinfectant container) for 5 s. This can be repeated, but should not be repeated more than three times, as the collecting reservoir will quickly become full.



Fig. 14



An error will be registered if the rinsing nozzle is activated before the suction unit. The 'Suction reservoir full' light on the control panel will flash alternately red and green. The tube rinsing system will in this case be deactivated). This may be repeated, but should not be repeated more than three times, as the collecting reservoir will quickly become full.



**Note!** We recommend using the tube rinsing system at least daily.

#### 4.7 Cannula rinsing system with disinfection solution (option)

Additionally optional to the simple tube irrigation is a cannula rinsing with a disinfectant. In this case, disinfectant is taken from a container (attached to the left side door) for rinsing the hose.

The cannula rinse is activated by holding the suction tube with the attached cannula, in the rinsing tube nozzle (Fig. 15). The cannula is immediately flushed with the disinfectant solution from the container. This process can be repeated, but should not be done more than three times consecutively, since the capacity of the collecting container (secretion glass) is quickly reached after repeated use.

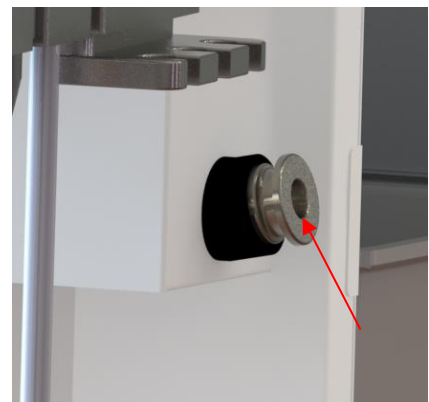


Fig. 15

#### 4.8 Second suction hose (option)

In addition to the main suction function, you have the possibility to order an optional second suction application, to which you can directly attach an ear irrigation cup or a spit bowl (only possible with original Heinemann accessories). This second suction hose is located separately, in the space provided in the swivel arm (Fig. 16).

To activate / deactivate the suction function, please move the slider up or down. Thus you have the possibility to regulate the suction strength. If the additional extraction function is no longer needed, please close the regulator. Otherwise, the performance of the main suction will be reduced.

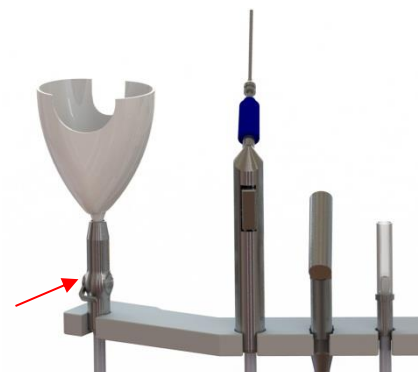


Fig. 16



## 4.9 Compressed air system (option)

The compressor is activated when the unit is switched on. It compresses air into a compressed air reservoir until the fixed or required pressure is achieved. The air pressure (bar) is displayed on the right manometer (Fig. 17). The delivered pressure can be adjusted using the lever on the compressed air sprayer (Fig. 19). If the lever is depressed with more force, more air is discharged from the air outlet. An optional continuously variable control knob allows air pressure to be adjusted within the range 0.2 to 2.5 bar (required for "Pulitzer"-application or for application on children!). For Pulitzer application or for use on children, the pressure must be set to 0.5 bar! To do this, please throttle the compressed air regulator until the desired pressure is displayed on the pressure gauge. The unit is able to generate a maximum pressure of 2.5 bar.

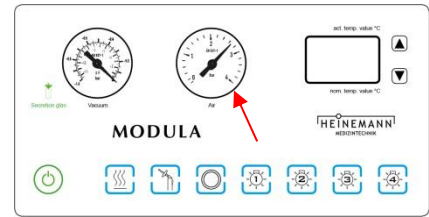


Fig. 17



Fig. 18



**Caution!** Politzer application may only be performed on units with an optional compressed air regulator and at a maximum pressure of 0.5 bar. Please check the pressure gauge and that the unit is functioning correctly beforehand.



Fig. 19

## 4.10 Ear irrigation system with water connection (option)

The hot water irrigation system is primarily used for ear irrigation. The hot water irrigation system is activated by touching the water irrigation key. A temperature indicator continuously displays the preset and actual water temperatures (Fig. 20). The top temperature is the actual temperature, the bottom temperature the factory-set target temperature (+37° C). An electronic safety system prevents the water temperature from rising and deactivates the water system if the temperature reaches +45° C.



**Caution!** Check the water temperature before using the ear irrigation system. Check the temperature display and run some water over the back of your hand if necessary.

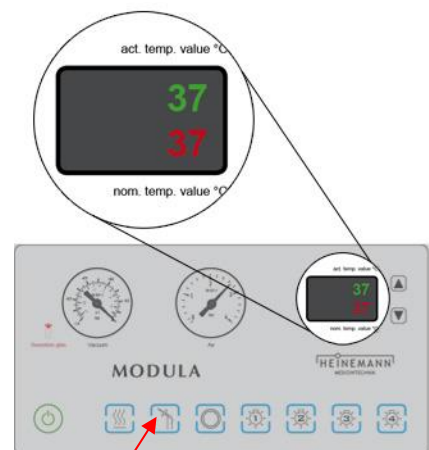


Fig. 20



**Caution!** The water jet must not be directed directly at the eardrum.

Flow rate (max. 500 ml/min) is adjusted using the lever on the ear irrigation handle (Fig. 21). **You have to change the water cannula after each patient!**



**Caution!** The unit should be taken out of service and customer services informed if severe fluctuations in temperature are experienced (persistent deviations of more  $\pm 3^{\circ}\text{C}$  from  $+37^{\circ}\text{C}$ ).

