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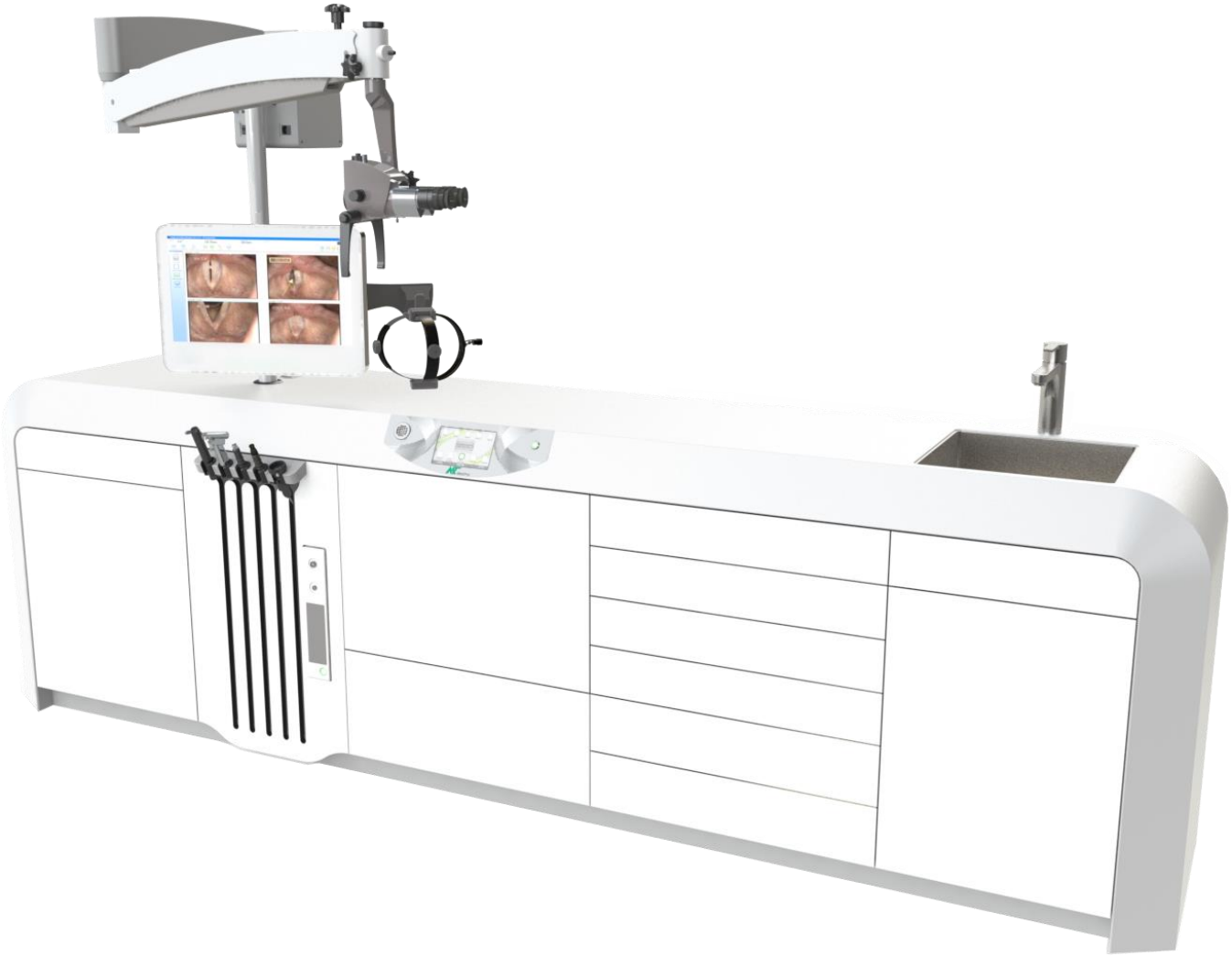

User Manual

ProminENT

CONTENT

CE
1912

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Warnings and Safety

- In case of incidents with the ProminENT, the manufacturer must be notified.
- To avoid the risk of an electric shock, this product should only be connected to an earthed mains power socket.

- The air outlet of the hot-air mirror heater gets hot during use. Do not touch it immediately after use.
- The metal outlet of the hot-air mirror heater may not be touched by the user simultaneously with the patient.
- The metal ring of the heated telescope holder(s) may not be touched by the user simultaneously with the patient.
- A PC without a medical power supply may not be connected to the ProminENT.
- A PC without a galvanic transformer separation may not be connected to the treatment unit and to the LAN.
- The ProminENT must be placed in such a way that the central switch is easily accessible.

- The light cable guide that goes into the light source can become very hot during use. To reduce the risk of burns when removing the cable from the light source, we recommend that one waits at least one minute after switching off the light source before taking the light cable out of the light source.
- No modifications are allowed on the ProminENT.
- No additional (multiple) socket extension leads may be connected to the ProminENT.
- Only apparatus may be connected that have been specified as part of the ProminENT or that have been specified as being compatible with the ProminENT.
- (Multiple) socket-outlets provided with the ProminENT shall only be used for supplying power to equipment that is intended to be a part of the ProminENT.
- Connection of equipment that is not supplied as part of the ProminENT to the (multiple) socket-outlet may lead to unsafe situations for the user and patient and may lead to electromagnetic disturbances because these devices have not been tested together with the ProminENT!
- Use the ProminENT treatment unit in accordance with this manual and applicable product labels.
- Do not use the pump consecutively for a prolonged period of time.
- Before plugging into the mains, please check if the supply voltage specified on the ProminENT is in accordance with the voltage of the power socket
- Occupational safety and usability of medical devices are determined not only by your ability, but also the maintenance of the device.
- Qualified service and use of original spare parts guarantee the operational safety, usability and integrity of your medical device is retained.
- After maintenance or repair, test the functioning of the ProminENT.
- After installation, the ProminENT must be tested for functionality and safety with the use of a medical electrical safety tester

1 ProminENT Treatment unit

1.1 Introduction

These operating instructions have been compiled for the ProminENT.
This unit is a Medical Electrical System (MES) which can be supplied for installation as a fixture.
Certain instrumentation section modules are available for ProminENT. The ProminENT can accommodate light sources for rigid and flexible telescopes and headlights. The ProminENT is designed for low maintenance and incorporates sensors in the handpiece holders to switch on and off various integrated functions.
When treated with care, the ProminENT treatment unit will provide years of trouble-free use.

1.1.1 Application(s)

The ProminENT is designed as a fixed unit workstation to be able to work on a neat and ergonomic manner in your ENT-practice.
These operating instructions have been compiled for the ProminENT ENT treatment unit which is a Medical Electrical System (MES).
This unit is supplied for installation as a fixture. Certain instrumentation section modules, sanitary part and desk are available for the ProminENT. The ProminENT can accommodate light sources for rigid and flexible telescopes and headlights. The ProminENT is designed for low maintenance and incorporates sensors in the handpiece holders to switch on and off various integrated functions.
The unit also incorporates functional storage areas for instruments and used instruments deposit as well as small waste disposal.

When treated with care, the ProminENT will provide years of trouble-free use.

1.1.2 Use

All external devices connected to the ProminENT treatment unit can be switched on and off individually.
If the ProminENT treatment unit will be centrally activated some features will be on "standby". (mirror heater, microscope) and other will be switched on (heated telescope holder, mirror pre-heater).
The stand-by devices can then be switched on and off by pressing a button on the control console (touch screen).
The integrated functions are automatically activated whenever a handpiece, hose, cable or probe (for example, suction, fibre optic light etc.) is taken out of the corresponding handpiece holder. If placed back in its holder, the device switches back off.

Only use original MediTop parts to replace any parts in the ProminENT.
Only by MediTop delivered system parts are allowed to be placed/integrated in the ProminENT.

1.1.3 Intended use

Medical Purpose
The ProminENT is intended for use during ENT examination and treatment and provides a table, drawers for ENT instruments and accessories, suction tubes, blowing, warming, light or current (A) and receptacles for connection with examination and treatment devices.

Intended User
The ProminENT should only be used by (ENT) physicians (assistants).
Alternatively, during installation, maintenance or repair, the ProminENT might also be operated by the technicians who install, maintain and repair the device.

User Characteristics
(ENT) physician (assistant)
Technicians either working for or trained by MediTop or its local partners.

Patient Population
Patients with ENT related complaints that require examination and/ or treatment using devices stored and/ or to be connected to the ProminENT.

Age:	Human patients of pediatric to geriatric age.
Health:	Not relevant
Nationality:	Not relevant

Measurement and treatment site: Ear, Nose & Throat

Intended Use Environments
The ProminENT is designed for outpatient use in a hospital environment.

Mobility
The ProminENT is designed as a fixed unit.

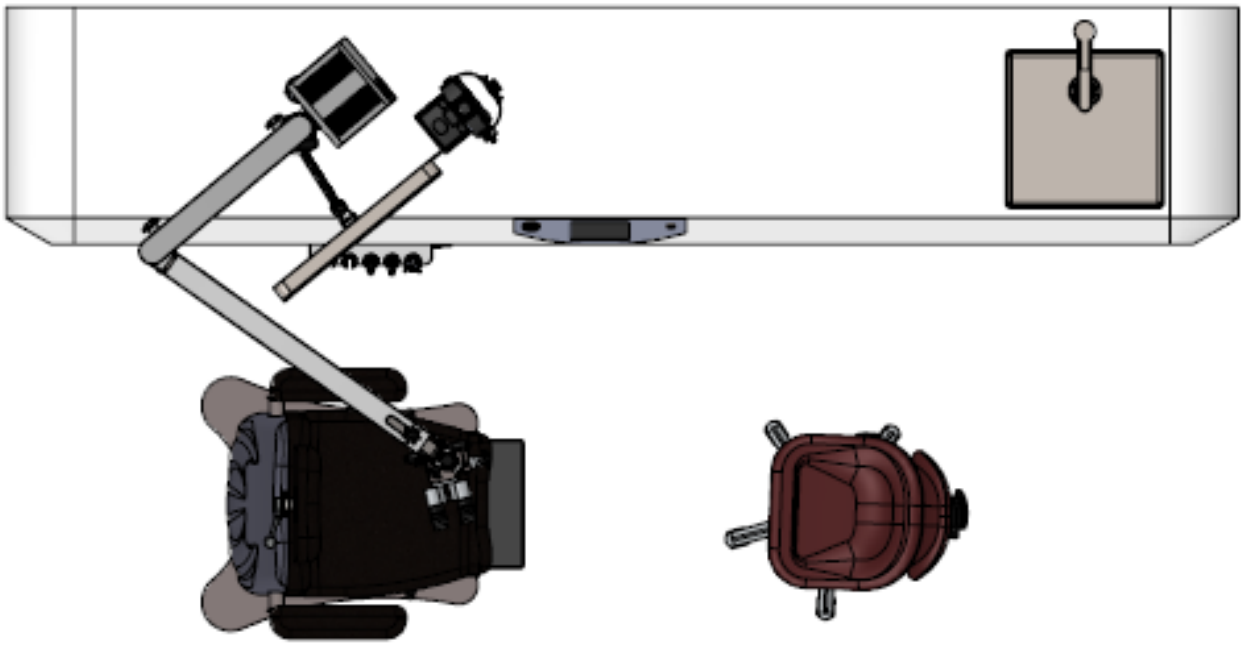
Precautions for Use
Warnings and cautions described in the instruction manual should be observed at all times.

Only by MediTop delivered system parts are allowed to be placed/integrated in the ProminENT.

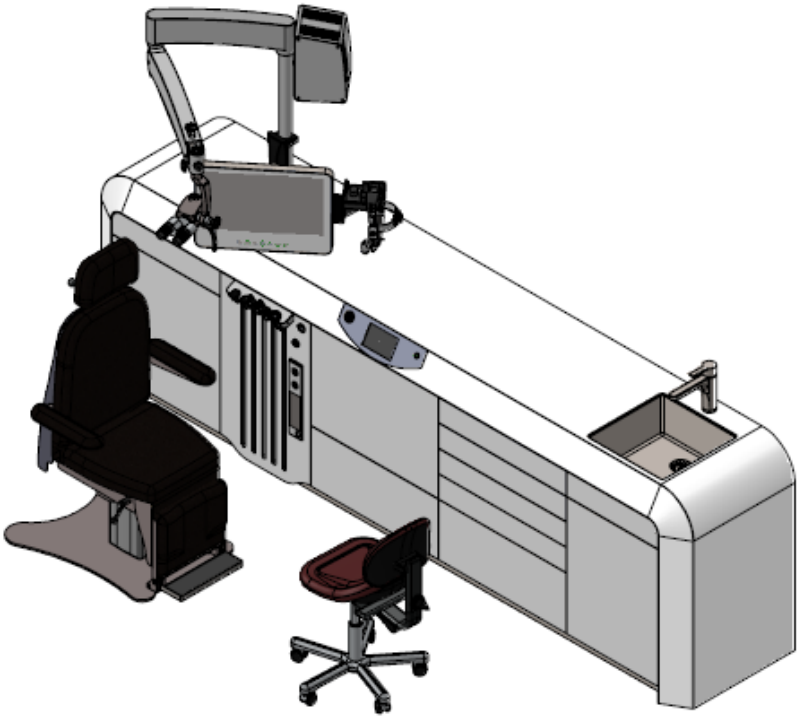
1.1.4 Central amenities

In some cases, hospitals have central amenities such as (drink)water, vacuum and compressed air.
These can be connected to the ProminENT treatment unit. If not available, a suction pump and compressor can be built in the ProminENT treatment unit. However, the ProminENT cannot accommodate a water tank.

1.1.5 Position of Patient and Physician



Patient Physician



1.2 Installation

1.2.1 Installation of the ProminENT

The installation of the ProminENT is done by an approved service agent.

1.2.2 Testing of the ProminENT

After installation, the ProminENT will be thoroughly tested by your approved service agent. Only when the entire unit is functioning satisfactory and safely will the ProminENT will be considered as delivered.

The ProminENT must be tested after maintenance and repair.

After installation, the ProminENT must be tested for functionality and safety using an approved medical electrical safety tester.

1.2.3 Short instruction of the ProminENT

After the test one of the employees of your approved service agent will give you an instruction, which will take about thirty (30) minutes to help you working with the ProminENT.

1.3 Operating the ProminENT

This chapter provides details on the operation of the ProminENT.
Read and understand all the information before operating the ProminENT.

Do not use the ProminENT or any available optional equipment without first completely reading and understanding the instructions outlined in this document and the respective manuals of installed optional equipment.

It is not allowed to service the unit during a treatment.
When service is needed the treatment has to be interrupted.

1.3.1 Parts of the ProminENT

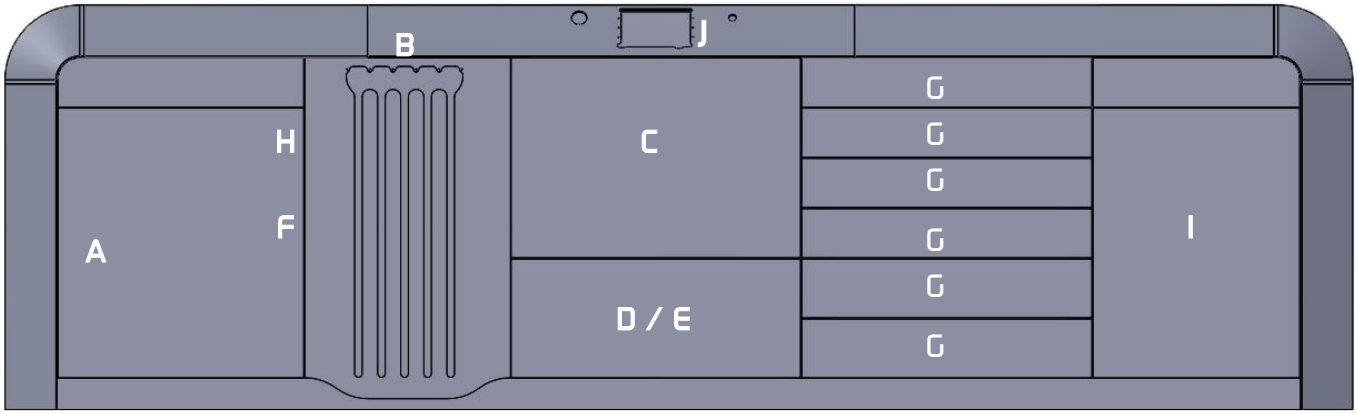


Figure A – Front view ProminENT

A = External device compartment
B = Handpiece holders
C = Instruments compartment
D = Waste container
E = Used instruments
F = Electronics compartment
G = Storage drawer
H = Mains switch (behind panel)
I = Sanitary part
J = Control console

A. External devices can be placed in this compartment.

B. Functions linked to an instrument can be switched ON and OFF by removing the handpiece from its holder and putting it back after use. (see chapter 1.4.3. – Handpiece holders)

C. This compartment houses two instrument plateaus in which instruments can be arranged for use.

D. Waste container

E. Container for depositing used instruments in.

F. The electronics compartment is located behind this panel.

G. Drawers for accessories and instruments

H. Mains power switch cuts the power to the ProminENT.

I. Sanitary part

J. Main control console (touch screen) with On/Off switch to switch the ProminENT On (On) and Off (Standby)
If this button glows green, it means that the ProminENT is plugged in and switched on at the mains power switch.

