

# ECMOLIFE HC

## Heater-cooler Unit for Extracorporeal Circulation



### INSTRUCTIONS FOR USE





This medical device bears the CE marking.

### Publication date

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### Validity of the present document

The present document, EU10815 Rev. 01, is valid for the ECMOLIFE HC equipment ref. EU3941 with SW release version 2.1 or higher.

### Manufacturer



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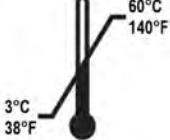
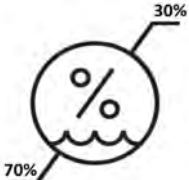
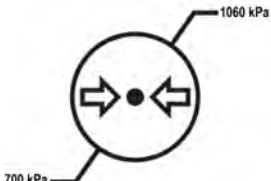




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## 1 Markings and symbols

Symbol	Explanation
	Catalogue number (code number)
	Serial number
	Manufacturer
	Date of manufacture
	Temperature limit 3°C(38°F)-60°C (140°C)
	Humidity limitation 30-70%
	Atmospheric pressure limitation 700-1060 hPa
	Keep away from sunlight
	Keep dry
	This way up
	Fragile, handle with care

Symbol	Explanation
	Do not use if package is damaged
	Refer to instruction manual
	Caution
	Separate collection of electrical and electronic equipment
	Medical Device
	Defibrillation-proof type BF applied part
	Planned preventive maintenance date (month/year).
	On/Off (Press/press)
	Audible alarm temporarily silenced

## 2 General information

Read the information provided here so that you can become familiar with the ECMOLIFE HC and use its functions to their full extent.

## 2.1 Information regarding these instructions

These operating instructions are part of the ECMOLIFE HC (hereinafter referred to as unit) and provide important information for the commissioning, safety, proper use and maintenance of the unit.

All figures and drawings in these operating instructions are for general illustration purposes and are not definitive for the details of their construction.

The operating instructions must always be available, preferably in the vicinity of the unit. They must be read and applied by all persons who are responsible for the:

- commissioning,
- operation,
- cleaning,
- maintenance,
- troubleshooting

of the unit.

## 2.2 Warnings

The following warning notes are used in these operating instructions:



### Warning

Indicates possibility of injury, death, or other serious adverse reaction associated with the use or misuse of the device.



### Caution

Indicates possibility of problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property.



### Note

Highlights additional information to assist in working with the unit.

## 2.3 Limitation of liability

The manufacturer accepts no responsibility for personal injuries and property damage in the event of:

- failure to comply with the operating instructions;
- unintended use;
- unprofessional repairs;



- technical modifications;
- use of non-approved spare parts and accessories;
- unauthorized conversions and changes.

## 2.4 Manufacturer Contact Details

For questions on the service, maintenance or safety check, please directly contact Eurosets S.r.l.

**Eurosets S.r.l.**

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## 3 Intended use

The heater-cooler unit ECMOLIFE HC is intended for cooling or heating water circulating through the heat exchanger during ECC procedures.

The unit must only be operated with its accessories.

## 4 Personnell requirements



### Note

- Work on/with the unit must only be carried out by persons who are authorized for this work because of their education and qualification. Apart from this these persons must also be entrusted with this work by the operator.
- Allow personnel to be trained, instructed, directed or undergoing general training to only work on or with the unit under the supervision of an experienced person.
- Dangers may arise from the unit if it is improperly used by untrained personnel.
- All generally valid legal and otherwise binding regulations for the avoidance of accidents and the protection of the environment, as well as general health and safety requirements must be observed in addition to the operating instructions. The operator must instruct his personnel accordingly.

- To ensure patient safety, the unit should be monitored continuously during operation.

## 5 Indications for use

The heater-cooler unit ECMOLIFE HC is indicated for circulating water through a heat exchanger to warm or cool a patient during extracorporeal circulation.

## 6 Clinical performances

The heater-cooler unit ECMOLIFE HC features a water circuit with temperature regulation.

## 7 Contraindications

When the heater-cooler unit ECMOLIFE HC is used by specially trained personnel under the supervision of a physician and in compliance with the intended use, no contradictions are to be expected.

Danger may arise from the unit if it is put to unintended use and/or if it is used for any other purposes.

## 8 Risks and side effects



### Warning

- Any serious incident occurring in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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 heat exchanger on the patient.

Uncontrolled hypo/hyperthermia associates the patient with increased mortality.

If the core body temperature falls below 32°C, there is a risk of life-threatening complications such as cardiac arrhythmias, metabolic disturbances and cardiac arrest.

### 8.1 Hypothermia

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

- Autonomous reactions (incl. shivering),

- Cardiac arrhythmias,
- Lower heart rate,
- Fluid/electrolytes/acid-base imbalance,
- Hyperglycemia,
- Reduced coagulation activity, increased bleeding,
- Reduced oxygen intake,
- Depressed drug metabolism, reduced elimination of sedatives and muscle relaxants,
- Changed solubility of blood gases/narcosis,
- Lower anesthesia requirements.

Some disadvantages of therapeutic hypothermia include:

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

with increased degree and duration of organ damage and tendency to bleed.

After hypothermia treatment, the patient should be warmed up again at no more than 0.25°C - 0.5°C per hour. Warming up too quickly also causes arrhythmias and ventricular fibrillation with subsequent risks.

## 8.2 Hyperthermia

There is general acceptance that blood temperature does not exceed 38,5°C.

Blood temperatures over 42°C have been associated with hemolysis and protein denaturation.

Hyperthermia can lead to:

- Brain injury,
- Increased heart rate,
- Increased cardiac output,
- Fluid/electrolytes/acid-base imbalance,
- Hyperglycemia,
- Blood cell damage, hemolysis,
- Liver/kidney damage,
- Pulmonary hypertension.



### Warning

Any serious incident occurring in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## 8.3 Contamination



### Warning

#### **Nontuberculous Mycobacteria Infections Associated with Heater-Cooler Devices**

There is the potential for NTM bacteria to grow in the water tank in the heater-cooler unit. Although the water in the heater-cooler unit does not come into direct contact with the patient, there is the potential for contaminated water to enter other parts of the device and contaminate the environment.

For this reason, ECMOLIFE HC water tank is air-tight and to further mitigate the risk of contamination, all operations of water filling and hoses connection shall be performed in a dedicated area different from Operating Room or Intensive Care Unit, in an aseptic manner using sterile water or water that has been filtered with a sterilizing filter with pore size  $\leq 0.22 \mu\text{m}$ .

In addition, periodic hygienic vigilance through microbiological monitoring of water shall be performed, followed by adequate cleaning and disinfection, as per this user manual procedures (chapter 15).

If failing to observe directions on periodic hygienic vigilance through microbiological monitoring together with setting up and cleaning/disinfection procedures, the risk of environment and patient contamination remains.

## 9 General Safety Information



### Warnings

Observe the following general safety information for safe handling of the unit:

- Ensure that the unit (power supply cable, housing, couplings, etc.) are in good condition before commissioning.
- Make sure there are no kinks in the hoses to the heat exchanger.
- Check that the hoses are connected correctly to the heat exchanger.
- Lay hoses without creases and buckling.
- Do not touch hoses with pointed or sharp objects.
- Fill the unit tank only with sterile water or water that has been filtered with a sterilizing filter with pore size  $\leq 0.22 \mu\text{m}$ , with a water hardness of  $\leq 14 \text{ }^\circ\text{dH}$  ( $2.5 \text{ mmol/l CaCO}_3$ ).
- Do not use deionized water.
- Operate the unit only after the tank has been closed with the screw cap.
- Stand the unit horizontally, inclination of the support area  $\leq 3\%$ .
- The height difference between the unit and heat exchanger/oxygenator must be  $< 1 \text{ m}$ .
- Do not cover the unit, there are ventilation openings at the sides, underneath and at the rear.
- Observe the automatic functional test when switching on the unit.
- If the unit is in continuous operation perform the automatic functional test manually at least once a day.
- During operation check the water flow and the water level at regular intervals.
- Operate the unit only with an appropriate water level (see MIN mark).
- Keep to ambient temperature range ( $10\text{-}30^\circ\text{C}$ ) during heating operation, ( $10\text{-}23^\circ\text{C}$ ) during cooling operation.
- Observe storage temperature range ( $3\text{-}60^\circ\text{C}$ ).
- Operate the unit with original accessories.
- Do not operate the unit in an oxygen-enriched environment or in the presence of combustible gases.
- Do not use the unit with other patient heating sources.
- Do not operate the unit in the vicinity of heat sources (light beams, direct sunlight, radiators/radiant heaters, etc.).
- Medical Electrical Equipment needs special precautions regarding EMC and must be installed and put into operation according to EMC information, contained in the accompanying documents.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

- Electrostatic discharges (ESDs) main cause malfunction of front panel display, not affecting the essential performances of the device; in case of permanent failure of the display contact Eurosets S.r.l. authorized Technical Service engineer.
- Perform maintenance and safety checks in accordance with these operating instructions.
- Allow only authorized personnel to operate the unit.
- The patient's body temperature must be continuously monitored separately from the system.

## 10 ECMOLIFE HC system components, accessories and spare parts

ECMOLIFE HC Ref. EU3941 is composed by:

Heater-cooler unit  
with EU Power supply cable



UK Power supply cable



**Hoses 1.5 m**

Heat  
Exchanger  
side

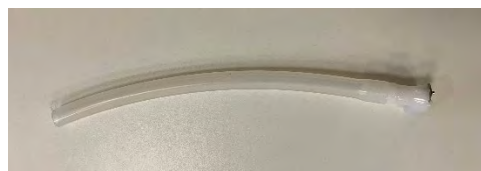


Heater-  
cooler  
side

**Hansen connection tube**



**Water discharge hose female**



## 10.1 ECMOLIFE HC accessories

ECMOLIFE HC accessories are listed below:

**Hoses 3 m**  
[Ref. EU3943]



## 10.2 ECMOLIFE HC spare parts

ECMOLIFE HC spare parts are listed below:

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Hoses 1.5 m  
[Ref. EU3944/SP]



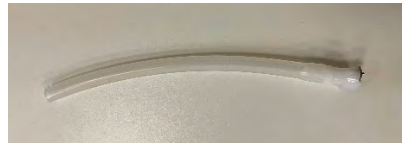
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Hansen connection tube  
[Ref. EU3945/SP]



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Water discharge hose  
[Ref. EU3949/SP]



---

EU Power supply cable  
[Ref. EU3946/SP]



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UK Power supply cable  
[Ref. EU3947/SP]





### **10.3 Eurosets medical devices for use with ECMOLIFE HC**

The heater-cooler unit ECMOLIFE HC is intended to operate in combination with Eurosets heat exchangers / oxygenators integrated with heat exchanger featuring water inlet and outlet ports suitable for connection with ECMOLIFE HC hoses Hansen-quick couplings 1/2" (12.7 mm).

Heat exchanger shall be compatible with the device which feature a max water flow rate of 5.5 l/min and a max. pressure of 0.21 bar. In addition, the user shall evaluate heat exchanger performance factor (R) claimed by the heat exchanger manufacturer, to ensure its compatibility in terms of performances vs. heater-cooler performances (i.e. flow rate, pressure, output temperature).

### **10.4 LEONARDO trolley**

This is an accessory manufactured by Eurosets that makes the stationary device mobile.

