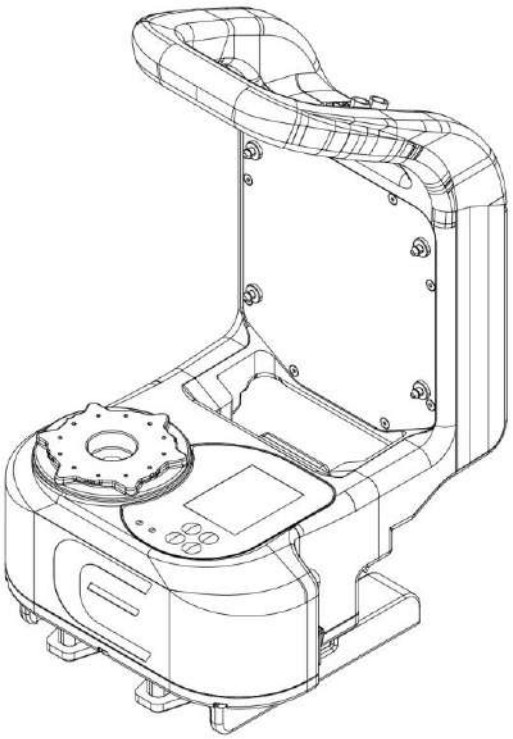
COLIBRÌ SYSTEM



CE 0123

INSTRUCTIONS FOR USE

EU11042_ENG Rev.08 - 2023-11-17

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

COLIBRÌ SYSTEM:
Composed by COLIBRÌ Console, COLIBRÌ Flowmeter and COLIBRÌ Power Module.

COLIBRÌ FLOMETER:
Corresponds to:

- COLIBRÌ FLOWMETER 3/8" X 3/32" for Adult/Paediatric configuration.
- COLIBRÌ AIR/FLOW SENS 1/4" X 3/32" for New Born configuration.

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

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 COLIBRÌ 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 COLIBRÌ System which, under normal conditions of use, is in physical contact with the patient in order to fulfil its function.

1.3. DESCRIPTION

COLIBRÌ System active medical device is composed by a programmable console (COLIBRÌ Console), a bearing-less motor driver and sensors for blood parameters detection.

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 COLIBRÌ 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 COLIBRÌ 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.
COLIBRÌ System shall be used in combination with the medical devices listed in section “MEDICAL DEVICES FOR USE WITH COLIBRÌ SYSTEM”.

1.7. CONTRAINDICATIONS

No contraindications.

1.8. INTENDED USER AND ENVIRONMENT

COLIBRÌ 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.
COLIBRÌ 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

COLIBRÌ 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

- This Instructions for Use Manual in paper form accompanies each COLIBRÌ System.
- The Instruction for Use Manual is also provided on Eurosets website.
- In case of incorrect visualization of Use Manual on Eurosets website, 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 COLIBRÌ 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.
- 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 COLIBRÌ System or shielding the environment.
    - Electromagnetic interference may lead to malfunctioning of the probes using during the treatment.
- Stop immediately the use of the device through the emergency switch button in case of fire/smoke from the device.
- Durable 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 COLIBRÌ 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.
- COLIBRÌ 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 COLIBRÌ 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.

1.11.4. 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 COLIBRÌ 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.

1.12. MEDICAL DEVICES FOR USE WITH COLIBRÌ SYSTEM

COLIBRÌ System is conceived to be used in combination with Eurosets Disposable Centrifugal Pump, Tubing Sets and Oxygenators. Alternatively, other commercially available (CE Marked) Tubing Sets and/or oxygenators approved for the concerned application may be used. COLIBRÌ System can be used also in combination with ECMOLIFE System.
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 P_{drain} 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 P_{drain} 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 COLIBRI System instructions for use shall be consulted.

1.13. 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)		

1.14. TRANSPORT AND STORAGE CONDITIONS

For storage and transport conditions refer to paragraph TECHNICAL SPECIFICATIONS.

1.15. LIMITED WARRANTY

The COLIBRÌ 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

COLIBRÌ System is composed by:

EU5095 – COLIBRÌ Console	
EU6714 – COLIBRÍ Flowmeter 3/8” x 3/32”	
EU6730 – COLIBRÌ AIR/FLOW SENS 1/4X3/32	
EU6716 – COLIBRÌ Power Module	

COLIBRÌ System primary unit has integrated electronic to measure the following parameters:

- Patient drainage pressure (Pdrain),
- Blood flow (LPM),
- Pump speed (RPM),
- Pre-oxygenator pressure (Pin),
- Post-oxygenator pressure (Pout),
- Air bubble presence in the blood return tube by means of Flowmeter.

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.

Warning

- An Eurosets centrifugal pump backup unit (as COLIBRÌ System and/or ECMOLIFE System) must be available in proximity of the device, next to the console.
- In order to make sure the backup device works correctly in case of emergency, switch it on and perform the diagnostic phase at least once every 48h while using the primary device.
- 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 Colibrì not checked.

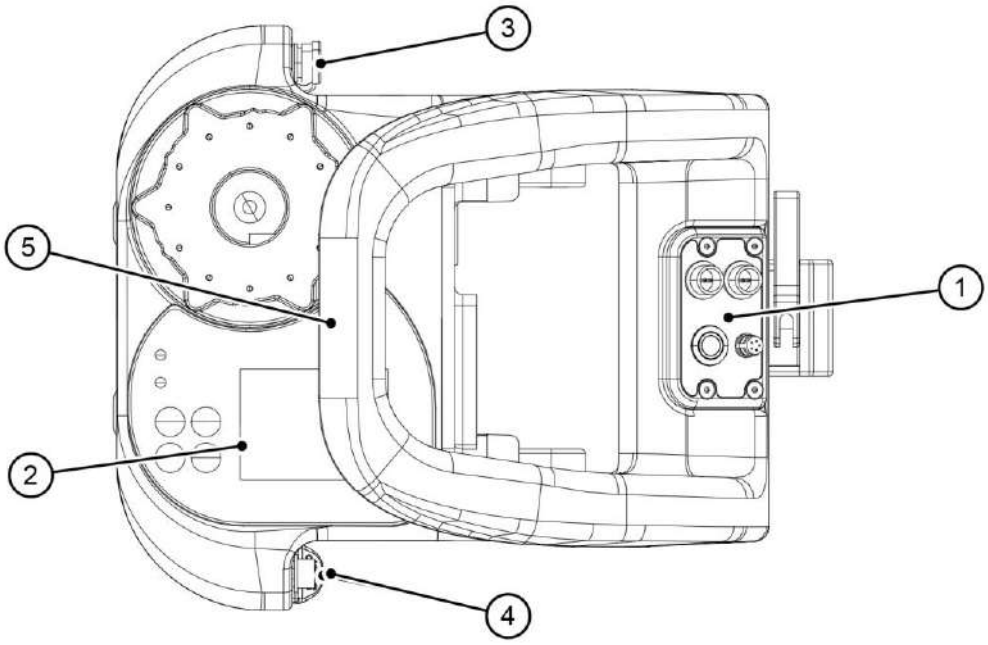
Caution

Place the equipment in order to not cover the air intakes to allow a proper heat dissipation.

2.2. CONSOLE

The console main parts are summarized as shown below:

1. COLIBRÌ top panel
2. COLIBRÌ display
3. COLIBRÌ right panel
4. COLIBRÌ left panel
5. COLIBRÌ bracket



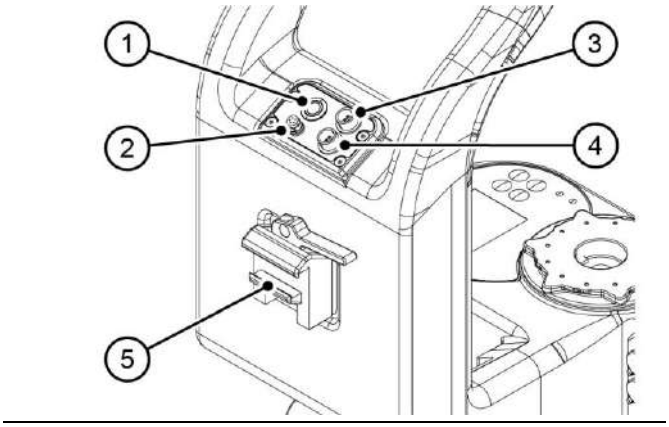
2.2.1. TOP PANEL

The top panel is composed by:

1. ON/OFF button;
2. P3to1 disposable pressure sensor connection;
3. Main Power Supply connection;
4. 24V connection;

Connected to the bracket rear side:

5. COLIBRÌ hanging system

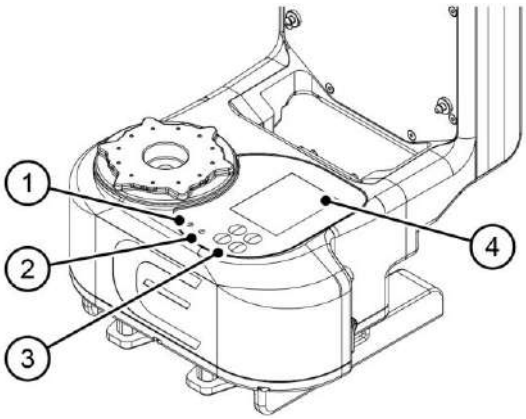


Warning
Do not install extra device, different from devices indicated by the manufacturer, on the COLIBRÌ hanging system.