Since the process water is low in germs but is not sterile, and because the system occasionally contains stagnant water, a water sterilization filter and splash guard must be used (Fig. 22). This filter (with a stand-life of 4 weeks) is an extension between the water syringe and the cannula and is included in the scope of delivery. We additionally recommend, that if the unit has not been used for a longer period, to activate the ear irrigation for a few minutes while also pressing the water syringe (without sterile filter).

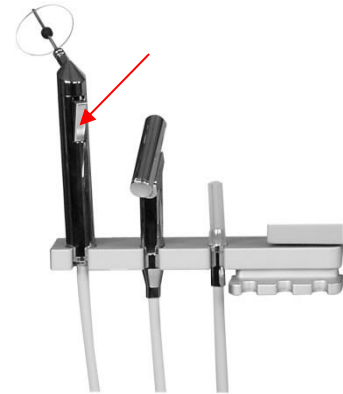


Fig. 21



Fig. 22

#### 4.11 Autonomous ear irrigation with water tank (option)

Treatment units equipped with an internal water system are supplied with water via a 5 liter tank installed behind the unit. The water is heated by a water heating system.



**Caution!** Before working with the water irrigation, ensure that there is enough water in the tank (the tank should ideally be full). Check water temperature before each use.

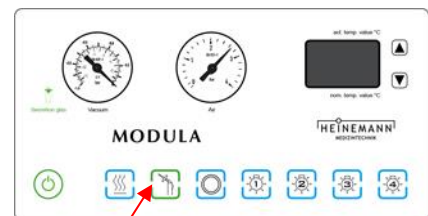


Fig. 23

Touching the key activates the ear irrigation system (Fig. 23). Water temperature is preset to  $+37^{\circ}\text{C}$  (**no** display indication). A thermostat and an additional safety system (activated at  $+45^{\circ}\text{C}$ ) provide redundant protection against excess temperatures.



**Note!** The irrigation system should be deactivated when not in use. This saves energy and extends the lifespan of the pump.

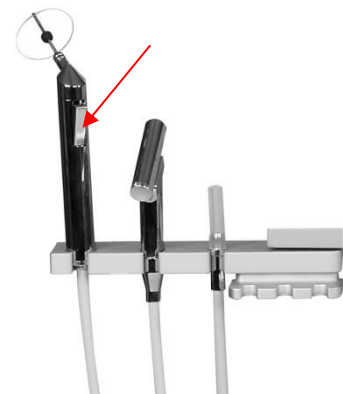


Fig. 24



**Caution! The water jet must not be directed directly at the eardrum.**

Flow rate is adjusted using the lever on the water handle, max. 500 ml/min. (Fig. 24). **You have to change the water cannula after each patient!**

Since the process water is low in germs but is not sterile, and because the system occasionally contains stagnant water, a water sterilization filter and splash guard must be used (Fig. 25). This filter (with a stand-life of 4 weeks) is an extension between the water syringe and the cannula and is included in the scope of delivery.

We additionally recommend, that if the unit has not been used for a longer period, to activate the ear irrigation for a few minutes while also pressing the water syringe (without sterile filter).



Fig. 25

#### 4.12 Cold light sources, halogen (option)

The system features four completely independent LED light sources. Light sources are activated by touching keys 1-4 (Fig. 26). After 15 minutes, the respective light source switches off automatically. If you want the illumination to remain switched on for a longer period of time (unlimited), then you must hold down the light button for about 2 seconds when activating the respective light source (OP mode). Only one light source can be activated at a time. If a cold light headlight is used, the cold light source will switch on when the headlight is removed from its holder. This cold light source can also be switched on from the control panel as a 'normal' cold light source using the corresponding key, should you subsequently prefer an alternative use. This requires the headlight holder to remain actuated or the jack to be removed in order to deactivate the holder.

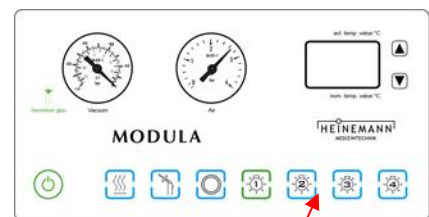


Fig. 26



Fig. 27

All treatment units are equipped with removable STORZ-type light outputs (Fig. 27 + 28) as standard. Other outputs can be supplied on request. An adaptor at the end of the optical cable can be used to connect lenses or endoscopes. Please ensure that you use the correct adaptor.



**Note! Save energy by only activating the cold light source when it is needed. This also extends the life of the lamps.**



Fig. 28



**Caution!** Never direct the light beam directly into the eyes! Always use a light output adapter (Storz, Olympus, Pentax, Wolf) on the light source side, otherwise the heat-absorbing glass or the lens could be damaged.

#### 4.13 Cold light sources, LED (option)

The system features four completely independent LED light sources. Light sources are activated by touching keys 1-4 (Fig. 29). After 15 minutes, the respective light source switches off automatically. If you want the illumination to remain switched on for a longer period of time (unlimited), then you must hold down the light button for about 2 seconds when activating the respective light source (OP mode). Only one light source can be activated at a time. If a cold light headlight is used, the cold light source will switch on when the headlight is removed from its holder. This cold light source can also be switched on from the control panel as a 'normal' cold light source using the corresponding key, should you subsequently prefer an alternative use. This requires the headlight holder to remain actuated or the jack to be removed in order to deactivate the holder. The LED cold light sources have light intensity adjustment close to the light output.

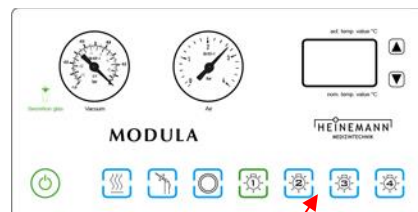


Fig. 29



**Note!** If an LED light source should fail, first check that the intensity adjustment has been accidentally turned to zero.