## 11 Function and design

### 11.1 Views of the unit

#### 11.1.1 Front panel, control and display elements

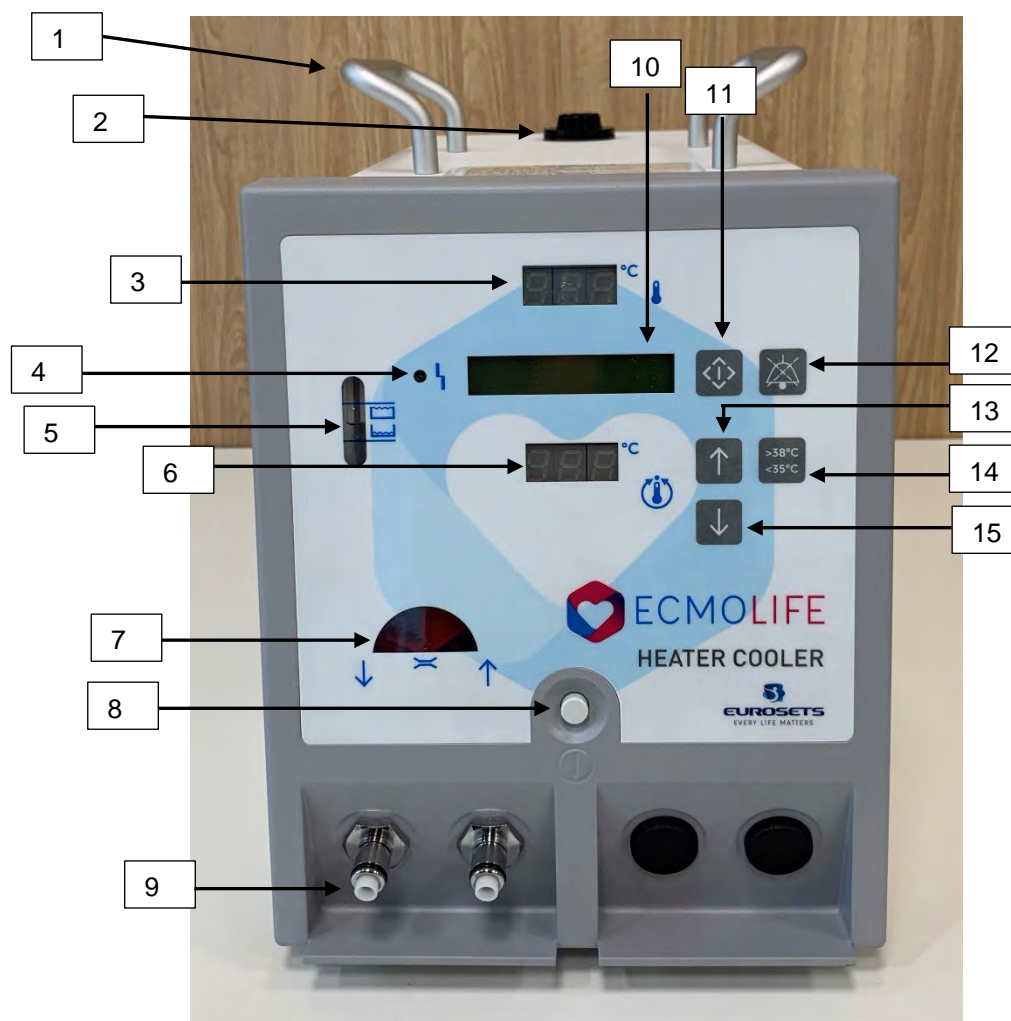


Figure 7 - Front View

The front panel of the ECMOLIFE HC is composed by:

- 1) Handles;
- 2) Water filling socket with screw cap;
- 3) Temperature display for actual value;
- 4) Fault lamp;

- 5) Water level indicator;
- 6) Temperature display for nominal value;
- 7) Water flow rate indicator;
- 8) Mains switch;
- 9) Couplings
- 10) Display for status and error messages;
- 11) Functional test;
- 12) Audio paused;
- 13) Increase nominal value;
- 14) Release key <35°C / >38°C;
- 15) Decrease nominal value.

### 11.1.2 Top, side and rear panel

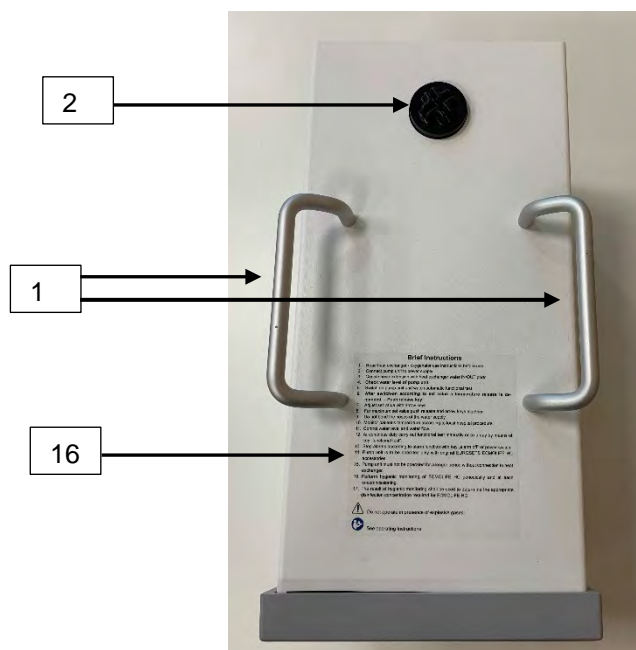


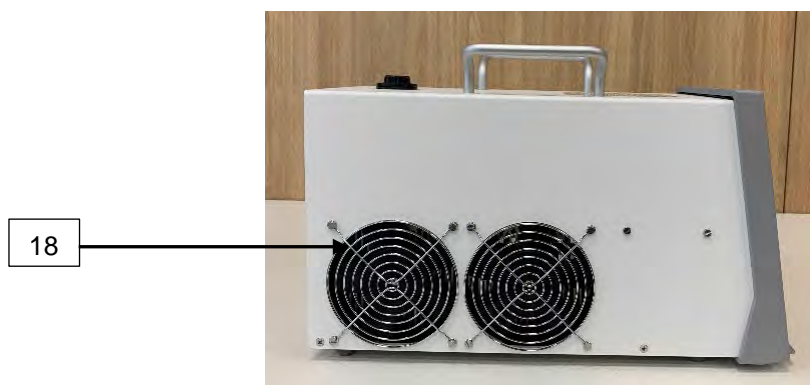
Figure 8 - Top view

The ECMOLIFE HC top features

- 1) Handles;
- 2) Water filling socket with screw cap;
- 16) Brief instructions for use.



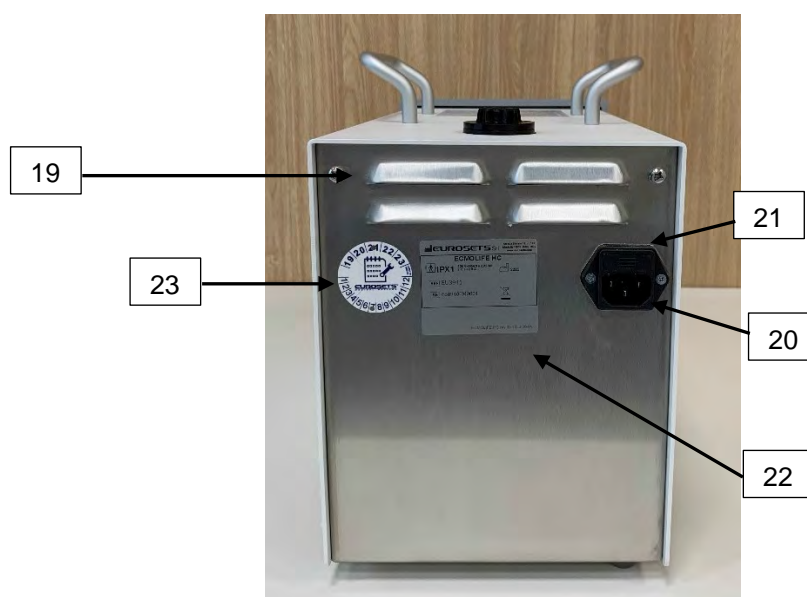
**Figure 9 - Right side view**



**Figure 10 - Left side view**

The right and left side panels of the ECMOLIFE HC are composed by:

- 17) air exhaust ventilation openings;
- 18) air inlet fans.



**Figure 11 - rear side view**

The rear panel of the ECMOLIFE HC is composed by:

- 19) ventilation openings;
- 20) mains socket;
- 21) microfuses;
- 22) Eurosets type plate;
- 23) Reminder for planned preventive maintenance date (month/year).

### 11.1.3 Sensors

ECMOLIFE HC heater-cooler unit has integrated sensors to monitor:

- the water level in the unit,
- whether the water temperature in the circuit corresponds with the set nominal value,
- whether power supply voltage is applied,
- whether the function is safe and
- emits alarms in case of malfunction (see chapter 14.3 “Alarms”).



#### Warning

**The unit has no monitoring function for measuring of the patient.**

- Monitoring core temperature of the patient to be treated must be carried out regularly independently of the application system.
- The temperature settings of the transition temperatures on the heat exchanger must be manually entered in the system by the user and the individual course of temperature conditioning should be corrected or adjusted accordingly.
- **The system should only be used/put into operations by users who are qualified in its intended use!**

## 11.2 Type plate

The type plate with the connection and performance data is located on the rear side of the unit.



## 11.3 Function Principles

The heater-cooler unit ECMOLIFE HC features a water circuit with temperature regulation.

ECMOLIFE HC water circuit interfaces with an extracorporeal perfusion heat exchanger.

The temperature conductance between patient and water circulating into ECMOLIFE HC is achieved by water surface contact with the heat exchanger water pathway, transmitting temperature to the blood pathway through a conductive septum physically and fluid-tightly separating the two pathways.

Thanks to its high heat capacity and heat conductivity, water is an ideal transmission medium for this type of application.

The water is cooled or heated in a water tank inside the unit by means of thermo-electrical elements and continuously pumped through the interfaced heat exchanger by a centrifugal pump allowing the water to go out from the unit and then coming back in.

The unit covers a wide range of temperatures that goes from 15°C to 39°C.

ECMOLIFE HC incorporates an automatic functional test together with water and temperature alarms with status displays to optimize operational safety and reliability.

The temperature at the heat exchanger will never exceed 40°C to prevent the risk of hyperthermia. At water temperature of more than 41°C, the ECMOLIFE HC switches off electronically and electrically to minimize the risk in case of an equipment fault when warming.

Temperatures at heat exchanger of <35°C and >38°C must be consciously set by the user and closely monitored.

In this way, the risk of local temperature accumulation is virtually ruled out, while ensuring compliance with the requirements concerning the place of installation.



### Warning

**Danger from overestimating/underestimating the performance of the system!**

- Dangers may arise from the unit if it is put to unintended use, and if desired temperatures under given conditions are not achieved.
- The reliable use of the system requires the user to carry out a careful risk assessment and continuous monitoring of the patient.

## 12 Transport and setup

### 12.1 Delivery contents and transport inspection

The delivery contents of ECMOLIFE HC include:

- ECMOLIFE HC heater-cooler unit,
- Power supply cable,
- Hoses 1.5 meters,
- Hansen connection tube,
- Water discharge hose,
- Operating instructions.



#### Note

- Check the delivery for completeness and visible damage.
- Immediately report an incomplete delivery or damage caused by inappropriate packaging or transport to the forwarding agent, the insurance company and the supplier.

## 12.2 Unpacking



#### Warning

##### **Personal and material damage may occur when unpacking the unit!**

Observe the following safety information to prevent hazards:

- The weight of the unit is approx. 17 kg.
- The unit shall be transported, unpacked and installed by two people.

To unpack the device:

- Take the unit out of its box and remove the packaging material.
- Stand the unit on an even and horizontal base with sufficient load bearing capacity.




#### Caution

##### **Condensation in the unit may cause it to fail.**

- After unpacking, the unit must be acclimatized for at least two hours before commissioning when there are temperature differences of more than 8°C of the intended environmental operating temperature.

## 12.3 Waste disposal of packaging material

The packaging protects the unit from transport damage. The packaging materials are selected on the basis of environmentally friendly and disposal related factors and are

therefore recyclable. 



