ECMOLIFE SYSTEM

CE 0123

INSTRUCTIONS FOR USE

EU10583_ENG Rev.12 - 2023-04-03

INDEX

1. GENERAL INFORMATIONS

1.1. SAFETY NOTES

Information to draw the user's attention to potentially dangerous situations and to ensure correct and safe use of the device is indicated in the text as follows:

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

1.2. DEFINITIONS

ECMOLIFE SYSTEM:
Composed by ECMOLIFE Console, ECMOLIFE Motor driver, ECMOLIFE Bracket, ECMOLIFE Venous Probe, ECMOLIFE Flowmeter, ECMOLIFE Bubble Sensor and ECMOLIFE Pressure Sensors.

ECMOLIFE FLOMETER:
Corresponds to

- Clamp on Transducer SCT 3/8" X 3/32" (Adult/Paediatric configuration)
- Clamp on Trasducer SCT 1/4" X 3/32" (NEW BORN Configuration),
- ECMOLIFE Flowmeter 3/8'' X 3/32''(Adult/Paediatric configuration),
- ECMOLIFE Flowmeter 1/4'' X 3/32'' (NEW BORN Configuration).

ECMOLIFE PRESSURE SENSOR:
Corresponds both to LOGICAL PRESSURE TRANSDUCER assembled with SMITH MEDICAL PRESSURE SENSOR, EDWARDS PRESSURE TRANSDUCER and DISPOSABLE PRESSURE SENSOR

ECMOLIFE BUBBLE SENSOR:
Corresponds to:

- AIR SENSOR 3/8'' X 3/32'' ECLS,
- AUXILIARY AIR/FLOW SENSOR 3/8'' x 3/32''
- AUXILIARY AIR/FLOW SENSOR 1/4'' X 3/32''.

ECMOLIFE CONSOLE:
Main electronic unit of ECMOLIFE System for operating, powering, controlling and regulating the operation of ECMOLIFE Motor driver.

DISPOSABLE CENTRIFUGAL PUMP:
Magnetic non-occlusive blood pump consisting in a rotating impeller arranged with vanes inside a plastic housing with inlet and outlet ports. Blood is moved by centrifugal force with bearing-less magnetic levitation generated by ECMOLIFE System.

HIGH PRIORITY ALARM:
Indicates that immediate intervention by the OPERATOR is required.

MEDIUM PRIORITY ALARM:
Indicates that timely intervention by the OPERATOR is required.

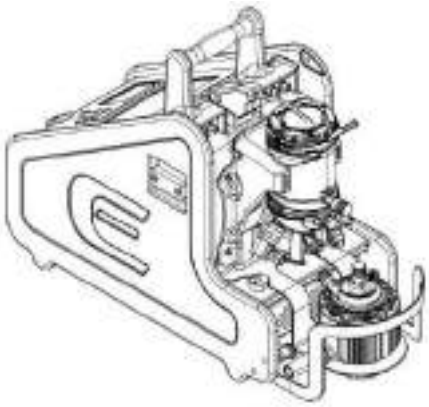
LOW PRIORITY ALARM:
Indicates that something requires the attention of the OPERATOR.

RESPONSIBLE ORGANIZATION:
The organization responsible for the use and the maintenance of the device. The RESPONSIBLE ORGANIZATION can be, for example, a hospital or a medical practitioner.

APPLIED PART:
The part of the ECMOLIFE System which, under normal conditions of use, is in physical contact with the patient in order to fulfil its function.

1.3. DESCRIPTION

ECMOLIFE System active medical device is composed by a programmable console (ECMOLIFE Console), a bearing-less motor driver (ECMOLIFE Motor driver) and sensors for blood parameters detection. The console features an integrated backup unit to be used in case of primary unit failure; additionally a backup motor driver and flowmeter are provided to ensure support continuity in case of need.



1.4. INTENDED PURPOSE

Extra-corporeal perfusion pump system intended to pump blood in extra-corporeal circulation for pulmonary/cardiac/circulatory support.

1.5. PATIENT POPULATION

Within the specified rated blood flow, the ECMOLIFE System, when used in combination with Eurosets Disposable Centrifugal Pump, can be used on patients specified on Eurosets Disposable Centrifugal Pump instructions for use.

1.6. INDICATIONS FOR USE

Within the specified rated blood flow, the ECMOLIFE System, when used in combination with Eurosets Disposable Centrifugal Pump, is indicated for the following medical support procedures: CPB, LVAS, RVAS and ECMO for full or partial cardiac, circulatory and pulmonary support.
ECMOLIFE System shall be used in combination with the medical devices listed in section “MEDICAL DEVICES FOR USE WITH ECMOLIFE SYSTEM”.

1.7. CONTRAINDICATIONS

No contraindications.

1.8. INTENDED USER AND ENVIRONMENT

ECMOLIFE System is intended to operate in the following hospital environments: Operating Room, Catheter Laboratory, Emergency Room, Intensive Care Unit and during intra-hospital and inter-hospital patient transportation from one to another Unit or Hospital.
ECMOLIFE System is intended to be used by qualified healthcare professionals specifically trained in the field of extracorporeal circulation: Perfusionists (Thoracic Cardiovascular Surgery - OR), Intensivists, ICU Nurses (ICU), Emergency physicians / Intensivists (ER), Cardiologist (CathLab).

1.9. CLINICAL BENEFITS

ECMOLIFE System contributes to achieve the following potential clinical benefits:

- improve survival rate respect the conventional (and/or medical) therapy;
- allow to perform CPB procedure.

1.10.RISKS AND SIDE EFFECTS

Possible risks and side effects include but are not limited to:

- Adverse reaction of the blood or the tissues to the extracorporeal perfusion system (e.g. activation of the coagulation system, inflammatory response, SIRS, thrombocytopenia, platelet dysfunction, disseminated intravascular coagulation, Allergic reaction, Anaphylactic shock, Systemic Toxic effects);
- Bleeding/Haemorrhage;
- Environmental damage (e.g. electromagnetic interference, fire, user contamination);
- Excessive blood flow: injury to circulatory system, hyperoxia;
- Haemodilution;
- Haemolysis (anemia, thrombosis, hypertension, stroke, shock);
- Hyperthermia;
- Hypovolemia;
- Hypotension;
- Infection/sepsis;
- Insufficient blood flow: insufficient oxygenation of blood (hypoxia, hypoxemia, brain injury, metabolic acidosis), insufficient CO2 removal (respiratory acidosis, hypercapnia), hypothermia;
- Stroke/CVA (ischemic/hemorrhagic);
- Thrombosis / thromboembolism.

These are the potential side effects of all extracorporeal blood circulation systems.

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.

1.11.GENERAL WARNINGS

1.11.1. WARNINGS FOR THE DEVICE

- The Instruction for Use Manual accompanies each ECMOLIFE System in paper format.
- The Instruction for Use Manual is also provided on Eurosets website.
- In case of incorrect visualization of Use Manual on Eurosets website. In addition, contact the technical service.
- The device must be used in accordance with these instructions. EUROSETS cannot be held responsible for damage deriving from improper use.
- Do not use the device for any purpose other than indicated. Use of the device for any other purposes is the responsibility of the user.
- Read these instructions together with Eurosets Disposable Centrifugal Pump instructions for use carefully before use. The device is intended for use in the hospital and institutional environment where healthcare professionals provide patient care. The device is intended for use by properly trained personnel under the direct supervision of a licensed physician.
- Do not use the device if the package is damaged.
- The product may only be operated and monitored by qualified medical staff.
- The incorrect reuse and reprocessing can compromise the electrical safety of the device and result in electric shock, insufficient insulation, and an unintended increase in the temperature of the device.
- Only use the ECMOLIFE CONSOLE as the drive for the Eurosets DISPOSABLE CENTRIFUGAL PUMP.
- Have a replacement set at the ready.
- Always keep 4 metal tube clamps at the ready.
- Do not install devices different from ECMOLIFE Bracket on left/right rails.
- Electromagnetic interference:
  - Do not use the device in the proximity of equipment not sufficiently screened from electromagnetic emissions higher than those indicated in IEC 60601-1-2: 2014+AMD1:2020.
  - This device/system may cause radio interference or may interfere with operation of nearby equipment, and mitigation measures may therefore be necessary, such as reorienting or relocating the ECMOLIFE System or shielding the environment.
- Stop immediately the use of the device through the emergency switch button in case of fire/smoke from the device.
- Reusable device. Do not discard after use.
- Do not dispose of WEEE (waste electric and electronic equipment) as solid household waste but collect it separately; the device can be returned to distributors/manufacturer. Hazardous substances contained in electrical equipment may be carcinogenic to man if dispersed into the environment.

1.11.2. WARNINGS FOR THE PATIENT

- The device user must always maintain full responsibility for proper perfusion and patient safety in all procedures.
- Before using carefully read the ELSO guidelines. Respect the absolute and relative contraindications of the ELSO guidelines. Any consequences of use on patients with absolute and / or relative contraindications are the responsibility of the user.
- It is the clinician's responsibility to ensure that all device settings are appropriate, even when "automatic" features such as default alarm setting are used. Ensure the alarm limits are appropriately set before you place the patient on the device preventing possible patient injury. Although you can set all alarms rapidly using the default alarm function, some settings are not appropriate under all clinical conditions.
- Eurosets recommends setting the alarms limits prior to start the procedure. If circumstances force to use the default alarm function, verify the correctness of the settings at the earliest opportunity.
- Do not silence the audible alarm when leaving the patient unattended.
- Locate the ECMOLIFE System close to the patient.
- Check the sensor cable integrity before starting the patient treatment.
- Observe the permissible maximum values for water temperature, water pressure, blood flow and pressure on the blood side.
- Monitor the blood temperature, the blood flow and the pump speed.
- Always ensure that the patient has a sufficiently high hematocrit and adequate blood volume. Substitute any losses in good time by administering red blood cell concentrates and, if necessary, physiological volume replacement solutions.
- Gently release occlusion on the blood outlet side when the pump is operating at high speed, sudden acceleration of the blood flow may cause negative pressure at the blood inlet side which can lead to collapse of the ventricle or blood vessels, inlet cannula obstruction, air aspiration, outgassing, cavitation and increased risk of embolism.

1.11.3. WARNINGS FOR THE PATIENT TRANSPORT

- If the patient is repositioned or transported, there is a risk of decannulation caused by strain on the tubing and mechanical damage. The greatest care should therefore be exercised when carrying out the safety measures.
- ECMOLIFE SYSTEM can be used for intra-hospital and inter-hospital patient transport.
    - Before transporting the patient, make sure that there is sufficient oxygen in the gas bottle and ECMOLIFE Console batteries are charged.
    - Take care during transportation in confined spaces, such as doorways and elevators.
    - Prevent the patient cooling down during transportation (e.g. with aluminum foil or heating mats), if it is not possible to connect a heater-cooler unit.

1.12.CAUTION

- This device is made of precision components. Do not drop it or subject it to strong impact. Never attempt to disassemble it.
- Do not wet the device except when cleaning the outer casing as described in Cleaning section.
- Only use the power supply cord provided.
- Any attempt to modify the ECMOLIFE System hardware or software without EUROSETS express written approval automatically voids all warranties and liabilities.
- Never operate the Disposable Centrifugal Pump without liquid.
- Avoid mechanical impacts and knocks.

1.13.MEDICAL DEVICES FOR USE WITH ECMOLIFE SYSTEM

ECMOLIFE System is conceived to be used in combination with the COLIBRÌ System and/or Eurosets Disposable Centrifugal Pump and/or Eurosets Tubing Sets and/or Eurosets Ooxygenators or other commercially available (CE Marked) Tubing Sets and/or oxygenators approved for the concerned application. Check device intended purpose, max use period and technical features, available on instructions for use for each medical device to ensure suitability of the device for the intended purpose.

Eurosets Disposable Centrifugal Pump is available in the following configurations:

- ECMOLIFE Centrifugal Pump standard model, present as standalone product ref. AG5078, or included in perfusion tubing sets;
- ECMOLIFE Centrifugal Pump with Pdrain port located on blood inlet port, included in perfusion tubing sets only, permanently connected with pressure monitoring probe;
- NEW BORN Centrifugal Pump standard model, present as standalone product ref. AG5087, or included in perfusion tubing sets;
- NEW BORN Centrifugal Pump with Pdrain port located on blood inlet port, included in perfusion tubing sets only, permanently connected with pressure monitoring probe.

Warning
For each medical device used in combination with ECMOLIFE System instructions for use shall be consulted.

1.14.SYMBOLS DESCRIPTION

Symbol	Explanation	Symbol	Explanation
	Manufacturer		CLASS II equipment
	Date of manufacture		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
	Serial number		Atmospheric pressure limitation
	Catalogue number		Temperature limit
	Do not use if package is damaged and consult instructions for use		Humidity limitation
	This way up		On/Off (Push/push)
	Fragile, handle with care		Refer to instruction manual / booklet
	Keep dry		Caution
	Keep away from sunlight		Collect separately as electric equipment
	Acoustic alarm pause (temporarily silenced)		External cord connected
	Acoustic alarm acknownledge (permanently silenced)		Battery charge status indicator
	Device Weight [kilograms]		Medical Device
	Planned preventive maintenance date (month/year)		

1.15.TRANSPORT AND STORAGE CONDITIONS

For storage and transport conditions refer to paragraph TECHNICAL SPECIFICATIONS.

1.16.LIMITED WARRANTY

The ECMOLIFE System is guaranteed for 12 months from the date of purchase as long as the device has not been modified and/or tampered with by unauthorized persons.

THE WARRANTY DOES NOT COVER:

- Failures and faults caused by improper use of the device, tampering or negligence,
- Operations performed for presumed defects or modifications made for convenience,
- Parts subject to normal wear.

In accordance with the above-mentioned conditions, in the event of malfunctioning, send the device together with the warranty certificate and a copy of the delivery note or the purchase invoice to:

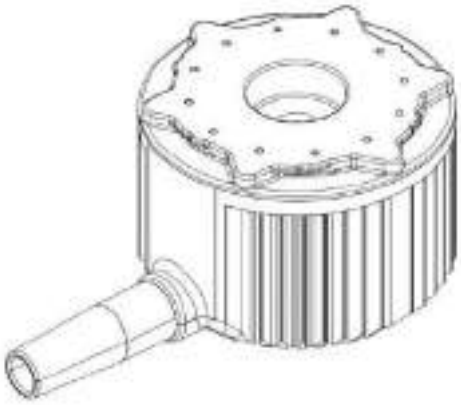
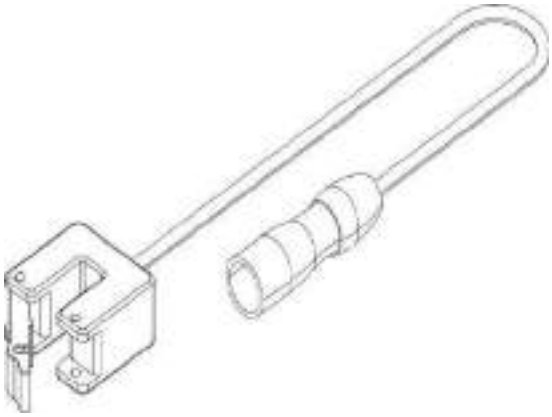
EUROSETS S.r.l.
Strada Statale 12 n°143
41036 Medolla (MO) ITALY

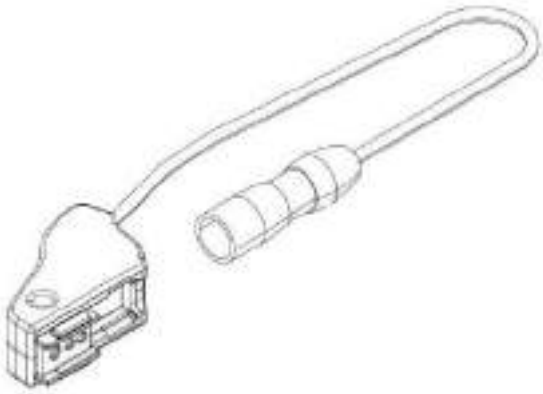
The device must be shipped carriage free. EUROSETS S.r.l. does not assume any responsibility for damage to the device or its loss during transport.

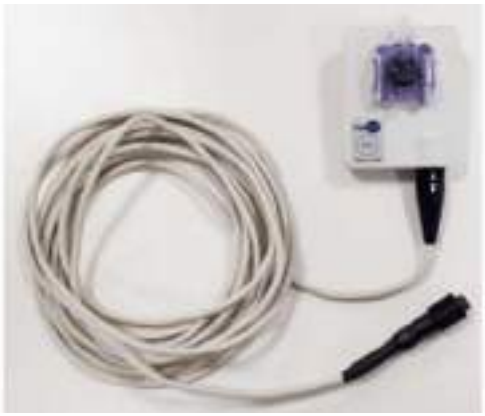
2. SYSTEM COMPONENTS

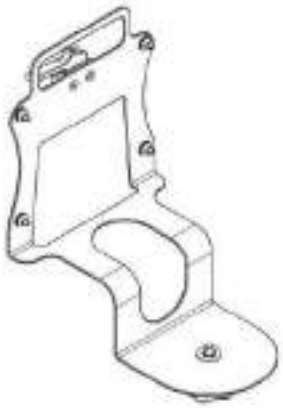
2.1. GENERAL DEVICE DESCRIPTION

ECMOLIFE System is composed by:

EU5085 - Console	
EU10566 – Motor driver	
EU10574 – Bubble sensor	
EU6727 - AUXILIARY AIR/FLOW SENSOR PROBE 3/8x3/32 (Valid only for device with the Colibrì connector on the front panel)	

EU6729 - AUXILIARY AIR/FLOW SENSOR PROBE 1/4''x3/32'' (Valid only for device with the Colibrì connector on the front panel)	
EU3896 – Venous probe	
EU1900 – Clamp on transducer SCT 3/8” x 3/32”	
EU1901 – Clamp on transducer SCT 1/4” x 3/32”	

EU6726 - ECMOLIFE FLOWMETER 3/8''x3/32'' (Valid only for device with the Colibrì connector on the front panel)	
EU6726 - ECMOLIFE FLOWMETER 1/4''x3/32'' (Valid only for device with the Colibrì connector on the front panel)	
MX960P1 – Logical pressure transducer EU3895 – Smith medical pressure cable	
EU6734 - Cable EDWARDS-ECMOLIFE	

EU11108 ECMOLIFE-COLIBRÌ CABLE	
EU3897 - Bracket	

ECMOLIFE System primary unit have integrated sensors to measure the following parameters:

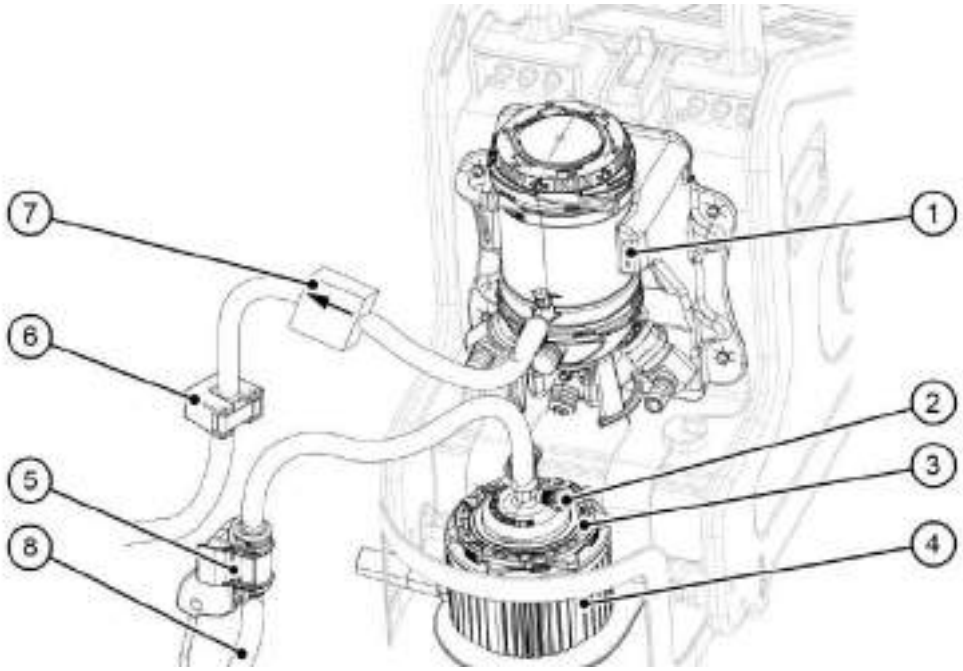
- EU3896 - Venous probe: Venous oxygen saturation (SvO2),
- EU3896 - Venous probe: Haemoglobin (Hb),
- EU3896 - Venous probe: Venous blood temperature (Tv),
- EU3895 - Smith medical pressure cable with MX960P1 – Logical pressure transducer or EU6734 – Cable EDWARDS-ECMOLIFE: Patient drainage pressure (Pdrain),
- EU1900 - Clamp on transducer SCT 3/8” x 3/32” or EU1901 – Clamp on transducer SCT 1/4” x 3/32” or EU6726 - ECMOLIFE FLOWMETER 3/8’’x3/32’’ or EU6726 - ECMOLIFE FLOWMETER 1/4’’x3/32’’: Blood flow (LPM), Pump speed (RPM),
- EU3895 - Smith medical pressure cable with MX960P1 – Logical pressure transducer or EU6734 - Cable EDWARDS-ECMOLIFE: Pre-oxygenator pressure (Pin),
- EU3895 - Smith medical pressure cable with MX960P1 – Logical pressure transducer or EU6734 - Cable EDWARDS-ECMOLIFE: Post-oxygenator pressure (Pout),
- EU10574 - Bubble sensor or EU6727 - AUXILIARY AIR/FLOW SENSOR PROBE 3/8x3/32 or EU6729 - AUXILIARY AIR/FLOW SENSOR PROBE 1/4’’x3/32’’: Air bubble presence in the blood return tube.

Caution
Do not cover the bearing-less motor in order to allow a proper heat dissipation.

2.2. CONSOLE

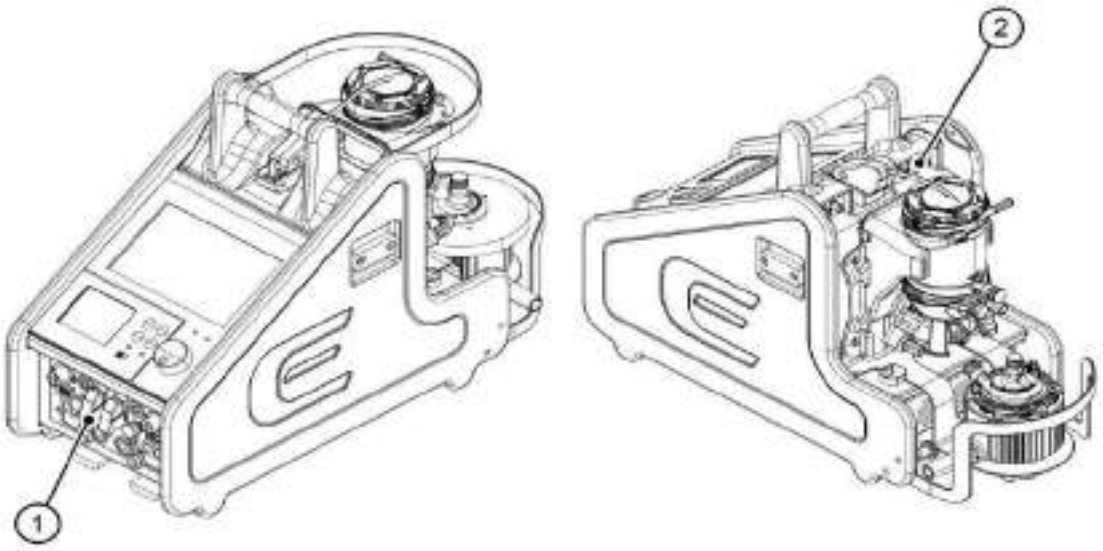
The console parts are assembled as shown below:

1. ECMO Module
2. ECMOLIFE Pressure sensor
3. Disposable Centrifugal Pump
4. ECMOLIFE Motor driver
5. ECMOLIFE Venous probe
6. ECMOLIFE Bubble sensor
7. ECMOLIFE Flowmeter
8. Tubing set



The console functioning can be managed through these panels:

1. Front panel
2. Rear panel



ECMOLIFE System is featured by an integrated backup system, defined as backup unit. Added to the primary system, it acts as a replacement of the primary unit if this fails or it’s damaged.

2.2.1. FRONT PANEL

On the front panel two separated areas are identified: Primary Unit on the left side while Backup Unit on the right side.

Warning

- Make sure that the power supply is available and the battery charge is full.
- The protective cap must always be placed in the relevant connectors if they are not used.
- Do not allow tubes or cables to hang down.
- Ensure that there is no strain on tubes or cables.
- Avoid kinking of tubes or cables.