Fig. 30

All treatment units are equipped with removable STORZ-type light outputs (Fig. 30 + 31) as standard. Other outputs can be supplied on request. An adaptor at the end of the optical cable can be used to connect lenses or endoscopes. Please ensure that you use the correct adaptor.



**Note!** Save energy by only activating the cold light source when it is needed. This also extends the life of the lamps.



Fig. 31



**Caution!** Never direct the light beam directly into the eyes! Always use a light output adapter (Storz, Olympus, Pentax, Wolf) on the light source side, otherwise the heat-absorbing glass or the lens could be damaged.

#### 4.14 Sensor control for the light sources (option)

If your treatment unit is fitted with an optional sensor control for the light sources, then the light will automatically switch on when the respective light cable is withdrawn. You can store a maximum of three light cables in the respective holder (Fig. 32).

Please note that the reliable function of the automatic system is only guaranteed if the light guide is in the appropriate holder on the swivel arm. The assignment of the light sources is from left to right, from 1 to 3.

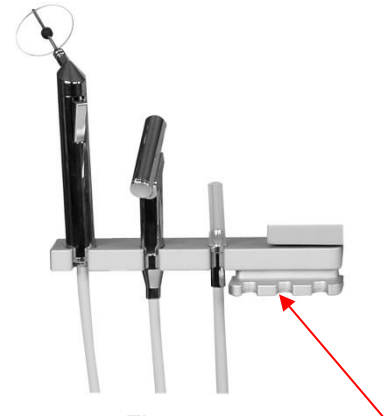


Fig. 32

#### 4.15 Endoscope holders (option)

ENT treatment unit may be equipped with pre-heated endoscope holders (Fig. 33) in order to store and warm up endoscopes. Endoscope holders are preheated to a preset temperature of +37° C. Adjustment of temperature can and only may be performed by authorized technical staff of G. Heinemann Medizintechnik GmbH or local representatives. Endoscope holders are also available without preheating system (optional).



Fig. 33



**Caution!** Only endoscopes which are suitable for warming should be placed in these holders!

**Caution!** Before using on patients, please check the temperature of the endoscope.

#### 4.16 Storage quivers for used endoscopes

The storage quivers can be filled with liquids (for example cleaning/ disinfecting solutions) and Endoscopes can be stored in. The particular shape of the quivers avoids contamination of endoscopes and surroundings. The complete silicone plug should be immersed in the disinfecting solution.

The quivers offer a safe storage of the sensitive endoscopes as well as an even wetting. They are suitable for all endoscopes (diameter from 2,7 to 12 mm) with maximum length of 190 mm. The endoscopes can be safely inserted and removed without any contact to the parts of the quivers which are not immersed in the disinfecting solution.

The storage quivers are made of medically approved polypropylene and silicone. They can be disinfected and sterilized (pressure 2,3 bar, temperature +134° C, holding time 10 min.). They fit in the appropriate openings in the ENT treatment unit.

The cleaning/ disinfection solution must be filled up in the quivers, like on the pictures 34 and 35: for laryngoscope, see figure 34; for all other endoscopes, see figure 35 (approx. 0,5 cm above the silicone plug)



**Attention!** The purpose of the storage quivers is not the treatment of contemned endoscopes. They should be properly sterilized according to the recommendations of the Commission for Hospital Hygiene and infection prevention (KRINKO) at the Robert Koch-Institut (RKI) and of the Federal Institute for drugs and medical products (BfArM). For the users, it is mandatory to follow the instructions for sterilization of the manufacturers.

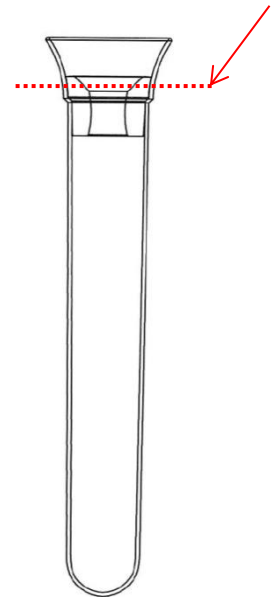


Fig. 34

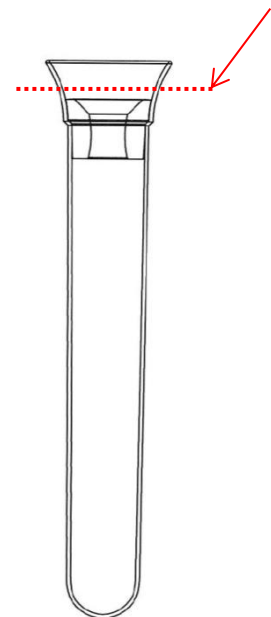


Fig. 35



#### 4.17 Pre-heated instrument level (option)

If your unit has a preheated instrument level, you can store your instruments in the tray and warm them (Fig. 34). The preheating takes place only at the top instrument level, and is factory set to approx. +38° C.

The preheating is switched on together with the unit at the main switch, and takes about 30 minutes to reach the set temperature. If you are dissatisfied with the temperature setting, you can adjust the temperature in small steps at the thermostat. The thermostat is located behind the left side panel (Fig. 35).