Feeding the packaging back into the material cycle save raw materials and decreases generated waste. Dispose of packaging materials that are no longer required at the collection points for the recycling system.



#### Note

- If possible, keep the original packaging throughout the unit's lifetime, so as to be able to repack the unit properly in case of repair.

## 13 Commissioning

This chapter contains important information for commissioning the unit. Please follow these notes to avoid dangers and damages.



#### Warning

**Personal and material damage may occur when commissioning the unit!**

Observe the following safety information to prevent hazards:

- The weight of the unit is approx. 17 kg.
- The unit shall be transported, unpacked and installed by two people.
- Avoid using the device directly beside or stacked with other devices.

### 13.1 Setting up



#### Warning

**Before setting up the ECMOLIFE HC clean and disinfect it thoroughly! First proceed with Intermediate level Disinfection referring to chapter 15.1.2 "Intermediate level Disinfection process" followed by cleaning and disinfection of the external surfaces referring to chapter 15.2 "Cleaning and Disinfecting the surfaces".**

#### 13.1.1 Requirements concerning the place of installation

For safe and fault-free operation of the unit the set up place must:

- have sufficient load-bearing capacity (unit weight approx. 17 kg);
- be even;
- be horizontal (inclination  $\leq 3\%$ );
- provide 20 cm space to either side of the unit and behind;
- ensure sufficient ventilation of the device on all sides;



- be located no more than 1 m below or above the heat exchanger;
- be free from devices with strong magnetic fields in the vicinity.

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



#### Note

The Leonardo trolley, which is available as an accessory, meets all these requirements.

- If the unit is not horizontal, the water level indicator (5) in the front of the unit will indicate the water level incorrectly.
- If the unit is well below the level of the heat exchanger, water can flow back from the heat exchanger into the unit and cause the tank to overflow when the water filling socket (2) is opened with the unit switched off.

For optimal operation of the unit, the place of installation should meet

- The following environmental conditions:
  - ambient temperature:  $20^{\circ}\text{C} \pm 3^{\circ}\text{C}$
  - relative air humidity:  $50\% \pm 20\%$
  - air pressure: 700 hPa to 1060 hPa

### 13.1.2 Setting up with LEONARDO trolley

By means of the Leonardo trolley, which is available as an accessory for the ECMOLIFE console, the ECMOLIFE HC heater cooler, designed as a standing unit, can be used also as a mobile unit.

Set up the unit with the Leonardo trolley as follows:

Assemble the Leonardo trolley as described in its instructions for use.

Place the ECMOLIFE HC heater cooler on the dedicated lower shelf as per figure 12. The unit shall be aligned inside the shaped plate borders.



Figure 12 - ECMOLIFE HC heater cooler placed on Leonardo dedicated shelf



#### Caution

Personal and material damage may occur when installing and using the Leonardo trolley with the unit!

- To assemble the trolley, observe the safety information in the assembly and operating instructions of the trolley!
- Do not use aggressive detergents; the trolley is not suitable for use in washing systems!
- The trolley should be checked for full functionality of all parts according to its operating instructions.
- If a fault is detected, only original spare parts may be used and only replaced by a Eurosets S.r.l. authorized Technical Service engineer.

## 13.2 Connecting ECMOLIFE HC



#### Warning

Danger caused by water in connection with electricity

- Connect the unit to the power supply only after it has been filled with water.

- Water can conduct electricity. If water has been spilled when filling the unit, the unit must be thoroughly dried and should only be connected to the power supply and switched on after it has completely dried out.



**Note**

The system is a closed circuit and the water line should not be disconnected in the Operating room or the Intensive Care Unit. Ensure that the connection of the hose to the heat exchanger has already taken place before the system is placed in the Operating room or Intensive Care Unit.

### 13.2.1 Filling the system with water



**Warning**

**Danger caused by water in connection with electricity**

Water is electrically conductive.

- If water has been spilled when filling the unit, the unit must first be thoroughly dried and should only be connected to the power supply and switched on after it has completely dried.

Perform the operations below in a suitable environment, using protective means (mask, gloves, clothes) to avoid contamination.

Unscrew the cap from the water filling socket (2), without contaminating the interior of the unit. Wear gloves when doing so.



Figures 13a and 13b - cap unscrewing

Take care not to lose the sealing ring of the cap.

Fill approximately 1 liter of sterile water with the help of a disinfected funnel into the water tank.



Figure 14 - procedure for filling the system with water



#### Warning

#### Water quality

- Do not use unfiltered and unsterilized main water!
- Water shall have a hardness of  $\leq 14$  °dH (2.5 mmol/l  $\text{CaCO}_3$ ) and must be sterile or filtered with a sterile filter with pore size  $\leq 0.22$   $\mu\text{m}$ .

Make sure that no foreign material enters the water tank (i.e. using a sieve).

Watch the water level indicator (5) while filling. After filling the water level should be slightly below the MAX-mark.

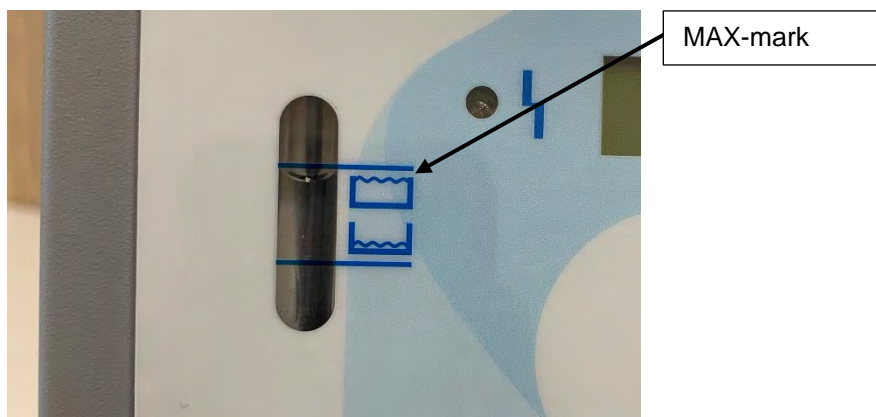


Figure 15 - water level indicator with water just below the MAX mark

Thoroughly disinfect with spray disinfectant (Chloramine-T or Sanosil S003 or Gioclorex 2% or chemically equivalent disinfectant) the water filling socket (2) and the internal part of the cap.



#### Warning

- Chloramine-T solution leaves residuals on the device surfaces. When performing disinfection using Chloramine-T solution, after disinfection a thorough rinsing shall be performed to efficiently remove all chemical residuals from the device.

After filling turn the screw cap hand-tight back onto the water filling socket (2), until it is properly sealed.

Check the microbial contamination regularly.



#### Warning

##### Danger caused by water in connection with electricity

Water is electrically conductive.

- If water has been spilled when filling the unit, the unit must first be thoroughly dried and should only be connected to the power supply and switched on after it has completely dried.



### 13.2.2 Connecting and disconnecting the heat exchanger /oxygenator with the unit

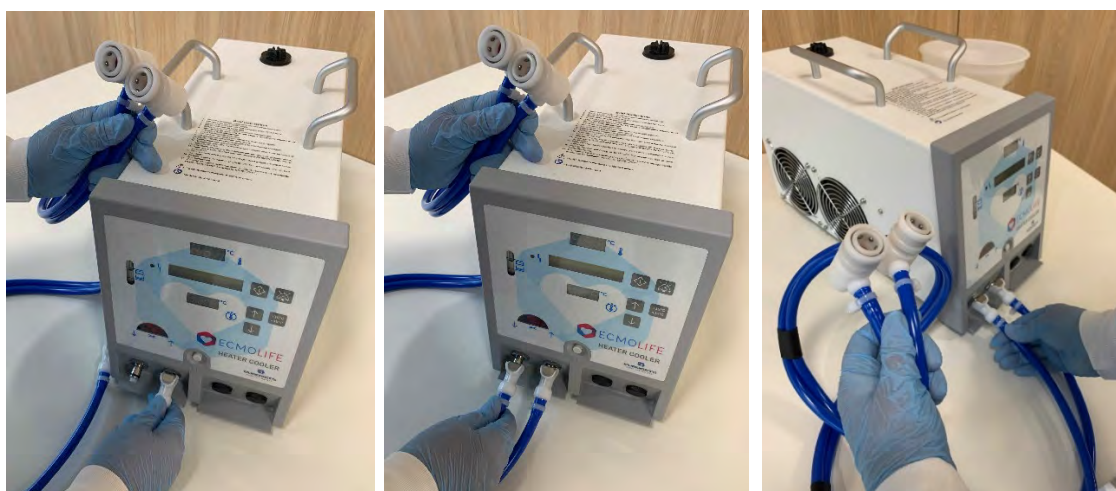
We recommend using Eurosets heat exchanger or oxygenators integrating heat exchanger.

Before connecting, check the heat exchanger / oxygenator for damage.

Only use undamaged heat exchangers / oxygenators. Follow the directions in the heat exchanger / oxygenator manual.

Heat exchanger / oxygenator can be connected or disconnected with the unit on or off.

- The Instructions for Use of the employed heat exchanger shall be observed. In particular, the connection and disconnection requirements, direction of flow and maximum possible pressure.
- Push the hose couplings onto the couplings on the unit (9). The couplings are plugged on correctly when the lock on the hose coupling engages in the coupling of the unit, so that the connection cannot come loose by itself.



Figures 16a, 16b, 16c - connection of hose couplings on unit couplings



#### Warning

As soon as hoses are connected, the unit water circuit opens, allowing water to flow inside the hoses.  
To prevent water dripping out from hoses, keep their distal end oriented upwards, higher than the unit.

- You can release the coupling again by pressing the small metal plate on the hose coupling and pulling off the hose.



Figure 17 - disconnection of hose couplings from unit couplings

- Hansen quick couplings are used to connect with the heat exchanger. The couplings are plugged on the heat exchanger water inlet and outlet ports correctly when the lock on the hose coupling engages in the coupling of heat exchanger water inlet and outlet ports, so that the connections cannot come loose by themselves.



Figures 18a and 18b - connection of Hansen quick couplings with Heat Exchanger inlet and outlet ports

- To unplug the couplings from the heat exchanger water inlet and outlet ports push back the locking ring of the Hansen quick coupling and disengage.



Figure 19 - disconnection of Hansen quick couplings from Heat Exchanger inlet and outlet ports



#### Note

- The connections between the unit and the heat exchanger 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 heat exchanger.
- The heat exchanger can also be disconnected while the unit is on.
- If the unit is not horizontal, the display in the front of the unit will indicate the water level incorrectly.
- 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).
- There will be a slight drip when the couplings are undone. This is normal and not a sign of a leak or defect.



### 13.2.3 Electrical connection



#### Warning

##### Danger caused by electric current

Defective cables and/or plugs as well as faults in the power supply can cause life threatening electric shock!

- Check the condition of unit cable and plug before connecting!
- To avoid the risk of electric shock, this unit must only be connected to the power supply with a protective earth conductor!

Please observe the following notes when connecting the unit electrically to ensure safe and fault free operation:

- Before connecting the unit compare the electric data (voltage and frequency) on the type plate with the data of your power supply. These data must match to prevent the unit from being damaged. Please ask your electrician for advice, if in doubt.
- The electric socket must be protected by a 16 A circuit breaker.
- Use the cable supplied with the unit to connect the unit to the power supply. The unit socket is on the rear side of the unit (chapter 11.1, "Views of unit").
- Power supply at the installation site must meet the requirement for electrical systems in hospital and medical environments. (IEC 60364-7-710:2002 Electrical installations of buildings Part 7-710: Requirements for special installations or locations Medical locations)

## 14 Control and operation

This chapter contains important information on handling the unit. Please follow these notes to avoid dangers and damages.

### 14.1 Inspection of the unit

The system is a closed circuit. The water lines should not be connected in the operating room / Intensive Care Unit.