1.3.2 Parts of the ProminENT Touch control console

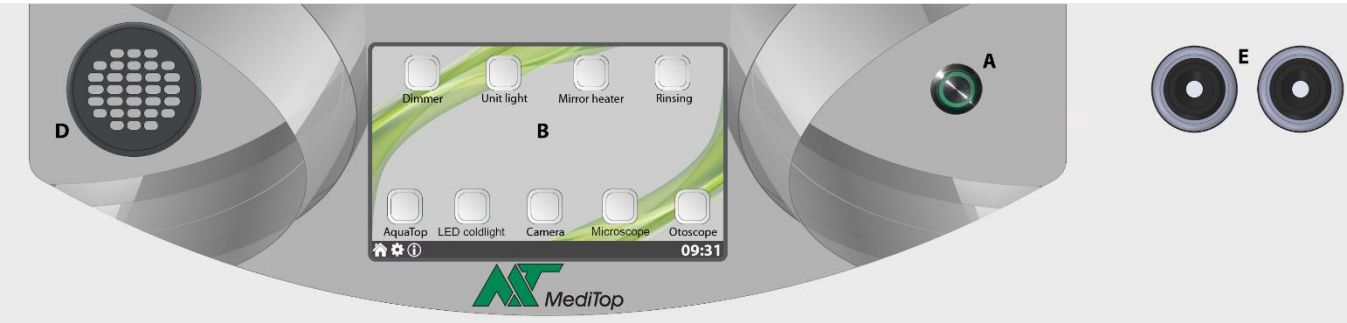


Figure B – Front view control console ProminENT

The following are located on the control console:

A - On/Off switch. This button switches on the ProminENT and puts it into standby mode.
If this button glows green, it means that the ProminENT treatment unit is plugged in and switched on at the mains power switch.

B - Touch control console

and when included in the unit's configuration

D – Hot-air mirror heater
The mirror heater has a hot-air vent and a button on the control console.
(see chapter 10 – Function: Hot-air Mirror heater (If present)on page 87)

E - (heated) telescope holder(s)
The heated telescope holder(s) keep the telescopes that are placed therein warm at a temperature that is comfortable for the patient and the warmth prevents fogging of the distal end.
(see chapter 12– Function: Heated telescope holder (If present)on page 94)

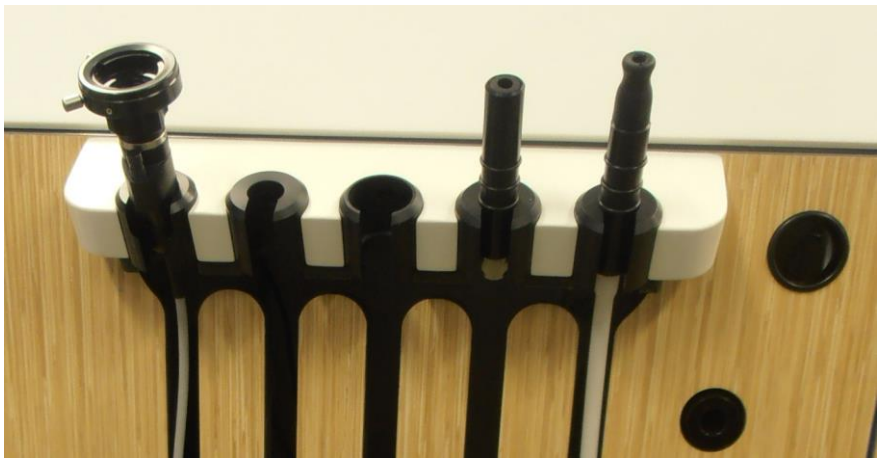


Figure C - Front view handpiece holders ProminENT

1.3.3 Start-up ProminENT

The standby button is located on the right side of the touchscreen on the control console. If the main of the unit is switched on the On/Off switch will glow green. When the standby button is pressed the button lights up green.

Please note:
When the ProminENT is ready for operation the relevant built-in functions can be activated by touching the dedicated buttons and will illuminate the touch screen. (See images below)

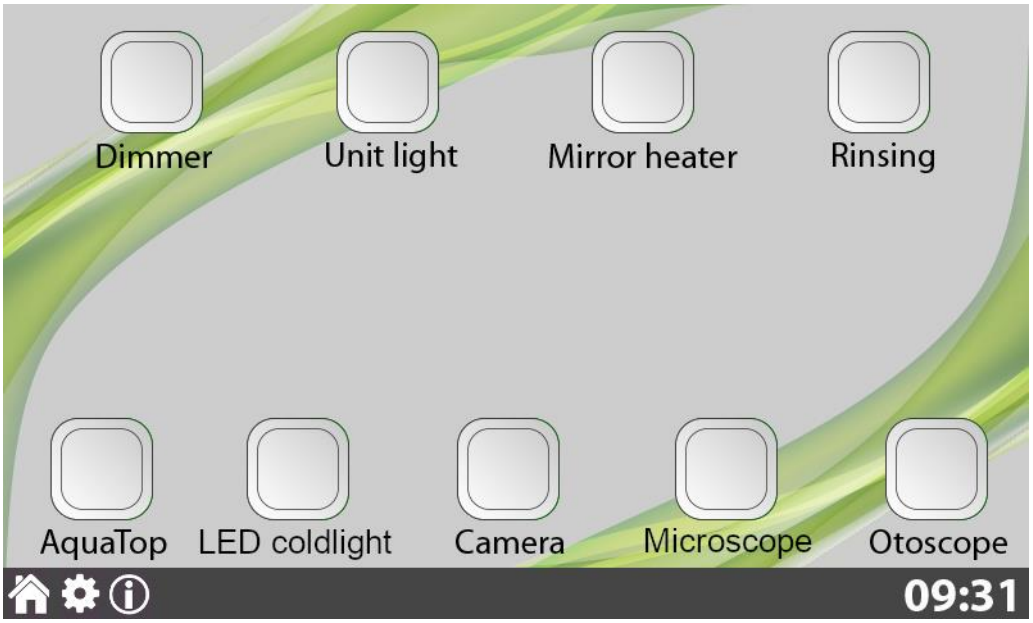


Figure D – Control panel (Touch screen) ProminENT treatment unit

The format and the number displayed buttons is customer-specific. Above a possible layout.
On the lower dark grey bar items are displayed as below:

 Home, return to start screen (figure D)

 Settings menu

 Information screen

09:31 Current time

1.3.4 Settings Menu

To open the Settings Menu press on: 
The following will be displayed.

Figure E – Settings Menu

1.3.4.1 Unit lightning settings

When you press on “Unit lightning” you can set the colour and brightness of the built in LED-lights.

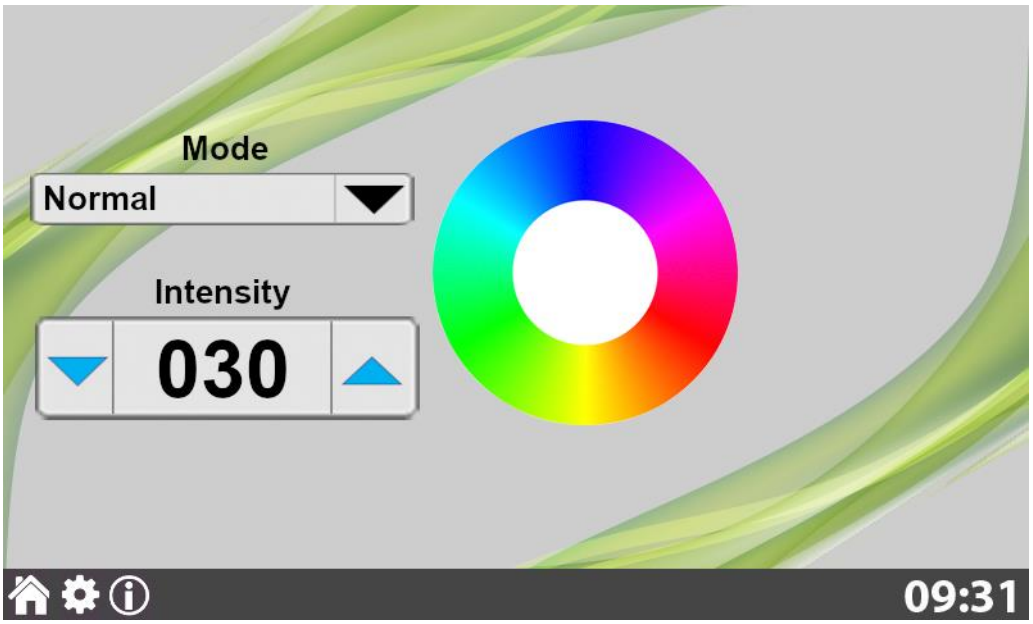


Figure F – Unit lightning settings

By pushing on a colour in the circle the LED-light will change accordingly.
The chosen colour appears in in the middle of the circle.
If for example you have pressed light green the middle of the circle will be:

Changing the brightness can be done with pressing the and buttons.

When all settings are done press to return to the Settings menu or press to return to the start screen.

1.3.4.2 Monitor settings

When pressed on “monitor” you can set the position of the Picture In Picture (PIP) screen.

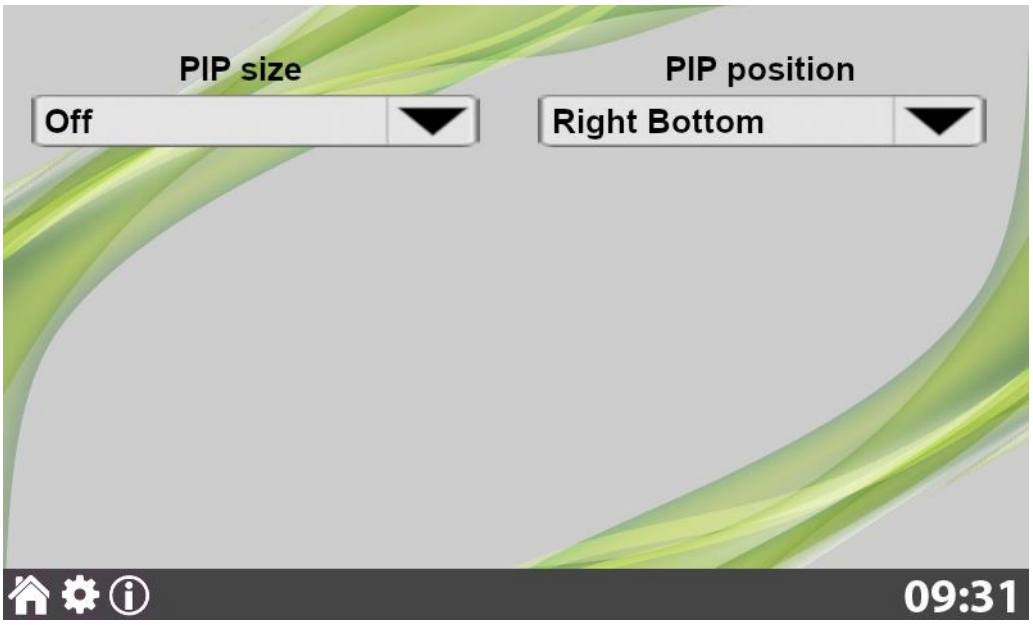


Figure 6 – Monitor settings

Setting PIP size:
You can choose from 4 options:

- Off
- Small
- Large
- Side by Side

Setting PIP position:
You can choose from 4 positions:

- Right Top
- Right Bottom
- Left Top
- Left Bottom

Changing size and position can be done by pressing .

When all settings are done press to return to the Settings menu or press to return to the start screen.

1.3.4.3 LED Fibre optic light settings

For setting the LED fibre optic light system we refer to chapter 8.1.4 on page 72.

1.3.5 Information display

To open the information display, press on 
The following will be displayed

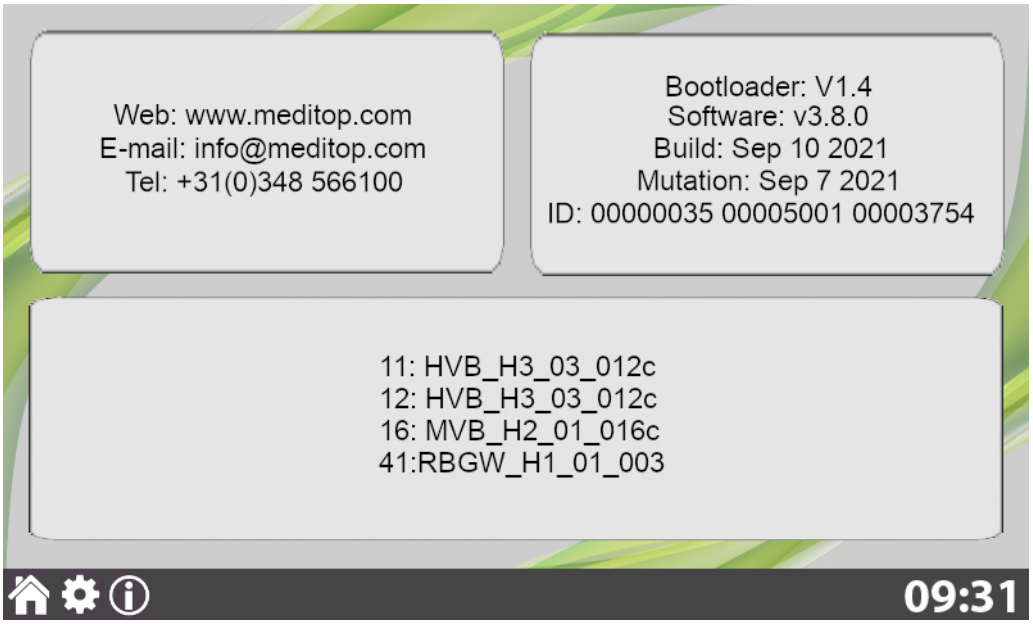


Figure H – Information display ProminENT

1.3.6 Setting Date and Time

Press on displayed time on the right side of the menu bar 

1.3.6.1 Setting the Time

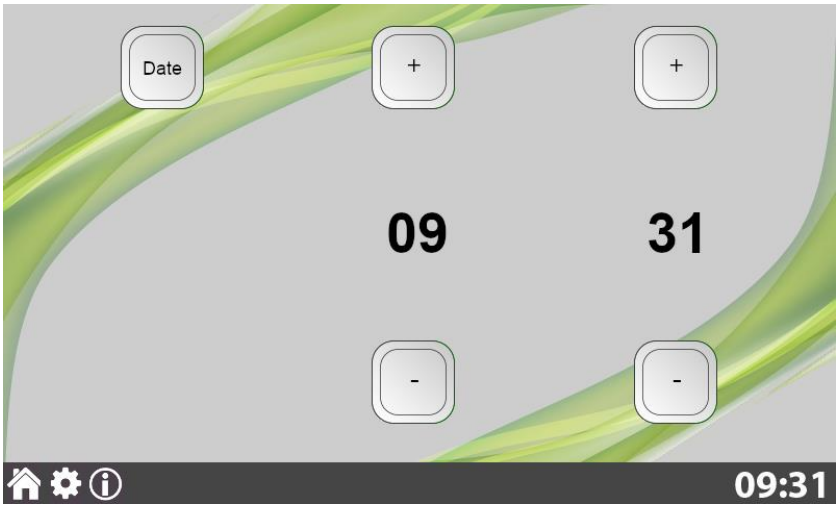


Figure 1 – Time settings

With the  and  buttons you can set the hours and minutes.

When time is set press on  to set the Date

1.3.6.2 Setting the Date

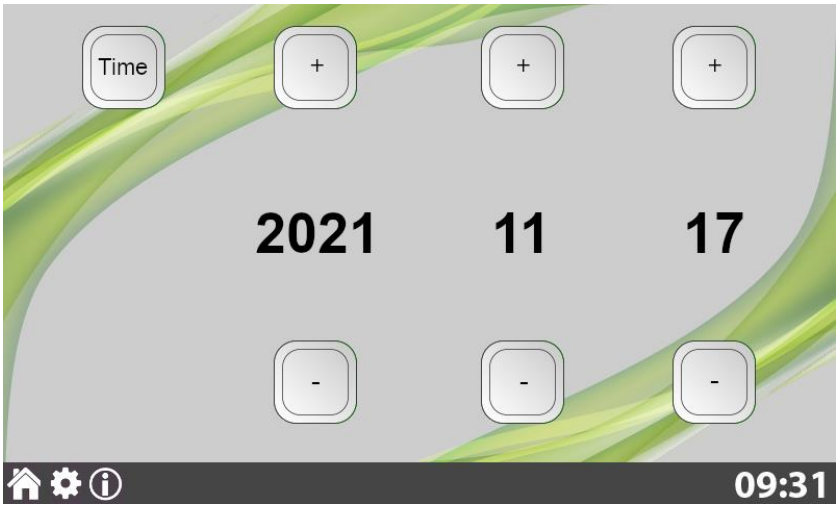


Figure 2 – Date settings

With the  and  buttons you can set the year, month and day.