2.2.2. DISPLAY

The display is composed by:

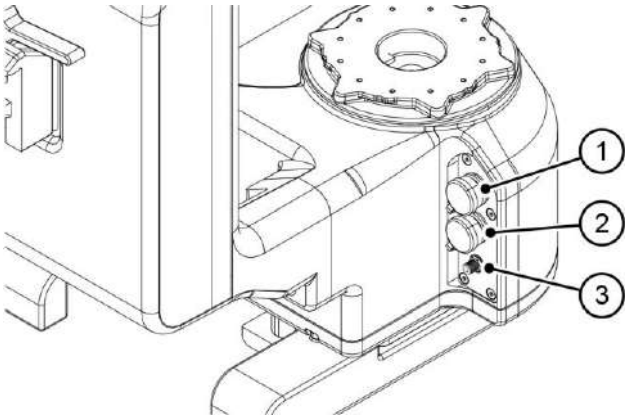
1. a Led RGB battery;
2. a Led RGB alarm
3. 4 membrane buttons;
4. a 3,5” Touch display;



2.2.3. RIGHT PANEL

The right panel is composed by:

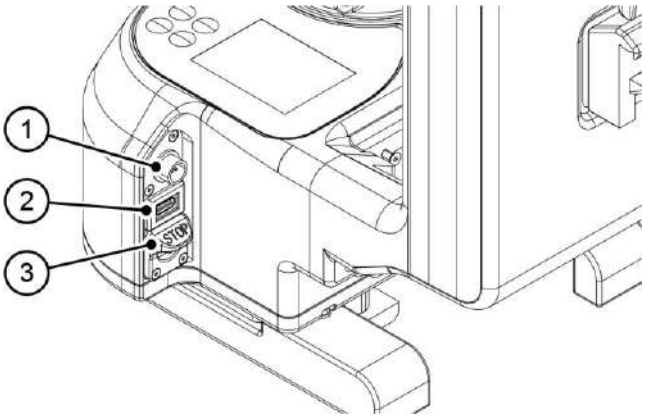
1. External Battery connection #1;
2. External Battery connection #2;
3. WiFi Antenna;



2.2.4. LEFT PANEL

The left panel is composed by:

1. Flowmeter/Air sensor connection;
2. USB;
3. Emergency switch.



Warning

- Only USB standard model is supported by the device.
- Do not connect any USB devices supplied by own power sources.

3. FLOWMETER / AIR SENSOR CONNECTION ON THE TUBING

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

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

Warning
- A backup flowmeter must be available in proximity of the device, next to the console.

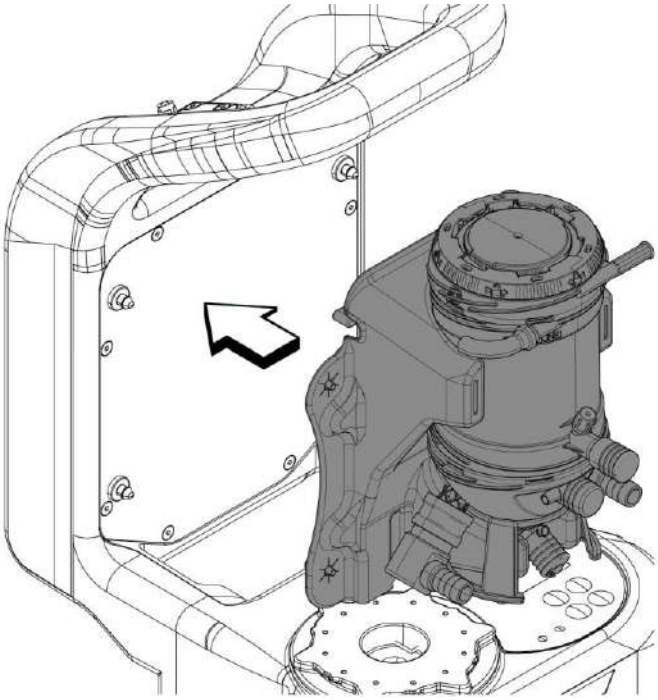
3.1. COLIBRI AND LANDING MONITOR FLOW MEASUREMENT

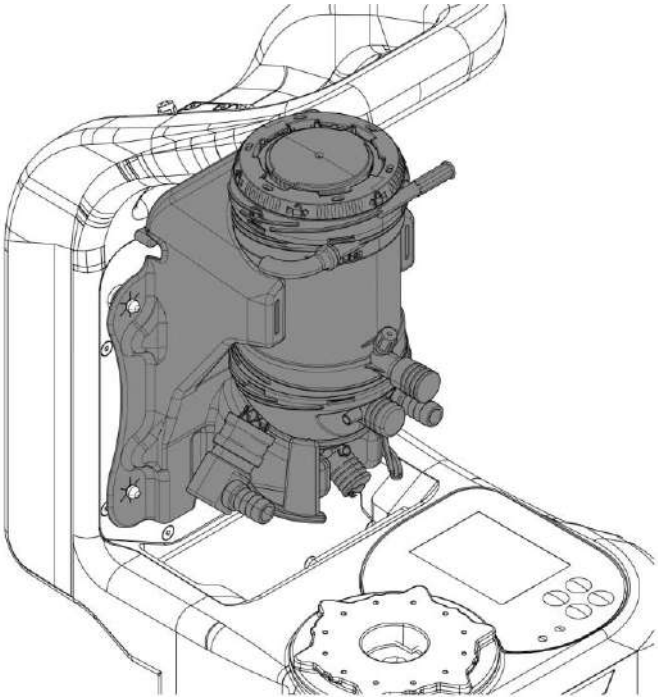
In order to achieve an adequate correspondence between the LANDING monitor flow measure and COLIBRÌ console flow measure make sure that the two flowmeters are attached to a 15cm straight tube before and after the transducers.

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

4. DISPOSABLE CENTRIFUGAL PUMP AND OXYGENATOR SETUP

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

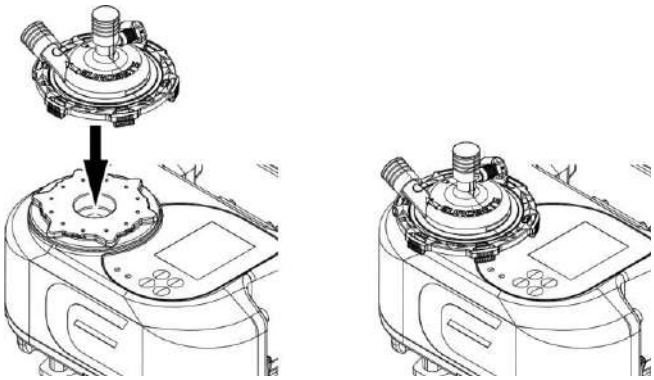




2. Ensure the COLIBRÌ System is ready, electrically connected with mains and flowmeter plugged in.
3. Ensure the COLIBRÌ System RMP is turned to Zero.
4. Insert blood pump on motor driver receptacle.

Caution

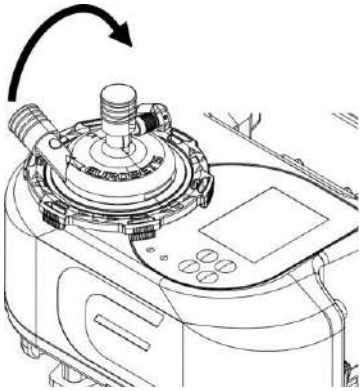
- Blood pump is magnetically attracted on motor driver receptacle.
- While inserting the blood pump keep it firmly in the hands to avoid fingers or skin pinching between pump and motor driver.



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. USER INTERFACE

5.1. DISPLAY

STATUS BAR

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

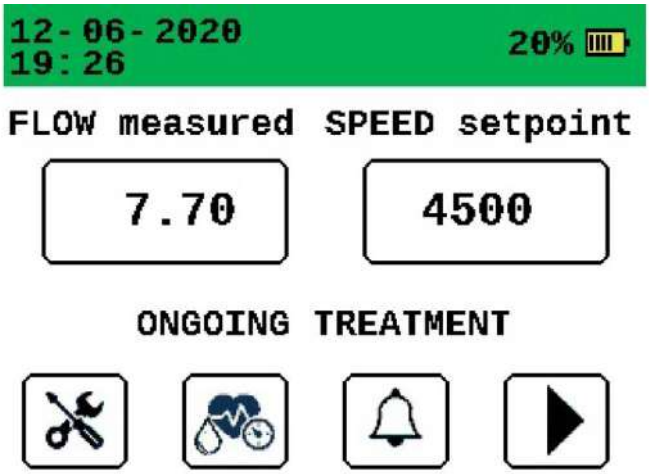
1. Date and Time;
2. Charge status Symbol and remaining time;

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



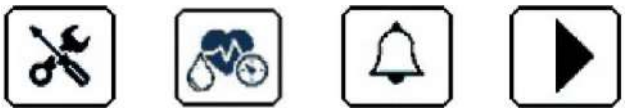
The central part of the COLIBRÌ display is composed by:

1. Blood Flow parameter;
2. RPM parameter;
3. Active page title

TOOLBAR

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

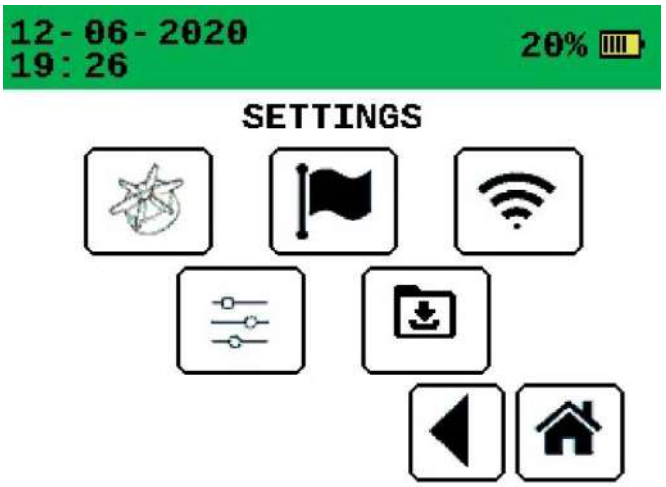
1. Settings,
2. Pressure,
3. Alarms,
4. Navigation button



SETTINGS

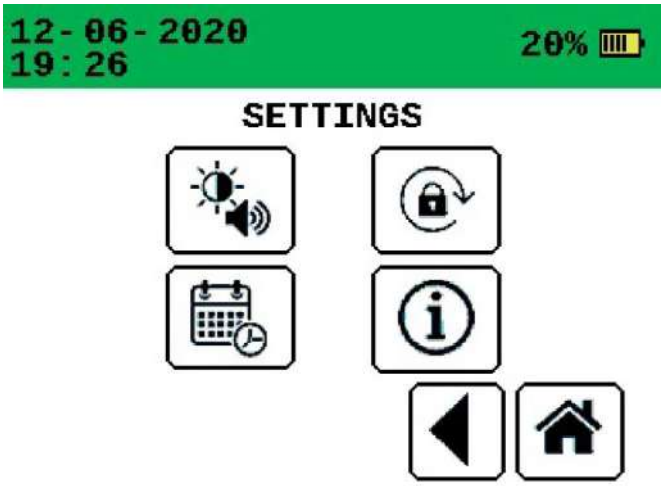
In the Settings screen you can modify the following options:

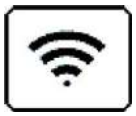
- Language
- Date/Time
- Brightness
- System
- Display
- Service (not available during treatment)



Language
Select language.

Parameters
Change the parameters Measure Unit.





Wi-Fi
Activate/Deactivate the Wi-Fi communication.

Date/Time
Change date and time info.

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

Brightness
Change device lightening. You can set 3 different level of display brightness,

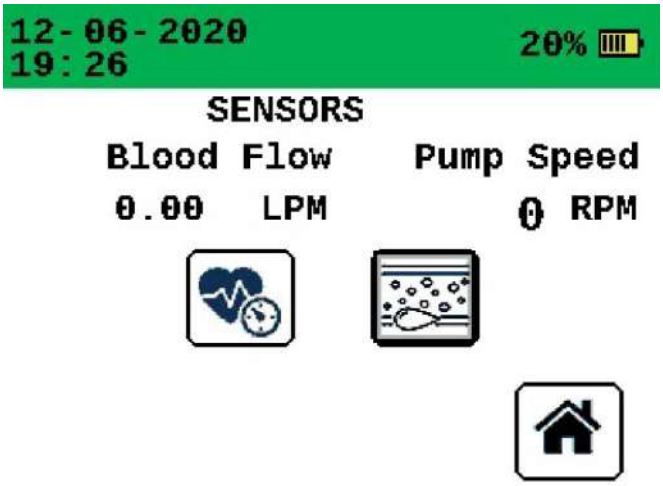
Service
Section available by authorized staff only by password.
This section will be available only when Setting Page is selected before starting treatment (through Select Modality Page). During the treatment, this menu will not be available.

System
Show system info. HW and SW version.

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.
To access to log data, please contact the manufacturer authorized technical assistance service.

PRESSURE AND BUBBLE SENSOR MENU

In this section you can enter the Pressure sensor and Bubble sensor menu.

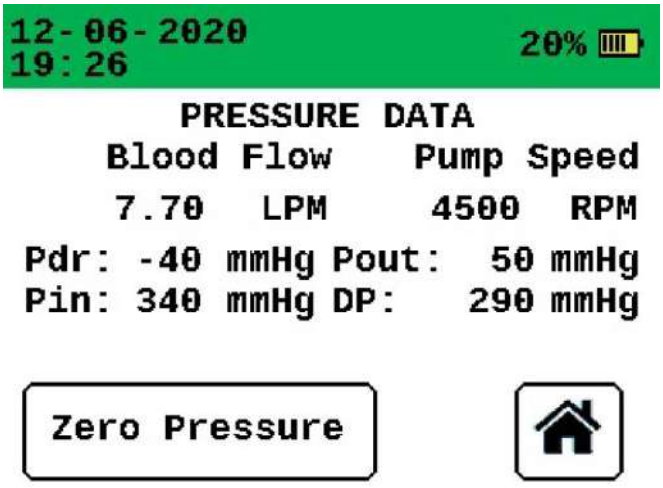


PRESSURE SCREEN

Selecting Pressure sensor menu you can monitor the following information:

- Blood Flow (LPM),
- Pump Speed (RPM),
- Drainage pressure (Pdrain),
- Pre-oxygenator pressure (Pin),
- Post-oxygenator pressure (Pout),
- Pressure drop (DP)

In this screen, you can also proceed with the zero pressure procedure.



Warning
Calibrate external and integrated pressure sensors before use.

BUBBLE SENSOR SCREEN

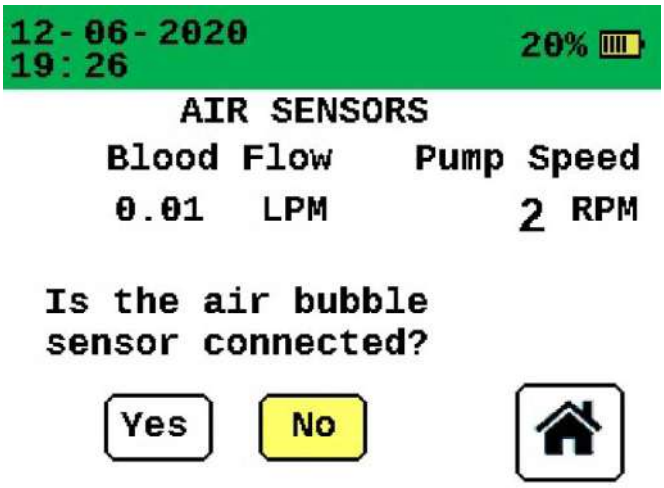
Select Bubble sensor menu you can enable or disable the air bubble detection.
By default, the the air bubble detection is not active.

The Menu Icon will be update in accordance with the bubble detection status:

The bubble detection is not activated

The bubble detection is activated.

The bubble sensor is in fault condition or disconnected by the tubing set from at least 1 minute.



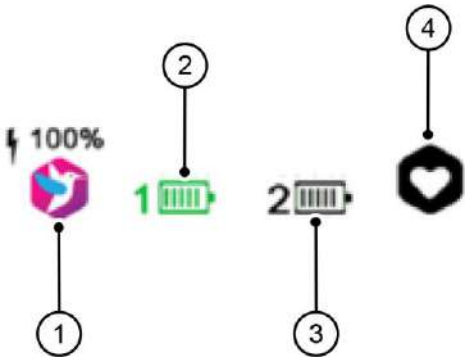
ALARMS

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.

NAVIGATION BUTTON

Using the Navigation you can monitor the information related to power source.
The power source information are displayed in the toolbar.
The following information are available:

1. Integrated battery: charging/not charging and battery level
2. External battery #1: connected/not connected and battery level,
3. External battery #2: connected/not connected and battery level,
4. 24V/ECMOLIFE: connected/not connected.



Warning

- Check the generation of audible alarm signals. In case of not generated audio signal 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.

5.2. TOOLBAR

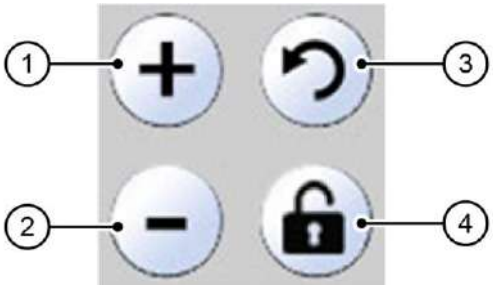
Parameters displayed in the main screen are listed below:

Parameter	Description	Sensor	Measure range	Measure unit	Accuracy
Blood flow	Detected blood flow speed	Colibrì FLOWMETER 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 (NEW BORN)	Detected blood flow speed	Colibrì FLOWMETER 1/4"x3/32"	0,0 ÷ 3,0	LPM	±0.07 l/min for flow value <= 1.0 l/min ± 7% for flow value > 1.0 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	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_{in}	Inlet pressure in oxygenator module and outlet pressure from driver engine	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	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

PARAMETERS EDITING

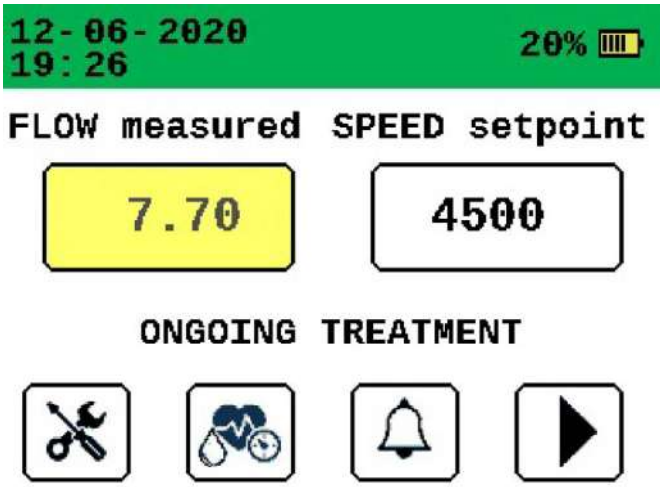
COLIBRÌ Console provides 4 membrane buttons:

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 seconds.
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

Automatic screen lock: 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.