Ensure that the water connections to the oxygenator have already been connected before the system is placed in the operating room / Intensive Care Unit.

Examine the unit for any external damage.

After switching on the unit, check the water level after connecting the Heat Exchanger / Oxygenator.

The water level must be between the two marks on the water level indicator (5), preferably just below the maximum mark. The filling difference between both marks is approx. 0.3 liter.

Fill with sterile water if the water level is below the minimum mark.



### Warning

- Fill the tank using a disinfected funnel and avoid contamination of water filling socket and cap (2).
- Only connect original Eurosets hoses to the unit.
- Always test the heat exchanger for water leaks before clinical use.

## 14.2 Operation

### 14.2.1 Switching on

- Prior to switch on check correct connection of the heat exchanger to the unit through the hoses Hansen quick couplings.
- Switch on the unit with the push button (8); in switched-off condition the push button is aligned with the front panel.
- The unit performs the functional test.

After switching on the unit performs a functional test. During this test observe whether all indicating elements behave as described below:

- a short audible alarm indicates that the unit is ready for a possible power failure alarm;

The unit now checks its self-sufficient protection and:

- the temperature displays (3) and (6) show **88.8**,
- the fault lamp (4) lights up,
- the audible alarm is on,
- the display (10) shows “FUNCTION.TEST”.

This test takes a few seconds.

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



### Caution

**If the functional tests were not completed successfully, the unit is no longer safe to operate.**

Do not operate the unit if:

- The unit does not emit the short signal for power failure alarm after switching on.
- The automatic functional test automatically switches off the unit because a defect in the independent protection was found.
- One or more displays are defective.

**In cases like these have the unit checked by the Eurosets S.r.l. authorized Technical Service.**

- Run the unit for about ten minutes to remove any air from the circuit in the unit. If necessary, manipulate the hoses to enable the air to dislodge and enter the unit.



#### Caution

In case of difficult air removal, signalled by the water flow indicator not moving, disconnect the hoses from the heat exchanger and create a loop with the Hansen connection tube.

Locate the hoses at the same height of the unit and run it for at least two minutes to achieve complete air removal. Check correct pump functioning observing water flow rate indicator.

Once air removal is achieved, reconnect the hoses to the heat exchanger.

- Check the heat exchanger for water leaks.
- Check the water level indicator (5); if necessary, switch off the unit, disconnect it from the power supply and fill up with sterile water.
- The height difference between heat exchanger and unit must not exceed 1 meter.
- In case of power supply disconnection due to water refill, reconnect again the unit to the power supply, switch it on and run it for another two minutes to force all air out of the circuit.
- Check the water level in the indicator (5) again; if necessary, switch off the unit, disconnect it from the power supply and fill up with sterile water.




#### Note


- 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.

### 14.2.2 Setting the temperature

- Set the nominal value for the water temperature - i.e., the temperature of the water

running to the heat exchanger - with the two arrow buttons (13)  and (15)



. The temperature can be set in steps of 0.1 °C from 15 to 39 °C. The temperature display (6) shows the nominal value.

- For nominal temperature values above 38 °C press the arrow button (13) while pressing the release key (14) at the same time.



- For nominal temperature values below 35°C press the arrow button (15) while pressing the release key (14) at the same time.



### Warning

- Time necessary to reach the desired temperature will take less than 10 minutes.
- In this timeframe, the difference between the nominal temperature display and the actual temperature display may differ up to 1°C. While achieving functional regimen temperature difference gradually smooths.
- Temperatures below 35°C withdraw heat from the patient at a higher rate.
- Temperatures above 38°C supply the patient with heat at a higher rate.

The heat transfer (heat supply or heat withdrawal) by heat exchanger to/from the patient's blood only occurs if the temperature of the water in the heat exchanger 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 heat exchanger.

## 14.2.3 Temperature control operation



### Warning

**There is a risk that the patient may be overheated or undercooled.**

- Monitor the patient's temperature when using the unit in combination with the heat exchanger on the patient.

If the set nominal temperature value is set between 35°C and 38°C, the unit will start normal operation after switching on and the functional test and regulate the water temperature in the circuit to the set value.

If the set nominal value is higher than 38°C or less than 35°C, the unit will emit an audible alarm and the message "SET VALUE <35 / >38°C", "RELEASE KEY" will appear in the display (10).

Check whether the nominal value is correct before pressing the release key (14).

The unit starts temperature control operation and the display (10) shows "HEATING ACTIVE" or "COOLING ACTIVE".



### Caution

- Only leave the water circulating around the heat exchanger in temperature control operation.

- Due to the excellent heat conductivity of water, the patient can cool down when the unit is switched off or the water hoses are disconnected from the heat exchanger.

#### 14.2.4 Obligations during operation



##### Warning

**Danger caused by overestimation and underestimations of the performance of the system!**

Dangers may arise from the unit if it is put to unintended use when:

- improper observation of physical connections in external unit accessories and environmental conditions (heat exchanger size, ambient temperature etc.),
- individual and unpredictable patient reactions.

**The reliable application of the system requires the user to carry out a careful risk assessment between the desired indication and performance of the system, as well as continuous monitoring of the patient, with regards to side effects.**

For low-risk application of hypo/hyperthermia, an external continuous monitoring of the body core temperature (e.g., by taking a measurement in the urinary bladder) is of the utmost importance, since uncontrolled hypo/hyperthermia is associated with increased patient mortality. See chapter 5, 7 and 8 respectively for indications for use, contraindications and risks and side effects.

##### Check the water flow rate


The sight glass of the water flow indicator (7) features an impeller wheel. With optimal water flow the individual blades of the impeller are not visible.

##### Monitor patient temperature

**During operation check the water flow in the unit and the heat exchanger at regular intervals.**

##### Carry out functional test

During long-term operation check the independent protection manually at least once a day.

To do this press the functional test button (11)  during operation. The unit now tests the safety electronics:

- the alarm sounds,
- the temperature displays (3) and (6) show **88.8** ,

- the fault lamp (4) lights up,
- the audible alarm is on,
- the display (10) shows “FUNCTION.TEST”.

After successful test the display shows the message “FUNCTION.TEST OK”, the unit will automatically resume normal operation.



#### Warning

**If the functional test is not successful, the unit is no longer safe to operate. In this case:**

- Do not longer use the unit on the patient.
- Have the unit inspected by the Eurosets S.r.l. authorized Technical Service.



#### Check temperature displays

During long-term operation check the nominal and actual values of the temperature displays.

### 14.2.5 Operator language

The status and error messages in the display (10) can be shown in the following languages: English, German, French, Spanish, Italian and Polish.

Adjust the language for the display as follows:

- Switch the unit on,
- Press and hold the button “Audio paused” (12)  for about 4 secs.; the last language set appears in the display.
- Keep pressing the arrow button “Nominal value higher” (13) , until the desired language appears in the display.
- Approx. 10 secs. after the last input the unit will return to its previous operating status, the last language displayed is active.

## 14.3 Alarms


### 14.3.1 General information

The unit always emits a visual and audible alarm. The operator is instantaneously informed about any malfunction, which in turn enhances the operating safety. The display (10) shows the fault condition, that has caused the alarm (except power failure alarm).

The alarms are arranged with a medium priority. Failure to comply could result in the following:

- Minor injuries or inconveniences within a period of time which is not long enough for manual corrective action (direct).
- Reversible injuries within a period of time which is not long enough for manual corrective action (immediate).
- Death or irreversible injury within an undefined period of time which is greater than the "immediate" named time period (delayed).

For the reasons described in chapter 14.3.2 a system alarm message is given, these can be cancelled as follows depending on the expected results.

- Pressing the "Audio paused" button (12)  interrupts the audible alarm for 10 minutes. The error message can be read in the display (10). The flashing fault lamp (4) stays on as long as the alarm condition is present. The alarm condition is correct according to the alert message on the display (10).
- The unit will switch off all functions. The audible alarm cannot be interrupted. Switch off the unit by the main switch (8), take it out of service and if necessary, have it inspected by Eurosets S.r.l. authorized Technical Service Engineer.




#### Note

Before pressing the "Audio paused" button (12) or the main switch (8) to suppress the alarm or take the unit out of service, please read the error message in the display!

### 14.3.2 Alarms description during operation

#### *Display message: WATER LEVEL!?*

The unit triggers this alarm if the water level drops below the MIN-mark on the water level indicator (5) during operation. The display shows "WATER LEVEL!?", the yellow fault lamp (4) flashes and a pulsating signal tone sounds.

- Press the "Audio paused" button (12)  to interrupt the audible alarm for 10 minutes.
- Immediately fill up with sterile water, until the water level is just below the MAX-mark (5) (see chapter 13.2.1 "Filling the system with water").




#### Caution

- In case of a too low water level, a sufficient water circulation can no longer be assured.
- A too low water level can cause damage to components of the unit and thus total failure of the unit.

***Display message: TEMP. DIFF >1°C:***

Should the water actual temperature deviate from the set nominal temperature by more than 1°C during operation, the unit will trigger this alarm. The display shows “TEMP. DIFF. >1°C”, the yellow fault lamp (4) flashes and a pulse signal tone sounds.

- Press the “Audio paused” button (12)  to interrupt the audible alarm for 10 minutes.
- Change the nominal value until the unit will be able to regulate the temperature reliably.



**Note**

- Connecting or disconnecting a heat exchanger during operation can cause a temperature difference triggering the alarm.
- The alarm can be triggered in cooling operation at high room temperatures because the specified nominal value (e.g., 15°C) can in this case not be achieved. Keep increasing the nominal value, until the unit will be able to regulate the temperature reliably.
- After switching on the unit and after changing the nominal temperature this alarm function is suppressed over a specified time period of time.

***Display message: ALARM TEST FAIL → CALL SERVICE***

The unit triggers this alarm if it has detected a fault during the automatic or manual functional test or has found that the independent protection does not respond. The display shows “ALARM TEST FAIL” and “→CALL SERVICE”, the yellow fault lamp (4) flashes and a pulse signal tone sounds.

The audible alarm cannot be interrupted with the “Audio paused” button (12).

- Switch off the unit with the main switch (8).
- Switch the unit back on.



**Caution**

If the unit still emits an alarm take it out of the service and have it inspected by a Eurosets S.r.l. authorized Technical Service Engineer.

***Display message: CHECK UNIT → TEMPERATURE LOW***

The unit triggers this alarm if the water tank temperature falls short of the measuring range (approx. 9°C). The display shows “CHECK UNIT → TEMPERATURE LOW”. The



yellow fault lamp (4) flashes and a pulsating signal tone sounds. The temperature display shows **---**.

The audible alarm cannot be interrupted with the “Audio paused” button (12).

- Switch off the unit with the main switch (8).
- Take the unit to a warmer environment and wait for about 2 hours.
- Switch the unit back on.



#### Caution

- Store the unit only in the permissible temperature range, the unit may otherwise be damaged (3-60°C).
- Only operate the unit only in the permissible temperature range, (10-30°C) when heating and (10-23°C) when cooling, otherwise it does not function in a fail-safe manner and may be damaged (observe chapter 13.1.1 Requirements concerning the place of installation!)

If the unit emits an alarm take it out of service and have it inspected by a Eurosets S.r.l. authorized Technical Service Engineer.

### ***Display message: CHECK UNIT → CALL SERVICE***

The unit triggers this alarm in case of various defects. The display shows “CHECK UNIT” and “→CALL SERVICE”, the yellow fault lamp (4) flashes and a pulse signal tone sounds.

The audible alarm cannot be interrupted with the “Audio paused” button (12).

- Switch off the unit with the main switch (8).

Take the unit out of the service and have it inspected by a Eurosets S.r.l. authorized Technical Service Engineer.

### ***POWER FAILURE ALARM***

The unit triggers this alarm if the power supply fails during operation. The yellow fault lamp (4) lights up and a permanent signal sounds. All other displays are without function. The power accumulator in the unit receives the alarm for at least 10 minutes without power supply.

