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User Manual

AquaTop XS

CONTENT

- Version 1.2 dated 14-01-2026 –

CE
1912

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Warnings and Safety issues

- Use the AquaTop XS in accordance with this manual and applicable product labels.
- The AquaTop XS must be placed on a flat and stable surface.
- The AquaTop XS front panel must always be visible to the user during examination/use.
- The supply voltage specified on the label of the AquaTop XS should be in accordance with the voltage in the building.
- Do not place the AquaTop XS near radiators or other heat sources.
- The AquaTop XS may only by medically qualified personnel, familiar with the basics of caloric examination be used on the patient.
- Repairs and maintenance may only be performed by qualified personnel that is authorized by MediTop.
- No modifications may be carried out on the AquaTop XS.
- Occupational safety and usability of medical devices are determined not only by your ability, but also the maintenance of the device (see chapter 6 - Maintenance).
- Qualified service and use of original spare parts guarantee the operational safety, usability and value of your medical device retained.
- As with all prescribed medical devices cannot consulting a doctor, not reading and follow all instructions before the device is used, lead to a malfunction of the product, and possibly (severe) injury.
- Check the temperature and the water pressure prior to each use.
- Turn off the AquaTop XS and the water supply when the device is not in use.
- If the AquaTop XS is not used, you must make sure that the hand piece is placed in the appropriate holder.
- Do not drop the hand piece! The hand piece can break down.
- The AquaTop XS should not be used in areas with explosive risk.
- In no event pour water over the AquaTop XS, immerse or rinse under the water tap.
- After maintenance or repair, test the working of the AquaTop XS.

1 Introduction

1.1 Application(s)

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

1.2 Intended use

Intended User
The AquaTop XS may only be used by (ENT) doctors (assistants). Alternatively during commissioning, maintenance or repair, the AquaTop XS can also be operated by the technicians who connect, maintain and repair the device.

User Characteristics
(ENT) physician (assistant)

Patient Population
All patients that require ear irrigation or caloric testing (vestibular function testing of a patient's body balance system)

Precautions for Use
Warnings and precautions described in the instruction manual must be followed at all times.

1.3 Use

When the apparatus is turned on and the water pressure is present, the equipment will heat up the water till 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 the equipment during transport. We strongly recommend you to take care that the temperature of the water inlet will not be higher than 20° C, and certainly not higher than 30° C, because in this case the setting of the temperature cannot take place.

1.4 How the device works

The AquaTop XS is a water irrigator with continues water flow so this keeps the water clean for every use.

The AquaTop XS operates on water pressure. The water flows through a reduction valve, which reduces it to high pressure. Next the water passes a labyrinth with a heating element.
A temperature-sensor passes information through to the electronics that directs the heating element. The warmed water next flows to the hand piece where a three-way-valve is located. If the button of the hand piece is not pushed in the water flows back to the water outlet.
If the button is pushed the outlet will be blocked and the water flows through the cannula out of the system.

1.5 Indications for use

Health care should assess the patient to ensure that the use of the AquaTop XS is rewarding for the patient. The device is intended for use:

1. As a stimulator for caloric testing.
   In medicine, the caloric reflex test (sometimes termed 'vestibular caloric stimulation') is a test of the vestibulo-ocular reflex that involves irrigating cold or warm water or air into the external auditory canal. This method was developed by Robert Bárány who won a Nobel prize in 1914 for this discovery. A caloric test is a useful tool that can help a clinician differentiate a central versus peripheral lesion in the patient who complains of dizziness. Monocaloric testing (MCT) using a warm medium can be used to triage patients in whom there is low clinical suspicion of a peripheral lesion.

2. As a device for irrigating the ear.
   Cerumen impaction is defined as "an accumulation of cerumen that is associated with symptoms, prevents the necessary assessment of the ear, or both." Irrigation of the ear is one method providers can use to treat cerumen impaction when appropriate.

