



MARKING AND SYMBOLS

MARKING AND SYMBOLS



Catalog number



Batch code



Manufacturer



Date of manufacture



Temperature limit 10-40 °C (50-104 °F)



Keep away from sunlight



Keep dry



Do not use if package is damaged



Consult instructions for use



Non sterile



Separate collection of
electrical and electronic equipment

COPYRIGHT

The copyright to these instructions for use is held by medos Medizintechnik AG. All rights reserved, including for translation. No part of this information may be reproduced or electronically processed, copied, translated or disseminated in any form (printed, photocopy, microfilm or by a different process) either in whole or in part without the written permission of medos Medizintechnik AG. All violations involving copyright can result in legal action.

DISTRIBUTOR

Xenios AG
Im Zukunftspark 1
74076 Heilbronn
Germany

Phone +49 7131 2706-0
Fax +49 7131 2706-299
info@xenios-ag.com
www.xenios-ag.com

MANUFACTURER

medos Medizintechnik AG
Obere Steinfurt 8-10
52222 Stolberg
Germany

Phone +49 7131 2706-300
Fax +49 7131 2706-498
info@xenios-ag.com
www.xenios-ag.com

PUBLICATION DATE

March 2018
Software version 1.02
IFU Version:
EN_003_2018_03
Item number:
MEDPHC0016

VALID FOR

ME DPHC 0001 Deltastream HC, 230 V
ME DPHC 0002 Deltastream HC, 115 V

AVAILABLE LANGUAGES

The following languages are available as hard copies:



These and all other product-specific language versions are available as PDF downloads at www.xenios-campus.com.

INTRODUCTION

INTRODUCTION

These instructions for use are intended to familiarize the user with the unit. They provide an insight into its setup, function and operation. Read these instructions for use

carefully, and make sure that you have understood them! Follow the instructions to ensure safe operation.

EXPLANATION OF SYMBOLS AND NOTICES

DANGER



This symbol indicates an immediate danger. The patient's life and health are at risk if it is ignored.

WARNING



This symbol indicates a possibly harmful situation. The unit will be damaged or destroyed if it is not prevented.

CAUTION



This symbol indicates a possible danger. There is a risk of damage to the unit or of personal injury if it is ignored. The patient's life and health could also be at risk.



This symbol refers you to more information or tips from practical use.

The following symbols are used in the text in order to clarify instructions:

- Identifies lists
- ⇒ Means »action to be performed«
- Means »important statement/information«

DIMENSIONS

All dimensions are given in millimeters »mm«. Other units of measurement are highlighted.

ILLUSTRATIONS

The shown product images in the following operating instructions comply with the current state of printing. Individual illustrations might differ from the delivery state.

TABLE OF CONTENTS

1	Information on the Instruction manual	7
1.1	Limitation of liability	7
2	Safety instructions	8
2.1	Proper use	8
2.2	Requirements of personnel	8
2.3	Sources of risk	9
2.3.1	Risk of unintended heating or cooling	9
2.4	General safety instructions	9
3	Transport and packaging	10
3.1	Delivery contents and transport inspection	10
3.2	Unpacking	10
3.3	Disposal of packaging	10
4	Initial operation	11
4.1	Set up	11
4.1.1	Requirements at the place of use	11
4.1.2	Setting up with the deltastream Trolley	11
4.2	Water quality	12
4.3	Connecting the deltastream heater cooler	12
4.3.1	Filling the system with water	12
4.3.2	Connecting the oxygenator	13
4.3.3	Electrical connection	14
5	Design and function	15
5.1	Unit views, controls and displays	15
5.2	Safety devices	16
5.2.1	Sensors	16
5.3	Type plate	16
5.4	Function	16
5.4.1	Basics	16
5.4.2	Indications/contra-indications/side-effects	17
6	Use and operation	17
6.1	Before switching on	17
6.1.1	Checking the unity	17
6.1.2	oxygenator	18
6.2	Operation	18
6.2.1	Switching on	18
6.2.2	Function test	19
6.2.3	Setting the temperature	19
6.2.4	Temperature regulation mode	20
6.2.5	Duties during operation	20

TABLE OF CONTENTS

6.2.6	Operating language	21
6.3	Alarms	21
6.3.1	General information	21
6.3.2	Low-priority alarms	22
6.3.3	High-priority alarms	23
6.3.4	Power failure alarm	24
7	Cleaning and disinfection	25
7.1	Unit	25
7.1.1	Surface cleaning and disinfection	25
7.1.2	Changing water and disinfecting the water circuit	26
7.1.3	Disinfection	27
8	Maintenance and safety-related checks	28
8.1	Maintenance	28
8.1.1	Unit	28
8.1.2	Hose couplings	28
8.2	Safety-related check	29
9	Repairs	30
9.1	Causes of faults and actions to take	30
10	Disposal of the old unit	31
11	Technical data and accessories	32
11.1	Technical data and accessories – deltapstream hc	32
11.2	Accessories	33
12	Guidelines and manufacturer's declaration	34
13	Quick Guide	38

LIST OF FIGURES

Figure 1:	Filling the system with water	12
Figure 2:	Connecting the device side	13
Figure 3:	Front view	15
Figure 4:	Rear view (section) of unit with ventilation slots, microfuse and mains socket	15
Figure 5:	Typeplate	16

1 INFORMATION ON THE INSTRUCTION MANUAL

This instruction manual is part of the deltastream heater cooler (referred to below as the “unit”) and provides important information on the initial operation, safety, correct usage, care and servicing of the unit.

All illustrations and drawings in this instruction manual are for general information only and not definitive in their design details.

The full instruction manual should ideally be kept close to the unit. It must be read and used by each person tasked with the

- initial operation,
- use,
- cleaning,
- care,
- servicing and
- repair

of the unit.

Make sure that you have read the instructions for use completely and have understood the content! Follow the directions and notes in these instructions for use carefully and conscientiously!

1.1 LIMITATION OF LIABILITY

In this instruction manual, all technical information, data and instructions for installation, operation, care and servicing correspond to the state of the art at the time of printing, are based on previous experience and correspond to the best of our knowledge and good manufacturing practice.

No claims may be derived from the details, illustrations and descriptions in this manual.

Warranty and liability claims for personal injuries and property damage shall be excluded if they are the result of one or more of the following:

- Ignoring the instructions in the manual in relation to transport, storage, installation, initial operation, use and servicing of the unit
- Improper use of the unit
- Incorrect initial operation, use and servicing of the unit
- Unauthorized structural and technical modifications to the unit
- Use of non-approved spare parts
- Incorrectly performed repairs and servicing

2 SAFETY INSTRUCTIONS

2.1 PROPER USE

The unit is intended exclusively for cooling or heating the water that is pumped during use of the unit through an attached oxygenator to regulate the temperature of the patient's blood. Any other form of use is regarded as improper.

The unit must only be operated with its associated components and a oxygenator in accordance with the instruction manual.

Proper use also includes following all the instructions in this manual and performing all inspection and servicing work in due time.

Claims of any kind relating to damage resulting from improper use shall be excluded.

The risk shall be borne exclusively by the operator.

CAUTION Danger due to improper use!



Improper use and/or any other type of use could put the patient and/or user at risk.