PRIMARY UNIT (left side)

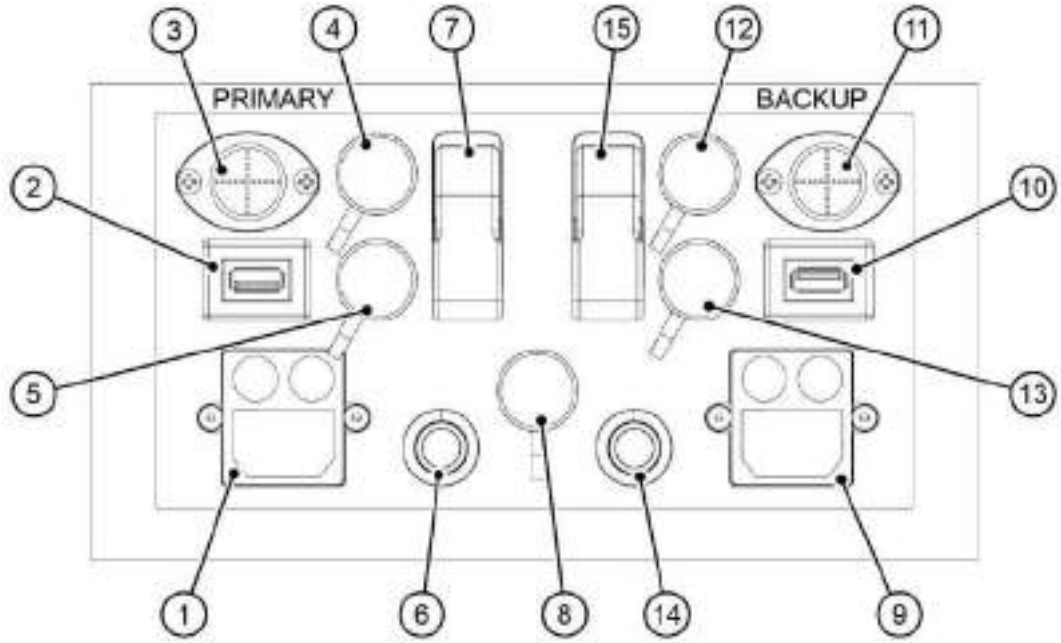
The Primary Unit located on the left side area is composed by:

1. Primary Main Power Supply connection;
2. Primary USB connection (data download and software update);
3. Primary Motor driver connection;
4. Primary Flowmeter connection;
5. Primary Auxiliary power supply connection;
6. Primary Power ON/OFF button;
7. Primary Emergency Switch (instantaneously interrupt the Primary power supply).
8. Primary Colibrì connector.

BACKUP UNIT (right side)

The Backup Unit located on the right side area is composed by:

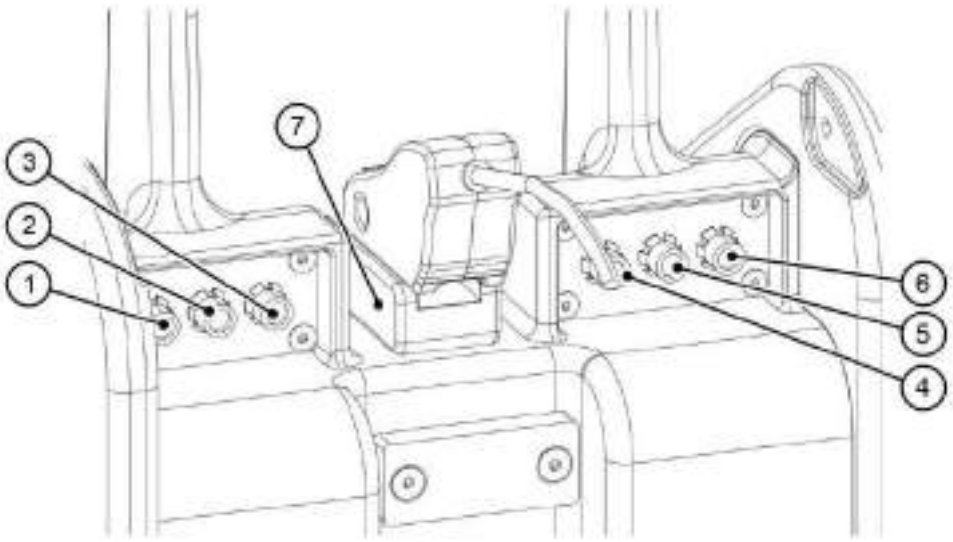
9. Backup Main Power Supply connection;
10. Backup USB connection (data download and software update);
11. Backup Motor driver connection;
12. Backup Flowmeter connection;
13. Backup Auxiliary power supply connection;
14. Backup Power ON/OFF button;
15. Backup Emergency Switch (instantaneously interrupt the Backup power supply)



2.2.2. REAR PANEL

The rear panel is composed by:

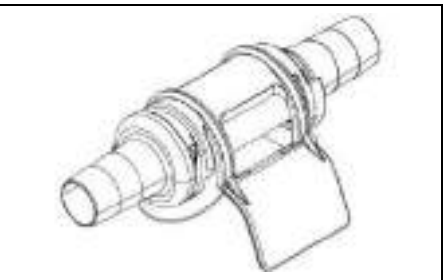
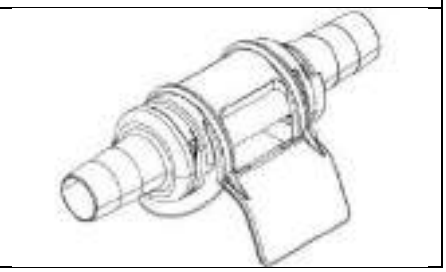
1. Pressure sensor P_{drain} socket;
2. Pressure sensor P_{in} socket;
3. Pressure sensor P_{out} socket;
4. Venous probe sensor socket;
5. Air Bubble sensor socket;
6. Pressure sensor P3to1 socket;
7. Venous probe holder.



3. SENSORS SETUP ON TUBING

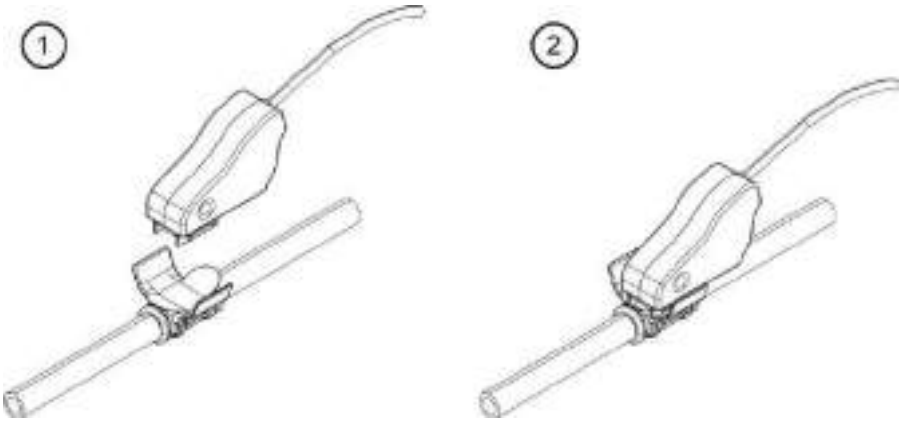
3.1. DISPOSABLE CUVETTE FOR VENOUS PROBE AND CONNECTION ON TUBING SET

The Venous Probe shall be used only in conjunction with the 3/8” – 3/8” or 1/4 – 1/4’’ disposable polycarbonate cuvette to be installed in the venous line tubing. The cuvette is available both with and without internal phosphorylcholine coating. For a proper cuvette connection, tubing size shall be 3/8” or 1/4” and tightness shall be ensured by means of tie wraps. Cuvettes ref. and details are given in the table below.

Ref.	Description	Tubing size	
EU3864	Arterial and venous cuvettes 3/8” – 3/8”	3/8” – 3/8”	
AG3864	Arterial and venous cuvettes 3/8” – 3/8” coated	3/8” – 3/8”	
EU3874	Arterial and venous cuvettes 1/4” – 1/4”	1/4” - 1/4”	
AG3874	Arterial and venous cuvettes 1/4” – 1/4” coated	1/4” - 1/4”	

3.2. VENOUS PROBE CONNECTION ONTO THE DISPOSABLE CUVETTE

To connect the venous probe onto the disposable cuvette press it onto the cuvette until retaining tabs click is heard signaling the probe is locked in place as shown below.
Check that the sensor probe is properly and securely attached to the cuvette.



Venous probe correctly installed onto the cuvette

Venous probe incorrectly installed onto the cuvette

Remove venous probe from cuvette by pressing the retaining tabs with the fingers. The retaining tabs will expand releasing the probe.

3.3. CLAMP-ON TRANSDUCER (FLOWMETER) CONNECTION ON THE TUBING

Connect the flowmeter to the tubing as shown below.

Caution
Check that the sensor is free from contamination or dust.

The flowmeter must be correctly installed on the tubing following the flowmeter arrow indicating the blood flow direction. The same procedure applies for backup unit flowmeter installation.

Warning

- Do not connect two flowmeters to tubings at the same time in order to not increase leakage current on device enclosure.
- A backup flowmeter must be available in promixity of the device, next to the console.

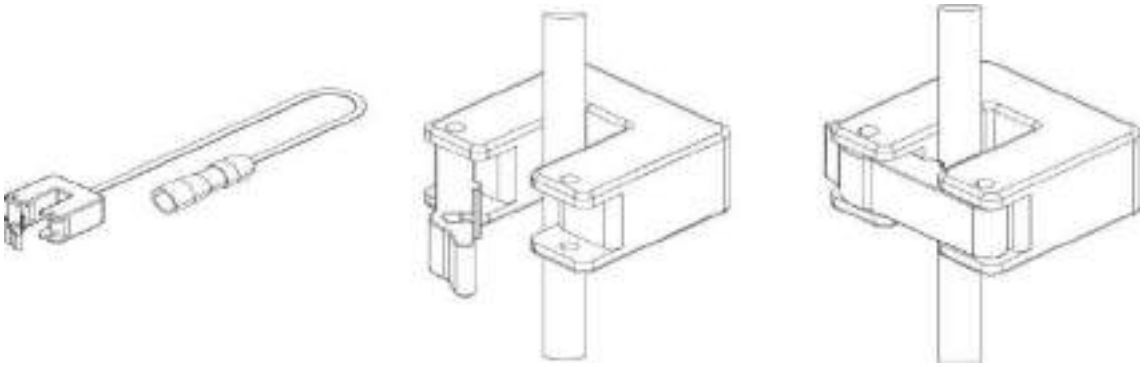
3.4. ECMOLIFE AND LANDING MONITOR FLOW MEASUREMENT

In order to achieve an adequate corrispondance between the LANDING monitor flow measure and ECMOLIFE console flow measure make sure that the two flowmeter are attached to a 15cm straight tube before and after the transducers.

Check the indications on the EUROSETS tubing set in order to identify the suggested flowmeter positioning in order to minimize the flow turbulence and the associated measurement inaccuracies related to the sensor.

3.5. BUBBLE SENSOR CONNECTION TO THE TUBING

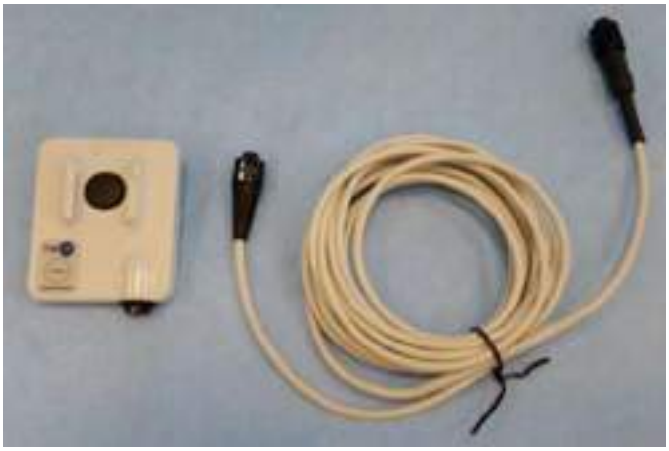
Connect the bubble sensor to the tubing as shown below.
Make sure that the sensor is correctly closed, pushing the clamp-on by pressure.

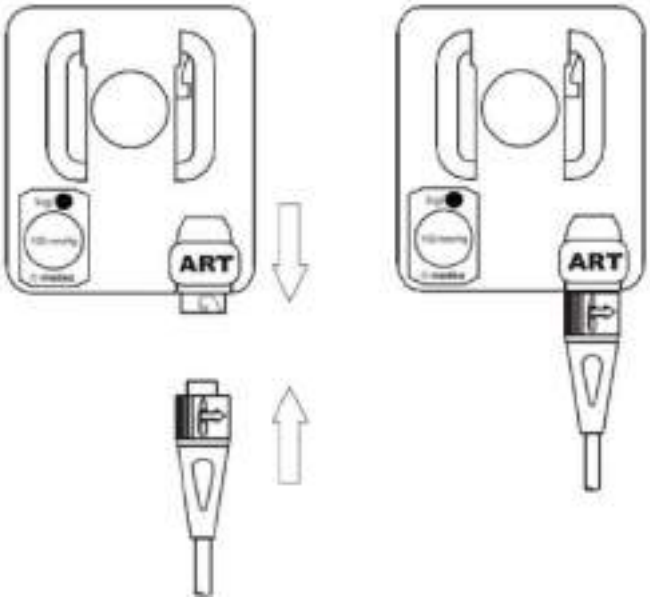


The air bubble sensor must be located on the patient return line at a distance of at least 50 cm from inlet of the cannula.

3.6. LOGICAL PRESSURE TRANSDUCER AND SMITH MEDICAL PRESSURE SENSOR CONNECTION TO THE ECMOLIFE CONSOLE

Connect the Logical Pressure Transducer to the connecting cable as indicated in the following images.
During the insertion the operator shall hear a click sound.





Insert the cable to the relevant pressure connector (Pin – Pout –Pdrain) on ECMOLIFE console.
For the assembly of Single use MEDEX (Smith Medical) pressure transducer refer to relevant instructions for use.

Ref.	Description	
EU1589	Single use MEDEX (Smiths medical) pressure transducer – type MX960	

Caution
MEDEX pressure transducers shall be used for a maximum of 96 hours.

3.7. EDWARDS PRESSURE SENSOR CONNECTION TO THE ECMOLIFE CONSOLE

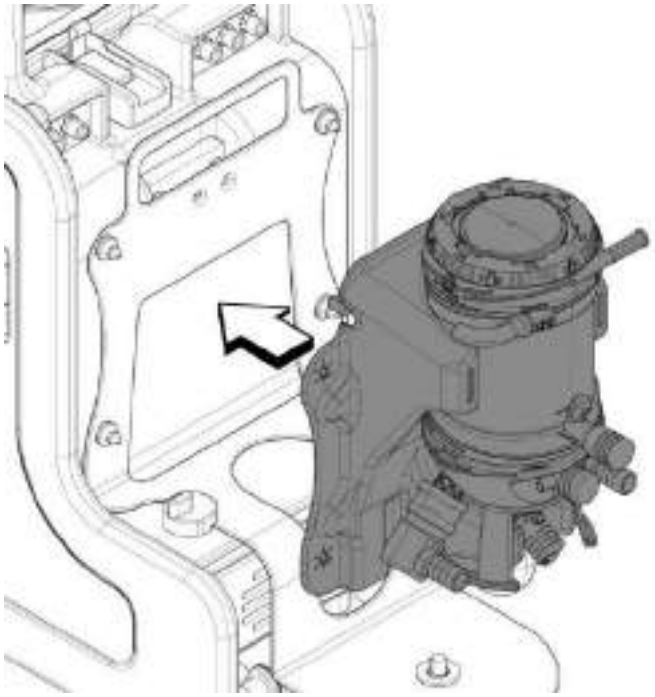
Insert the cable to the relevant pressure connector (Pin – Pout –Pdrain) on ECMOLIFE console.
For the assembly of Single use EDWARDS Pressure transducerr refer to relevant instructions for use.

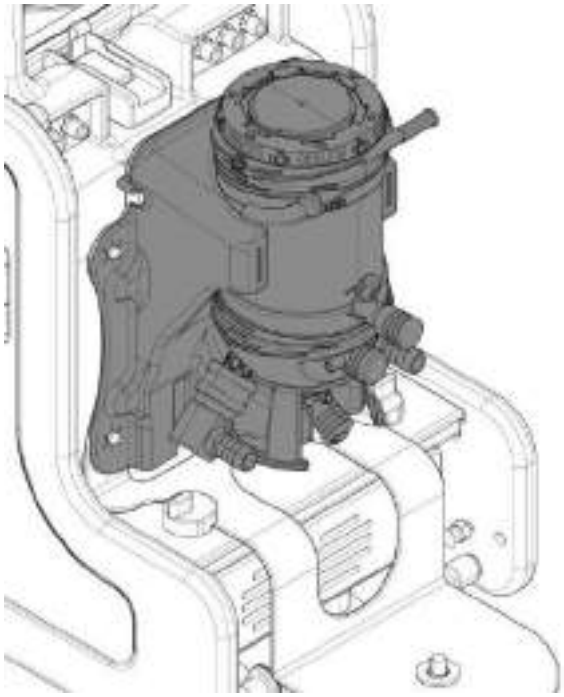
Ref.	Description	
T100209B	EDWARDS pressure transducer	

Caution
EDWARDS pressure transducers shall be used for a maximum of 96 hours.

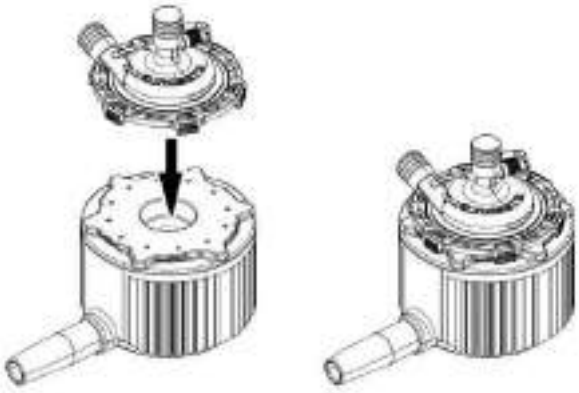
4. DISPOSABLE CENTRIFUGAL PUMP AND OXYGENATOR SETUP

1. Exctract the ECMOLIFE disposable set from the package and lock the Oxygenator plastic holder to the four bracket pins





2. Ensure the ECMOLIFE Centrifugal System is ready, electrically connected with mains and flowmeter plugged in.
3. Ensure the ECMOLIFE Centrifugal System RMP is turned to Zero.
4. Insert blood pump on motor driver receptacle.



Caution

- Blood pump is magnetically attracted on motor driver receptacle.
- While inserting the blood pump keep it firmly in the hands to avoid fingers or skin pinching between pump and motor driver.

5. Rotate clockwise the locking ring while pressing it, until full locking (click) is achieved.

Caution

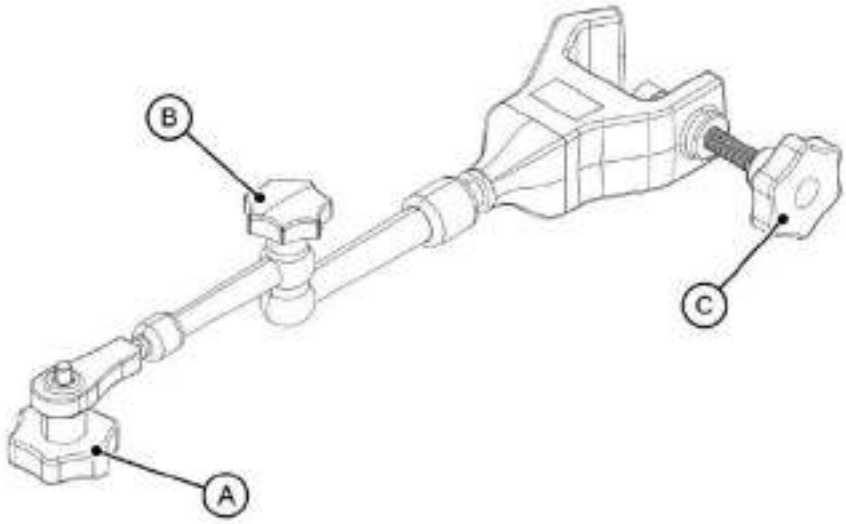
If locking fails, replace blood pump with a new one.

6. If a most convenient pump orientation is desired, to better place blood inlet and outlet tubings, unlock the pump with one hand by rotating counter-clockwise the locking ring, adjust pump orientation with the other hand, then lock again.

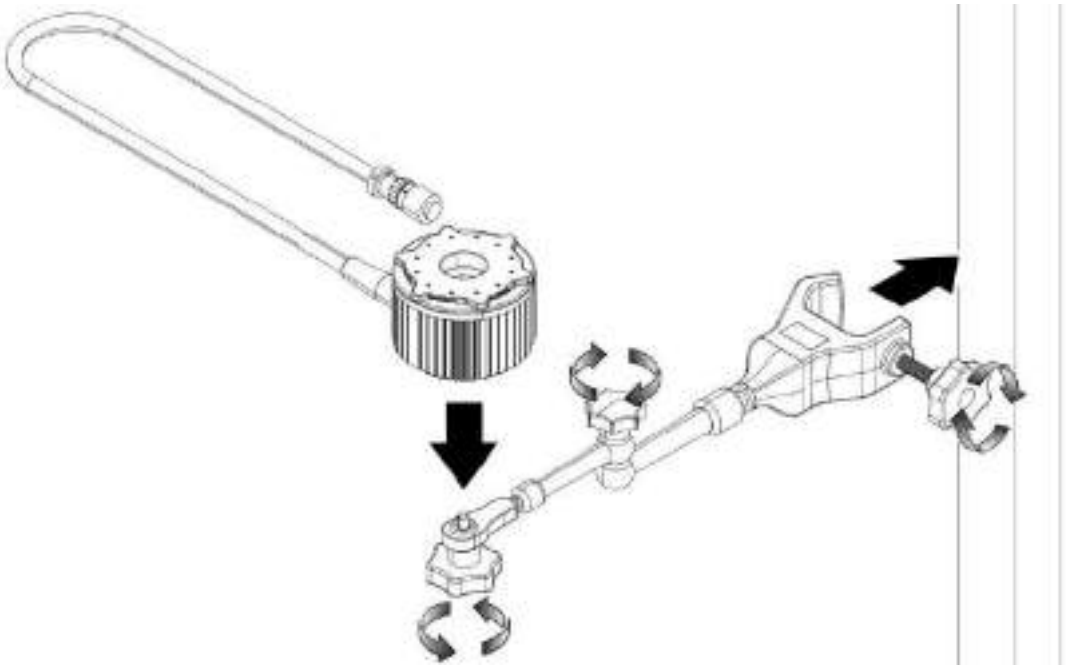
Warning

Eurosets Disposable Centrifugal Pump instructions for use shall be consulted.

5. ECMOLIFE DRIVER MOTOR HOLDER AND SETUP



1. Extract the “EU2511 Ecmolife holder motor driver” from the package and use the central knob (**A**) to loose or tight the holder in the desired position
2. Use the front knob (**B**) to attach the holder motor driver to the pole
3. Use the rear knob (**C**) to fix the driver motor to a pole

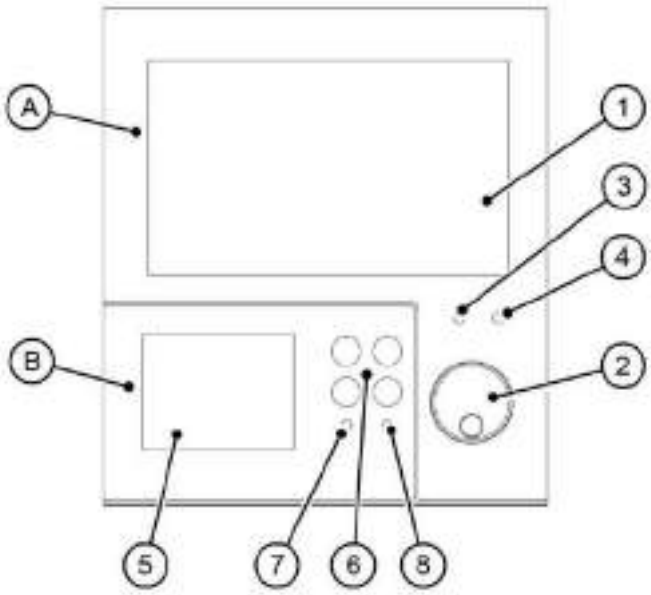


6. DISPLAY

DISPLAY SUBDIVISION

On the display panel two separated areas are identified:

A. Primary Unit
B. Backup Unit



Primary Unit display

The Primary Unit display is composed by:

1. a 8,1” Touch display;
2. a knob;
3. a Led RGB battery;
4. a Led RGB alarm.

Backup Unit display

The Backup Unit display is composed by:

5. a 3,5” Touch display;
6. 4 membrane buttons;
7. a Led RGB battery;
8. a Led RGB alarm

Warning

- A backup motor must be available in proximity of the device, next to the console.
- Check the activation of Alarm LED. In case of failure in the activation the use of the device must be interrupted.
- Eurosets disclaims the relevant risk of a use of a device with backup section not tested.

7. PRIMARY UNIT

7.1. DISPLAY

STATUS BAR

On the top of touchscreen there is the status bar with the following settings:

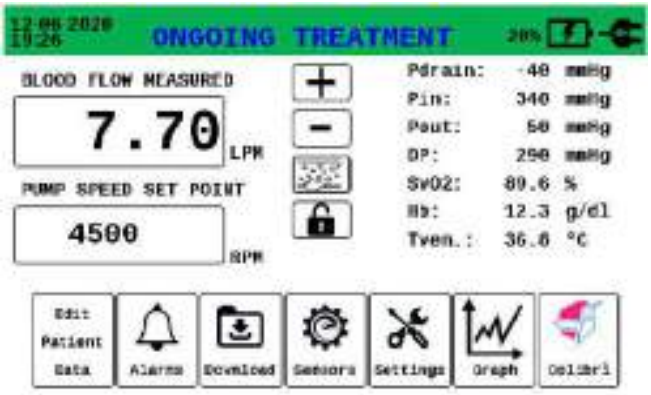
1. Date and Time;
2. Title of the active page;
3. Charge status Symbol and remaining time;
4. Main power supply indicator: connected / disconnected.