When date and time are set press  to save the time and date and to return to the start screen.
The ProminENT is now ready for use again.

1.3.7 Shut down the ProminENT

1.3.7.1 Shut down when rinsing system automatic secretion discharge system is not available

Firmly press the standby button (A).

The button starts blinking green for approximately 10 seconds. After the 10 seconds the button will glow green (fade in/fade out). This indicates that the ProminENT is in its standby mode.

Notice that the standby mode does not shut down the ProminENT completely.

1.3.7.2 Shut down when rinsing system automatic secretion discharge system is available

Firmly press the standby button (A).

The button starts blinking green for a period of approximately 7 minutes during the cycling mode. After the 7 minutes the button will glow green (fade in/fade out). This indicates that the ProminENT is in its standby mode.

Notice that the standby mode does not shut down the ProminENT completely.

1.4 Construction and operation of the ProminENT

1.4.1 General

The ProminENT treatment unit offers space for a variety of devices and instruments. In the following chapters the control console and handpiece holders will be reviewed.

In separate enclosed user manuals, the rest of the built-in functions will be explained, and reference is made to here, because the number of possible configurations of the ProminENT is very extensive.

1.4.2 Touchscreen control console

The integrated touch-screen control console is located on the front of the therapy section.
The type of icons on the touch screen are depending of the chosen optional functions by the customer.
The touchscreen control console features up to ten (10) buttons indicating which function/device is being operated and an optical signal.

Default (not activated) the button is light grey. 

If the function/device integrated in the ProminENT is activated the button will be green outlined. 

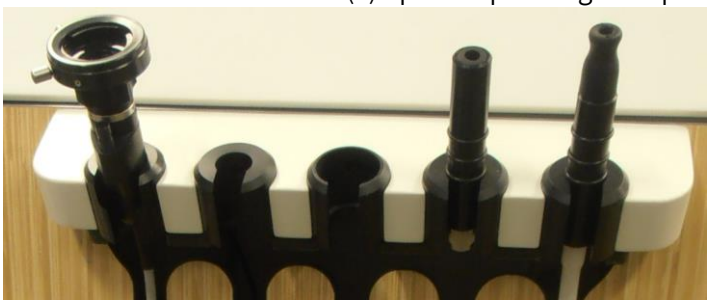
The round button to the right of the control panel  functions as central ON / OFF button.
If this key glow green, it means that the ProminENT is plugged in and switched on by the main switch.

Is the ProminENT switched on with this button, the touch screen control panel will light up and the various functions connected to the system can be used.
If the ProminENT will be centrally switched on, all devices are at first standby or off.
This setting is adapted at delivery to the connected function, but can be changed.

1.4.3 Handpiece holders

Various functions may only be activated when treatment requires this function. These functions are integrated in the handpiece holders which detect the presence or absence of the handpiece.

The ProminENT features five (5) optical operating handpiece holders.



If the handpiece of the assigned function is present the function switches off.
Whenever the handpiece is removed from its holder, the assigned function will switch on until the handpiece is placed back in its holder.

1.4.4 Other devices and functions

For use of the other devices and functions we refer to the separate enclosed user manuals.

1.5 Maintenance

The ProminENT is constructed of a combination of materials for optimum hygiene, durability and appearance. The dual-component finish on the wooden front panels and metal parts is non-porous and easy to clean. It is resistant to alcohol and other disinfectants.
The Thermopal laminated finish on the worktop is highly suited to a medical environment due to its durability and resistance to aggressive cleaning agents and disinfectants.
The same applies to the optional Marlan worktops. Only this Marlan material is advantageous in that it can easily be refurbished.

Special attention needs to be paid to the cleaning of our drawer fronts, these do not have handles on them. The wide grip in the top of the drawer fronts makes for an excellent handle and it can be wiped clean effortlessly.

Remove any coloured chemical residue from the unit immediately.

Do not use abrasive cleaning chemicals.

1.5.1 Daily

- Rinsing of the hoses of the suction system by sucking up about 30 cc disinfectant liquid;
- Emptying the waste container;
- Emptying and disinfecting the used instruments container.

Cleaning of the ProminENT and removing medicine residues must be in accordance with current local environmental regulations.

1.5.2 Weekly

For hygienic reasons it is recommended that the ProminENT is cleaned weekly. This prevents the accumulation of bacteria in the treatment unit. The cleaning solutions used for the ProminENT should be of the domestic, non-abrasive type.

1.5.3 Preventive maintenance

MediTop recommends to perform annual preventive maintenance on the unit by a qualified technician.

During the annual preventive maintenance MediTop recommends to check the following:

- Check all functions (i.e. suction pump, compressor, cold light, heaters, rinsing system, computer programmes) and setting of date and time.
- Check, clean and adjust microscope, ensure that the assembly and weight distribution is stable.
- Check the mains power cord and the appliance couplers for damage.
- Check all cables (i.e. foot pedal, electrode, examination camera). Carefully examine cables to detect breaks in the insulation and to ensure that they are securely fixed in the connectors at each end.
- Check all plumbing and connections.
- Visual inspection of the printed circuit boards, check for the presence of abnormal phenomena. (i.e. deformed components, moisture, excessive heat)
- Check the exterior of the unit for cleanliness and general physical condition.
- Check lacquer surfaces, repair chipped areas, refer to the documentation for the correct RAL colour.
- Check the drawers and drawer rails, adjust and lubricate these.
- Check the sliding rail with the handpiece holders
- Align drawer fronts and doors.
- Check for loose panels and fasten these.
- Visually inspect the muffler on the suction pump, check for (abnormal) presence of moisture.
- Visually inspect and clean entire automatic secretion discharge system and suction parts and components.
- Visually inspect polyurethane tubing for kinking, damage or leakage.
- Visually inspect fibre optic cables and measure their optical conductivity.
- Visually inspect and clean the heat protection glass(es) under the light bulb(s).
- Inspection of all cooling fans.
- Ensure all fixings, screws and fasteners are in place and tight.

1.5.4 Periodical Inspection

MediTop recommends you to have the ProminENT checked once (1) a year by a qualified technician from your dealer.

In order to ensure that the water supply system in which the cleaning system is connected remains free of impurities, the non-return valve has to be cleaned at least one (1) times a year, and checked for proper functioning.

The one-way valve protection should be replaced every 10 years!

1.6 Warranty

1.6.1 Total warranty

The warranty for the ProminENT treatment unit is 12 months from the date of invoice, unless otherwise in writing agreed.

This warranty includes all parts that fail during the 12-month period and on-site labour.

1.6.2 Exclusions

NOT covered by the above warranty:

- Faults in or at parts, apparatus and instruments related to misuse or abuse by untrained personnel.;
- Defects related to normal wastage in or at parts, apparatus and instruments.
- Unauthorized alteration or repair.
- Misuse, abuse and incorrect maintenance.
- Damage caused by wrong handling or transportation.
- Damage caused by peaks in supply voltage or wrong voltage characteristics, damaged cause by incorrect ambient conditions or other non-adherence to the applicable ambient requirements.
- Alteration, defacement or removal of the serial number.

The warranty of a component, device, or instrument is void if misuse, abuse or unauthorized use within the warranty period, results to a claim for the above warranty "from any shortage" to the delivered parts, equipment or tools.
"Any shortage" means material or manufacturing error that causes the component, device or mechanism not working properly

In case of a malfunction, never attempt to repair a MediTop treatment unit yourself.
Notify your local distributor. Only qualified technical personnel authorized by the manufacturer may perform repairs to the ProminENT.

1.6.3 Consumables

Warranty on consumables, such as suction tubing, disposables, waste bags, etc. will explicit not be granted.

1.7 Technical specifications

1.7.1 Safety standards

Reference	Standards	Revision date
QMS		
EN ISO 13485 + A11:2021	Medical Devices -Quality Management systems – Requirements for regulatory purposes.	2016
Product		
EN-IEC 60601-1:2006 + AC:2010 + A1:2013 + A12:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2006
EN-IEC 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	2015
EN-IEC 60601-1-6 + A1:2015 + A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	2010
EN-IEC 62304:2006 + C11:2006 + A1:2015	Medical device software - Software life-cycle processes	2006/A1:2015
EN-IEC 61000-3-2	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	2014
EN-IEC 61000-3-3	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection	2013
EN ISO 14971 +A 11:2021	Medical devices - Application of risk management to medical devices	2019
EN IEC 62366-1 + A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices	2015
Information supplied		
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices	2008/A1:2013
EN-ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2021
Sterility		
N.A.		
Sterile barrier system		
N.A.		

1.7.2 Specifications

Classification (according IEC 601-1)	:	1.
Type (according IEC 601-1)	:	B.
Classification (according 93/42/EEC)	:	IIa
Power supply	:	230 Volt AC - 50 Hz.
Voltage internal electronics	:	+12V DC and 3V3 DC.
Maximum use	:	2300 VA (circa 2000 Watt).
Safety	:	Glass fuse T10A.
Weight	:	150 kg.

Environment (during use)

Protection class [1)]	:	IP22
Operating temperature	:	+10° C to +40° C
Humidity	:	10 to 90%, non-condensing
Atmospheric pressure	:	700 to 1100 hPa
Minimum water pressure	:	2.0 Bar (very important with option AquaTop XS)
Maximum water pressure	:	6.0 Bar
Water hardness	:	<7dH

Transport and Storage

Ambient temperature	:	max. 50° C
Relative humidity	:	10 to 90%, non-condensing
Atmospheric pressure	:	no restrictions

1) *The **IP**-code, International Protection Rating, classifies and rates the degree of protection provided against the intrusion of solid objects (including body parts such as hands and fingers), dust, accidental contact, and water in mechanical casings and with electrical enclosures. It is published by the International Electrotechnical Commission (IEC).*
The standard aims to provide users more detailed information than vague marketing terms such as waterproof.
This device, rated IP22 is protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water.

If present:

Compressed air system

Maximum allowable air pressure	:	8 bar.
Pressure set to	:	1.8 bar
Connections	:	8 mm PU-tubing.
Power consumption pump	:	450 VA.
Power consumption valve	:	15 VA.

Suction system

Maximum suction pressure	:	No restriction
Connections	:	8 mm PU tubing.
Power consumption pump	:	90 VA.
Power consumption valve	:	15 VA.
Power supply electronics automatic discharge	:	24 Volt AC.

Fibre optic light system

Power consumption	:	60 VA.

Hot-air Mirror heater

Power consumption	:	360 VA.

Mirror pre-heater

Power consumption	:	38 VA

Heated telescope holder

Power consumption (per holder)	:	12.2 VA.

AquaTop XS warmwater irrigator

Maximum use	:	1100 VA
Safety	:	Glass fuse T6.3A
Temperature settings	:	30° C, 37° C, 44° C
Maximum water pressure	:	6.0 bars [2)]
Water pressure setting	:	1.8 bars

Socket-outlet (Internal)

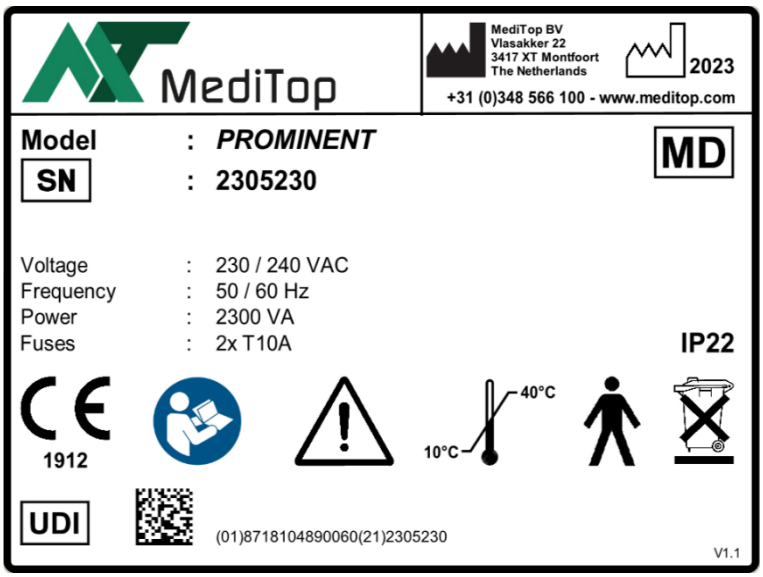
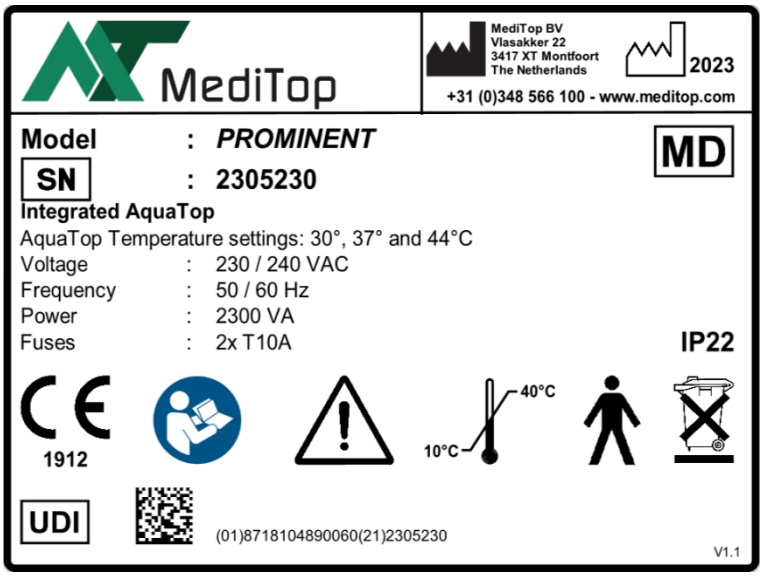
Maximum use	:	15VA

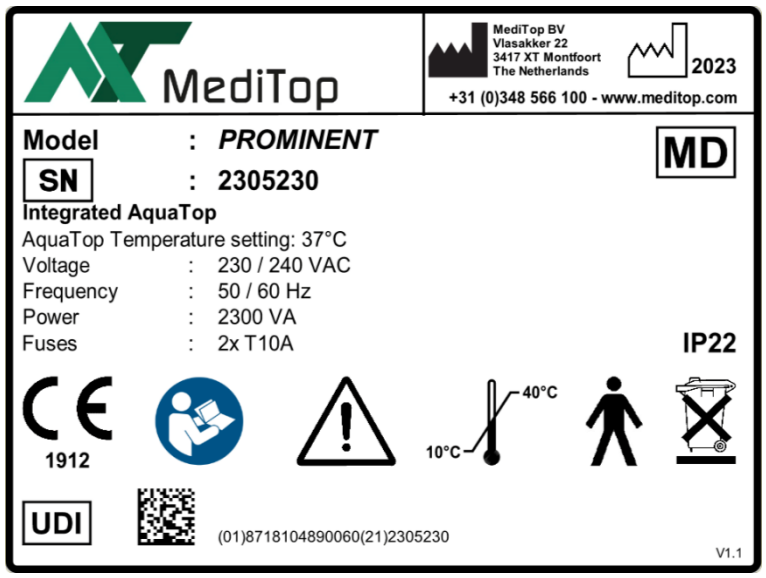
Note:
(Multiple) socket outlets provided with the ProminENT shall only be used for supplying power to equipment that is intended to form part of the ProminENT.

[2)] *If the supply is higher than 6 bar, you must place a reducing valve between the water supply and the water inlet of the AquaTop XS*

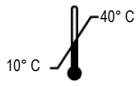
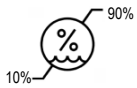
1.7.3 Identification label

The identification label can be found on the electronics compartment.
In the examples below the serial number is: 2305230
This can be deciphered as follows: 2305230 = yymm sequence number#(3 digits)
The unit is manufactured in the 5th month of 2023 and it is the 230th unit produced in this example.

	Version without AquaTop XS warmwater irrigator.
	Version with integrated AquaTop XS warmwater irrigator 3 temperatures.

	Version with integrated AquaTop XS warmwater irrigator 1 temperature.