The alarm **cannot** be interrupted with the “Audio paused” button (12).

- Switch off the unit with the main switch (8).



#### Note

- The alarm automatically goes out when the power supply returns.
- The temperature set last is stored in the unit.

- With restoration of the power supply, the temperature stored must be controlled by the user and approved before the device returns to normal operation (see chapter 14.2 Operation)

## 14.4 Alarms Table

ALARM SITUATION	ALARM DISPLAYED	PRIORITY	CORRECTIVE ACTION
The water level drops below the MIN-mark in the water level indicator (5) during operation	<b>WATER LEVEL!?</b>	<b>MEDIUM</b>	<ul style="list-style-type: none"> <li>• Press the “Audio paused” button (12) to interrupt the audible alarm for 10 minutes.</li> <li>• Immediately fill up water, until the water level is just below the MAX-mark (5).</li> </ul>
Deviation of the water temperature from the set nominal value by more than 1°C.	<b>TEMP. DIFF. &gt;1°C</b>	<b>MEDIUM</b>	<ul style="list-style-type: none"> <li>• Press the “Audio paused” button (12) to interrupt the audible alarm for 10 minutes.</li> </ul>
Fault during the automatic or manual functional test or independent protection does not respond	<b>ALARM TEST FAIL → CALL SERVICE</b>	<b>MEDIUM</b>	<ul style="list-style-type: none"> <li>• Switch off the unit with the main switch (8).</li> <li>• Leave the unit switched off for approx. 2 hours.</li> <li>• Switch the unit back on.</li> <li>• If the unit still emits the alarm take it out of service and have it inspected.</li> </ul>
The water tank temperature falls short of the measuring range.	<b>CHECK UNIT → TEMPERATURE LOW</b>	<b>MEDIUM</b>	<ul style="list-style-type: none"> <li>• Switch off the unit with the main switch (8),</li> <li>• Take the unit to a warmer environment for about 2 hours.</li> <li>• Switch the unit back on.</li> <li>• If the unit still emits the alarm take it out of service and have it inspected.</li> </ul>
In case of various defects.	<b>CHECK UNIT → CALL SERVICE</b>	<b>MEDIUM</b>	<ul style="list-style-type: none"> <li>• Switch off the unit with the main switch (8),</li> <li>• Take the unit out of service and have it inspected.</li> </ul>

## 15 Cleaning and disinfecting

This chapter contains important information about the cleaning and disinfection of the unit. Please follow these instructions to avoid damage caused by incorrect cleaning or disinfection of the unit, to assure trouble-free operation and the correct disinfection of the product.



## Warnings

- 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 (routine hand washing, 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.
- During the water change or the disinfection no heat exchanger may be connected to the water circuit.
- The hoses Hansen quick couplings not connected to the heat exchanger shall be connected using the cleaning Hansen connection tube, in order to create a loop.
- Do not use methods for descaling, cleaning and disinfection other than those recommended by Eurosets S.r.l.
- Use only liquids and substances specified by Eurosets S.r.l. Not recommended substances could damage the device and compromise the cleaning and disinfection effectiveness.
- Check with Eurosets S.r.l. before introducing new processes. This is the only way to ensure that these processes will not damage the unit.
- When cleaning and disinfecting the ECMOLIFE HC surfaces the safety instruction from the manufacturer of cleaning and disinfection agents must be observed.
- For surface cleaning and disinfection of ECMOLIFE HC housing and accessories use a disposable clean, non-linting cloth.
- Avoid the use of cleaning agents containing oil or grease.
- For surface cleaning of ECMOLIFE HC use only allowed disinfectants. Avoid the use of phenol derivatives.
- Only use sterile water for cleaning and disinfecting the device!
- Fill sterile water into the tank only with auxiliaries (i.e. funnel) that have been previously disinfected, removing any residues of disinfectant before use.
- Switch the ECMOLIFE HC off and unplug the ECMOLIFE HC from the external power supply before surface cleaning.
- Do not use chemical solvents such as ether or acetone and do not spill anesthetics such as Foram (isoflurane). They can damage the ECMOLIFE HC.
- Do not allow liquid to penetrate the ECMOLIFE HC. Therefore, do not use sprays.
- Let the unit dry completely before switching it on again.
- Prior to unit storage, in order to preserve the device from biofilm formation, perform high level disinfection process, empty completely the device, leave the cap of water filling socket (2) and store in a dry place.

## 15.1 Descaling and disinfection of the water circuit

ECMOLIFE HC water circuit comprises a pump, a water tank, couplings and hoses.

The guide for routine disinfection does not replace regular hygiene monitoring of water. It may be necessary to shorten the disinfection degree and interval.

Depending on how contaminated the ECMOLIFE HC is and the hygienic situation in the hospital, the necessary water quality may not be achieved after routine disinfection, and disinfection must therefore be repeated. If atypical microbial contamination (e.g. Mycobacteria) is present, highly effective disinfection must be performed.

### Equipment for descaling/disinfection



#### Warning

#### Water quality

- Do not use unfiltered and unsterilized main water!
- Water shall have a hardness of  $\leq 14$  °dH (2.5 mmol/l  $\text{CaCO}_3$ ) and must be sterile or filtered with a sterile filter with pore size  $\leq 0.22$   $\mu\text{m}$ .

The following equipment is required for descaling/disinfection:

- Water of the proper quality,
- Sterile in-line filter with a pore size of 0.22  $\mu\text{m}$ ,
- Personal protective clothing (as specified on the safety data sheet for the descaling/disinfection agent):
  - Chemical-resistant gloves made of nitrile or butyl rubber;
  - Dust mask for P2 respiratory protection;
  - Protective goggles;
  - Laboratory coat.

The following equipment is additionally required:

- Canister (chemical-resistant, for example made of polypropylene) with a capacity of at least 10 l;
- Measuring spoon (chemical-resistant);
- Powder funnel (chemical-resistant) for approx. 100 ml;
- Scales for weighing the descaling/disinfection agent;
- Beaker (chemical-resistant) for approx. 3 l;
- Small flat tray (chemical-resistant) for the disinfection of cleaning Hansen connection tube;
- 1 liter Bottle with spray (chemical-resistant, for example made of polypropylene).



## Warnings

- Disinfection and descaling are two separate processes. The processes are not substitute for each other. Do not perform them at the same time.
- When descaling and disinfection have to be performed, perform the descaling before disinfection.
- Only use specified agents for descaling/disinfection.
- In order to disinfect ECMOLIFE HC water circuit use the approved disinfectant Clorina (active agent: tosylchloramide sodium, known as Chloramine-T) or another chemically identical disinfectant.
- The disinfectant Clorina has been tested for use with ECMOLIFE HC water circuits. Other disinfectants may influence the material compatibility. Use of any other, not chemically identical disinfectants is explicitly not allowed.
- Thoroughly follow the manufacturer's safety instructions for the disinfectant/descaling agent during the disinfection/descaling of ECMOLIFE HC.
- Check the water level in ECMOLIFE HC water tank. If the water level is too low, fill up the tank to the maximum mark of the water level display.
- Provide adequate ventilation for the disinfection process. Avoid generation of dust from the disinfectant. Do not breathe in dust from the disinfectant. Avoid contact of the disinfectant with skin, eyes and clothes.
- Use personal protection equipment (e.g. gloves resistant to chemicals made of Nitrile rubber or Butyl caoutchouc (butyl rubber), dust mask for respiratory protection P2, goggles and a protective lab coat) according to the Safety Data Sheet for the disinfectant/descaling agent.
- The system must be checked before descaling/disinfection starts:
  - device functional test ok
  - no leakage in water line or leakage of the device
  - water flow ok
  - water in tank ok.
- All connected parts must be firmly and correctly connected. Check the mechanical stability.
- Do not kink the hoses. Do not touch the hoses, the Hansen connection tube and the water discharge tube with pointed or sharp objects.
- Periodically check the conditions of the hoses and Hansen connection tube and replace them in case of deterioration or water leaks.
- The disinfectant/descaling agent must only be used pre- and post-operatively, never intraoperatively.
- Do not use the heat exchanger when performing disinfection/descaling procedure of ECMOLIFE HC; the heat exchanger must be replaced by the cleaning Hansen connection tube. The disinfectant/descaling agent could damage or contaminate the heat exchanger and the disinfection/descaling procedure may result compromised.

- Perform the descaling process every 6 months with a concentration of 2% citric acid in the water system of ECMOLIFE HC.
- If ECMOLIFE HC is used regularly, disinfection must be performed after each use or at least every 7 days of use.
- Disinfection must be performed with 2% Chloramine-T in the water system of ECMOLIFE HC.
- If ECMOLIFE HC is out of use, in order to preserve the device from biofilm formation, perform high level disinfection process, empty completely the device, leave the cap of water filling socket (2) and store in a dry place.
- Check the microbial contamination regularly. If atypical microbial contamination (e.g., Mycobacteria) is present, perform the high-level disinfection process with a concentration of 5% Chloramine-T in the water system of ECMOLIFE HC.
- For an effective descaling/disinfection, the required amount of descaling agent/ disinfectant has to be determined depending on the tubing lengths connected to ECMOLIFE HC.
- The results of hygienic vigilance microbiological monitoring shall be used to determine the appropriate disinfection concentration required for each ECMOLIFE HC.
- The re-commissioning of the device shall only be performed by accompanied regular hygienic monitoring, followed by adequate disinfection in consideration of the hygienic conditions.
- Use a sterile in-line filter with 0.22 µm porosity for filling ECMOLIFE HC with water.
- ECMOLIFE HC tank shall be filled with sterile filtered water with a water hardness of  $\leq 14^{\circ}\text{dH}$  (2.5 mmol/l  $\text{CaCO}_3$ ). Do not use deionized water.
- De-air the system by running the unit for about ten minutes while manipulating the hoses to dislodge air if necessary, to achieve an even distribution of the disinfectant/descaling agent in the water system.
- After the descaling/disinfection procedure, rinse the device 3 times to remove residual descaling /disinfectant agent.
- When performing descaling/disinfection the hoses Hansen quick couplings shall be connected using the cleaning Hansen connection tube.

### 15.1.1 Descaling process

The descaling process is performed every 6 months with a concentration of 2% citric acid in the complete water volume of the ECMOLIFE HC.

Perform the following steps for descaling the system:

- Emptying.
- Descaling.
- Rinsing.

### 15.1.1.1 EMPTYING



#### Warning

**Personal and material damage may occur when emptying the unit!**

Observe the following safety information to prevent hazards:

- The weight of the unit is approx. 17 kg.
- The unit shall be emptied by two people.

- Switch the device off.
- Disconnect the device from the power supply.
- Disconnect the heat exchanger connected to the water circuit.



Figure 20 - Heat exchanger disconnection from water circuit



- Disconnect the water hoses from ECMOLIFE HC.



Figures 21a and 21b - disconnection of hoses from ECMOLIFE HC

- Empty the water hoses through the Hansen couplings over an outflow.



Figure 22 - Water hoses emptying

- Put a container (bucket, bowl, etc.) under ECMOLIFE HC or place the device over an outflow or other means of drainage.
- Connect the water discharge hose to the unit coupling marked with the ↓ (9).



### Warnings

- Be aware that immediately after the connection of the water discharge hose, a quick flushing of water appears out of the hose and you need to be ready with the container.
  - Do not attach the water discharge hose if you do not have readily available the container.
- Unscrew the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
  - Drain the tank contents into the container or outflow via the connected water discharge hose.



Figure 23 - Tank content drainage

- Tip the ECMOLIFE HC forward to completely empty the device unit.
- 
- Disconnect the water discharge hose and connect it to the other unit coupling indicated by the ↑ marking (9) to allow complete emptying of the internal water circuit.
- Drain the tank contents into the container or outflow via the connected water discharge hose.
- Tip the ECMOLIFE HC forward to completely empty the device unit.
- Disconnect the water discharge hose and put it apart.
- Connect the water hoses to ECMOLIFE HC.

