

Users manual

ENT Diagnostic & Treatment Unit MODULA Model Europa



Introduction

Thank you for choosing our MODULA 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 Heinemann Medizintechnik 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 Heinemann Medizintechnik.

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!



Manufacturer



Date of manu-
facture



Serial number



Medical product



Article number

Contact details of the manufacturer:



G. Heinemann Medizintechnik GmbH, Leibnizstraße 13-15, 24568 Kaltenkirchen

T: +49 4191-95379-0, F: +49 4191-9537937, E-Mail: info@heinemann-ent.de

Web: www.heinemann-ent.de

Table of contents

| | | |
|------|--|----|
| 1. | General Notes for Use | 5 |
| 1.1 | Intendend use | 5 |
| 1.2 | Indications / Contraindications | 6 |
| 2. | Delivery and Unpacking | 7 |
| 2.1 | Claims | 7 |
| 2.2 | Installation | 7 |
| 3. | Safety instructions | 9 |
| 4. | Operation instructions | 11 |
| 4.1 | Glasdisplay | 11 |
| 4.2 | Main power switch | 11 |
| 4.3 | Mirror Heater (warm air) | 12 |
| 4.4 | Suction System with manual emptying (option) | 12 |
| 4.5 | Suction System with automatic emptying „Sekretomatik“ (option) | 13 |
| 4.6 | Tube rinsing system (option) | 14 |
| 4.7 | Cannula rinsing system with cleaning solution (option) | 14 |
| 4.8 | Second suction hose (option) | 14 |
| 4.9 | Compressed air system (option) | 15 |
| 4.10 | Ear irrigation system with water connection (option) | 15 |
| 4.11 | Autonomous ear irrigation with water tank (option) | 16 |
| 4.12 | Cold light sources, LED (option) | 17 |
| 4.13 | Sensor control for the light sources (option) | 18 |
| 4.14 | Endoscope holders (option) | 18 |
| 4.15 | Storage quivers for used endoscopes | 18 |
| 4.16 | Pre-heated instrument level (option) | 19 |
| 4.17 | Mirror pre-warmer (option) | 19 |
| 4.18 | UV-hygiene drawer (option) | 20 |
| 5. | Maintenance and Service | 22 |
| 5.1 | Cleaning | 22 |
| 5.2 | Replacing the suction filter | 23 |
| 5.3 | Emptying the secretion glass | 23 |
| 5.4 | Compressed air filter | 24 |
| 5.5 | Replacing the waste bin | 26 |
| 5.6 | Cold light cable (option) | 26 |
| 6. | Hygiene | 27 |
| 7. | Warranty | 27 |
| 8. | Annex | 28 |
| 8.1 | Technical data | 28 |
| 8.2 | Pictures (standard and options) | 29 |
| 8.3 | Consumables and spare parts | 30 |
| 9. | Electromagnetic compatibility (EMC) | 33 |
| 10. | Disposal | 37 |
| 11. | Reporting of incidents | 37 |

1. General notes for usage

The MODULA ENT treatment unit may only be used by persons offering a guarantee of correct usage of the device and who have been instructed in its use. Instruction may only be given by authorised Heinemann Medizintechnik personnel. As for all highly developed technical devices, care and regular maintenance of the treatment unit is very important. You should also ensure that you are thoroughly familiar with the functions and specifications of the device.



Caution! Before actually using the device in practice, it is essential that you thoroughly familiarise yourself with the functions of the treatment unit!



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

1.1 Intended purpose

The ENT treatment unit is used for diagnostic (e.g. endoscopy) and therapeutic (e.g. ear irrigation, medication administration, secretion suctioning) purposes. It is used as the main workplace for ENT doctors in hospitals or doctors' practices and is therefore part of the practice equipment. In addition to the above-mentioned purposes, they are also used for storing instruments and consumable materials, but also as a shelf for accessories.

Medical purpose:

- Temporary diagnosis and therapy in the ENT area
- The main functions (to be used in the ENT area) are to flush body orifices (water spray), deliver medication to the body (compressed air) and suction body fluids (suction)
- Therapy for the diseases listed under indications

1.2 Medical indication and contraindication

Indication:

- Ear irrigation: Ear canal cleaning, vestibular examination
- Suctioning: of blood (in case of emergency/bleeding/after surgery), suctioning of wound fluids after surgery, secretion suctioning, ear canal cleaning (cerumen removal), cleaning of nose and sinuses, oral suction (tonsil stones/pus)
- Compressed air: Medication introduction (atomisation, also on surfaces), carrying out the Politzer manoeuvre
- Light sources: Illumination in endoscopy, illumination in microscopy, headlamp examination

Contraindication:

- Ear irrigation: Perforation of the eardrum, cholesteatome (fistula syndrome), otitis media chronica, acute episodes of vertigo, otitis externa, tympanoplasty surgery
- Suction: Cerumen removal in tinnitus patients
- Compressed air: Intracranial injuries, orbit (eye socket) - injuries, CSF fistula following middle ear surgery, sinusitis (sinus infection), purulent rhinorrhoea, petrous bone fracture

Side effects:

- no side effects have been identified for use with the MODULA ENT units

Intended patient group:

- Restriction of compressed air: Children from 3 years of age (risk of spasm)
- Light sources, suction and water: No restriction (qualified ENT doctor)

Intended body part

- Ear canal to eardrum, nose, oropharyngeal cavity

Intended user profile

- Medical professionals, more specifically ENT specialists, doctors in training and ENT practice personnel, who have received instruction from Heinemann or authorised partners

Intended environment of use

- Treatment rooms in hospitals and with doctors in private practice

Physical environment

- Brightness: Daylight, room light
- Ambient temperature: +5 to +40°C
- Humidity (without condensation): 30 – 65%
- Air pressure: 700 to 1060 hPa
- Noise: no restrictions
- Contamination: medically prepared treatment room
- Transport/storage): Temperature: -20 to +50°C, humidity without condensation: 10 to 95%, air pressure 700 to 1060 hPa

Social environment

- Shift work (possibly also attending physicians in the hospital)

Technical environment

- Mains connection: according to DIN VDE 0100-7-710: Earth leakage circuit breaker with rated fault current < 30 mA, max. 1.5 m away, separate supply circuit, 2300 VA
- Water connection: ½" angle valve with 3/8x10 mm compression fitting or ½" WAS valve with ¾" outlet, easy to shut off, minimum height 10 cm, max. 150 cm from tap. Pressure 3–5 bar, drinking water according to WHO and country-specific guidelines, water hardness below 2.5 millimole total hardness or upstream limescale protection system
- Wastewater: 32 – 50 mm sleeve, alternatively ¾" or 1" threaded connection, max. height 60 cm, distance to drain 150

Clinical environment

- If necessary, wear protective equipment (mouth protection, protective goggles, gloves) e.g. when using the water sprayer and suction system
- Cleaned and disinfected environment

Functionality, physical principle, main functions:

- Ear irrigation (+37°C ±2°C, flow rate: max. 500 ml/min)
- Compressed air compressor (max. 2.5 bar; optionally adjustable from 0.2 to 2.5 bar)
- Suction system (60 l/min at -0.85 bar capacity secretion glass: 1250 ml)
- Light sources for endoscopes, headlamps and microscopes (approx. 30 VA, 12 V, light intensity 900 lm, light-temperature 5,700 K)
- Instrument preheating (+37°C ±4°C)
- Mirror reheating

Other intended use

- Multiple use, preparation(see hygiene booklet and hygiene plan)
- Transport in tight-fitting packaging film and wooden crates (specially made), e.g. vacuum pump is removed or fixed
- Storage of instruments
- Accessory adaptation (headlamp, microscope, monitor, fibre optic cable)
- Switching off external devices

Exclusions

- Contraindications or presumption of a contraindication
- Earthed socket does not meet requirements
- Environmental conditions that do not correspond to the specifications
- Operation with devices that do not comply with the standard EN 60601-1 "Medical electrical equipment" and EN 60601-1-2 "Electromagnetic compatibility"
- Damage to the unit

2. Delivery and unpacking

Please examine the treatment unit for any damage during transportation and check that the unit is complete immediately after delivery. Check the enclosed delivery note. Failure to do so may result in loss of possible claims for compensation. Some accessories are packed within the treatment unit.

2.1 Complaints

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

2.2 Connecting and initial operation



Caution! The company Heinemann Medizintechnik accepts no liability for the safety and proper functioning of the device where it has been installed, extended or repaired by persons who have not been authorised by the manufacturer! The treatment unit is not intended for operation in potentially explosive areas.

An authorised service technician will properly connect and put the treatment unit into operation after delivery. Please ensure that building water and power connectors are properly installed by your fitter. Further information can be obtained from our service department.



Caution! In the event of repairs, the mains connection cable may only be replaced by service employees authorised by Heinemann Medizintechnik.

A water and power supply connection diagram follows. When making the water connections it is essential to ensure that the dimensions specified in the plan are 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)

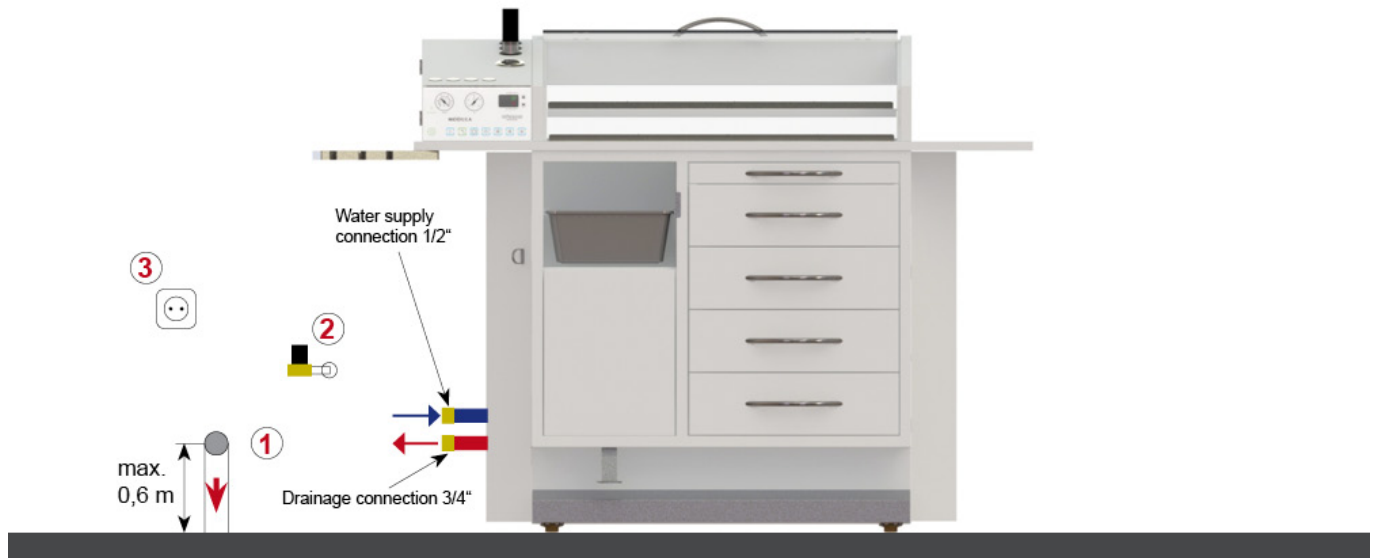
Water connection / water inflow:

- To an easily accessible ½" angle valve with a 3/8" x 10 mm compression fitting or a ½" WAS valve with ¾" 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: ¾" 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.



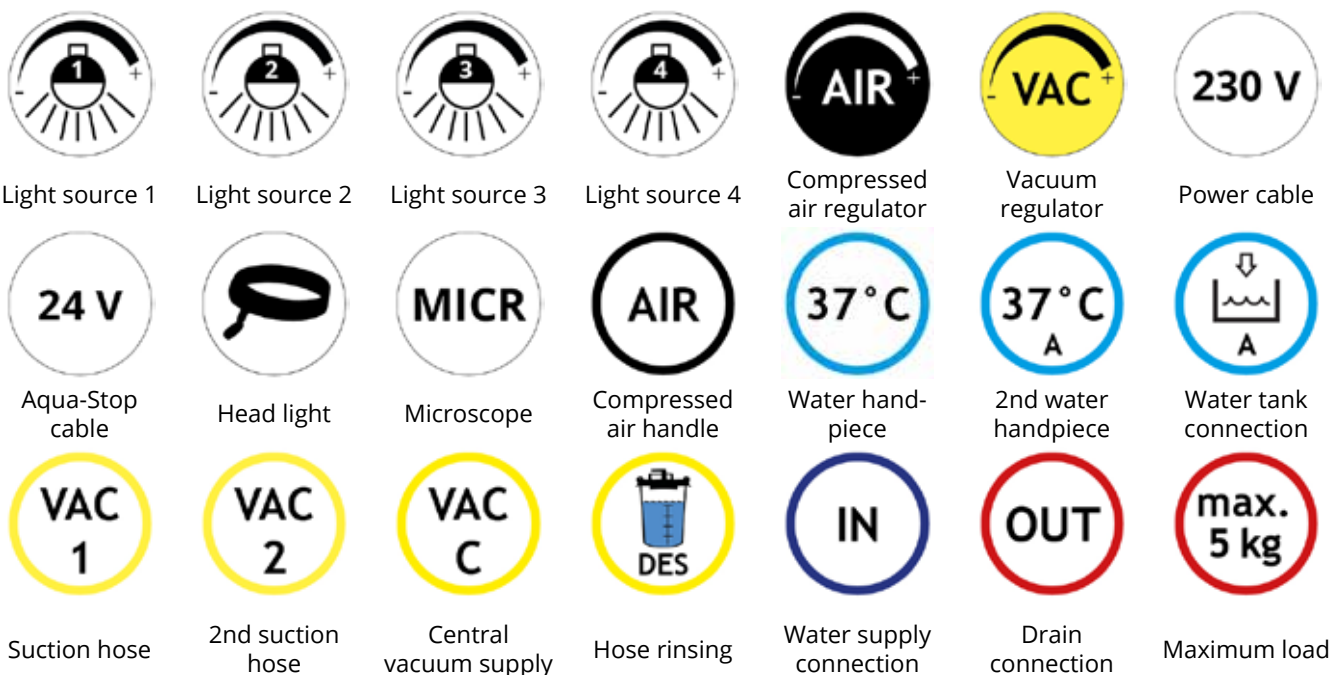
- ① Drainage: drainage pipe Ø 50 mm, max. height over ground 0.6 m
- ② Water supply: Aqua-Stop with angle valve (compression fitting) 3/8", recommended water pressure 3 - 5 bar
- ③ Power supply: 230 V, 50/60 Hz, max. 10 A

3. Safety instructions

- The device must be directly connected to a properly installed earthed socket, that is easily accessible at all times. 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. To avoid the risk of electric shock, this appliance may only be connected to a supply network with a protective earth conductor.
- The power cord may only be replaced or repaired by authorized technical staff from Heinemann HNO 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 Heinemann HNO 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
- 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.

3.1 Labelling on the product



4. Operation instructions

4.1 Glasdisplay

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!