1.7.4 Explanation of symbols

CE 1912	This symbol indicates that the ProminENT is a class IIa product which is in accordance with the medical directive 93/42/EEC, Annex II.
	The exclamation mark within an equilateral triangle is intended to alert the user to the presence of important operating and maintenance (servicing) instructions in the literature accompanying the appliance.
	This symbol is to signify that the instruction manual must be read.
	This symbol indicates that the ProminENT is type B according to IEC601-1.
	This symbol indicates the presence of the protective earth conductor.
	Year of manufacture
	Manufacturer Information.
SN	Serial number.
MD	This symbol indicates that the ProminENT is a Medical Device.
UDI	Unique Device Identifier for Medical Devices.
	Temperature limit for use.
	Temperature limit for transport and storage.
	Humidity limitation.
	Fragile, handle with care.
	Keep dry.
	Warning for hot surface
	Separate waste collection for electrical and electronic devices.

1.7.5 Guidance and manufacturer's declaration – electromagnetic immunity

⚠	The ProminENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the user manual.
⚠	Wireless communication devices, such as wireless devices in the home network, mobile phones, cordless phones and their base stations, walkie-talkies can affect the ProminENT.
⚠	We advise you not to place the ProminENT very close to other electronic equipment. Should this be the case, the operation of the ProminENT should be regularly monitored.
⚠	Although this device complies with the standard of IEC 60601-1-2 concerning electromagnetic compatibility, all electrical appliances may cause interference.
⚠	If you suspect that interference occurs, you must separate the equipment and contact your local dealer or MediTop

1.7.5.1 Applied standards

Test	Standard	Class / Level
Emission	NEN-EN-IEC 60601-1-2:2015	B
Immunity	NEN-EN-IEC 60601-1-2:2015	Professional healthcare facility environment
Emission	NEN-EN-IEC 61000-3-2:2014	A
Emission	NEN-EN-IEC 61000-3-3:2013	--

1.7.5.2 Table 4 - Enclosure port

Phenomenon	Basic EMC standard or test method	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM fields [a)]	IEC 61000-4-3	3 V/m f) 80 MHz – 2,7 GHz [b)] 80 % AM at 1 kHz [c)]	10 V/m f) 80 MHz – 2,7 GHz [b)] 80 % AM at 1 kHz [c)]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See 8.10 of NEN EN ISO 60601-1-2:2015	
Rated power frequency magnetic fields [d) e)]	IEC 61000-4-8	30 A/m [g)] 50 Hz or 60Hz	

a) The interface between the patient physiological signal simulation, if used, and the ME Equipment or ME System shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME Equipment or ME System.
b) ME Equipment and ME Systems that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the Risk Management Process. This test assesses the Basic Safety and Essential Performance of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during test.
c) Testing may be performed at other modulation frequencies identified by the Risk Management Process.
d) Applies only to ME Equipment and ME Systems with magnetically sensitive components or circuitry.
e) During the test, the ME Equipment or ME System may be powered at any nominal input voltage, but with the same frequency as the test signal (see Table 1).
f) Before modulation is applied.
g) This test level assumes a minimum distance between the ME Equipment or ME System and sources of power frequency magnetic field of at least 15 cm. If the Risk Analysis shows that the ME Equipment or ME System will be used closer than 15 cm to sources of power frequency magnetic field, the immunity test level shall be adjusted as appropriate for the minimum expected distance.

1.7.5.3 Table 5 - Input a.c. power port

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrical fast transients / bursts [a) l) o)]	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges [a) b) j) o)] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges [a) b) j) k) o)] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields [c) d) o)]	IEC 61000-4-6	3 V m) 0,15 MHz – 80 MHz 6 V [m)] in ISM bands between 0,15 MHz and 80MHz n) 80% AM at 1 kHz [e)]	3 V m) 0,15 MHz – 80 MHz 6 V [m)] in ISM and amateur radio bands between 0,15 MHz and 80MHz n) 80% AM at 1 kHz [e)]
Voltage dips [f) p) r)]	IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [q)]	
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles [h)] Single phase: at 0°	
Voltage interruptions [f) i) o) r)]	IEC 61000-4-11	0 % UT; 250/300 cycle [h)]	

a) The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.
b) All ME EQUIPMENT and ME SYSTEM cables are attached during the test.
c) Calibration for current injection clamps shall be performed in a 150 Ω system.
d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.
g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.
h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.
i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.
j) ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).
k) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.
l) Direct coupling shall be used.
m) r.m.s., before modulation is applied.
n) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.
p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.
q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip.
If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.
r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltage. ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input voltage within the range. See Table 1 Note c) for examples calculations.

1.7.5.4 Table 6 - Input d.c. power port

There is no such a port in the ProminENT, so this test is Not Applicable.

1.7.5.5 Table 7 - Patient coupling port

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic discharge [c)]	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Conducted disturbances induced by RF fields [a)]	IEC 61000-4-6	3 V b) 0,15 MHz – 80 MHz 6 V [b)] in ISM bands between 0,15 MHz and 80MHz 80% AM at 1 kHz	3 V b) 0,15 MHz – 80 MHz 6 V [b)] in ISM and amateur radio bands between 0,15 MHz and 80MHz 80% AM at 1 kHz

a) The following apply:
All PATIENT-COUPLED cables shall be tested, either individually or bundled
PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
b) r.m.s., before modulation is applied
c) Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation.
PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

1.7.5.6 Table 8 - Signal input/output parts port

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic discharge [e]	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Electrical fast transients / bursts [b] [f]	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency	
Surges Line-to-ground [a]	IEC 61000-4-5	± 2 kV	
Conducted disturbances induced by RF fields [b] [d] [g]	IEC 61000-4-6	3 V h) 0,15 MHz – 80 MHz 6 V [h] in ISM bands between 0,15 MHz and 80MHz [i] 80% AM at 1 kHz [c]	3 V h) 0,15 MHz – 80 MHz 6 V [h] in ISM and amateur radio bands between 0,15 MHz and 80MHz [i] 80% AM at 1 kHz [c]

a) This test applies only to output lines intended to connect directly to outdoor cables.
b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.
c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
d) Calibration for current injection clamps shall be performed in a 150 Ω system.
e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.
f) Capacitive coupling shall be used.
g) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
h) r.m.s., before modulation is applied.
i) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

1.7.5.7 Table 9 - Test specifications for enclosure port immunity to RF wireless communications

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation [b]	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 [b], RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 [a]	Pulse modulation [b] 217 Hz	0,2	0,3	9
5500						
5785						

NOTE:
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

1.7.6 Manufacturer

Name: MediTop BV
Address: Vlasakker 22
ZIP code: 3417 XT
City: Montfoort
Country: The Netherlands

Phone: +31 348 566 100
Email: info@meditop.com

1.7.7 Disposal

When the ProminENT has reached the end of its lifetime and needs to be replaced, the ProminENT should be disposed of in accordance with local laws and regulations.

Before disposal of the unit, the suction system needs to be carefully and thoroughly flushed and disinfected to prevent infectious material from remaining in the system.

The ProminENT can be dismantled and divided in 3 major parts:

- Metal
- Plastics
- Electronic/electrical parts (please follow the local laws and regulations for electrical equipment)

This symbol means that the product must not be disposed of as normal domestic waste.

Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste, it should be disposed in accordance with the DIRECTIVE 2012/19/EC.
The correct disposal of electrical or electronic devices helps to protect the environment and to prevent potential hazards to the environment and/or human health which may occur as a result of improper handling of the devices concerned. For detailed information on the disposal of the product, please contact your local dealer or the device manufacturer or its legal successor. Please also note the manufacturer's current information on the Internet. In the event of resale of the product or its components, the seller is required to inform the buyer that the product must be disposed of in accordance with the applicable national regulations currently in force.

For regions outside the European Union disposal should be in accordance with local regulations, so this product should be disposed of as an electronic device separately.

1.7.8 Shelf life

The ProminENT has no limited shelf life before commissioning.

1.7.9 Life

The life of the ProminENT is 10 years, provided that the annual maintenance is performed.

1.8 Troubleshooting

NOTE: Troubleshooting may only be performed by an authorised technician.

1.8.1 The ProminENT treatment unit is not functioning at all.

Is the main switch on and is the On/Off switch burning green?

- Yes, have an authorised technician check the ProminENT or consult an approved service agent.
- No, switch the unit on

1.8.2 One of the built-in functions is not functioning.

If a function/device integrated in the ProminENT treatment unit is activated (button will be green outlined) or if a handpiece is taken out of the holder and the assigned function/device is not working we refer you to the separate enclosed user manuals.

2 Function: Suction system with Automatic Secretion Discharge system (If present)

2.1 Introduction

2.1.1 Application(s)

The intended use of the suction system with automatic secretion discharge system is to collect the sucked-up secretions and automatically discharge the medium to the waste pipe after suction has ended.
The suction system with automatic secretion discharge system can only be used in combination with the ProminENT.

2.1.2 Use

Whenever the suction handpiece is removed from its holder, the pump will be activated or the solenoid valve opens allowing vacuum activation at the handpiece.
A suction tube can be placed in the handpiece. The function is now ready for use.
The sucked-up secretions are collected in the automatic discharge. If you place the handpiece back in the handpiece holder the vacuum will be stopped and the collected secretions will be discharged to the waste pipe.
We recommend disinfectant solution or water is sucked through the suction tube before it is removed and placed in the used instrument container. This ensures the suction tube does not get blocked.

2.1.3 How the Equipment functions

The sucked-up secretions are collected in the automatic secretion discharge system. If you place the handpiece back in the handpiece holder the vacuum will be stopped and the collected secretions will be discharged to the waste pipe.
When the receptacle fills up during use, the float valve cuts off the vacuum to the suction hose.
The electronics will now activate the valves of the automatic secretion discharge system for two (2) minutes.
The secretion receptacle will now be emptied to the waste pipe.
During these two (2) minutes there is no suction available at the handpiece, so there is no possibility to suck up secretions!

There is also a float-valve reservoir installed to prevent contamination from entering the suction pump or central vacuum system in the event of a failure of the solenoid valve or mechanical valve protection in the automatic secretion system

2.2 Maintenance

2.2.1 Cleaning the suction system

- The suction handpiece with rubber tip can be disconnected from the hose. If wanted it can be cleaned or sterilized;
- The suction tube needs to be sterilized after use. Also, it needs to be replaced by change of patient.

The suction handpiece is part of the ProminENT suction system. This suction handpiece does not come into contact with the patient; it is a connection piece between the suction tube instrument that does have contact with the patient and the suction system. The suction tube instrument that fits into this suction handpiece needs to be cleaned/disinfected/sterilized according to the regulations of the manufacturer of the instrument. The suction handpiece must be cleaned regularly.

ATTENTION:
The suction handpiece and the rubber suction tip ***cannot*** be sterilized on a temperature of 134°C.

The suction handpiece consists of 2 parts

1 2

1. Rubber suction tip, material Rubber – NBR
   This material is resistant to a maximum temperature of 125°C and it is resistant to, for example, oils, acids, alkaline and chemicals. This material can be cleaned briefly with alcohol.

2. Handpiece, material Delrin – POM
   This material is briefly resistant to temperature of 105°C to 120°C and continually resistant to 90°C.
   This material can be cleaned with alcohol.

Procedure:

- Pull the suction handpiece of the suction tube.
- Unscrew the rubber suction tip off the suction handpiece.
- Brush the inside of the rubber suction tip and the suction handpiece clean with a brush.
- The internal diameter of the suction tip and suction handpiece is Ø 4.0 mm!
- The outside can be cleaned/disinfected with 'for instance' an antibacterial cloth which is suitable to clean medical equipment for instance IzoPro (70 % isopropyl alcohol)
- We recommend when cleaning in a thermal disinfection device not to allow the temperature to exceed 90°C.
- After cleaning/disinfection screw the tip back onto the handpiece.

Cleaning and removing medicine residues must be in accordance with current local environmental regulations.

2.2.2 Maintenance

After using one of the suction tubes and before it is deposited in the used instrument container, always suck some disinfectant through the suction tube to be sure suction tube clean and clear.
The disinfectant will also clean the hoses inside the ProminENT.

It is necessary to replace the flexible hoses on the outside and from the secretion receptacle to the handpiece every six (6) months.

Suck after each session approximately half (½) a liter of water so that the system is thoroughly flushed.

CAUTION:

- Be sure not to suck up any foamy disinfectants or foaming cleaning agents with the suction hose; foam gets past the valve in the automatic suction device canister and little by little fills the float-valve reservoir.
- Do not suck up hot water into the suction system. Hot water condenses in the float-valve reservoir and also passes along the suction lines.

In order to ensure that the water supply system in which the cleaning system is connected remains free of impurities, the non-return valve has to be cleaned at least one (1) times a year, and checked for proper functioning

The one-way valve protection should be replaced every 10 years!

The equipment should only be serviced and supported by an authorised technician.
Service contracts are available on request.

2.3 Trouble shooting at the central suction

NOTE: Trouble shooting should be carried out by an authorised technician.

2.3.1 No vacuum at the handpiece when it is taken out of the handpiece holder

Is the ProminENT switched on?

- Yes, go to the next question
- No, please switch on the ProminENT

Is vacuum available on the central circuit?

- Yes, go to the next question
- No, have the central circuit tested by an authorised technician.

Is the collecting jar completely filled?

- Yes, go to "Secretion receptacle does not empty automatically"
- No, go to the next question

Is the valve blocked or broken?

- Yes, clean or replace the valve.
- No, go to the next question

Is there grime in the float-valve reservoir? (to be checked by an authorised technician)[3]

- Yes: Clean the float-valve reservoir well after emptying it to prevent the float becoming stuck in the lid.
  Ensure the float rests on the bottom of the reservoir.
  Make sure the float-valve reservoir is fitted back into its bracket properly.
- No: proceed to the next question

Is(are) the hose(s) blocked?

- Yes, replace the hose(s).
- No, consult an approved service agent.

[3] *Moisture/residue getting into the float-valve reservoir from the canister indicates that there is a problem with the automatic secretion discharge system.*
Automatic secretion discharge system check

- *Is the seal on the canister intact?*
- *Check the mechanical seal; is there dirt on the O-ring in the drain valve float?*
- *Check the operation of the solenoid valve. When activated an orange LED lights up on the PCB.*
- *Make sure that the automatic drain valve is hanging straight so the valve responds as it is intended*
- *Check the operation of the aeration valve.*

2.3.2 Insufficient vacuum at the handpiece when it is taken out of the handpiece holder

Is the lid of the secretion receptacle tightly closed?

- Yes, go to the next question
- No, please close it tightly

Is there a leaky hose?

- Yes, replace the hose(s).
- No, go to the next question

Is sufficient vacuum available on the central circuit?

- Yes, consult an approved service agent.
- No, have the central circuit tested by an authorised technician.

2.3.3 Secretion receptacle does not empty automatically

Is the valve for emptying opened?

- Yes, go to the next question
- No, consult an approved service agent.

Is the waste blocked?

- Yes, clean/unblock the waste
- No, consult an approved service agent.

2.4 Trouble shooting at the suction pump

NOTE: Troubleshooting may only be performed by an authorised technician.

2.4.1 No suction at the handpiece when it is taken out of the handpiece holder

Is the ProminENT switched on?

- Yes, go to the next question
- No, please switch on the ProminENT

Is the vacuum pump running?

- Yes, go to the next question
- No, check if the fuse on the relays board is not burnt out. If it is not burnt out please wait for another 15 minutes. It is possible that the thermal switch on the pump is activated. If the pump after these 15 minutes still is not working please consult an approved service agent

Is the collecting jar completely filled?

- Yes, go to “Collecting jar does not empty automatically”
- No, go to the next question

Is there grime in the float-valve reservoir? (to be checked by an authorised technician)[4]

- Yes: Clean the float-valve reservoir well after emptying it to prevent the float becoming stuck in the lid.
  Ensure the float rests on the bottom of the reservoir.
  Make sure the float-valve reservoir is fitted back into its bracket properly.
- No: proceed to the next question

Is(are) the hose(s) blocked?

- Yes, replace the hose(s).
- No, consult an approved service agent.

2.4.2 Insufficient suction at the handpiece when it is taken out of the handpiece holder

Is the lid of the secretion receptacle tightly closed?

- Yes, go to the next question
- No, please close it tightly

Is there leakage in one of the hoses?

- Yes, replace the hose(s).
- No, consult an approved service agent.

[4] *Moisture/residue getting into the float-valve reservoir from the canister indicates that there is a problem with the automatic secretion discharge system.*
Automatic secretion discharge system check

- *Is the seal on the canister intact?*
- *Check the mechanical seal; is there dirt on the O-ring in the drain valve float?*
- *Check the operation of the solenoid valve. When activated an orange LED lights up on the PCB.*
- *Make sure that the automatic drain valve is hanging straight so the valve responds as it is intended*
- *Check the operation of the aeration valve.*

2.4.3 Secretion receptacle does not empty automatically

Is the valve for emptying opened?

- Yes, go to the next question
- No, consult an approved service agent.

Is the waste blocked?

- Yes, clean/unblock the waste
- No, consult an approved service agent.