ECMOLIFE HC is emptied.

### 15.1.1.2 DESCALING



#### Warnings

- Use personal protection equipment (e.g., gloves resistant to chemicals made of Nitrile rubber or Butyl caoutchouc (butyl rubber), dust mask for respiratory protection P2, goggles and a protective lab coat) according to the Safety Data Sheet for the disinfectant/descaling agent.
- For the preparation of the solution use sterile or disinfected material free of chemical residues.

- Connect the open hose ends to the cleaning Hansen connection tube supplied.
- Prepare a citric acid solution:

When connecting hoses measuring 2 x 1.5 m to the ECMOLIFE HC: Use a powder funnel to put 30 g of citric acid into a chemical-resistant 10 liter canister with watertight lid. Add 1.5 liters of sterile, filtered, warm water (approx. +35°C). Close the canister, check that it is leak-tight and dissolve the citric acid by shaking.

Or

When connecting hoses measuring 2 x 3 m to the ECMOLIFE HC: Use a powder funnel to put 34 g of citric acid into a chemical-resistant 10 liter canister with watertight lid. Add 1.7 liters of sterile, filtered, warm water (approx. +35°C).

Close the canister, check that it is leak-tight and dissolve the citric acid by shaking.

- Fill the citric acid solution up to the maximum mark on the tank's water level indicator (5).
- Close the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
- Connect the device to the power supply.
- Switch on the device.
- Run the ECMOLIFE HC for approx. 20 minutes.

The hoses are filled with citric acid solution.

- When connecting hoses measuring 2 x 3 m to the ECMOLIFE HC:
  - Switch off the device.
  - Unscrew the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
  - Fill the device with the remaining citric acid solution up to the maximum mark on the water level indicator (5).
  - Close the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
  - Switch on the device.
- Return the setpoint temperature to +38°C.
- Run the ECMOLIFE HC for 60 minutes.
- Switch off the device.
- Disconnect the device from the power supply.

- Empty the ECMOLIFE HC following the steps in chapter 15.1.1.1.



**Note**

- Use a suitable drain for disposing of disinfection/descaling agent solutions.

Descaling of the ECMOLIFE HC is now complete.

The ECMOLIFE HC is now empty.

### 15.1.1.3 RINSING

- Disconnect the water discharge hose.
- Connect the open hose ends to the cleaning Hansen connection tube supplied.
- Unscrew the cap of the water filling socket (2). Do not lose the sealing ring of the cap.

Fill the ECMOLIFE HC with sterile filtered water with specifications shown in the previous warnings up to the maximum mark on the water level indicator (5).

- Close the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
- Connect the device to the power supply.
- Switch on the device.
- Set the setpoint temperature to +37°C.
- Run the ECMOLIFE HC for 3 minutes.
- Switch off the device.
- Disconnect the device from the power supply.
- Using the disinfected water discharge hose proceed with device emptying (following the steps in chapter 15.1.1.1 “EMPTYING”):



**Note**

- Use a suitable drain for disposing of disinfection/descaling agent solutions.

- Repeat the rinsing steps outlined above twice so that the ECMOLIFE HC is rinsed a total of three times.

The ECMOLIFE HC has now been rinsed.

### 15.1.2 Intermediate level Disinfection process

If ECMOLIFE HC is used regularly, disinfection must be performed after each use or at least every 7 days of use. Disinfection must be performed with 2% Chloramine-T in the water system of ECMOLIFE HC.

Perform the following steps for disinfection:

- Emptying.

- Disinfection.
- Rinsing.

If atypical microbial contamination (e.g., Mycobacteria) is present, a 5% Chloramine-T concentration must be used in the entire water volume of the ECMOLIFE HC. Special, highly effective disinfection and biofilm removal with 5% Chloramine-T are described under chapter 15.1.3 "High Level Disinfection and Biofilm Removal Process for ECMOLIFE HC".

### 15.1.2.1 EMPTYING

Perform emptying steps indicated in chapter 15.1.1.1.

### 15.1.2.2 DISINFECTION



#### Warnings

- Use personal protection equipment (e.g., gloves resistant to chemicals made of Nitrile rubber or Butyl caoutchouc (butyl rubber), dust mask for respiratory protection P2, goggles and a protective lab coat) according to the Safety Data Sheet for the disinfectant/descaling agent.
- Create a sufficient quantity of 2% concentration Chloramine-T solution to allow disinfection procedure for external parts and accessories.
- Soak in a tray the water discharge hose and the cleaning Hansen connection tube supplied.
- Thoroughly disinfect with spray disinfectant (Chloramine-T or Sanosil S003 or Gioclorex 2% or chemically equivalent disinfectant) the unit couplings (spray at least four/five times).



#### Warnings

- Chloramine-T solution leaves residuals on the device surfaces. When performing disinfection using Chloramine-T solution, after disinfection a thorough rinsing shall be performed to efficiently remove all chemical residuals from the device.
- Prior to connect the hoses to the unit couplings, disinfect thoroughly with a spray disinfectant each hose coupling (spray at least four/five times).
- Connect the hoses couplings to the unit couplings.
- Thoroughly disinfect with spray disinfectant the open hose ends with Hansen quick couplings by pushing back the locking ring (spray at least four/five times). Release the locking ring and spray again on the Hansen quick couplings (spray at least four/five times).
- Thoroughly disinfect with spray disinfectant both ends of the cleaning Hansen connection tube supplied (spray at least four/five times).



- Connect the open hose ends to the cleaning Hansen connection tube supplied.



Figure 24 - Connection of Hansen connection tube to hoses

- Create a Chloramine-T solution for the disinfection of the water circuits:  
When connecting hoses measuring 2 x 1.5 m to the ECMOLIFE HC: Use a powder funnel to put 30 g of Chloramine-T into a chemical-resistant 10 liter canister with watertight lid. Add 1.5 liters of sterile, filtered, warm water (approx. +35°C). Close the canister, check that it is leak-tight and dissolve the Chloramine-T by shaking.  
Or  
When connecting hoses measuring 2 x 3 m to the ECMOLIFE HC: Use a powder funnel to put 34 g of Chloramine-T into a chemical-resistant 10 liter canister with watertight lid. Add 1.7 liters of sterile, filtered, warm water (approx. +35°C). Close the canister, check that it is leak-tight and dissolve the Chloramine-T by shaking.
- Unscrew the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
- Thoroughly disinfect with spray disinfectant the water filling socket (2) and the internal part of the cap.
- Fill the Chloramine-T solution, using a disinfected funnel, up to the maximum mark on the tank's water level indicator (5).
- Close the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
- Connect the device to the power supply.
- Switch on the device.
- Run the ECMOLIFE HC for approx. 20 minutes.

The hoses are filled with Chloramine-T solution.

- When connecting hoses measuring 2 x 3 m to the ECMOLIFE HC:
  - Switch off the device.

- Unscrew the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
- Thoroughly disinfect with spray disinfectant the water filling socket (2) and the internal part of the cap.
- Fill the device with the remaining Chloramine-T solution, using a disinfected funnel, up to the maximum mark on the water level indicator (5).
- Close the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
- Switch on the device.
- Set the setpoint temperature to +38°C.
- Run the ECMOLIFE HC for 60 minutes.
- Switch off the device.
- Disconnect the device from the power supply.
- Using the disinfected water discharge hose proceed with device emptying (following the steps in chapter 15.1.1.1 “EMPTYING”), with the following exceptions:
  - Thoroughly disinfect with spray disinfectant (Chloramine-T or Sanosil S003 or Gioclorex 2% or chemically equivalent disinfectant) the unit couplings (spray at least four/five times).



#### Warnings

- Chloramine-T solution leaves residuals on the device surfaces. When performing disinfection using Chloramine-T solution, after disinfection a thorough rinsing shall be performed to efficiently remove all chemical residuals from the device.

- Prior to connect the water discharge hose to the unit coupling, disinfect thoroughly with a spray disinfectant the water discharge hose coupling (spray at least four/five times).



#### Note

- Use a suitable drain for disposing of disinfection/descaling agent solutions.

Disinfection of the ECMOLIFE HC is now complete.

The ECMOLIFE HC is now empty.

### 15.1.2.3 RINSING

- Disconnect the water discharge hose.
- Thoroughly disinfect with spray disinfectant (Chloramine-T or Sanosil S003 or Gioclorex 2% or chemically equivalent disinfectant) the unit couplings (spray at least four/five times).





### Warnings

- Chloramine-T solution leaves residuals on the device surfaces. When performing disinfection using Chloramine-T solution, after disinfection a thorough rinsing shall be performed to efficiently remove all chemical residuals from the device.

- Prior to connect the hoses to the unit couplings, disinfect thoroughly with a spray disinfectant each hose coupling (spray at least four/five times).
- Connect the water hoses to ECMOLIFE HC.
- Thoroughly disinfect with spray disinfectant the open hose ends with Hansen quick couplings by pushing back the locking ring (spray at least four/five times). Release the locking ring and spray again on the Hansen quick couplings (spray at least four/five times).
- Thoroughly disinfect with spray disinfectant both ends of the cleaning Hansen connection tube supplied (spray at least four/five times).
- Connect the open hose ends to the cleaning Hansen connection tube supplied.
- Unscrew the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
- Thoroughly disinfect with spray disinfectant the water filling socket (2) and the internal part of the cap.
- Fill the ECMOLIFE HC with sterile filtered water, using a disinfected funnel, up to the maximum mark on the water level indicator (5).
- Close the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
- Connect the device to the power supply.
- Switch on the device.
- Set the setpoint temperature to +37°C.
- Run the ECMOLIFE HC for 3 minutes.
- Switch off the device.
- Disconnect the device from the power supply.
- Using the disinfected water discharge hose proceed with device emptying (following the steps in chapter 15.1.1.1 “EMPTYING”), with the following exceptions:
  - Thoroughly disinfect with spray disinfectant (Chloramine-T or Sanosil S003 or Gioclorex 2% or chemically equivalent disinfectant) the unit couplings (spray at least four/five times).



### Warnings

- Chloramine-T solution leaves residuals on the device surfaces. When performing disinfection using Chloramine-T solution, after disinfection a thorough rinsing shall be performed to efficiently remove all chemical residuals from the device.

- Prior to connect the water discharge hose to the unit coupling, disinfect thoroughly with a spray disinfectant the water discharge hose coupling (spray at least four/five times).



#### Note

- Use a suitable drain for disposing of disinfection/descaling agent solutions.
- 
- Repeat the rinsing steps outlined above twice so that the ECMOLIFE HC is rinsed a total of three times.
  - Fill the ECMOLIFE HC with sterile filtered water up to the maximum mark on the water level indicator (5). Filling shall be performed following instruction at chapter 13.2.1 “Filling the system with water”.
  - Thoroughly disinfect with spray disinfectant the water filling socket (2) and the internal part of the cap.
  - Close the cap of the water filling socket (2). Do not lose the sealing ring of the cap.



#### Warnings

- Each time the water filling socket (2) is opened perform disinfection with spray disinfectant of both water filling socket and cap, as explained in the previous paragraph. The same disinfection process with spray disinfectant shall be applied whenever couplings (i.e. unit couplings, hose couplings and Hansen quick couplings) are plugged out and in.

The ECMOLIFE HC has now been rinsed.

### 15.1.3 High level Disinfection and Biofilm Removal Process

If atypical microbial contamination (e.g. Mycobacteria) is present, a concentration of 5% Chloramine-T in the complete water volume of the ECMOLIFE HC must be used for the special high level disinfection and biofilm removal. This process requires 24 hours contact time with Chloramine-T.

Perform the following steps for high level disinfection and biofilm removal:

- Emptying.
- High Level Disinfection.
- Rinsing.