1.6 Contra indications

Caloric testing:

- Medical use of pharmaceuticals that can affect the vestibular system (antiemetics, anxiolytics, and antidepressants) within 48 hours of testing is a relative contraindication.
- Significant degree of space occupying wax
- Otitis externa
- Middle ear fluid/effusion
- Hypermobile or atrophic tympanic membrane - care should be taken for severe hyper-mobility and a second medical opinion obtained
- Tympanic membrane perforation (may be suitable for air calorics)
- Patients with mastoid cavities may be considered for air calorics, but interpretation should be carried out with caution. Staff performing the test should be aware of these contraindications and the specific relevant specialist should be contacted for advice on individual patients

Ear irrigation:

There are a few contraindications to performing irrigation of the ear including lack of patient consent. These contraindications are:

- a patient's inability to sit upright,
- a patent tympanostomy tube,
- a patient who is unwilling or unable to sit still, foreign body present in the ear canal, perforated tympanic membrame, an opening into the mastoid, and severe swimmer's ear.
- Also, a history of middle ear disease, ear surgery, inner ear problems (especially vertigo), or radiation in the area is an additional reason to choose another method for cerumen dis-impaction

1.7 Precautions/Risks

Caloric testing:

Risks involved with caloric stimulation:

- The test may cause some minor discomfort, especially when cold water is inserted. The test may cause brief feelings of vertigo, which can lead to nausea in some people.
- Although rare, it is possible for excessive water pressure to injure an eardrum. For this reason, only a small amount of water is used for this test.
- An injury is more likely to occur if the eardrum has been previously damaged. A doctor should check the eardrum before the procedure, and this test should not be used if it is damaged.

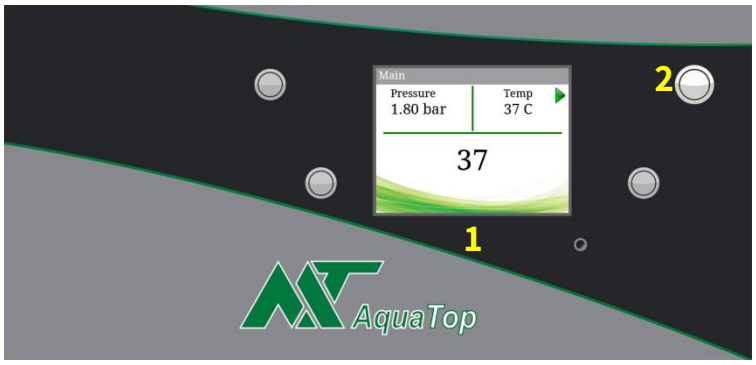
Ear irrigation:

The main complications reported after aural irrigation are:

- Pain,
- Injury to the skin of the ear canal with or without hemorrhage, and
- Acute otitis externa.

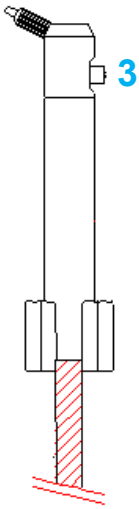
2 Parts of the AquaTop XS

2.1 Name of the parts



- 1 Digital display (see also Figure D)
- 2 Temperature setting button

Figure A – Front panel AquaTop XS



- 3 On button hand piece

Figure B – Hand piece AquaTop XS

Figure C – 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 MediTop ENT treatment system
- 9 Reduction valve
- 10 Water outlet
- 11 Water inlet – Maximal 6 Bar [1]

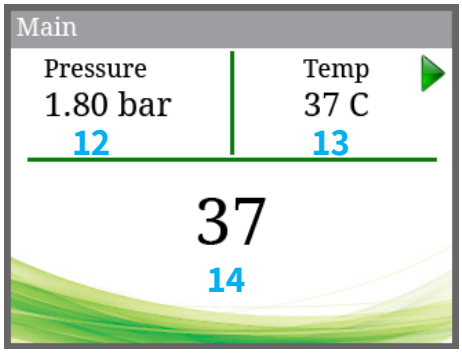


Figure D – LCD Display AquaTop XS

- 12 Current pressure
- 13 Set temperature
- 14 Current water temperature

[1]) *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*

2.2 Purpose / Functioning of the parts of the AquaTop XS

1. Digital display (Also On/Off indicator)
   This display digitally shows the water pressure, set and current temperature. It also indicates when there is no or too low water pressure or when the temperature is too high. (See also Chapter 4)
   If On/Off switch is Off the display is not light up.
2. Temperature setting button
   For the AquaTop XS with 3 temperatures, part number 1040600 and 1040600-CAL:
   This switch makes it possible to choose the temperature: 0, 30° C, 37° C or 44° C.

   For the AquaTop XS with 1 temperature, part number 1040700:
   This switch makes it possible to choose the temperature: 0 or 37° C.
3. Button hand piece
   When pressed the warmed water will flow out the device through the cannula.
4. On/Off switch
   The switch on the back of the AquaTop XS turns the device on or off.
5. Fuse
   Fuse T 6.3 A.
6. 230 Volts - 50 Hz connection
   230 Volts euro plug connection.
7. Potential equalization point
   Connection for potential equalization.

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

9. Reduction valve
   With this reducing 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.
    The maximum pressure of the entered water is 6 Bar. 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.
12. Current pressure
    Shows the current water pressure.
13. Set temperature
    Shows the setting of the temperature
14. Current temperature
    Shows the current water temperature.

3 Connecting and Testing

3.1 Connecting the AquaTop XS

Put the AquaTop XS on a place where the temperature setting switches and the digital display are within reach.
Do not place the AquaTop XS near radiators or other heat sources.

Connect the water inlet and outlet with the delivered set of water tubing.
Please ensure that the water tubing are not bend or cannot be bend or trapped so it could restrict the water flow.

Check if the power supply matches the voltage as written on the back of the AquaTop XS.
Place the power cable in an earthen socket outlet.
If available the external earth can be connected on the back of the AquaTop XS

The user must be able to reach both ears without having to move the patient.

We recommend you place the AquaTop XS approximately 75 cm from the head of the patient in the same direction as the patient.
The maximum distance between the device and the ears of the patient is 175 cm.

If the AquaTop XS is not used, you must make sure that the hand piece is placed in the appropriate holder.

Do not drop the hand piece! The hand piece can break down. (This is not covered under warranty)

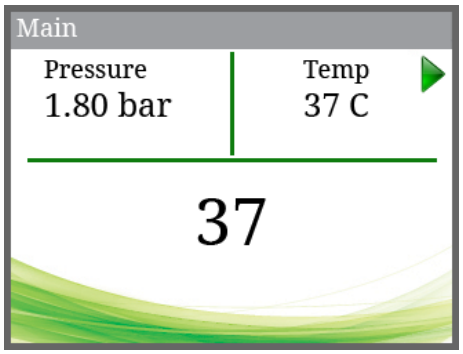
3.2 Testing the AquaTop XS

Turn the AquaTop XS on by pushing on the On/Off switch on the back of the AquaTop XS and open the water supply.
Set the pressure on 1,8 bars by turning the reduction valve on the back of the AquaTop XS.
Now the AquaTop will starts to heat up the water till 37° C.

After maintenance or repair, test the working of the AquaTop XS.

4 Operation

If the AquaTop XS is switched on it will start up with the default setting of 37 ° C.



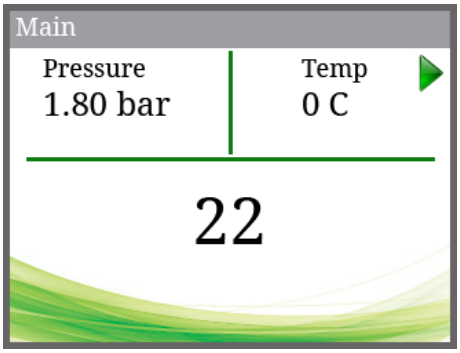
On this screen is displayed by default:

- Current pressure in bar
- Set temperature in ° C
- Current water temperature in ° C

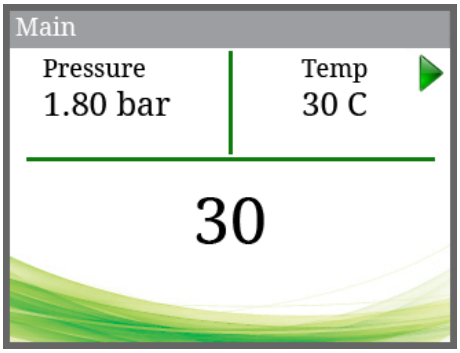
With the push-button directly next to  the temperature can be set.

4.1 Temperature settings AquaTop XS with 3 temperatures, product code 1040600

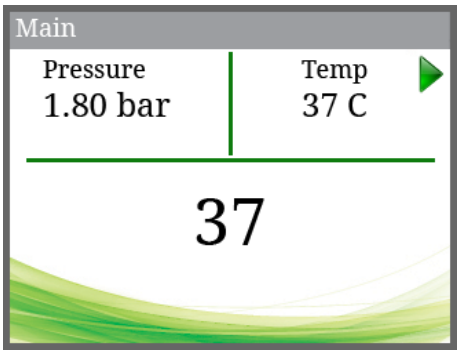
0 C
At this setting, the supplied water will not be heated.



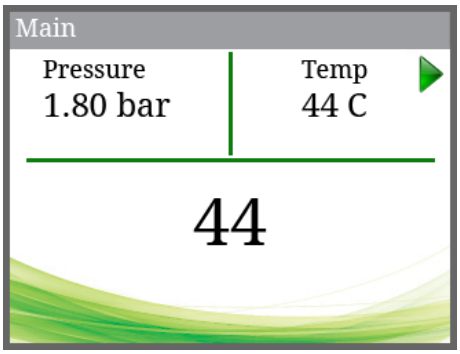
30 C
At this setting, the water will be heated to 30 ° C.
(For use in caloric examination)



37 C
At this setting, the water will be heated to 30 ° C.
(For cleaning the ear)



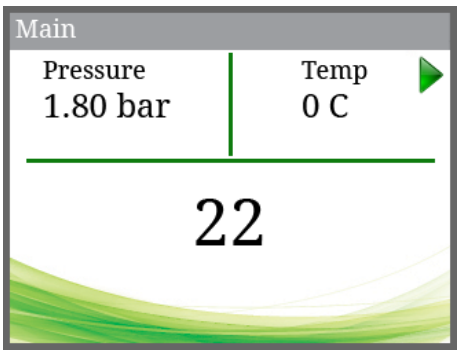
44 C
At this setting, the water will be heated to 44 ° C.
(For use in caloric examination)



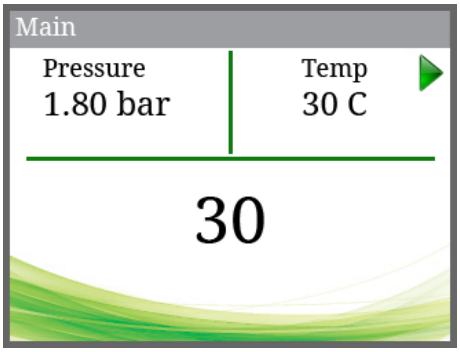
4.2 Temperature settings AquaTop XS Calorization with 3 temperatures, product code 1040600-CAL

This is a special version intended for caloric examination.
The AquaTop XS Calorization has a minimum flow of 430 ml per minute.
Due to the higher flow, there is less pressure, making this version less suitable for irrigating the ear.

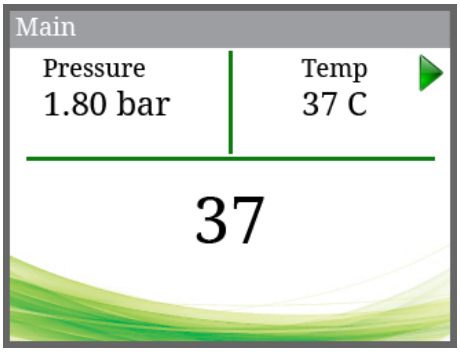
0 C
At this setting, the supplied water will not be heated.



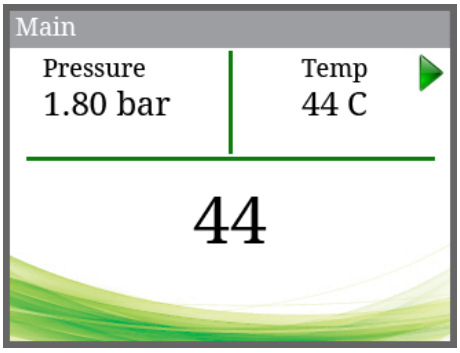
30 C
At this setting, the water will be heated to 30 ° C.
(For use in caloric examination)



37 C
At this setting, the water will be heated to 30 ° C.
(For cleaning the ear. However, due to the higher flow, there is less pressure, making this version less suitable for irrigating the ear.)

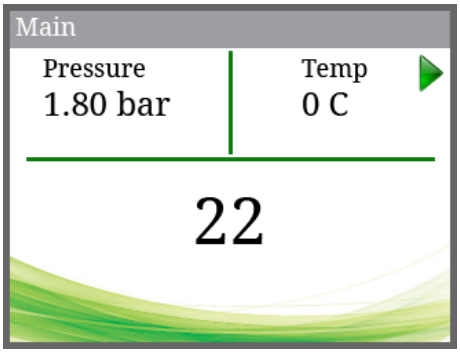


44 C
At this setting, the water will be heated to 44 ° C.
(For use in caloric examination)

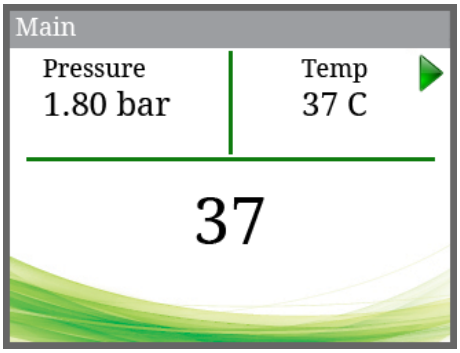


4.3 Temperature settings AquaTop XS with 1 temperature, product code 1040700

0 C
At this setting, the supplied water will not be heated.



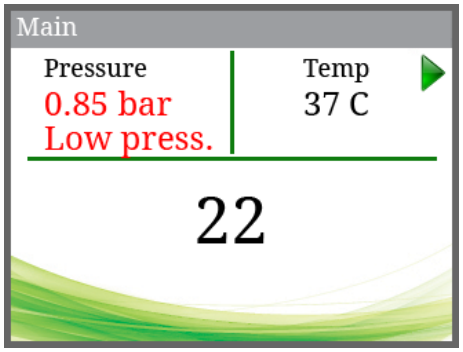
37 C
At this setting, the water will be heated to 30 ° C.
(For cleaning the ear)



5 Warnings

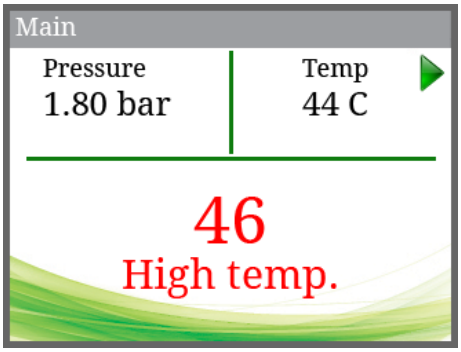
5.1 Warning at insufficient water pressure

If the pressure is below 1.0 bar there will be both an audible signal and a visual signal displayed to indicate that the pressure is too low. As long as this Warning is activated the heating element will not heat the water!
This warning is to eliminate by turning the pressure to at least 1.0 bar, advised is 1.8 bars.
Also there will be a blue LED displayed!



5.2 Overheating warning

If the temperature is above 46 degrees C, there will be both an audible signal and a visual signal displayed to indicate that the temperature is 46° C or higher. As long as this warning is activated the heating element will not heat the water!
When the temperature falls below 46° C the warning will be switched off.



5.3 LED-Indicator

The LED indicates the status of the AquaTop XS

The LED has 4 possible colors:

Green	→	Temperature within preset setting. Device ready to use.
Orange	→	Temperature deviation of + or - 1° C relative to set temperature. Device not ready for use!
Blue	→	Pressure too low Device not ready for use!
Red	→	Temperature above 46° C. Device not ready for use!

6 Maintenance

6.1 Cleaning the AquaTop XS

The AquaTop XS may only be cleaned using a moistened cloth and if necessary liquid disinfectant.
In no event 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 opening of the cannula is very small, any further narrowing of the cannula by calcium will raise the pressure, which will decrease the water flow. This may lead to instability of the water temperature.
We recommend you to descale the cannulas at least once a year. The number of times depends on the concentration of calcium in the water supply.

6.2 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 hand piece, and if necessary oil or replace.

Cleaning or replacing the filter in the water inlet should take place at least once every six months.
The equipment should only be serviced and supported by qualified service personnel.

After maintenance or repair, test the working of the AquaTop XS.

After installation, the AquaTop XS must be tested for functionality and safety by a medical electrical safety tester.

7 Warranty

7.1 Total warranty

The warranty for the AquaTop XS treatment system 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.

7.2 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 the AquaTop XS yourself.
Notify your local distributor. Only qualified technical personnel authorized by the manufacturer may perform repairs to the AquaTop XS.

7.3 Consumables

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

8 Technical specifications

8.1 Safety standards

Reference	Standards	Revision date
QMS		
EN ISO 13485:2016	Medical Devices -Quality Management systems – Requirements for regulatory purposes.	2016
EN ISO 14971	Medical devices - Application of risk management to medical devices	2019
EN IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2015
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/A12:2014
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 60601-1-6:2010	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 61000-3-2:2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	2014
EN-IEC 61000-3-3:2013	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
Information supplied		
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices	2008/A1:2013
EN-ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016
Sterility		
N.A.		
Sterile barrier system		
N.A.		

8.2 Specifications

Type (according IEC 60601-1)	:	B
Classification (according IEC 60601-1)	:	I
Classification (according/ 93/42/EEG)	:	IIa
Voltage	:	230 Volt AC / 50 Hz
Maximal use	:	1100 Watt
Security	:	Glass fuse T6.3A
Temperature settings	:	30° C, 37° C, 44° C or no heating of the water or 37° C or no heating of the water
Maximal water pressure	:	6.0 bars [2)]
Water pressure setting	:	1.8 bars
Weight	:	3 kg

8.3 Environment

Protection class [3)]	:	IP22
Operating temperature	:	+5° C to +25° C
Storage temperature	:	+5° C to +70° C
Humidity	:	5 to 93%, non condensing
Atmospheric pressure	:	850 to 1100 hPa

[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*

[3] *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.
The Enitherm, 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.

8.4 Identification Label

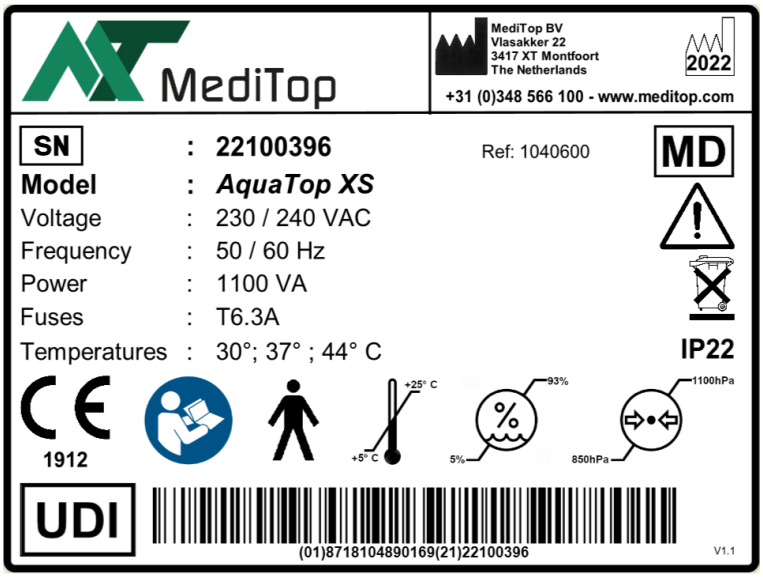


Figure E - Label AquaTop XS with 3 temperatures.

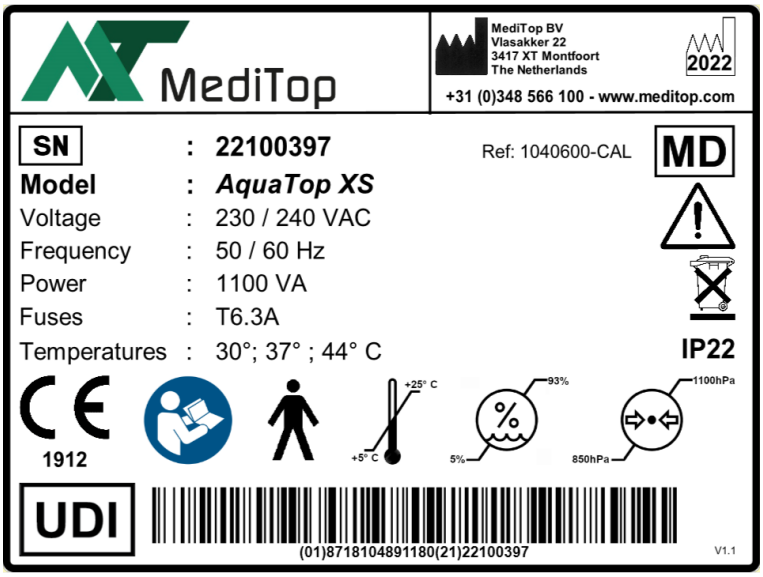


Figure F - Label AquaTop XS Calorization with 3 temperatures.

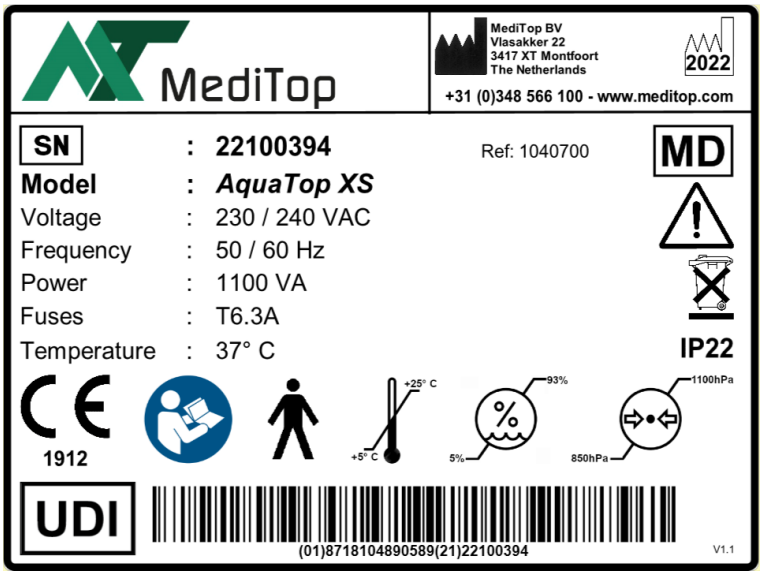
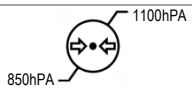
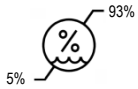


Figure G - Label AquaTop XS with 1 temperature

You can find the label on the side of the housing

8.5 Explanation of symbols

CE 1912	This symbol indicates that the AquaTop XS 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 AquaTop XS is type B according to IEC601-1.
	Year of manufacture
	Manufacturer Information.
SN	Serial number.
MD	This symbol indicates that the AquaTop XS is a Medical Device
UDI	Unique Device Identifier
	Temperature limit for use.
	Temperature limit for storage.
	Atmospheric pressure limitation.
	Humidity limitation.
	Fragile, handle with care.
	Keep dry.
	Separate waste collection for electrical and electronic devices.

8.6 Guidance and manufacturer's declaration – electromagnetic immunity

The AquaTop XS 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 AquaTop XS.

We advise you not to place the AquaTop XS very close to other electronic equipment.
Should this be the case, the operation of the AquaTop XS 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

8.6.1 Applied standards

Test	Standard	Class / Level
Emission	NEN-EN-IEC 60601-1-2:2015	--
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	--

8.6.2 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.

8.6.3 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.

8.6.4 Table 6 - Input d.c. power port

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

8.6.5 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.

8.6.6 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.

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

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.

8.7 Manufacturer

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

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

8.8 Disposal

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

The AquaTop XS 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.

8.9 Shelf life

The AquaTop XS has a limited shelf life before commissioning of 5 years.

8.10 Life

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

9 Trouble shooting

9.1 Display shows "Low press."

Meaning there is no or an insufficient water pressure available, the heating element will not be activated.

Is water pressure available in the device?

- Yes, go to the next question.
- No, put the pressure on.

Turn the pressure reducing valve to increase the pressure:
Is the pressure increased to the required 1.8 bar?

- Yes, the device is now suitable for use again.
- 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 approved service agent.

9.2 Display shows "High temp."

Temperature is above 46 ° C. The electronics have switched off the heating element and will not heat until the temperature has dropped.

Is water still flowing from the hand piece when the button is pressed??

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

9.3 Display shows nothing

Is the main switch turned on?

- Yes, have the device checked by a technically qualified person whether the main fuse is not broken and replace the fuse when necessary. If the display still does not show anything, please contact the technical department of MediTop or your approved service agent.
- No, Turn the switch on.

9.4 Temperature not stable

Cause: No constant flow. The button on the hand piece should be fully depressed to have the same flow as when it is not pressed.
Solution: Make sure that the cannula is not blocked or that the return line is not blocked.

9.5 Water is not heated

Is the AquaTop XS set to 0 C?

- Yes, Set the correct value for the temperature
- No, See below

Cause: Hardware temperature switch entered into force because temperature is above 50° C, with the result that heating has stopped.
Solution: Have a technically qualified person open the device and reset the temperature switch.