3 Function: Suction system with secretion receptacle (If present)

3.1 Introduction

3.1.1 Application(s)

The intended use of the suction system with secretion receptacle is to collect the sucked-up secretions in the secretion receptacle (1.0L). This receptacle needs to be emptied every day either at the beginning of the day or at the end of the day, or earlier whenever the receptacle is completely full.
The suction system with secretion bottle function can only be used in combination with the ProminENT.

3.1.2 Use

Whenever the suction handpiece is removed from its holder, the solenoid valve opens allowing vacuum activation at the handpiece.
A suction tube can be fitted into the handpiece. The suction system is now ready for use.
The sucked-up secretions are collected the secretion receptacle.
This receptacle needs to be emptied at the beginning or end of the day, or earlier when the receptacle is completely filled.
We recommend disinfectant solution or water is sucked through the suction tube before it is removed and placed in the used instrument container. This ensures the suction tube does not get blocked.

3.1.3 How the Equipment Functions

The sucked-up secretions are collected in the secretion receptacle. If you place the handpiece back in the handpiece holder the vacuum will be stopped.
When the receptacle fills up during use, the float valve cuts off the vacuum to the suction hose. Secretions can no longer be sucked up. The vacuum stays however active.
The handpiece needs to be put back in its holder and the secretion liner needs to be replaced.

There is also a float-valve reservoir installed to prevent contamination from entering the suction pump or central vacuum system in the event of a failure of the mechanical valve protection in the secretion receptacle.

3.2 Maintenance

3.2.1 Cleaning the suction system

- The suction handpiece with rubber tip can be disconnected from the hose. If wanted it can be cleaned or sterilized;
- The suction tube needs to be sterilized after use. Also, it needs to be replaced by change of patient.

The suction handpiece is part of the ProminENT suction system. This suction handpiece does not come into contact with the patient; it is a connection piece between the suction tube instrument that does have contact with the patient and the suction system. The suction tube instrument that fits into this suction handpiece needs to be cleaned/disinfected/sterilized according to the regulations of the manufacturer of the instrument. The suction handpiece must be cleaned regularly.

ATTENTION:
The suction handpiece and the rubber suction tip ***cannot*** be sterilized on a temperature of 134°C.

The suction handpiece consists of 2 parts

1 2

3. Rubber suction tip, material Rubber – NBR
   This material is resistant to a maximum temperature of 125°C and it is resistant to, for example, oils, acids, alkaline and chemicals. This material can be cleaned briefly with alcohol.

4. Handpiece, material Delrin – POM
   This material is briefly resistant to temperature of 105°C to 120°C and continually resistant to 90°C.
   This material can be cleaned with alcohol.

Procedure:

- Pull the suction handpiece of the suction tube.
- Unscrew the rubber suction tip off the suction handpiece.
- Brush the inside of the rubber suction tip and the suction handpiece clean with a brush.
- The internal diameter of the suction tip and suction handpiece is Ø 4.0 mm!
- The outside can be cleaned/disinfected with 'for instance' an antibacterial cloth which is suitable to clean medical equipment for instance IzoPro (70 % isopropyl alcohol)
- We recommend when cleaning in a thermal disinfection device not to allow the temperature to exceed 90°C.
- After cleaning/disinfection screw the tip back onto the handpiece.

Cleaning and removing medicine residues must be in accordance with current local environmental regulations.

3.2.2 Maintenance

Ensure there always is some disinfectant liquid (± 0,1 L) in the secretion receptacle.
After using one of the suction tubes and before it is deposited in the used instrument container, always suck some disinfectant through the suction tube to be sure suction tube clean and clear.
The disinfectant will also clean the hoses inside the ProminENT.
The canister can also be cleaned with disinfectant.

It is necessary to replace the flexible hoses on the outside and from the secretion receptacle to the handpiece every six (6) months.

CAUTION:

- Be sure not to suck up any foamy disinfectants or foaming cleaning agents with the suction hose; foam gets past the float-valve in the secretion receptacle and little by little fills the float-valve reservoir.
- Do not suck up hot water into the suction system. Hot water condenses in the float-valve reservoir and also passes along the suction lines.

The equipment should only be serviced and supported by an authorised technician.
Service contracts are available on request.

3.3 Trouble shooting at the central suction

NOTE: Trouble shooting should be carried out by an authorised technician.

3.3.1 No suction at the handpiece when it is taken out of the handpiece holder

Is the ProminENT switched on?

- Yes, go to the next question
- No, please switch on the ProminENT

Is suction available on the central circuit?

- Yes, go to the next question
- No, have the central circuit tested by an authorised technician.

Is the secretion receptacle completely filled?

- Yes, empty the secretion receptacle
- No, go to the next question

Is the valve blocked or broken?

- Yes, clean or replace the valve.
- No, go to the next question

Is there grime in the float-valve reservoir? (to be checked by an authorised technician)[5]

- Yes: Clean the float-valve reservoir well after emptying it to prevent the float becoming stuck in the lid.
  Ensure the float rests on the bottom of the reservoir.
  Make sure the float-valve reservoir is fitted back into its bracket properly.
- No: proceed to the next question

Is(are) the hose(s) blocked?

- Yes, replace the hose(s).
- No, consult an approved service agent.

3.3.2 Insufficient suction at the handpiece when it is taken out of the handpiece holder

Is the lid of the secretion receptacle tightly closed?

- Yes, go to the next question
- No, please close it tightly

Is there a leaky hose?

- Yes, replace the hose(s).
- No, go to the next question

Is sufficient suction available on the central circuit?

- Yes, consult an approved service agent.
- No, have the central circuit tested by an authorised technician.

[5] *Moisture/residue getting into the float-valve reservoir from the canister indicates that there is a problem with the secretion receptacle. Check*

- *Is the seal on the secretion receptacle intact?*
- *Check the mechanical seal; is there dirt on the O-ring in the drain valve float?*
- *Check the operation of the float-valve.*
- *Make sure that the secretion receptacle valve is hanging straight so the valve responds as it is intended*

3.4 Trouble shooting at the suction pump

NOTE: Trouble shooting should be carried out by an authorised technician.

3.4.1 No vacuum at the handpiece when it is taken out of the handpiece holder

Is the suction pump running?

- Yes, go to the next question
- No, check if the fuse on the relays board is not burnt out. If it is not burnt out please wait for another 15 minutes. It is possible that the thermal switch on the pump is activated. If the pump after these 15 minutes still is not working please consult an approved service agent

Is the secretion receptacle completely filled?

- Yes, empty the secretion receptacle
- No, go to the next question

Is there grime in the float-valve reservoir? (to be checked by an authorised technician)[6]

- Yes: Clean the float-valve reservoir well after emptying it to prevent the float becoming stuck in the lid.
  Ensure the float rests on the bottom of the reservoir.
  Make sure the float-valve reservoir is fitted back into its bracket properly.
- No: proceed to the next question

Is(are) the hose(s) blocked?

- Yes, replace the hose(s).
- No, consult an approved service agent.

3.4.2 Insufficient vacuum at the handpiece when it is taken out of the handpiece holder

Is the lid of the secretion receptacle tightly closed?

- Yes, go to the next question
- No, please close it tightly

Is there a leaky hose?

- Yes, replace the hose(s).
- No, go to the next question

[6] *Moisture/residue getting into the float-valve reservoir from the canister indicates that there is a problem with the secretion receptacle. Check*

- *Is the seal on the secretion receptacle intact?*
- *Check the mechanical seal; is there dirt on the O-ring in the drain valve float?*
- *Check the operation of the float-valve.*
- *Make sure that the secretion receptacle valve is hanging straight so the valve responds as it is intended*

4 Function: Suction system with disposable secretion liners (If present)

4.1 Introduction

4.1.1 Application(s)

The intended use of the suction system with disposable secretion liners is to collect the sucked-up secretions in the secretion receptacle liner (1.5L). This liner needs to be disposed and replaced every begin or end of the day, or earlier when the bag is completely full.
The suction system with disposable secretion receptacle liners function can only be used in combination with the ProminENT.

4.1.2 Use

Whenever the suction handpiece is removed from its holder, the solenoid valve opens allowing vacuum activation at the handpiece.
A suction tube can be placed in the handpiece. The function is now ready for use.
The sucked-up secretions are collected in the disposable secretion liner.
This liner needs to be emptied at the beginning or end of the day, or earlier when the receptacle is completely filled.
We recommend disinfectant solution or water is sucked through the suction tube before it is removed and placed in the used instrument container. This ensures the suction tube does not get blocked.

4.1.3 How the Equipment Functions

The sucked-up secretions are collected in the disposable secretion liner. If you place the handpiece back in the handpiece holder the vacuum will be stopped.
When the receptacle fills up during use, the float valve cuts off the vacuum to the suction hose. Secretions can no longer be sucked up. The vacuum stays however active.
The handpiece needs to be put back in its holder and the secretion liner needs to be replaced.
There is also a float-valve reservoir installed to prevent contamination from entering the suction pump or central vacuum system in the event of a failure of the mechanical valve protection in the secretion receptacle.

4.2 Maintenance

4.2.1 Cleaning the suction system

- The suction handpiece with rubber tip can be disconnected from the hose. If wanted it can be cleaned or sterilized;
- The suction tube needs to be sterilized after use. Also, it needs to be replaced by change of patient.

The suction handpiece is part of the ProminENT suction system. This suction handpiece does not come into contact with the patient; it is a connection piece between the suction tube instrument that does have contact with the patient and the suction system. The suction tube instrument that fits into this suction handpiece needs to be cleaned/disinfected/sterilized according to the regulations of the manufacturer of the instrument. The suction handpiece must be cleaned regularly.

ATTENTION:
The suction handpiece and the rubber suction tip ***cannot*** be sterilized on a temperature of 134°C.

The suction handpiece consists of 2 parts

1 2

5. Rubber suction tip, material Rubber – NBR
   This material is resistant to a maximum temperature of 125°C and it is resistant to, for example, oils, acids, alkaline and chemicals. This material can be cleaned briefly with alcohol.

6. Handpiece, material Delrin – POM
   This material is briefly resistant to temperature of 105°C to 120°C and continually resistant to 90°C.
   This material can be cleaned with alcohol.

Procedure:

- Pull the suction handpiece of the suction tube.
- Unscrew the rubber suction tip off the suction handpiece.
- Brush the inside of the rubber suction tip and the suction handpiece clean with a brush.
- The internal diameter of the suction tip and suction handpiece is Ø 4.0 mm!
- The outside can be cleaned/disinfected with 'for instance' an antibacterial cloth which is suitable to clean medical equipment for instance IzoPro (70 % isopropyl alcohol)
- We recommend when cleaning in a thermal disinfection device not to allow the temperature to exceed 90°C.
- After cleaning/disinfection screw the tip back onto the handpiece.

Cleaning and removing medicine residues must be in accordance with current local environmental regulations.

4.2.2 Maintenance

Ensure that there always is some disinfectant liquid (± 0,1 L) in the secret liner.
After using one of the suction tubes and before it is deposited in the used instrument container, always suck some disinfectant through the suction tube to be sure suction tube clean and clear.
The disinfectant will also clean the hoses inside the ProminENT.
The canister can also be cleaned with disinfectant.

It is necessary to replace the flexible hoses on the outside and from the secretion receptacle to the handpiece every six (6) months.

CAUTION:

- Be sure not to suck up any foamy disinfectants or foaming cleaning agents with the suction hose; foam gets past the float-valve in the secretion receptacle and little by little fills the float-valve reservoir.
- Do not suck up hot water into the suction system. Hot water condenses in the float-valve reservoir and also passes along the suction lines.

The equipment should only be serviced and supported by an authorised technician.
Service contracts are available on request.

4.3 Trouble shooting at the central suction

NOTE: Trouble shooting should be carried out by an authorised technician.

4.3.1 No suction at the handpiece when it is taken out of the handpiece holder

Is the ProminENT switched on?
- Yes, go to the next question
- No, please switch on the ProminENT on

Is suction on the central circuit?
- Yes, go to the next question
- No, have the central circuit tested by an authorised technician.

Is the disposable secretion liner completely filled?
- Yes, dispose and replace the disposable secretion liner
- No, go to the next question

Is the valve blocked or broken?
- Yes, clean or replace the valve.
- No, go to the next question

Is there grime in the float-valve reservoir? (to be checked by an authorised technician)[7]
- Yes: Clean the float-valve reservoir well after emptying it to prevent the float becoming stuck in the lid.
  Ensure the float rests on the bottom of the reservoir.
  Make sure the float-valve reservoir is fitted back into its bracket properly.
- No: proceed to the next question

Is(are) the hose(s) blocked?
- Yes, replace the hose(s).
- No, consult an approved service agent.

4.3.2 Insufficient suction at the handpiece when it is taken out of the handpiece holder

Is the lid of the canister tightly closed?
- Yes, go to the next question
- No, please close it tightly

Is there a leaky hose?
- Yes, replace the hose(s).
- No, go to the next question

Is sufficient suction available on the central circuit?
- Yes, consult an approved service agent.
- No, have the central circuit tested by an authorised technician.

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[7] *Moisture/residue getting into the float-valve reservoir from the canister indicates that there is a problem with the secretion receptacle or the disposable secretion liners.*
Check
- *Is the seal on the secretion receptacle intact?*
- *Check the mechanical seal; is there dirt on the O-ring in the drain valve float?*
- *Check the operation of the float-valve.*
- *Make sure that the secretion receptacle valve is hanging straight so the valve responds as it is intended*

4.4 Trouble shooting at the suction pump

NOTE: Trouble shooting should be carried out by an authorised technician.

4.4.1 No suction at the handpiece when it is taken out of the handpiece holder

Is the treatment unit switched on?

- Yes, go to the next question
- No, please switch on the ProminENT

Is the suction pump running?

- Yes, go to the next question
- No, have an authorised technician check if the fuse on the relays board is not burnt out.
  If it is not burnt out please wait for another 15 minutes. It is possible that the thermal switch on the pump is activated. If the pump after these 15 minutes still is not working please consult an approved service agent

Is the disposable secretion liner completely filled?

- Yes, dispose and replace the disposable secretion liner
- No, go to the next question

Is there grime in the float-valve reservoir? (to be checked by an authorised technician)[8]

- Yes: Clean the float-valve reservoir well after emptying it to prevent the float becoming stuck in the lid.
  Ensure the float rests on the bottom of the reservoir.
  Make sure the float-valve reservoir is fitted back into its bracket properly.
- No: proceed to the next question

Is(are) the hose(s) blocked?

- Yes, replace the hose(s).
- No, consult an approved service agent.

4.4.2 Insufficient vacuum at the handpiece when it is taken out of the handpiece holder

Is the lid of the canister tightly closed?

- Yes, go to the next question
- No, please close it tightly

Is there a leaky hose?

- Yes, replace the hose(s).
- No, consult an approved service agent

[8] *Moisture/residue getting into the float-valve reservoir from the canister indicates that there is a problem with the secretion receptacle or the disposable secretion liners.*
Check

- *Is the seal on the secretion receptacle intact?*
- *Check the mechanical seal; is there dirt on the O-ring in the drain valve float?*
- *Check the operation of the float-valve.*
- *Make sure that the secretion receptacle valve is hanging straight so the valve responds as it is intended*

5 Function: Rinsing system automatic secretion discharge system (If present)

5.1 Introduction

5.1.1 Application(s)

The intended use of the rinsing system is automatic cleaning of the automatic secretion discharge system, to prevent blockage.
The rinsing system automatic secretion discharge system function can only be used in combination with the ProminENT.

5.1.2 Use

When you switch the treatment unit in stand-by mode the rinsing system will switch on and starts cleaning the automatic secretion discharge system.

5.1.3 How the equipment functions

When you switch the treatment unit in stand-by mode the rinsing system will be activated and starts cleaning the automatic discharge.
The automatic discharge will fill and empty with water for three (3) times during ten (10) minutes.

5.2 Parts of the rinsing system automatic secretion discharge system

Mechanical water valve

- 24V= water valve

5.3 Trouble shooting

NOTE: Trouble shooting should be carried out by an authorised technician.

5.3.1 The rinsing system does not start up when the ProminENT is switched in stand-by mode

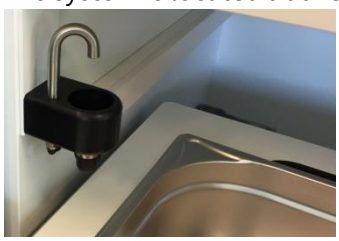
- Please consult an approved service agent.

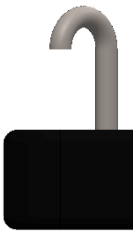
6 Function: Suction rinse system (If present)

6.1 Introduction

6.1.1 Application(s)

The intended use of the rinse function is for cleaning the suction tubes.
The rinse function can only be used in combination with the ProminENT.
The system is located above the drawer for waste and used instruments.





6.1.2 Use

After the assigned button 

on the main control console of the ProminENT is pressed water will flow during a period of 15 or 30 seconds depending on the set configuration.
Suck up some water to clean the suction tube. Excess water will be discharged via the waste pipe.