#### 15.1.3.1 EMPTYING

Perform emptying steps indicated in chapter 15.1.1.1.

### 15.1.3.2 HIGH LEVEL DISINFECTION

High level disinfection process steps are mainly the same as intermediate level disinfection except for Chloramine-T concentration which shall be 5% instead of 2% and prolonged contact time.

All disinfections steps are listed and differences with respect to intermediate level disinfection are provided in bold.



#### Warnings

- Use personal protection equipment (e.g. gloves resistant to chemicals made of Nitrile rubber or Butyl caoutchouc (butyl rubber), dust mask for respiratory protection P2, goggles and a protective lab coat) according to the Safety Data Sheet for the disinfectant/descaling agent.

- Create a sufficient quantity of **5% concentration Chloramine-T solution** to allow disinfection procedure for external parts and accessories.
- Soak in a tray the water discharge hose and the cleaning Hansen connection tube supplied.
- Thoroughly disinfect with spray disinfectant (Chloramine-T or Sanosil S003 or Gioclorex 2% or chemically equivalent disinfectant) the unit couplings (spray at least four/five times).



#### Warnings

- Chloramine-T solution leaves residuals on the device surfaces. When performing disinfection using Chloramine-T solution, after disinfection a thorough rinsing shall be performed to efficiently remove all chemical residuals from the device.

- Prior to connect the hoses to the unit couplings, disinfect thoroughly with a spray disinfectant each hose coupling (spray at least four/five times).
- Connect the hoses couplings to the unit couplings.
- Thoroughly disinfect with spray disinfectant the open hose ends with Hansen quick couplings by pushing back the locking ring (spray at least four/five times). Release the locking ring and spray again on the Hansen quick couplings (spray at least four/five times).
- Thoroughly disinfect with spray disinfectant both ends of the cleaning Hansen connection tube supplied (spray at least four/five times).
- Connect the open hose ends to the cleaning Hansen connection tube supplied.
- Create a Chloramine-T solution for the **high-level disinfection** of the water circuits.

When connecting hoses measuring 2 x 1.5 m to the ECMOLIFE HC: Use a powder funnel to put **75 g of Chloramine-T** into a chemical-resistant 10 liter canister with

watertight lid. Add 1.5 liters of sterile, filtered, warm water (approx. +35°C). Close the canister, check that it is leak-tight and dissolve the Chloramine-T by shaking.

Or

When connecting hoses measuring 2 x 3 m to the ECMOLIFE HC: Use a powder funnel to put **85 g of Chloramine-T** into a chemical-resistant 10 liter canister with watertight lid. Add 1.7 liters of sterile, filtered, warm water (approx. +35°C). Close the canister, check that it is leak-tight and dissolve the Chloramine-T by shaking.

- Unscrew the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
- Thoroughly disinfect with spray disinfectant the water filling socket (2) and the internal part of the cap.
- Fill the Chloramine-T solution, using a disinfected funnel, up to the maximum mark on the tank's water level indicator (5).
- Close the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
- Connect the device to the power supply.
- Switch on the device.
- Run the ECMOLIFE HC for approx. 20 minutes.

The hoses are filled with Chloramine-T solution.

- When connecting hoses measuring 2 x 3 m to the ECMOLIFE HC:
  - Switch off the device.
  - Unscrew the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
  - Thoroughly disinfect with spray disinfectant the water filling socket (2) and the internal part of the cap.
  - Fill the device with the remaining Chloramine-T solution, using a disinfected funnel, up to the maximum mark on the water level indicator (5).
  - Close the cap of the water filling socket (2). Do not lose the sealing ring of the cap.
  - Switch on the device.
- Set the setpoint temperature to +38 °C.
- **Run the ECMOLIFE HC for 90 minutes.**
- **Switch off the device.**
- **Disconnect the device from the power supply.**
- **Leave the Chloramine-T to work for 24 hours in the water system.**
- **Connect the device to the power supply.**
- **Switch on the device.**
- **Run the ECMOLIFE HC for 5 minutes.**
- Switch off the device.
- Disconnect the device from the power supply.
- Using the disinfected water discharge hose proceed with device emptying (following the steps in chapter 15.1.1.1 “EMPTYING”), with the following exceptions:

- Thoroughly disinfect with spray disinfectant ((Chloramine-T or Sanosil S003 or Gioclorex 2% or chemically equivalent disinfectant) the unit couplings (spray at least four/five times).



#### Warnings

- Chloramine-T solution leaves residuals on the device surfaces. When performing disinfection using Chloramine-T solution, after disinfection a thorough rinsing shall be performed to efficiently remove all chemical residuals from the device.

- Prior to connect the water discharge hose to the unit coupling, disinfect thoroughly with a spray disinfectant the water discharge hose coupling (spray at least four/five times).



#### Note

- Use a suitable drain for disposing of disinfection/descaling agent solutions.

Highly effective disinfection of the ECMOLIFE HC is now complete.

The ECMOLIFE HC is now empty.

### 15.1.3.3 RINSING

Perform rinsing steps indicated in Chapter 15.1.2.3.

## 15.2 Cleaning and Disinfecting the surfaces

Apart from the hygienic aspect, it is essential for the operational safety of the heater-cooler and accessories that it is clean.

After having disinfected the unit water circuits and the couplings, carry out a surface cleaning followed by disinfection (device housing, hoses and couplings).



#### Warnings

- If in doubt that couplings (i.e., unit couplings, hose couplings and Hansen quick couplings) and water filling socket and cap (2) haven't been disinfected, perform disinfection with spray disinfectant of these parts, as explained in chapter 15.1.2 "Intermediate level Disinfection process". Disinfection with spray disinfectant shall be performed whenever water filling socket is opened and when couplings are unplugged and re-plugged.

## 15.2.1 Required material

- Disposable, clean, non-linting clothes;
- Cleaning solution: aqueous alcohol solution (70% ethanol / 30% water), or cleaning solution for sensitive medical devices.
- Disinfecting solution, chosen among the followings or others having chemically equivalent active substances:

Company	Product Name	Active Substance
Sanosil	Sanosil S003	1,5 % H <sub>2</sub> O <sub>2</sub> , 0.003% Ag
Giochemica	Gioclorex 2%	2% chlorhexidine digluconate solution in 70% isopropyl alcohol

- When using a disinfectant follow the instructions of the manufacturer.

## 15.2.2 Unit housing and hoses

### 15.2.2.1 SURFACE CLEANING

- Clean the unit housing, cable, hoses and couplings on all its accessible surfaces by wiping surfaces thoroughly with a disposable, clean, non-linting cloth moistened with the suggested cleaning solution, ensuring that moisture does not enter critical areas of the device (e.g., power connections) until all visible soil (i.e., blood and fluids) is removed.
- In particular clean the following critical areas/items:
  - main switch (8),
  - control and display elements (chapter 11.1.1 “Front panel, control and display elements”),
  - water filling socket and screw cap (2),
  - unit couplings,
  - ventilations openings,
  - handles.
  - hose couplings, hoses external surfaces, Hansen quick couplings,
  - Hansen connection tube,
  - HC water discharge hose female.
- If using the aqueous alcohol solution (70% ethanol / 30% water), no rinsing is required, while if using other cleaning solution for sensitive medical devices, where rinsing of residuals is required, rinse all cleaned parts by wiping surfaces thoroughly with a damp, disposable, clean, non-linting cloth until all loosened soil and residual detergent is removed.
- Hand-dry using a disposable clean, non-linting cloth. Disposable cloths should be discarded after each use.



### Warning

- Residuals remaining on the surfaces might react with the disinfectant.
- Cleaning solution and water should be changed at each cleaning session and when visibly soiled.
- Chemical disinfection prior to cleaning is unnecessary, ineffective and of little value in the presence of organic matter.
- Drying prevents microbial growth and dilution of chemical disinfectants, which may render them ineffective.

#### 15.2.2.2 SURFACE DISINFECTION

After thorough cleaning, disinfect all accessible surfaces, power supply cable, hoses and couplings, ensuring that moisture does not enter critical areas of the device.

- In particular disinfect the following critical areas/items:
  - main switch (8),
  - control and display elements (chapter 11.1.1 “Front panel, control and display elements”),
  - water filling socket and screw cap (2),
  - unit couplings,
  - ventilations openings,
  - handles.
  - hose couplings, hoses external surfaces, Hansen quick couplings,
  - Hansen connection tube,
  - HC water discharge hose female.

Use a disposable, clean, non-linting cloth moistened with the recommended disinfecting solution.

Connect the device with power supply and switch on the unit only after the disinfectant has evaporated completely.

## 16 Maintenance - Servicing - System lifespan

Maintenance includes all measures which ensure the device is functioning properly and is free of damage in order to enable safe use for the intended purpose:

- Maintenance by the operator,
- Maintenance by authorized Technical Service Engineer,
- Repair by authorized Technical Service Engineer.



Interval	Task	Procedure by
After each use	System water emptying Perform routine disinfection (Intermediate Level) of the water circuits including hoses, couplings, Hansen connection tube and Water discharge hose Perform surface cleaning and disinfection of the device	Operator
Daily	Inspect water level Perform functional test Check hoses for water leaks.	Operator
Weekly	System water emptying Perform routine disinfection (Intermediate Level) of the water circuits including hoses, couplings, Hansen connection tube and Water discharge hose Perform surface cleaning and disinfection of the device	Operator
At regular basis according to clinical guidelines	Perform hygiene monitoring of water	Operator
Every 6 months	Perform descaling Check coupling seal rings Check hoses and Hansen connection tube for deterioration	Operator
Every 12 months	Check ventilation openings with external cleaning	Operator
	Inspection	Authorized Technical Service
Every 24 months	Replacement of water internal hoses Replacement of coupling seal rings	Authorized Technical Service

## 16.1 Maintenance by the Operator

This section contains all of the regular inspection and maintenance measures which are required to ensure the device is functioning properly and is free of damage.

### 16.1.1 DAILY TASKS

- Every day check that the water level in the tank is sufficient and perform functional test.
- In addition check hoses for water leaks.



#### Warnings

- If an error occurs during functional test, you must not continue to use the device. Notify to the Eurosets S.r.l. authorized Technical Service Engineer).

### 16.1.2 EVERY SIX MONTHS

- Check hoses and Hansen connection tube for deterioration. In case of damage or water leaks replace them with new ones.
- Check coupling seal rings, if damaged ask for their replacement to Eurosets S.r.l. authorized Technical Service Engineer.

### 16.1.3 EVERY TWELVE MONTHS

- Check the ventilation openings on both sides of the unit for dirt. Remove external dirt, as far as this is possible. Dust deposits inside the unit will reduce the performance of the system. Have the dirt inside the unit cleaned out by a Eurosets S.r.l. authorized Technical Service Engineer. Do not open the unit yourself.

## 16.2 Equipment

Make sure that Eurosets S.r.l. Customer Service or the Medical Engineer complies with the maintenance and safety related inspection intervals.

### 16.2.1 Device lifetime

Provided that the above-mentioned maintenance schedule and procedures are observed, the device lifetime is 10 years (120 months) from the date of delivery to the end customer/healthcare facility.

## 16.3 Water tank

Replacement of water in the water tank shall be done only following each disinfection process.

Perform emptying of the system as per chapter 15.1.1.1 “EMPTYING”.

After completion of disinfection process, perform water filling of the system as per chapter 13.2.1 “Filling the system with water”.

## 16.4 Maintenance and Repair by Authorized Technical Service

The regular maintenance by authorized Technical Service Engineer includes a safety check and extensive maintenance measures.

In order to maintain legal conformity and operational reliability the unit needs to be subjected to a safety related inspection every 12 months. The operator is solely responsible for the performance of this safety related inspection. This safety related inspection must only be performed by Eurosets S.r.l or a qualified person.