The status bar color indicates priority of ongoing alarm:

Color	Priority
Red	High priority alarm
Yellow	Medium priority alarm
Blue	Low priority alarm
Green	Normal operations

If several alarms are simultaneously present with the same priority, the status bar will show the one more recently actuated.
If several alarms are simultaneously present with different priority, the status bar display will show the higher priority alarm first then the others in order of priority then appearance.
The touchscreen underlines alarms also by highlighting the parameter concerned (See the alarm section).

CENTRAL PART



The central part of the display is divided into the following main sections.

Primary settings

The left section is dedicated to primary treatment parameters as blood flow and pump speed. During the navigation into the several sections provided by toolbar, this section will be relocated in the upper part of central area so that the data is ALWAYS displayed.

Secondary settings

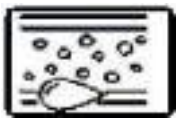
The right section is dedicated to secondary and/or browsing parameters. During the navigation into the several sections provided by toolbar, this section will be relocated in the upper part of central area so that the data is ALWAYS displayed.

Main buttons

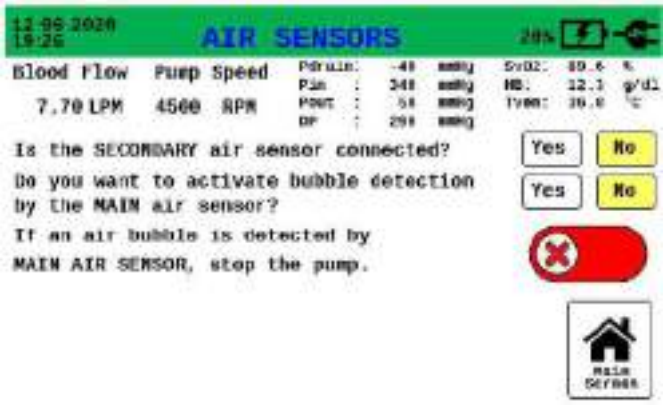
In the center of the screen the following buttons are displayed:

- +/- buttons: to increase/decrease parameters value;
- BUBBLE SENSORS MANAGEMENT MENU: to enable/disable bubble detection functionality and enable/disable of pump stop functionality;
- SCREEN LOCK button: if kept pressed for 3 seconds, it activates the display screen lock.

BUBBLE SENSORS MANAGEMENT MENU



In this section you can enable or disable the air bubble detection.
By default, the air bubble detection is not activated.

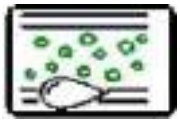


Through this menu it is possible to:

- Enable/disable air bubble detection by the primary sensor;
- Enable/disable air bubble detection by the secondary sensor.

If the bubble detection is not activated the icon menu will be updated as follow:

If the bubble detection is activated by main and/or secondary sensor the icon menu will be updated as follow.



If the main sensor is in fault condition or disconnected by the tubing set from at least 1 minute, the menu icon will be updated as follow:

Through this menu, you can enable the pump stop function.
The pump stop function can only be activated if air bubble detection is active for the primary bubble sensor. The pump stop function will stop the pump if an air bubble of 50 microlitres is detected. in this condition, the corresponding alarm is activated and the pump speed is set to 0 RPM.

If the pump stop function is activated, the icon menu will be updated as follow:

Toolbar

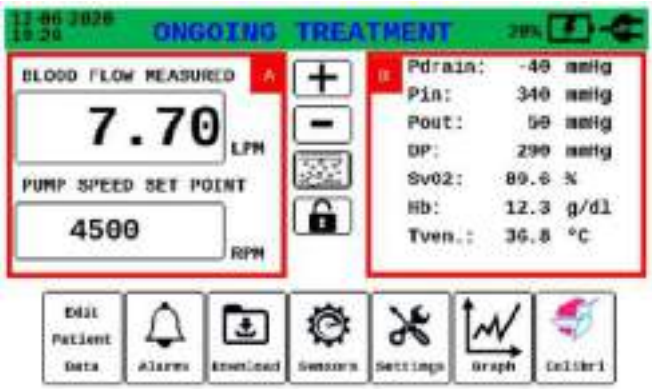
At the bottom of the touchscreen, the toolbar collects the main features provided by the device:

1. Main screen
2. Edit patient data
3. Alarms
4. Download
5. Sensors
6. Settings
7. Graphs
8. Colibrì

7.2. TOOLBAR

MAIN SCREEN

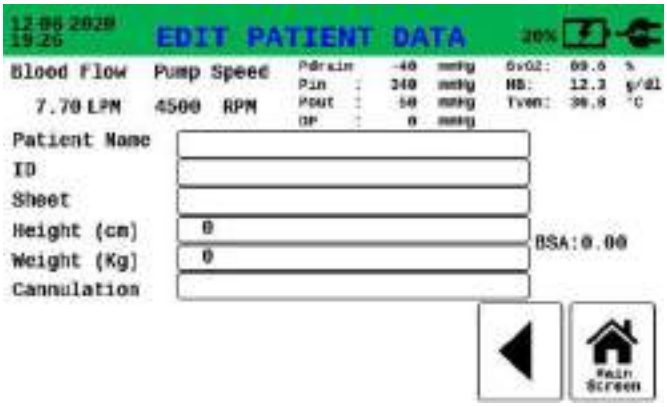
Through the main screen menu you can set primary treatment parameters (section A) as blood flow (LPM) and pump rotation speed (RPM) and you can track secondary settings (section B) sampled through pressure sensors and venous probe.



EDIT PATIENT DATA

On the Edit Patient Data screen, you can fill all the patient information by selecting the box that you want to edit.

The screen will be opened with an active keyboard which permits to user put in the data.



BSA CALCULATION

BSA calculation will be performed by Du Bois formula:

$$BSA = 0.007184 \times Height^{0.725} \times Weight^{0.425}$$

ALARMS

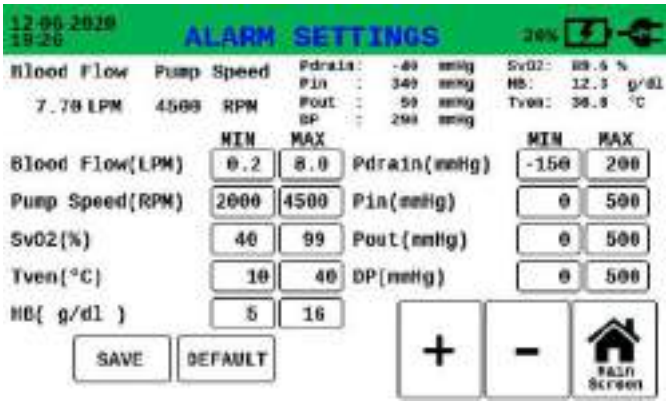
In this section you can enter the Alarm Menu:

Using Alarm Menu you can manage:

- Alarm Settings Menu,
- Alarm List Menu.

In Alarm Settings Menu you can configure alarm ranges of treatment parameters where you can establish alarms minimum and maximum threshold value. Out of the set limits the device sends an alarm signal.

During the treatment, if you change alarm ranges, you can save the new configuration using the “SAVE” button. This configuration will be saved and restored at next power on of the device. (see chapter “PARAMETERS CONFIGURATION PHASE”).



If during the treatment you change alarms ranges, using “RESUME” button, you can restore the default alarm ranges of treatment parameters.

In the Alarm List Menu you can visualize all the alarms that occurred from the beginning of the treatment until the moment you enter the page. Using the left and right arrow, you can scroll the list.

Warning

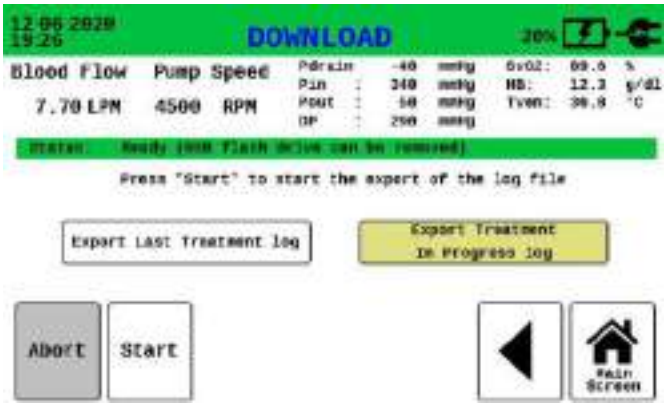
- Check the generation of audible alarm signals. In case of audio signal not generated the use of the device must be interrupted.
- Suspend the use of the device should the audio alarm system does not function properly during start-up test.
- Setting audio alarm to maximum/minimum values could disable the proper detection of physiological alarms.

DOWNLOAD

In this section you can download the patient data and save it into any memory drive by connecting an USB key to the Primary USB key connection in the front panel.

During the treatment, is possible to download the last treatment performed and/or the treatment ongoing.

Before starting the treatment, it is possible to download the last treatment log file or the complete log file, with all the treatment data performed until then.
Download process duration for the complete log file might takes several minutes, depending on the amount of data stored inside the console memory.

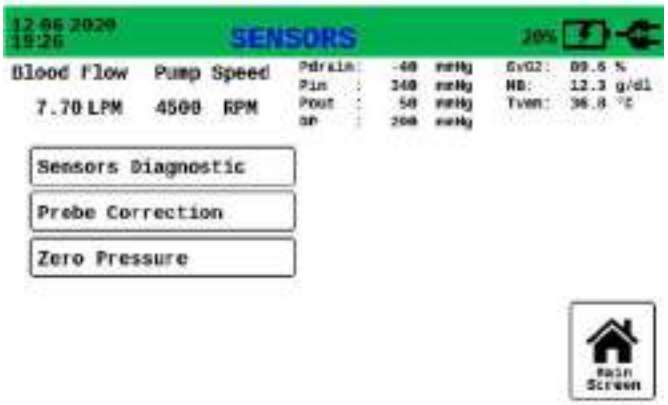


Data can be downloaded both at the end of the treatment and during the treatment (sampled data will be saved up to that point).
The user will receive a confirmation of data successful transfer.

SENSORS

By clicking the Sensors button you can perform diagnostic operations and sensors adjustment.
In the screen left section the following menu will appear:

- Sensors diagnostic
- Probe correction
- Zero pressure

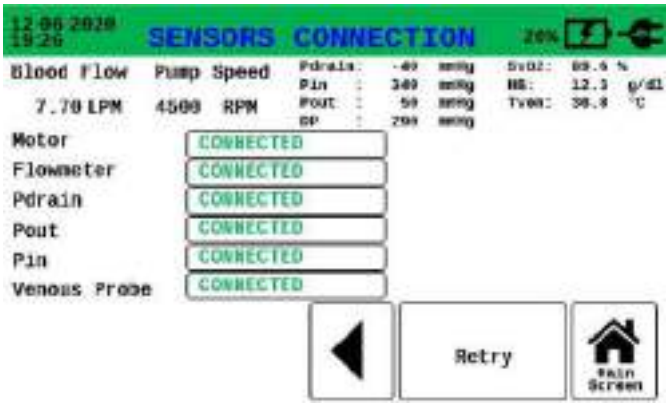


Warning

- Calibrate external and integrated pressure sensors before use.
- Electromagnetic disturbances may lead to malfunctioning of the pressure sensors.

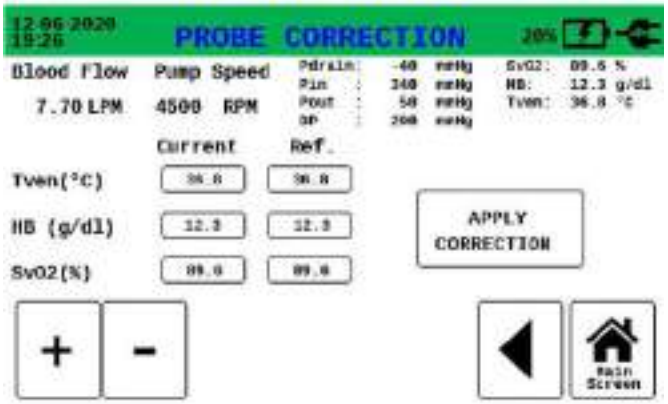
Sensors diagnostics

Sensors verification shall be performed during treatment through the Sensor Diagnostic page:



Probe correction

In this section you can apply correction of the parameters values currently detected by the venous probe compared to reference system such as a gas analyzer.



Zero pressure

In this section you can adjust pressure sensors to zero.

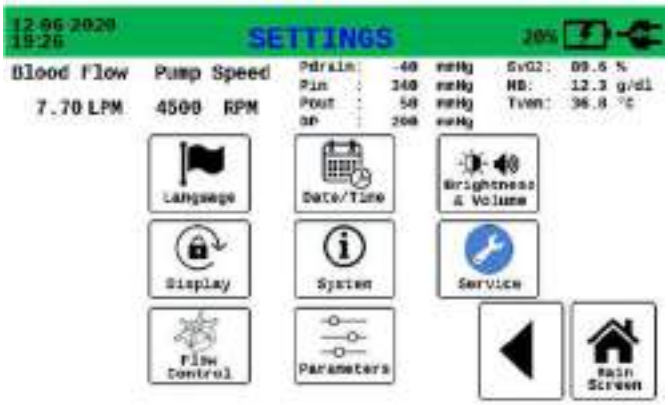
Caution

Zero adjustment shall be performed only when pressure values fall within -200/+200 mmHg.

SETTINGS

In the Settings screen you can modify the following options:

- Language
- Date/Time
- Brightness & Volume
- System
- Display
- Service (not available during treatment)



Language

Select language.

Date/Time

Change date and time info.

Flow Control

Activate/deactivate the Blood Flow (LPM) Mode control.

Brightness & Volume

Change device lightening and volume. You can set:

- 3 different level of display brightness,
- set 3 different volume level (Low, Medium, High).

Caution

If you set low or medium volume level, the following icon will be displayed on the screen.

Service

Section available by authorized staff only by password.
This section will be available only when Setting Page is selected before starting treatment (through Select Modality Page). During the treatment, this menu will not be available.

System

Show system info. HW and SW version, serial number, latest update date, remaining days to recommended maintenance.

Parameters

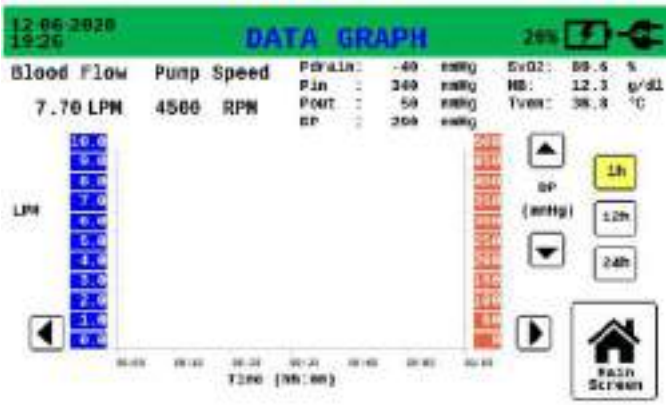
Change the parameters Measure Unit

Display

Can select deactivation time of touchscreen after 1-2-5-10-30-60 min of inactivity (5 min default). It can select back time to homescreen after 5-10-30-60 min of inactivity in the secondary sections (5 min default).
Can set 3 different sensitivity of touchscreen: slow – medium – fast.

GRAPHS

In this section you can visualize the real time parameters trend.



The graphs of follow parameters are available:

- Blood Flow (LPM)
- Pump Speed (RPM)
- Pre-oxygenator pressure (Pin)
- Post-oxygenator pressure (Pout),
- Venous oxygen saturation (SvO2),
- Pressure drop (ΔP)

The above listed parameters are grouped as follow:

- Blood Flow (LPM) – Pump Speed (RPM)
- Blood Flow (LPM) - Pre-oxygenator pressure (Pin)
- Blood Flow (LPM) - Post-oxygenator pressure (Pout),
- Blood Flow (LPM) - Venous oxygen saturation (SvO2),
- Blood Flow (LPM) - Pressure drop (ΔP)

To change the displayed graph, use the arrow available on the right part of the graph.

Each graph can be visualized using different time scale. The following time scale are available:

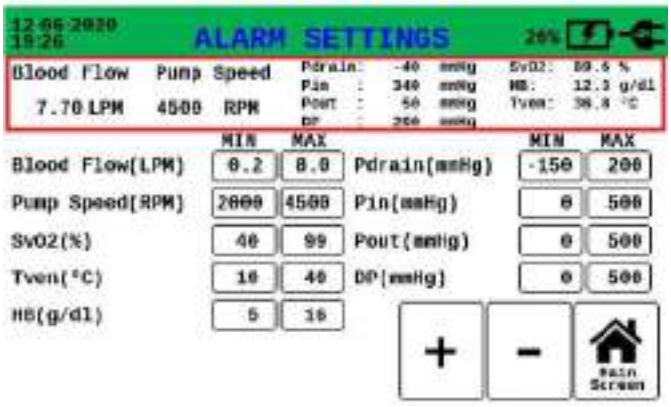
- 1 hour
- 12 hours
- 24 hours

You can select the time scale using 1h, 12h and 24h buttons displayed on the right of the screen.

To scroll the graph use the arrow display on the bottom part of the screen.

7.3. PARAMETERS

For safety reasons, the flow and speed parameters of the pump are always visible in any active navigation screen.



Parameters displayed in the main screen are listed below:

Parameter	Description	Sensor	Measure range	Measure unit	Accuracy
Blood flow	Detected blood flow speed	EU1900 - Clamp on transducer sct 3/8" x 3/32"	0,0 ÷ 10,0	LPM	±0.07 l/min for flow value <= 1.0 l/min ± 7% for flow value > 1.0 l/min
Blood flow	Detected blood flow speed	EU6726 - ECMOLIFE FLOWMETER 3/8''x3/32''	0,0 ÷ 10,0	LPM	±0.05 l/min for flow value <= 1.0 l/min ± 5% for flow value > 1.0 l/min
Blood flow (NEW BORN)	Detected blood flow speed	EU1901- Clamp on transducer sct 1/4" x 3/32"	0,0 ÷ 4,0	LPM	±0.07 l/min for flow value <= 1.0 l/min ± 7% for flow value > 1.0 l/min
Blood flow (NEW BORN)	Detected blood flow speed	EU6728 - ECMOLIFE FLOWMETER 1/4''x3/32''	0,0 ÷ 4,0	LPM	±0.02 l/min for flow value <= 0.4 l/min ± 5% for flow value > 0.4 l/min
Speed pump	Pump speed revolutions per minut	/	0 ÷ 5000	RPM	± 50 RPM
Speed pump (NEW BORN)	Pump speed revolutions per minut	/	0 ÷ 4500	RPM	± 50 RPM
P_{drain}	Suction pressure	MX960P1 Logical pressure transducer + EU3895 smith medical pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	± 5%
P_{drain}	Suction pressure	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	± 10mmHg for pressure value < -50 mmHg ± 5mmHg for -50 mmHg <= pressure value <= +50 mmHg ± 10mmHg for +100 mmHg < pressure value <= +300 mmHg ± 15mmHg for pressure value > +300 mmHg
P_{drain}	Suction pressure	EU6734 Edwards pressure transducer + Edwards pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	± 5%

Pin	Inlet pressure in oxygenator module and outlet pressure from driver engine	MX960P1 Logical pressure transducer + EU3895 smith medical pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	± 5%
P_{in}	Inlet pressure in oxygenator module and outlet pressure from driver engine	Logical pressure transducer + smith medical pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	± 10mmHg for pressure value < -50 mmHg ± 5mmHg for -50 mmHg <= pressure value <= +50 mmHg ± 10mmHg for +100 mmHg < pressure value <= +300 mmHg ± 15mmHg for pressure value > +300 mmHg
P_{in}	Inlet pressure in oxygenator module and outlet pressure from driver engine	EU6734 Edwards pressure transducer + Edwards pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	± 5%
P_{out}	Outlet pressure from oxygenator module	MX960P1 Logical pressure transducer + EU3895 smith medical pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	± 5%
P_{out}	Outlet pressure from oxygenator module	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	± 10mmHg for pressure value < -50 mmHg ± 5mmHg for -50 mmHg <= pressure value <= +50 mmHg ± 10mmHg for +100 mmHg < pressure value <= +300 mmHg ± 15mmHg for pressure value > +300 mmHg
P_{out}	Outlet pressure from oxygenator module	EU6734 Edwards pressure transducer + Edwards pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	± 5%
SvO_2	Venous saturation	EU3896 - Venous probe	40 - 99,9	%	± 3% as absolute value
Hb	Hemoglobin	EU3896 - Venous probe	5,0 - 16,0	g/dl (convertible in mmol/l)	± 0,5 g/dl
Tv	Venous temperature	EU3896 - Venous probe	4,0 - 42,0	°C (convertible in °F)	± 1,0 °C
Bubble	Air bubble detection	EU6727 - Auxiliary air/flow sensor probe 3/8”x3/32”	> 50	µl	NA
Bubble	Air bubble detection	EU6729 - Auxiliary air/flow sensor probe 1/4”x3/32”	> 50	µl	NA

PARAMETERS EDITING

Parameters selection

You can activate the parameter selection by pushing on the display the value that you want to modify, for at least 1 second.

Increase and decrease parameters value

By turning the knob clockwise (+) or anticlockwise (-) or using the +/- display buttons, it is possible to increase / decrease the value of the selected parameter.

Edit confirmation or refusal

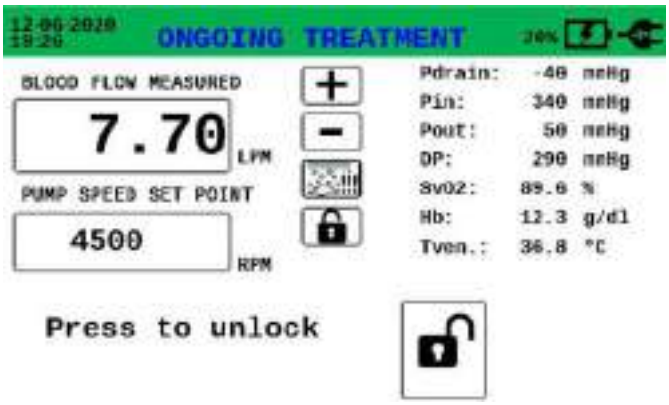
Following the treatment parameter editing (e.g. RPM, LPM) it is necessary to confirm the set value by re-pushing the selected value on the display or re-pushing the knob within at least 3 second.
The parameter editing will be performed only if the user confirms.
If you delete the operation using the RETURN button, or if it takes more than 3 seconds to confirm, the device will restore the value to the previous one.

SCREEN LOCK

Automatic lock screen

To avoid editing of unwanted settings or functions, all display buttons will be automatically locked after 5 minutes of inactivity.

You can reactivate the touchscreen by pushing the unlock button.



The touchscreen will be reactivated in case of alarm. If the user does not intervene within the set time limit, the touch will be deactivated.

Display lock

The user can lock the display by pushing the lock button for at least 3 seconds.

Display unlock

To enable the display, press at least 1sec the unlock button present in the footer bar or in the central bar of the main buttons.

Automatic return to main screen

Following an inactivity state of 5 minutes in any secondary section (with the exception of *Graphs Page*), the display automatically returns to main screen.

7.4. FUNCTIONALITIES

7.4.1. TURNING ON THE DEVICE

At power on, you can select between 3 different device configurations:

- Colibrì,
- Adult/Paediatric,
- New Born.

The Colibrì option allows you to configure the device to manage the Colibrì system and start the treatment in combination. For more details see Chapter 9 PRIMARY UNIT: COMBINATION SYSTEM ECMOLIFE_COLIBRÌ

The Adult/Paediatric option allows to configure the device to manage the ECMOLIFE Centrifugal Pump with 3/8x3/32'' tubing sets.

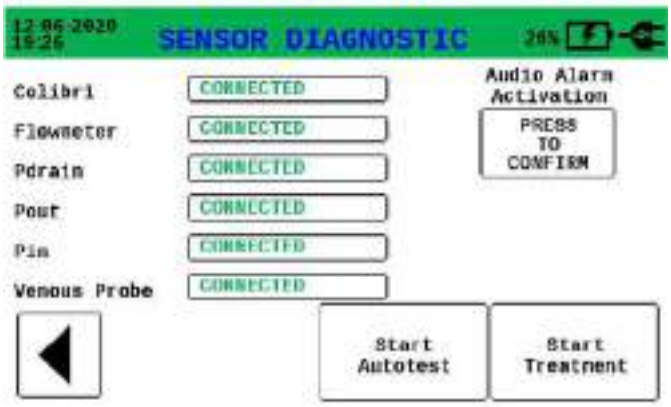
The New Born option allows to configure the device to manage the NEW BORN Centrifugal Pump and 1/4X3/32'' tubing sets.

Caution
Adult/Paediatric configuration have LPM, RPM and alarm range customize for Adult/paediatric patients.

Caution
New Born configuration have LPM, RPM and alarm range customize for newborn patients.

7.4.2. DIAGNOSTIC PHASE

In diagnostic screen the device will check all the sensors are properly connected.
To start the diagnostic phase, press Start Autotest button.
To retry the check, press Retry button.



Each subsequent connection of probes or sensors in this phase or during the treatment shall be confirmed in the diagnostic page by clicking the Retry button.
All undetected probes or sensors won't sample parameters.
In order to safetely proceed with the operations, acoustic Audio Alarm detection shall be confirmed manually.
If you connect the pressure sensors after the diagnostic phase, during the setup, perform the diagnostic phase at the beginning of treatment phase. After that, you can proceed with the zero pressure alignment.
If you want go back to previously page, press the button displayed on the left of the screen.