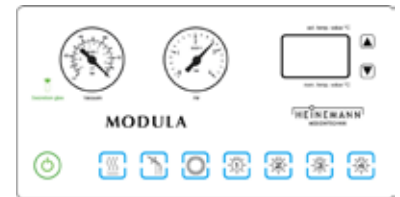


Fig. 01

The unit is operated using a touch-sensitive glass surface (Fig. 1), 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.

4.2 Main power switch

Pressing the main power switch (Fig. 02) sets the treatment unit into standby mode. Fig. 02 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. 03) 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. 02



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

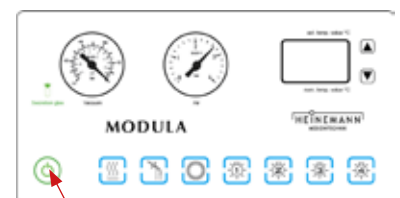


Fig. 03

4.3 Mirror Heater (Standard)

After touching the mirror heater key (Fig. 04), warm air is blown out of the mirror heater (Fig. 05). 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.

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!

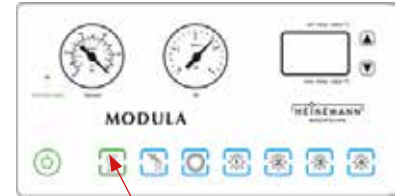


Fig. 04



Fig. 05

4.4 Suction System with manual emptying (Option)



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.

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

The end of the suction tube has an adaptor (Fig. 06) 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. 08), where they are collected until the reservoir is full.



Fig. 06

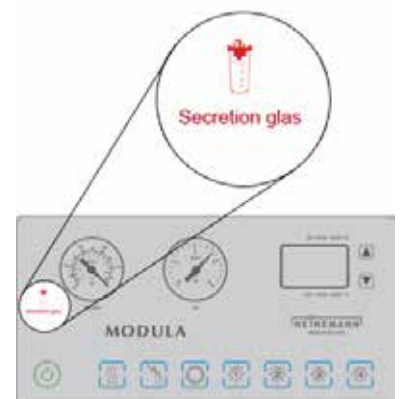


Fig. 07

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. 07). The reservoir must be emptied when this warning light is illuminated.

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. 08

4.5 Suction System with automatic emptying „Sekretomatik“ (option)



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.

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

The end of the suction tube has an adaptor (Fig. 09) 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).



Fig. 09

After the suction tube is placed in the swivel arm, the „Sekretomatik“ function is automatically activated. The suction bottle (secretion glass) 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. 10). Please check the suction bottle (open side cover, Fig. 11) and empty the suction bottle manually. If the defect occurs again, please contact Heinemann HNO Medizintechnik authorized technical staff.

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

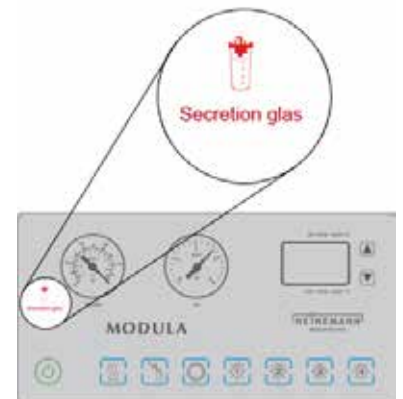


Fig. 10



Fig. 11

4.6 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. 12) 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. 12



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

4.7 Cannula rinsing system with cleaning solution (option)

Additionally optional to the simple tube irrigation is a cannula rinsing with a cleaning solution. In this case, cleaning solution 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. 13). The cannula is immediately flushed with the cleaning 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. 13

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. 14).

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.

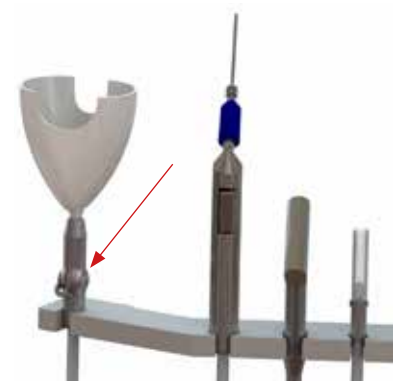


Fig. 14

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. 15). The delivered pressure can be adjusted using the lever on the compressed air sprayer (Fig. 16).

If the lever is depressed with more force, more air is discharged from the air outlet. An optional continuously variable control knob (Fig. 17) allows air pressure to be adjusted within the range 0.2 to 2.5 bar (required for "Poltzer"-application or for application on children!).

For Poltzer 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.

The medicament sprayers (Fig. 16) are included with the unit, Poltzer olives (optional) or other devices can be attached to the front end of the compressed air sprayer.



Caution! Poltzer 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.

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. 18). 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. 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. 19). You have to change the water cannula after each patient!