When active the button will be green outlined 

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6.1.3 How the equipment functions

See “Use”.

6.2 Parts of the suction rinse system

Mechanical water valve

- 24V= water valve

6.3 Trouble shooting

NOTE: Trouble shooting should be carried out by an authorised technician.

6.3.1 No water flow after switching on the function

Is the ProminENT switched on?

- Yes, go to the next question
- No, please switch on the ProminENT

Check if the water supply is available
Is water supply available?

- Yes, go to the next question
- No, please make sure water supply is available.

Is the fuse on the printed circuit board intact?

- Yes, please consult an approved service agent
- No, replace the fuse

6.3.2 Water keeps flowing after pushing the button

Probable cause would be a blocked water valve.

First ensure the ProminENT is switched off!

Check the 24V= valve.
Is the valve blocked?

- Yes, clean/unblock the valve
- No, please consult an approved service agent.

7 Function: Compressed air system (If present)

7.1 Introduction

7.1.1 Application(s)

The intended use of the compressed air system is the application of medications, aesthetics and boric acid in powder form.
The compressed air system function can only be used in combination with the ProminENT.

7.1.2 Use

Whenever the compressed air pistol is removed from its holder, the solenoid valve opens.
A power or liquid applicator can be fitted into the air pistol by pressing the thumb plate forward and inserting the applicator into the pistol.
The applicator with the fine nozzle is for liquid and the one with the large one is for power. It is important not to use the powder applicator for liquid.
The function is now ready for use.
When the applicator is fitted in the pistol, the trigger can be pulled to open the valve and allow air to pass through the pistol, which then passes through the applicator and either the liquid sprays out through the nozzle or the powder blows out from its nozzle. This depends on which applicator is being used.
When the handpiece is placed back in the handpiece holder the compressor stops or the valve closes.

7.1.3 How the Equipment Functions

Whenever the air pistol is removed from its holder, the compressor starts or the solenoid valve opens depending on whether a central vacuum system is involved or whether the unit is equipped with its own compressor.
A spray or powder applicator can be attached to the handpiece by pushing the pressing the handpiece thumb plate forward and fitting an applicator into the pistol.
(The nozzle with the fine aperture is for liquid and the one with the large aperture is for powder)
The function is now ready for use.
By pulling the trigger on the handpiece it will start to spray liquid or blow powder.
You can adjust the pressure by twisting the black knob on the pressure regulator in the compartment behind the handpiece holders.
The actual pressure is shown on a manometer.
When the air pistol is returned to its handpiece holder the compressor stops or the valve closes.

7.2 Parts of the compressed air system

- Handpiece
- 2 x applicator for liquid
- 1 x applicator for powder

7.3 Testing

7.3.1 Testing of the compressed air system

The manometer is mounted next to the regulator in the compartment behind the handpiece holder section. The pressure must be individually set. By spraying once in the bin, the atomisation can be determined.

7.3.2 Short instructions (compressed air system)

Make sure the compressed air system is used regularly. When the compressed air system is not going to be used for a while, spray air through the applicator at the end of the consultation to prevent it from becoming clogged.
Check the level in the bottles once a week.

7.4 Trouble shooting central compressed air

NOTE: Trouble shooting should be carried out by an authorised technician.

7.4.1 No air coming out the air pistol when it is taken out of the its holder and the trigger is pulled

Is the ProminENT switched on?

- Yes, go to the next question
- No, please switch on the ProminENT

Is there pressure at the central air connection?

- Yes, go to the next question
- No, have the central circuit tested by an authorised technician.

Is the regulator valve blocked or broken?

- Yes, clean or replace the regulator valve.
- No, go to the next question

Is(are) the hose(s) blocked?

- Yes, replace the hose(s).
- No, consult an approved service agent.

7.4.2 Insufficient compressed air coming out the air pistol when it is taken out of its holder and the trigger is pulled

Is the pressure set correctly?

- Yes, go to the next question
- No, adjust accordingly

Is there a leaky hose?

- Yes, replace the hose(s).
- No, go to the next question

Is sufficient pressure available on the central circuit?

- Yes, consult an approved service agent.
- No, have the central circuit tested by an authorised technician

7.5 Trouble shooting at the compressed air pump

NOTE: Trouble shooting should be carried out by an authorised technician.

7.5.1 No air coming out the air pistol when it is taken out of its holder and the trigger is pulled

Is the ProminENT switched on?

- Yes, go to the next question
- No, please switch on the ProminENT

Is the compressed air pump running?

- Yes, go to the next question
- No, Check if the fuse on the relays board is not burnt out. If it is not burnt out please wait for another 15 minutes. It is possible that the thermal switch on the pump is activated. If the pump after these 15 minutes still is not working please consult an approved service agent

Is(are) the hose(s) blocked?

- Yes, replace the hose(s).
- No, consult an approved service agent.

7.5.2 Insufficient compressed air coming out the air pistol when it is taken out of its holder and the trigger is pulled

Is(are) the hose(s) blocked?

- Yes, replace the hose(s).
- No, consult an approved service agent.

8 LumiTop LED Fibre optic light system (If present)

Figure K – LumiTop LED

8.1 Introduction

8.1.1 Application(s)

The intended use is a light source for connection to rigid and flexible endoscopes. Light is emitted via a fibre optic cable, which is connected to the endoscopes.
The device may only be used in combination with the ProminENT..
Colour temperature of the LED is 5700K.
Lifetime of the LED lamp is approx. 40.000 hours.

8.1.2 Use

The fibre optic light cable is placed in one of the instrument holders.
Whenever the fibre optic cable is removed from its holder, the light comes on automatically and the cable can be connected to the endoscope. When the cable has been connected to the endoscope, the endoscope is ready for use and the endoscopic examination can commence.
You can now connect a rigid- or flexible scope to the fibre optic light cable and start your examination.
When the fibre optic cable is returned to its holder, the light with automatically switch off.
It is also possible to connect an examination headlight to the fibre optic light source (cold light). The setup for an examination headlight involves a switchable hook which automatically switches the light on whenever the headlight is removed from the hook. After the examination, the examination headlight is placed back on the hook and the light automatically switches off.

NOTE:	
	The light cable adapter placed in the light source can become very hot during use. To eliminate the risk of burns when taking out the light cable out of the light source please wait one minute to allow the device to cool down before removing the light cable.
	Never look through the lens or opening when the device is on (without having a fibre optic cable in place). • UV is not emitted from the lamp. • Never look into the end of the fibre optic cable, possible skin or eye irritations can result from exposures exceeding 15 minutes in a day.

8.1.3 How the equipment functions

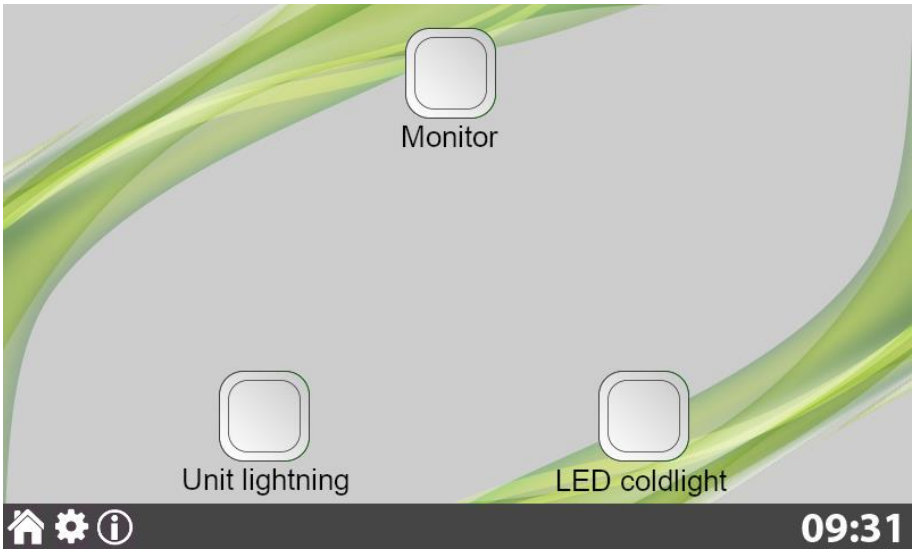
The LumiTop LED fibre optic light source operates on 230 volts a/c. The LED is cooled by a fan.
If the LumiTop LED becomes too hot, it switches off thermally.

8.1.4 Adjusting brightness

The brightness can be adjusted.

Press on: 

The following will be displayed.



Press on “LED coldlight”

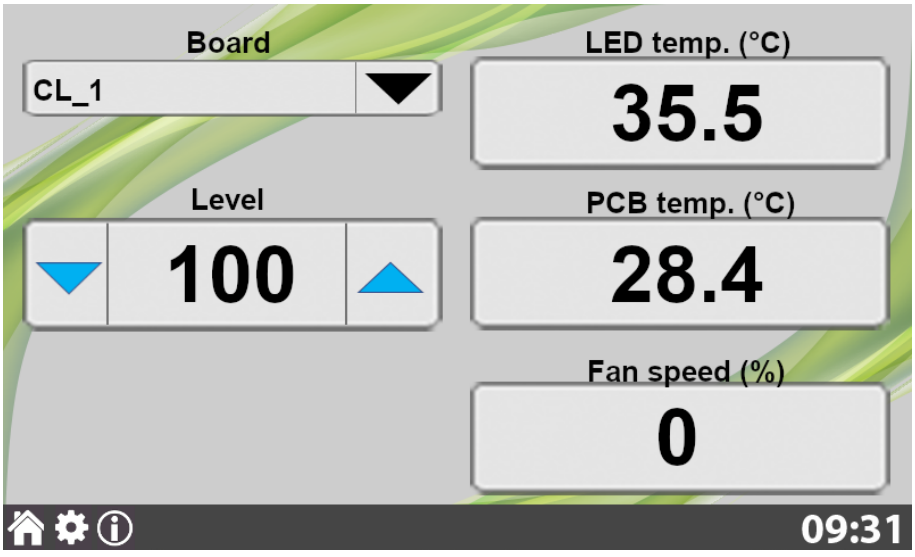


Figure – LED Coldlight settings

Select the light source to be set. Up to 4 light sources can be connected.
The corresponding light source will switch on.

With the  and  buttons the desired brightness can be set.

If the setting is right press on  to return to the Start screen.

8.2 Parts of the MediTop LumiTop LED

1. Fibre optic light entry point

2. Fan

3. Mains 230V
4. Potential equalization
5. UTP connection for control by the ProminENT

6. Label

8.3 Testing

8.3.1 Testing the LumiTop LED

Check if the LumiTop LED comes on.

8.3.2 Short instruction of the LumiTop LED light source

If connected the device can be used.

We recommend you:

- To be care with the fibre optic cable as these are fragile and the fibres within can break easily.

8.4 Maintenance

8.4.1 Cleaning the LumiTop LED

Cleaning of the LumiTop LED with a dry cloth is sufficient.

Cleaning and removing medicine residues must be done in accordance with current local environmental regulations.

8.4.2 Technical maintenance

There is no regular maintenance required for the LumiTop LED.
The LED has a lifespan of approx. 40,000 hours.
Have the LumiTop LED checked annually for correct functioning and safety by an authorised technician.

8.5 Trouble shooting

NOTE: Trouble shooting should be carried out by an authorised technician.

8.5.1 The LED does not light up when in use

An authorised technician must perform the checks!

Is the LED broken?

- Yes, replace the LED.
- No, go to the next question.

Is the fuse of the LumiTop LED intact?

- Yes, go to the next question.
- No, replace the fuse.

Is the fan working?

- Yes, wait for about 3 – 5 minutes for re-use. It could be that the thermal switch is activated. If after these 5 minutes the LumiTop LED still does not work, please consult an approved service agent.
- No, please consult an approved service agent.

9 Function: Warmwater irrigator AquaTop XS (If present)

9.1 Introduction

The ProminENT overrides the controls on the AquaTop XS.
The user interface on the AquaTop XS cannot be used. The buttons are disabled.
The display is dimmed and shows: "Remote control enabled"

Figure L – Front view AquaTop XS integrated in the ProminENT

9.1.1 Application(s)

The AquaTop XS is a warm water irrigator, which can be used for cleaning the ear as well as a stimulator for caloric testing.

9.1.2 Use

Operating the device requires no special skills, but may only be used by medically qualified personnel, familiar with the basics of caloric examination and ear syringing.
The AquaTop XS must be installed by a technically competent person unless it is integrated in the ProminENT.
The AquaTop XS is not a mobile device that can be moved around.

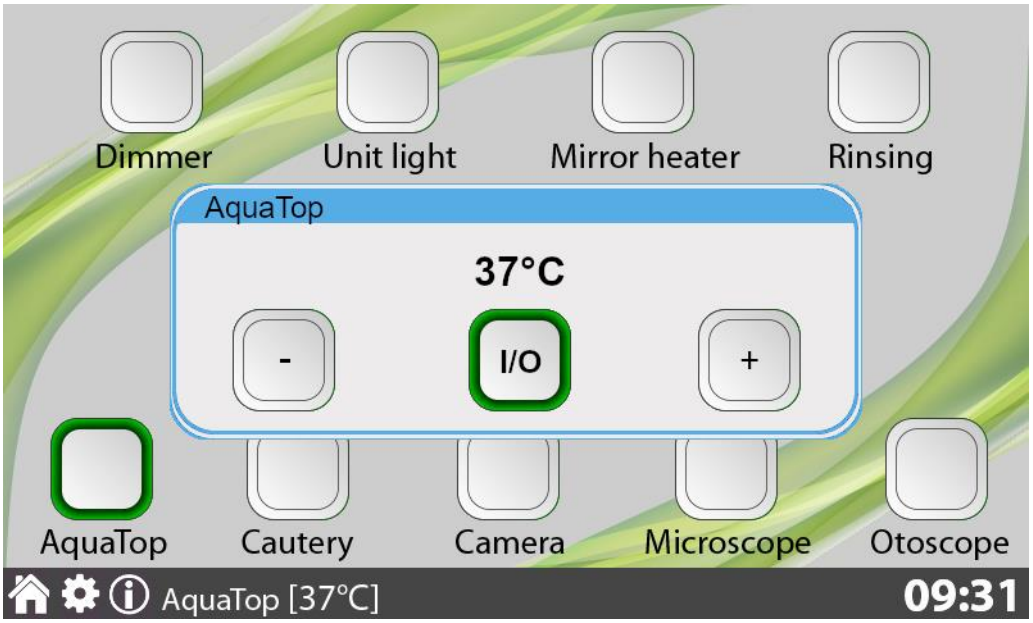
Warnings:

- Check the temperature and the water pressure prior to each use;
- Switch off the AquaTop XS and the water supply when the device is not in use;
- If the AquaTop XS is not used, you must ensure that the handpiece is placed in the appropriate holder:
- Do not drop the handpiece! The handpiece can get broken;

When the AquaTop XS is switched on and water pressure is present, the device heats up the water to 37° C.
The AquaTop XS is sensitive to environmental influences. The AquaTop XS is drained of all water for transport, which ensures no damage occurs to it in transit. It is strongly advisable not to connect the device to water supply with a water temperature of higher than 20° C and certainly no higher than 30° C, as this will disallow the setting of the temperature.

9.1.3 How the AquaTop XS functions

Switch on the AquaTop XS.
Press on the button “AquaTop” on the touch screen control panel.
The button becomes green outlined and the temperature setting buttons appear.



The AquaTop XS is a warm water irrigator with a continuous flow to prevent microbe growth in the water.

The AquaTop XS requires water pressure to function. The water passes through a regulator valve which reduces the flow to high pressure. Then the water passes through a labyrinth with an integrated heating element. A temperature sensor relays information to the electronics that control the heating element. The warmed water next flows to the handpiece where a 3-way valve is located. Whenever the button on the handpiece is released, the water flows down the drain. Whenever the button is pressed, the water is diverted to flow out of the cannula on the handpiece.

With the buttons 

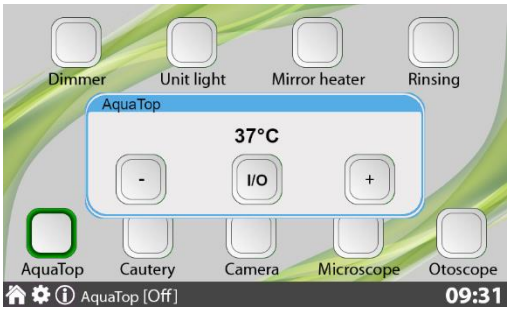
en 

the desired temperature can be set.

If the AquaTop XS with 3 temperatures (stimulator for caloric examination) is integrated, you can choose from the following options, otherwise only 37°C is available:

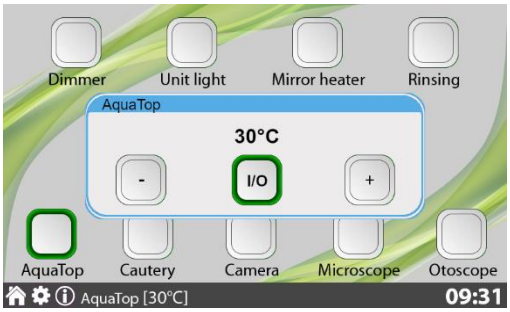
OFF

At this setting, the water will not be heated.