### Warnings

- The maintenance may only be carried out by a Service Engineer authorized by Eurosets S.r.l.

The safety related inspection covers at least the following points:

- Inspection of the device and application components for external damage, wear, aging and legibility of displays and inscriptions;
- Measurements of the protective conductor resistance and the earth leakage current according to the test equipment and manufacturer’s data;
- Inspection of all functions by following the operating instructions;
- Inspections of all safety functions acc. to manufacturer’s data;
- Inspection of all sensors acc. to manufacturer’s data.

For this purpose, Eurosets S.r.l provides a Service Manual for authorized persons.

In order to maintain conformity with statutory safety regulations we recommend to conclude a Safety Related Inspection Contract with Eurosets S.r.l., which in this case will carry out the annual safety related inspections.

Repairing restores the proper functioning of the device and ensures it is free from damage. It is necessary if, for example, a fault has occurred in the device.



### Warnings

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



### Warnings

- Repairs may only be carried out by a Service Engineer authorized by Eurosets S.r.l.



#### Note

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

### Send Device to Authorized Technical Service Point

- Switch off the device.
- Unplug the device from power supply.
- Empty the device completely (chapter 15.1.1.1 “EMPTYING”).
- Remove all accessories.
- Before packaging, perform disinfection process (chapter 15.1.2 “Intermediate level Disinfection process”).



#### Caution

For heavily soiled units or accessories returned to us for maintenance or repair, with which there is a suspicion of contamination by contact with specific pathogens (e.g., MRSA), the system must pre-disinfected in accordance with the recommended disinfecting process then packaged for transport. Otherwise, we reserve the right to reject such units or components for safety reasons, or, to subject these to additional treatment (chemo-thermal) before performing a technical revision or damage analysis. Any additional costs arising from this must be borne by the customer.

- Package the device so that it is protected from damage. If possible, use the original packaging or the packaging of the loaned or replacement device.
- Enclose a description of the problem together with the name, address, and telephone number of the contact person.

### Authorized Technical Service

For an inspection or repair, contact your local service agent.

We recommend the conclusion of a maintenance contract with Eurosets S.r.l.

Furthermore, maintenance by our experts ensures maximum operational reliability and longevity of the unit.

## Manufacturer

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## 17 Troubleshooting

This chapter contains important information for fault localization and trouble shooting. Please follow these notes to avoid dangers and damages.

### 17.1 Fault cases and troubleshooting



#### Caution

- Repairs on electric devices must only be carried out by skilled professionals, which may have been trained by the manufacturer.
- Inappropriate repairs can cause considerable dangers for the user and damage to the unit.



#### Note

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

FAULT	POSSIBLE CAUSES	ACTION
No or insufficient water circulation detected through water flow indicator (7)	1. Hoses kinked or heat exchanger obstructed or partially obstructed.	1. Ensure correct hose laying and positioning, ensure correct patency of heat exchanger, if patency cannot be restored replace heat exchanger
	2. Couplings are not engaged	2. Insert couplings firmly into each other
	3. Device positioned far below the heat exchanger / oxygenator	3. Position unit higher or the heat exchanger lower
	4. Pump worn/defective	4. Call Service*
	5. Air in system	5. Remove air from system
Couplings stiff	Seal rings dry and brittle	Replace seal rings
Coupling connection drips constantly	Outer, visible seal ring damaged or missing	Replace seal ring*
Coupling valve on the non-connected coupling drips constantly	1. Inner seal ring damaged	1. Call Service*
	2. Inner seal ring dirty/contaminated	2. Insert and loosen coupling several times, if necessary Call Service*
Alarm + display message: “ALARM TEST FAIL” “->CALL SERVICE”	1. Independent protection device defective 2. Pump electrically defective	Call Service*
Alarm + display message: “TEMP. DIFF. >1°C”	Coupling or decoupling of the exchanger / oxygenator during operation	Acknowledge alarm with “Audio paused” button
Alarm + display message every 10 minutes: “TEMP. DIFF. >1°C”	1. Coupling or decoupling of heat exchanger / oxygenator during operation	1. Acknowledge alarm with “Audio paused” button
	2. Cooling power insufficient	2. See next line
	3. Cooling elements or pump defective	3. Call Service*
	4. Bypass interrupted	4. Call Service*
Nominal value not reached during cooling	Cooling power insufficient because: 1. ambient temp. too high and/or 2. nominal value too low	Both these causes reinforce each other unfavorably, so that at least one cause must be needs to be changed.
Alarm + display message: “WATER LEVEL!?” Can be acknowledge for 10 mins. Using the “Audio paused” button	1. Water level too low	1. Refill water
	2. Unit not in horizontal position	2. Place unit horizontally
	3. Sensor deviation	3. Call Service*
Alarm + display message: “CHECK UNIT”	1. Various defects	1. Call Service*
	2. Water tank empty	2. Fill up water
	3. Sensor break/closure T1	3. Call Service*

FAULT	POSSIBLE CAUSES	ACTION
"-> CALL SERVICE"	4. Sensor closure T1	4. Call Service*
Alarm + display message: "CHECK UNIT" "-> TEMPERATURE LOW"	1. Unit too cold (<9°C)	1. Heat up unit at room temperature for some time*
	2. Sensor break T2	2. Call Service*
	3. Water tank frozen	3. Defrost unit*; examine unit for frost damage (is water flowing out of the unit?) → Call Service
Entire device not functioning audible alarm	1. Power supply failure	1. Switch off the unit, until the power returns
	2. Power supply plug has no contact	2. Check plug on unit and power supply socket for correct fit
	3. Fuse defective	3. Call service*
	4. Unit defective	4. Call service*

\* Switch off the unit immediately.

## 18 Waste disposal of old unit



Old electric and electronic equipment contain 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.

## 19 Limited warranty

The ECMOLIFE HC has been developed according to latest knowledge and is manufactured and tested by Eurosets s.r.l. in strict compliance with highest technical standards.

However, should any defects occur during the period of 12 months starting with the date of purchasing by the end user, we guarantee free of charge replacement of free of charge repair of defects caused by material, design or production faults.

Under the following conditions, among others, warranty becomes null and void.

- Damage caused by improper transport;
- Damage caused by environmental effects;
- Damage caused by improper handling;
- Use of impermissible accessories;
- Opening of the unit by unauthorized persons.





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The device must be shipped carriage free. EUROSETS S.r.l. does not assume any responsibility for damage to the device or its loss during transport.

## 20 Technical Data

<b>Article- No. (REF)</b>	<b>EU3941</b>
<b>Rated voltage</b>	230 VAC 50/60 Hz
<b>Power input</b>	320 W - 350VA
<b>Current consumption</b>	Approx. 1.5 A
<b>Nominal value range</b>	15-39°C
<b>Essential Performances</b>	Maintenance of the set temperature in the range from 15 to 39°C, with a maximum deviation of $\pm 1^\circ\text{C}$ .  Achievement of a maximum temperature in the heat exchanger always $< 41^\circ\text{C}$ .
<b>Safety system and shutdown</b>	Set temperature is monitored through a temperature regulation safety system. When the actual temperature deviates more than $\pm 1^\circ\text{C}$ with respect to nominal temperature a visual and acoustical alarm is emitted.  An autonomous safety system switches off the pump and heater immediately when a water temperature of 41.1-41.5°C is attained.  This shutdown leads to an achievement of a maximum temperature in the heat exchanger always $< 41^\circ\text{C}$ . In case of temperature above 41.1-41.5°C a visual and acoustic alarm is triggered. The pump can only be switched back on again once the water temperature has fallen below 41°C.
<b>Correction value</b>	0.5°C (water temp- temp. display)
<b>Sensor element</b>	2 x NTC 5 K
<b>Pump capacity</b>	Max. 5.5 l/min. max. 0.21 bar
<b>Warm-up time</b>	Approx. 5-10 mins. (20-37°C)
<b>Cooling-down time</b>	Approx. 5-10 mins. (20-15°C)

<b>Fuse rating</b>	2 x T 3,15 A; L 250V
<b>Class/type of protection</b>	 ,  type BF (defibrillation proof) Heat exchanger - type BF (defibrillation proof) applied part.
<b>Type of protection IP</b>	IP X1 (drip proof)
<b>Power supply</b>	Must correspond with IEC 60364-7-710:2002 Electrical installations of buildings - Part 7-710: Requirements for special installations or locations - Medical locations
<b>Risk class</b>	II b
<b>Ambient temperature</b>	10-30°C (heating operation) 10-23°C (cooling operation)
<b>Relative air humidity</b>	Approx. 30-70 %
<b>Transport / storage temp.</b>	3-60°C
<b>Air pressure</b>	700-1060 hPa
<b>Tank volume</b>	Approx. 0.5/0.8 l (min./max.)
<b>Permissible height difference</b>	Max 1 m (unit/heat exchanger)
<b>Dimensions (WxHxD)</b>	Approx. 200 x 290 x 440 mm
<b>Weight</b>	Approx. 17 kg (empty)
<b>Noise emission</b>	Approx. 50 dB(A) (1m)
<b>Alarm level</b>	>55 dB(A) (3m)
<b>Test basis</b>	Medical Product Directive 93/42/ECC, EN 60601-1, EN 60601-1-2

## 21 Guidelines and declaration of manufacturer

### 21.1 Electromagnetic Compatibility

<b>EMC Emissions</b>		
The device is suitable for use in the specified electromagnetic environment defined in this Instruction for use manual. The purchaser or user of the equipment should assure that it is used in an electromagnetic environment as described below:		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment</b>
RF Emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	Equipment suitable for use in domestic establishments (1) and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	NA	If the more stringent class B limits are passed, also the class A limits can be considered as fulfilled.

<b>EMC Immunity</b>			
The device is suitable for use in the specified electromagnetic environment. The purchaser or user of the equipment should assure that it is used in an electromagnetic environment as described below:			
<b>Immunity Test</b>	<b>EN 60601-1-2 Test level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment</b>
Electromagnetic discharge (ESD) EN 61000-4-2	enclosure Port, Patient coupling Port, Signal input/output Port: Contact: $\pm 8$ kV Air: $\pm 15$ kV	chap 4.2 and 4.5 EN 60601-1-2 Test Report	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	Input a.c. Power Ports: $\pm 2$ kV;	chap 4.2 and 4.5 EN 60601-1-2 Test Report	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	LtL: $\pm 1.0$ kV LtG: $\pm 2.0$ kV (Line to Line);	chap 4.2 and 4.5 EN 60601-1-2 Test Report	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips EN 61000-4-11	0 % U T for 0.5 cycle (1 phase) 0 % U T for 1 cycle 70 % U T for 25/30 cycles (50/60 Hz)	chap 4.2 and 4.5 EN 60601-1-2 Test Report	Mains power quality should be that of a typical commercial or hospital environment.

<b>EMC Immunity</b>			
The device is suitable for use in the specified electromagnetic environment. The purchaser or user of the equipment should assure that it is used in an electromagnetic environment as described below:			
<b>Immunity Test</b>	<b>EN 60601-1-2 Test level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment</b>
Voltage interruption EN 61000-4-11	0 % UT for 250/300 cycles and Sync Angle 0°.	chap 4.2 and 4.5 EN 60601-1-2 Test Report	Mains power quality should be that of a typical commercial or hospital environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m @ 50 or 60 Hz	chap 4.2 and 4.5 EN 60601-1-2 Test Report	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF EN 61000-4-3	3 V/m @ 80 MHz to 2.7 GHz - Professional Healthcare	chap 4.2 and 4.5 EN 60601-1-2 Test Report	Portable and mobile RF communication equipment should be used no closer to any part of the equipment, including cables,
RF Continuous Conducted EN 61000-4-6	3 V RMS outside the ISM band, 6 V RMS in the ISM band - Non-Life Supporting Equipment 150 kHz to 80 MHz	chap 4.2 and 4.5 EN 60601-1-2 Test Report	