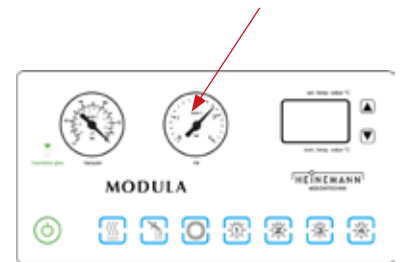


Fig. 15



Fig. 16



Fig. 17

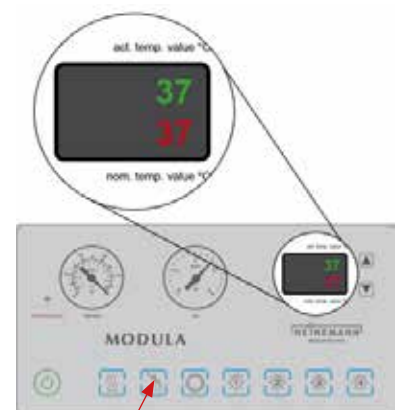


Fig. 18



Fig. 19



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 (Fig. 20) and splash guard must be used. 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).

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

Touching the key activates the ear irrigation system (Fig. 21). 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.



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.

In order to fill the water tank, the inlet hose must be removed from the tank (Fig. 23). To do this, please hold the hose attachment with your fingers (Fig. 22) and push the outer ring of the quick-release fastener, direction forward. So, the hose should come off. Hang the hose on the holder provided (metal hook with magnet).

By pressing the button (Fig. 21), the ear irrigation device will be activated.



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



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



Note! If you no longer require the autonomous ear irrigation system, please have the system completely deactivated by our service department or an authorised service partner.



Fig. 20



Fig. 21



Fig. 22



Fig. 23



Fig. 24

Since the processed water is low in bacteria, but not sterile, and the system occasionally also contains some staying water, you must either use a liquid concentrate to disinfect the water in the water tank (e.g. Alpron from Alpro Medical company) or a sterile water filter (fig. 24).

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, LED (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).

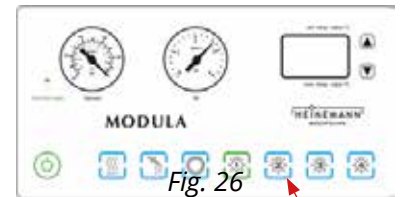


Fig. 26

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. 27).



Fig. 27



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

All treatment units are equipped with removable STORZ-type light outputs (Fig. 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.



Fig. 28



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



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 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 four light cables in the respective holder (Fig. 29).

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 4.



Fig. 29

4.14 Endoscope holders (option)

ENT treatment unit may be equipped with pre-heated endoscope holders (Fig. 30) 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 Heinemann HNO Medizintechnik GmbH or local representatives. Endoscope holders are also available without pre-heating system (optional).



Fig. 30



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.

4.15 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 31 and 32: for laryngoscope, see figure 31; for all other endoscopes, see figure 32 (approx. 0,5 cm above the silicone plug)

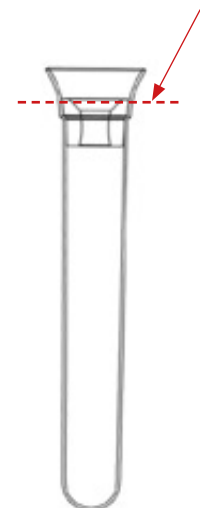


Fig. 31



Attention! The purpose of the storage quivers is not the treatment of contaminated 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. 32

4.16 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. 33). The preheating takes place only at the top instrument level, and is factory set to approx. +38° C.

The pre-heating 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).

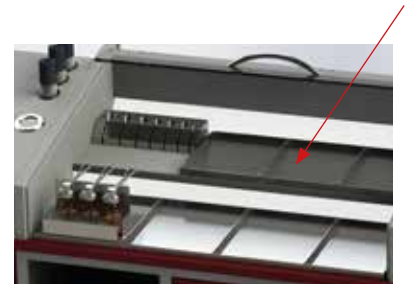


Fig. 33

4.17 Mirror pre-warmer (option)

If your unit has a mirror pre-heater, you can warm and store laryngeal mirrors of various sizes here (Fig. 34). 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. 35).

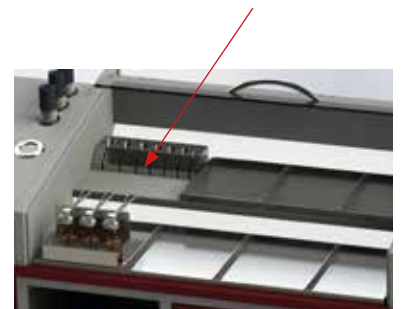


Fig. 34

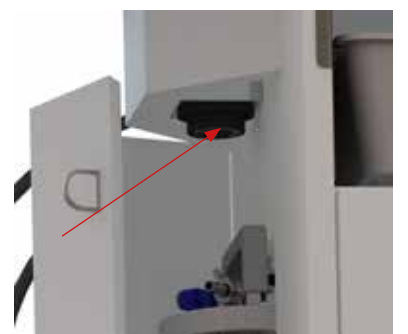


Fig. 35

4.18 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. 36).



Fig. 36

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 HNO Medizintechnik. It is based on the manufacturer's information (in the case Purion® GmbH) and theoretical basics of UV light treatment



Fig. 37

The instruments to be used can be placed directly in the instrument drawer after preparation (Fig. 38). 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.

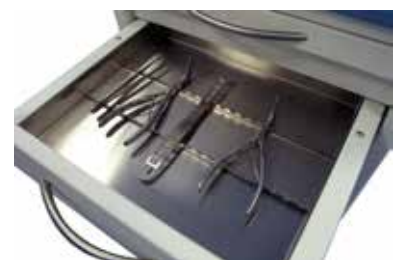


Fig. 38



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!