Warning
Do not continue in case of acoustic alarm is not detected at the end of this phase. ALARM SYSTEM might be compromised.

At the end of the diagnostic phase, by pressing the start treatment button the device is able to check the compatibility between the chosen configuration and the flow probe connected to the device. If the connected probe is not compatible with the chosen configuration, a dedicated warning is activated.

7.4.3. PARAMETERS CONFIGURATION PHASE

After the autotest phase, the device will inform you that a new configuration of device parameters, saved during the previous treatment, is available.

If a saved configuration is available you can select between “Default Configuration” and “Saved Configuration”.

The “Default Configuration” is the parameters set defined by manufacturer (see table below).

The “Saved Configuration” is the parameters set defined saved by the user during the previous treatment (see chapter “Alarms”).

DEFAULT PARAMETERS – ADULT/PAEDIATRIC CONFIGURATION

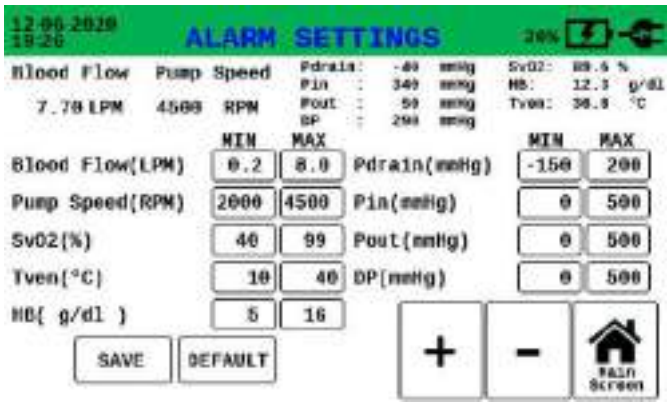
Parameter	Default configuration ADULT/PAEDIATRIC	Default configuration NEW BORN
Blood flow (LPM) MIN	0,2 LPM	0,2 LPM
Blood Flow (LPM) MAX	8,0 LPM	1,5 LPM
Speed pump (RPM) MIN	2000 RPM	1500 RPM
Speed pump (RPM) MAX	4500 RPM	4000 RPM
P_{drain} MIN	- 80 mmHg	- 150 mmHg
P_{drain} MAX	25 mmHg	+50 mmHg
P_{in} MIN	0 mmHg	-50 mmHg
P_{in} MAX	500 mmHg	+500 mmHg
P_{out} MIN	0 mmHg	-50 mmHg
P_{out} MAX	500 mmHg	+500 mmHg
DP MIN	0 mmHg	-50 mmHg
DP MAX	500 mmHg	+400 mmHg
SvO_2 MIN	60 %	40 %
SvO_2 MAX	90%	90%
Hb MIN	5 g/dl	5 g/dl
Hb MAX	16 g/dl	30 g/dl
Tv MIN	10 °C	10 °C
Tv MAX	40 °C	40 °C
Volume	Medium	Medium
Brightness	Medium	Medium
Touch screen sensitivity	Medium	Medium
Screen lock timer	5 minutes	5 minutes

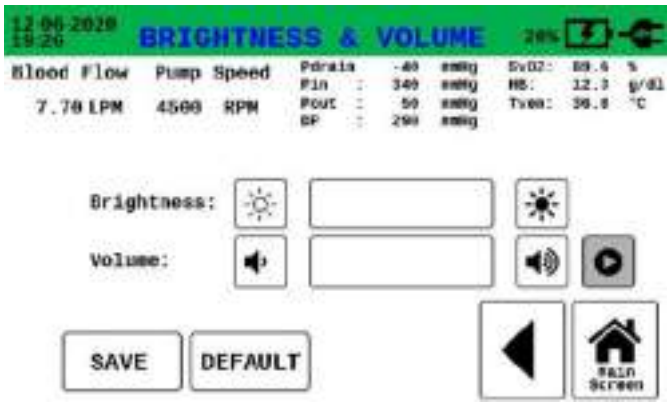
To create a new configuration, you can use the “SAVE” button in the following pages:

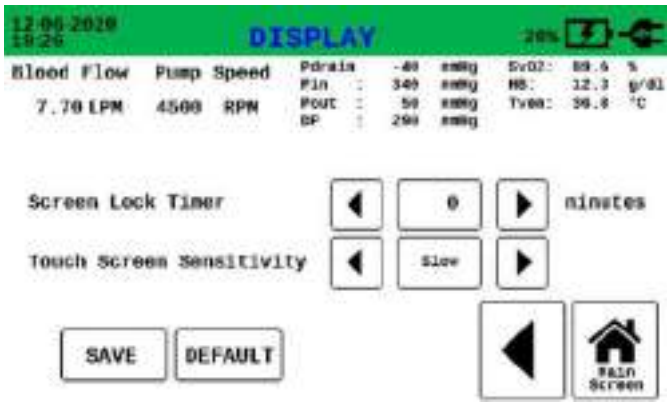
- Alarm settings,
- Display,
- Parameters,
- Brightness and volume.

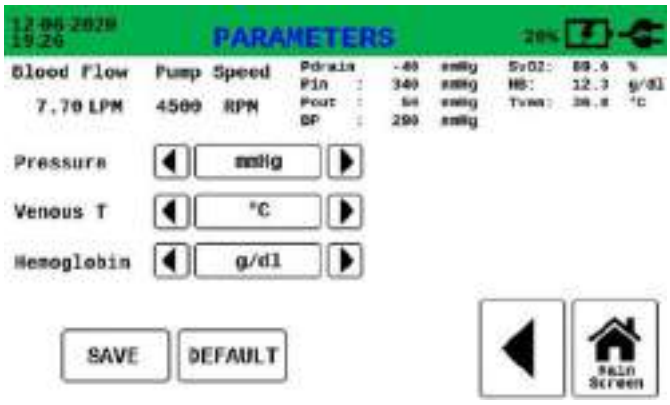
If you choose to start the device with the “Saved Configuration” of parameters, you will have the possibility to restore the Default configuration during the treatment using the “DEFAULT” button in the following page:

- Alarm settings,
- Display,
- Parameters,
- Brightness and volume.









7.4.4. PRIMING PHASE

Perform the priming with an isotonic solution NaCl 0.9%.
Priming shall be performed first by following the procedure indicated in the Disposable centrifugal pump instructions for use, ensuring all components are correctly deareated.

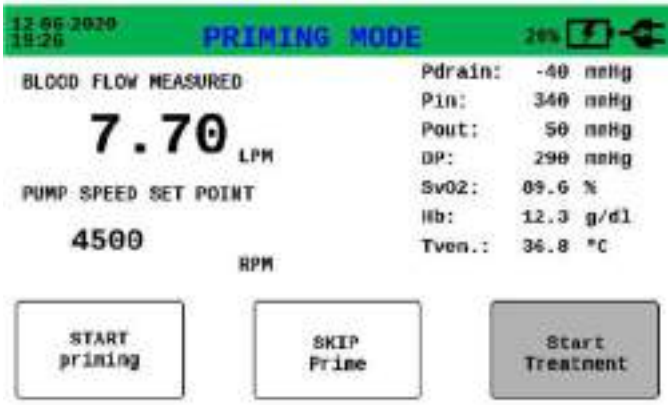
AUTOMATIC PRIMING AND SELF LEARNING PROCEDURE – ADULT/PAEDIATRIC CONFIGURATION.

After manual priming is possible to continue with the automatic priming operation which also perform a centrifugal pump self-learning procedure in order to improve the centrifugal pump safety and performances.

Warning
Automatic Priming must be executed once the circuit has been correctly filled with priming solution.
Empty circuit might cause disposable centrifugal pump rupture or device malfunctions.

START / STOP PROCEDURE

You can select “START PRIMING” in order to start the automatic procedure.
ECMOLIFE will set and hold for few minutes different RPM targets within the range 0-5000RPM.
During this phase, the circuit will be automatically primed and the centrifugal pump impeller will be further verified in a self-learning procedure.



In case of emergency, procedure can be stopped and restarted many time as necessary.
If the procedure is interrupted and restarted while in progress, already verified set-point won’t be executed again.
Priming procedure requires a maximum of 4 minutes.
Once completed, it is possible to continue with the patient connection.

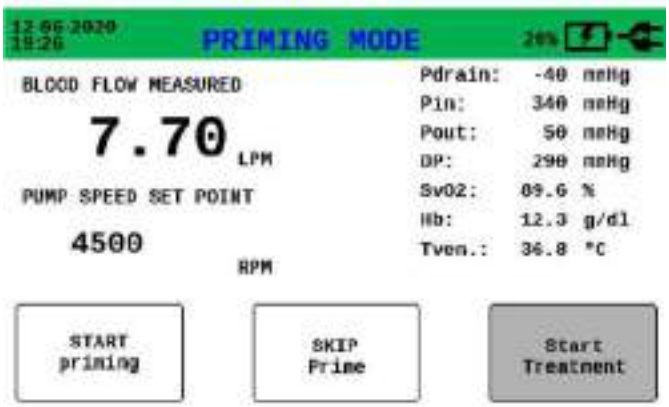
AUTOMATIC PRIMING AND SELF LEARNING PROCEDURE – NEW BORN CONFIGURATION

After manual priming is possible to continue with the automatic priming operation which also perform a centrifugal pump self-learning procedure in order to improve the centrifugal pump safety and performances.

Warning
Automatic Priming must be executed once the circuit has been correctly filled with priming solution. Empty circuit might cause disposable centrifugal pump rupture or device malfunctions.

START / STOP PROCEDURE

You can select “START PRIMING” in order to start the automatic procedure.
ECMOLIFE will set and hold for few minutes different RPM targets within the range 0-4500RPM.
During this phase, the circuit will be automatically primed and the centrifugal pump impeller will be further verified in a self-learning procedure.



In case of emergency, procedure can be stopped and restarted many time as necessary.
If the procedure is interrupted and restarted while in progress, already verified set-point won’t be executed again.
Priming procedure requires a maximum of 4 minutes.
Once completed, it is possibile to continue with the patient connection.

SKIP PROCEDURE – ADULT/PAEDIATRIC/NEW BORN CONFIGURATION

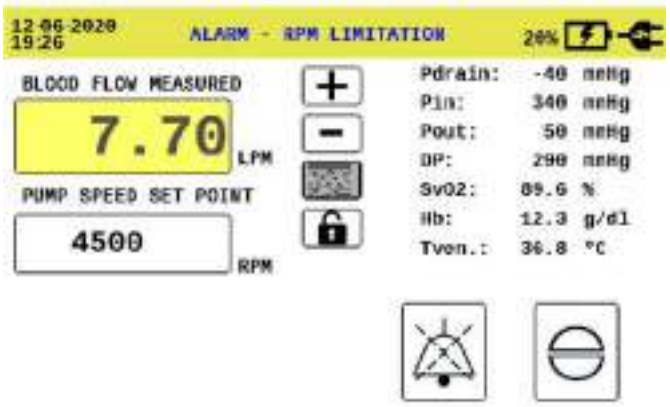
In case of urgency you can SKIP the automatic procedure and complete the priming phase by manually setting the RPM from the main screen.
Skipping the automatic procedure doesn't allow the device to perform the impeller self-learning operation.
For safety reason a RPM upper range limitation will be set for RPM values higher than 3500RPM and 4500RPM..

In order to reach an RPM set-point higher than 3500RPM and 4500RPM it's necessary to allow the device to perform a two minutes of calibration in a range between these two target.

An alarm message will appear to inform the calibration is running and after a few minutes it will be possible to increase the RPM setpoint. The alarm message and the yellow bar will disappear at the end of calibration procedure.

When 3500 RPM or 4500 RPM setpoint is reached, the calibration will be performed by console by remaining for at least 2 minutes in a range within 1550RPM-3450RPM for the first self-learning setpoint and 4300RPM-4450RPM for the second self-learning setpoint.

Once both of the 3500RPM and 4500RPM setpoint has been validated, the device can be set in all the 0-5000 RPM range for adult/paediatric configurator 0-4500 for new born configuration.



7.4.5. OPERATING MODE

During the use of the device, the desired RPM or pump blood flow values can be set by the user.

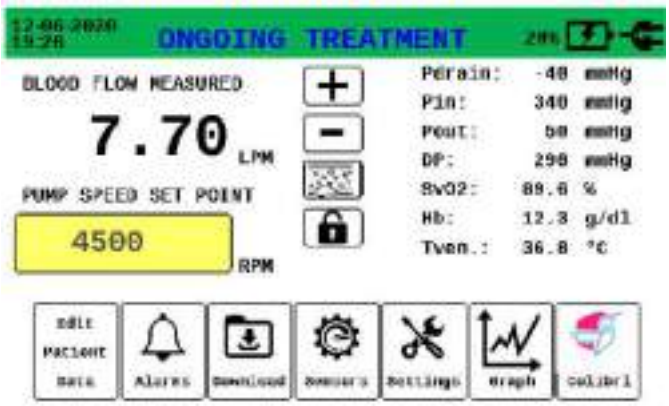
DRIVER RPM MONITORING MODE (DEFAULT MODE)

Default mode allows to control the centrifugal pump RPM, the blood flow will adapt to the set RPM.
RPM values can be set by rotating the knob or using the touch screen +/- buttons.

Edit confirmation or refusal.

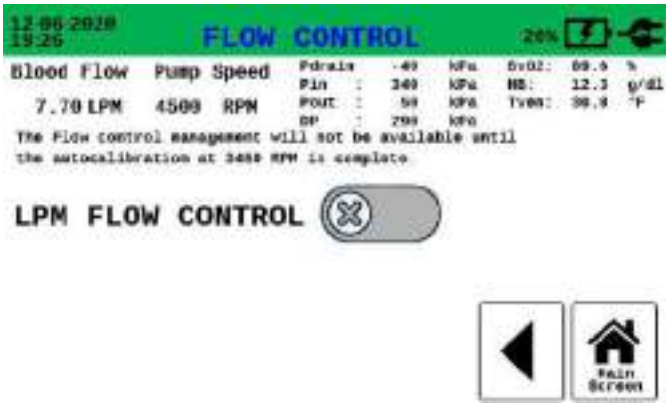
It is necessary to confirm the set value by re-pushing the selected value on the display or re-pushing the knob within at least 3 second.
The parameter editing will be performed only if the user confirms.
If you delete the operation using the RETURN button, or if it takes more than 3 seconds to confirm, the device will restore the value to the previous one.

During the RPM selection the parameter will be highlighted in yellow and the user selected target point will be displayed.
After confirmation the yellow highlighting will disappear and the actual RPM value will be displayed



7.4.6. BLOOD FLOW MONITORING MODE (ADDITIONAL MODE)

Blood Flow control shall be disabled by default.
Blood Flow control mode can be enabled by the Flow Control page in Settings device menu.



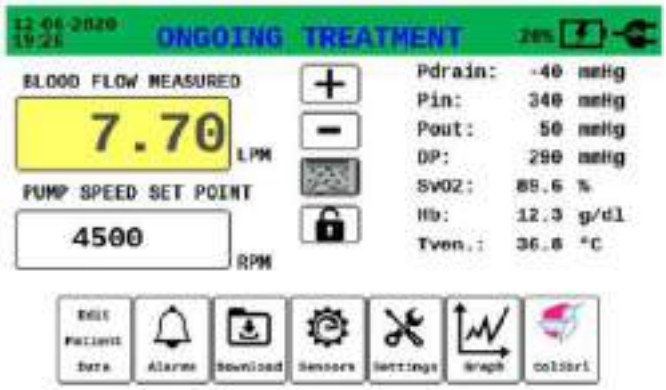
Warning
If you skip the automatic priming, the Blood Flow Control Mode will not be available until the first autocalibration, at 3450 RPM, is complete.

When setting a new blood flow value, by increasing or decreasing it in the main parameters screen, the device will automatically adjust the RPM to reach the desired flow.
LPM values can be set by rotating the knob or using the touch screen +/- buttons.

Edit confirmation or refusal.

It is necessary to confirm the set value by re-pushing the selected value on the display or re-pushing the knob within at least 3 second.
The parameter editing will be performed only if the user confirms.
If you delete the operation using the RETURN button, or if it takes more than 3 seconds to confirm, the device will restore the value to the previous one.

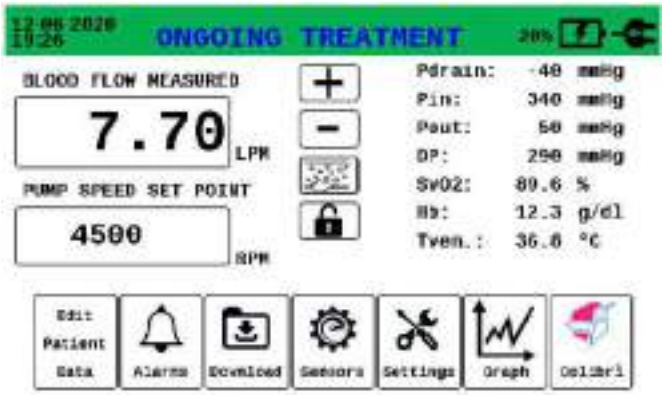
During the LPM selection the parameter will be highlighted in yellow and the user selected target point will be displayed.
After confirmation the yellow highlighting will disappear and the actual LPM value will be displayed



Warning
When blood flow control mode is used, RPM will be automatically adjusted in order to reach the desired flow. RPM may reach high values depending on the extracorporeal circuit pressures.
When blood flow control mode is used and reaching the desired flow requires more time than expected, an incorrect flow alarm activation might occurr.
When blood flow control mode is used, the desired flow may not be reached depending on the extracorporeal circuit pressures.

7.4.7. LPM CONTROL ENABLED/DISABLED MODE VIEW

LPM control activation is shown by the visualization of a frame around the parameter.



8. PRIMARY UNIT - ALARMS

8.1. ALARM RANGE AND PARAMETERS

It is possible to set the alarm limits in the Alarm screen.
The alarm activates whenever the parameter value exceeds the warning limits, i.e:

- Value measured above the upper limit
- Value measured above the lower limit

You can set the alarm limits within the parameters summarized in the following table.

8.1.1. ALARM LIMIT – ADULT/PAEDIATRIC CONFIGURATION

Parameter	Description	Sensor	Measure range	Measure unit	Alarm threshold	Default alarm threshold
Blod flow	Detected blood flow speed	Clamp on transducer Sct 3/8" x 3/32"	0,0 ÷ 10,0	LPM	0,0 ÷ 10,0	0,2 ÷ 8,0
Speed pump	Speed revolutions per minute pump	/	0 ÷ 5000	RPM	0 ÷ 5000	2000 ÷ 4500
P_{drain}	Suction pressure	Logical pressure transducer + smith medical pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	-200 ÷ +800	-80 ÷ 25
P_{drain}	Suction pressure	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	-200 ÷ +600	-80 ÷ 25
P_{in}	Inlet pressure in oxygenator module and outlet pressure from driver engine	Logical pressure transducer + smith medical pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	-200 ÷ +800	0 ÷ 500
P_{in}	Inlet pressure in oxygenator module and outlet pressure from driver engine	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	-200 ÷ +600	0 ÷ 500
P_{out}	Outlet pressure from oxygenator module	Logical pressure transducer + smith medical pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	-200 ÷ +800	0 ÷ 500
P_{out}	Outlet pressure from oxygenator module	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	-200 ÷ +600	0 ÷ 500
DP	Pressure Drop	//	-200 ÷ +600	mmHg (convertible in kPa)	-10 ÷ +600	0 ÷ +500
SvO_2	Venous saturation	Venous probe	40 – 99,9	%	40 – 99,9	60 ÷90
Hb	Hemoglobin	Venous probe	5,0 - 16,0	g/dl (convertible in mmol/l)	5,0 - 16,0	5 ÷16
Tv	Venous temperature	Venous probe	4,0 - 42,0	°C (convertible in °F)	4,0 - 42,0	10 ÷ 40
Bubble	Air bubble detection	Bubble sensor	> 50	µl	(not modifiable)	> 50

Parameters range and alarm threshold are the same both on Primary and Backup Unit.

Every time you switch on the device, you will be able to choose between the default alarm threshold parameters and the saved alarm threshold parameters. For more details see chapter "PARAMETERS CONFIGURATION PHASE".

8.1.2. ALARM LIMIT – NEW BORN CONFIGURATION

It is possible to set the alarm limits in the Alarm screen.
The alarm activates whenever the parameter value exceeds the warning limits, i.e:

- Value measured above the upper limit
- Value measured above the lower limit

You can set the alarm limits within the parameters summarized in the following table.

Parameter	Description	Sensor	Measure range	Measure unit	Alarm threshold	Default alarm threshold
Blod flow	Detected blood flow speed	Clamp on transducer Sct 3/8" x 3/32"	0,0 ÷ 3,0	LPM	0,0 ÷ 3,0	0,2 ÷ 1,5
Speed pump	Speed revolutions per minute pump	/	0 ÷ 4500	RPM	0 ÷ 4500	0 ÷ 4500
Pdrain	Suction pressure	Logical pressure transducer + smith medical pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	-200 ÷ +800	-150 ÷ +50
Pdrain	Suction pressure	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	-200 ÷ +600	-150 ÷ +50
Pin	Inlet pressure in oxygenator module and outlet pressure from driver engine	Logical pressure transducer + smith medical pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	-200 ÷ +800	-50 ÷ +500
Pin	Inlet pressure in oxygenator module and outlet pressure from driver engine	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	-200 ÷ +600	-50 ÷ +500
Pout	Outlet pressure from oxygenator module	Logical pressure transducer + smith medical pressure sensor	-200 ÷ +800	mmHg (convertible in kPa)	-200 ÷ +800	-50 ÷ +500
Pout	Outlet pressure from oxygenator module	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	-200 ÷ +600	-50 ÷ +500
DP	Pressure Drop	//	-100 ÷ +600	mmHg (convertible in kPa)	-100 ÷ +600	-50 ÷ +400
SvO2	Venous saturation	Venous probe	40 – 99,9	%	40 – 99,9	40 ÷90
Hb	Hemoglobin	Venous probe	5,0 - 16,0	g/dl (convertible in mmol/l)	5,0 - 16,0	5 ÷30
Tv	Venous temperature	Venous probe	4,0 - 42,0	°C (convertible in °F)	4,0 - 42,0	10 ÷ 40
Bubble	Air bubble detection	Bubble sensor	> 50	µl	(not modifiable)	> 50

Parameters range and alarm threshold are the same both on Primary and Backup Unit.
Every time you switch on the device, you will be able to choose between the default alarm threshold parameters and the saved alarm threshold parameters. For more details see chapter "PARAMETERS CONFIGURATION PHASE".

8.1.3. ZERO FLOW MODE

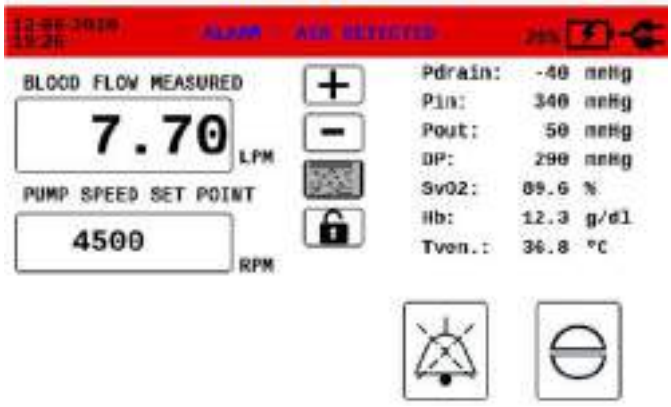
In order to avoid any kind of back flow once the user set a Blood Flow value = 0, the device automatically maintains a minimum rotation of the impeller (which may vary depending on the pressure detected at the Centrifugal Pump outlet line).
For this purpose the device monitors the blood flow, displays the alarms at the defined limits and reacts by intervening in the pump control.
The device has an extra alarm limit of - 0.2 LPM not settable by the user. In any moment if the blood flow falls below that limit for more than 1 sec, a medium priority alarm is generated and a prompt automatic RMP adjustment occurs to prevent back flow. The alarm ends as soon as the measured blood flow value rises above the alarm limit.

8.2. ALARMS PRIORITY

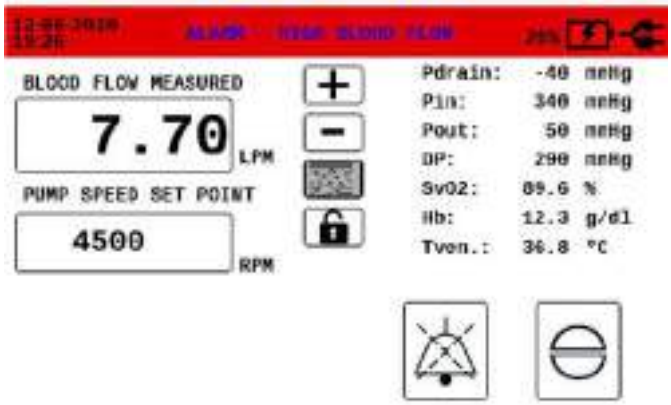
Alarms activation depends strictly from the priority ranking of parameter involved, according to the following table.