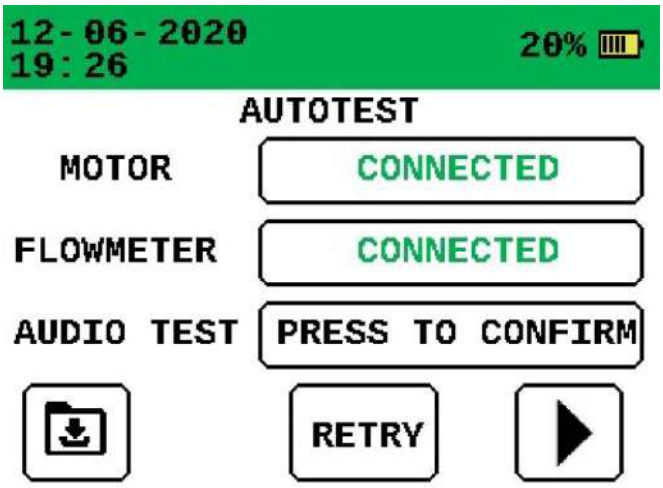
5.3. FUNCTIONALITIES

TURNING ON THE DEVICE

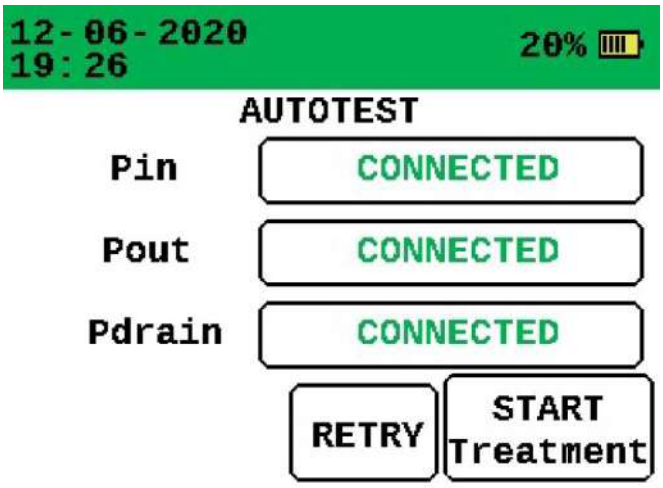
Once COLIBRÌ Console is turned on, the diagnostic page will be displayed.

DIAGNOSTIC PHASE

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



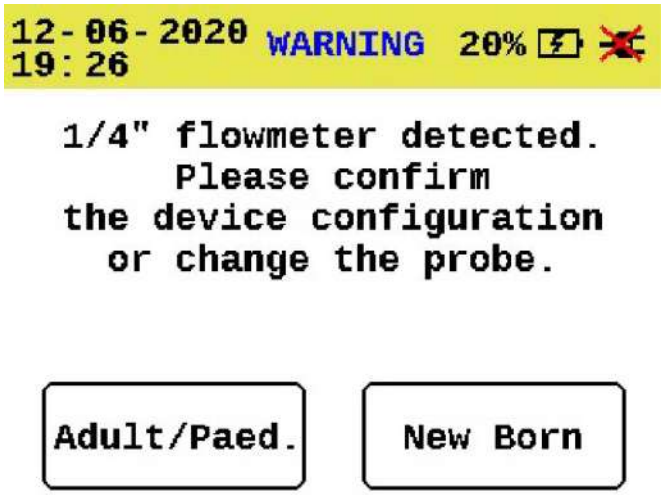
After conformation of Audio Alarm detection, you can switch second diagnostic page in which the device will check if pressure sensors are properly connected.

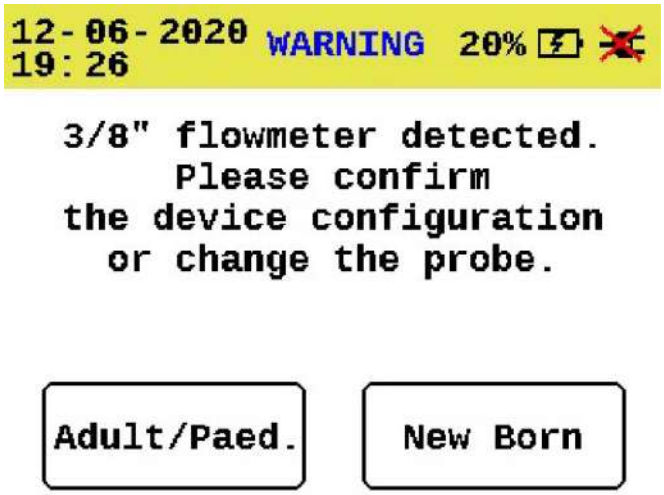


Each subsequent connection of pressure sensors in this phase or during the treatment shall be confirmed in the diagnostic page by clicking the Retry button.
All undetected probes or sensors won't sample parameters.

Warning
Do not continue if 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 type of flow probe connected to the device.
A warning screen will then appear where it will be necessary to confirm the type of treatment to be carried out (Adult/Paediatric or New Born) compatible with the type of flowmeter connected to the Colibrì.





PRIMING PHASE

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

5.3.1. 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.

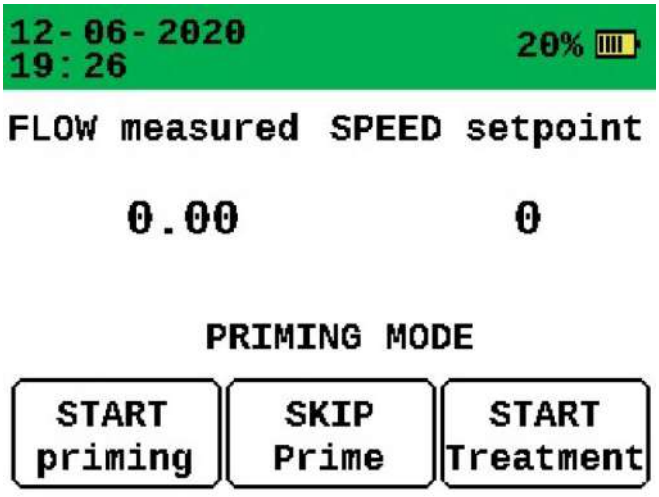
Warning

- 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.
- In case of automatic priming failure, Eurosets Disposable Centrifugal Pump, Tubing Sets and Oxygenators instruction for use shall be consulted to perform manual priming.

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.



5.3.2. AUTOMATIC PRIMING AND SELF LEARNING PROCEDURE – NEW BORN CONFIGURATION

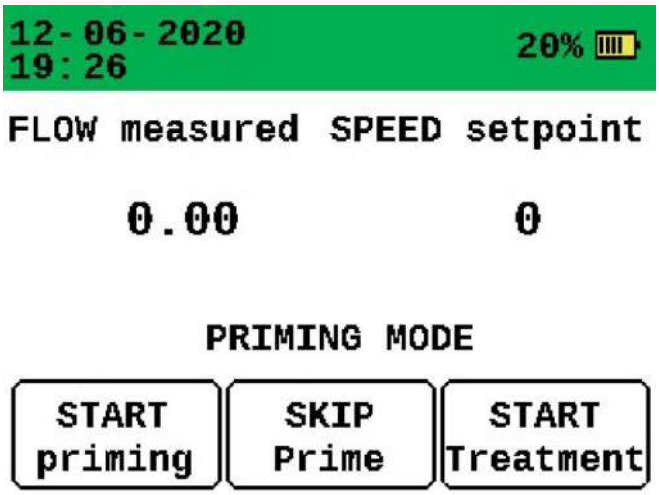
After manual priming is possible to continue with the automatic priming operation which also perform a centrifugal pump self-learning procedure in order to improve the centrifugal pump safety and performances.

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 possible 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 3450 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 configuration or 0-4500 RPM range for New Born configuration.

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

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 seconds.
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

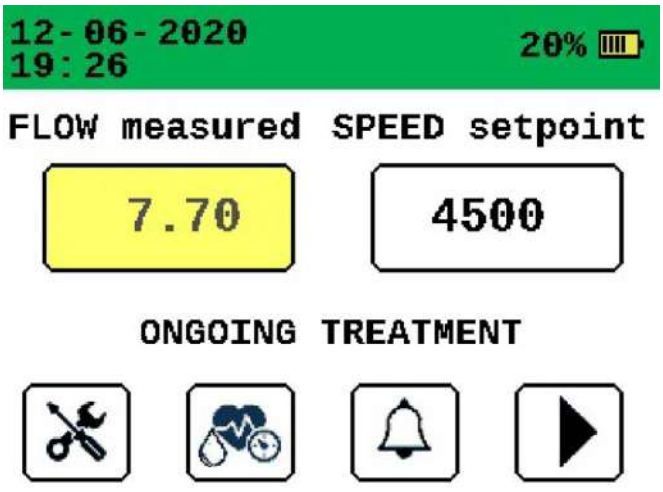
It is necessary to confirm the set value by re-pushing the selected value on the display within at least 3 second.
The parameter editing will be performed only if the user confirms.
If you delete the operation using the RETURN button, or if it takes more than 3 seconds to confirm, the device will restore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



6. ALARMS

6.1. 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.