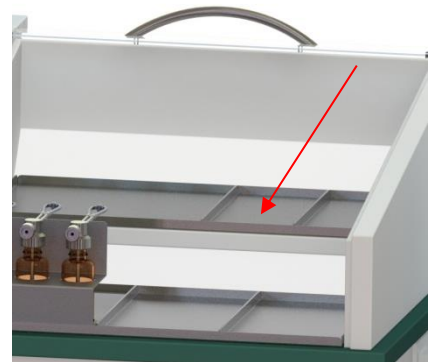


Fig. 36

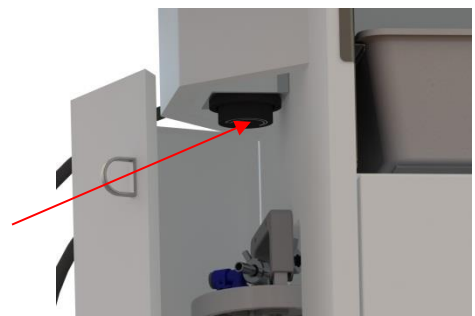


Fig. 37

#### 4.18 Mirror pre-warmer (option)

If your unit has a mirror pre-heater, you can warm and store laryngeal mirrors of various sizes here (Fig. 36). The laryngeal mirrors are less prone to fogging during use due to the preheated mirror surface.

The preheating is switched on together with the unit at the main switch, and takes about 30 minutes to reach the set temperature. The temperature is factory set to approx. +38° C. If you are dissatisfied with the temperature setting, you can adjust the temperature with a thermostat in small steps. The thermostat is located behind the left side panel.

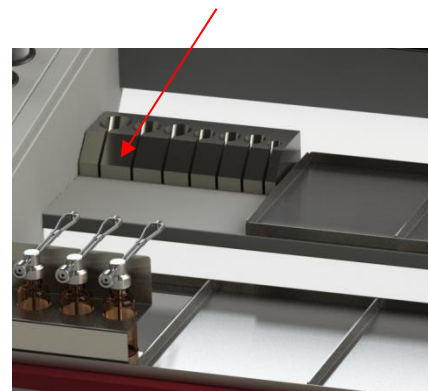


Fig. 38

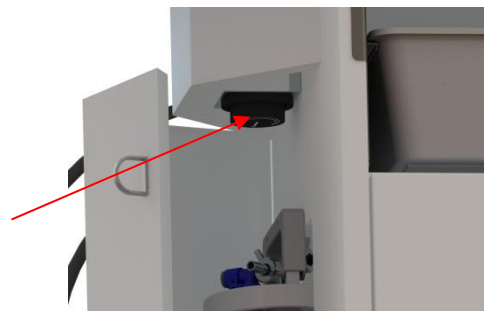


Fig. 39

#### 4.19 UV-hygiene drawer (option)

UV-C radiation damages the DNA of bacteria, viruses and fungi, so it acts germicidal. The germs are thereby killed or disabled and can no longer multiply. Since the radiation must reach the germs directly, the effect depends on the geometry of the surface to be sterilized. Care must be taken that there are no shadow zones that are not irradiated. The reflection plates made of treated aluminium or stainless steel plates can be applied giving an efficiency of 88%. Furthermore, the intensity of the irradiation decreases with the square of the distance.



**Caution! UVC radiation represents a danger to skin and eyes; direct exposure can cause cancer and eye damage, including complete blindness!**

The UVC instrument drawer is designed to minimize the number of germs on instruments such as ear speculum, tweezers, scissors, surgical scalpels (Fig. 38 + 39).



**Note! It is clearly stated here, that the UVC drawer does not replace sterilization measures or automatic and manual disinfection of instruments! Instruments must be prepared in accordance with national or international guidelines and according to the specifications and specifications of the instrument manufacturers (sterilization and disinfection)! The UVC disinfection drawer is designed to limit germ growth after sterilization and before the use of the instruments. The disinfecting effect of the UVC sterilization drawer has not been validated by Heinemann Medizintechnik. It is based on the manufacturer's information (in the case Purion® GmbH) and theoretical basics of UV light treatment.**

The instruments to be used can be placed directly in the instrument drawer after preparation. The inside of the drawer is lined with a treated stainless steel sheet. A holder can also be installed to fix the instruments. Instruments with complex geometric surfaces such as nose and ear speculum should be placed as centrally as possible in the drawer. Furthermore, for an optimal UVC radiation treatment, the irradiation of instruments should be direct and from both sides, so turn over the instruments and return them to the drawer.

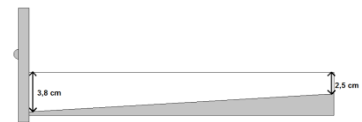


Fig. 40

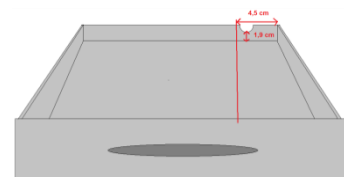


Fig. 41





**Note! Place the instruments behind and next to each other and do not stack them, otherwise the UVC radiation will not reach the surfaces! The instruments to be treated should not exceed a height of 3.8 cm, otherwise they will hit the upper cover plate when closing the drawer!**

The drawer is lower at the front than at the back, so instruments like nasal speculum, which are higher at the front should be placed in the drawer with the handle pointing backwards.

The UVC lamp has a flange which protrudes into the drawer, so that at this position, the maximum instrument height is limited (smaller than 1.9 cm). This means that e.g. nasal speculum must be turned over, as they would otherwise hit the flange, and the drawer would not close properly. The UVC lamp is automatically switched on when the drawer is completely closed and remains active for a period of 30 seconds. The option button lights up in green for the duration of the process. After the 30 seconds, the UVC lamp is automatically switched off by the internal controller. When the drawer is opened, the UVC lamp switches off immediately so that the user and the patient are not exposed. Regardless of whether the drawer is opened during UVC activation or remains closed all the time, the internal control switches the UVC lamp off after 30 seconds. After that, the option key is again illuminated blue.