5. Maintenance and Service

An electrical safety test in accordance with DIN 62353 is mandatory for our ENT treatment unit. This test must be carried out annually.

In order to ensure reliable and uninterrupted operation of your ENT treatment unit and to maintain the warranty claims, we strongly recommend that the treatment unit is serviced annually in accordance with a defined maintenance protocol and that the safety equipment in the treatment unit is checked (safety check) by us or by service staff with proven expertise and qualifications.

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. Do not use cleaning agents containing alcohol when cleaning the acrylic cover. Do not use any abrasive cleaning agents, as these can damage the surfaces.

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 manual.

5.2 Replacing the suction filter

For hygiene reasons, the suction system is equipped with a bacteria/virus 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 month (30 days after installation), or before when the suction power has decreased significantly.

The filter are to be found near the secretion glass, behind the left side door (Fig. 39). 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.

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. 41). 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.

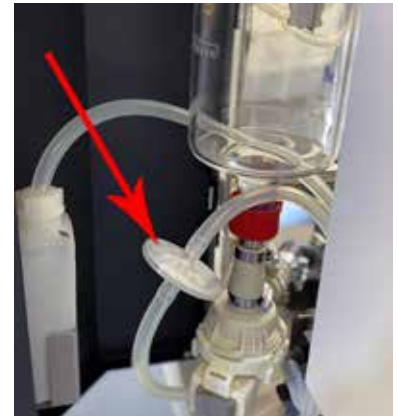


Fig. 39



Fig. 40



Fig. 41

5.4 Compressed air filter

For hygienic reasons, the compressed air unit is equipped with a compressed air filter (Fig. 42). The filter can be reprocessed up to 25 times by machine and is located behind the right side door of the treatment unit.



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.

Filter extraction:

- activate the compressed air handpiece until no more air escapes. To check that the housing is really depressurised, check that there is no pressure on the steam trap
- unscrew the housing clockwise (fig. 44). Pull the element out of the filter head and put the filter element aside for reprocessing (fig. 45)

Installation of a new or sterilised filter element:

- remove the new filter element from the cardboard box and grease the O-ring.
- insert the new filter element into the lower part of the filter housing (fig. 45 und 46)



Caution: Ensure that the three wings on the filter element slide into the corresponding recesses. Ensure that the O-ring slides into the guide; hand-tight tightening is sufficient.

- Check the O-ring in the filter housing and grease if necessary as well as the thread of the filter bottom part.
- Remove any dirt in the lower part of the filter.
- Screw the filter bottom part with the inserted filter back onto the filter head in an anti-clockwise direction (fig. 47)
- Switch the unit back on.
- The compressed air tank is automatically refilled by the compressor starting to operate, creating a noise. If the compressor remains in continuous operation (noise does not stop after a few seconds), a leak has occurred



fig. 42



fig. 43



fig. 44

- In case of leakage: Switch the unit off again and actuate the compressed air handpiece until no more air escapes. Then fix the leak (not properly tightened? The wings of the filter element are not located in the recesses provided for this purpose?)

Filter element reprocessing:

- the filter element must be reconditioned or replaced on a weekly basis
- reprocessing takes place in an autoclave at +121° C, 110 KPA (1.1 bar) and 30 minutes or in a washer-disinfector with demineralised water at +93° C and 5 minutes
- each filter element is released for 25 sterilisation cycles. This means that two filter elements are required per year (included in the scope of delivery)
- the filter elements should be re-ordered for annual maintenance



fig. 45



fig. 46



fig. 47

5.5 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.

4 punktas. Stalčius - šiukšliadėžė atidaroma
koja per paspaudimo plokštelę (pažymėta
žaliai)



Fig. 48

5.6 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 (Fig. 49). Optional detachable light outputs for connecting Storz, Wolf, Olympus and Pentax connectors.



Fig. 49

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.



Fig. 50

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.

7. Warranty

We offer warranty for all parts of the MODULA treatment unit for 12 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