6.1.1. ALARM LIMIT – ADULT/PAEDIATRIC CONFIGURATION

Parameter	Description	Sensor	Measure range	Measure unit	Alarm threshold	Default alarm threshold	Preliminary Verification (*)
Blood 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	Check no occlusions or any other case which may compromise the flow are presents.
Speed pump	Pump speed revolutions per minute	/	0 ÷ 5000	RPM	0 ÷ 5000	2000 ÷ 4500	Check no occlusions or any other case which may compromise the flow are presents.
P_{drain}	Suction pressure	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	-200 ÷ +600	-80 ÷ 25	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set.
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	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set.
P_{out}	Outlet pressure from oxygenator module	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	-200 ÷ +600	0 ÷ 500	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set.
Bubble	Air bubble detection	Bubble sensor	> 65	µl	(not modifiable)	> 65	Check any leakage on tubing set are present.

6.1.2. ALARM LIMIT – NEW BORN CONFIGURATION

Parameter	Description	Sensor	Measure range	Measure unit	Alarm threshold	Default alarm threshold	Preliminary Verification (*)
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	Check no occlusions or any other case which may compromise the flow are presents.
Speed pump	Speed revolutions per minute pump	/	0 ÷ 4500	RPM	0 ÷ 4500	0 ÷ 4500	Check no occlusions or any other case which may compromise the flow are presents.
P_{drain}	Suction pressure	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	-200 ÷ +600	-150 ÷ +50	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set.
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	-50 ÷ +500	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set.
P_{out}	Outlet pressure from oxygenator module	Single use pressure sensor	-200 ÷ +600	mmHg (convertible in kPa)	-200 ÷ +600	-50 ÷ +500	Check for and resolve a physiological or mechanical cause. Ensure appropriate pressure alarms are set.
Bubble	Air bubble detection	Bubble sensor	> 65	µl	(not modifiable)	> 50	Check any leakage on tubing set are present.

*For any detail about corrective action refer to ANNEX 1: ALARMS TABLE

6.2. 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.

6.3. 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

6.4. 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.

6.5. 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.

6.6. ALARMS TABLE

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

7. COMBINATION SYSTEM ECMOLIFE-COLIBRI

It is possible to use the Colibrì system in combination with the Primary section of ECMOLIFE System.

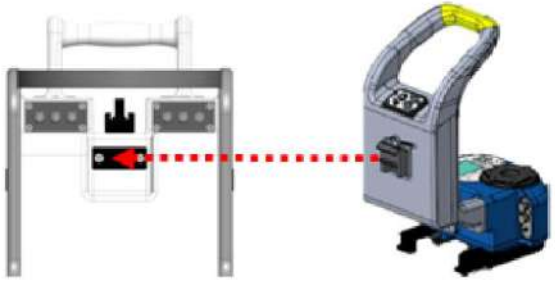
- The combined system must be used in accordance with these instructions and EU10583 IFU ECMOLIFE SYSTEM. EUROSETS cannot be held responsible for damage deriving from improper use.
- Read these instructions together with DISPOSABLE Centrifugal Pump instructions for use and Ecmolife System instruction 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-COIBRÌ 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.

7.1. COLIBRÌ-ECMOLIFE 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.

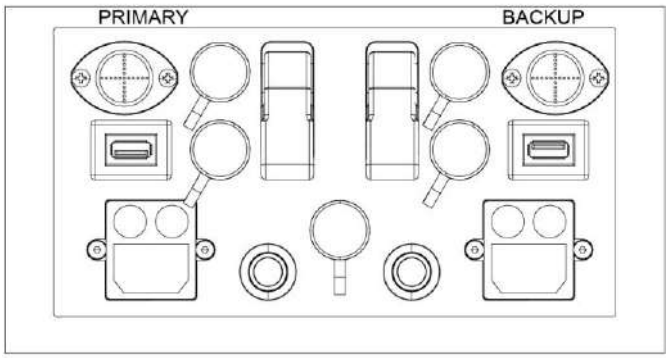
3. Move the lever of the COLIBRÌ bracket to the 'CLOSED' position in order to fix the COLIBRI' Console on the ECMOLIFE Console.



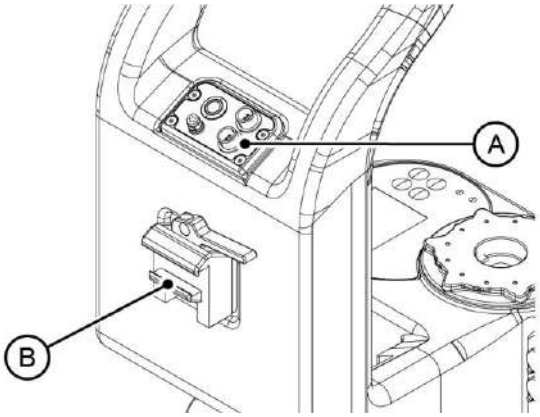
FUNCTIONAL CONNECTION

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

1. Check the integrity of ECMOLIFE-COLIBRÌ cable.
2. Ensure the ECMOLIFE-COLIBRÌ cable to the dedicated socket of ECMOLIFE connector panel.



3. Ensure the ECMOLIFE -COLIBRÌ cable to the 24V connector socket (**A**) of COLIBRÌ top panel.
4. Using the Colibrì hanging system (**B**), fix the Colibrì System on the rear side of ECMOLIFE console.
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.
- Before starting the support, check that the Backup Unit battery is fully charged
- Activate the ECMOLIFE Backup Unit only in case of ECMOLIFE Primary Unit and COLIBRÌ Unit failure.
- Keep a backup flowmeter sensor ready for use.
- In case of double fault condition of ECMOLIFE System and COLIBRÌ System, please active the backup device and proceed with the treatment.

7.2. FUNCTIONALITIES

7.2.1. TURNING ON THE ECMOLIFE-COLIBRI' SYSTEM

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

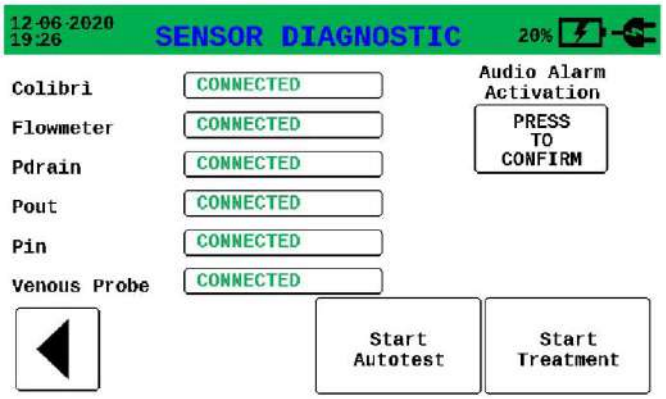
It is possible to connect the COLIBRI System to ECMOLIFE in any treatment phase. Likewise, it is possible to regain control on COLIBRI disconnecting the connection cable or through the "COLIBRI" menu on ECMOLIFE System at any time

At power on, 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.

7.2.2. DIAGNOSTIC PHASE

If the ECMOLIFE-COLIBRÌ is correctly connected, in ECMOLIFE SYSTEM diagnostic screen the device will check colibri device is 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.
- Before starting the diagnostic phase, check that the flowmeter is correctly connected to the Colibrì System

Caution

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.

For other information related to treatment, alarms, parameters and more, refer to EU10583 IFU ECMOLIFE SYSTEM.

8. POWER SUPPLY

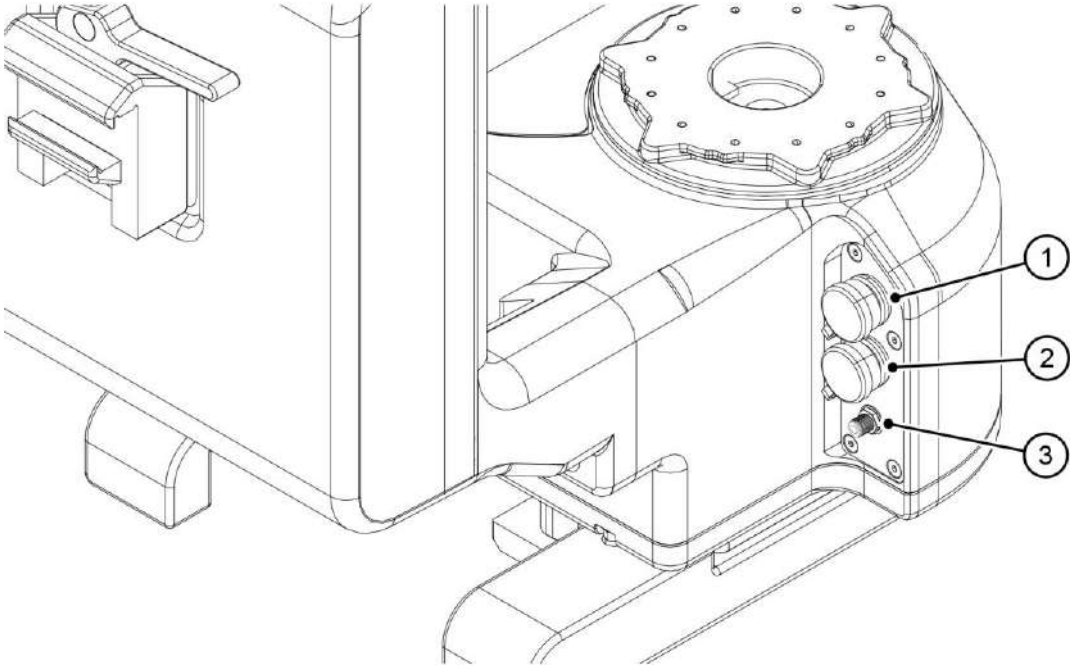
8.1. INTERNAL BATTERY

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 200 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.
The internal battery can be recharged while the sections are turned off.