The drawer switches via two roller switches and therefore do not switch until the drawer is closed. This prevents stray radiation from leaking into the room and reaching the user or patient. The second roller switch is installed as a fail-safe, because both switches must always be actuated. If a switch is stuck or has an error, the series connection of the roller switches prevents the UVC lamp from continuing to light when the drawer is opened. The drawer is provided with a clear warning safety label. When opening the back wall of the ENT unit, this function should be switched off, otherwise there is the risk of the direct exposure of skin and eyes! As a warning, a safety label is again attached to the back wall!

## 5 Maintenance and Repair

**The treatment unit should be serviced annually!**

As a medical device user, you are required to have a safety inspection carried out once a year by us or by one of our authorized companies.

### 5.1 Cleaning



**Caution!** Switch off at the main power switch and unplug the unit from the mains before cleaning or disinfecting. To check that the unit is not under electrical power, turn it on at the main power switch.



**Caution!** Apply cleaning or disinfectant liquids with a soft cloth, do not pour directly onto the device body. Extra care is required when using flammable liquids. Do not allow any liquid to run into the device.



**Caution!** Never switch on the treatment unit when the suction bottle is not installed!



**Note!** Complete instructions for cleaning and disinfection are given in the hygiene management brochure.

### 5.2 Replacing the suction filter

For hygiene reasons, the suction system is equipped with a bacteria and overflow filter (Fig. 40). The filter is placed in the suction compartment on the left side of the treatment unit. The filter is installed between suction bottle and vacuum pump, protecting the pump from humidity, bacteria and overflow



**Caution!** Please dispose of contaminated waste correctly. The filter may be contaminated. Please use gloves when handling the filter.

The filter must be changed once a year, or when the suction power has decreased significantly. Three replacement filters are included.



Fig. 42

The filter are to be found near the secretion glass, behind the left side door (Fig. 41). To change the filter, remove the two silicone hoses from the filter and then connect the hoses to the new filter. The flow direction does not matter.



Fig. 43

### 5.3 Emptying the secretion glass

If your MODULA has a manual suction system, it must be emptied at least once a day at the end of the day, and more frequently when it is filled (indicated by a warning lamp).

To do this open the left side door of the treatment centre (Fig. 42). Remove the lid with the hoses, hang the lid on the holder provided, remove the secretion glass and clean it thoroughly.



**Note! Complete instructions for cleaning and disinfection are given in the hygiene management brochure.**



**Note! The reservoir is resistant to disinfectants (not autoclavable).**

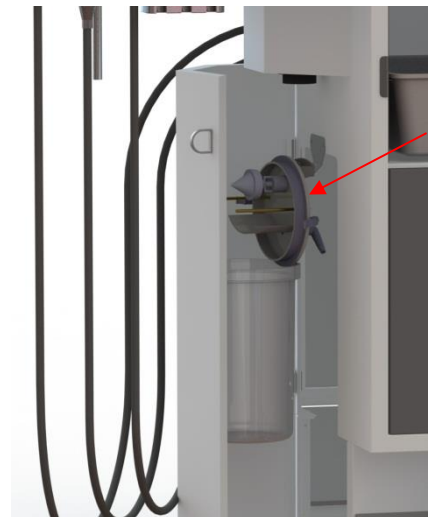


Fig. 44

## 5.4 Replacing the waste bin

For hygiene reasons, check the waste bag at the end of every day and dispose it even when it is only partly filled.



**Caution!** Pay attention to the proper disposal of contaminated waste! Always use glove when handling waste.



Fig. 45

## 5.5 Cold light cable (option)

If your unit has one or more cold light sources, a range of endoscopes can be attached to the cold light adaptor via an optical cable. The light adaptors have a STORZ connector. Optional detachable light outputs for connecting Storz, Wolf, Olympus and Pentax connectors.



Fig. 46

There is a pre-set locking screw beneath the light cable connector. This can also be used to adjust the force with which the locking screw secures the cable. To fix the optical cable more tightly in the connector, carefully tighten the screw and check the force required. To fix the optical cable less tightly, carefully loosen the screw. A range of optional optical cable adapters (Wolf, Storz, Olympus, etc.) can be ordered separately.

## 5.6 Replacing halogen light bulbs (option)



**Caution!** Always switch off at the main power switch before replacing the halogen lamp. Unplug the treatment unit at the mains. To check that the unit is not under electrical power, turn it on at the main power switch.



**Caution!** Allow the halogen lamp to cool down for at least 15 minutes before replacing, as it may be very hot.

To replace the halogen lamp a screwdriver (size 2.5 mm) is required to unscrew both screws (Fig. 45) to open the front hatch.

The device must be permitted to cool down before replacing defective halogen lamps, as the lamps may be very hot. Use only lamps which conform to the device specifications.



Fig. 47



**Caution!** Use only 15 V/ 150 VA halogen lamps.

To remove a halogen lamp, pull off the cable (Fig. 46) and then pull forward out of the bulb socket. To insert a new halogen lamp, perform this process in reverse (replacements are included with the device).

After replacing the halogen lamp, close the console hatch and tighten the two screws.



**Caution!** The console hatch must be closed before the treatment unit is reconnected to the main power supply!



Fig. 48

## 6 Hygiene

Bear in mind that the tap water supplied to the unit for warm water irrigation has low level of micro-organisms, but it is not sterile. (36-42 % of nosocomial *Pseudomonas aeruginosa* infections are traceable to tap water primarily contaminated at the tap. *Source: RKI, Gesundheitsschutz 4/2004*). To protect yourself and patients, we therefore recommend incorporating a downstream sterile filter. In addition, we recommend that after a longer unit down-time, to activate the ear irrigation for a few minutes while also pressing the water syringe (without sterile filter).