Priority Ranking	Parameter	Priority level	Color
1	Blood Flow	High	Red
2	Pump Speed	High	Red
3	Bubble	High	Red
4	Pdrain	Medium	Yellow
5	Pin	Medium	Yellow
6	Pout	Medium	Yellow
7	SvO2	Low	Blue
8	Hb	Low	Blue
9	Tv	Low	Blue

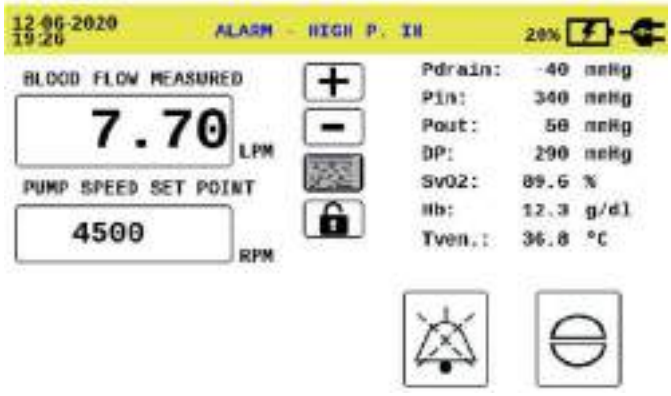
8.2.1. AIR BUBBLE DETECTION ALARM (HIGH PRIORITY)



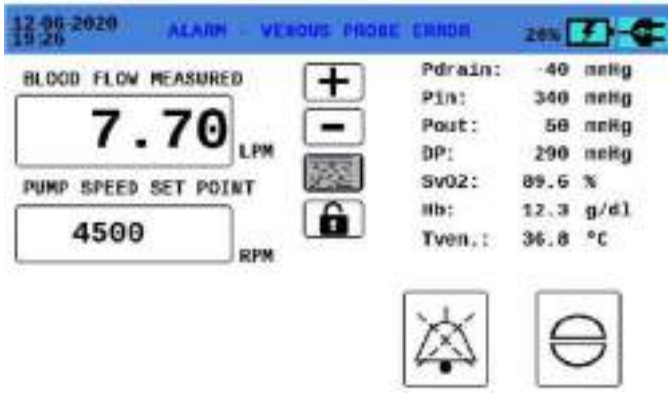
8.2.2. BLOOD FLOW DETECTION ALARM (HIGH PRIORITY)



8.2.3. SECONDARY PARAMETERS ALARM (MEDIUM PRIORITY)



8.2.4. SECONDARY PARAMETERS ALARM (LOW PRIORITY)



8.2.5. ALARM PAUSE

When an alarm is activated, on the main buttons section, the button is displayed in the "variable" button which allows the alarm sound to be silenced for 2 minutes.
The visual alarm status is kept active until it is resolved or the alarm is deactivated for that specific parameter.

8.2.6. ALARM ACKNOWNLEDGE

When an alarm is activated, on the main buttons section, the button is displayed in the "variable" button which allows the alarm sound to be silenced permanently.
The visual alarm status is kept active until it is resolved or the alarm is deactivated for that specific parameter.

Warning
When power is lost for less than or equal to 30 s, the ALARM SETTINGS prior to the power loss is restored automatically.

8.3. ALARMS TABLE

Refere to ANNEX 1 – PRIMARY: Alarms table for the complete list of alarm messages.

9. PRIMARY UNIT: COMBINATION SYSTEM ECMOLIFE-COLIBRÌ (Valid only for device with the Colibrì connector on the front panel)

It is possible to use the Primary section of ECMOLIFE console in combination with the Colibrì system (EU5096).
Colibrì system is composed by: COLIBRÌ Console, COLIBRÌ Flowmeter and COLIBRÌ Power Module.
For more details about Colibrì System, please refer to EU11042 IFU COLIBRÌ SYSTEM.

- The combined system must be used in accordance with these instructions and EU11042 IFU COLIBRÌ SYSTEM. EUROSETS cannot be held responsible for damage deriving from improper use.
- Read these instructions together with ECMOLIFE Centrifugal Pump and NEW BORN Centrifugal Pump instructions for use and Colibrì System instruction for use carefully before use.
- The device is intended for use in the hospital and institutional environment where healthcare professionals provide patient care. The device is intended for use by properly trained personnel under the direct supervision of a licensed physician.
- Do not use the device if the package is damaged.
- The product may only be operated and monitored by qualified medical staff.
- The incorrect reuse and reprocessing can compromise the electrical safety of the device and result in electric shock, insufficient insulation, and an unintended increase in the temperature of the device.
- Only use the ECMOLIFE-COLIBRÌ System as the drive for the ECMOLIFE CENTRIFUGAL PUMP SYSTEM.
- Have a replacement set at the ready.
- Always keep 4 metal tube clamps at the ready.
- Electromagnetic interference:
  - Do not use the ECMOLIFE-COLIBRÌ system in the proximity of equipment not sufficiently screened from electromagnetic emissions higher than those indicated in IEC 60601-1-2: 2014+AMD1:2020.
  - This system may cause radio interference or may interfere with operation of nearby equipment, and mitigation measures may therefore be necessary, such as reorienting or relocating the ECMOLIFE-COLIBRÌ System or shielding the environment.
- Stop immediately the use of the system through the emergency switch button in case of fire/smoke from the device.

9.1. ECMOLIFE-COLIBRÌ CONNECTION

MECHANICAL CONNECTION.

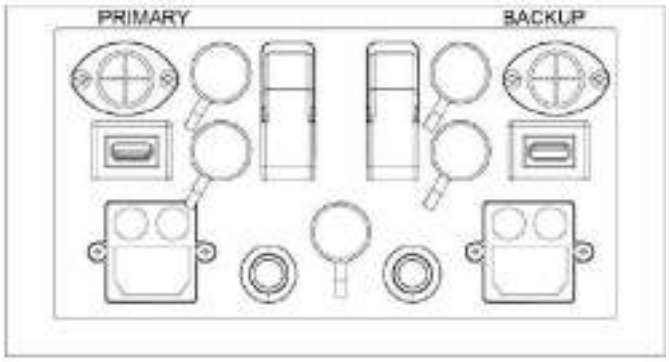
1. Move the lever of the COLIBRÌ bracket to the 'OPEN' position.
2. Insert the COLIBRÌ Bracket into the support plate on the wall of the ECMOLIFE Console facing the two stand poles.

3. Move the lever of the COLIBRÌ bracket to the 'CLOSED' position in order to fix the COLIBRI' Console on the ECMOLIFE Console.

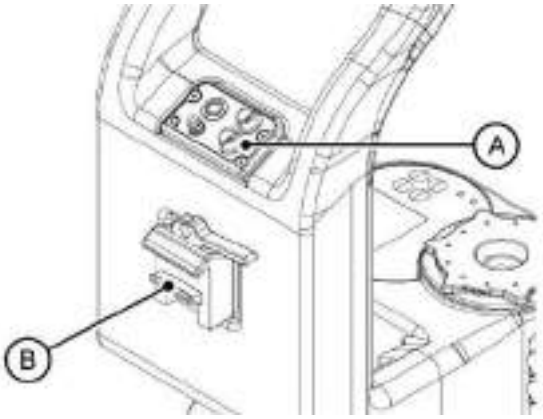
FUNCTIONAL CONNECTION

Using the dedicate cable (ECMOLIFE-COLIBRÌ cable EU11108), you can connect the ECMOLIFE system to the Colibrì System as follow:

1. Using the Colibrì hanging system (**B**), fix the Colibrì System on the rear side of ECMOLIFE console.
2. Check the integrity of ECMOLIFE-COLIBRÌ cable EU11108.



3. Ensure the ECMOLIFE-COLIBRÌ cable to the dedicated socket of ECMOLIFE connector panel.
4. Ensure the ECMOLIFE -COLIBRÌ cable to the 24V connector socket (**A**) of Colibrì top panel.
5. Turn on the ECMOLIFE console e proceed with the diagnostic phase.



Warning

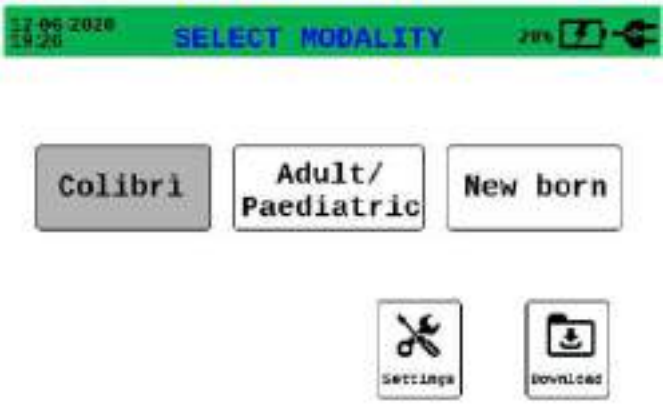
- In case of Primary Unit failure, keep the Primary Emergency Button activated in order to prevent any electric interference and proceed the treatment using the Colibrì in standalone configuration. For more details about Colibrì standalone configuration and functionalities refer to EU EU11042 IFU COLIBRÌ SYSTEM.
- Before starting the support, check that the Backup Unit battery is fully charged.
- Activate the Backup Unit only in case of Primary Unit and Colibrì Unit failure.
- Keep a backup motor driver ready for use.
- Keep a backup flowmeter sensor ready for use
- In case of double fault condition of ECMOLIFE and Colibrì system, please active the backup unit and proceed with the treatment.

9.2. FUNCTIONALITIES

9.2.1. TURNING ON THE ECMOLIFE-COLIBRI' SYSTEM

In the Select Modality page of ECMOLIFE System select between “COLIBRÌ Configuration”.

It is possible to connect the COLIBRI System to ECMOLIFE in any treatment phase.



ECMOLIFE System is able to detect if the connection cable is connected to COLIBRI and if COLIBRI is turned off or turned on. If colibrì is turned off, ECMOLIFE will information about how to start the treatment on COLIBRI System before switch to ECMOLIFE control.

If the ECMOLIFE System is already on and the COLIBRI configuration treatment page, it is possible to connected or disconnect the COLIBRI System through the softkey in the COLIBRI menu (See 9.2.4) or disconnecting and connecting the connection cable.
If the COLIBRI System is connected to ECMOLIFE and the treatment is ongoing, it is possible to disconnect the cable and switch the control to COLIBRI System. If the cable is than reconnected, the treatment swith automatically to ECMOLIFE System.

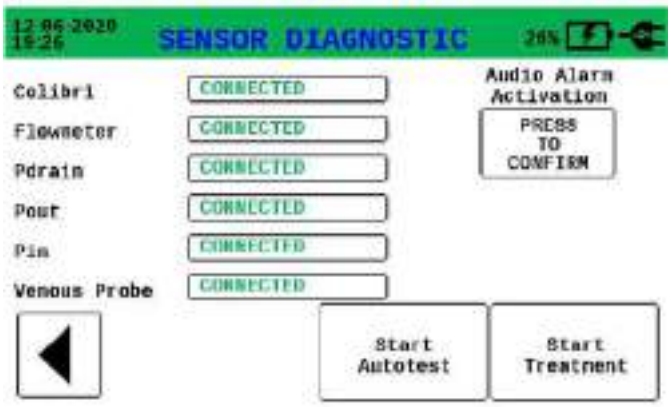
In particular, if COLIBRI System is turned off, a warning will be displayed on ECMOLIFE System informing the user to switch on the COLIBRI System, perform the autotest and enter the automatic priming page. Than, it will be possible to switch to ECMOLIFE System.

Moreover, ECMOLIFE System is able to check the Software version of COLIBRI System and inform the user in case the two Software versions are not compatible and it is therefore not possible to proceed with treatment on ECMOLIFE System.

9.2.2. DIAGNOSTIC PHASE

If the ECMOLIFE-COLIBRÌ cable is correctly connected and COLIBRI System is turned on,
in diagnostic screen the device will check colibri device are properly connected.
To start the diagnostic phase, press Start Autotest button.
To retry the check, press Retry button.

During the diagnostic check the motor driver, the pressure sensors and the flowmeter are related to Colibrì system. Otherwise, venous probe and bubble sensor are related to ECMOLIFE system.
During the Diagnostic phase the audio alarm of ECMOLIFE system is checked and the acoustic detection shall be confirmed manually.



If you want go back to previously page, press the button displayed on the left of the screen.

Warning
Do not continue in case of acoustic alarm is not detected at the end of this phase. ALARM SYSTEM might be compromised.

When the treatment control switches from Colibrì to ECMOLIFE, the Colibrì device will entry in a stand-by condition.
By pressing Start Treatment, all action will only be possible using the ECMOLIFE display.

When the AUTOTEST is performed and the “Start Treatment” softkey is pressed, the ECMOLIFE System takes the control of COLIBRI treatment.
When COLIBRI is connected to ECMOLIFE System, it is no longer possible to control the treatment through the COLIBRI screen: treatment flow and RPM information will be displayed, together with colibrì charge level.
“Refer to Ecmolife” will be displayed on screen.

9.2.3. TREATMENT PHASE

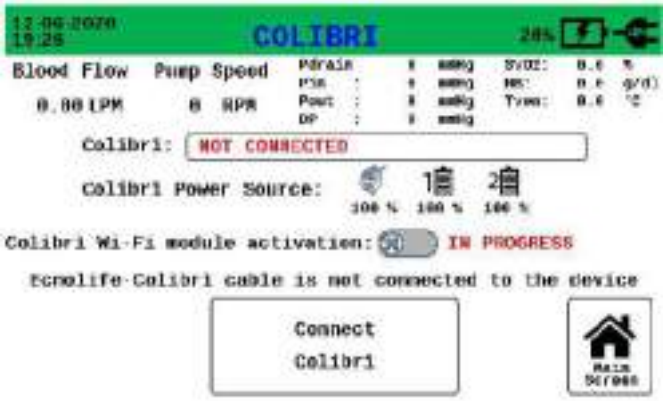
After diagnostic phase, pressing Start Treatment the ECMOLIFE System will take the control of Colibrì treatment.

From ECMOLIFE Main screen (refer to paragraph 7 and 8) you will able to:

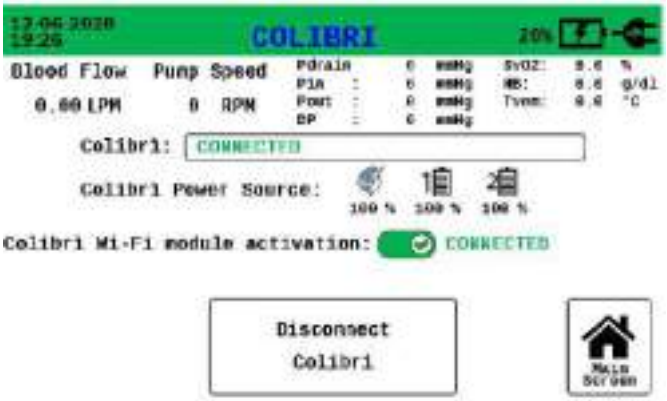
- Monitoring and editing RPM and LPM value,
- Monitoring pressure sensors values,
- Monitoring venous probe functionalities,
- Monitoring bubble sensor behaviour,
- Manage and editing the alarm limits (refer to paragraph 8.1),
- Monitoring the parameters graph;
- Enter the COLIBRI menu page.

9.2.4. COLIBRI MENU

Through the COLIBRI menu page it is possible to check the COLIBRI connection status, the internal battery charge level and the external batteries charge level if connected to COLIBRI device.



Through COLIBRI menu it is also possible to activate or deactivate the COLIBRI WIFI Module. Through the “Connect Colibrì” or “Disconnect Colibrì” softkey it is possible to connect or disconnect the Colibrì device without disconnecting the cable from the devices.

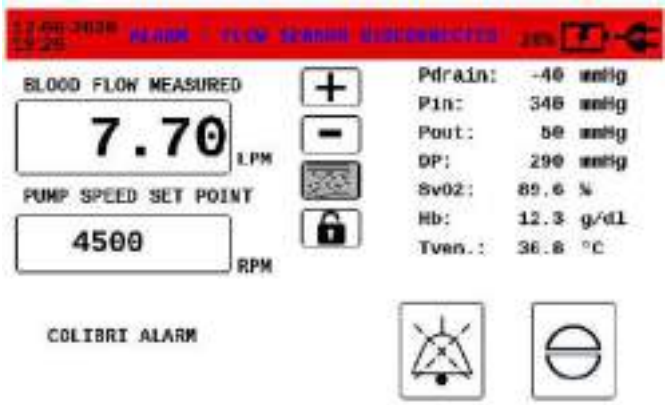


If the “Disconnect Colibrì” softkey is selected, it will be answered to the user to confirm if the Colibrì shall be disconnected or not.

It will always be possible to re-connect the colibrì system, if it is already in treatment phase

9.2.5. ALARMS

During the treatment, the ECMOLIFE-COLIBRÌ system will be able to detect alarm condition and warn.
The alarm activation will be display and manage on ECMOLIFE console; in particular when an alarm condition is detected by the system the related screen will be showed on ECMOLIFE display. To manage and resolve the alarm you must take action on ECMOLIFE display. For COLIBRI technical alarms, “COLIBRI ALARM” will be displayed on screen



The alarms priority and the alarm management will be the same explained in paragraph 8

9.2.6. BATTERY MANAGEMENT

When the Colibrì system is connected to Ecmolife System, Ecmolife will maintain the internal battery level of Colibrì. If the Colibrì system is disconnected from Ecmolife but the connection cable is still connected to the Ecmolife console, the Ecmolife will continue to maintain the Colibrì internal battery level. From the Colibrì menu on Ecmolife it is possible to visualize the internal battery level of Colibrì device and the thunderbolt icon will inform if the Colibrì System is in charge. The internal battery level will remain visible also on the Colibrì screen, with the thunderbolt icon if in charge.

9.2.7. TURNING OFF THE ECMOLIFE-COLIBRÌ SYSTEM

In any moment you can disconnect the ECMOLIFE from the Colibrì system.
Through the “Disconnect COLIBRI” softkey it is possible to disconnect the COLIBRI without physically disconnecting the cable. The internal battery charge level of COLIBRI device will be checked and reported if less than 20%.

The disconnection can also take place by disconnecting the ECMOLIFE-COLIBRÌ cable.

When the disconnection is concluded the Colibrì system takes the control of all setting and editing of the treatment

9.3. ECMOLIFE-COLIBRÌ PARAMETERS EDITING

9.3.1. PARAMETERS SELECTION

You can activate the parameter selection by pushing on the ECMOLIFE display the value that you want to modify, for at least 1 second.
The parameters displayed on Colibrì display can not be selected and editable.

9.3.2. INCREASE AND DECREASE PARAMETERS VALUE

By turning the ECMOLIFE knob clockwise (+) or anticlockwise (-) or using the +/- ECMOLIFE display buttons, it is possible to increase / decrease the value of the selected parameter.

9.3.3. EDIT CONFIRMATION OR REFUSAL

Following the treatment parameter editing (e.g. RPM, LPM) it is necessary to confirm the set value by re-pushing the selected value on the ECMOLIFE display or re-pushing the ECMOLIFE knob within at least 3 second.
The parameter editing will be performed only if the user confirms. Once confirmed the parameters will be updated on the Colibrì screen.
If you delete the operation using the RETURN button, or if it takes more than 3 seconds to confirm, the device will restore the value to the previous one and the parameters does not change on Colibrì display.

9.4. SCREEN LOCK

9.4.1. ECMOLIFE SCREEN LOCK

To avoid editing of unwanted settings or functions, the ECMOLIFE display buttons will be automatically locked after 5 minutes of inactivity. The user can lock the ECMOLIFE display by pushing the lock button for at least 3 seconds. To enable the display, press at least 1sec the unlock button present in the footer bar of the ECMOLIFE screen or in the central bar of the ECMOLIFE main buttons.

You can reactivate the touchscreen by pushing the unlock button displayed on ECMOLIFE screen.

9.4.2. COLIBRÌ SCREEN LOCK

The colibri display will be automatically locked when connected to ECMOLIFE console. You can not reactivate the touchscreen if the ECMOLIFE is still connected.

During disconnection phase the Colibrì display automatically unlocked.

10. BACKUP UNIT

In case of failure of the following:

- Primary ECMOLIFE Console
- Primary ECMOLIFE Flowmeter
- Primary ECMOLIFE Motor driver

Backup Unit ECMOLIFE Console shall be activated, Backup Unit Motor driver installed and Backup Unit Flowmeter connected to allow fast switching to Backup Unit to safely continue the patient support.

Warning

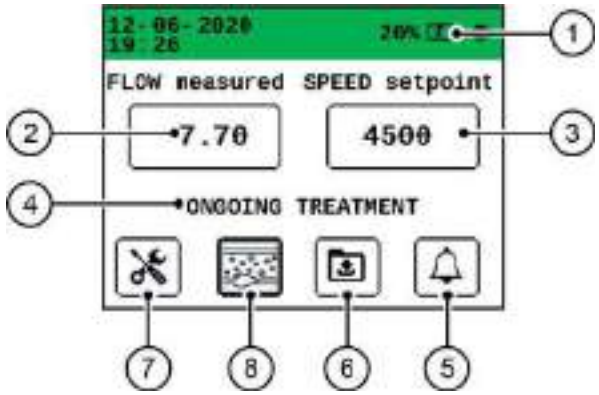
- Before starting the support, check that the Backup Unit battery is fully charged.
- Activate the Backup Unit only in case of Primary Unit failure.
- Keep a backup motor driver ready for use.
- Keep a backup flowmeter sensor ready for use.
- In case of Primary Unit failure, keep the Primary Emergency Button activated in order to prevent any electric interference.

10.1.DISPLAY

Backup Unit display shows an essential view of the main display.
The Backup Unit display is composed by:

1. The status bar, which shows date, time, residual charge and main power supply connection;
2. Blood Flow parameter;
3. RPM parameter;
4. Active page title;
5. Alarm button;
6. Download data button;
7. Settings button;
8. Bubble sensor management menu (available only for device with the Colibrì connector on the front panel).

Every section fulfills the same functionalities already described in the Primary Unit relevant section as well as the alarm management logic.



The status bar color indicates priority of ongoing alarm:

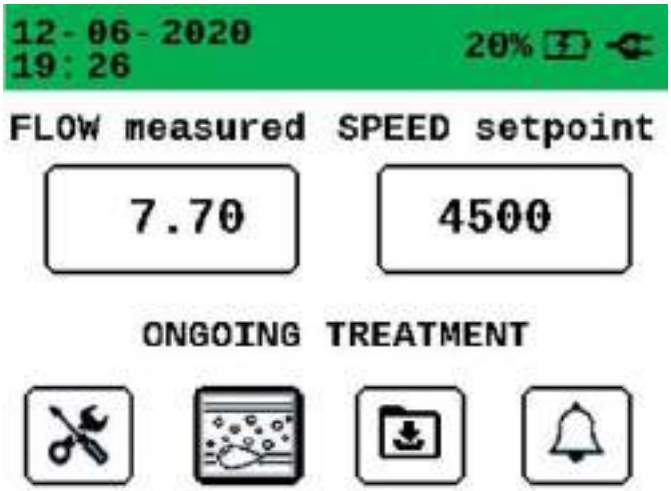
Color	Priority
Red	High priority alarm
Yellow	Medium priority alarm
Blue	Low priority alarm
Green	Normal operations

If several alarms are simultaneously present with the same priority, the status bar will show the one more recently actuated.
If several alarms are simultaneously present with different priority, the status bar display will show the higher priority alarm first then the others in order of priority then appearance.
The touchscreen underlines alarms also by highlighting the parameter concerned (See the alarm section).

10.2.TOOLBAR

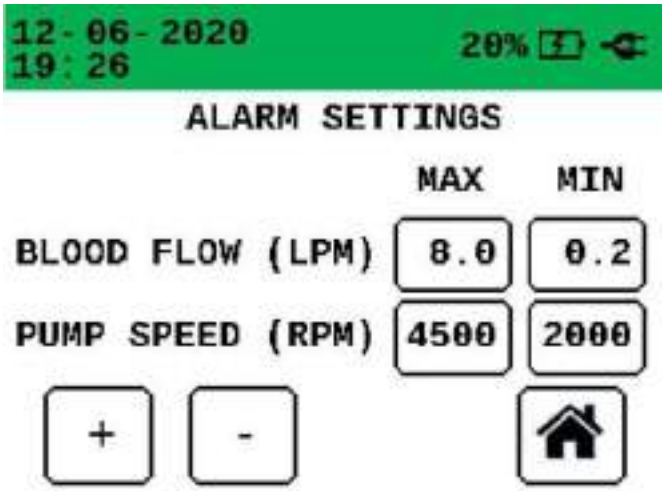
MAIN SCREEN

Through the main screen menu you can set primary treatment parameters as blood flow (LPM) and pump rotation speed (RPM)



ALARMS

In this section you can enter the Alarm Screen and configure RPM and LPM parameters alarm ranges where you can establish alarms minimum and maximum threshold value. Out of the set limits the device sends an alarm signal.



Warning

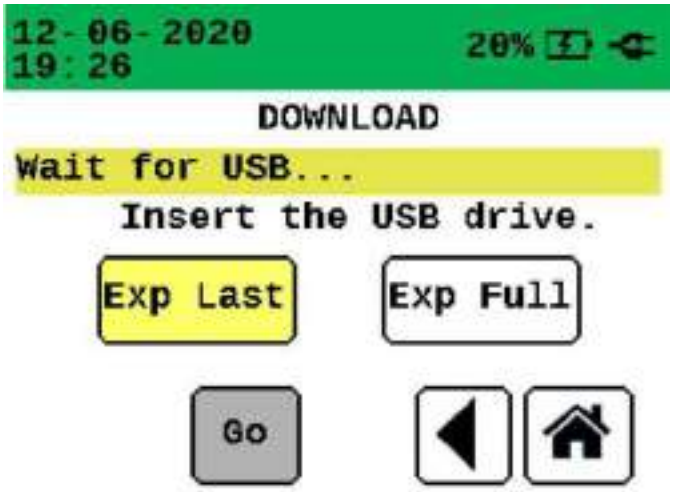
- Check the generation of audible alarm signals. In case of audio signal not generated the use of the device must be interrupted.
- Suspend the use of the device should the audio alarm system does not function properly during start-up test.
- Setting audio alarm to maximun/minimun values could disable the proper detection of physiological alarms.

DOWNLOAD

In this section you can download the patient data and save it into any memory drive.

During the treatment, it is possible to download the last treatment performed and/or the treatment ongoing.

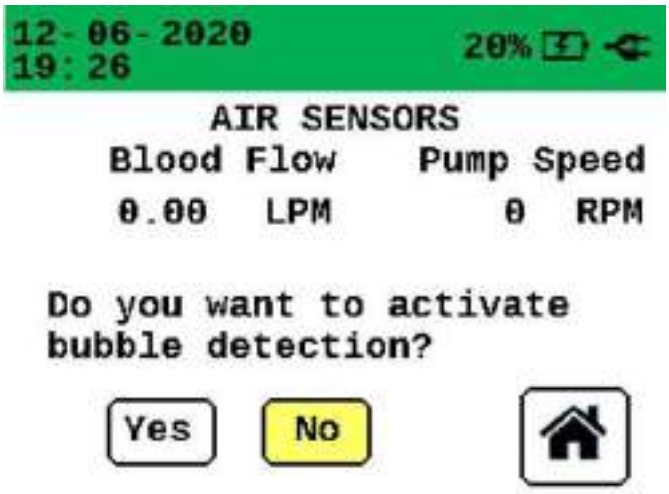
Before starting the treatment, it is possible to download the last treatment log file or the complete log file, with all the treatment data performed until then.
Download process duration for the complete log file might takes several minutes, depending on the amount of data stored inside the console memory.



Data can be downloaded both at the end of the treatment and during the treatment (sampled data will be saved up to that point).
The user will receive a confirmation of data successful transfer.

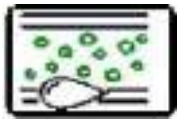
BUBBLE SENSORS MANAGEMENT MENU – (available only for device with the Colibrì connector on the front panel

In this section you can enable or disable the air bubble detection.
By default, the air bubble detection is not activated.



If the bubble detection is not activated the icon menu will be updated as follow:

If the bubble detection is activated by main and/or secondary sensor the icon menu will be updated as follow.



If the main sensor is in fault condition or disconnected by the tubing set from at least 1 minute, the menu icon will be updated as follow:

SETTINGS

In the Settings screen you can modify the following options:

- Language
- Date/Time
- Brightness & Volume
- System
- Display
- Service (not available during treatment)

Language
Select language.

Date/Time
Change date and time info.

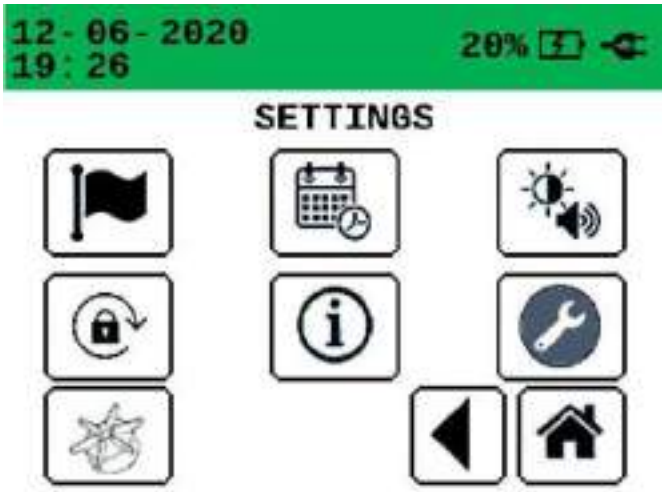
Brightness & Volume
Change device lightening, change device lightening and volume. You can set:

- 3 different level of display brighteness,
- 3 different volume level (Low, Medium, High).

Caution
If you set low or medium volume level, the following icon will be displayed on the screen.

System
Show system info. HW and SW version, serial number, latest update date, remaining days to recommended maintenance.

Display
Can select deactivation time of touchscreen after 1-2-5-10-30-60 min of inactivity (5 min default). It can select back time to homescreen after 5-10-30-60 min of inactivity in the secondary sections (5 min default).
Can set 3 different sensitivity touchscreen: slow – medium – fast.



Flow Control
Activate/deactivate the Blood Flow (LPM) Mode control.

Service
Section available by authorized staff only by password.
This section will be available only when Setting Page is selected before starting treatment (through Select Modality Page). During the treatment, this menu will not be available.

10.3.PARAMETERS

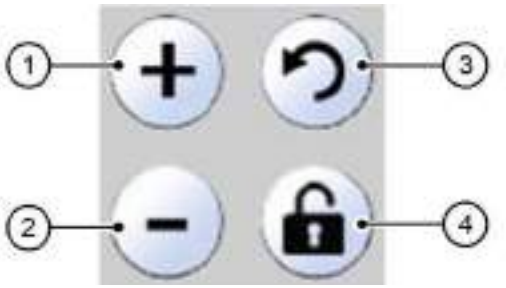
Parameters displayed in the main screen are listed below:

Parameter	Description	Sensor	Measure range	Measure unit	Accuracy
Blood flow (Adult/Paediatric)	Detected blood flow speed	Clamp on transducer sct 3/8” x 3/32”	0,0 ÷ 10,0	LPM	±0.07 l/min for flow value <= 1.0 l/min ± 7% for flow value > 1.0 l/min
Blood flow (Adult/Paediatric)	Detected blood flow speed	ECMOLIFE FLOWMETER 3/8’’x3/32’’	0,0 ÷ 10,0	LPM	±0.05 l/min for flow value <= 1.0 l/min ± 5% for flow value > 1.0 l/min
Blood flow (NEW BORN)	Detected blood flow speed	Clamp on transducer sct 1/4” x 3/32”	0,0 ÷ 4,0	LPM	±0.07 l/min for flow value <= 1.0 l/min ± 7% for flow value > 1.0 l/min
Blood flow (NEW BORN)	Detected blood flow speed	ECMOLIFE FLOWMETER 1/4’’x3/32’’	0,0 ÷ 4,0	LPM	±0.02 l/min for flow value <= 0.4 l/min ± 5% for flow value > 0.4 l/min
Speed pump	Speed revolutions per minut pump	/	0 ÷ 5000	RPM	± 50 RPM
Bubble	Air bubble detection	Bubble sensor	> 50	µl	NA

PARAMETERS EDITING

Backup Unit provides 4 membrane buttons:

1. Increase parameter value;
2. Decrease parameter value;
3. Return button;
4. Lock Screen button.



Parameter selection

You can activate the parameter selection that you want change, pushing for at least 1 second directly on the value that you want to modify on the touchscreen.

Increase and decrease values

Using the +/- selection display buttons it is possible to increase / decrease the value of the selected parameter.

Edit confirmation or refusal

Following the treatment parameter editing (e.g. RPM, LPM) it is necessary to confirm the set value by re-pushing the selected value on the display, within at least 3 second.
The parameter editing will be performed only if the user confirms.
If you delete the operation using the RETURN button, or if it takes more than 3 seconds to confirm, the device will restore the value to the previous one.

10.4.FUNCTIONALITIES

Backup Unit allows all the essential operations necessary to ensure the patient blood flow circulation.
For this reason, only Flowmeter and Motor driver can be connected to the Backup Unit.

Warning
All the auxiliary sensors:

- Pressure Sensors
- Venous Probe
- Bubble Sensor (available only for device with the Colibrì connector on the front panel)

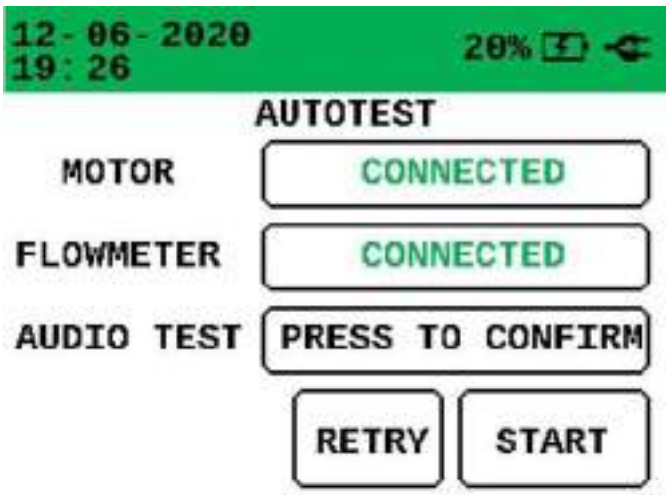
will not be available while using the backup section.

TURNING ON THE DEVICE

Once backup unit is turned on, the diagnostic page will be displayed.

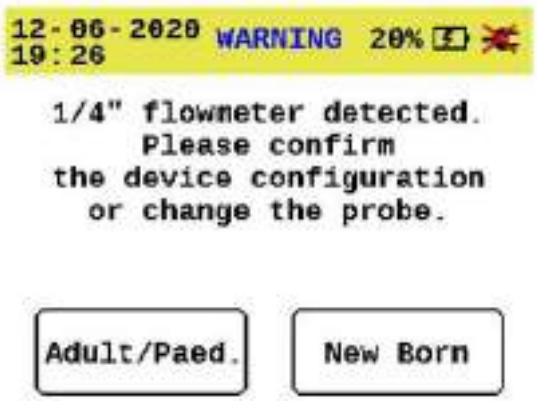
DIAGNOSTIC PHASE

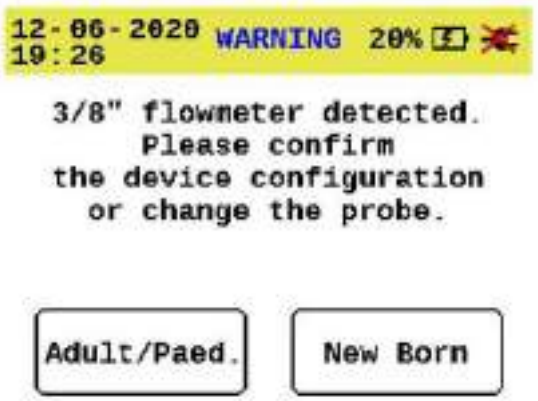
In diagnostic screen the device will check motor driver and flowmeter are properly connected.
Be sure the centrifugal pump is inserted and correctly primed during the diagnostic phase.
In order to safetely proceed with the operations, acoustic Audio Alarm detection shall be confirmed manually.



Warning
Do not continue in case of acoustic alarm is not detected at the end of this phase. ALARM SYSTEM might be compromised.
In order to make sure the backup section works correctly in case of emergency, perform this diagnostic phase once every 48h while using the primary section.

At the end of the diagnostic phase, by pressing the start treatment button the device is able to check the compatibility between the chosen configuration and the flow probe connected to the device. If the connected probe is not compatible with the chosen configuration, a dedicated warning is activated.



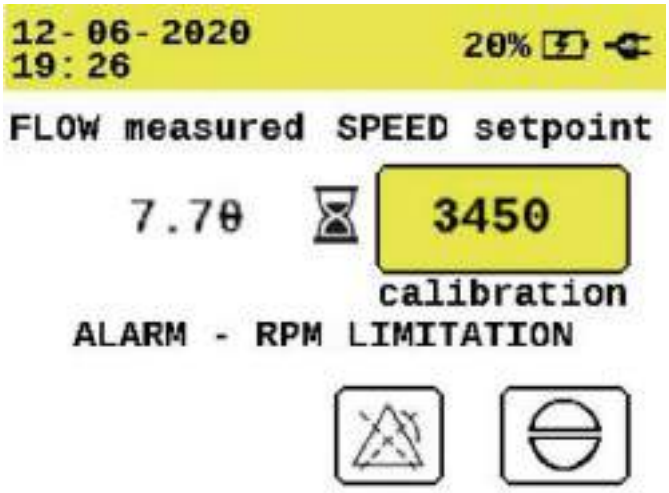


In order to guarantee a fast treatment resume due the emergency switch from the primary, the backup section doesn't perform the automatic priming and the impeller self-learning operation.
For safety reason a RPM upper range limitation will be set for RPM values higher than 3500RPM and 4500RPM.
In order to reach an RPM set-point higher than 3500RPM and 4500RPM it's necessary to allow the device to perform a two minutes of calibration in a range between these two target.

An alarm message will appear to inform the calibration is running and after a few minutes it will be possible to increase the RPM setpoint. The alarm message and the yellow bar will disappear at the end of calibration procedure.

Calibration will be performed by console by remaining for at least 2 minutes in a range within 1550RPM-3450RPM for the first self-learning setpoint and 4300RPM-4450RPM for the second self-learning setpoint.

Once both of the 3500RPM and 4500RPM setpoint has been checked, the device can be set in all the 0-5000 RPM range.



OPERATING MODE

When using the device, the desired RPM or pump blood flow values can be set by the user.

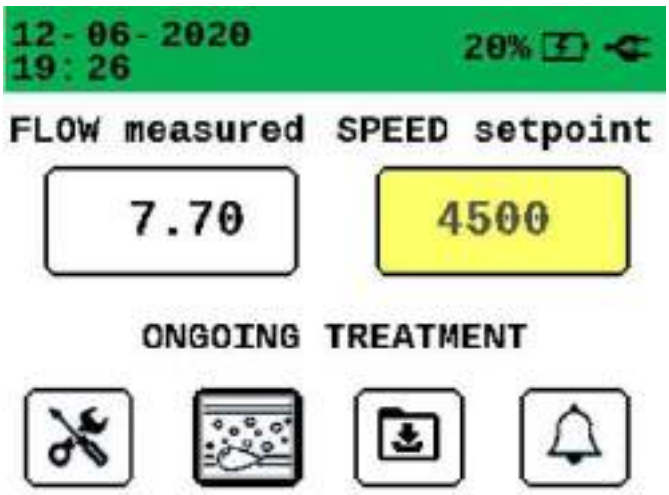
DRIVER RPM MONITORING MODE (DEFAULT MODE)

Default mode allows to control the centrifugal pump RPM, the blood flow will adapt to the set RPM.
RPM values can be set by using the panel +/- buttons.

Edit confirmation or refusal

It is necessary to confirm the set value by re-pushing the selected value on the display within at least 3 second.
The parameter editing will be performed only if the user confirms.
If you delete the operation using the RETURN button, or if it takes more than 3 seconds to confirm, the device will restore the value to the previous one.

During the RPM selection the parameter will be highlighted in yellow and the user selected target point will be displayed.
After confirmation the yellow highlighting will disappear and the actual RPM value will be displayed



BLOOD FLOW MONITORING MODE (ADDITIONAL MODE)

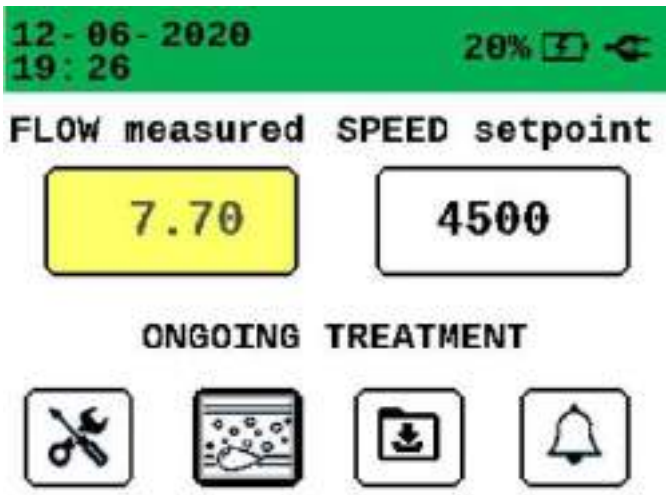
Blood Flow control shall be disabled by default.
Blood Flow control mode can be enabled by the Flow Control page in Settings device menù.
When setting a new blood flow value, by increasing or decreasing it in the main parameters screen, the device will automatically adjust the RPM to reach the desired flow.

LPM values can be set by using the panel +/- buttons.

Edit confirmation or refusal

It is necessary to confirm the set value by re-pushing the selected value on the display within at least 3 second.
The parameter editing will be performed only if the user confirms.
If you delete the operation using the RETURN button, or if it takes more than 3 seconds to confirm, the device will restore the value to the previous one.

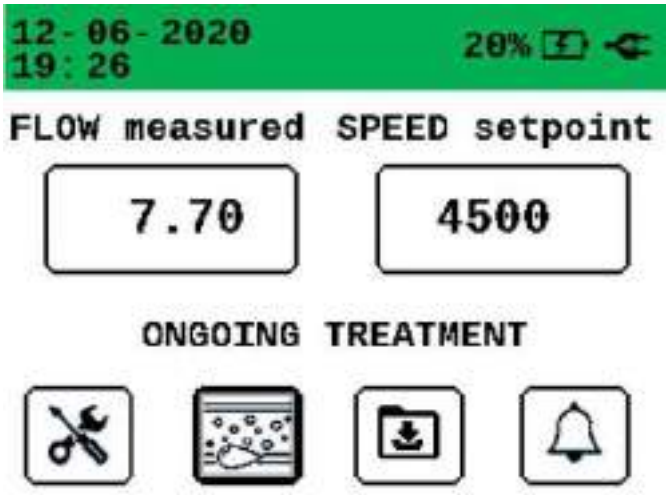
During the LPM selection the parameter will be highlighted in yellow and the user selected target point will be displayed.
After confirmation the yellow highlighting will disappear and the actual LPM value will be displayed



Warning
When blood flow control mode is used, RPM will be automatically adjusted in order to reach the desired flow. RPM may reach high values depending on the extracorporeal circuit pressures.

LPM CONTROL ENABLED/DISABLED MODE VIEW

LPM control activation is shown by the visualization of a frame on the parameter.



11. BACKUP UNIT - ALARMS

11.1.ALARM RANGE AND PARAMETERS

It is possible to set the alarm limits in the Alarm screen.
The alarm activates whenever the parameter value exceeds the warning limits, i.e:

- Value measured above the upper limit
- Value measured above the lower limit

You can set the alarm limits within the parameters summarized in the following table.

11.1.1. ALARM LIMIT – ADULT/PAEDIATRIC CONFIGURATION

Parameter	Description	Sensor	Measure range	Measure unit	Alarm threshold	Default alarm threshold
Blod flow	Detected blood flow speed	Clamp on transducer Sct 3/8" x 3/32"	0,0 ÷ 10,0	LPM	0,0 ÷ 10,0	0,2 ÷ 8,0
Speed pump	Speed revolutions per minute pump	/	0 ÷ 5000	RPM	0 ÷ 5000	2000 ÷ 4500
Bubble (*)	Air bubble detection	Bubble sensor	> 50	µl	(not modifiable)	> 50

(*) Available only for device with the Colibrì connector on the front panel.

Parameters range and alarm threshold are the same both on Primary and Backup Unit.

11.1.2. ALARM LIMIT – NEW BORN CONFIGURATION

Parameter	Description	Sensor	Measure range	Measure unit	Alarm threshold	Default alarm threshold
Blod flow	Detected blood flow speed	Clamp on transducer Sct 3/8" x 3/32"	0,0 ÷ 3,0	LPM	0,0 ÷ 3,0	0,2 ÷ 1,5
Speed pump	Speed revolutions per minute pump	/	0 ÷ 4500	RPM	0 ÷ 4500	0 ÷ 4500
Bubble (*)	Air bubble detection	Bubble sensor	> 50	µl	(not modifiable)	> 50

(*)Available only for device with the Colibrì connector on the front panel.

11.1.3. ZERO FLOW MODE

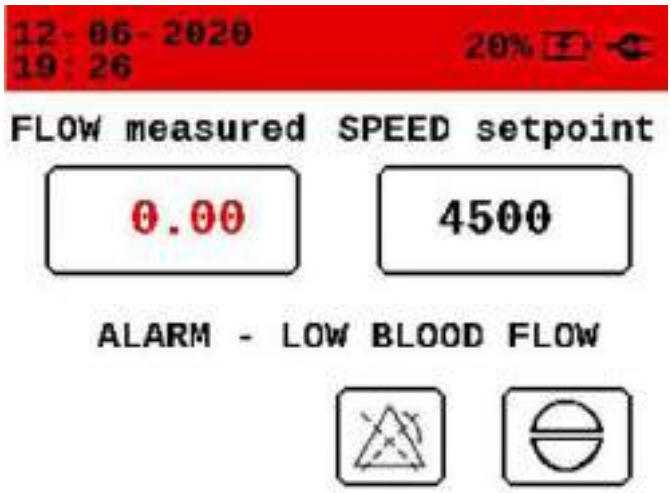
In order to avoid any kind of back flow once the user set a Blood Flow value = 0, the device automatically maintains a minimum rotation of the impeller (which may vary depending on the pressure detected at the Centrifugal Pump outlet line).
For this purpose the device monitors the blood flow, displays the alarms at the defined limits and reacts by intervening in the pump control.
The device has an extra alarm limit of - 0.2 LPM not settable by the user. In any moment if the blood flow falls below that limit for more than 1 sec, a medium priority alarm is generated and a prompt automatic RMP adjustment occurs to prevent back flow. The alarm ends as soon as the measured blood flow value rises above the alarm limit.

11.2.ALARMS PRIORITY

Alarms activation depends strictly from the priority ranking of parameter involved, according to the following table.

Priority Ranking	Parameter	Priority level	Color
1	Blood Flow	High	Red
2	Pump Speed	High	Red

11.2.1. BLOOD FLOW DETECTION ALARM (HIGH PRIORITY)



11.2.2. ALARM PAUSE

When an alarm is activated, on the main buttons section, the button is displayed in the "variable" button which allows the alarm sound to be silenced for 2 minutes.
The visual alarm status is kept active until it is resolved or the alarm is deactivated for that specific parameter.

11.2.3. ALARM ACKNOWNLEDGE

When an alarm is activated, on the main buttons section, the button is displayed in the "variable" button which allows the alarm sound to be silenced permanently.
The visual alarm status is kept active until it is resolved or the alarm is deactivated for that specific parameter.

Warning
When power is lost for less than or equal to 30 s, the ALARM SETTINGS prior to the power loss is restored automatically.

11.3.ALARMS TABLE

Refere to ANNEX 2 – BACKUP: Alarms table for the complete list of alarm messages.

12. POWER SUPPLY

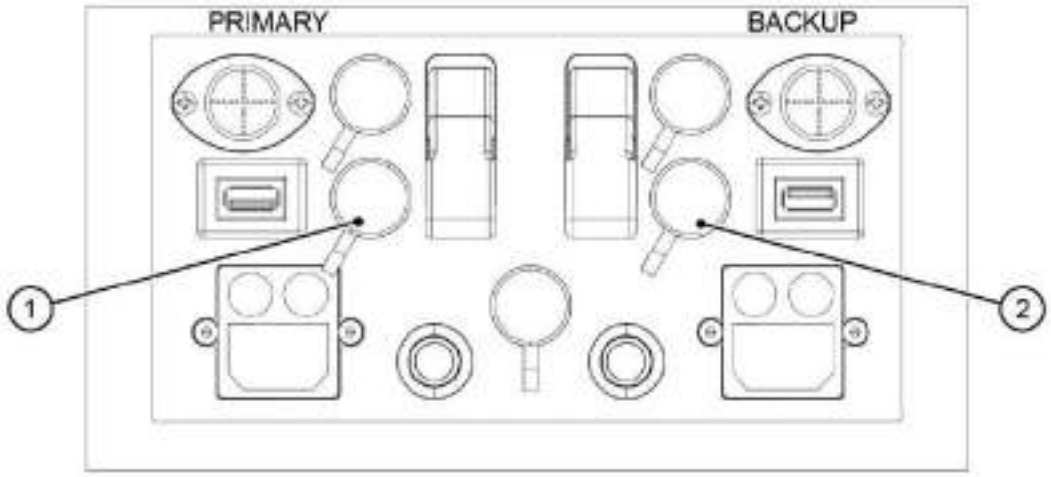
12.1.INTERNAL BATTERY

The device can work with both mains and internal battery powers.
In battery operation mode, in full charged condition, the guaranteed time for the device to function correctly is at least 90 min.
The device automatically switches to battery operation when the power supply is interrupted. When the external main power supply is available again, the device automatically returns to the external power supply. The internal batteries are automatically charged when the device is connected to external main power supply.
When the device is stored or not used, it can be left connected to the external current to preserve the full charge of the batteries. Check that the "Battery" LED is blinking during charging.
The internal battery of both units can be recharge while the sections are turned off.
The internal battery of backup section can be recharge while a treatment is ongoing on primary section.

Warning
If you decide to recharge the internal battery of backup section while a treatment is on going on primary section, don't turn on the backup unit.

12.2.EXTERNAL BATTERY

During transport or in case main supply is not available, the device can be powered from the ECMOLIFE Auxiliary Battery kit EU3899 both from Primary and Backup section from their relevant external battery sockets (1-2).



Once connected, the device will be powered from the external source which will guarantee the charge retention of the system for at least 90 minutes.

Battery charge status can be checked from led indicators by pressing the status button directly on the external batteries.

Warning
Connect only full recharged external battery to the device.
Once connected, external battery will not charge the internal device batteries.
Do not let fully discharge the internal battery before using the Auxiliary Battery Kit.

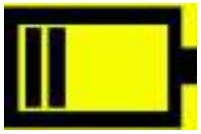
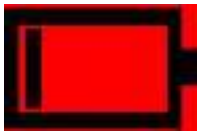
12.3.RECHARGEABLE BATTERY AUTONOMY

In battery operation mode, in full charged condition, the guaranteed time for the device to function correctly is at least 90 min.
The reported autonomy value is purely approximate, it may vary greatly due to different factors such as the number of connected sensors, the residual charge in the battery, the operating temperature, the natural decay of the battery over time, etc.
If necessary, clean the sensors with a cloth soaked in a well-wrung water-based disinfectant solution and with the device switched off and disconnected from the power supply.
This cleaning method does not pose any risk to the product for the entire lifetime.

12.4.BACKLIT ON-OFF BUTTONS AND BATTERY LED

Button / LED	Element	Meaning
	Backlight blinking ring ON/OFF	Green ring: the device is turned ON.
	Battery LED	LED OFF: with power connection connected indicates battery not charging or absent. Red blinking LED on (0,25Hz): battery charging. Battery level less than 20%. Yellow blinking LED on (0,25Hz): battery charging. Battery level between 20% and 70%. Permanent green LED on: device charged. Battery level between 70% and 100% Permanent yellow LED on: device works in battery mode. Battery not charging. Battery level between 20% and 70%. Permanent red LED on: device works in battery mode. Battery not charging. Battery level less than 20%.

12.5.SUPPLY MODE

Mains power indicator	Battery power indicator	Description
		Mains power supply connected. Battery charging with indication of remaining battery.
		Mains power supply connected. No battery detected.
		Mains power supply not connected, battery operation with the indication of remaining battery.
		Mains power supply not connected, battery operation with the indication of remaining battery. Battery level between 20% and 90%
		Mains power supply not connected, battery operation with the indication of remaining battery. Battery level less than 20%.
		Mains power supply not connected, external battery connected.

13. INTRA-HOSPITAL AND INTER-HOSPITAL ECMOLIFE TRANSPORTATION

LEONARDO TROLLEY AND LEONARDO SLIM

LEONARDO Trolley EU5093 and LEONARDO slim EU5094 are the trolley conceived to safely support and transport the ECMOLIFE CONSOLE during intra-hospital transport.

Warning
Consult the specific User Manuals/IFU EU10814 IFU Leonardo Trolley/IFU EU10814/S Leonardo Slim for the related technical data (weight, connections, etc.) and for its correct use.

Caution
LEONARDO Trolley and LEONARDO Slim are not available for Brazilian country.

ROAD AMBULANCE PLATE HOLDER

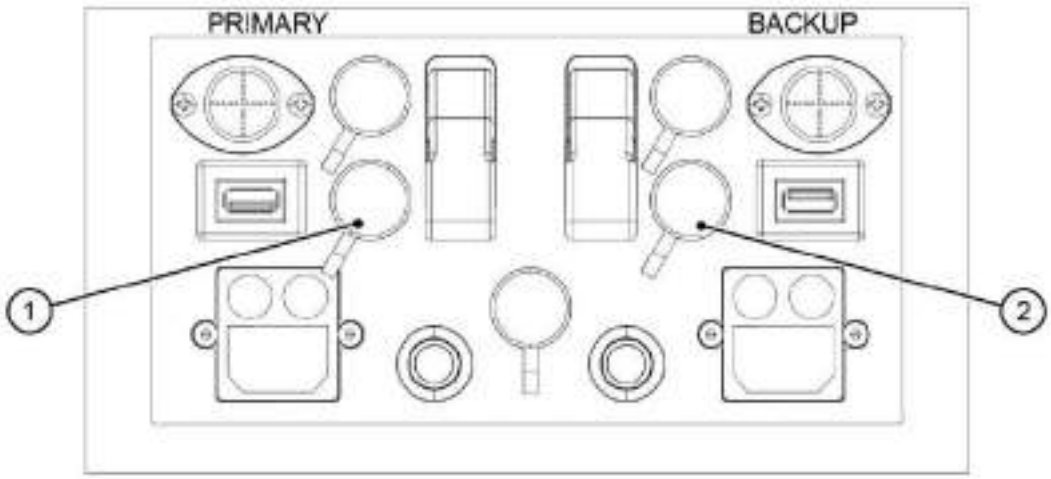
ECMOLIFE Ambulance Plate Holder EU3898 is conceived to safely support and transport the ECMOLIFE CONSOLE during road ambulance transport through a dedicated hooking interface which can be easily adapted to the ambulance mounting rails.

Warning
Consult the specific User Manuals/IFU EU10831 IFU ECMOLIFE Plate Holder for the related technical data (weight, connections, etc.) and for its correct use.

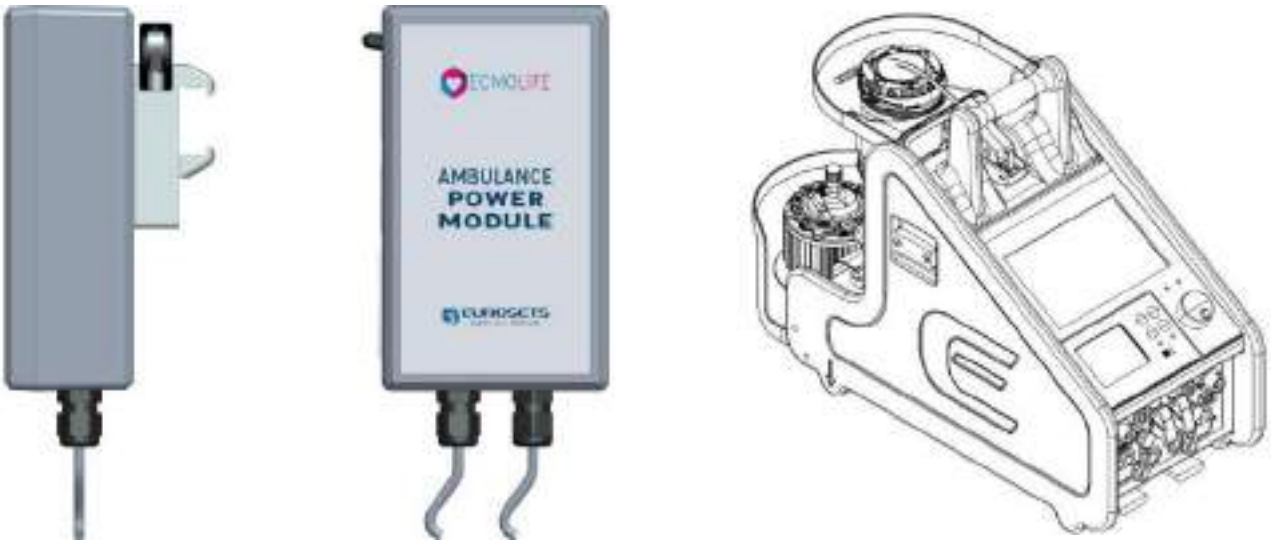
Caution
ROAD AMBULANCE PLATE HOLDER EU3898 are not available for Brazilian country.

AMBULANCE POWER MODULE

During road ambulance transport, in case of low battery and/or main supply not available, the device can be powered from the 24V Ambulance socket both on Primary and Backup section to their relevant external battery sockets (1-2).



In order to avoid any electrical interference between ECMOLIFE device and ambulance on board systems The dedicated Ambulance Power Module interface EU3953 must be used.



Using its clip hanging system Ambulance Power Module can be mounted on the side rails of ECMOLIFE.
Figures below describe module connectors

24V ECMOLIFE connector

24V Ambulance connector

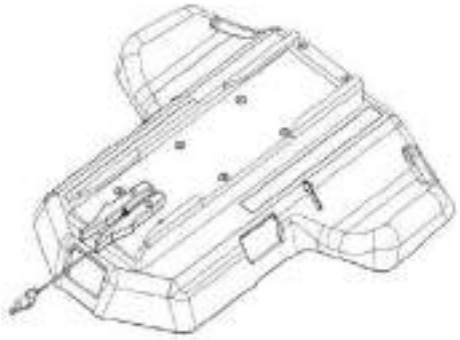
Warning

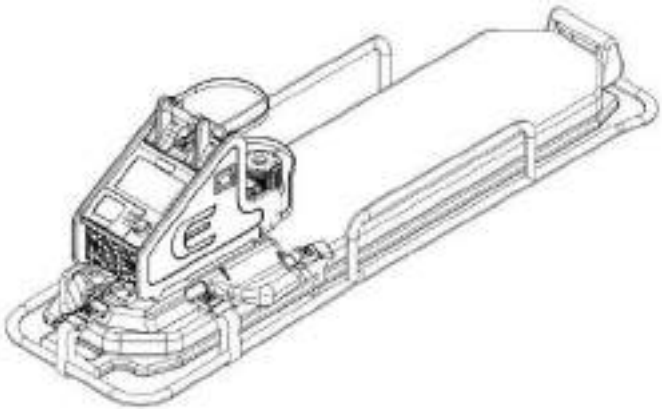
- Do not connect the ECMOLIFE 24V connection directly to the Ambulance 24V power source
- Check the integrity of Ambulance Power Module before using the module.
- In case of Ambulance Power Module malfunctions, disconnect the Power Module and connect a charged auxiliary battery.
- Ambulance Power Module meets ECE R10 regulation requirements.

Caution

AMBULANCE POWER MODULE **are not available for Brazilian country**.

FOIL STRETCHER HOLDER PLATE





FOIL STRETCHER HOLDER PLATE EU3996 is conceived to safely support and transport the ECMOLIFE CONSOLE during road ambulance transport through a dedicated interface which can be located between the legs of the patient.

Warning
Consult the specific User Manuals/IFU EU11053 IFU FOIL for the related technical data (weight, connections, etc.) and for its correct use.

14. TECHNICAL SPECIFICATIONS

Regulations	
Classification	Classified in accordance with Regulation (EU) 2017/745 (MDR).
Reference standards	• IEC 60601-1:2005+AMD1:2012+AMD2:2020 ed.3 • IEC 60601-1-2: 2014+AMD1:2020 • IEC 60601-1-8:2006+AMD1:2012 + AMD2:2020 – ed. 2.2 • IEC 62304:2006 + AMD1:2015 • IEC 60601-1-6:2010+AMD1:2013 + AMD2:2020 – ed. 3.2 • IEC 60601-1-12:2014+AMD1:2020 • IEC 62366-1:2015 + AMD1:2020 • IEC 62353:2014 • EN ISO 14971:2019 • UNI EN 1789:2014 (same as EN 1789:2007 + A2:2014)

Conditions of use	
Conditions of use	Device for continuous operation
Safety of use in the presence of flammable anesthetic mixtures with air or oxygen or nitrous oxide:	Device not suitable for use in the presence of flammable anesthetic mixtures with air or oxygen or nitrous oxide.
Environment	During operation: • Temperature:10 to +40°C, • Humidity: 15-90%, • Pressure range of 760-1060 hPa. During transient operation: • Temperature:10 to +40°C, • Humidity: 15-90%, • Pressure range of 760-1060 hPa. During storage/transport, when the device is not operating: • Temperature:-18 to +50°C, • Humidity: 15-90%, • Pressure range of 620-1060 hPa.

Technical specifications	
Air flow	• Forced air flow, from openings in the rear part of the device • 0,45 m³/h internal axial fan – 24 Vdc – 1,92 W • Each device unit has its own cooling fan
Heat emission	• The device dissipates the heat produced by the electronic circuits through the enclosure and through the convective air flow • Heat generated by the bearing-less motor is dissipated through the motor enclosure
Display	Primary Unit: Active Thin Film Transistor (TFT) size 8,1'' Backup Unit: Active Thin Film Transistor (TFT) size 3,5''
Keyboard	Primary Unit: touch screen (resistive) and knob Backup Unit: touch screen (resistive) and 4 membrane buttons
Acoustic energy generated by device operation	< 32 dB
Volume of auditory alarm signals	• > 65 dB at a distance of 1 m in free field conditions as specified by ISO 3744 for medium/high priority alarms • > 60 dB at a distance of 1 m in free field conditions as specified by ISO 3744 for low priority alarms
Dimensions	Device 340 x 265 x 432 mm (w x d x h)
Weight	Console: 14,5 kg Bracket and Motor: 2,5 kg Circuit Primed: 0,5 kg Complete System: 17,5 kg
Blood pump type	Centrifugal Pump, driven by a bearing-less motor
Pump flow	(0 + 0,5)-(10± 0,5) LPM @ 0 – 5000 RPM depending on pressure conditions.
Blood flow sensor	• Ultrasonic flow sensor • Measuring range: 0÷10 LPM • Accuracy: ± 7%
Air detection	• Ultrasonic, Foam/Bubbles • Air Detection Threshold: ≥ 50 µl
Hemoglobin sensor	• Optical Sensor • Measuring range: 5 – 16 g/dl • Accuracy ± 0,5 g/dl
Blood Oxygen Saturation sensor	• Optical Sensor • Measuring range: 40 – 99,9 % • Accuracy ± 3% as absolute value
Blood Temperature sensor	• Optical Sensor • Measuring range: 4 – 42 °C • Accuracy ± 1°C

Pressure sensors	Single use pressure sensor: • Measuring range: (-200) ÷ (+600) mmHg • Accuracy: o range ≤-200 mmHg: ±10 mmHg o range -50 mmHg/+100 mmHg: ±5 mmHg o range +100 mmHg/+300 mmHg: ±10 mmHg o range ≥ +300 mmHg: ±15 mmHg LogiCal pressure transducer + Smith Medical pressure sensor: • Measuring range: (-200) ÷ (+800) mmHg • Accuracy: ± 5% EDWARDS pressure transducer + EDWARDS pressure sensor: • Measuring range: (-200) ÷ (+800) mmHg • Accuracy: ± 5%

Electrical specifications	
Power supply	• Connection to electric power distribution system through power cord • Electromagnetic environment: hospital - dedicated supply systems • Connection to continuous current power source (24 Vdc) • Li-Ion rechargeable batteries, 25.9 V, 10.4 Ah (inside the device), Manufacturer: AccuPower, model: Lithium Battery 7S4P • NiMH rechargeable battery, 7.2 V, 4500 mAh
Mains insulation	• Bipolar emergency switch • Power supply cord detachable with lock system and mains plug
Power supply cord	• Default cable: Shurter 3-101-795 • Mains plug: CEE 7/7 (E/F) - straight • Rated Voltage: 250 V~ • Length: 3 m
Supply voltage	• 100 – 240 V~ • 50 – 60 Hz • 24 Vdc
Absorbed input power	190 VA
External Accessible Fuses (Appliance Inlet)	T4 A – 250 V – 5x20 mm
Applied part (IEC 60601-1)	Tubing Set including ECMOLIFE Centrifugal Pump
Classification of degree of protection against electrical hazards (IEC 60601-1)	Class II type CF
Degree of protection against penetration of liquids	IP33

15. ELECTROMAGNETIC COMPATIBILITY

ECMOLIFE System is intended for use in the electromagnetic environment specified below. User shall ensure that ECMOLIFE System is used in such environment.

Guidance and manufacturer's declaration – electromagnetic emissions

Emissions test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	ECMOLIFE System 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 A	ECMOLIFE System is suitable for use in all establishments other than domestic and those directly connected to the low voltage power supply network which supplies buildings used for domestic purposes
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/flicker emissions EN 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

Immunity Test	EN 60601-1-2 Test level	Compliance level	Electromagnetic Environment
Electrostatic discharge (ESD) EN 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	EN 60601-1-2 Test level	Hospital
Electrical fast transient/burst EN 61000-4-4	±2 kV for power supply lines 100 kHz repetition rate	EN 60601-1-2 Test level	Hospital
Surge EN 61000-4-5	±1 kV differential mode ±2 kV common mode	EN 60601-1-2 Test level	Hospital
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% Un (*) for 0.5 cycles 70% Un (*) for 25 cycles 0% Un (*) for 250 cycles	EN 60601-1-2 Test level	Hospital
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	30 A/m	EN 60601-1-2 Test level	Hospital

(*) Un is the a.c. mains voltage prior to application of the test level.

16. MAINTENANCE - SERVICING - SYSTEM LIFESPAN

16.1. LIFECYCLE OF THE RECHARGEABLE INTERNAL BATTERY

The battery pack must be changed every 36 months at the time of the third scheduled maintenance.

16.2. PERIODICAL MAINTENANCE PROGRAM

ECMOLIFE System shall undergo periodical maintenance at 12 months intervals.
The maintenance shall be carried out exclusively by manufacturer authorized personnel.

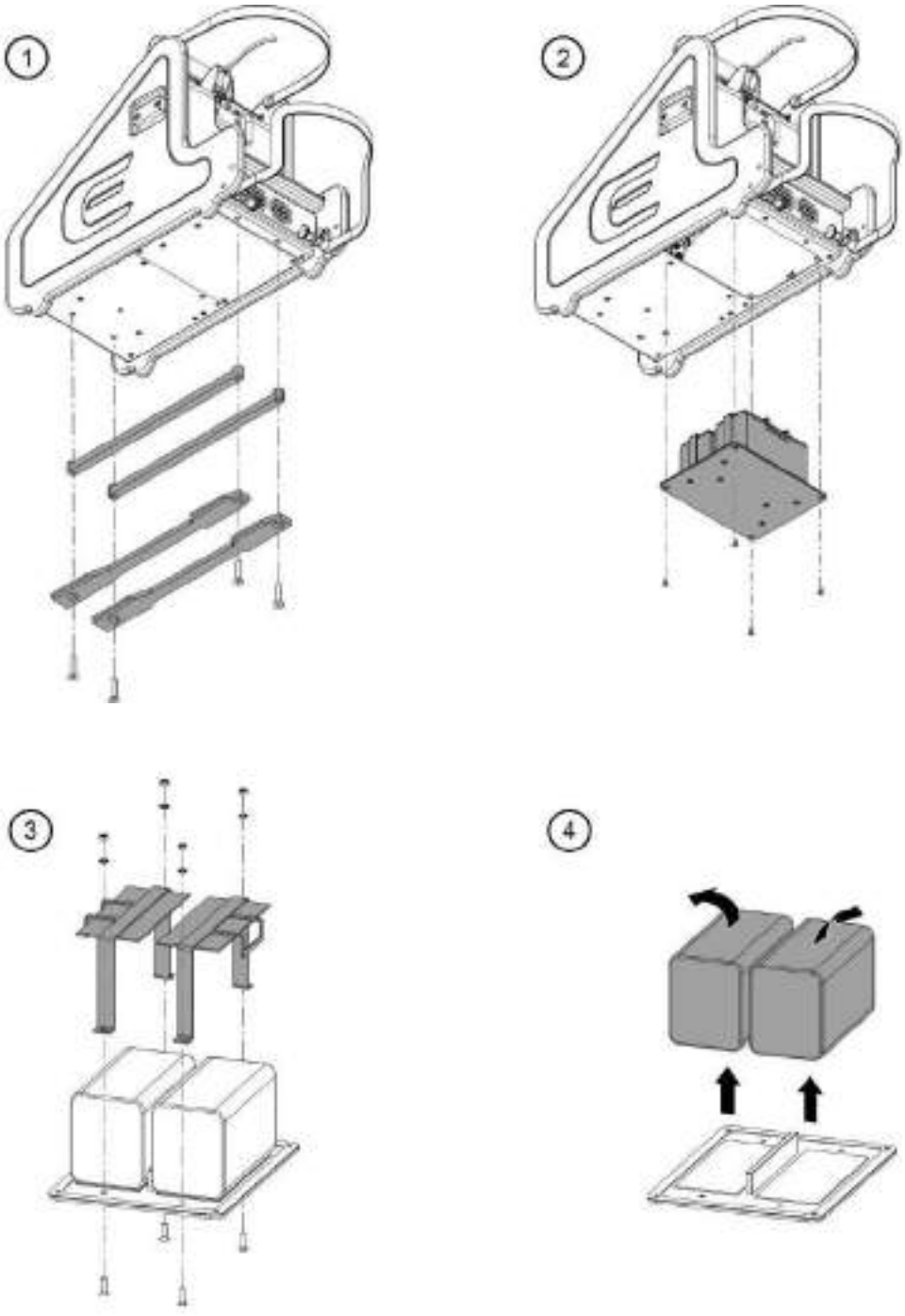
Warning

- No servicing action is admitted on ECMOLIFE System when the device is operating or when the patient is connected to it.
- Check the integrity of visible insulation and do not use the device if the equipment is damaged.

It is responsibility of the healthcare facility using the device to ask for technical service to the manufacturer or authorized agent.

16.3.BATTERY REPLACEMENT

Warning
Internal battery replacement must be performed only by EUROSETS authorized personnel.



16.4.POSSIBLE ANOMALIES OCCURRING DURING DEVICE FUNCTIONING

Whenever a device malfunctioning occurs, suspected or communicated through display messages, the user shall contact the manufacturer or manufacturer authorized representative.
The operator is not authorized to carry out servicing or calibration operations on the device.
It is allowed to perform adjustments of venous probes and pressure sensors as indicated in the present user manual.
The operator is responsible for checking device integrity before and during each use.

Warning

- Whenever the operator suspects a device component failure, device use shall be immediately discontinued and manufacturer authorized technical assistance service contacted.
- Check the integrity of visible insulation and do not use the device if damaged.

16.5.MEDICAL EQUIPMENT LIFESPAN

Assumed that the maintenance program is observed, the medical equipment has a lifespan of 10 years from the delivery date to the final customer / healthcare facility.

Warning

Essential performance and safety are not guaranteed in case of:

- Maintenance actions (included battery pack replacement) and hardware modifications not performed by manufacturer or authorized representative.
- Missed observation of the required periodical maintenance program by the manufacturer or authorized representative.

17. CLEANING AND DISINFECTION

This chapter contains important information about the cleaning and disinfection of the device to guarantee the operational safety of the device. 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.

During cleaning and disinfection, be careful not to let the internal parts of the device come into contact with liquids.
The outer casing must be cleaned/disinfected by healthcare workers.
The cleaning/disinfection operations should always be carried out before transferring the device to another patient.

Warning

- Cleaning and disinfection procedures shall be carried out on switched off equipment, disconnected from the mains.
- Do not let liquids drip into the device during the cleaning operations.
- Do not spray or pour disinfectant directly onto the device to avoid the liquid penetration into ECMOLIFE System.
- Pay attention to hygienically clean work processes (routine hand washing, disposable gloves, protective mask, hood).
- Do not use methods for 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 System surfaces the safety instruction from the manufacturer of cleaning and disinfection agents must be observed.
- For surface cleaning and disinfection of ECMOLIFE System housing and accessories use a disposable clean, non-linting cloth.
- Avoid the use of cleaning agents containing oil or grease.

17.1.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 % H2O2, 0.003% Ag
Giochemica	Gioclorex 2%	2% chlorhexidine digluconate solution in 70% isopropyl alcohol

- When using a disinfectant follow the instructions of the manufacturer

17.2.CLEANING PHASE

- Clean the units housing, cable 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,
    - control and display elements (chapter 6 “DISPLAY”),
    - unit couplings of front and rear panel,
    - knob,
    - handle,
    - motor driver (EU10566),
    - air bubble sensor (EU10574),
    - venous probe (EU3896),
    - clamp on transducer SCT 3/8” x 3/32” (EU1900),
    - Logical pressure transducer (MX960P1),
    - Smith medical pressure cable (EU3895),
    - Bracket (EU3897).
- 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:

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.

17.3.DISINFECTION PHASE

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

- In particular disinfect the following critical areas/items:
    - main switch,
    - control and display elements (chapter 6 “DISPLAY”),
    - unit couplings of front and rear panel,
    - knob,
    - handle,
    - motor driver (EU10566),
    - air bubble sensor (EU10574),
    - venous probe (EU3896),
    - clamp on transducer SCT 3/8” x 3/32” (EU1900),
    - Logical pressure transducer (MX960P1),
    - Smith medical pressure cable (EU3895),
    - Bracket (EU3897).
- 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:

18. ANNEXES

18.1.ANNEX 1 - PRIMARY: ALARMS TABLE

Physiological (P) Technical (T)	Alarm displayed	Alarm description	Priority	Corrective action
P	Main Absence	The device is not connected to main power supply	High	Press the acknowledge button and continue the treatment. The alarm will disappear when the device will be connected to the main power supply.
P	Internal Battery in reserve	Internal battery level lower than 70%	Medium	Press the acknowledge button and continue the treatment. If you desire connect the device to main power supply or to external battery.
P	Internal Battery depleted	Internal battery level lower than 20%	Medium	Press the acknowledge button and continue the treatment. Connect, in a few time, the device to main power supply or to external battery.
P	Low Blood Flow	Measured blood flow is less than minimum value sets in Alarm Page	High	Check no occlusions or any other case which may compromise the flow are presents. Ensure appropriate flow alarms are set. Do not increase RPM without confirming adequate blood volume is available.
P	High Blood Flow	Measured blood flow is bigger than maximum value sets in Alarm Page	High	Check any case which may compromise the flow are presents. Ensure appropriate flow alarms are set. Consider to decreased RPM to decrease the flow if appropriate.
P	Low RPM	Measured/selected RPM value is less than minimum value sets in Alarm Page	High	Check any case which may compromise the flow are presents. Ensure appropriate RPM alarms are set. Consider to increase LPM (if LPM control is enable) to increase RPM if appropriate.
P	High RPM	Measured/selected RPM value is bigger than maximum value sets in Alarm Page	High	Check any case which may compromise the flow are presents. Ensure appropriate RPM alarms are set. Consider to decreased LPM (if LPM control is enable) to decrease the flow if appropriate.
P	Negative Blood Flow	Measured blood flow is less than 0.00 LPM	High	Check for and resolve a physiological or mechanical cause. Consider to increased RPM to increase the flow if appropriate.
P	Low Pdrain	Measured drainage pressure is less than minimum value sets in Alarm Page	Medium	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting.
P	High Pdrain	Measured drainage pressure is bigger than maximum value sets in Alarm Page	Medium	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting. Consider reducing RPM to reduce the pressure if appropriate.

P	Pdrain not connected	Pdrain probe is detected as not inserted	Medium	Check the Pdrain probe or 3to1 probe connection on back of Console. If necessary, try to disconnect and reconnect the flowmeter to its relevant connector. Press the alarm acknowledge button. Switch to the backup Flow Probe, if the alert message repeats.
P	Low Pin	Measured pre-oxygenator pressure is less of minimum value sets in Alarm Page	Medium	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting.
P	High Pin	Measured pre-oxygenator pressure is bigger than maximum value sets in Alarm Page	Medium	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting. Consider reducing RPM to reduce the pressure if appropriate.
P	Pin not connected	Pin probe is detected as not inserted	Medium	Check the Pin probe or 3to1 probe connection on back of Console. If necessary, try to disconnect and reconnect the flowmeter to its relevant connector. Press the alarm acknowledge button. Switch to the backup Flow Probe, if the alert message repeats.
P	Low Pout	Measured post-oxygenator pressure is less than minimum value sets in Alarm Page	Medium	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting.
P	High Pout	Measured post-oxygenator pressure is bigger than maximum value sets in Alarm Page	Medium	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set. Consider recalibrating the transducer if alert cannot be explained by conventional troubleshooting. Consider reducing RPM to reduce the pressure if appropriate.
P	Pout not connected	Pout probe is detected as not inserted	Medium	Check the Pout probe or 3to1 probe connection on back of Console. If necessary, try to disconnect and reconnect the flowmeter to its relevant connector. Press the alarm acknowledge button. Switch to the backup Flow Probe, if the alert message repeats.
P	Low DP	Calculated pressure drop value is less than minimum value sets in Alarm Page	Medium	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure drop alarms are set.
P	High DP	Calculated pressure drop value is bigger than maximum value sets in Alarm Page	Medium	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure drop alarms are set.
P	Low SVO2	Measured venous oxygen saturation is less than minimum value sets in Alarm Page	Low	Check the Venous Probe connection to the tubing set (see Paragraph 3.2). Ensure appropriate SVO2 alarms are set.
P	High SVO2	Measured venous oxygen saturation is bigger than maximum value sets in Alarm Page	Low	Check the Venous Probe connection to the tubing set (see Paragraph 3.2). Ensure appropriate SVO2 alarms are set.
P	Low HB	Measured haemoglobin is less than minimum value sets in Alarm Page	Low	Check the Venous Probe connection to the tubing set (see Paragraph 3.2). Ensure appropriate HB alarms are set.
P	High HB	Measured haemoglobin is bigger than maximum value sets in Alarm Page	Low	Check the Venous Probe connection to the tubing set (see Paragraph 3.2). Ensure appropriate HB alarms are set.

P	Low Blood Temperature	Measured blood temperature is less than minimum value sets in Alarm Page	Low	Check the Venous Probe connection to the tubing set (see Paragraph 3.2). Ensure appropriate Tven alarms are set.
P	High Blood Temperature	Measured haemoglobin is bigger than minimum value sets in Alarm Page	Low	Check the Venous Probe connection to the tubing set (see Paragraph 3.2). Ensure appropriate Tven alarms are set.
P	Air Detected	Air Bubble is detected	High	The device is able to detect air bubble higher than 50 µL. Check any leakage on tubing set are present. Check the Bubble sensor connection to the tubing (see Paragraph 3.5)
P	Main sensor air detected (*)	Air Bubble is detected by bubble sensor integrated on flowmeter	High	The device is able to detect air bubble higher than 50 µL. Check any leakage on tubing set are present. Check the Bubble sensor connection to the tubing (see Paragraph 3.5)
P	Secondary sensor air detected (*)	Air Bubble is detected by secondary bubble sensor	High	The device is able to detect air bubble higher than 50 µL. Check any leakage on tubing set are present. Check the Bubble sensor connection to the tubing (see Paragraph 3.5)
P	RPM Limitation	Calibration is running	Medium	Press the alarm acknowledge button and wait the end of the calibration procedure. At the end of calibration procedure the yellow bar disappear and it is possible research higher RPM/LPM.
T (***)	Motor disconnection	Motor driver is not connected to device	High	Press the alarm acknowledge button and check that an automatic restarting procedure is executed by the device. The automatic restarting procedure restore the previously pump speed reduced by 10%. If this procedure doesn't start, check that the connector of the Motor is fully inserted into the front of the Console. Resume support. If the anomaly persist, clamp the return tubing and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T (***)	Speed Error	In the range 1500 – 5000 RPM, the setting speed is different from measured speed	High	An audible alarm will sound and the System will continue to operate. Press the alarm acknowledge button, if the visual alarm message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T (***)	Motor Control Optimization	In the range 400-1500 RPM the setting speed is different from measured speed	High	Press the alarm acknowledge button and check that an automatic restarting procedure is executed by the device. The automatic restarting procedure restore the previously pump speed increase them of +50 RPM. If the anomaly persist, the device will be try to optimize the motor control two times until the setting RPM value is the range 400-1500 RPM after that the "Motor Control Execute" Alarm will be activated.

T (***)	Motor Control Execute	In the range 400-1500 RPM the setting speed is different from measured speed and the device try for the last time to restore the motor control stability	High	In the bottom part of the display the following message will be display: “Instable motor control has been detected. Please if you can, set 1500 RPM to improve the motor control stability” and an automatic restarting procedure is executed by the device. Pressing the acknowledge button you accept the instability condition of motor control and the device will not attempt to optimize the motor control as long as the set RPM value is within the range 400-1500 RPM. If you exit from this range and then go back, the optimization procedure will be evaluate again.
T (***)	Overcurrent Error	An overcurrent condition is detected	High	Press the alarm acknowledge button and check that an automatic restarting procedure is executed by the device. The automatic restarting procedure restore the previously pump speed reduced by 10%. If this procedure doesn’t start, check the correct functioning of the Centrifugal Disposable Pump and set new pump speed value. If no anomalies are perceived, continue the treatment and contact Technical Assistance. If the anomaly persist, clamp the return tubing and switch to the backup Console, Motor and Flowmeter and contact Technical Assistance.
T (***)	Pumping Body not inserted	Body pump is detected as not inserted	High	Press the alarm acknowledge button and check that an automatic restarting procedure is executed by the device. The automatic restarting procedure restore the previously pump speed reduced by 10%. If this procedure doesn’t start, verify that the Centrifugal Pump is fully inserted into motor driver and set a new pump speed value. If the anomaly persist, clamp the return tubing and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T (***)	Flow sensor error	Blood Flow management error	High	Check the Flow Probe connection to the tubing set. This error may occur after the LPM set-point modification in case of the device can’t reach the desired flow within two seconds. In this case be sure no occlusions or any other case which may compromise the flow are presents. In case of persistent error, disconnect and reconnect the flowmeter to its relevant connector. If the problem persists, connect the backup flowmeter.
P	Flow sensor detachment (**)	Blood Flow probe is detected as detached from the tubing set	High	Check the Flow Probe connection to the tubing set (see paragraph. 3.3). Check there is no air in the tubing set. This error may occur at the beginning of priming phase, when the tubing are completely full of air. In case of persistent error, disconnect and reconnect the flowmeter to its relevant connector. If the problem persists, connect the backup flowmeter to the primary section.
P	Flow sensor disconnected	Blood Flow probe is detected as not inserted	High	Check the Flow Probe connection on front of Console. If necessary, try to disconnect and reconnect the flowmeter to its relevant connector. Press the alarm acknowledge button. Switch to the backup Flow Probe, if the alert message repeats.

P	Secondary air sensor disconnected (*)	Secondary air sensor probe is detected as not inserted	High	Check the air sensor probe connection on back of Console. If necessary, try to disconnect and reconnect the probe to its relevant connector. Press the alarm acknowledge button. Record the alarm message and contact Technical Assistance.
T (***)	Flow Sensor Error Temp	An over temperature is detected on Blood Flow board	High	This error may occurs when the internal temperature is too high. From now on the Blood Flow value will be not available. Clamp the return tubing and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T (***)	Flow Sensor Disconnected	An error is detected on Blood Flow board	High	Check the Flow Probe connection on front of Console. In case of persistent error, try to disconnect and reconnect the flowmeter to its relevant connector and repeat the diagnostic phase. If the anomaly persist, clamp the return tubing and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T (***)	Flow Sensor Data Error	A technical error communication is detected on Blood Flow board	High	Check the Flow Probe connection on front of Console. In case of persistent error, try to disconnect and reconnect the flowmeter to its relevant connector and repeat the diagnostic phase. If the anomaly persist, clamp the return tubing and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
P	Low volume setting	Low or medium audio alarm level is set	Medium	This alarm occurs when you set low or medium audio alarm level. Manage the alarm using Pause and Acknowledge button. From now on, the related icon (see chapter Brightness and Volume) will be displayed on the screen until the audio alarm is set to high level.
P	Temperature Probe Error	Venous Probe communication error	Low	Check the Venous Probe connection on back of Console. In case of persistent error, disconnect and reconnect the venous probe to its relevant connector and retry the diagnostic phase. If the problem persists, disconnect the venous probe and continue the treatment without the venous probe
P	Blood Parameters Error	Venous Probe communication error	Low	Check the Venous Probe connection on back of Console. In case of persistent error, disconnect and reconnect the venous probe to its relevant connector and retry the diagnostic phase. If the problem persists, disconnect the venous probe and continue the treatment without the venous probe
P	Venous Probe Error	Venous Probe communication error	Low	Check the Venous Probe connection on back of Console. In case of persistent error, disconnect and reconnect the venous probe to its relevant connector and retry the diagnostic phase. If the problem persists, disconnect the venous probe and continue the treatment without the venous probe

P	Venous Probe Timeout Error	Venous Probe communication error	Low	Check the Venous Probe connection on back of Console. In case of persistent error, disconnect and reconnect the venous probe to its relevant connector and retry the diagnostic phase. If the problem persists, disconnect the venous probe and continue the treatment without the venous probe.
P	Air sensor test Failed (**)	An error is detected on air sensor board	High	Check the Air sensor probe connection on back of Console. In case of persistent error, disconnect and reconnect the air sensor probe to its relevant connector If the problem persists, disconnect the air sensor probe and continue the treatment without it.
P	Secondary air sensor error (*)	An error is detected on secondary air sensor	High	Check the Air sensor probe connection on back of Console. In case of persistent error, disconnect and reconnect the air sensor probe to its relevant connector If the problem persists, disconnect the air sensor probe and continue the treatment without it.
P	Main air sensor error (*)	An error is detected on main air sensor	High	Check the Air sensor probe connection on the fornt of Console. In case of persistent error, disconnect and reconnect the air sensor probe to its relevant connector If the problem persists, switch to the backup section and contact the Technical Assistance.
T (***)	Audio System Failure	A technical Alarm is detected on Audio board	High	Press the alarm acknowledge button, if the message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the fault code message and contact Technical Assistance.
P	Flow Control Error	Flow management error	High	Check the Flow Probe connection to the tubing set. This error may occur after the LPM/RPM set-point modification in case of the device can't reach the desired flow within five seconds. In this case be sure no occlusions or any other case which may compromise the flow are presents. In case of persistent error, disconnect and reconnect the flowmeter to its relevant connector. If the problem persists, connect the backup flowmeter.
P	Internal Battery Fault	Fault condition is detected on Internal Battery	High	An audible alarm will sound and the System will continue to operate. Press the alarm acknowledge button, if the visual alarm message does not disappear don't disconnect the device from main power supply. If you need to disconnect the device from poer supply, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.

P	Internal Battery not detected	Broken fuse is detected on the Internal Battery	High	An audible alarm will sound and the System will continue to operate. Press the alarm acknowledge button. From now on, don't disconnect the device from main power supply. If you need to disconnect the device from power supply, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
P	External Battery not in used	External Battery is disconnected	Medium	Check the External Battery connection to front of Console. Try to disconnect and reconnect the external battery. If the error persists, verify the charge level of the battery or change the battery.
P	SD Card Error	An error is detected on the SD Card memory	Medium	Try to resume the device. If the error persists, starts the treatments and contact Technical Assistance. In this case, the graphs and the data log file will not be available during all treatment duration.
T (***)	SPI Master Motor Timeout	A technical error is detected on Motor board	High	An audible alarm will sound and the System will continue to operate. Press the alarm acknowledge button, if the visual alarm message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T (***)	SW ERROR (LPSM)	A SW error is detected	High	An audible alarm will sound and the System will continue to operate. Press the alarm acknowledge button, if the visual alarm message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T (***)	Motor Fault	An expected error occurs on Motor board	High	Press the alarm acknowledge button, if the message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the fault code message and contact Technical Assistance.
T	Colibrì Disconnected	Colibrì device has been disconnected, the treatment control switch to Colibrì device	High	The connection between ECMOLIFE system and COLIBRI system has been interrupt. If the connection cable has been detached, re-connect it to the console. If the "Disconnect COLIBRI" softkey has been pressed, reconnect the systems through the "Connect COLIBRI" softkey. If the connection fails, continue the treatment on COLIBRI device.
T (***)	Error Code E03	CRC Error	High	This error might be caused by a SW update. Restart the device. If the problem persists please record the fault code message and contact Technical Assistance.
T (***)	Error Code E05	Reset Master board	High	Clamp the return line and switch to back-up section to proceed the treatment. Record the fault code message and contact Technical Assistance
T (***)	Error Code E06	Unexpected reset	High	Clamp the return line and switch to back-up section to proceed the treatment. Record the fault code message and contact Technical Assistance.

T (***)	Error Code E07	UnexpectedPower reset	High	This error might be caused by an unexpected power interruption due to battery discharge or emergency button activation. Normal operation can be restored by turning off and on the device. If none of those circumstances occurred, record the fault code message and contact Technical Assistance.
T (***)	Error Code E08	Reset motor failure	High	Clamp the return line and switch to back-up section to proceed the treatment. Record the fault code message and contact Technical Assistance.
T (***)	Error Code E09	Internal Battery Error	High	This error might be displayed if, during the previous treatment, the Internal battery fault error is activated. Restart the device. If the problem persists please record the fault code message and contact Technical Assistance.
T (***)	Error Code E10	Slave SW version fail	High	This error might be caused by a incorrect SW update. Restart the device. If the problem persists please record the fault code message and contact Technical Assistance.
T (***)	Error Code E11	Internal Battery Failure	High	The fuse of the internal battery has been detected as broken. From now on, if you disconnect the power supply corde, the device will be shut down. Turn off the device and switch to back-up section. Contact Technical Assistance.

(*) Available only for device with the Colibrì connector on the front panel.
(**) Not Available for device with the Colibrì connector on the front panel
(***) In the Alarm List, Technical Alarms will be preceded by a “C” when referred to Colibrì only when used in combination with Ecmolife.

18.2.ANNEX 2 - BACKUP: ALARMS TABLE

Physiological (P) Technical (T)	Alarm displayed	Alarm description	Priority	Corrective action
P	Main Absence	The device is not connected to main power supply	High	Press the acknowledge button and continue the treatment. The alarm will disappear when the device will be connected to the main power supply.
P	Internal Battery in reserve	Internal battery level lower than 70%		Press the acknowledge button and continue the treatment. If you desire connect the device to main power supply or to an external power supply.
P	Internal Battery depleted	Internal battery level lower than 20%		Press the acknowledge button and continue the treatment. Connect, in a few time, the device to main power supply or to an external power supply.
P	Low Blood Flow	Measured blood flow is less than minimum value sets in Alarm Page	High	Check no occlusions or any other case which may compromise the flow are presents. Ensure appropriate flow alarms are set. Do not increase RPM without confirming adequate blood volume is available
P	High Blood Flow	Measured blood flow bigger than maximum value sets in Alarm Page	High	Check any case which may compromise the flow are presents. Ensure appropriate flow alarms are set. Consider to decreased RPM to decrease the flow if appropriate.
P	Low RPM	Measured/selected RPM value is less than minimum value sets in Alarm Page	High	Check any case which may compromise the flow are presents. Ensure appropriate RPM alarms are set. Consider to increase LPM (if LPM control is enable) to increase RPM if appropriate.
P	High RPM	Measured/selected RPM value is bigger than maximum value sets in Alarm Page	High	Check any case which may compromise the flow are presents. Ensure appropriate RPM alarms are set. Consider to decreased LPM (if LPM control is enable) to decrease the flow if appropriate.
P	Negative Blood Flow	Measured blood flow is less than 0.00 LPM	High	Check for and resolve a physiological or mechanical cause Consider to increased RPM to increase the flow if appropriate.
P	RPM Limitation	Calibration is running	Medium	Press the alarm acknowledge button and wait the end of the calibration procedure. At the end of calibration procedure the yellow bar disappear and it is possible research higher RPM/LPM.
P	Low volume setting	Low or medium audio alarm level is set	Medium	This alarm occurs when you set low or medium audio alarm level. Manage the alarm using Pasue and Acknowledge button. From now on, the related icon (see chapter Brightnes and Volume) will be displayed on the screen until the audio alarm is set to high level.
P	Main sensor air detected (*)	Air Bubble is detected by bubble sensor integrated on flowmeter	High	The device is able to detect air bubble higher than 50 µL. Check any leakage on tubing set are present. Check the Bubble sensor connection to the tubing (see Paragraph 3.5)

T	Motor disconnection	Motor driver is not connected to device	High	Press the alarm acknowledge button and check that an automatic restarting procedure is executed by the device. The automatic restarting procedure restore the previously pump speed reduced by 10%. If this procedure doesn't start, check that the connector of the Motor is fully inserted into the front of the Console. Resume support. If the anomaly persist, clamp the return tubing and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message.
T	Speed Error	In the range 1500 – 5000 RPM, the setting speed is different from measured speed	High	An audible alarm will sound and the System will continue to operate. Press the alarm acknowledge button, if the visual alarm message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T	Motor Control Optimization	In the range 400-1500 RPM the setting speed is different from measured speed	High	Press the alarm acknowledge button and check that an automatic restarting procedure is executed by the device. The automatic restarting procedure restore the previously pump speed increase them of +50 RPM. If the anomaly persist, the device will be try to optimize the motor control two times until the setting RPM value is the range 400-1500 RPM after that the "Motor Control Execute" Alarm will be activated.
T	Motor Control Execute	In the range 400-1500 RPM the setting speed is different from measured speed and the device try for the last time to restore the motor control stability	High	In the bottom part of the display the following message will be display: "Set 1500 RPM." and an automatic restarting procedure is executed by the device. Pressing the acknowledge button you accept the instability condition of motor control and the device will not attempt to optimize the motor control as long as the set RPM value is within the range 400-1500 RPM. If you exit from this range and then go back, the optimization procedure will be evaluate again.
T	Overcurrent Error	An overcurrent condition is detected	High	Press the alarm acknowledge button and check that an automatic restarting procedure is executed by the device. The automatic restarting procedure restore the previously pump speed reduced by 10%. If this procedure doesn't start, check the correct functioning of the Centrifugal Disposable Pump and set new pump speed value. If no anomalies are perceived, continue the treatment and contact Technical Assistance. If the anomaly persist, clamp the return tubing and switch to the backup Console, Motor and Flowmeter and contact Technical Assistance.
T	Pump Body not inserted	Body pump is detected as not inserted	High	Press the alarm acknowledge button and check that an automatic restarting procedure is executed by the device. The automatic restarting procedure restore the previously pump speed reduced by 10%. If this procedure doesn't start, verify that the Centrifugal Pump is fully inserted into motor driver and set a new pump speed value. If the anomaly persist, clamp the return tubing and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.

T	Flow sensor error	Blood Flow management error	High	Check the Flow Probe connection to the tubing set. This error may occur after the LPM set-point modification in case of the device can't reach the desired flow within two seconds. In this case be sure no occlusions or any other case which may compromise the flow are presents. In case of persistent error, disconnect and reconnect the flowmeter to its relevant connector. If the problem persists, connect the backup flowmeter.
P	Flow sensor detachment (**)	Blood Flow probe is detected as detached from the tubing set	High	Check the Flow Probe connection to the tubing set (see paragraph. 3.3). Check there is no air in the tubing set. This error may occur at the beginning of priming phase, when the tubing are completely full of air. In case of persistent error, disconnect and reconnect the flowmeter to its relevant connector. If the problem persists, connect the backup flowmeter to the primary section.
P	Main air sensor error (*)	An error is detected on main air sensor	High	Check the Air sensor probe connection on the front of Console. In case of persistent error, disconnect and reconnect the air sensor probe to its relevant connector If the problem persists, switch to the backup section and contact the Technical Assistance.
P	Flow sensor disconnected	Blood Flow probe is detected as not inserted	High	Check the Flow Probe connection on front of Console. If necessary, try to disconnect and reconnect the flowmeter to its relevant connector. Press the alarm acknowledge button. Switch to the backup Flow Probe, if the alert message repeats.
T	Flow Sensor Error Temp	An over temperature is detected on Blood Flow board	High	This error may occurs when the internal temperature is too high. From now on the Blood Flow value will be not available. Clamp the return tubing and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T	Flow Sensor Disconnected	An error is detected on Blood Flow board	High	Check the Flow Probe connection on front of Console. In case of persistent error, try to disconnect and reconnect the flowmeter to its relevant connector and repeat the diagnostic phase. If the anomaly persist, clamp the return tubing and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T	Flow Sensor Data Error	A technical error is detected on Blood Flow board communication	High	Check the Flow Probe connection on front of Console. In case of persistent error, try to disconnect and reconnect the flowmeter to its relevant connector and repeat the diagnostic phase. If the anomaly persist, clamp the return tubing and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T	Audio System Failure	A technical Alarm is detected on Audio board	High	Press the alarm acknowledge button, if the message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the fault code message and contact Technical Assistance.

P	Flow Control Error	Flow management error	High	Check the Flow Probe connection to the tubing set. This error may occur after the LPM/RPM set-point modification in case of the device can't reach the desired flow within five seconds. In this case be sure no occlusions or any other case which may compromise the flow are presents. In case of persistent error, disconnect and reconnect the flowmeter to its relevant connector. If the problem persists, connect the backup flowmeter.
P	Internal Battery Fault	Fault condition is detected on Internal Battery	High	An audible alarm will sound and the System will continue to operate. Press the alarm acknowledge button, if the visual alarm message does not disappear don't disconnect the device from main power supply. If you need to disconnect the device from poer supply, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
P	Internal Battery not detected	Broken fuse is detected on the Internal Battery	High	An audible alarm will sound and the System will continue to operate. Press the alarm acknowledge button. From now on, don't disconnect the device from main power supply. If you need to disconnect the device from poer supply, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
P	External Battery not in used	External Battery is disconnected	Medium	Check the External Battery connection to front of Console. Try to disconnect and reconnect the external battery. If the error persists, verify the charge level of the battery or change the battery.
P	SD Card Error	An error is detected on the SD Card memory	Medium	Try to resume the device. If the error persists, starts the treatments and contact Technical Assistance. In this case, the graphs and the data log file will not be available during all treatment duration.
T	SPI Master Motor Timeout	A technical error is detected on Motor board	High	An audible alarm will sound and the System will continue to operate. Press the alarm acknowledge button, if the visual alarm message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T	SW ERROR (LPSM)	A SW error is detected	High	An audible alarm will sound and the System will continue to operate. Press the alarm acknowledge button, if the visual alarm message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T	Motor Fault	An expected error occurs on Motor board	High	Press the alarm acknowledge button, if the message does not disappear, clamp the return tubing, stop the Pump and switch to the backup Console, Motor and Flowmeter. Resume support. Record the fault code message and contact Technical Assistance.

T	Error Code E03	CRC Error	High	This error might be caused by a SW update. Restart the device. If the problem persists please record the fault code message and contact Technical Assistance.
T	Error Code E05	Reset Master board	High	Clamp the return line and switch to back-up section to proceed the treatment. Record the fault code message and contact Technical Assistance
T	Error Code E06	Unexpected reset	High	Clamp the return line and switch to back-up section to proceed the treatment. Record the fault code message and contact Technical Assistance.
T	Error Code E07	UnexpectedPower reset	High	This error might be caused by an unexpected power interruption due to battery discharge or emergency button activation. Normal operation can be restored by turning off and on the device. If none of those circumstances occurred, record the fault code message and contact Technical Assistance.
T	Error Code E08	Reset motor failure	High	Clamp the return line and switch to back-up section to proceed the treatment. Record the fault code message and contact Technical Assistance.
T	Error Code E09	Internal Battery Error	High	This error might be displayed if, during the previous treatment, the Internal battery fault error is activated. Restart the device. If the problem persists please record the fault code message and contact Technical Assistance.
T	Error Code E10	Slave SW version fail	High	This error might be caused by a incorrect SW update. Restart the device. If the problem persists please record the fault code message and contact Technical Assistance.
T	Error Code E11	Internal Battery Failure	High	The fuse of the internal battery has been detected as broken. From now on, if you disconnect the power supply cords, the device will be shut down. Turn off the device and switch to back-up section. Contact Technical Assistance.

(*) Available only for device with the Colibrì connector on the front panel
(**) Not Available for device with the Colibrì connector on the front panel

EU10583_ENG Rev.12 - 2023-04-03

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