Warning
If you decide to recharge the COLIBRÌ Console during the use of the device, internal battery may require longer time to fully recharge depending on the treatment power consumption.

8.2. EXTERNAL BATTERY

During transport or in case main supply is not available, the device can be powered from the COLIBRÌ Auxiliary Battery kit EU3968 from their relevant external battery sockets located on the COLIBRÌ right panel (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 200 minutes.

Battery charge status can be checked from display menu, according to the table below:

	Battery #1 connected. Battery status >70%
	Battery #2 connected. Battery status >70%
	Battery #1 connected. Battery status between 20% and 70%
	Battery #2 connected. Battery status between 20% and 70%
	Battery #1 connected. Battery status <20%
	Battery #2 connected. Battery status <20%
	Internal battery in use. Battery status available in the header bar
	Internal battery not in use. This icon will appear in case of External Batteries connection

8.3. POWER CONNECTIONS PRIORITY

In case multiple power sources are connected, COLIBRÌ Console will be powered according to the priority list below:

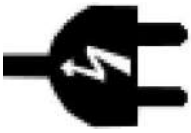
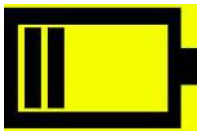
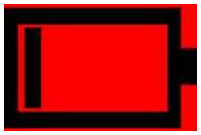
1. 24V connection
2. EXTERNAL BATTERY #1
3. EXTERNAL BATTERY #2
4. INTERNAL BATTERY or COLIBRÌ POWER MODULE (if connected)

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

8.4. RECHARGEABLE BATTERY AUTONOMY

In battery operation mode, in full charged condition, the guaranteed time for the device to function correctly is at least 200 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.

8.5. 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%.

9. MEDICAL DEVICES FOR USE WITH COLIBRÌ SYSTEM

The Colibrì System shall be used in combination with Colibrì Tablet display.

Code	Description	Image
EU5256	COLIBRÌ TABLET	

The Colibrì Tablet is equipped with Colibrì APP to mirroring all treatment parameters.
The connection between Colibrì System and Colibrì tablet is achieve via Wi-Fi communication.

Warning
Colibrì Tablet device is not a life – supporting device and it shall not substitute the Colibrì System. For this reason, any adjustment / evaluation related to the treatment must be defined taking into consideration the Colibrì System display.

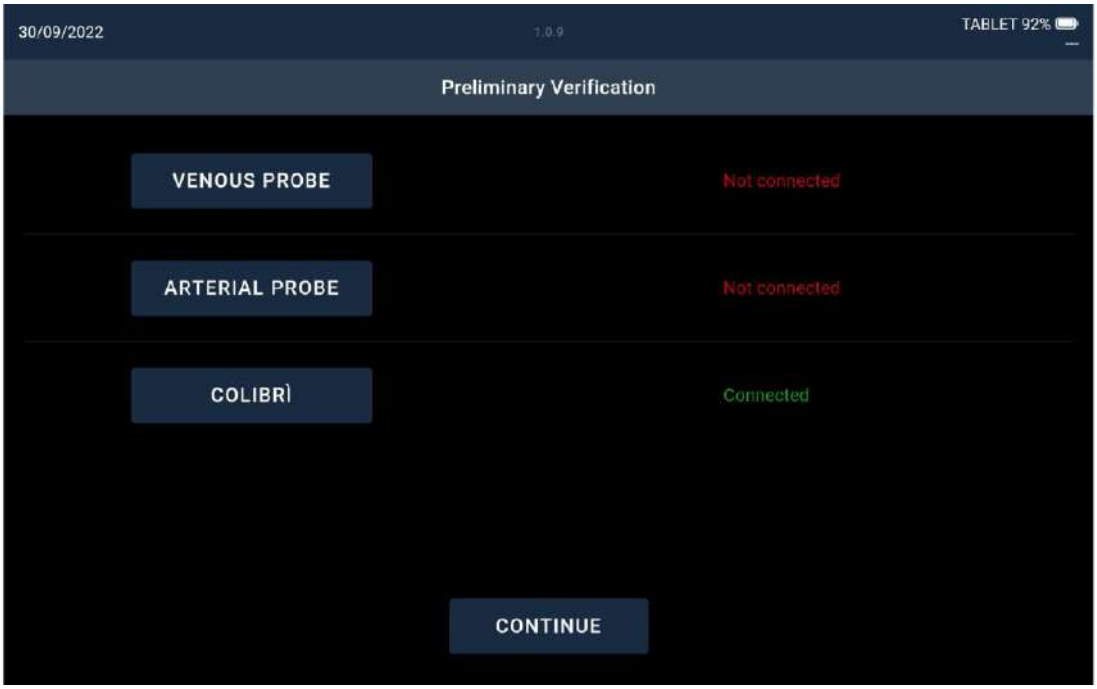
CONNECTION TO MEDICAL TABLET

Active the Wi-Fi module of Colibrì System (for more details see chapter 5.1 Display Wi-Fi).
Active the Hotspot functionality on Colibrì Tablet.
Start the app from Colibrì Tablet and proceed with tablet diagnostic phase.

DIAGNOSTIC PAGE

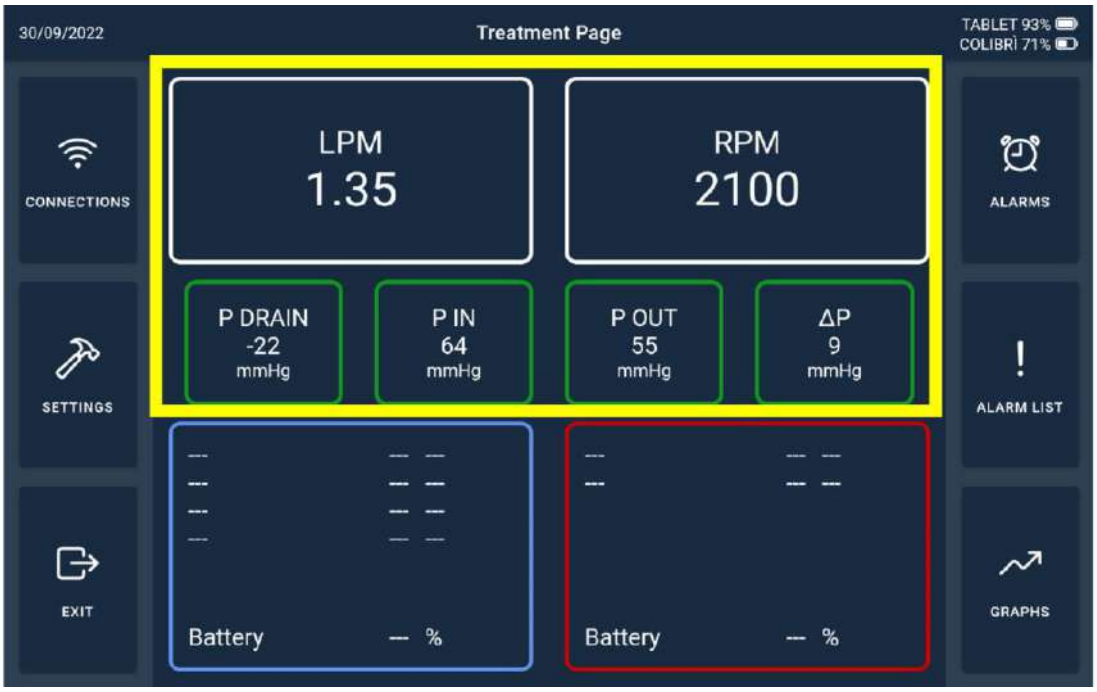
The diagnostic page shows the list of probes that can be interfaced with the device.
Once the probe is connected to the device, the message "connected" will be displayed. Otherwise "not connected".
Connection of all 3 probes/device is not mandatory to access to the “Treatment” page.

If the Colibrì is connected, proceed with the Treatment mirroring pressing the “Continue” button.



TREATMENT PAGE

The information related to Colibrì System treatment are shown in the upper part of the treatment Page.



The following parameters are mirrored:

- LPM,
- RPM,
- Pdrain,
- Pin,
- Pout,
- DP.

In the two side bars of the screen, the toolbar collects the main features provided by the APP:

- Graphs
- Connections
- Settings (not available)
- Exit
- Alarms (not available)
- Alarms list (not available),

CONNECTION PAGE

In the Connection screen you can visualize client devices connected to the network. For each of them, the following information are reported:

- The serial number
- The probe model (in case of accessories probe such as arterial/venous probe)
- The probe software version of Colibrì System

A colored badge allows to visualize the status of the connection:

- Green: the sensor is connected and works correctly
- Red: the sensor is not connected
- Yellow: the sensor is connected but the medical hand -portable display does not receive any data because another sensor of the same type is connected

SETTINGS PAGE

In the Settings screen you can visualize:

- The list of clients ID connected to the network with the respective IP address.
- IP Address of the Hand-portable display device.
- Identification of the port connection.