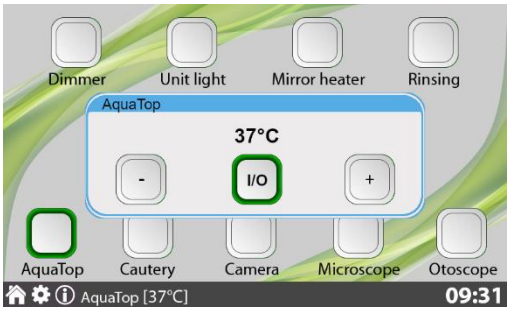
30°C

At this setting, the water will be heated to 30° C.
(For use in caloric examination)



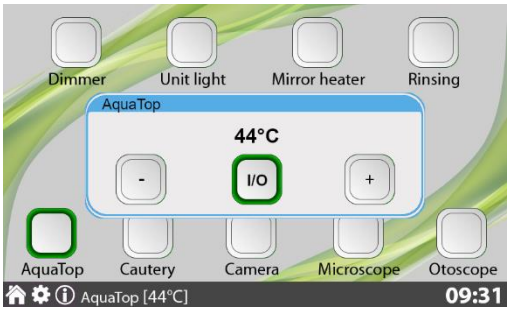
37°C

At this setting, the water will be heated to 37° C.
(For cleaning the ear)



44°C

At this setting, the water will be heated to 44° C.
(For use in caloric examination)



The current water temperature is shown on the left of the bottom bar.

9.1.4 Warnings

9.1.4.1 Warning insufficient water pressure [EP]

Whenever the water pressure drops below 1 bar an audible signal will sound and a visual waring will show on the display below the on/off button. This indicates that the pressure is too low. The heating element will not heat the water as long as this warning shows on the display. The warning will disappear when the water pressure increases to at least 1 bar. A water pressure of 1.8 bar is recommended for correct functioning of the AquaTop XS.

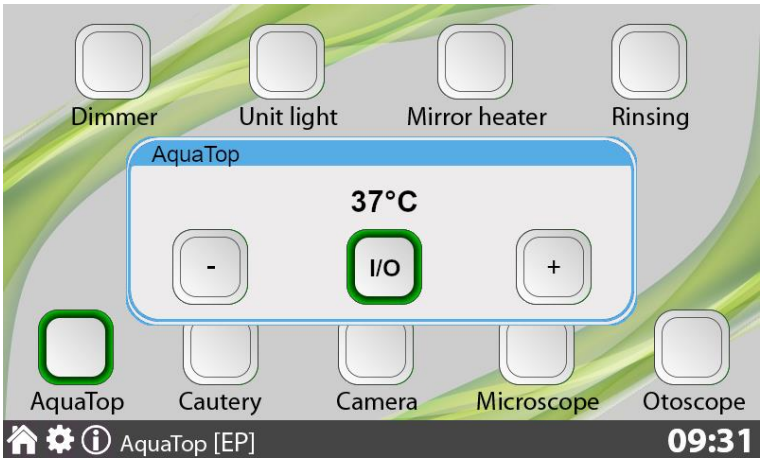


Figure M - AquaTop XS Pressure warning

9.1.4.2 Overheating warning [ET]

If the temperature is above 46° C, an audible signal will sound and a visual signal will be displayed on the control console to indicate that the temperature is 46°C or higher.
As long as this warning is showing the heating element will not heat the water!
When the temperature falls below 46°C the warning will disappear.

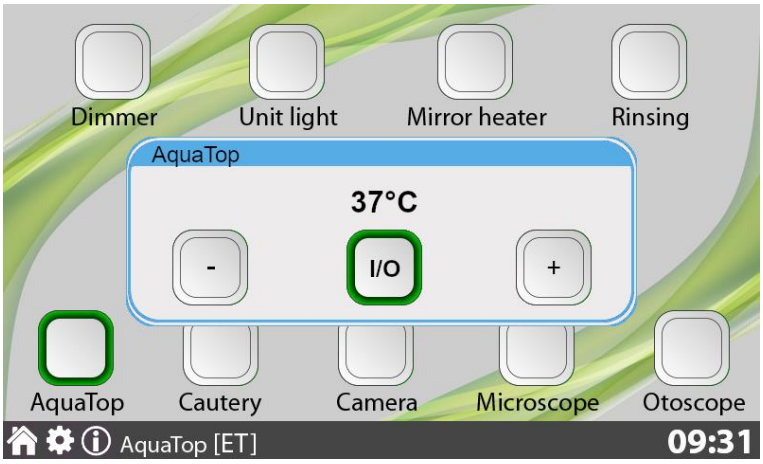
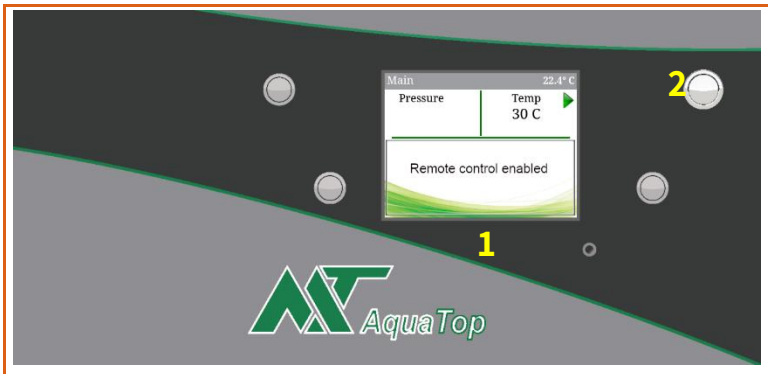


Figure N - AquaTop XS Overheating warning

9.2 Parts of the AquaTop XS

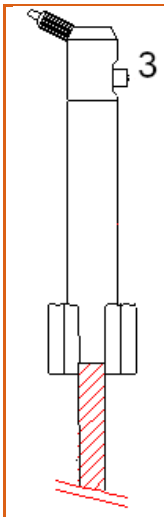


Front view AquaTop XS

1. Digital display
2. Temperature setting button (Disabled)

1. Digital display
   The ProminENT overrides all controls of the AquaTop XS.
   The user interface in this case cannot be used.
   The buttons are disabled and the display is dimmed and shows: "Remote control enabled"

2. Temperature setting button
   Disabled when the AquaTop XS is integrated in the ProminENT.



Handpiece AquaTop XS

3. Button on handpiece

3. Button on handpiece
   When pressed the warmed water will flow out the device through the cannula.

Rear view AquaTop XS

4. On/Off switch
5. Fuse T 6.3 A
6. 230 Volt - 50 Hz connection
7. Potential equalization connection
8. RJ-45 connection for control by the ProminENT
9. Regulator valve
10. Water outlet
11. Water inlet – Maximum 6 Bar [9])

4. On/Off switch
   The switch on the back of the AquaTop XS switches the device on or off.

5. Fuse
   Fuse T 6.3 A.

6. 230 Volt - 50 Hz connection
   230 Volt euro plug connection.

7. Potential equalization connection
   Connection for potential equalization.

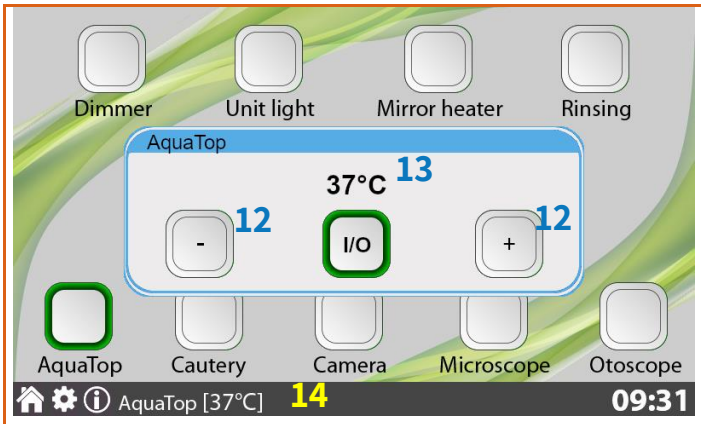
8. RJ-45 connection
   This connector allows the ear irrigator to be connected to the ProminENT.
   Do not connect a standard network cable!

9. Regulator valve
   With this regulator valve, the water pressure can be set.
   The standard set pressure for the AquaTop XS is 1.8 bars.

10. Water outlet
    3/8” screw connector for connection to waste.

11. Water inlet
    3/8” screw connector for connection on the water supply.

[9] *The maximum pressure of the water supply is 6 Bar. If the water supply is higher than 6 bar, you must place a regulator valve between the water supply and the water inlet of the AquaTop XS*



Touchscreen console; AquaTop XS

12. Temperature setting buttons
13. Set temperature
14. Current water temperature

12. Temperature setting buttons
    These buttons allow water temperature selection (depending on version):
    30° C, 37° C of 44° C

13. Set temperature
    Shows the setting of the temperature

14. Current water temperature
    Shows the current water temperature or [EP] at a pressure too or [ET] at temperature too high (see also 9.1.4.1 and 9.1.4.2)

9.3 Maintenance

9.3.1 Cleaning the AquaTop XS

The AquaTop XS may only be cleaned using a moistened cloth and if necessary, liquid disinfectant.
Under no circumstances immerse the AquaTop XS or rinse it under the tap.

The cannula must always be disinfected after use as described in the manufacturer's manual, PB_IG Rev. 11/2018_04/2019_20000.
The cannula needs to be descaled regularly also. Since the cannula aperture is very small, any further narrowing of the aperture by calcium will raise the pressure, which will decrease the water flow. This may lead to instability of the water temperature.
We recommend you the cannulas are descaled at least once a year. The number of times depends on the concentration of calcium in the water supply.

9.3.2 Maintenance

To avoid potential problems, we recommend you to have the device checked regularly.

The next items should be checked at least once a year:

- Descaling the water circuit of the AquaTop XS
- Check, clean and if necessary, replace the set of water tubing
- Check the O-rings in the handpiece, and if necessary, oil or replace.

Cleaning or replacing the filter in the water inlet should be done at least once every six months.
The equipment should only be serviced and supported by an authorised technician.

9.4 Troubleshooting

NOTE: Troubleshooting may only be performed by an authorised technician.

9.4.1 Warning insufficient water pressure [EP]

This means there is low pressure or no pressure at all and the heating element will not come on.

Is water pressure available in the device?

- Yes, go to the next question.
- No, Ensure the water supply pressure is at a minimum of 1.0 bar.

Turn the pressure regulator valve to increase the pressure:
Has the pressure been increased to the required 1.8 bar?

- Yes, the device is now ready for use.
- No, go to the next question.

Is the water filter blocked?

- Yes, clean or replace the filter.
- No, contact the technical department of MediTop or your local approved service agent.

9.4.2 Overheating warning [ET]

If the temperature increases above 46 degrees C, an audible warning will sound and a visual signal will be displayed on the touchscreen console to indicate that the temperature is 46° C or higher.
The electronics switch off the heating element and the heating element will remain off until the temperature has dropped.

Is water still flowing from the handpiece when the button is pressed??

- Yes, if the temperature of the water has not fallen within 5 minutes has not fallen to the selected setting, please contact the technical department of MediTop or your local approved service agent.
- No, Check the water outlet and/or three-way-valve for blockages.

9.4.3 Display shows nothing

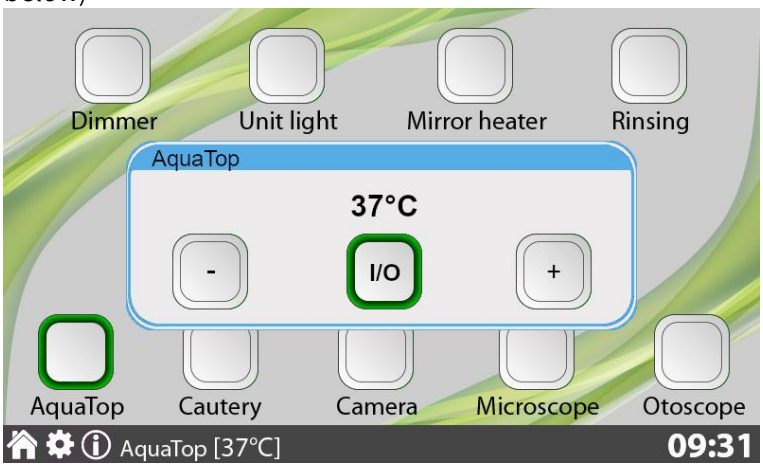
Is the main switch on the back of the AquaTop XS switched on?

- Yes, go to the next question.
- No, switch the device on.

Is the water valve control set to off? (Can be checked by an authorised technician)

- Yes, turn the water valve control on
- No, go to the next question.

Is the AquaTop XS switched on at the ProminENT's control console?
The button with "AquaTop" and I/O should be green outlined and AquaTop should be displayed. (see figure below)



- Yes, have the AquaTop XS checked by an authorised technician to determine whether the main fuse has not blown and to have the fuse replaced if necessary. If the display still does not show anything, please contact MediTop's technical department or your local approved service agent.
- No, switch the AquaTop XS on with the assigned button on the control console of the ProminENT.

9.4.4 Temperature not stable

Cause: Fluctuations in the water flow. Fully depress the button on the handpiece and measure the water emitted through the cannula. This should be the same as the water emitted down the drain when the button on the handpiece is not depressed.

Solution: Make sure that the cannula and the drain line are not obstructed.

9.4.5 Water is not being heated

Is the AquaTop XS set to "Off"?

- Yes, Select a temperature
- No, See below

Cause: Thermostat activated due to water temperature surpassing 50°C resulting in the heating element deactivating.

Solution: Have an authorised technician internally reset AquaTop XS thermostat.

10 Function: Hot-air Mirror heater (If present)

10.1 Introduction

10.1.1 Application(s)

The intended use of the hot-air mirror heater is to heat up laryngeal mirrors up to working temperature (± 40° C).
The mirror heater function can only be used in combination with the ProminENT.

10.1.2 Use

When the assigned button on the main control panel of the treatment unit is pressed, hot air will flow out of the outlet for about 5 seconds to heat up a laryngeal mirror. After 5 seconds the heating element turns off automatically and the fan turns off after approx. 20 seconds. During use, the button shows a green outline.

Figure 0 – Hot-air mirror heater active

10.1.3 How the equipment functions

When the assigned button on the main control console of the ProminENT is pressed, hot air will flow out of the outlet for about 5 seconds to heat up a laryngeal mirror.
Once the button has been pressed, the function will be available again after the fan has stopped. This takes between 30 and 40 seconds, depending on the set configuration.
If the mirror heater overheats the built-in safety components will cut the power supply to the heating element at approximately 50° C.
When the grey button is pressed, only the fan will run.
After the temperature drops to below 45°C, the system is ready for use.

NOTE:	
	The Air outlet of the hot-air mirror heater becomes hot during use. Do not touch the outlet directly after use. 
	The metal air outlet of the hot-air mirror heater may not be touched by the user simultaneously with the patient.

10.2 Parts of the mirror heater

Mechanical switches:
Temperature switches which will cut the power supply at approximately 50° C:

- Temperature switch in the heating element (230V A/C)

Heating Element:

- Heating element powered with 230V A/C

10.3 Trouble shooting

NOTE: Trouble shooting should be carried out by an authorised technician.

10.3.1 Hot-air mirror heater does not blow hot air

Is the ProminENT switched on?

- Yes, go to the next question
- No, please switch on the ProminENT

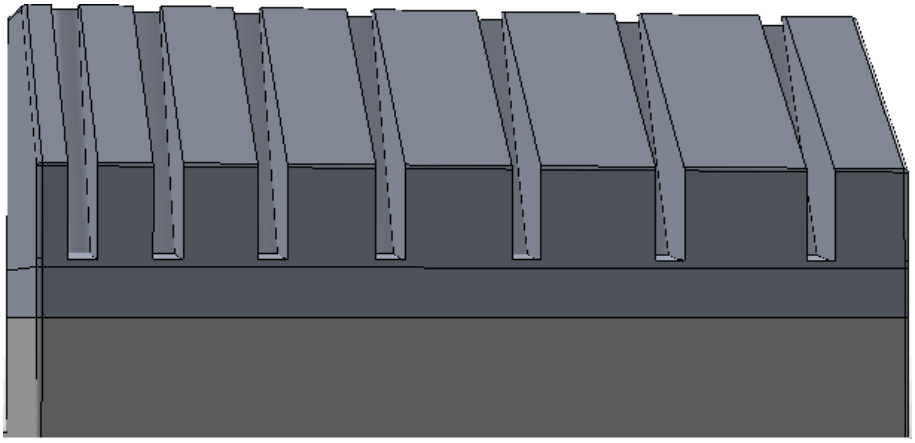
Is the fan working when the grey pushbutton is pushed?