2.2 REQUIREMENTS OF PERSONNEL

WARNING



- To ensure patient safety, the unit should be monitored continuously during operation.
- The product may only be used on the instructions of a doctor, under medical supervision and only by medically-trained personnel (e.g. cardiovascular technician/doctor/critical care staff).
- Only persons whose training and qualifications entitle them to do so should work on/with the unit. They must also be instructed to do so by the operator.
- Personnel being trained, taught or instructed, or taking part in a course of general training, may only operate the unit under the supervision of an experienced person.

WARNING



- Persons under the influence of drugs, alcohol or medication affecting the response capacity must not use this device.
- The device may cause dangers if used improperly by untrained staff.
- In addition to the instructions for use, the general legal and other contractual regulations for accident prevention and environmental protection as well as essential health and safety requirements must be observed. The operator must instruct the staff accordingly.

2.3 SOURCES OF RISK

2.3.1 RISK OF UNINTENDED HEATING OR COOLING

CAUTION



There is a risk that the patient's blood could be heated or cooled excessively.

- The patient's body temperature must be continuously monitored when the unit is used with the oxygenator/on the patient.

2.4 GENERAL SAFETY INSTRUCTIONS

WARNING



For safe handling of the unit, observe the following general safety instructions:

- Before initial operation, make sure the unit (mains cable, housing, connections, hoses, etc.) and the oxygenator are in proper order.
- Make sure there are no kinks in the hoses to the oxygenator.
- Check that the hoses are connected correctly to the oxygenator.
- Do not touch the hoses with pointed or sharp items.
- Fill the unit tank with sterile water.
- Operate the unit only with the screw-cap on the tank closed.
- Position the unit for operation so that it is level. The slope of the supporting surface must be $\leq 3\%$.
- The height difference between the unit and oxygenator must be <75 cm.
- Do not cover the unit. There are ventilation openings at the sides, underneath and at the rear.

WARNING



- Pay attention to the automatic function test when switching on the unit.
- Perform the automatic function test manually at least once a day if the unit is in continuous operation.
- During operation, check the water flow and level at regular intervals.
- Operate the unit only with sufficient water in it (see MIN mark).
- Observe the specified ambient temperature (10-39 °C)
- We recommend only operating the unit with Medos oxygenators and their original accessories.
- Do not operate the unit in the presence of flammable gases.
- Do not use the unit in heating/cooling mode in conjunction with other sources of heat.
- Do not operate the unit in the vicinity of heat sources (beams of light, heaters/radiators, direct sunlight, etc.).
- Perform servicing and safety-related checks in accordance with this instruction manual.
- Allow only authorized personnel to operate the unit.
- The patient's body temperature must be continuously monitored separately from the system.

3

TRANSPORT AND PACKAGING

CAUTION Do not use unfiltered and unsterilized main water!



- Main water must be filtered with sterile filter with pore size $\leq 0.22 \mu\text{m}$ and subsequently sterilized to avoid a germ borne contamination.
-

3 TRANSPORT AND PACKAGING

3.1 DELIVERY CONTENTS AND TRANSPORT INSPECTION

The delivery contents for the deltastream heater cooler include:

- deltastream heater cooler unit
- Mains cable
- Instruction manual
- Two hoses with Hansen couplings
- deltastream Trolley (optional with order)
- Disinfectant (optional with order)



Check the contents of the delivery for completeness and visible damage.

If items are missing or if there is damage resulting from unsatisfactory packaging or transport, report this immediately to the shipper, insurance company and the supplier.

3.2 UNPACKING

To unpack the unit:

- Take the unit out of the box and remove the packaging material.
- Place the unit on a sturdy, level and horizontal surface.

CAUTION

The unit weights approximately 17 kg.



Use two people to transport, unpack and set up the unit.

3.3 DISPOSAL OF PACKAGING



The packaging protects the unit from transport damage. The packaging materials have been chosen for their environmental compatibility and are recyclable.

Returning the packaging to the material cycle saves raw materials and reduces the amount of waste generated. Dispose of packaging materials that are no longer needed at an appropriate collection point.



Where possible, keep the original packaging for the duration of the unit's warranty period so it can be repacked correctly in the event of a warranty claim.

4 INITIAL OPERATION

CAUTION



Personal injury or material damage can occur during initial operation.

Follow the safety instructions in order to avoid risks.

- The unit weights approximately 17 kg.
- Use two people to transport, unpack and set up the unit.

4.1 SET UP

4.1.1 REQUIREMENTS AT THE PLACE OF USE

For safe and problem-free operation of the unit, the place of use must

- Be sturdy (when filled, the unit weighs approximately 17 kg)
- Be level
- Be horizontal ($\leq 3\%$ angle)
- Provide 20 cm of space on all sides of the unit
- Guarantee sufficient ventilation on all sides of the unit
- Be located no more than 75 cm below or above the oxygenator
- Be free from devices with strong magnetic fields in the vicinity.

For safety reasons, the unit must not be operated on the floor.



The deltastream Trolley which is available as an accessory, meets all these requirements.

- If the unit is not horizontal, the water indicator at the front will show the incorrect water level.
- If the unit is well below the level of the oxygenator, water can flow back from the oxygenator into the unit and cause the tank to overflow when the filler stopper is opened and the unit switched off.

4.1.2 SETTING UP WITH THE DELTASTREAM TROLLEY

By means of the deltastream Trolley, which is available as an accessory for the deltastream console, the deltastream heater cooler, which was designed as a standing unit, can also be used as a mobile standing unit.

Set up the unit with the deltastream Trolley as follows:

Put the deltastream Trolley together as shown in its assembly manual.

There is a locking screw in the support plate of the deltastream Trolley. Place the deltastream heater cooler on the plate so that the screw and thread align in the base of the unit.

4 INITIAL OPERATION

4.2 WATER QUALITY

- Do not use unfiltered and unsterilized main water! Main water must be filtered with sterile filter with pore size $\leq 0.22 \mu\text{m}$ and subsequently sterilized to avoid a germ borne contamination.
- For filling the system, approx. 1 liter of sterile water is necessary.

4.3 CONNECTING THE DELTASTREAM HEATER COOLER

CAUTION Risk due to water coming into contact with electricity.



Do not connect the unit to the mains until it has been filled with water.

CAUTION Risk due to water coming into contact with electricity.



Water can conduct electricity.

If the water overflows when the unit is being filled, it must be dried thoroughly and be completely dry before it is connected to the mains and switched on.



When filling the unit for the first time, please follow the instructions on disinfecting (see “Maybe some of the listed products are not available in your country. Take care about the availability!” on page 27).



The system is a closed circuit and the water line should not be disconnected in the operating room. Ensure that the connection of the hose to the oxygenator has already taken place before the system is placed in the operating room.

4.3.1 FILLING THE SYSTEM WITH WATER

- Unscrew the cap on the water filler (2) without contaminating the interior of the unit. Wear gloves when doing so.
- Be careful not to lose the seal on the cap.
- Add sterile water, for example by placing a funnel in the water tank.
- We recommend using a sieve to prevent foreign material entering the water circuit.
- Watch the water level gage (5) during filling. The water level should be just under the MAX mark after filling.
- Screw the cap on the water filler tightly until it is sealed.