EXIT

By pressing EXIT button you can close the application.
A confirmation message is shown.

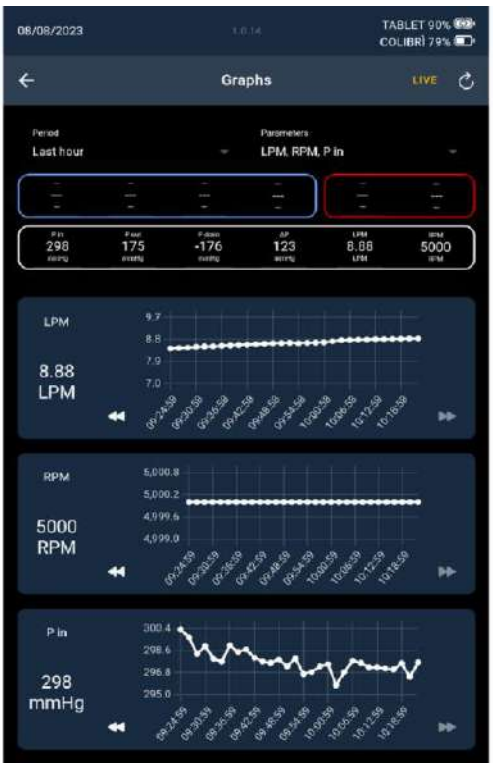
GRAPHS PAGE

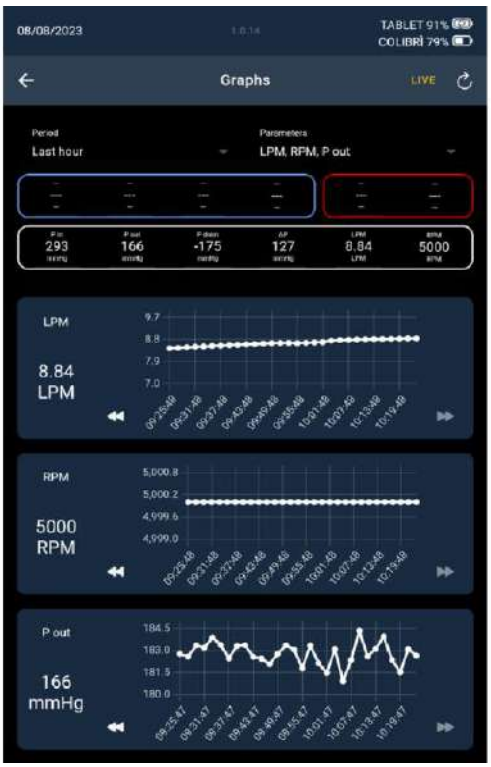
In this section you can visualize the real time parameters trends.

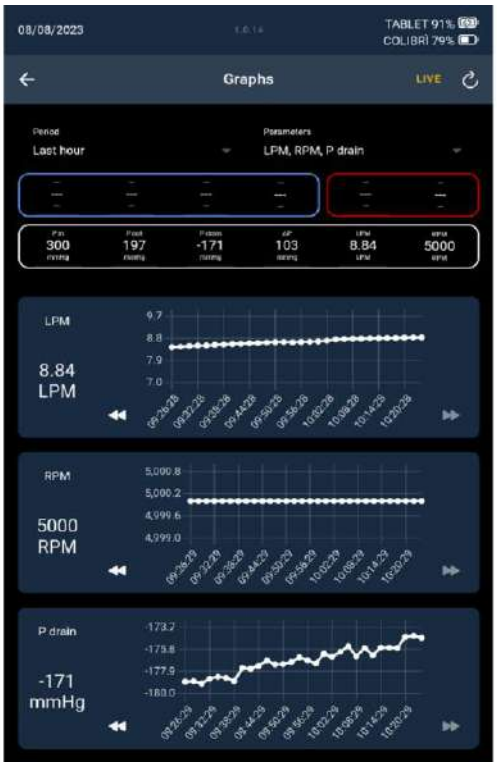
From a PARAMETERS drop-down menu, you can choose the parameters to display on the interface. You can graph from a minimum of one to a maximum of three parameters at the same time in the page.
The graphs of follow parameters are available:

- Blood Flow (LPM)
- Pump Speed (RPM)
- Drainage pressure sensor (PDrain),
- Pre-oxygenator pressure (Pin)
- Post-oxygenator pressure (Pout),
- Pressure drop (Δ P)

Parameters' graphs will be shown as follow:







A TIME drop-down menu allows the operator to select the time scale to visualize the trend.
The following time scale (period) are available:

- Last 5 min;
- Last 15 min;
- Last 30 min;
- Last 60 min.

To scroll the graph, use the arrow displayed near each graph.

By pressing LIVE button you will able to activate/deactivate the real time parameters update.
By pressing the GO BACK button you can return to treatment screen.

10. INTRA-HOSPITAL AND INTER-HOSPITAL ECMOLIFE TRANSPORTATION

10.1. LEONARDO TROLLEY AND LEONARDO SLIM

LEONARDO Trolley EU5093 and LEONARDO Slim EU5094 are the trolleys conceived to safely support and transport the COLIBRÌ Console during intra-hospital transport.

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

10.2. ROAD AMBULANCE PLATE HOLDER

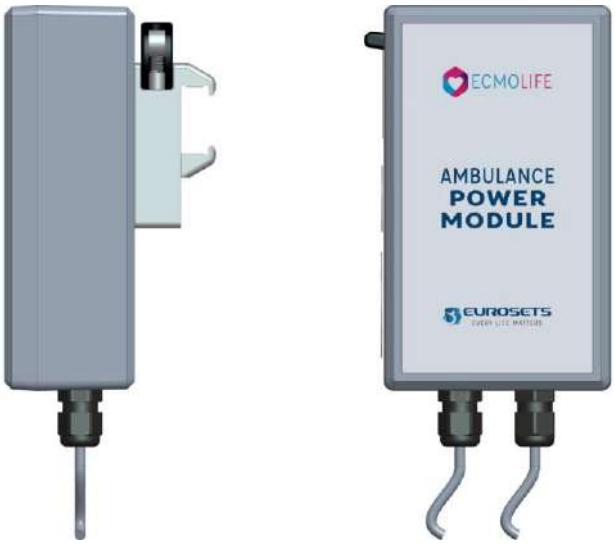
ECMOLIFE Ambulance Plate Holder EU3898 is conceived to safely support and transport the ECMOLIFE CONSOLE during road ambulance transport through a dedicated hooking interface which can be easily adapted to the ambulance mounting rails.

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.

10.3. 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 to its relevant 24V socket.

In order to avoid any electrical interference between COLIBRÌ System 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 COLIBRÌ Console. Figures below describe module connectors

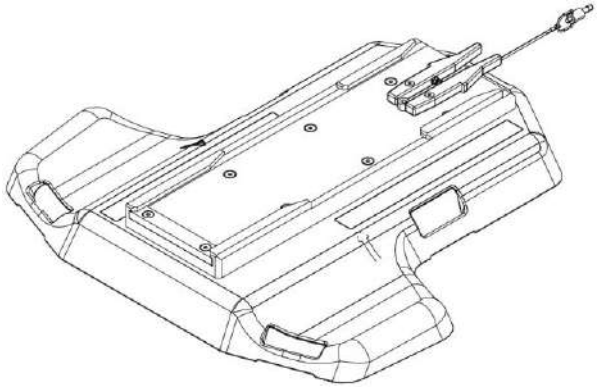
24V POWER MODULE connector

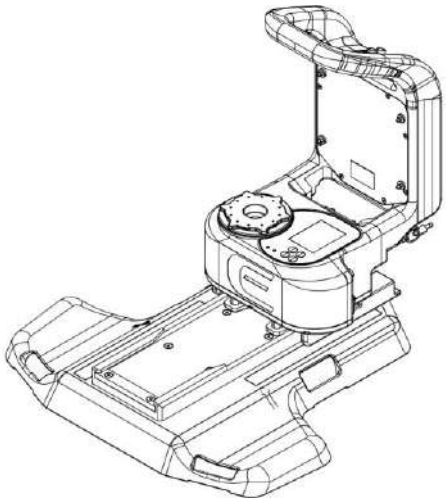
24V Ambulance connector

Warning

- Do not connect the 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 failures, disconnect the Ambulance Power Module and connect a charged auxiliary battery.
- Ambulance Power Module meets ECE R10 regulation requirements.

10.4. FOIL STRETCHER HOLDER PLATE

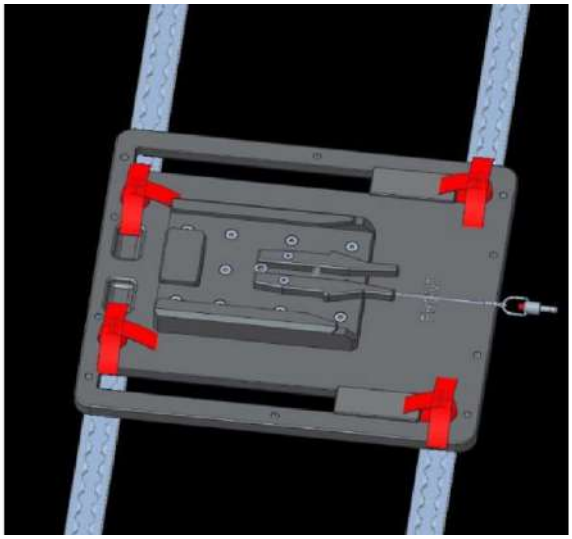


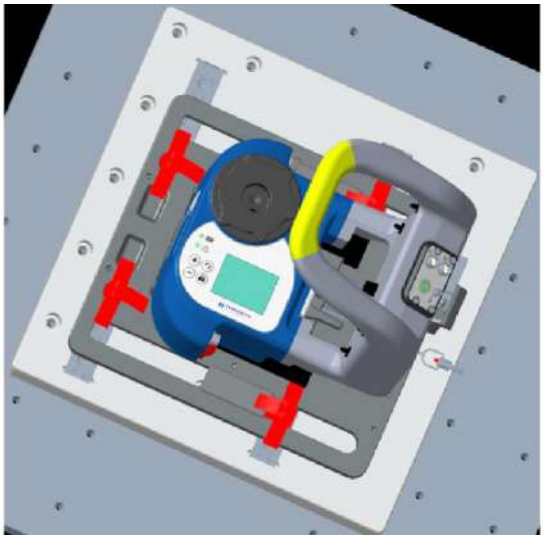


FOIL STRETCHER HOLDER PLATE EU3996 is conceived to safely support and transport the COLIBRÌ SYSTEM during road ambulance transport through a dedicated interface which can be located between the legs of the patient.

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

10.5. AIR AMBULANCE TRANSPORT ON HELICOPTER - COLIBRÌ PLATE HOLDER





Colibrì System must be used for Helicopter transport only when in combination with Colibrì Plate Holder EU5266.

Warning
- Colibrì System and Colibrì Holder Plate must be used for Helicopter transport only with AW139 Helicopter Model.
- Before air ambulance transport on helicopter be sure that the internal battery of the device is fully charged.

Warning
Consult the specific User Manuals/IFU EU11224 COLIBRÌ PLATE HOLDER for the related technical data (weight, connections, etc.) and for its correct use.

11. TECHNICAL SPECIFICATIONS

Regulations	
Classification	Classified in accordance with Regulation (EU) 2017/745 (MDR)
Reference standards	• IEC 60601-1:2005+AMD1:2012+AMD2:2020 • IEC 60601-1-2: 2014+AMD1:2020 • IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 • IEC 62304:2006 + AMD1:2015 • IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 • IEC 60601-1-12:2014+AMD1:2020 • IEC 62366-1:2015+AMD1:2020 • IEC 62353:2014 • EN ISO 14971:2019 • UNI EN 1789:2020 • BS EN IEC 62311:2020 • ETSI EN 301 489-1 V2.2.3 2019 • ETSI EN 301 489-17 V3.2.4 2020 • ETSI EN 300 328 V2.2.2 2019 • UNI EN13718-1 2014 + A1 2020 • RTCA DO160G: section 4, 6, 7, 8, 20, 21, 26 - only AW139 helicopter model

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 m^3/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	Active Thin Film Transistor (TFT) size 3,5''
Keyboard	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 290x330x500 mm (w x d x h)
Weight	Console: 8,9 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 (EU6714-COLIBRÌ FLOWMETER 3/8X3/32)	• Ultrasonic flow sensor
	• Measuring range: 0 ÷ 10 LPM
	• Accuracy:
	  ○ ± 0.07 l/min for flow value <= 1 l/min
	  ○ ± 7% for flow value > 1 l/min

Blood flow sensor - Adult/Paediatric configuration (EU6730-COLIBRÌ FLOWMETER 1/4X3/32)	• Ultrasonic flow sensor
	• Measuring range: 0 ÷ 4 LPM
	• Accuracy:
	  ○ ± 0.07 l/min for flow value <= 1 l/min
	  ○ ± 7% for flow value > 1 l/min

Air detection	• Ultrasonic, Foam/Bubbles • Air Detection Threshold: ≥ 65 µl

Pressure sensors	Single use pressure sensor:
	• Measuring range: (-200) ÷ (+600) mmHg
	• Accuracy:
	  ○ range ≤-200 mmHg: ± 10 mmHg
	  ○ range -50 mmHg/+100 mmHg: ± 5 mmHg
	  ○ range +100 mmHg/+300 mmHg: ± 10 mmHg
	  ○ range ≥ +300 mmHg: ± 15 mmHg

Electrical specifications	
Power supply	• Connection to electric power distribution system through power cord Colibrì Power Module EU6716 • Electromagnetic environment: hospital - dedicated supply systems • Connection to continuous current power source (24 Vdc) • Internal Battery: Li-Ion rechargeable batteries, 25.9 V, 10.4 Ah • Internal Battery: NiMH rechargeable battery, 7.2 V, 4500 mAh • External Battery: AccuPower, model: Lithium Battery 7S4P
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	• Colibrì Power Module: 100-240 Vac / 0.9-1.8 A (Test condition: 230/115 V) / 210 VA 50 – 60 Hz • Integrated battery or DC External Power Supply: 24-29.4Vdc / 5A / 147W
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

12. ELECTROMAGNETIC COMPATIBILITY

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

Guidance and manufacturer's declaration – electromagnetic emissions

Emissions test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	COLIBRÌ 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	COLIBRÌ 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
Radiated fields in close proximity EN 61000-4-39	8 A/m for 30 kHz 65 A/m for 134.2 kHz 7.5 A/m for 13.56 MHz	EN 60601-1-2 Test level	Hospital
Radiated, radio-frequency, electromagnetic field EN 61000-4-3	3 V/m for 80 MHz – 1 GHz 27 V/m for 380 MHz – 390 MHz 28 V/m for 430 MHz – 470 MHz 9 V/m for 740 MHz – 787 MHz 28 V/m for 800 MHz – 960 MHz 3 V/m for 1 GHz – 2.7 GHz 28 V/m for 1.7 GHz – 1.99 GHz 28 V/m for 2.4 GHz – 2.57 GHz 9 V/m for 5.1 GHz – 5.8 GHz	EN 60601-1-2 Test level	Hospital

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

13. MAINTENANCE - SERVICING - SYSTEM LIFESPAN

13.1. LIFECYCLE OF THE RECHARGEABLE INTERNAL BATTERY

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

13.2. PERIODICAL MAINTENANCE PROGRAM

COLIBRÌ 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 COLIBRÌ 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.

13.3. 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.

13.4. 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.

14. 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 COLIBRÌ System.
- Pay attention to hygienically clean work processes (routine hand washing, disposable gloves, protective mask, hood).
- Do not use cleaning and disinfection methods 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 COLIBRÌ System surfaces the safety instruction from the manufacturer of cleaning and disinfection agents must be observed.
- For surface cleaning and disinfection of COLIBRÌ System housing and accessories use a disposable clean, non-linting cloth.
- Avoid the use of cleaning agents containing oil or grease.

14.1. 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

14.2. 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”),
    - bracket,
    - COLIBRÍ Flowmeter
- • 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.

14.3. 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 “DISPLAY”),
    - unit couplings of front and rear panel,
    - bracket,
    - COLIBRÍ Flowmeter
- 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:

15. ANNEXES

15.1. ANNEX 1: ALARMS TABLE

When connected to Ecmolife, alarms will appear and be handled by the Ecmolife screen. Only the alarm string will be displayed on Colibrì, and the top bar will color according to the priority of the alarm itself.
On Ecmolife, Colibrì technical (T) alarms will be identified by a "C" within the alarm list, and by the string "COLIBRI ALARM" on the main alarm screen

Physiological (P) Technical (T)	Alarm displayed	Alarm description	Priority	Corrective action
P	Internal battery not charging	The device is not connected to main power supply	High	Verify the power module is correctly connected to the device; otherwise if you what to proceed without main power connect press the acknowledge button and continue the treatment.
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 power module 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 power module or to external battery.
P	Battery one in reserve	External battery one level lower than 70%	Medium	Press the acknowledge button and continue the treatment. If you desire connect the device to power module or to external battery two.
P	Internal one depleted	External battery one level lower than 20%	Medium	Press the acknowledge button and continue the treatment. If you desire connect the device to power module or to external battery two.
P	Battery two in reserve	External battery two level lower than 70%	Medium	Press the acknowledge button and continue the treatment. If you desire connect the device to power module or to external battery one.
P	Battery two depleted	External battery two level lower than 20%	Medium	Press the acknowledge button and continue the treatment. If you desire connect the device to power module or to external battery one.
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	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	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-oxygenatoer 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	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	Air Detected	Air Bubble is detected	High	The device is able to detect air bubble higher than 65 µL. Check any leakage on tubing set are present. This error may occur at the beginning of priming phase, when the tubing are empty.

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	Speed Error	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 COLIBRI', Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
T	Overcurrent Error	An overcurrent condition is detected		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 COLIBRI', 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 COLIBRI', 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 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 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 COLIBRI', 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 COLIBRI', Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
P	Air sensor error	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.
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 COLIBRI', 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 COLIBRI', 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 COLIBRI', Motor and Flowmeter. Resume support. Record the alarm message and contact Technical Assistance.
P	External Battery 1 not in used	External Battery 1 is disconnected	Medium	Check the External Battery 1 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	External Battery 2 not in used	External Battery 2 is disconnected	Medium	Check the External Battery 2 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 COLIBRI', 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 COLIBRI', 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 COLIBRI', 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 corde, the device will be shut down. Turn off the device and switch to back-up section. Contact Technical Assistance.
T	ECMOLIFE Disconected	ECMOLIFE 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 ON ECMOLIFE has been pressed, reconnect the systems through the “Connect COLIBRI” softkey. If the connection fails, continue the treatment on COLIBRI device.

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