**Note!** Over-diluted or ineffective disinfectant solutions can become sources of infection, particularly with gram-negative bacterial (especially enterobacteriaceae, pseudomonads), especially when prepared in contaminated containers and stored for long periods.



**Note!** Complete instructions for cleaning and disinfection are given in the hygiene management brochure.



**Caution!** The MODULA ENT treatment unit should only be connected to water supplies which meet the water hygiene standards and regulations in the country where the device is installed.

## 7 Warranty

We offer warranty for all parts of the MODULA treatment unit for 24 months from the date of installation. Longer guarantee periods may be agreed in your purchase agreement. The warranty includes the fastest possible repair by our service department in the event of a fault. For your own benefit, you should therefore contact us immediately (contact).

The following cases are not covered by our warranty:

- incorrect use of the MODULA ENT treatment unit, accessories or special equipment
- access by or operation by unauthorized persons (e.g. electricians, water engineers)
- force majeure (e.g. fire, water ingress, lightning strike, etc.)

The manufacturer holds itself responsible for effects on the safety and reliability of the treatment unit only if:

- extensions, reinstallation, modification or repairs have been performed exclusively by persons authorized by the manufacturer.
- the room electrical and water systems meet the requirements of IEC-60601.
- the treatment unit is used in accordance with these operating instructions



**Caution!** Repair and maintenance of the MODULA treatment unit may only be carried out by G. Heinemann Medizintechnik GmbH or agents expressly authorized to carry out such work.