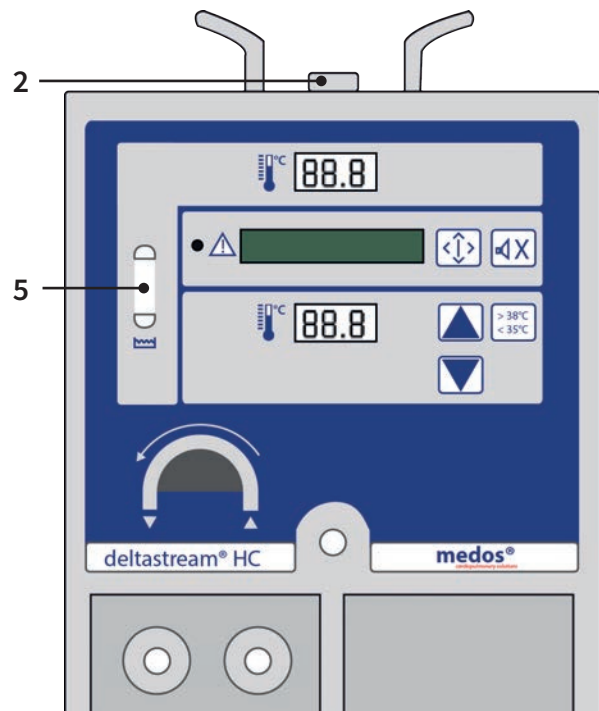


Figure 1: Filling the system with water

4.3.2 CONNECTING THE OXYGENATOR

- Attach the hose couplings to the couplings on the unit. The couplings are connected correctly if the coupling on the hose coupling locks into place in the coupling on the unit such that it cannot come loose.
- Undo the couplings by pressing on the metal plate on the hose coupling and pulling out the hose.
- An adapter is used to connect the hose to the Hansen coupling on the oxygenator. Hansen couplings are couplings that can be connected to all Medos oxygenators. The couplings are connected correctly if the coupling on the hose locks into the coupling on the unit such that it cannot come loose.



Figure 2: Connecting the device side



- The connections between the unit and the oxygenator are correct if the water flow meter rotates when the unit is switched on.
- Before use, check that the hoses are connected correctly to the oxygenator
- The oxygenator can also be disconnected while the unit is on.
- There will be a slight drip when the couplings are undone. This is normal and not a sign of a leak or defect.
- In heating mode: Lower the target temperature before disconnecting the oxygenator. Otherwise, the water in the unit's circuit will briefly heat up above the target temperature and trigger the alarm TEMP.DIFF > 1 °C (depending on the time lapse).



Further instructions for the oxygenator can be found in its instruction manual.

4.3.3 ELECTRICAL CONNECTION

WARNING Risk due to electrical current

Faulty mains cables and/or plugs can result in a fatal electric shock.

- Check that the unit's mains cable and plug are in perfect condition before switching on the unit.
-

To ensure safe and problem-free operation of the unit, follow the instructions below when connecting the power:

- Before switching on the unit, compare the connection details (voltage and frequency) on the type plate with those of your mains electricity. They must be the same to prevent damage to the unit. If in doubt, ask your qualified electrician.
- The socket must be protected by a 16 A fuse.
- Use the mains cable supplied to connect the unit to the mains. The plug is located on the back of the unit (see "5.1 Unit views, controls and displays" on page 15).

5 DESIGN AND FUNCTION

5.1 UNIT VIEWS, CONTROLS AND DISPLAYS

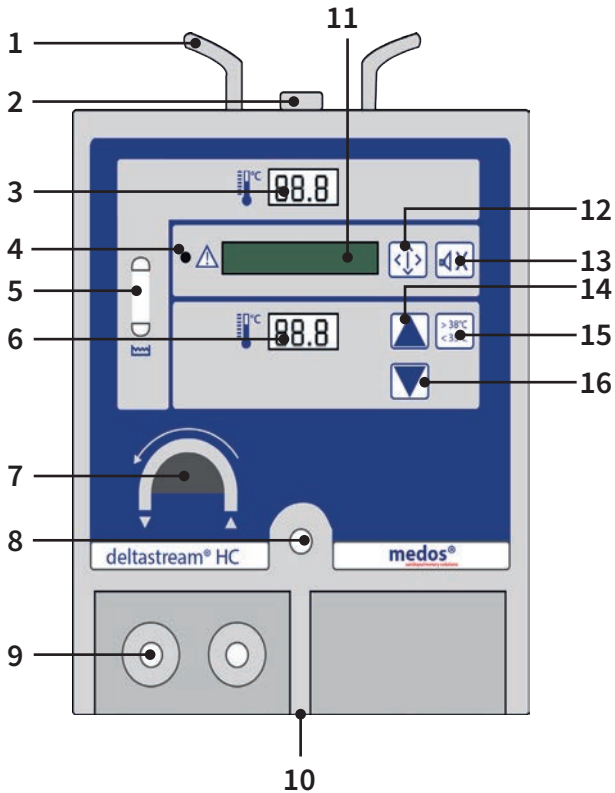


Figure 3: Front view

1. Handles
2. Water filler with screw cap
3. Temperature display for actual value
4. Fault indicator
5. Water level gage
6. Temperature display for target value
7. Water flow rate indicator
8. Mains switch
9. Hose couplings
10. Thread for locking screw (in base plate)
11. Display for status and fault messages
12. Function test
13. Alarm off
14. Increase target value
15. Confirm button <35 °C / >38 °C
16. Decrease target value



Figure 4: Rear view (section) of unit with ventilation slots, microfuse and mains socket

5 DESIGN AND FUNCTION

5.2 SAFETY DEVICES

5.2.1 SENSORS

The deltastream heater cooler monitors the following during operation:

- The water level in the unit
- Whether the water temperature in the circuit corresponds to the set target value
- Whether there is mains voltage
- Whether its own functional safety is in order

and triggers an alarm if there is a fault (see “6.3 Alarms” on page 21).

5.3 TYPE PLATE

The type plate (here an example) featuring the connection and output data is located on the back of the unit:

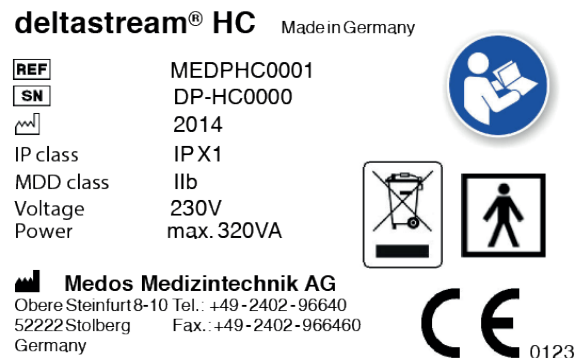


Figure 5: Typeplate

5.4 FUNCTION

5.4.1 BASICS

The deltastream heater cooler unit are used to heat or cool the patient’s blood between 15 °C and 39 °C with the aid of a oxygenator.

The temperature line between the patient’s blood and the water circuit runs via a membrane in the oxygenator. Because of its high thermal capacity and good heat-conduction properties, water is an ideal transfer medium for this application.

The water is cooled or heated in a water tank in the unit using thermo electric elements and, when operated with a oxygenator, is continuously fed to a rotary pump.

The correct operation of the unit is shown by various indicators on the front of the unit. Its electronic controls can accurately set the temperature transfer to the patient’s blood while simultaneously ensuring the unit is operating safely.

5.4.2 INDICATIONS/CONTRA-INDICATIONS/SIDE-EFFECTS

The unit is used for the following:

- Heat transfer during inter-operative or post-operative hypothermia
- Heat supply or removal to stabilize the patient's temperature (normothermia)
- Heat removal in the case of malignant hyperthermia

During cold transfer and associated deliberate lowering of the patient's temperature (therapeutic hypothermia), the following side-effects may occur:

- Autonomous reactions (incl. shivering),
- Electrolyte shift,
- Hyperglycemia,
- Reduced oxygen intake,
- Reduced coagulation activity,
- Changed solubility of blood gases/narcosis,
- Changed pH value,
- Lower heart rate,
- Lower anesthesia requirements.