- Yes, probably one of the built-in safety components is preventing the device from running. If after 3 minutes the hot-air mirror heater is still not blowing hot air please consult an approved service agent
- No, go to the next question

The fuse on the 230V or High Voltage Board found not to be intact?

- Yes, replace the broken fuse.
- No, please consult an approved service agent.

11 Function: Mirror Pre-Heater (If present)



11.1 Introduction

11.1.1 Application(s)

The mirror pre-heater is used for organising and warming laryngeal mirrors up to a temperature of around 40°C. The mirror pre-heater has 7 different storage channels increasing in diameter from ø 10, ø 16, ø 18, ø 22, ø 26 (2x) till ø 30 mm, and can take 60 to 70 mirrors.
The mirror pre-heater function can only be used in combination with the ProminENT.

11.1.2 Use

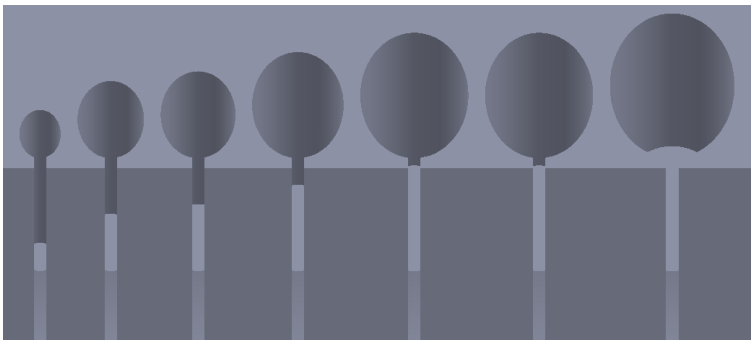
When the ProminENT is switched on the heating resistors will warm up the base and subsequently the heating block to ± 40°C and ultimately warm up the stored mirrors in it.

11.1.3 How the equipment functions

When the ProminENT is switched on the power resistors will warm up the base and the mirror block to ± 40°C. If the temperature reaches 50°C or higher the thermostat shall open and cut the power to the heating resistors. When the temperature drops to about 35°C to 40°C The thermostat will close again and the resistors will start heating again.

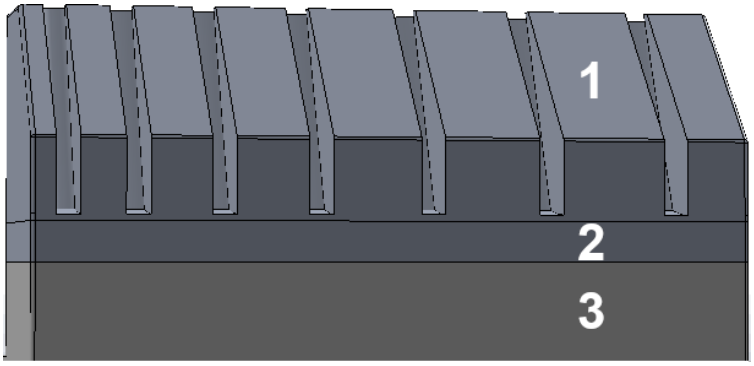
If for any reason the mechanical switch does not work, the built-in temperature-fuse will melt at about 70 °C. (One-time use, this fuse has to be replaced)
Result of this is that the apparatus will not warm up anymore.
Before it can be used again a technician shall have to open the heating block and replace the temperature-fuse.

11.2 Parts of the pre mirror heater



7 different storage compartments rising in diameter from:
ø 10, ø 16, ø 18, ø 22, ø 26 (2x) till ø 30 mm

Mirror pre-heater view from above



1- Mirror block stores 60 to 70 laryngeal mirrors

2- Base

3- Base plate

Front view mirror pre-heater

11.3 Maintenance

11.3.1 Cleaning the pre mirror heater

To clean the mirror holder block, it needs to be removed from the lower base of the device. The lower base of the mirror pre-heater may not come into contact with fluids. get into the base, as fluid must not come in contact with power resistors and the thermostat are located.
You can rinse the block with water or disinfectants.

The base may only be cleaned with a moist cloth.
Under no conditions may water be thrown over the heating block, or may this heating block be rinsed with water.
Used mirrors have to be cleaned by change of patient.

Cleaning and removing medicine residues must be in accordance with current local environmental regulations

11.4 Trouble shooting

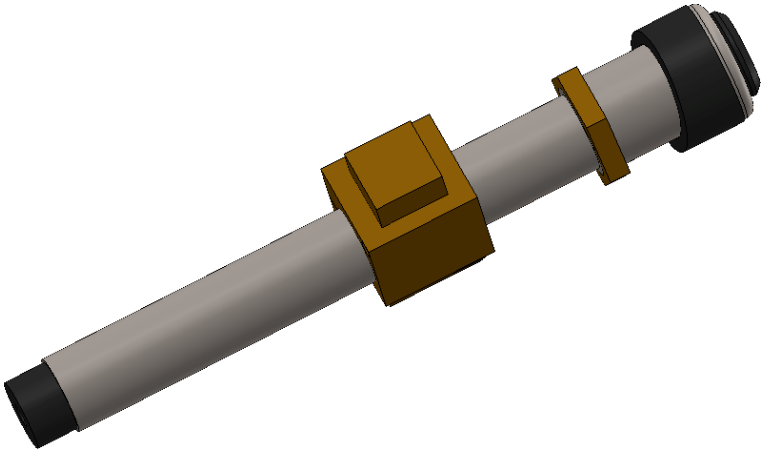
NOTE: Trouble shooting should be carried out by an authorised technician.

11.4.1 Mirror pre-heater does not warm up

Is the power of the ProminENT switched on?

- Yes, have the mirror pre-heater checked by an authorised technician to determine whether the the transformer fuses and/or the thermostat in the base are not broken.
- No, switch the ProminENT on.

12 Function: Heated telescope holder (If present)



12.1 Introduction

12.1.1 Application(s)

The intended use of heated telescope holder is to heat up rigid endoscopes or laryngoscopes up to working temperature (± 40° C).
The heated telescope holder function can only be used in combination with the ProminENT.

12.1.2 Use

Place the rigid endoscope or laryngoscope in the heated telescope holder.
When the ProminENT will be switched on the heated telescope holder function automatically starts heating up.

NOTE:	
⚠	The metal ring around the heated telescope holder(s) may not be touched by the user simultaneously with the patient.

12.1.3 How the equipment functions

When the ProminENT is switched on the heated telescope holder function automatically starts heating up to about 40° C.
If the temperature of the heating element reaches 50° C an automatically re-setting thermal switch will cut the power supply to the heating element. When the temperature drops below the 40°C the heating element will be powered again.
If for any reason the re-setting thermal switch is not functioning a second thermal switch will melt when the heating element reaches the 70° C. This switch is for one time use en needs to be replaced by an authorised technician before you can use the function again.

12.2 Parts of the heated scope holder

Automatically re-setting thermal switch:
If the temperature of the heating element reaches 50°C an automatically re-setting thermal switch will cut the power supply to the heating element. When the temperature drops below the 40°C the heating element will be powered again.

Temperature fuse:
A thermal switch will melt when the heating element reaches the 70°C. This switch is for one time use and needs to be replaced by an authorised technician before the function can be used again.

12.3 Trouble shooting

NOTE: Trouble shooting should be carried out by an authorised technician.

12.3.1 Heated telescope holder is not heated up

Is the ProminENT switched on?

- Yes, go to the next question
- No, please switch on the ProminENT

Is the fuse on the 230V or High Voltage board intact?

- Yes, go to the next question
- No, replace the fuse

Is the thermal switch of 70° C melted?

- Yes, have the thermal switch replaced by an authorised technician
- No, please consult an approved service agent

13 Function: Video switch (If present)

13.1 Introduction

13.1.1 Application(s)

The intended use is as switch between live video of two (2) connected camera systems.
The video switch function can only be used in combination with the ProminENT.

13.1.2 Use

A. In combination with the master-slave-print board:
In this case the live-video of the camera for rigid scopes and flexible scopes/ or stroboscope will be shown on the display. As soon as the microscope with integrated camera system will be switched on the live-video on the display automatically switches to the live-video of the microscope. When the microscope is switched off the live-video of the camera system for rigid and flexible scopes/ or stroboscope will be shown again on the display.

B. As “stand-alone” (without master-slave-print board)
In this case the live-video of the camera for rigid scopes and flexible scopes/ or stroboscope will be shown on the display. As you press on the “Video-button” on the main control panel of the treatment unit the live-video on the display automatically switches to the live-video of the microscope. When pressed again the live-video of the camera system for rigid and flexible scopes/ or stroboscope will be shown again on the display.

13.1.3 How the equipment functions

See “Use”

13.2 Parts of the video switch

NOT APPLICABLE

13.3 Trouble shooting

NOTE: Troubleshooting may only be performed by an authorised technician.

13.3.1 Live-Video does not switch between the cameras

Is the ProminENT switched on?

- Yes, go to the next question
- No, please switch on the ProminENT

Check the S-VHS cables connecting the camera systems to the video switch
Are these well connected?

- Yes, go to the next question
- No, please connect the cable(s) properly.

Is the fuse on the printed circuit board intact?

- Yes, please consult an approved service agent
- No, replace the fuse

14 Function: Multimedia Centre (If present)

14.1 Introduction

14.1.1 Use

The multimedia centre is a computer system used for viewing live video image. The system should be connected to a camera/stroboscopy system. Also, external devices like tympanometry and a rhinomanometry can be connected.
The system is controlled by the MediTop ProminENT
If there is a video switch built into the unit live-video will automatically switch between the connected video sources. Live-video will be switched automatically when a connected device is activated.
The multimedia centre can be equipped with the Image & Video Manager digital storage system from STAR Medical Systems.

For operation of the connected devices in the multimedia centre and installed software we refer to the separately attached instructions for use.

14.2 Maintenance to the Multimedia centre

We recommend that you perform the following preventive maintenance at the multimedia centre:
(If you have chosen a maintenance contract for the ProminENT where the media centre is built in this will be carried out by our technician during the annual maintenance)

- Check the fans annually on operation;
- Annual cleaning of the fans;
- Annual suctioning the inside of the PC or lightly blow with a light compressor
- Take note, that when blowing with compressed air you should keep the fans silent because they otherwise can turn quickly causing unnecessary wear of the bearings.
- When blowing the power supply this can be done the best from the inside out so that the dust is blown out of the PC.
- Annual physical check of capacitors standing on globe on the motherboard. This is an indication of breakage of the motherboard.
- We recommend preventive replacement of the motherboard battery every three years.
  You need to reset the BIOS settings back on our suggested settings.

14.3 Trouble shooting

In improper functioning of the system, we recommend you to consult an internally expert or contact the Technical Support of your approved service agent.

15 Function: Dimmer spots / PL (If present)

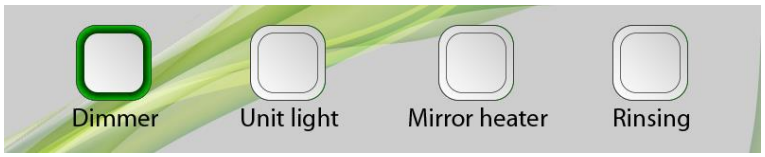
15.1 Introduction

15.1.1 Application(s)

The intended use of the dimmer module is to switch on/off or dim the available spots / PL lightning in the room.
The dimmer module can only be used in combination with the ProminENT.

15.1.2 Use

When you press the assigned button on the main control console of the ProminENT the spots / PL lightning can be set On or Off.



When set to On the button will be green outlined and this button can be used to dim the lightning.
Please hold the button until the wanted level is reached.

15.1.3 How the equipment functions

See “Use”

15.2 Parts of the dimmer

NOT APPLICABLE

15.3 Trouble shooting

NOTE: Troubleshooting may only be performed by an authorised technician.

15.3.1 Dimmer module does not function:

Is the ProminENT switched on?

- Yes, go to the next question
- No, please switch on the ProminENT

Is the fuse on the printed circuit board intact?

- Yes, please consult an approved service agent
- No, replace the fuse

16 Function: multifunctional foot switch (If present)

16.1 Introduction

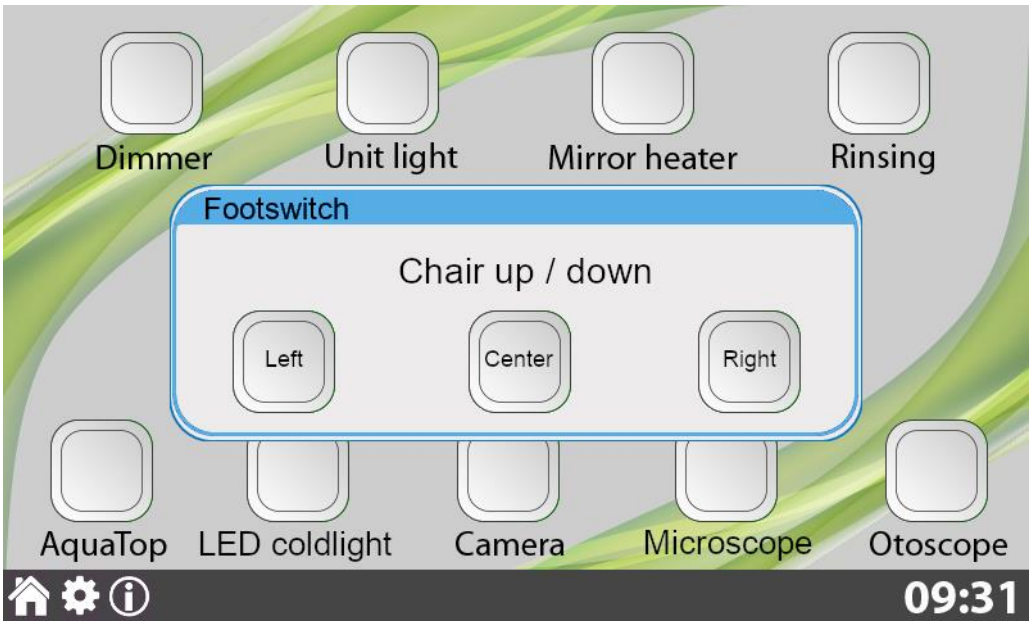
16.1.1 Application(s)

The multifunctional foot switch may only be used together with the ProminENT ENT treatment unit and can be used to operate connected devices such as Patient Chair, Erbe coagulation and Multimedia Centre.

16.1.2 Use

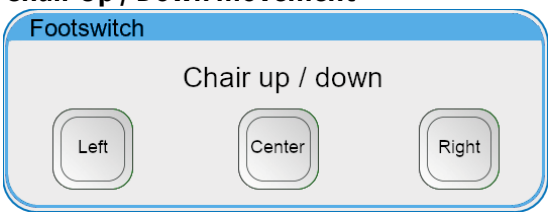
Foot switch:

If the round button in the middle of the foot switch is pressed the operation of the multifunctional foot switch will be displayed:



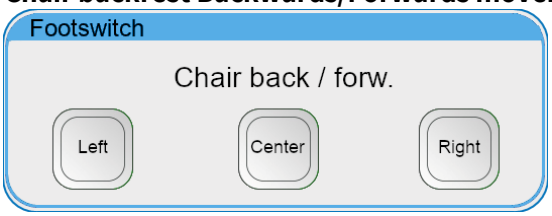
There are four possibilities regarding the multifunctional foot switch:

1. Chair Up / Down movement



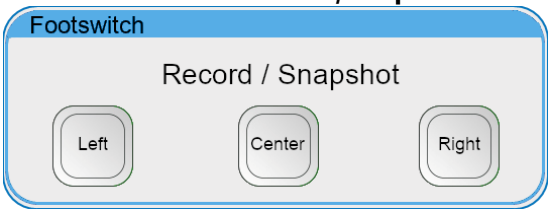
	Left pedal or button	Right pedal or button
Hold	Chair up	Chair down
Double clicking	To selected saved position. (optional)	Automatically to zero-position

2. Chair backrest Backwards/Forwards movement



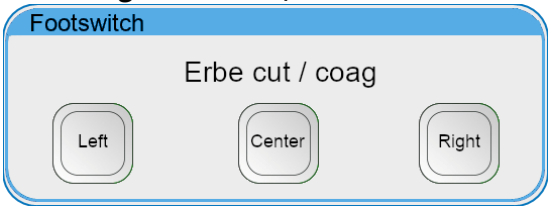
	Left pedal or button	Right pedal or button
Hold	Backrest backwards.	Backrest forwards.
Double clicking	To selected saved position. (optional)	Automatically to vertical-position

3. Multimedia centre Record/Snapshot of images



	Left pedal or button	Right pedal or button
Press	Start / Stop capturing movie	Snapshot

4. Erbe Coagulation CUT/COAG



	Left pedal or button	Right pedal or button
Hold	CUT	COAG