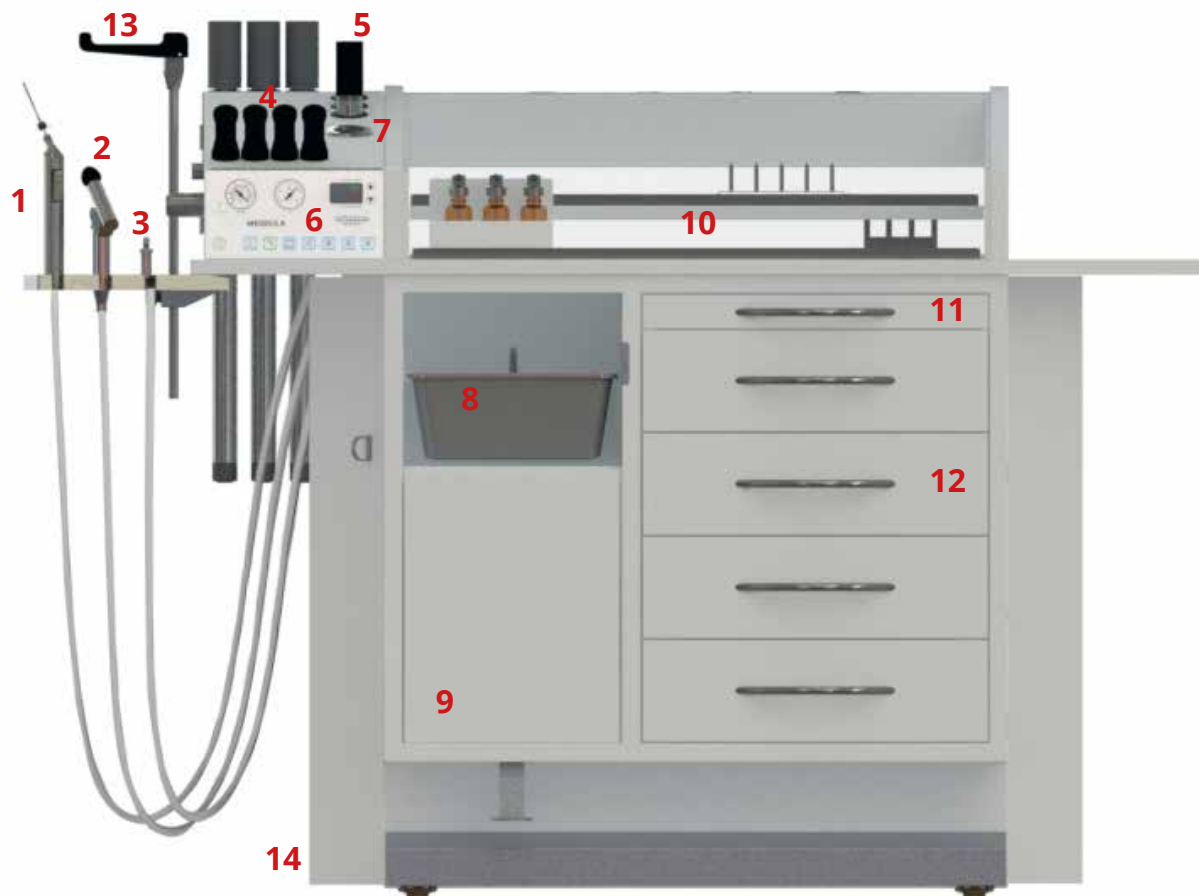
Caution! Repair and maintenance of the MODULA treatment unit may only be carried out by Heinemann Medizintechnik or agents expressly authorized to carry out such work.

8. Annex

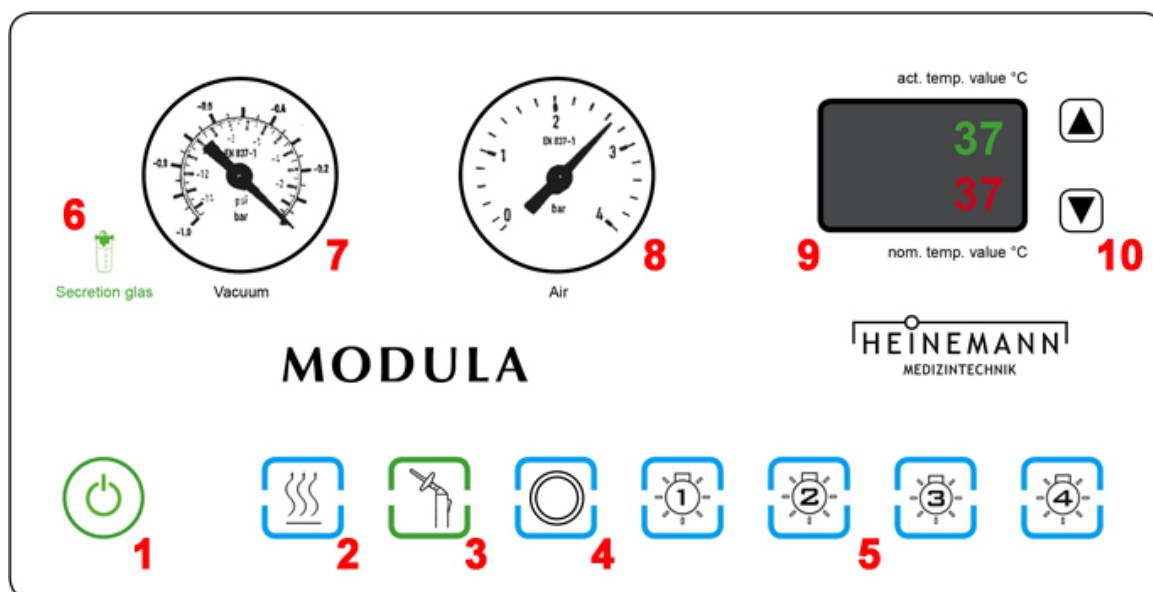
8.1 Technical data

| | |
|--|---|
| 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 |
| Compressed air (option): | Compressor oil free, 12 l/min @2700 rpm and 138 VA, max. 2.5 bar; optional 0.2 - 2.5 bar adjustable, autoclavable compressed air filter |
| Automatic Suction System (option): | Vacuum pump oil free, 40 - 60 l/min at -0,85 bar / -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 |
| Light source, LED (option): | approx. 30 VA, 12 V, light intensity 900 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 (W x H x D): | 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 +40° C, Humidity (without condensation): 30 to 65%, air pressure 700 to 1060 hPa |
| 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 |