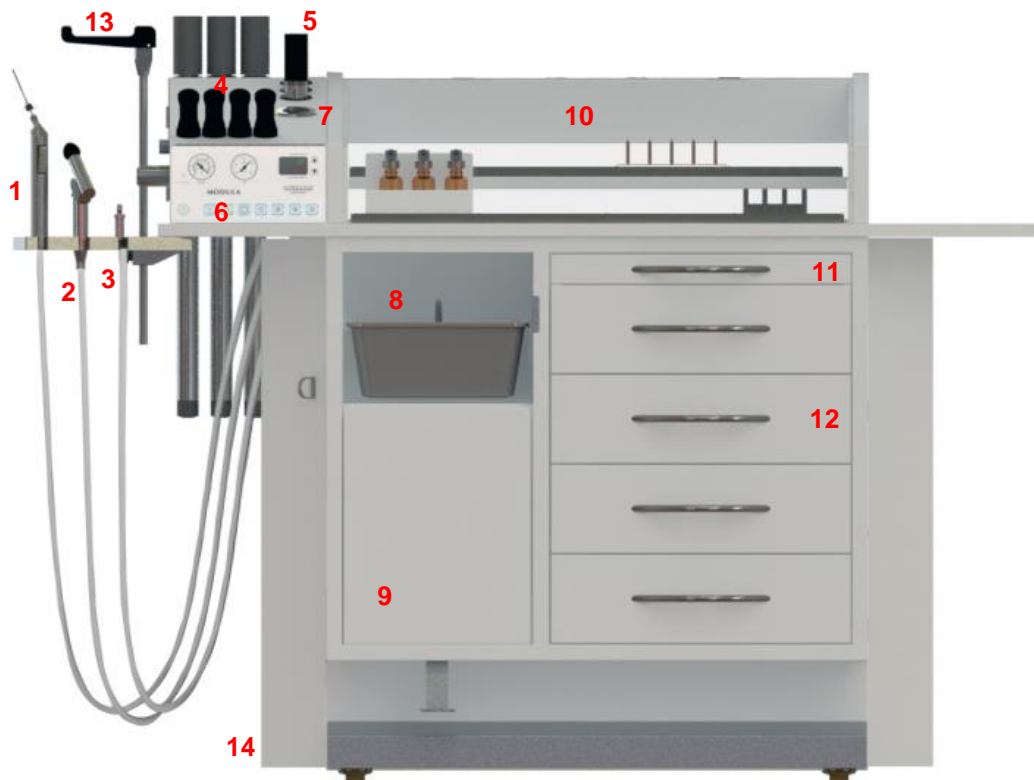
## 8 Annex

### 8.1 Technical data

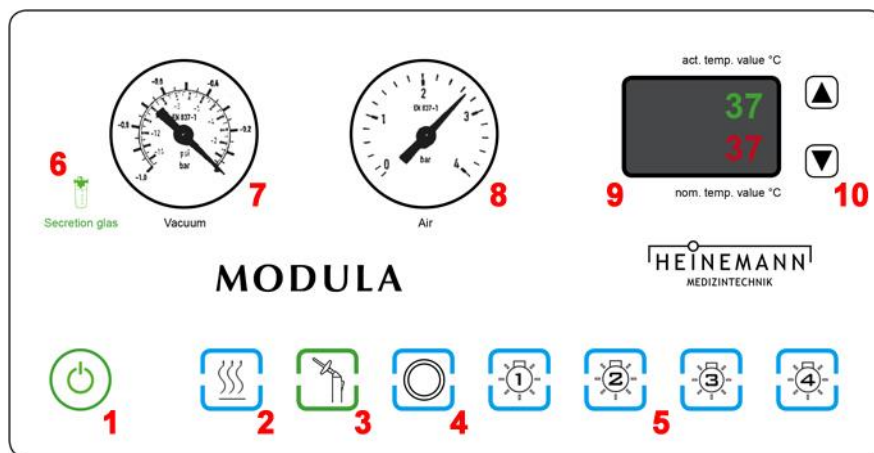
Power supply	230 V, 50 Hz
Current consumption:	max. 10A
Power consumption:	max. 2,3 kVA
Classification acc. 93/42/EEC:	Ila
Protection class:	I
Degree of protection (insulation class) (applied parts):	B: ear irrigation handle, suction handle; BF: compressed air handle, cold light source (Caution: BF properties are only given for the cold light source when the cold light source is used in conjunction with an insulating cold light cable)
IP-Code:	IP20
Fuses:	F1 = 10 AT (L) F2 = 10 AT (N) F3 = 2 AT (suction, Sekretomatik) F4 = 8 AT (ear irrigation) F5 = 3 AT (mirror heater, compressor) F6 = 3 AT (Int. power supply) F7 = 6 A (24 V) (circuit breaker) F8 = 10 A (15 V) F9 = 10 A (12 V) F10 = 2 A (15 V) F11 = 3 A (12 V) F12 = 1 A (6 V) Rated voltage fuses : F1-F6 : 250V Rated voltage fuses : F7-F12 : 240V Breaking capacity fuses F1-F6: 1500A Breaking capacity fuses F7-F12: 2000A
Compressed air (option):	Compressor oil free, 12 l/min @2700rpm and 138 VA, max. 2.5 bar; optional 0.2-2.5 bar adjustable
Automatic Suction System (option):	Vacuum pump oil free, 40 l/min at -0,85bar / -85 kPa and 150 VA / capacity of suction bottle: 1000 ml
Water heater (option):	max. 1500 VA (nonstop operation), min. water supply pressure 3.0 bar, max. water supply pressure 5.0 bar
Water temperature (option):	37°C +/-3° C, flow rate: max. 500 ml/min
Water tank (Option):	5 liter
Light source, halogen (option):	150 VA, 15 V
Light source, LED (option):	approx. 30 VA, 12 V, light intensity 2000 lm, light color: 5.700 K
Endoscope holder, pre-heated (option):	37°C ± 4°C
Instrument tray, pre-heated (option):	37°C ± 4°C
UV-C drawer (option):	12 VDC, 14 VA
Total weight:	max. 160 kg (depending on equipment options)
Dimensions (B x H x T):	1123 x 970 x 545 mm
Connections:	Power cable and AquaStop-Valve cable: 2 m Water supply and drainage hoses: 2 m Max. water supply pressure: 5.0 bar
Ambience conditions (transport, storage):	Temperature: -20 to +50° C, Humidity (without condensation): 10 to 95%, air pressure 700 to 1060 hPa
Ambience conditions (operation):	Temperature: +5 to +35° C, Humidity (without condensation): 30 to 65%, air pressure 700 to 1060 hPa



## 8.2 Pictures



1: Ear irrigation handle, 2: Compressed air handle, 3: Suction handle, 4: Endoscope holders, 5: Quivers for used endoscopes, 6: Control panel, 7: Mirror heater, 8: Tray for used instruments, 9: Waste bin, 10: Instrument levels with illumination, 11: Writing desk, 12: Drawer with soft-close system, 13: Head light holder, 14: Left cover

























1: Stand-By-key, 2: Mirror heater key, 3: Ear irrigation key, 4: Option key, 5: Cold light sources keys 6: „Secretion glass full“, 7: Manometer „Vacuum“, 8: Manometer „Air“, 9: Ear rinsing temperature, 10: Keys for Vestitherm function (+20° to +44°C)








### 8.3 Consumables and spare parts

Product description	REF	
<b>Light system</b>		
Replacement lamp 150 VA (halogen)	MOD10-02701	
Cold light cable, 90°, l = 180 cm	0150-30000	
Cold light cable, 0°, l = 180 cm	0150-30100	
Light cable adapter, endoscope side (Storz, Wolf...), 1 pc	0150-31000	
Light cable adapter, light source side (Storz, Wolf...), 1 pc	0150-32000	
Quiver for used rigid endoscopes, autoclavable	0150-50250	
Adapter for quiver, material: silicone (for used rigid endoscopes)	0150-50260	
Endoscope quiver for rigid endoscopes, 5 mm diameter	0150-50100	
Endoscope quiver for rigid endoscopes, 12 mm diameter	0150-50110	
<b>Suction system</b>		
Silicon tubes for suction hose (10 pcs.)	0120-50200	

Overflow-/ bacterial filter (for units after 2011), 1 pc	0120-50300	
Adapter for suction hoses (autoclavable)	0120-50250	
Fingertips for the temporary reduction of the suction performance (100 pcs.)	0120-50100	
Nose olives (metal), adapted on the suction hose, small	0120-50210	
Nose olives (metal), adapted on the suction hose, medium	0120-50220	
Nose olives (metal), adapted on the suction hose, large	0120-50230	
Suction bottle for manual emptying, 2 L (material: PSU, autoclavable)	MOD18-05820	
Cover for Suction bottle (manual emptying) with overflow sensor	MOD18-05810	
<b>Water system</b>		
Cannula for ear irrigation handle (Luer-Lock), 80 mm	0130-50025	
Cannula for ear irrigation handle (Luer-Lock), 110 mm	0130-50026	
Cannula for ear irrigation handle (Luer-Lock), 40 mm	0130-50027	

Splash guard for the ear irrigation handle	0130-50030	
Ear rinsing bowl, adaptable to suction hose	0130-50000	
Spit bowl, adaptable to the suction hose	0130-50010	
<b>Air pressure system</b>		
Politzer olives (plastic) for adaption to the handle for compressed air - set with 3 different sizes	0140-21300	
Politzer olives (plastic), small	0140-21301	
Politzer olives (plastic), medium	0140-21302	
Politzer olives (plastic), large	0140-21303	
Spray bottle for fluids, complete (glass and sprayer)	0140-60101	
Spray bottle for powder, complete (glass and sprayer)	0140-60102	
Drug nebuliser for liquids, with detachable and autoclavable front part, complete (sprayer and spray bottle)	0140-60108	
Sprayer for fluids (without bottle)	0140-60103	

Sprayer for powder (without bottle)	0140-60105	
Drug nebuliser for liquids, with detachable and autoclavable front part (without bottle)	0140-60107	
Detachable front part for drug nebuliser (for REF 0140-60107)	0140-60109	
Spray bottle glass for fluids	0140-60104	
Spray bottle glass for powder	0140-60106	

## 9 Electromagnetic compatibility (EMC)

Electric medical devices are subject to specific EMC requirements. Modula ENT treatments units may only be used according to the intended use given by this manual. Installation and operation of the treatment unit may only be performed under electromagnetic compatibility conditions given here. Emission of high frequency energy by mobile communication devices may influence function of electric medical devices. Use of mobile communication devices (e.g. mobile phones) is not permitted around electric medical devices.

### 9.1 Guideline and Declaration – Electromagnetic Emissions

Modula ENT treatment units are intended for use under the following EMC conditions. The user/operator must assure that the device is operated under such conditions.

Measurement of interference	Compliance	EMC instructions
RF emissions CISPR 11	Group 1	Modula Europa deploys HF energy only for internal functions (not for applied parts). HF emission is very low. It is highly unlikely that other electric devices are interfered by Modula Europa.
RF emissions CISPR 11	Class B	Modula Europa is suitable for use in all facilities which are connected to public power networks which also supply residential buildings.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 3: Electromagnetic emissions

## 9.2 Guideline and Declaration – Electromagnetic Compatibility


The device is suitable for use under the following electromagnetic conditions. The user/operator must assure that proper electromagnetic conditions are given.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floor should be wool, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst according to IEC 61000-4-4	±2 kV for power supply line ±1 kV for input and output lines	±2 kV for power line not applicable	Quality and stability of power supply lines must be appropriate for industrial/healthcare facilities
Surges according to IEC 61000-4-5	± 1 kV Line(s) to line (s) ± 1 kV Line(s) to earth	± 2 kV Line(s) to line (s) ± 1 kV Line(s) to earth	Quality and stability of power supply lines must be appropriate for industrial/healthcare facilities
Voltage drops, short interruptions, voltage variations on power supply input lines according to IEC 61000-4-11	< 5 % $U_T$ (> 95 % dip in $U_T$ ) for 0.5 cycle  40 % $U_T$ (60% dip in $U_T$ ) for 5 cycles  70% $U_T$ (30 % dip in $U_T$ ) for 25 cycles  < 5 % $U_T$ (>95 % dip in $U_T$ ) for 5s	< 5 % $U_T$ (> 95 % dip in $U_T$ ) for 0.5 cycle  40 % $U_T$ (60% dip in $U_T$ ) for 5 cycles  70% $U_T$ (30 % dip in $U_T$ ) for 25 cycles  < 5 % $U_T$ (>95 % dip in $U_T$ ) for 5s	Quality and stability of power supply lines must be appropriate for industrial/healthcare facilities If the user wishes to use Modula Europa during power interruptions, the Modula Europa should be connected to interruption-save power supply or battery.
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	3 A/m	Not applicable	Magnetic fields at power frequency should correspond to usual strength in an industrial/healthcare environment

**NOTE:**  $U_T$  is the AC mains voltage prior to application of test level.

Table 4: Electromagnetic compatibility

Immunity test	IEC 60601 – test level	Compliance level	Electromagnetic environment - guidance
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Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part to Modula Europa, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance:</b></p> <p><math>d = (3,5 / V1) * \sqrt{P}</math> <math>d = (3,5 / E1) * \sqrt{P}</math> 80 - 800 MHz <math>d = (7 / E1) * \sqrt{P}</math> 0,8 - 2,5 GHz</p> <p>Where <b>P</b> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <b>d</b> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div></div>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

Note 1: At 80MHz and 800MHz, the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**a** Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the locations in which the Modula Europa is used exceeds the applicable RF compliance level above, the Modula Europa should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Modula Europa.

**b** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

*Talbe 5: Electromagnetic compatibility*

### 9.3 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and MODULA Europa

Modula Europa is intended for operation in an electromagnetic environment where radiated RF signals are controlled. The operator/user of Modula Europa can help to prevent electromagnetic interference by adhering to separation distances between RF communications equipment and Modula Europa as given in below table.

	Separation distance (d) according to frequency of transmitter in (m)		
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = [3,5 / 3] \sqrt{P}$	$d = [3,5 / 3] \sqrt{P}$	$d = [7,0 / 3] \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
<p>Note 1: At 80MHz and 800MHz, the higher frequency range applies</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Table 6: Separation distances

## 10 Disposal

This symbol indicates that this device may not be disposed into normal household waste according to directive 2002/96/EC. The black bar in the symbol indicates that the device has been manufactured later than August 13th 2005.



Prior to disposal, the device must be prepared by the operator. Contaminated components must be disposed as medical special waste. This includes the following components:

- Suction bottle
- Tubes (Suction tube, connection tubes etc.)
- Ear irrigation handle
- Syphon pump
- Drainage valve
- Drainage connections, incl. drainage tube



All other components may be disposed at an authorized collection point for electronic waste. Prior to disposal, surface disinfection must be performed on the device (see hygiene management brochure). As an alternative, the device may be returned to the manufacturer (G. Heinemann Medizintechnik GmbH) who will take care of proper disposal. Inappropriate handling of used devices can have negative effects on the environment and on human health. Disposal into household waste is prohibited. We are always available for further requests in regard to disposal of Modula treatment units.

**Manufacturer:**

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