Disadvantages of therapeutic hypothermia include:

- Extended bypass time from cooling to heating,
- Increased blood viscosity,

with increasing degree and duration of organ damage and tendency to bleed

6 USE AND OPERATION

6.1 BEFORE SWITCHING ON

6.1.1 CHECKING THE UNITY

The system is a closed circuit. The water lines should not be connected or disconnected in the operating room. Ensure that the water connections to the oxygenator have already been connected before the system is placed in the operating room.

Check the unit for external damage.

After switching on the unit, check the water level every time before and after connecting a oxygenator.

The water level must be between both marks on the gage, preferably just below the maximum mark. The fill difference between the minimum and maximum marks is about 0.5 liters.

Top up with sterile water if the level is below the minimum mark.

6

USE AND OPERATION

6.1.2 OXYGENATOR

We recommend using Meods oxygenators.

- We recommend using Medos oxygenators.

Before connecting, check the oxygenator for damage. Only use undamaged oxygenators. Follow the directions in the oxygenator manual.

WARNING



Only use oxygenators than can sustain a water pressure of 0.15 bar.

Oxygenators can be connected or disconnected with the unit on or off.



Disconnecting oxygenators during operation

- **In heating mode:**

Reduce the target temperature before disconnecting the oxygenator. Otherwise, the water in the unit's circuit will briefly rise above the target temperature and may trigger the alarm TEMP.DIFF > 1 °C (depending on the time lapse).

- **In cooling mode:**

Increase the target temperature before disconnecting the oxygenator. Otherwise, the water in the unit's circuit will briefly fall below the target temperature and may trigger the alarm TEMP.DIFF > 1 °C (depending on the time lapse).

6.2 OPERATION

6.2.1 SWITCHING ON

Fill the water tank (see „4.3.1 Filling the system with water“ on page 12) to the MAX mark with sterile water.

- Switch on the unit using the push button (8). The push button at the front of the unit remains pushed in while the unit is on.
- Allow the unit to run until the air is eliminated from the unit and the hoses. For this pupose position the hoses level with the unit or lower.
- Check the water level on the gage (5). If necessary, switch the unit off, disconnect the power and top up with sterile water.
- Connect the oxygenator to the unit. Check the water level on the gage (5), especially if you have connected an empty oxygenator.

Follow the instructions on disinfecting (see “7.2.2 Changing water and disinfecting the water circuit” on page 27).

- The height difference between oxygenator and unit must not exceed 75 cm.
- Reconnect the unit to the power supply, switch it on and allow it to run for about two minutes to remove air from the circuit.
- Check the water level on the gage (5) again. If necessary, switch the unit off, disconnect the power and top up the water.



Please note that the tank contents may leak out if there is a fault. For this reason, be prepared in advance to take corrective action

6.2.2 FUNCTION TEST

The unit performs a function test after being switched on. Watch during the test to see whether the indicators behave as described below:

- A short audible alarm indicates that the unit is ready for a possible mains failure alarm.

The unit now checks its own safety devices::

- Temperatures (3) and (6) on the display (11) read **88.8**.
- The red fault indicator (4) comes on.
- The audible alarm sounds.
- The display (11) shows FUNCTION TEST.

If the function test is successful, the display shows the message FUNCTION TEST OK and the unit automatically starts normal operation.

This test lasts a few seconds.

WARNING



If the function test is not successful, the unit is not safe for operation.

The unit cannot be operated if:

- No beep indicating the mains failure alarm sounds after the unit is switched on.
- The automatic function test switches the unit off automatically because it detects a fault in its own safety devices.
- One or more indicators are faulty.

In these cases, have the unit checked by a Medos-approved customer service.

6.2.3 SETTING THE TEMPERATURE



- Use the two arrow keys (14) and (16) to set the target value for the water temperature. The temperature can be adjusted in increments of 0.1 °C from 15 to 39 °C.
- The temperature display (6) shows the set target value.



- For target temperature values above 38 °C, press and hold the Confirm button (15) while pressing the arrow key (14) at the same time.



- For target temperature values below 35 °C, press and hold the Confirm button (15) while pressing the arrow key (16) at the same time.

WARNING



- A considerable amount of heat will be removed from the patient's blood at a temperature below 35 °C.
- A considerable amount of heat will be added to the patient's blood at a temperature above 38 °C

The addition or removal of heat by the Medos oxygenator to/from the patient's blood only occurs if the temperature of the water in the oxygenator is higher or lower than the patient's blood temperature.

The amount of heat transfer is directly proportional to the temperature difference between the blood and the water in the oxygenator.

6.2.4 TEMPERATURE REGULATION MODE

> 38°C
< 35°C

If the target temperature value is between 35 °C and 38 °C, the unit starts operating automatically after being switched on and the function test, and adjusts the water temperature in the circuit to the set value.

If the set target value is higher than 38 °C or lower than 35 °C, the unit sounds an alarm and the display (11) shows the following message: "TARGET VALUE <35 / >38 °C!", "CONFIRM BUTTON". In this case, check whether the target value is correct, then press the Confirm button (15). The unit starts temperature regulation mode and the display (11) shows "HEATING ACTIVE" or "COOLING ACTIVE"

CAUTION

There is a risk that the patient's blood could be heated or cooled excessively.

The patient's body temperature must be continuously monitored if the unit is used on the patient with a oxygenator.

6.2.5 DUTIES DURING OPERATION

Checking the water flow rate

Check the water flow in the unit and oxygenator at regular intervals. There is an impeller in the viewing window of the water flow rate indicator (7). The individual impellers cannot be seen at the optimum water flow rate.

Monitoring patient temperature

During operation, check the patient's body temperature at regular intervals.

**Performing a function test**

If the unit is in use for an extended period, check the separate safety devices manually at least once a day. To do this, press the Function test key (12) during operation.

The unit now tests its safety electronics:

- The alarm sounds,
- Temperatures (3) and (6) on the display (11) read **88.8**,
- The red fault indicator (4) comes on,
- The display (11) shows FUNCTION TEST.

If the test is successful, the display shows the message FUNCTION TEST OK. The unit then resumes operation automatically.

CAUTION

If the test is not successful, the unit is not safe for operation. In this case,

- do not continue to use the unit on the oxygenator/patient.
- have the unit checked by a medos Medizintechnik AG-approved customer service..

6.2.6 OPERATING LANGUAGE

The status and fault messages can be shown on the display (11) in German, English, French, Spanish, Nederlands and Italian.



Set the display language as follows:

- Switch on the unit.
- Press and hold the “Alarm off” button (13) for about 4 seconds. The last selected language appears on the display.
- Use the arrow key (14) to select the desired language.
- About 10 seconds after the last input, the unit automatically returns to the original operating mode. The last selected language is now active.

6.3 ALARMS

6.3.1 GENERAL INFORMATION

The unit always displays a visual alarm and sounds an audible alarm if there is a fault. This means that the operator is quickly informed of any faults, thereby increasing the operating safety of the system. The fault condition that triggered the alarm is shown on the display (11) (with the exception of power failure alarms).



In the case of **low priority** alarms (see “6.3.2 Low-priority alarms” on page 22), pressing the “Alarm off” button (13) cancels the audible alarm for 10 minutes. The fault message on the display (11) is deleted, and the fault indicator (4) stays on for the duration of the alarm condition.

In the case of **high-priority** alarms (see “6.3.3 High-priority alarms” on page 23), the unit switches all functions off. The audible alarm cannot be canceled. Use the mains switch (8) to switch the unit off. Use the mains switch (8) to switch the unit off. Take it out of service and, if necessary, have it checked by an authorized service technician.

6 USE AND OPERATION

6.3.2 LOW-PRIORITY ALARMS

TEMP.DIFF > 1 °C

The unit triggers this alarm if the water temperature during operation varies by more than 1 °C from the set target temperature value.

The display shows “TEMP.DIFF > 1 °C”, the red fault indicator (4) flashes and a beep sounds



- Press the “Alarm off” button (13) to cancel the audible alarm for 10 minutes.

WATER LEVEL!?

The unit triggers this alarm if the water level during operation falls below the MIN mark on the water level gage (5). The display shows “WATER LEVEL!?”, the red fault indicator (4) comes on and a beep sounds.



- Press the “Alarm off” button (13) to cancel the audible alarm for 10 minutes.
- Top up with sterile water immediately until the level is just below the MAX mark (see “4.3.1 Filling the system with water” on page 12).

If the water is not topped up, a high-priority alarm, “WATER LOW”, is triggered (see “6.3.3 High-priority alarms” on page 23).



- Connecting or disconnecting a oxygenator during operation can cause a temperature difference which triggers the alarm.
- In cooling mode, the alarm can be triggered at high room temperatures because the target value (e.g. 15 °C) cannot be reached. Increase the target value until the unit is able to reliably control the temperature.
- After the unit has been switched on and after a change in the target temperature value, this alarm function is suppressed for a set time.

WARNING



- If the level is too low, there may not be adequate water circulation.
- Too little water can damage components and cause the unit to fail.

6.3.3 HIGH-PRIORITY ALARMS

WATER LOW!?

The unit triggers this alarm if operating safety is compromised by a low water level. The display shows “WATER LOW!?”, the red fault indicator (4) comes on and a beep sounds. The unit switches off the heater and pump.

The audible alarm can be canceled with the “Alarm off” button (13).

- Switch off the unit at the mains switch (8).
- Leave it off for 30 minutes.
- Then, top up with sterile water until the level is just below the MAX mark (5) (see “4.3.1 Filling the system with water” on page 12).
- Switch the unit on again.

ALARM TEST FAILED → CUSTOMER SERVICE

The unit triggers this alarm if it detects a fault during the automatic or manual function test, or finds that the separate safety devices are not responding. The display shows “ALARM TEST FAILED” and → “CUSTOMER SERVICE”, the red fault indicator (4) comes on and a beep sounds.

The audible alarm can be canceled with the “Alarm off” button (13).

- Switch off the unit at the mains switch (8).
- Leave it off for about 2 hours.
- Switch the unit on again.

WARNING



Follow the sequence of steps described in this manual. Otherwise, the unit may be damaged.

If the unit continues to sound an alarm, take it out of service and have it checked by an authorized service technician.

If the unit continues to sound an alarm, take it out of service and have it checked by an authorized service technician.

6 USE AND OPERATION

LOW TEMPERATURE CHECK UNIT

The unit triggers this alarm if the water tank temperature is below the measurement range (about 9 °C). The display shows “LOW TEMPERATURE” and “CHECK UNIT”.

The red fault indicator (4) comes on and a beep sounds.

The temperature gage shows $-\cdot-\cdot-$.

The audible alarm can be canceled with the “Alarm off” button (13).

- Switch off the unit at the mains switch (8).
- Move the unit to a warmer environment and leave it off for about 2 hours.
- Switch the unit on again.

WARNING



- Store the unit only in the approved temperature range of 10 °C-40 °C. Otherwise, it could be damaged.
 - Operate the unit only in the approved ambient temperature range of 10 °C-30 °C. Otherwise, it is not safe to use and could be damaged.
-

If the unit continues to sound an alarm, take it out of service and have it checked by an authorized service technician.

CHECK UNIT → CUSTOMER SERVICE

The unit triggers this alarm if a variety of faults occur.

The display shows “CHECK UNIT” and “CUSTOMER SERVICE”, the red fault indicator (4) comes on and a beep sounds.

The audible alarm can be canceled with the “Alarm off” button (13).

- Switch off the unit at the mains switch (8).

Take the unit out of service and have it checked by an authorized service technician.

6.3.4 POWER FAILURE ALARM

The unit triggers this alarm if the power fails while it is in operation. The red fault indicator (4) comes on and a beep sounds. All other indicators are inactive.

The power supply in the unit will maintain the alarm for at least 10 minutes without mains power.

- Switch off the unit at the mains switch (8).



The alarm ceases automatically when the power is restored.

7 CLEANING AND DISINFECTION

CAUTION



During the water change or the disinfection, no oxygenator may be connected to the water circuit.

Pay attention to hygienic handling when cleaning the device!

WARNING



Read the safety instructions below before starting to clean the unit:

- The system is a closed circuit. The water line should not be disconnected in the operating area. Do not perform water changes and disinfection in the operating area.
- Carry out water changes and disinfection only in hygienically clean surroundings.
- Pay attention to hygienically clean work processes. (Disposable gloves, protective mask, hood).
- Make sure you and your staff are aware of mycobacteria and their effects.
- Regularly check the system for microbial contamination. We recommend to test the water quality once a month, nevertheless the system is in use or stored.
- Disconnect the mains plug before starting to clean and disinfect the unit.
- For all surfaces and parts use only disinfectants based on aldehydes, ammonium components or alcohols that do not attack ABS plastic, PVC or PU. As far as possible, do not use disinfectants based on phenol derivatives because they shorten the life of plastics. Please note the list of surface disinfectants on this page 26.
- Make sure no liquid enters the unit (e.g. through the ventilation slots).
- Only switch on the device if neither the surface is wetted nor if liquid is inside the device outside the tank.
- Only use sterile water for disinfecting the device!
- Fill sterile water into the tank only with auxiliaries that have been previously disinfected.

7.1 UNIT

7.1.1 SURFACE CLEANING AND DISINFECTION

Surface

- After each water change, carry out a surface disinfection (device housing, hose set and connectors).
- If the device is contaminated by contact with body fluids, disinfect the surface and, if necessary, the watercarrying parts.
- Make sure that after surface disinfection no residues of the cleaning agent are left on the surface and the housing resp. interior of the device is dry before use.
- For disinfecting the surface of the device, please note the list of surface disinfectants on this page 26. When using the disinfectant, observe the manufacturer's instructions.
- Also clean and disinfect the screw thread of the filler neck.
- Do not switch the unit on again until the disinfectant has evaporated fully.

7 CLEANING AND DISINFECTION

Ventilation slots

Check the ventilation slots on the sides of the unit for dirt regularly, but at least every six months. Do not open the device yourself.

Dust deposits in the unit will reduce the efficiency of the system. Have any inside dirt removed by an authorized service technician.

Company	Product name	Active substance
	Isopropanol	Isopropanol (70%)
Bode Chemie GmbH	Kohrsolin™	Aldehyde
	Sterilium™	Propanol
	Bacilol Plus™	Propanol
Ecolab Healthcare GmbH	Incidin Schaum™	Propanol/Ethanol
	Incidin Spray Liquid™	Propanol/Ethanol
B.Braun Melsungen AG	Meliseptol™	Propanol
Clorox Company USA	Clorox Healthcare Bleach Germicidal Wipes™	Hypochlorid
Schülke&Mayr	Mikrozid Liquid AF	Propanol/Ethanol
Metrex	Cavi Wipes	Isopropanol/Butoxyethanol
PDI	Super Sani Cloth	Isopropanol

Maybe some of the listed products are not available in your country. Take care about the availability!

7.1.2 CHANGING WATER AND DISINFECTING THE WATER CIRCUIT

We recommend changing the water with the subsequent disinfection of the water cycle as follows in order to kill water-borne pathogens (including non-tuberculous mycobacteria) and other germs:

- After each therapy,
- As part of the initial commissioning,

- at latest 30 days after the start of therapy,
- in case of storage and / or prolonged non-use
- generally after 30 days, also with stored devices
- every 12 months as part of the safety inspection.
- Replace hose set and couplings every 12 months.

Filling the device during initial operation and recommissioning:

- Fill approximately 1 liter of sterile water, e.g. with the help of a disinfected funnel into the water tank of the device.
- Make sure that no foreign objects enter the water tank.
- Observe the water level indicator during filling. The water level should be slightly below the MAX mark after filling.
- After filling, screw the screw cap of the water filler neck back in until the screw cap seals.
- Check the microbial contamination regularly. We recommend to test the water quality once a month, nevertheless the system is in use or stored.

Emptying the device:

- Disconnect the device from the mains.
- Place a container (bucket, bowl, etc.) under the device or place it on a drain (e.g. sink).
- Unscrew the cap of the water filler neck in sterile condition.
- Drain the tank contents into the collector via the connected hoses. To do this, remove the adapter between the Hansen couplings. Make sure that the hoses are also completely emptied afterwards.

7.1.3 DISINFECTION

- Empty the system as described.
- Insert the adapter between the Hansen couplings.
- Fill the device again with the chosen H₂O₂ solution until the tank is completely filled.
- Leave the fuel cap open during the cleaning process, as overpressure may occur.
- Switch on the device and allow the disinfectant solution to circulate at 35 °C. Ventilate the hose set.
- Complete this process after a total of 30 minutes and drain the used disinfectant solution from the water circuit as described.
- Refill with sterile water
- Take the device for 5 min. in operation and then drain the water from the water cycle. Repeat this procedure several times with fresh sterile water.
- The water cycle must be flushed until a suitable detection medium (e.g. test strips „Sanosil and pH test“) no longer detects disinfectant residues.
- If the device continues to operate, recharge it with sterile water until it is slightly below the MAX mark on the level gauge.
- Stored devices must be disinfected every 30 days to prevent the formation of a biofilm.
- If a biofilm has formed, all water-bearing parts must be replaced.
- Liquids should never penetrate the inside of the device outside of water-bearing parts. medos Medizintechnik AG recommends removing devices whose internal parts have come into contact with foreign fluids from the surgical area and to disinfect them afterwards. Contaminated devices may only be used again once disinfection and maintenance have taken place.

For the disinfection of the water cycle a H₂O₂ - containing solution is recommended.

Concentration of H₂O₂ should be between 3% - 7.5%.

For a 3% H₂O₂ solution of Sanosil™ S015 mix 400 ml of Sanosil™ S015 with 600 ml of sterile water.

Sanosil™ S015 is not available in every region! Please make sure that a suitable product is approved in your region! (e.g., Amity™ 75).

8 MAINTENANCE AND SAFETY-RELATED CHECKS

8.1 MAINTENANCE

We recommend concluding a service contract with Medos Medizintechnik AG. By concluding a service contract, you will meet the requirements of the following:

- The BetrSichV (German Ordinance on Industrial Safety and Health) BGV A2 (German employers' liability association regulations) (VBG 4 [German Industrial Association Specification]) – new BGV A3,
- The Medical Devices Directive 93/42/EEC,
- and the MPBetreibV (German Medical Device Operator Ordinance),

all of which call for regular technical checks of devices. The unit must be fully serviced at least every 12 months. Servicing by our experts also guarantees the maximum operating safety and long life of the unit.

WARNING



Do not use methods for cleaning and decontamination other than those recommended by Medos Medizintechnik AG.

Check with Medos Medizintechnik AG before introducing new processes.

That is the only way to ensure that these processes will not damage the unit.

Please use the disinfection protocol as described in chapter 7.

8.1.1 UNIT

- Check the ventilation slots on the sides of the unit for dirt at least every six months. Dust deposits in the unit will reduce the efficiency of the system. Have a service technician (Xenios Customer Service) remove any dirt inside the unit.
- Do not open the unit yourself.
- Have Xenios Customer Service advise you of the servicing and safety-related check intervals.

8.1.2 HOSE COUPLINGS

The seals (O-rings) on all couplings age and become dry and brittle. Apply a thin film of silicon paste or grease (e.g. Vaseline) at least every six months.

8.2 SAFETY-RELATED CHECK

To guarantee conformity with the Medical Devices Directive 93/42/EEC (Annex 1, item 13.6.d) and the MPBetreibV (German Medical Devices Operator Ordinance) (Section 6 (1)), the unit must undergo a safety-related check every 12 months.

The operator is responsible for the performing the safety-related check properly. The MPBetreibV (Section 6 (4) 1. + 3.) states that the safety-related check can only be performed by Medos Medizintechnik AG or a qualified person. The safety-related check must include at least the following:

- Checking the unit and the operating parts for external damage, wear, aging and legibility of the displays and lettering;
- Measuring the protective conductor resistance and the earth current in accordance with the test equipment and the manufacturer's data;
- Checking all functions as per the instruction manual;
- Checking all safety functions as per the manufacturer's data;
- Checking the sensors as per the manufacturer's data (Medos Medizintechnik AG provides a service

manual for authorized persons).



To ensure conformity with the legal safety guidelines, we recommend concluding a safety-related check contract with Medos Medizintechnik AG. We will then carry out the annual safety-related check.

In the case of very dirty units or accessories sent for servicing where there is the suspicion of contamination, we reserve the right to refuse these for safety reasons or to subject them to a technical examination or damage analysis after discussing this additional process. Any additional costs incurred shall be borne by the customer.

9 REPAIRS

WARNING



- Repairs to electrical equipment may only be performed by specialists trained by the manufacturer.
- Improper repairs can result in considerable risks for the user and damage to the unit.



The opening of the unit by unauthorized persons will void warranty and guarantee claims

9.1 CAUSES OF FAULTS AND ACTIONS TO TAKE

Fault	Possible causes	Actions to take
No or low water circulation	<ol style="list-style-type: none"> 1. Hoses kinked 2. Couplings not firmly connected 3. Unit is positioned much lower than the oxygenator 4. Pump worn/defective 5. Air in system 	<ol style="list-style-type: none"> 1. Ensure correct routing and positioning 2. Insert couplings firmly into each other 3. Position the unit higher or the oxygenator lower 4. Customer Service* 5. Remove air from system
Couplings stiff	O-ring dry and brittle	Lubricate O-ring, e.g. with silicone paste or Vaseline
Coupling connection drips constantly	Outer, visible O-ring damaged or missing	Replace O-ring*
Valve on unconnected coupling drips constantly	<ol style="list-style-type: none"> 1. Inner O-ring damaged 2. Inner O-ring dirty 	<ol style="list-style-type: none"> 1. Customer Service* 2. Insert and remove coupling several times or contact Customer Service
Alarm + display message: “ALARM TEST FAILED” “-> CUSTOMER SERVICE”	<ol style="list-style-type: none"> 1. Separate protective devices defective 2. Pump has electrical fault 	Customer Service*
Alarm + display message: “TEMP.DIFF .>1 °C”	<ol style="list-style-type: none"> 1. Oxygenator is connected or disconnected during operation 2. Cooling output insufficient 3. Cooling elements or pump faulty 4. Bypass interrupted 	<ol style="list-style-type: none"> 1. Cancel alarm using “Alarm off” button 2. See next fault 3. Customer Service* 4. Customer Service*
Target cooling value not achieved	Cooling output insufficient because: <ol style="list-style-type: none"> 1. Ambient temperature too high and/or 2. Target value too low 	Both of these causes have negative effects on the other, so at least one cause must be eliminated.
Alarm + display message: “WATER LEVEL!?” Cancel alarm for 10 minutes using “Alarm off” button	<ol style="list-style-type: none"> 1. Water level too low 2. Unit is not horizontal 3. Sensor variation 	<ol style="list-style-type: none"> 1. Top up water 2. Make sure unit is horizontal 3. Customer Service*

*Switch off the unit immediately

Fault	Possible causes	Actions to take
Alarm + display message: “CHECK UNIT” “-> CUSTOMER SERVICE”	<ol style="list-style-type: none"> 1. Water tank empty 2. Sensor T1 broken/closed 3. Various faults 	<ol style="list-style-type: none"> 1. Top up water* 2. Customer Service* 3. Customer Service*
Alarm + display message: “CHECK UNIT” “LOW TEMPERATURE”	<ol style="list-style-type: none"> 1. Unit too cold (< 9 °C) 2. Sensor T2 broken 3. Water tank frozen 	<ol style="list-style-type: none"> 1. Allow unit to warm up for a while at room temperature* 2. Customer Service* 3. Allow unit to defrost*; check unit for frost damage (is water running out of the unit?) → Customer Service
Unit completely inoperative and extra audible alarm	<ol style="list-style-type: none"> 1. Power failure 2. Mains plug not making contact 3. Faulty fuse 4. Faulty unit 	<ol style="list-style-type: none"> 1. Switch off unit until power is reinstated 2. Check plug is seated correctly in socket 3. Customer Service* 4. Customer Service*

*Switch off the unit immediately

10 DISPOSAL OF THE OLD UNIT



Old electrical and electronic equipment contains a number of valuable materials. It also contains hazardous materials needed for its operation and safety.

If handled incorrectly in residual waste, these pose a risk to human health and the environment. This unit must not be disposed of with general industrial or domestic waste.



In accordance with product responsibility as per Section 22 of the Kreislaufwirtschafts- und Abfallgesetz (German Closed Substance Cycle and Waste Management Act) and the Elektro- und Elektronikgesetz (German Electrical and Electronic Equipment Act) Section 2(1), no. 8, this unit must be taken to an appropriate communal collection point or returned to the manufacturer.

11 TECHNICAL DATA AND ACCESSORIES

11 TECHNICAL DATA AND ACCESSORIES

11.1 TECHNICAL DATA AND ACCESSORIES – DELTASTREAM HC

Item no. (REF)	ME DPHC 0001; ME DPHC 0002
Rated voltage	230 VAC, 50/60 Hz – 115 VAC, 50/60 Hz – 220 VAC, 50/60 Hz
Power consumption	320 W max.
Current draw	Approx. 1.5 A (220/230 V) - 3 A (115 V)
Target value range	15 °C - 39 °C
Safety cut-off	42.1 °C - 42.5 °C
Measurement range	Approx. 9 °C - 50 °C
Measurement variation	≤ ±0.1 °C (water temperature gage)
Correction value	0.5 °C (water temperature temperature gage)
Sensor element	2 × NTC 5K
Pump output	Max. 5.5 l/min., max. 0.15 bar
Heat output	Approx. 750 W max. (at 27 °C)
Cold output	Approx. 500 W max. (at 27 °C)
Heat-up time	Approx. 5-10 min. (20 °C - 37 °C)
Cool-down time	Approx. 5-10 min. (20 °C - 15 °C)
Fuse rating	2 × T 3, 15 L 250 V (220/230 V); 2 × T 5A, L 250 V (115 V)
Protection class/type	I, BF
IP rating	IPX1 (drip-proof)
Risk class (93/42/EEC)	II b
Ambient temperature	10 °C - 40 °C
Relative humidity	Approx. 30 - 70%
Storage temperature	10 °C - 40 °C
Tank contents	Approx. 0.5 l/1.0 l (MIN/MAX)
Permitted height difference	Max. 0.75 m (unit/oxygenator)
Dimensions W×H×D	Approx. 200 × 290 × 440 mm
Weight	Approx. 17 kg (filled)
Noise level	Approx. 45 dB(A) (1 m)
Alarm level	> 55 dB(A) (3 m)
Test basics	Medical Device Directive 93/42/EEC, EN 60601-1, EN 60601-1-2, 80601-2-35

Subject to technical modifications.

The level of electrical protection for parts in use corresponds to TYPE BF.

11.2 ACCESSORIES

Item	Item no
Water connection adapter with Hansen nipple, m/m hilite 7000 (exp.)	ME ZW02 0002
Water connection adapter with Hansen nipple, m/m hilite child and newborn oxygenator	ME ZW05 0002
Water connection adapter for hollow fiber oxygenator hilite 7000 (exp.); hose nozzle, HC 90° coupling	ME ZW02 0008
Water connection adapter for hollow fiber oxygenator hilite 7000 (exp.), metal nozzle 1/4", straight	ME ZW02 0010
Water connection for hollow fiber oxygenator hilite 2800, 2400 LT, 1000, 800 LT (children and newborns), HC coupling	ME ZW05 0009
Water connection for hollow fiber oxygenator hilite 2800, 2400 LT, 1000, 800 LT (children and newborns), HC 90° coupling	ME ZW05 0010
Water connection for hollow fiber oxygenator hilite 2800, 2400 LT, 1000, 800 LT (children and newborns), metal nozzle, 1/4", straight	ME ZW05 0011
Disinfectant	ME DPHC 0014
pH litmus paper	ME DPHC 0005
deltastream Trolley	ME DP 100321

We recommend the use of oxygenators from the Medos hilite series. The deltastream heater cooler can be used with the deltastream Trolley available as an accessory.

Additional information on Medos hilite oxygenators and deltastream Trolley can be found in the relevant brochures and price lists.

12 GUIDELINES AND MANUFACTURER'S DECLARATION

Guidelines and manufacturer's declaration – electromagnetic interference

The deltastream heater cooler is designed for operation in an electromagnetic environment as described below. The customer or user of the deltastream heater cooler should ensure that it is operated in this type of environment.

Interference measurements	Compliance	Electromagnetic environment guidelines
HF emissions as per CISPR11	Group 1	The deltastream heater cooler units use HF power exclusively for their internal functions. Its HF emissions are therefore very low, and are unlikely to affect nearby electronic equipment.
HF emissions as per CISPR11	Class B	The deltastream heater cooler units are suitable for use in places other than living areas and such like that are directly connected to the public supply mains that also supply buildings used for residential purposes.
Emission of harmonics as per IEC 61000-3-2	Class A	
Emission of surges/flickers as per IEC 61000-3-3	Not applicable	

Guidelines and manufacturer's declaration – electromagnetic interference immunity


The units of the deltastream heater cooler are intended for operation in the electromagnetic environment described below. The customer or user of the units should ensure that they are used in such an environment.

Interference immunity testing	IEC 60601 test level	Compliance level	Electromagnetic environment guidelines
Static electricity discharge as per IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Flooring should be made of wood or concrete or covered in ceramic tiles. If the floor is covered in synthetic material, the relative humidity must be at least 30%.
Quick, transient electrical disturbances/bursts as per IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables	The quality of the supply voltage should be suitable for a typical commercial or hospital environment.
Surges as per IEC 61000-4-5	±1 kV external conductor - external conductor ±2 kV external conductor - earth	±1 kV ±2 kV	The quality of the supply voltage should be suitable for a typical commercial or hospital environment.
Voltage dips, short interruptions and variations in the supply voltage as per IEC 61000-4-11	<5% UT (> 95% dip in UT) for 1/2 period 40% UT (60% dip in UT) for 5 periods 70% UT (60% dip in UT) for 25 periods <5% UT (> 95% dip in UT) for 5 seconds	<5% UT (> 95% dip in UT) for 1/2 period 40% UT (60% dip in UT) for 5 periods 70% UT (60% dip in UT) for 25 periods <5% UT (> 95% dip in UT) for 5 seconds	The quality of the supply voltage should be suitable for a typical commercial or hospital environment. If the user of the unit requires advanced functions even when power supply interruptions occur, it is recommended to supply the unit from an uninterruptible power supply or a battery.
Magnetic field and supply frequency (50/60 Hz) as per IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequencies should correspond to the typical values found in commercial and hospital environments.

NOTE: UT is the mains AC voltage before applying the test level.

Guidelines and manufacturer's declaration – electromagnetic interference immunity

The deltastream heater cooler is designed for operation in an electromagnetic environment as described below. The customer or user of the deltastream heater cooler should ensure that it is operated in this type of environment.

Interference immunity testing	IEC 60601 test level	Compliance level	Electromagnetic environment guidelines
<p>HF conducted disturbances as per IEC 61000-4-6</p> <p>HF radiated disturbances as per IEC 61000-4-3</p>	<p>$3 V_{\text{eff}}$ 150 kHz to 80 MHz</p> <p>$3 V_{\text{eff}}$ 80 MHz to 2,5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile telecommunications equipment should not be used at a closer distance from the unit, including the cable, than the recommended safety distance calculated using the equation that applies to the transmission frequency.</p> <p>Recommended safe distance:</p> <p>$d = 1.17 \sqrt{P}$</p> <p>$d = 1.17 \sqrt{P}$ for 80 MHz to 800 MHz</p> <p>$d = 2.33 \sqrt{P}$ for 800 MHz to 2.5 GHz</p> <p>with P as the maximum rated output of the transmitter in watts (W) as per the transmitter manufacturer's data and d as the recommended safe distance in meters (m).</p> <p>The field strength of stationary radio transmitters should at all frequencies be a) less than the compliance level as per a test performed on site, and b) no interference should be possible in the vicinity of devices that display the following sign.</p> 
Note 1	The higher frequency range applies to 80 MHz and 800 MHz.		
Note 2	These guidelines may not apply in all cases. The spread of electromagnetism is influenced by the absorption and reflection of buildings, objects and people.		

- The field strength of stationary transmitters such as base stations of mobile phones and land mobile radios, amateur radio stations, AM and FM radio and TV transmitters cannot be precisely predetermined in theory. A study of the location should be considered in order to determine the electromagnetic environment with regard to the stationary transmitters. If the measured field strength at the location where the unit is being used exceeds the aforementioned conformity level, the unit should be observed in order to verify proper functioning. If unusual performance characteristics are observed, additional measures may be necessary such as a different alignment or a different location for the unit.
- The field strength should be less than 3 V/m above a frequency range of 150 kHz to 80 MHz.

Recommended safe distances between portable and mobile HF telecommunications devices and the deltastream heater cooler

The deltastream heater cooler is intended for operation in electromagnetic environments where HF interference is controlled. The customer or user of the deltastream heater cooler can therefore help to prevent electromagnetic interference if they maintain the minimum distance between portable and mobile HF telecommunications equipment (transmitters) and the unit depending on the power output of the communication device, as shown below.

Rated output of transmitter [W]	Safe distance as a factor of transmission frequency in m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.17 \sqrt{P}$	$d = 1.17 \sqrt{P}$	$d = 2.33 \sqrt{P}$
0.01	0.12 m	0.12 m	0.24 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.34 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.34 m

In the case of transmitters whose maximum rated output is not given in the table above, the distance can be determined using the equation for each column, where P is the maximum rated output of the transmitter in watts (W) in accordance with the data from the transmitter manufacturer.

Note 1	The higher frequency range applies to 80 MHz and 800 MHz.
Note 2	These guidelines may not apply in all cases. The spread of electromagnetism is influenced by the absorption by and reflection of buildings, objects and people.

13 QUICK GUIDE

- Connect unit to mains.
- Connect oxygenator to unit.
- Check water level in unit.
- Main Switch (8) on unit using mains switch (0/I) and watch automatic function test.
- If target temperature value on start-up is $< 35^{\circ}\text{C}$ or $> 38^{\circ}\text{C}$, an alarm will sound. Cancel and start by pressing the Confirm button.



- Set temperature using arrow keys.



- Press and hold Confirm key for temperatures above 38°C while pressing arrow keys at the same time.



- Press and hold Confirm key for temperatures below 35°C while pressing arrow keys at the same time.

- Continuously monitor patient's body temperature.
- Monitor water level and water flow through the unit.



- In continuous operation, run the function test manually once a day using the "Function test" button.



- Low-priority audible alarms can be canceled using the "Alarm off" button.

- High-priority alarms cannot be canceled. Switch the unit off at the mains switch.

WARNING



The quick guide does not absolve the user of the need to follow the full instruction manual.



The unit switches all functions off in the case of high-priority alarms. Take it out of service and hand it over to a service technician to perform checks and restore operating safety.

CAUTION



There is a risk that the patient's blood could be heated or cooled excessively.

Monitor the patient's body temperature if the unit is used on the patient with a oxygenator.

WARNING



Do not operate the unit if:

- The display has failed;
- Individual segments of the temperature display have failed (temperature can no longer be read clearly);
- The red fault indicator (4) stays on or does not come on at all (function test);
- The beep continues to sound or does not sound at all (function test);
- The unit does not respond when buttons are pressed;
- When the unit is switched on or during the function test, the unit does not react as described in the instruction manual (see "6.2.2 Function test" on page 19).



24/7 Xenios Clinical Support +49 7131 2706 345

www.xenios-ag.com

Manufacturer



medos Medizintechnik AG

✉ Obere Steinfurt 8-10
52222 Stolberg
GERMANY

☎ +49 7131 2706-300
☎ +49 7131 2706-498
@ www.xenios-ag.com
info@xenios-ag.com

Distributor

Xenios AG

✉ Im Zukunftspark 1
74076 Heilbronn
GERMANY

☎ +49 7131 2706-0
☎ +49 7131 2706-299
@ www.xenios-ag.com
info@xenios-ag.com