8.2 Pictures (standard and options)



















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 | |
|--|------------|---|
| 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 |  |
| Silicon tubes for suction hose (10 pcs.) | 0120-50200 |  |
| Overflow-/ suction filter, 10 pcs. | 0120-50360 |  |
| Adapter for suction hoses (autoclavable) | 0120-50250 |  |
| Fingertips for the temporary reduction of the suction performance (100 pcs.) | 0120-50100 |  |

| Product description | REF | |
|--|-------------|---|
| 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 |  |
| 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 |  |
| Water decontamination filter, inline hollow-membrane filter for water hygiene in ENT units, 4 weeks lifespan, for insertion between irrigation handle and irrigation cannula | 0130-42000 |  |
| Filter cartridge for compressed air, autoclavable 121° C, 1.1 bar, 30 minutes, max. 25 cycles | 0140-10210 |  |

| Product description | REF | |
|--|------------|---|
| 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 |  |

8.4 Spare parts and Troubleshooting



Spare parts



Troubleshooting

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.

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 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. |
| RF emissions CISPR 11 | Class B | Modula 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 | |

Electromagnetic emissions

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 | $\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 6 \text{ kV}, \pm 8 \text{ kV}$ contact discharge $\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 8 \text{ kV}, \pm 15 \text{ kV}$ air discharge | $\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 6 \text{ kV}, \pm 8 \text{ kV}$ contact discharge $\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 8 \text{ kV}, \pm 15 \text{ kV}$ 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 | $\pm 2 \text{ kV}$ for power supply line $\pm 1 \text{ kV}$ for input and output lines | $\pm 2 \text{ kV}$ 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 | $\pm 0,5 \text{ kV}, \pm 1 \text{ kV}$ Line(s) to line (s) $\pm 0,5 \text{ kV}, \pm 1 \text{ kV}, \pm 2 \text{ kV}$ Line(s) to earth | $\pm 0,5 \text{ kV}, \pm 1 \text{ kV}$ Line(s) to line (s) $\pm 0,5 \text{ kV}, \pm 1 \text{ kV}, \pm 2 \text{ kV}$ 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 | $< 5 \% \text{ UT}$ ($> 95 \% \text{ dip in UT}$) for 0.5 cycle $40 \% \text{ UT}$ (60% dip in UT) for 5 cycles $70\% \text{ UT}$ (30 % dip in UT) for 25 cycles $< 5 \% \text{ UT}$ ($>95 \% \text{ dip in UT}$) for 5s | $< 5 \% \text{ UT}$ ($> 95 \% \text{ dip in UT}$) for 0.5 cycle $40 \% \text{ UT}$ (60% dip in UT) for 5 cycles $70\% \text{ UT}$ (30 % dip in UT) for 25 cycles $< 5 \% \text{ UT}$ ($>95 \% \text{ dip in UT}$) for 5s | Quality and stability of power supply lines must be appropriate for industrial/healthcare facilities. If the user wishes to use Modula during power interruptions, the Modula should be connected to interruption-save power supply or battery. |
| Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8 | 30 A/m | 30A/m 50 Hz / 60 Hz | 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.

Electromagnetic compatibility

| Immunity test | IEC 60601 – test level | Compliance level | Electromagnetic environment - guidance |
|-------------------------------|--------------------------------|------------------|---|
| 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 Duo, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance: $d = (3,5 / V1) * \sqrt{P}$ $d = (3,5 / E1) * \sqrt{P}$ 80 - 800 MHz $d = (7 / E1) * \sqrt{P}$ 0,8 - 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> |
| Radiated RF IEC 61000-4-3 | 10 V/m 80 MHz to 2,7 GHz | 10 V/m | <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> |

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 is used exceeds the applicable RF compliance level above, the Modula 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.

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

Electromagnetic compatibility

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and MODULA

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

| Rated maximum output power of transmitter (W) | Separation distance (d) according to frequency of transmitter in (m) | | |
|---|--|--------------------------|--------------------------|
| | 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. | | | |
| 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. | | | |

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 (Heinemann HNO 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.

11. Reporting of incidents

Report all serious incidents that have occurred in relation to the product (damages, injuries, infections, etc.) to the manufacturer and the competent authority of the EU Member State in which you are established. In Germany, the competent authority is BfArM. Current contact information can be found on the BfArM website: <https://www.bfarm.de>.

Corresponding MIR forms for reporting incidents can be found on the BfArM page. These can be found at the following link:

https://www.bfarm.de/DE/Medizinprodukte/Antraege-und-Meldungen/Vorkommnis-melden/Anwender-Betreiber-Haendler/_node.html

Manufacturer:

G. Heinemann Medizintechnik GmbH
Leibnizstraße 13-15
24568 Kaltenkirchen

T: +49 4191-95379-0
F: +49 4191-9537937

E-Mail: info@heinemann-ent.de
Web: www.heinemann-ent.de

Distributor:

