ESCO MEDICAL

User Manual



MIRI® M Multiroom IVF Incubator

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Rx only

CE 0123

Esco Medical Technologies, UAB
Gamybos g. 2 • Ramuciai, Kauno r., 54468 Lithuania
Tel +370 37 470 000
www.esco-medical.com • support-medical@escolifesciences.com

For Technical Service, contact:

Europe

Esco Medical Technologies, UAB
Gamybos g. 2 • Ramuciai, Kauno r., 54468 Lithuania
Tel +370 37 470 000
www.esco-medical.com • support-medical@escolifesciences.com

North America

Esco Technologies, Inc.
903 Sheehy Drive, Suite F, Horsham, PA 19044, USA
Tel 215-441-9661 • Fax 484-698-7757
www.escolifesciences.us • eti.admin@escoglobal.com

Rest of the World

Esco Micro Pte. Ltd.
19 Changi South Street 1 • Singapore 486 779
Tel +65 6542 0833 • Fax +65 6542 6920
www.escolifesciences.com • mail@escolifesciences.com

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The information in this manual and the accompanying product is copyrighted and all rights are reserved by Esco.
Esco reserves the right to make periodic minor design changes without obligation to notify any person or entity of such change.
Sentinel™ is a registered trademark of Esco.

Caution: Federal law restricts this device to sale by or on a licensed healthcare practitioner's order.

Only to be used by a trained and qualified professional. The device is sold under exemption 21 CFR 801 Subpart D.

“Material in this manual is provided for informational purposes only. The contents and the product described in this manual (including any appendix, addendum, attachment or inclusion) are subject to change without notice. Esco makes no representations or warranties as to the accuracy of the information contained in this manual. In no event shall Esco be held liable for any damages, direct or consequential, arising out of or related to the use of this manual.

Unpacking and Inspection

Follow standard receiving practices upon receipt of the medical device. Check the shipping carton for damage. If the damage is found, stop unpacking the medical device. Notify the freight carrier and ask for an agent to be present while the medical device is unpacked. There are no special unpacking instructions, but be careful not to damage the medical device when unpacking it. Inspect the medical device for physical damage such as bent or broken parts, dents, or scratches.

Claims

Our routine method of shipment is via common carrier. If physical damage is found, upon delivery, retain all packing materials in their original condition and immediately contact the carrier to file a claim.

If the device is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact your local sales representative or Esco Medical Technologies, UAB immediately.

Standard Terms and Conditions

Refunds & Credits

Please note only serialized products (products labeled with a distinct serial number) and accessories are eligible for a partial refund and/or credit. Non-serialized parts and accessory items (cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. In order to receive a partial refund/credit, the product must not have been damaged. It must be returned complete (meaning all manuals, cables, accessories, etc.) within 30 days of original purchase, in “as new” and resalable condition. The *Return Procedure* must be followed.

Return Procedure

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number obtained from Esco Medical Technologies, UAB Customer Service. All items being returned must be sent *prepaid* (freight, duty, brokerage and taxes) to our factory location.

Restocking Charges

Products returned within 30 days of original purchase are subject to a minimum restocking fee of 20% of the list price. Additional charges for damage and/or missing parts and accessories will be applied to all returns. Products that are not in “as new” and resalable condition are not eligible for credit return and will be returned to the customer at their own expense.

Certification

This device has been thoroughly tested/inspected and found to meet Esco Medical Technologies, UAB manufacturing specifications when shipped from the factory. Calibration measurements and testing are traceable and done according to Esco Medical Technologies, UAB ISO certification.

Warranty and Product Support

Esco Medical Technologies, UAB warrants this device to be free from defects in materials and workmanship under regular use and service for two (2) years from the original purchase date, provided the device is calibrated and maintained following this manual. During the warranty period, Esco Medical Technologies, UAB will, at our option, either repair or replace a product that proves to be defective at no charge, provided you return the product (shipping, duty, brokerage and taxes prepaid) to Esco Medical Technologies, UAB. Any transportation charges incurred are the purchaser's responsibility and are not included within this warranty. This warranty extends only to the original purchaser. It does not cover damage from abuse, neglect, accident or misuse, or as the result of service or modification by parties other than Esco Medical Technologies, UAB.

IN NO EVENT SHALL ESCO MEDICAL TECHNOLOGIES, UAB. BE LIABLE FOR CONSEQUENTIAL DAMAGES.

No warranty shall apply when any of the following causes damage:

- Power failure, surges, or spikes.
- Damage in transit or when moving the device.
- An improper power supply such as low voltage, incorrect voltage, defective wiring or inadequate fuses.
- Accident, alteration, abuse or misuse of the device.
- Fire, water damage, theft, war, riot, hostility, acts of God such as hurricanes, floods, etc.

Only CultureCoin® products (those items bearing a distinct serial number tag) and their accessory items are covered under this warranty.

PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY. Items such as cables and non-serialized modules are not covered under this warranty.

This warranty gives you specific legal rights and you may have other rights, which vary from province to province, state to state, or country to country. This warranty is limited to repairing the device per Esco Medical Technologies, UAB specifications.

When you return the medical device to Esco Medical Technologies, UAB, for service, repair or calibration, we recommend shipment using the original shipping foam and container.

If the original packing materials are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all device surfaces. Use non-abrasive material around all projecting parts.

- Use at least four inches of tightly packed, industrial-approved, shock-absorbent material all around the device.

Esco Medical Technologies, UAB, will not be responsible for lost shipments or medical devices received in damaged condition due to improper packaging or handling. All warranty claim shipments must be made on a prepaid basis (freight, duty, brokerage, and taxes). No returns will be accepted without a Return Materials Authorization ("RMA") number. Please contact Esco Medical Technologies, UAB to obtain an RMA number and receive help with shipping/customs documentation.

Re-calibration of the medical devices, which have a recommended annual calibration frequency, is not covered under warranty.

Warranty Disclaimer

If your medical device is serviced and/or calibrated by someone other than Esco Medical Technologies, UAB, and their representatives, please be advised that the original warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization.

In all cases, breaking the tamper-resistant Quality Seal should be avoided at all cost, as this seal is key to your original medical device warranty. In an event where the seal must be broken to gain internal access to the medical device, you must first contact Esco Medical Technologies, UAB.

You will be required to provide us with the serial number for your medical device, as well as a valid reason for breaking the Quality Seal. You should break this seal only after you have received factory authorization. Do not break the Quality Seal before you have contacted us! Following these steps will help ensure that you will retain the original warranty on your medical device without interruption.

WARNING

Unauthorized user modifications or applications beyond the published specifications may result in an electrical shock hazard or improper operation. Esco Medical Technologies, UAB will not be responsible for any injury sustained due to unauthorized equipment modifications.

ESCO MEDICAL DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

THIS PRODUCT CONTAINS NO USER-SERVICEABLE COMPONENTS.

UNAUTHORIZED REMOVAL OF THE MEDICAL DEVICE COVER SHALL VOID THIS AND ALL OTHER EXPRESSED OR IMPLIED WARRANTIES.

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1 How to Use This Manual

The manual is designed to be read by sections and not ideally from cover to cover. It means that if the manual is read from start to finish, there will be some repetition and overlap. We recommend the following method for going through the manual: first, familiarize yourself with the safety instructions; then, proceed to the essential user functions needed for operating the device on a day-to-day basis; then, review the alarm functions. The menu function of the user interface details information that is needed only for advanced users. All parts must be read before the device is taken into use. The validation guide is described in detail in sections 31 – 34. The maintenance guide is described in detail in section 35. The installation procedures are described in detail in section 36.

Digital version of the English user manual and all available translated versions are available on our website www.esco-medical.com.

To locate this user manual, simply follow these steps:

1. Click on the "Products" tab in the navigation menu.
2. Scroll down and select "MIRI® M Multiroom Incubator".
3. Continue scrolling further down to find the " Literature & Resources" section.
4. Click on the "Information for Users" tab.

2 Safety Warning

- Only personnel operating this equipment must read the user manual. Failure to read, understand and follow the instructions given in this documentation may result in damage to the device, injury to the operating personnel and/or poor device performance.
- Any internal adjustment, modification or maintenance to this device or its parts must be undertaken by qualified service personnel.
- If the device must be relocated, make sure it is appropriately fixed on a support stand or base and move it on a flat surface. When necessary, move the device and the support stand/base separately.
- The use of any hazardous materials in this device must be monitored by an industrial hygienist, safety officer or other suitably qualified individuals.
- Before you proceed, you must thoroughly read and understand the installation procedures and adhere to environmental/electrical requirements.
- If the device is used in a manner not specified by this manual, the protection provided by this equipment may be impaired.
- Do not attempt to remove, replace, or modify the battery. Only qualified service personnel should replace it.

- In this manual, important safety-related points will be marked with the following symbols:



NOTE

Used to direct attention to a specific item.



WARNING

Use caution.

3 Intended Purpose/Use

The Esco Medical MIRI® M multiroom IVF incubators are intended to be used by trained healthcare professionals in the *in vitro* fertilisation (IVF) / assisted reproduction technology (ART) facilities to maintain and provide a stable culture environment with controlled temperature and CO_2/O_2 gas concentration for fertilised oocytes to the blastocyst stage during IVF / ART treatments and optionally to capture time lapse images of these during incubation.

4 About the Product

MIRI® M multiroom IVF incubator is a system consisting of stationary (docking station) and mobile (chambers) where the mobile devices are intended to be connected to the docking station for supply of gas and power. The term system refers to a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose.

The docking station includes docking positions for up to 18 chambers by default, with each chamber being movable in MIRI® M multiroom IVF incubator's docking stations.

The chamber is versatile enough to accommodate different combinations of Petri dishes, such as the capability to hold two 35 mm Petri dishes, two 60 mm Petri dishes or a single 4–well Petri dish. With the possibility of undocking chambers from the docking stations, the system must furthermore allow for easy access to the Petri dishes at any given moment.

A stable temperature level is kept within the individual chambers, both when they're docked and undocked. Furthermore, when a lid is opened, the temperature level recovers to the preconfigured setpoint within 1 minute after the lid is closed again, even if the lid was open for 10 seconds.*

* Based on internal testing. Performance may vary depending on various factors and environmental conditions.

To ensure maximum performance and stability, each chamber has separate temperature controllers for the lid and bottom heating optimization plates, controlling and regulating the temperature in the chambers. The chambers are separate parts and therefore do not affect the conditions in surrounding chambers.

The MIRI® M multiroom IVF incubators are CO_2/O_2 gas incubators and must use a combination of 100% CO_2 and 100% N_2 gas to reach and maintain CO_2 and O_2 concentrations in the chambers (a combination could be 5% CO_2; 5% O_2 and 90% N_2).

A dual–beam infrared CO_2 sensor with extremely low drift rates monitors the CO_2 concentration, while a chemical medical-grade oxygen sensor monitors the level of O_2.

The system features a recirculated gas system where gas is continuously flowing through the chambers. Gas is cleaned via a VOC/HEPA filter and via a 254 nm UVC light. The UVC light has filters that inhibit any 185 nm radiation that would produce dangerous ozone. The VOC/HEPA filter is located after the UVC light.

For safety reasons, the MIRI® M multiroom IVF incubator is fitted with a gas pressure regulator, limiting input gas pressure. Additionally, the incubators are fitted with pressure, flow, and concentration sensors to continuously monitor the gas system status and trigger alarms if the conditions in the system deviate beyond the acceptable thresholds.

To validate the gas concentration levels, the MIRI® multiroom IVF incubator is fitted with a gas sample port that allows the user to sample gas from the whole system. Alternatively, the gas composition may be measured directly in each chamber using a small CO_2 and O_2 sensor, e.g., using an external gas analyzer with the possibility of adding a measuring probe in the chamber.

When a lid on a docked chamber is opened, the gas immediately disperses from the chamber but recovers in approx. 3 minutes for CO_2 and less than 5 minutes for O_2 after the lid is closed again.* If the chamber is opened while undocked, it must first be re-connected to the docking station to restore gas concentration inside it. A complete gas repletion in the system takes less than 60 min.

The MIRI® M multiroom IVF incubators are primarily developed and designed for the incubation of gametes and embryos with an overlay of either Paraffin or mineral oil.

Each chamber has an individual display showing the chamber temperature and the treatment information, simplifying the process of locating and identifying patients.

* Based on internal testing. Performance may vary depending on various factors and environmental conditions.

Only individuals with formal education in healthcare or medical discipline may work with Esco Medical MIRI® M multiroom IVF incubators.

Esco Medical MIRI® M multiroom IVF incubators are used for *in vitro* fertilization (IVF) patients. Patients are women in their reproductive years who have fertility health issues. The intended target group indication is IVF treatment. There are no intended target group contraindications.

The device is manufactured under a full EU certified 13485 ISO quality management system.

This product fulfils the requirements of EN60601-1 3rd edition standards as a Class I type B equivalent device suited for continuous operation. It also conforms to the requirements of the Regulation (EU) 2017/745 concerning medical devices and is classified as a Class IIa device under rule II.

Personal Protective Equipment (89/686/EEC) and Machine Directive (2006/42/EC) is not applicable for the MIRI® M multiroom IVF incubators. Also, the MIRI® M multiroom IVF incubators do not contain or incorporates: a medical substance, including a human blood or plasma derivate; tissues or cells, or their derivates, of human origin; or tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) NO. 722/2012.

5 Transport, Storage and Disposal

5.1 Transportation requirements

After packing, a visual inspection should be done if there is any damage. If no damage is found, the packed device can be prepared for transport.

MIRI® M Chamber comes packed in a carton box. It features a rechargeable lithium-ion battery pack to ensure safe and reliable operation during transport and use. For safe transportation:

- Use the original packaging or equivalent to protect the device from mechanical shocks.
- Do not transport a damaged device or one showing battery issues (e.g., swelling, leaks).
- Do not expose the device to open flames or high heat sources.
- Do not drop, crush, or subject the device to strong impacts.
- Avoid exposing the device to temperatures above 60°C (140°F) during transport (e.g., inside cars under direct sunlight).
- Each device is packaged to comply with UN 3481 (lithium-ion batteries contained in equipment) standards for safe transport.

MIRI® M Docking station is packed in a wooden plywood box and wrapped in polyethylene film.
These labels are glued on the box:

- Label with the product name, serial number and 1D format UDI-DI barcode, handling symbols, and the marked “must be installed before” date.

5.2 Storage and operation environment requirements

5.2.1 Storage requirements

The device may only be stored under the following conditions:

- The device can be in storage for one year. If stored longer than one year, the device must be returned to the manufacturer, registered and handled as non-conformity with NCR provided to QA.
- Both MIRI® M Docking Station and MIRI® M Chambers can be stored at temperatures between -20 °C and +50 °C (-4°F to 122°F).
- Away from direct sunlight.
- Keep dry.

⚠ **Do not use if the packing material is damaged.**

⚠ **Consult the accompanying documents for important safety–related information such as warnings and precautions that cannot be presented on the device itself for various reasons.**

5.2.2 Operation environment requirements

The device may only be used under the following conditions:

- Environmental temperatures from 18° C to 30 °C (64.4°F to 86°F).
- MIRI® M Chamber should be charged only at temperatures between 0°C to 45°C (32°F to 113°F).
- Away from direct sunlight.
- Kept dry.
- For indoor use only.
- Operating humidity: 5 – 95% RH (Non-Condensing).
- Operating altitude – up to 2000 meters (6560 feet or 80kPa – 106kPa).
- Non-operating altitude – more than 2000 meters (6560 feet or more than 80kPa – 106kPa).

⚠ **The device should not be installed or operated near windows.**

⚠ **Do not use the device if it emits smoke, heat, unusual odours, or shows signs of damage. Turn off the device and contact Esco Medical Technologies, UAB immediately.**

⚠ **Charge the device only with the provided docking station or approved power supply.**

5.3 Disposal

The device should be disposed of in accordance with the WEEE Directive (Waste Electrical and Electronic Equipment).

⚠ **The device may have been used for treating and processing infectious substances. Therefore, the device and device components may be contaminated. Device must be disinfected or decontaminated prior to disposal.**

The device contains reusable materials. All components (except for the VOC/HEPA and HEPA filters) can be discarded as electrical waste after cleaning and disinfection.

Please note that the VOC/HEPA and HEPA filters must be discarded following the applicable national regulations for special solid waste.

MIRI® M Chamber features an integrated lithium-ion battery. Therefore:

- Do not disassemble or tamper with the battery.
- Do not dispose of the device in household waste.
- Return the device to Esco Medical Technologies, UAB for disposal.

6 Supplied Service Parts and Accessories

Service parts provided with the device are listed below:

- 1 VOC/HEPA filter capsule (only for MIRI® M Docking station).
- 2 HEPA filters for input gas supply (only for MIRI® M Docking station).
- 1 heating optimization plate per chamber.
- 1 medical grade power cord.
- 1 USB stick containing a PDF version of the user manual and translations.
- 1 3.5mm external alarm jack connector.
- 1 set of fast male connectors with 15 silicone pipes.

⚠ **Included service parts vary depending on the configuration of the device. For the exact part list, please refer to the Packing List document provided together with the device.**

Accessories do not apply with the MIRI® M multiroom IVF incubator.

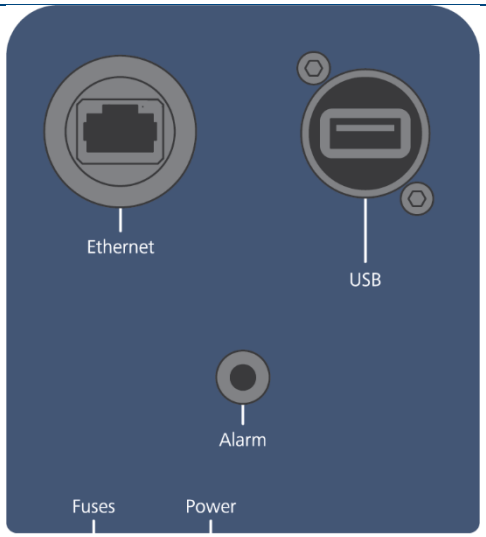
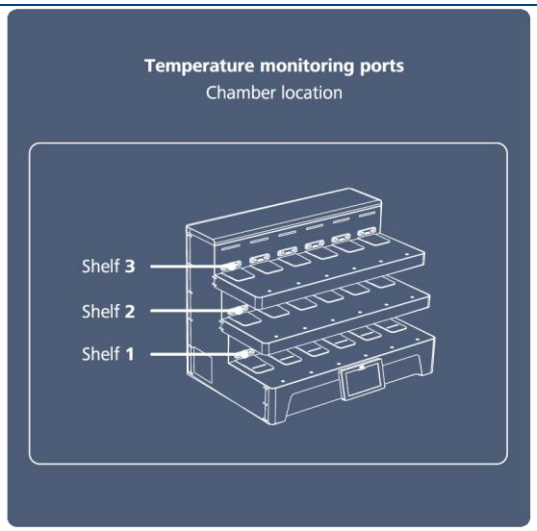
7 Safety Symbols and Labels

Table 7.1 Product information labels

Label	Description
	CE mark and notified body number
	Unique device identifier
	Temperature limit
	Keep away from direct sunlight
	Do not use it if the packing material is damaged
	Rx only
	Medical device
	Keep dry

Label	Description
	Fragile
	**Caution:** consult the accompanying documents for important safety-related information such as warnings and precautions that cannot be presented on the device itself for various reasons.
	Consult instructions for use
	Not protected against the ingress of water
	Manufacturer name and address
SN:	Serial number
 YYYY-MM	Date of manufacture
	Potential risk of electrical shock (never remove any cover)
	Observe WEEE

Table 7.2 Info labels on the MIRI® M multiroom IVF incubator

Image	Description
	N_2 inlet / Calibration / CO_2 inlet
	VOC/HEPA filter
	MIRI® M Docking station ON/OFF button
	Temperature monitoring ports
	Gas sample ports
	Maximum pressure 1,5 bar
	Connection ports
	Temperature monitoring ports

The connected external device to signal input/output connections should be compliant with the appropriate safety standard for medical device EN 60601-1. It applies to USB and Ethernet.

When chambers are docked to the docking station, they are not numbered. However, they can be easily identified by counting from left to right (from number 1 to 6) on the top, middle and bottom shelves. The numbers are shown in the figure below:

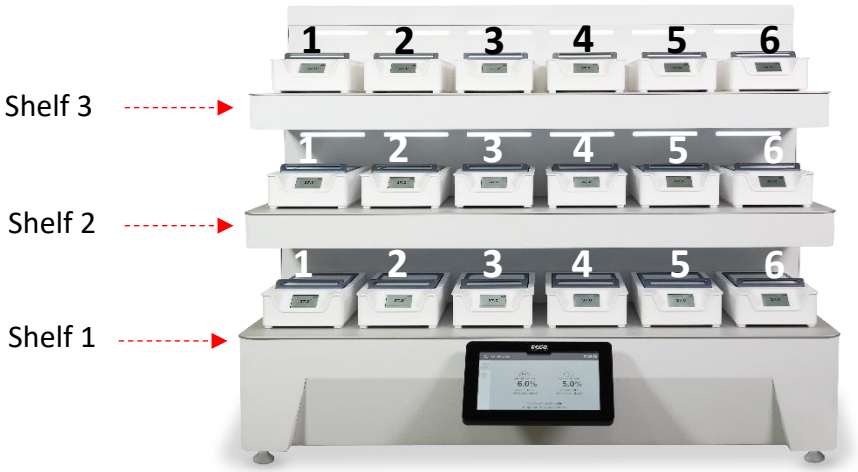


Figure 7.1 MIRI® M multiroom IVF incubator docking position numbers and shelf names

8 Important Safety Instructions and Warnings

8.1 Before installation

1. Do not use the product if the package is damaged. Contact Esco Medical Technologies, UAB or the local Representative.
2. Do not use the device if it emits smoke, heat, unusual odours, or shows signs of damage. Disconnect and contact Esco Medical Technologies, UAB immediately.
3. Read the user manual thoroughly before use.
4. Always keep these instructions easily accessible near the device.

8.1.1 Handling the Unit

To ensure safe handling operation and avoid personal injury or device damage, the device must be handled, lifted, and moved in accordance with the requirements of the international safety standard **IEC 60601-1**:

1. When moving the unit, lift only at the four lifting straps that are already attached to the unit. These lifting straps are looped around the levelling feet on both sides of the unit (see Figures 8.1 and 8.2).



Figure 8.1 Lifting straps attached around the left-side levelling feet of the MIRI® M multiroom IVF incubator



Figure 8.2 Lifting straps attached around the right-side levelling feet of the MIRI® M multiroom IVF incubator

⚠ **The lifting straps are factory-installed. No additional assembly is needed.**

2. Firmly grasp all four lifting straps.

⚠ **Only lift the incubator by the lifting straps. Never attempt to lift the incubator by the docking station shelves or display, as this could damage the structural frame, electronic components, or cause misalignment of the docking connectors. Lift from both sides of the unit (left and right).**

3. Carefully move the incubator to the operational location while holding the unit only by lifting straps. Ensure that the lifting force is applied evenly on both sides to maintain unit stability.

⚠ **Take adequate safety measures when moving this device. Ensure that a sufficient number of trained personnel are available to lift the unit safely into place, following proper lifting techniques.**

⚠ **This incubator weighs 85 kg (187.4 lbs). The device must be lifted by at least two persons working together to move it. However, for optimal safety and handling, it is recommended that four persons carry out the lifting operation.**

⚠ **Do not push or pull the incubator along the floor, as this could damage the levelling feet.**

4. After placing the unit, remove all lifting straps and store them for further use.

8.2 During installation

1. Never place this device on top of other equipment that gives off heat.
2. Place this device on a flat, hard, and stable surface.
3. Do not place the device on a carpet or similar surfaces.
4. Do not defy the safety purpose of the grounding-type (earthing) plug.
5. A grounding-type (earthing) plug with two blades and a third prong are provided for your safety. If the provided plug does not fit into your outlet, consult an electrician to replace the outlet.
6. Always connect the power cord to a properly grounded outlet and only use the cord that came with the device.
7. Do not install near any heat sources such as radiators, heat registers, stoves or other apparatus that produce heat.
8. Do not use this device near water sources.
9. Use only 100% concentration CO_2, 100% concentration N_2 gases.
10. Always use an external 0,22µm HEPA filter to input CO_2 and N_2 gases.
11. Do not use this product if the room temperature exceeds 30 °C or is below 18°C.
12. Place this device in a location with adequate ventilation to prevent internal heat build-up. Leave at least 10 cm clearance from the rear, 30 cm from the top and 20 cm from left and right to prevent overheating and allow access to the ON/OFF switch in the back.
13. This device is intended for indoor purposes only.
14. The device must be connected to a suitable uninterrupted power supply (UPS) source.

⚠ **The emissions characteristics of this equipment make it suitable for use in industrial**

areas and hospitals (CISPR 11 class A). If it used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocation or re-orienting the equipment.

⚠ **Do not use portable RF communications equipment closer than 30 cm (12 inches) to any part of MIRI® M multiroom IVF incubator or its cables as this can affect the performance of the equipment.**

⚠ **Stacking and placement of other electronic equipment close to any part of MIRI® M multiroom IVF incubator or its cables should be avoided as this can affect the performance of the equipment.**

⚠ **Cables and accessories other than those specified by the manufacturer must not be used as use of such may compromise safety and may negatively affect EMC performance.**

8.3 Post-installation

1. Refer all servicing procedures to qualified service personnel.
2. Servicing is required according to the service manual as well as cases when the device has been damaged in any way, e. g. suppose the device has been dropped, exposed to rain or moisture, or does not operate normally. The MIRI® M multiroom IVF incubators contain high voltage components that may be hazardous.
3. Unplug this device during lightning storms or when unused for an extended period of time.
4. Protect the power cord from being walked on or pinched, particularly at the plug, the socket and the point where it exits from the device.
5. Perform temperature and gas calibration at the intervals described in the manuals.
6. Never leave the lid of the chamber open for more than 10 sec while in use.
7. VOC/HEPA filters must be changed every 3 months.
8. A maintenance plan must be fulfilled to keep the device safe.
9. NEVER block gas supply holes in the chamber.
10. Ensure that CO_2 and N_2 gas supply pressures are kept stable at 0.7 – 1.5 bar (10.15 – 21.76 PSI). The recommended pressure is 1 bar (14.50 PSI).
11. Never use any other filter except those provided by Esco Medical Technologies, UAB. Otherwise, the warranty will be void.
12. Do not use the device without a proper Esco Medical Technologies, UAB VOC/HEPA filter attached.

8.4 Cybersecurity & IT Environment

8.4.1 Requirements

To ensure the continued safety, performance and data integrity of the MIRI® M system, the following environmental and operational security requirements must* be maintained by the user's facility:

1. Network Isolation (Mandatory)

- **Dedicated Network:** The MIRI® M system is a standalone device and should not be connected to any local or public network.
- **No Unauthorized Connections:** Do not connect the MIRI® M device to the general hospital intranet or the public internet unless specifically configured and authorized by Esco Medical support.

2. Physical Security & Access Control

- **Controlled Environment:** The system must be operated in an access-controlled laboratory environment. Physical access to the MIRI® M device must be restricted to authorized clinical and technical personnel only.
- **Hardware Integrity:** Internal components are encased to prevent tampering. Any unauthorized disassembly of the device or removal of computer internals is strictly prohibited and may compromise device security and patient data.

3. Operating System & Software Integrity

- **Hardened Configuration:** The MIRI® M device is a dedicated medical appliance. The main Operating System (Linux) has been factory-hardened to ensure performance of the device and environmental control.
- **Managed Software Installation:** To prevent system instability, performance degradation, or the introduction of security vulnerabilities, the installation of any third-party software (such as antivirus or malware protection) and drivers is **not allowed**.
- **Consultation with Esco Medical:** For any modifications to the software environment of the MIRI® M device, the user's facility **must** consult with Esco Medical Support. Under any circumstances, the proposed software **must** be evaluated for compatibility with the MIRI® M application, to ensure that patient safety and data integrity are not compromised.
- **User Authentication:** Access to the Linux Operating System files and critical settings is restricted to authorized personnel via administrative password. Do not share administrative passwords with unauthorized personnel or third-party vendors without Esco Medical supervision.

⚠**The MIRI® M software does not implement internal automated mechanisms for software file verification or tampering protection. Protection against unauthorized modification of system settings and application files relies heavily on the measures described above. Unauthorized access to the file system or modification of application data**

may lead to risks of functional disruption of the MIRI® M system and loss, corruption or leakage of patient data and incubation logs. It is the user facility's responsibility to ensure the integrity of the operating environment to prevent such incidents*.

⚠ **User must always inform Esco Medical Technologies, UAB, without any undue delay upon becoming aware of a cybersecurity vulnerability incident or any suspected security events.**

9 Getting Started

⚠ **The MIRI® M multiroom IVF incubators must be installed by authorized and trained personnel only!**

9.1 Starting up the system

1. Follow the guidelines in the safety instructions and warnings section.
2. Connect the medical grade power cord to the UPS.
3. Connect the medical grade power cord to the MIRI® M multiroom IVF incubator.
4. Connect the gas lines.
5. Set the gas pressure on the external gas regulator at 0.7 – 1.5 bar (10.15 – 21.76 PSI), recommended 1 bar (14.50 PSI).
6. Switch on the MIRI® M multiroom IVF incubator in the back.
7. Observe for standard functionality on the docking station display.
8. Connect all chambers to the docking station by docking them in any of the available docking positions (see section "14.6 Chamber mobility" of the User Manual).
9. Once connected to the power supply in the docking station, the chambers will automatically switch ON and initiate a warm-up sequence to reach the default temperature setpoint. The default temperature setpoint is 37.0 °C.
10. Let the connected chambers warm up and stabilize for 60 min (please refer to Figure 9.1 to see how the warm-up procedure is indicated on the display).
11. The system will not trigger any gas or temperature alarms during the warm-up phase, until **one** of the conditions is satisfied: the default setpoint is reached once or 60 minutes have passed since docking the chamber.
12. When the default temperature setpoint is reached in the chambers, the warm-up icon will disappear, and the default IDLE view will be displayed (see Figure 9.2).
13. Follow the guidelines in the Validation guide (see section "31 Validation Guide" of the User Manual).
14. Complete user training and finish reading instructions (instructions must be read prior to setting up the device).
15. After a burn-in phase of 24 hours, the system is ready for use IF the testing is **successful**.

⚠ **For Ethernet connectivity, use twisted pair Ethernet cables of Category 6 (Cat 6) or higher, compliant with ISO/IEC 11801-1. Shielded cables are recommended for environments with high electromagnetic interference (EMI).**

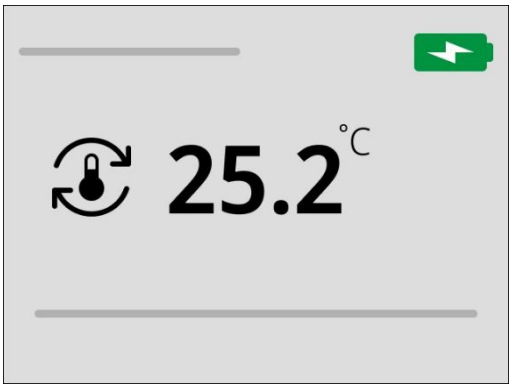


Figure 9.1 Chamber display indicating the warm-up sequence

☞ **The docking station offers a total of 18 docking positions across 3 shelves, but it is not required to dock chambers in all positions at once. For optimal* performance it is recommended to have at least 6 chambers docked in the docking station.**

☞ **The gas system is capable of running in one of two ways: with CO_2 and N_2 connected to their respective inlet or only with CO_2 connected.**

☞ **Clean and disinfect the device before use. It is not delivered sterile or in a clinically acceptable cleanliness state. Refer to the "19 Cleaning Instructions" section of the User Manual for the manufacturer's recommended guidelines.**

☞ **The system's performance may also be affected by the environmental conditions it is installed in.**

* While the incubator will function as intended with fewer than 6 chambers docked, performance may be slightly altered. Docking at least 6 chambers helps ensure the most consistent environmental conditions across all chambers.

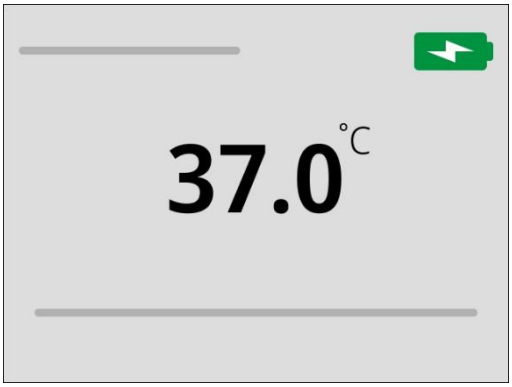


Figure 9.2 The default idle chamber display view

9.2 Adding more chambers

Additional chambers can be connected to the docking station at any time during the lifespan of the system using the same process as described in section “9.1 Starting up the system” of the User Manual (please follow instructions described in points 8 – 15).

When the chamber is registered in the clinic's internal log of devices, the chamber may also be stored for later use. To do this, simply remove the chamber from the docking station, power it off, and store it in an appropriate location within the clinic. The number of docking locations does not limit the number of chambers in the clinic, the number of chambers could be higher.

Clean and disinfect the device before use. It is not delivered sterile or in a clinically acceptable cleanliness state. Refer to the “19 Cleaning Instructions” section of the User Manual for the manufacturer's recommended guidelines.

10 Mains Connection

The MIRI® M multiroom IVF incubators come with a detachable medical grade power cord. The power cord is prepared for the country in which the device is intended to be used.

The ON/OFF switch provides the user with a means to isolate the MIRI® M multiroom IVF incubator from the main power source.

Do not defy the safety purpose of the grounding-type plug! A grounding-type plug has two blades and a prong, which is provided for your safety. If the provided plug does not fit into your outlet, consult an electrician to replace the outlet.

The power requirement is 230V 50Hz or 115V 60Hz. The built-in power supply has a switch mode that automatically adjusts to the correct mains power between 100V to 240V at 50-

60Hz. Make sure that power requirements in the country where the device will operate meets the listed power and frequency requirements above.



Figure 10.1 Power supply

11 Gas Connections

MIRI® M Docking station is designed in such a way that it can be connected to several types of gases (CO_2 and N_2). Inlet ports for CO_2 and N_2 gases are located at the back. The left connector is for N_2, and the right one is for CO_2. These ports are marked "CO_2 100% Inlet" and "N_2 100% Inlet".

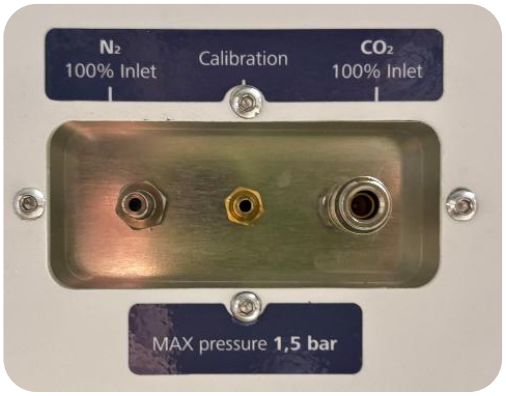


Figure 11.1 Gas inlets on the back of the MIRI® M multiroom IVF incubator

CO_2 inlet should be connected to a 100% concentration of CO_2. CO_2 control in the chamber is available in the range from 3.0% – 12.0%.

N_2 inlet should be connected to a 100% concentration N_2 if low oxygen conditions are required. O_2 control, in the chambers, is available in the range from 3.0% – 10.0% by infusing N_2 gas.

Gas pressure for both inlets should be between at 0.7 – 1.5 bar (10.15 – 21.76 PSI), recommended 1 bar (14.50 PSI), and it must be kept stable!

Always use a high-quality pressure regulator that can be set with the required precision for all gases.



Figure 11.2 Pressure regulator

Connect CO_2 gas to the CO_2 inlet with a suitable silicone tube. Ensure that the tube is fastened with a clip so that it does not accidentally loosen itself during a sudden pressure fluctuation. Use the supplied 0.22µm HEPA filter on the gas line just before the inlet on the MIRI® M multiroom IVF incubator. Notice the flow direction.

Connect the N_2 gas to the N_2 inlet in a similar way.



Figure 11.3 0.22 µm external HEPA filter for incoming CO_2 / N_2 gas

⚠ **Always wear protective eyewear before opening the gas line valve at the wall connection. The inline filter is located outside of the device (between the wall gas outlet and the back of the unit).**

12 VOC/HEPA Filter

Volatile organic compounds (VOCs) are hydrocarbon-based compounds that are found in fuel, solvents, adhesives, and other compounds. Examples of VOCs include isopropanol, benzene, hexane, formaldehyde, vinyl chloride.

VOCs can also occur in medical gases, such as CO_2 and N_2. It is essential to use in-line VOC filters to prevent these fumes from entering your MIRI® M multiroom IVF incubators.

Unexpected sources of VOCs are commonly found in IVF labs. These can include cleaning agents, perfumes, cabinetry, grease on the wheels of equipment and sources in HVAC equipment.

VOCs are typically measured in parts per million (ppm.) They can also be reported in parts per billion (ppb.) For IVF, the recommended count is below 0.5 ppm; the total quantity of VOCs should be below <0.2 ppm or **preferably zero**.

High levels of VOCs (over 1 ppm) are toxic to embryos, resulting in poor embryo development and even probable failure to reach the blastocyst stage.

VOC levels in the 0.5 ppm range will typically allow acceptable blastocyst development and reasonable pregnancy rates but will likely result in a high percentage of miscarriages.

A combined VOC/HEPA filter is integrated into the construction of the MIRI® M multiroom IVF incubator. Before entering the MIRI® M multiroom IVF incubator, the gas is sent through the filter in a single pass. Then, upon return from the chamber, the gas is filtered again. The recirculation system constantly filters gas in the MIRI® M multiroom IVF incubator.

The combined VOC/HEPA filter is mounted on the device's left side behind push-to-open doors to ease access and replacement.

12.1 Installation procedure of a new VOC/HEPA filter

The VOC/HEPA filter must be replaced every 3 months. Mark the date when it is initially installed and make sure to uphold this interval. Correct filter performance is crucial for the system’s performance.

Start by unpacking the new filter. The two safety caps installed on the filter’s elbows can be discarded during this process. On the left-hand side of the docking station, push the *push-to-open* hatch inwards on the top of the hatch.



Figure 12.1 The push-to-open hatch

Push-to-open hatch is designed as separate part, not attached to the Docking station. It must be held securely when opening to prevent it from falling down.

The push-to-open hatch is not required for the VOC/HEPA filter to function correctly but should nonetheless be reattached upon completing the filter change.

Using one hand, navigate the VOC/HEPA filter horizontally into the designated slot in the VOC/HEPA filter housing with the straight blue fitting first. Using the guide near the slot, users can insert the filter without the need to visually check its position. Ensure it is securely connected before letting go of the filter (please refer to Figure 12.2 for the correct installation procedure).



Figure 12.2 Filter's straight blue fitting inserted

Navigate the blue elbow fitting in the opposite end into the specified socket located on the side of the filter housing. Ensure it is securely connected before letting go (please refer to Figure 12.3 for the correct installation procedure).



Figure 12.3 Filter's elbow blue fitting inserted

When the VOC/HEPA filter change procedure is completed, make sure to reattach the hatch and reset the counter of the last filter change time on the docking station display. The VOC/HEPA filter reset counter is located in the maintenance settings (please refer to the "14.5 Maintenance settings" section of the User Manual).

To comfortably install the VOC/HEPA filter, the left side of the MIRI® M Docking Station needs a minimum clearance of 100 mm.

The device must not contain embryos in any connected chambers, while the VOC/HEPA filter is being changed.

A VOC/HEPA filter that has been installed incorrectly may cause gas leakage and contaminate the incubator's contents.

Never run the MIRI® M multiroom IVF incubator if the filter element is missing! Dangerous particle contamination and gas leakage could occur!

12.2 Removal procedure of a VOC/HEPA filter

On the left-hand side of the docking station, push the *push-to-open* hatch inwards on the top of the hatch.



Figure 12.4 The push-to-open hatch

Push-to-open hatch is designed as separate part, not attached to the Docking station. It must be held securely when opening to prevent it from falling down.

Using one hand, grip the blue elbow fitting and push the filter to the right. This will release the blue elbow fitting from its housing. You may need to move the filter a bit back to the left afterwards to comfortably grab it with one hand.



Figure 12.5 Filter‘s blue elbow fitting pushed out

Grab the filter with one hand and gently pull it out of the filter housing. Make sure it moves upwards while pulling it.

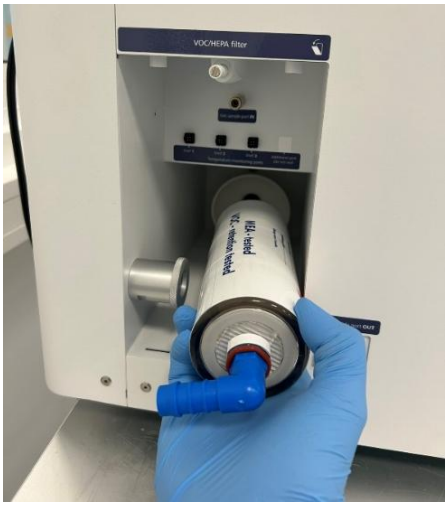


Figure 12.6 Filter push out of the device

The left side of the MIRI® M Docking Station needs a minimum clearance of 100 mm to comfortably replace the VOC/HEPA filter.

13 Battery Information

All MIRI® M multiroom IVF incubator Chambers contain a **rechargeable lithium-ion battery pack** that ensures continued operation during power interruptions. The battery pack consists of Li-Ion cells, protected with fireproof material, a 5 A PTC fuse, and a Molex SPOX 5-pin connector to ensure safety and reliability. The battery is compliant with international safety and transport standards:

- **UN 38.3**: Ensures battery safety during transportation.
- **UL 62133-2 & IEC 62133-2**: Ensures battery safety during use.

- **IEC 60601-1**: Ensures device safety for medical applications.

To ensure safe operation and avoid injury or damage:

- DO NOT attempt to replace, remove, or service the battery. Replacement is restricted to qualified service personnel only.
- DO NOT expose the battery to open flames, direct sunlight, or temperatures above 60°C.
- DO NOT disassemble, crush, puncture, or short-circuit the battery terminals.
- DO NOT immerse the device or battery in water or any liquid.
- Use only the manufacturer-approved battery pack to avoid safety hazards.
- Unauthorized battery replacement may result in fire, explosion, device malfunction, and void the warranty.

☞ **The battery pack is designed for a long service life under normal operating conditions. Replacement should occur only when indicated by the service schedule, outlined in the “35 Maintenance Guide" section of the User Manual.**

⚠ **Battery replacement must be performed exclusively by qualified service personnel.**

⚠ **Unauthorized handling may cause electric shock, fire, or device failure.**

13.1 Battery disposal

To prevent environmental harm and comply with regulations:

- DO NOT dispose of the battery in household waste.
- Dispose of batteries at authorized electronic waste collection points.
- Follow local, regional, and national guidelines for battery disposal.
- Contact your service provider for information on proper disposal methods.

13.2 Battery emergency procedures

If you notice any of the following: smoke, heat, swelling, leaking, or unusual odours from the device:

1. Immediately disconnect the device from docking station if it is safe to do so.
2. Move the device away from flammable materials.
3. DO NOT use water to extinguish battery fires. Use a Class D fire extinguisher or cover with dry sand.
4. Evacuate the area and contact emergency services if fire or smoke persists.
5. Notify Esco Medical Technologies, UAB or your local distributor for further assistance.

⚠ **The laboratory must be equipped with adequate safety measures to address potential fire-related risks associated with the integrated batteries inside the chambers. This includes appropriate fire suppression systems, fire extinguishers suitable for battery fires (such as Class D or lithium-ion-specific extinguishers), proper ventilation, and emergency response protocols. It is essential to follow general fire safety procedures to minimize risks and enhance overall laboratory safety.**

14 User Interface

The following sections provide an overview of the functions associated with UI keys and menu items. The UI facilitates both routine operations and advanced configurations of the device. A summary of the primary keys and their respective functions is presented in the table below.

Table 14.1 The main keys and their purpose

Description	Image
MIRI® M Docking station	
ON/OFF Button The power connection and ON/OFF button are located at the REAR of the device. Connect the power cord and press the button next to it to power ON the MIRI® M multiroom IVF incubators.	
Docking Station Display Panel The 7-inch docking station display provides real-time status updates about the conditions of the incubator, including displaying live values for CO_2 and O_2 gas concentrations, as well as the inlet pressure for CO_2 and N_2. The display is operated by touch interaction and allows users to manage incubation functions, adjust setpoints, perform maintenance, and receive alarm and warning notifications, including guidance on resolving them.	
Shelf LED Backlight Panel The LED bars above each docking position indicate the status of the corresponding docked chamber. No light means no chamber is docked, a flashing white light signifies an idle chamber not assigned to a patient, and a flashing blue light indicates a chamber assigned to a patient with cells undergoing treatment. This allows users to identify specific or idle chambers from a distance, with the further option of setting the light to pulsate from an external PC for enhanced visibility. Additionally, the backlight panel also signals alarm and warning states in docked chambers by pulsating red and yellow, respectively. These indicators remain active	

Description	Image
until the issue is resolved or the chamber is undocked, at which point the notification is removed from the docking station, and the LED light for that position turns OFF.	
Gas inlets The incubator has separate inlets for CO_2 and N_2, both located at the rear of the device. Additionally, a dedicated inlet for calibration gases is also positioned in the same area.	
Additional connections Additional connections for ethernet, USB, and external alarm are located at the REAR of the device.	

Description	Image
MIRI® M Chamber	
Chamber Display Panel The display on the mobile chamber unit is the primary communicator of the temperature in the chamber as well as whether any patients are assigned to it or not. The live temperature value is prominently centred with a potential patient name beneath it and a unique patient ID in the top-left corner. The temperature value always remains visible while the chamber is powered ON, except for a brief 3-second visual confirmation shown during successful docking and undocking. Other notifications are communicated to the user through icons and colour changes (most prominently during alarm and warning scenarios).	

Description	Image
Alarm and OFF button In an alarm scenario with an undocked chamber, the chamber provides both visual and audible feedback to alert the user. To mute the alarm, the chamber features its own mute button, which silences the alarm for 5 minutes before it resumes notifying the user. For assigned chambers, pressing and holding the mute button also functions as a reset for patient information. This action triggers a 3-second countdown, after which the chamber resets. Holding the button for an additional 3 seconds, or doing so on an unassigned chamber, will power off the chamber, with corresponding feedback displayed on the screen.	

14.1 Activating the heat and gas controls

The system is powered on by pressing the ON/OFF switch in the rear of the docking station, which also activates the heat and gas control systems. While the system is booting up, a "Please Wait" message will appear on the docking station display.



Figure 14.1 Loading view

Soon after system activation, the main display will show the following parameters:

- CO_2 concentration, CO_2 setpoint and CO_2 inlet pressure.
- O_2 concentration, O_2 setpoint and N_2 inlet pressure.
- Temperature setpoint.

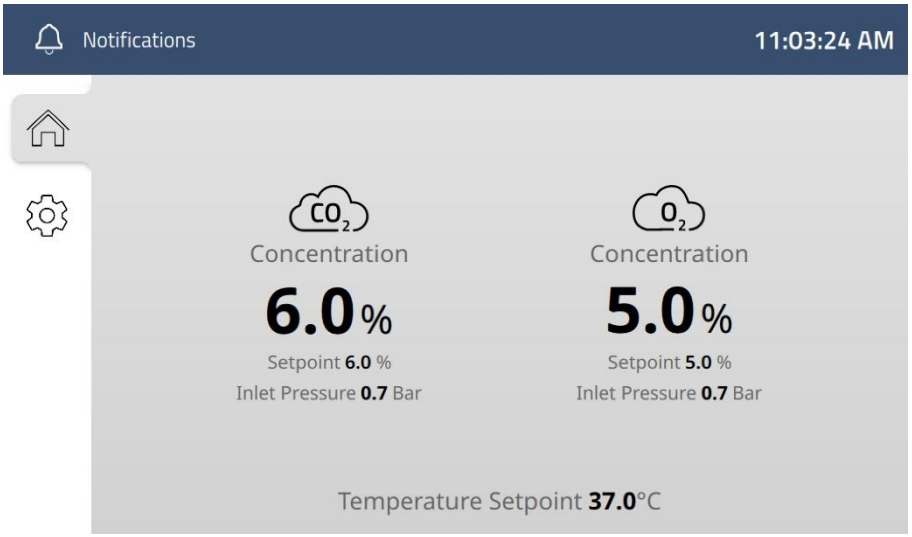


Figure 14.2 MIRI® M incubator main display view

14.2 Settings menu

Tapping the ⚙ icon in the main display view will open the settings menu:

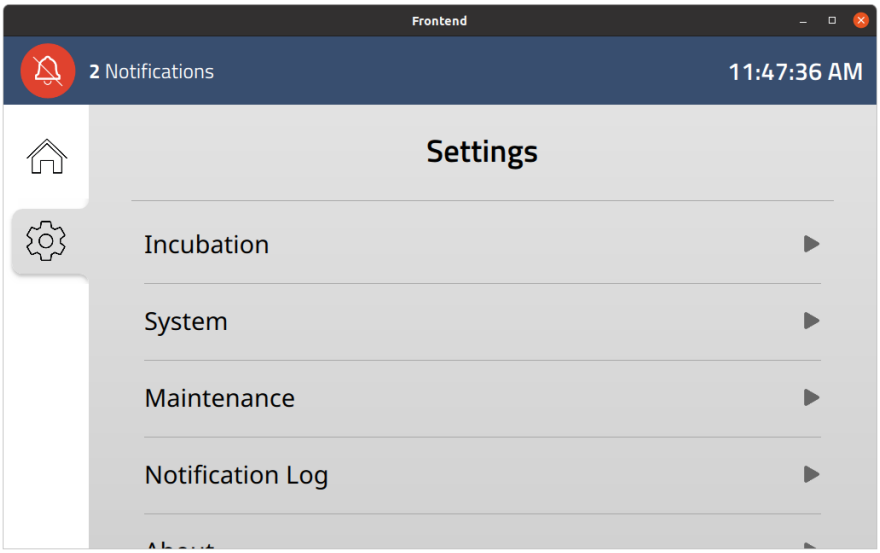


Figure 14.3 Settings view

This menu offers access to all the available aspects of the system, allowing adjustments to settings related to incubation and the system itself.

Notification Log provides access to the system's notification history, allowing users to review past system events, warnings and alarms. This log supports system monitoring by offering a chronological record of notifications generated by the system.

Additionally, the system offers a maintenance section for service-related settings.

14.3 Incubation settings

The Incubation menu provides a range of options for regulating and optimizing the system's incubation conditions.

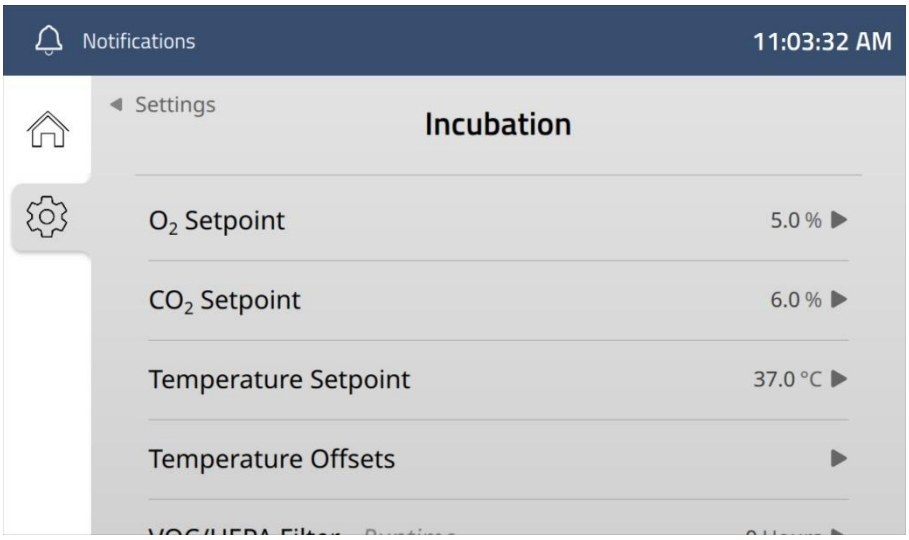


Figure 14.4 Incubation Settings view

Temperature and gas setpoints can be adjusted, temperature offsets can be configured, and the VOC/HEPA filter runtime counter can be reset. The menu also includes the option to enable or disable the UV light. The gas system can be set to operate either with a combination of CO_2 and O_2 or with CO_2 only.

14.3.1 Changing the O_2 concentration setpoint

The O_2 setpoint can be adjusted in the range from 3.0% – 10.0%.

The default O_2 setpoint is 5.0%.

To change the setpoint for O_2 concentration, please follow these instructions:

1. In the Incubation Menu tap *O_2 Setpoint* to change the O_2 setpoint.
2. Tap (-) or (+) keys to adjust the O_2 setpoint to the desired concentration.
3. When the setpoint is reached, tap *Apply*. The display will revert back to the Incubation Settings Menu, and you must manually navigate back to the main page.



Figure 14.5 O_2 Setpoint view

The system changes the setpoint to the configured concentration and will not trigger any gas alarms until the setpoint for O_2 is reached once or 60 minutes have passed.

Gas offset calibration may be beneficial when setting the setpoint for the first time or making adjustments. Due to the complexity of the gas system, variations in pressure, flow dynamics, and sensor response may impact accuracy. Performing a calibration ensures optimal performance and precise control. For instructions on how to perform gas offset calibration, please refer to "14.5.2 Gas offset calibration" section of the User Manual or contact Esco Medical Technologies, UAB or your local distributor.

14.3.2 Changing the CO_2 concentration setpoint

The CO_2 setpoint can be adjusted in the range from 3.0% – 12.0%.

The default CO_2 setpoint is 6.0%.

To change the setpoint for the CO_2 concentration, follow these instructions:

1. In the Incubation Menu tap *CO_2 Setpoint* to change the CO_2 setpoint.
2. Tap (-) or (+) keys to adjust the CO_2 setpoint to the desired concentration.
3. When the setpoint is reached, tap *Apply*. The display will revert back to the Incubation Settings Menu, and you must manually navigate back to the main page.

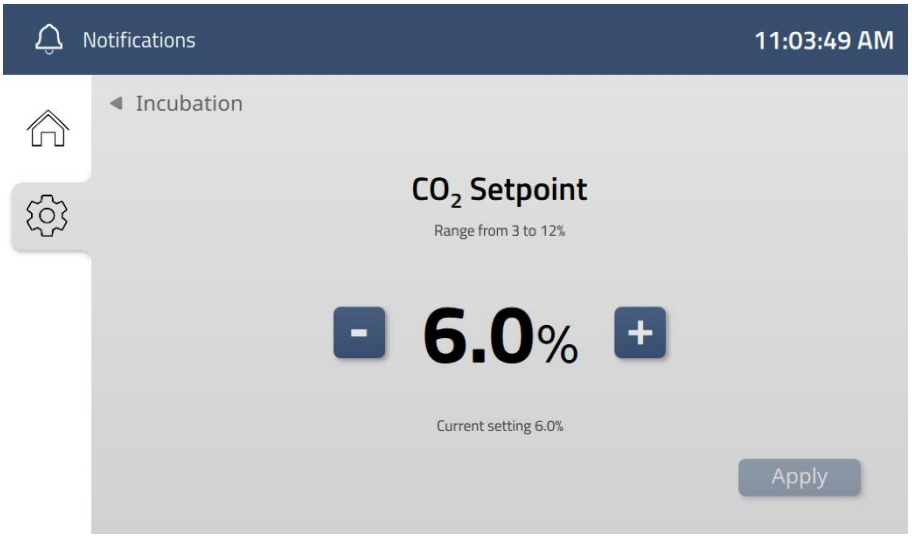


Figure 14.6 CO_2 Setpoint view

The system changes the setpoint to the configured concentration and will not trigger any gas alarms until the setpoint for CO_2 is reached once or 60 minutes have passed.

Gas offset calibration may be beneficial when setting the setpoint for the first time or making adjustments. Due to the complexity of the gas system, variations in pressure, flow dynamics, and sensor response may impact accuracy. Performing a calibration ensures optimal performance and precise control. For instructions on how to perform gas offset calibration, please refer to "14.5.2 Gas offset calibration" section of the User Manual or contact Esco Medical Technologies, UAB or your local distributor.

Achieving a 12% CO_2 concentration setpoint may be challenging at elevations below 2000 meters. Users should take this limitation into account when configuring high CO_2 concentration levels.

14.3.3 Changing the temperature setpoint

A single temperature setpoint can be adjusted in the range from 35.0 °C to 39.0 °C for the whole system, meaning every chamber docked in the docking station has the same setpoint.

The default temperature setpoint is 37.0 °C.

To change the temperature setpoint, please follow these instructions:

1. In the Incubation Menu tap *Temperature Setpoint* to change the temperature setpoint for the whole system.
2. Tap the (-) or (+) keys to adjust the temperature setpoint to the desired level.
3. When the desired level is reached, tap *Apply*. The display will revert back to the Incubation Settings Menu, and you must manually navigate back to the main page.

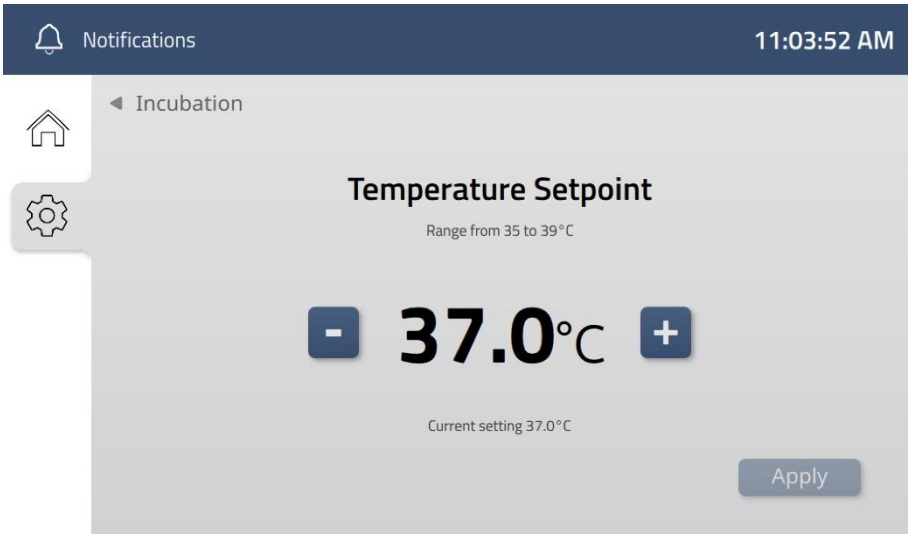


Figure 14. Temperature Setpoint view

The system changes the setpoint to the configured level and will not trigger any temperature alarms until the setpoint is reached once or 30 minutes have passed.

This change will affect all connected chambers, including an automatic adjustment for any chambers with other settings being docked in the same docking station.

For the MIRI® M multiroom IVF incubator to work as intended, the temperature setpoint should be at least 5°C higher than the ambient temperature.

14.3.4 Changing temperature offsets

Temperature offset values should only be changed by a trained user or technician, according to specific measurements done with the calibrated device.

To adjust the temperature offset for either the lid or the bottom of the chambers, please follow these instructions:

1. In the Incubation Menu tap *Temperature Offsets* and select either *Lid Offset* or *Bottom Offset.*



Figure 14.8 Temperature Offset settings

2. Tap the (–) or (+) keys to adjust the temperature offset to the desired level.
3. When the desired level is reached, tap *Apply*. The display will revert back to the Incubation Settings Menu, and you must manually navigate back to the main page.

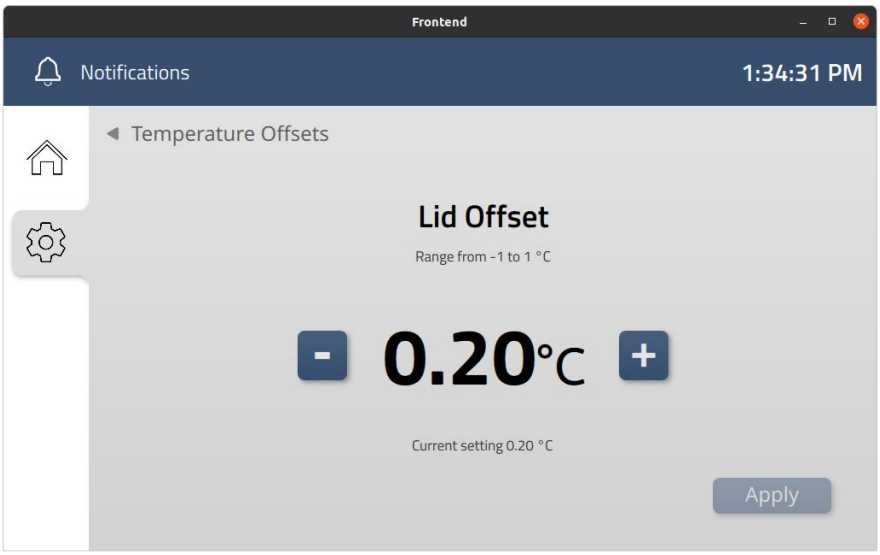


Figure 14.9 Lid temperature offset

While the temperature setpoint is changed by adjusting a single value, this functionality offers more freedom to adjust the specific difference between top and bottom temperature zones.

This change will affect all connected chambers, including an automatic adjustment for any chambers with other settings being docked in the same docking station.

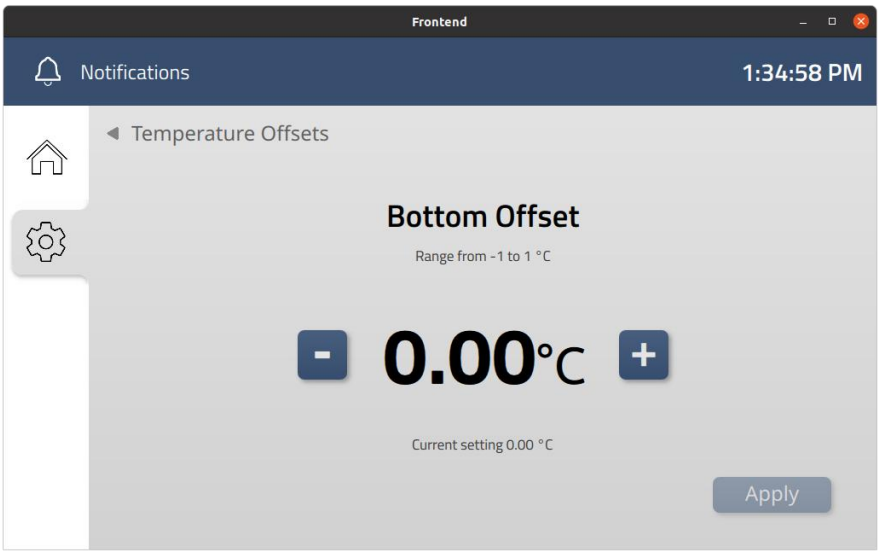


Figure 14.10 Bottom temperature offset

14.3.5 VOC/HEPA filter runtime counter

The VOC/HEPA filter in the MIRI® M multiroom IVF incubator must be replaced every 3 months. The system monitors the running hours since the last replacement and when the change date is a configured number of days away, the system will display a visual reminder on the MIRI® M docking station display to notify of the upcoming filter replacement.

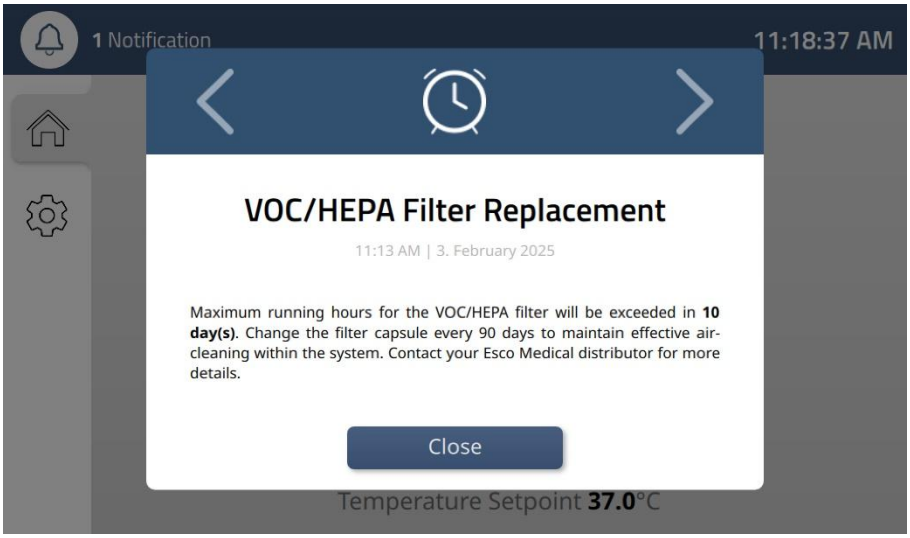


Figure 14.21 The VOC/HEPA filter reminder

After replacing the VOC/HEPA filter, the running hours counter must be reset on the MIRI® M docking station display. This function is located at the top of the maintenance menu and consists of simply tapping the reset button and confirming on the 2-step confirmation pop-up.

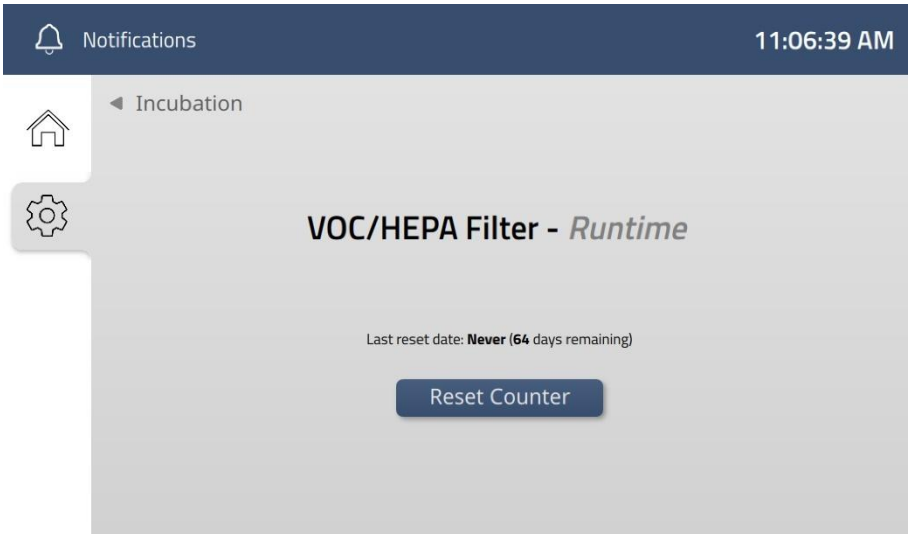


Figure 14.22 The VOC/HEPA filter runtime reset button

Please refer to the "12 VOC/HEPA Filter" section of the User Manual for instructions on how to remove and install VOC/HEPA filters.

14.3.6 Activating/Deactivating the UV Light

To enable or disable the UV light in the system, follow these instructions:

1. In the Incubation Menu tap *UV Light* to access the setting.
2. Make the desired change by tapping the *ON/OFF* buttons.
3. Tap *Apply* when finished. The display will revert back to the Incubation Settings Menu, and you must manually navigate back to the main page.

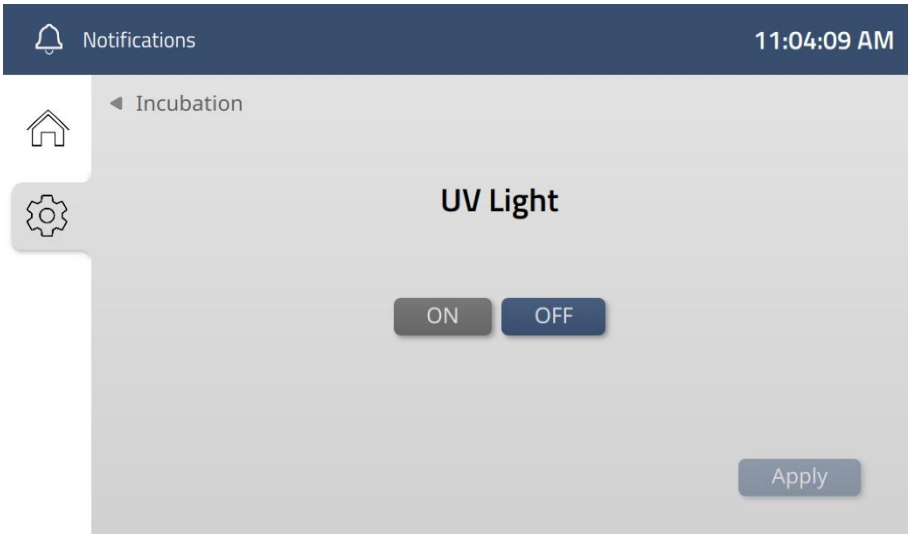


Figure 14.11 UV light regulation in the system

The UV light's default status is "OFF." After being turned on, it will automatically switch off again when the unit is turned off.

For gas disinfection insurance, it is recommended that the UV light be "ON" when using the device.

14.3.7 Changing gas system mode

The system offers two ways of running the gas system, either with CO_2 and O_2 regulation or only with CO_2 regulation. To switch between the two modes, follow these instructions:

1. In the Incubation Menu tap *Gas System Mode*.
2. Tap the desired gas system mode.
3. Tap *Apply* when finished. The display will revert back to the Incubation Settings Menu, and you must manually navigate back to the main page.

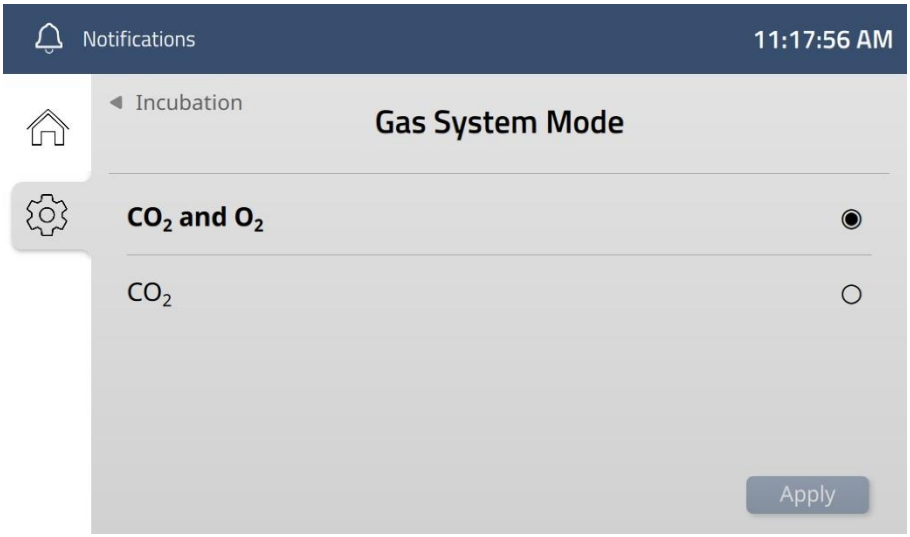


Figure 14.12 Gas system mode settings

When returning to the main page, the entire right column displaying the O_2/N_2 values is greyed out, with an icon overlay indicating that O_2 regulation is turned off. All the values are shown as 0. It is possible to re-enter the gas system mode settings at any time to reactivate O_2 regulation.

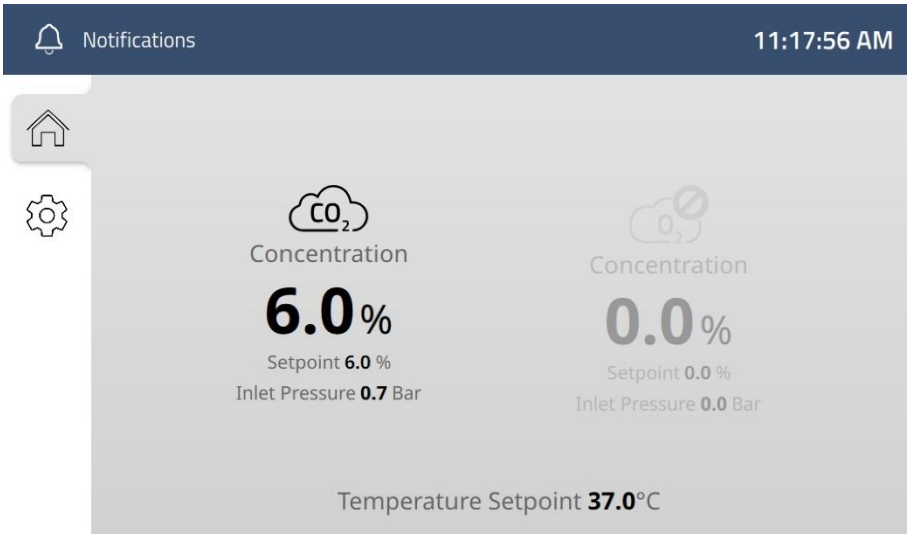


Figure 14.13 Main page with O_2 regulation turned off

The default setting is for the system to run with CO_2 and O_2 regulation.

When operating in CO_2-Only Mode, the system's CO_2 recovery time will increase to 4 minutes.* Please consider this when planning operations that require precise CO_2 levels.

14.4 System settings

The system settings menu offers settings directly related to the system itself, non-related to incubation and maintenance.

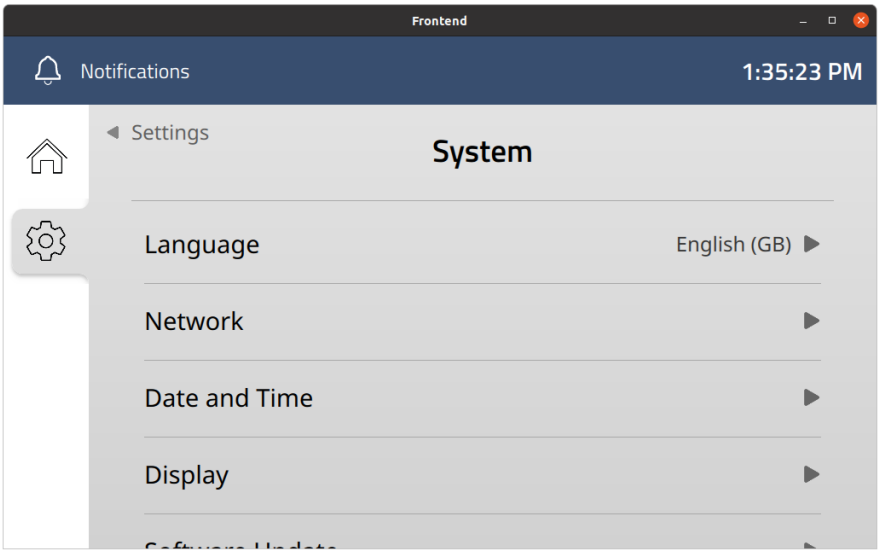


Figure 14.14 System settings menu

* Based on internal testing. Performance may vary depending on various factors and environmental conditions.

From here, it is possible to set up network settings, adjust display settings, and update the software for both the docking station and the chambers.

14.4.1 Language settings

The “Language” submenu allows the user to choose between various display languages supported in the MIRI® M.

Only the Danish language option is available in the 1.2.0 software version release.

After saving the new language option the menu will appear in the language of choice.

Hebrew language support is available only for the chamber display, allowing patient information to be displayed in Hebrew.

14.4.2 Network settings

In the network settings, the user can connect the MIRI® M multiroom IVF incubator to an external server to enable treatment management from a PC on the same network.

1. In the System Settings Menu tap *Network*, followed by *External Server.*
2. Input the IP address for the network at your location by tapping directly on the input box or tap ⇕ on the right side of the box to let the system search for a server.
3. Tap *Apply* when finished. The display will revert back to the System Settings Menu, and you must manually navigate back to the main page.

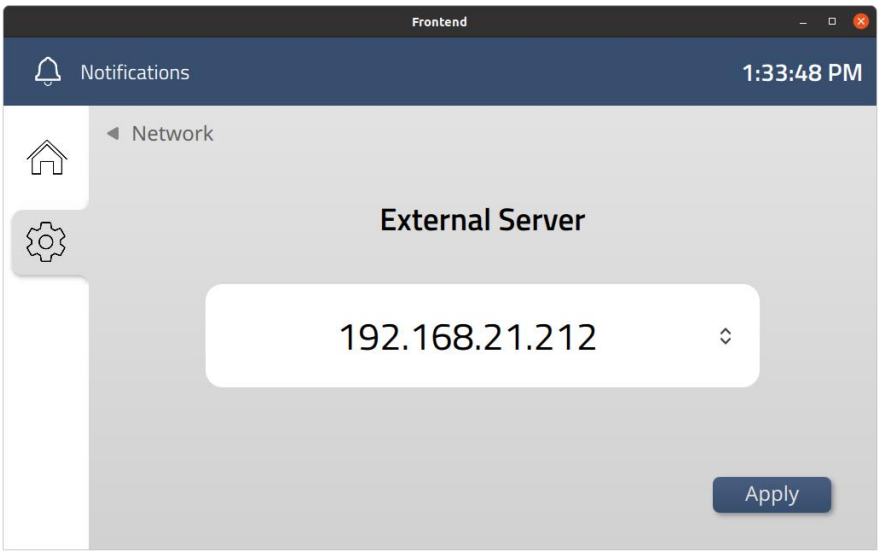


Figure 14.15 IP address input

When connecting the MIRI® M multiroom IVF incubator to the network, the user must ensure the network’s safety. The software controls the incubation parameters of the MIRI®

M multiroom IVF incubator; therefore, in case of software breakdown or cybersecurity breach, the embryos may be at risk.

⚠ **For Ethernet connectivity, use twisted pair Ethernet cables of Category 6 (Cat 6) or higher, compliant with ISO/IEC 11801-1. Shielded cables are recommended for environments with high electromagnetic interference (EMI).**

14.4.3 Date and time

The Date and Time settings page offers options for configuring the system's date, time, and timezone. The following options are available:

- **Automatic Date and Time**: Enable this option to allow the system to set the date and time automatically based on network-provided information.
- **Date (Manual Input)** – Choose this option to manually enter the current date, if automatic date and time is not available.
- **Time (Manual Input)** – Choose this option to manually adjust the current time, if automatic date and time is not available.
- **Timezone** – Select the appropriate timezone for your location to ensure accurate time display.
- **NTP Server** – Configure a Network Time Protocol (NTP) server to synchronize the system's date and time with an external source.



Figure 14.16 Date and Time settings

14.4.4 Display settings

The display settings offer two types of adjustments: changing the display brightness and calibrating the touch functionality in the display.

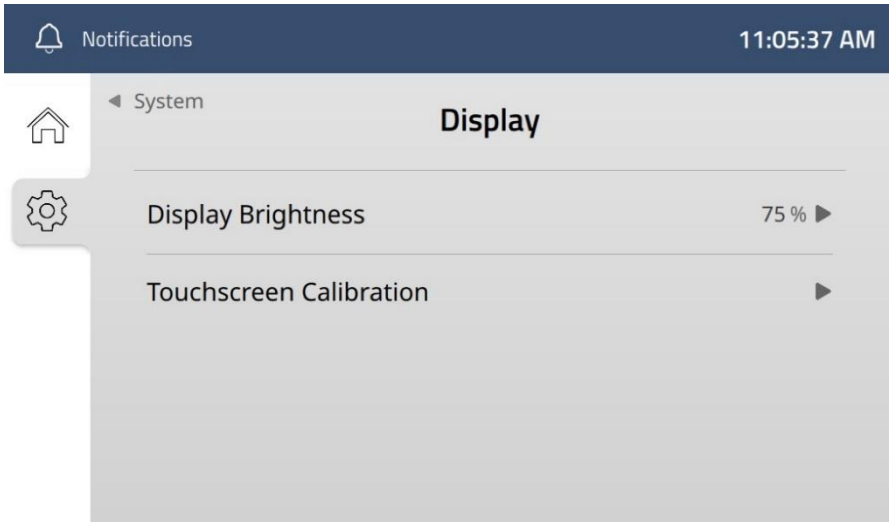


Figure 14.17 Display settings

To change the display brightness, tap the setting and use the slider to set your preferred brightness, as depicted below.

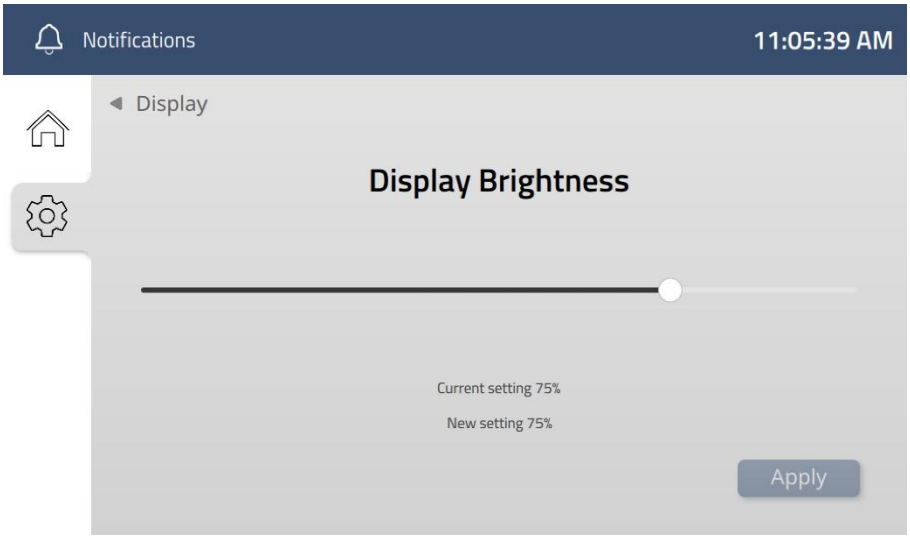


Figure 14.18 Display Brightness

If the touch functionality in the display requires recalibration, the tool for this is also located in the display sub-menu. By tapping *Touchscreen Calibration,* the tool takes over the display as depicted below:

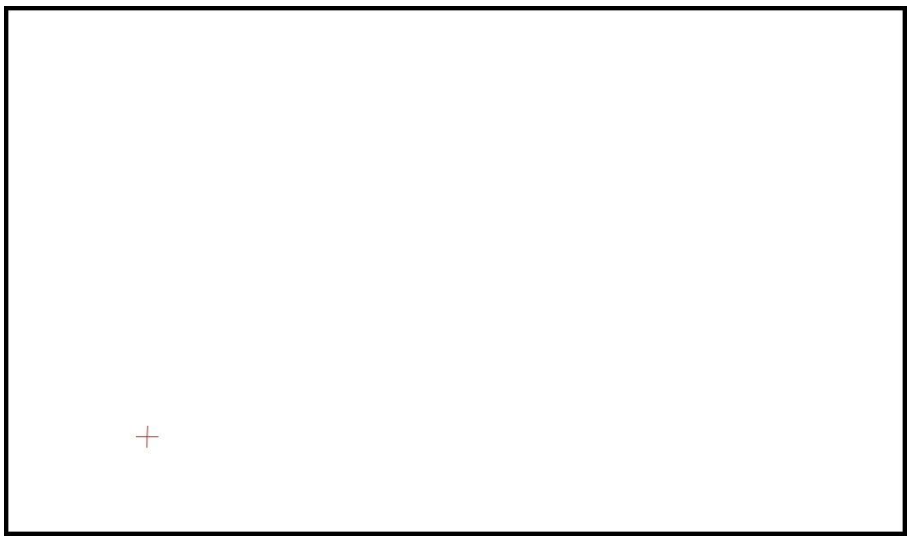


Figure 14.19 Touchscreen calibration tool

The entire display turns white with a red cross displayed in one corner. Follow the calibration process by tapping the center of the red cross – if done correctly, a green tick will appear on the display for 4 seconds. The process repeats for each corner, with the red cross moving accordingly. Upon completion, the system will automatically return to the display sub-menu.

Once started, the calibration process cannot be aborted and must be completed to return to the main display.

14.4.5 Software updates

If Esco Medical Technologies, UAB has released a new version of the system software, this should be installed on the MIRI® M multiroom IVF Incubator during the yearly scheduled service.

Please refer to the service manual for instructions on how to update the software in the system.

14.5 Maintenance settings

To access the maintenance settings, tap it on the main settings page and enter the login credentials using the virtual keyboard. This menu provides options for performing gas sensor calibration, gas offset calibration, and temperature calibration.

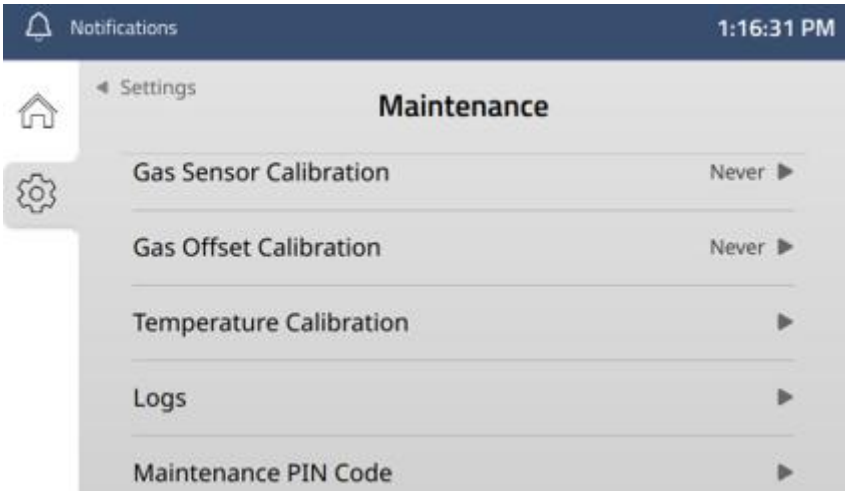


Figure 14.20 Maintenance setting page

⚠ **Calibration values should only be changed by a trained user or technician, according to specific measurements done with the calibrated device.**

14.5.1 Gas sensor calibration

The calibration of the CO_2 and O_2 sensors requires the involvement of a service technician, typically during a planned service, as they have the required expertise to perform the calibration accurately.

1. In the settings menu on the docking station display tap *maintenance settings*.
2. From here navigate to *Gas sensor calibration* and tap it.
3. This unveils the gas sensor calibration page with a high and low reference value for both CO_2 and O_2.

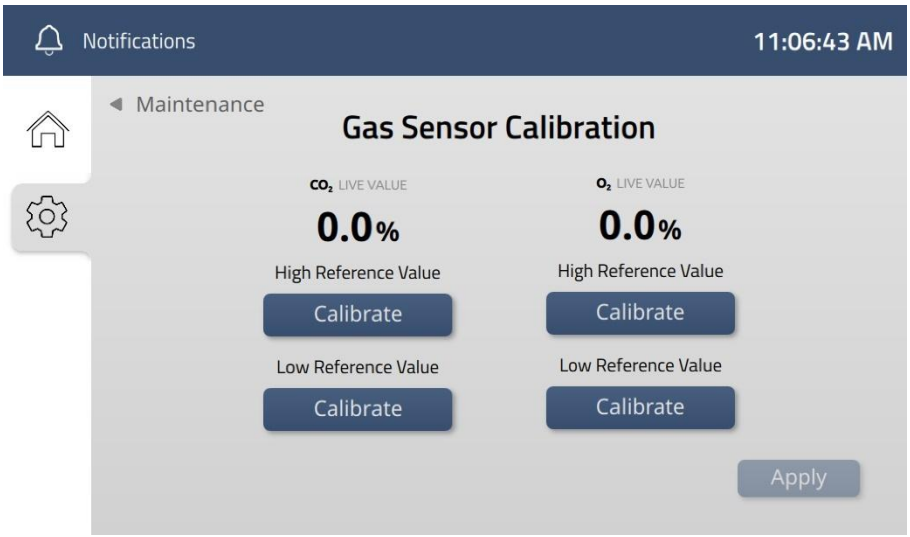


Figure 14.23 Gas sensor calibration page

Accessing the gas sensor calibration page disables the normal gas regulation mode and any irrelevant gas alarms while increasing the gas status frequency to at least one measurement per second.

4. Attach one of the known reference concentration gasses to the gas sample port and wait for a stable measurement on the device.
5. If the values don't match the reference values, tap *Calibrate* to access the tool for inputting the correct values:
6. Tap the (-) or (+) keys to calibrate them to the correct values.

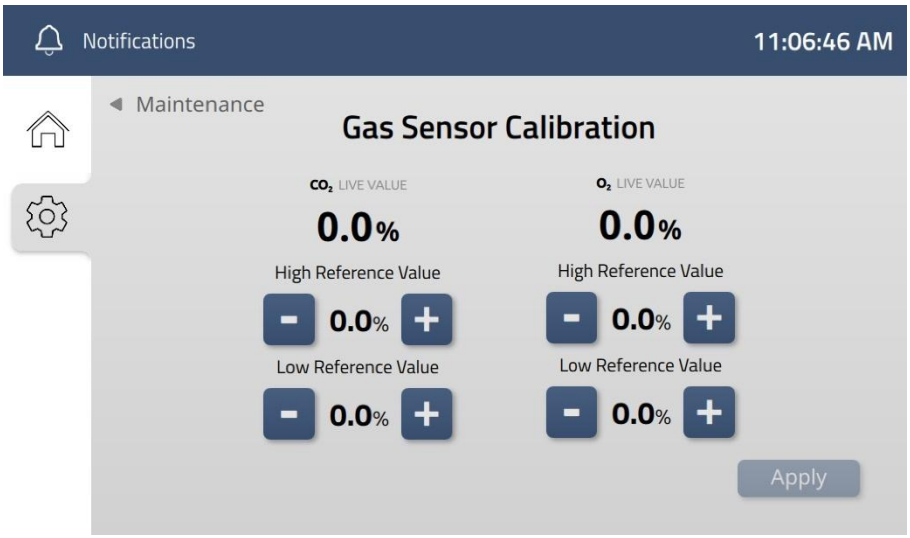


Figure 14.24 High reference value for CO_2 being calibrated

The reference gases contain known concentrations of CO_2 and O_2, with the high reference value for CO_2 being calibrated against the low reference value for O_2, and vice versa.

7. Remove the reference gas from the gas sample port, connect the other reference gas and follow the same procedure.
8. Once completed, remove the reference gas, and tap *Back* on the display.
9. This prompts a 2-step confirmation for updating the calibration timestamp. The same message will appear if the page is left prematurely.

Each tap of the (-) or (+) keys makes the system save the changes, eliminating the need for a dedicated "Save calibration" or "Apply" button.

If left inactive, the gas sensor calibration page will automatically return to the main page, requiring a new log in to access the maintenance settings again.

14.5.2 Gas offset calibration

The calibration of the CO_2 and O_2 offsets requires the involvement of a service technician, typically during a planned service, as they have the required expertise to perform the calibration accurately.

1. In the settings menu on the docking station display tap *maintenance settings*.
2. From here navigate to *Gas offset calibration* and tap it.
3. This unveils the gas offset calibration page for both CO_2 and O_2.

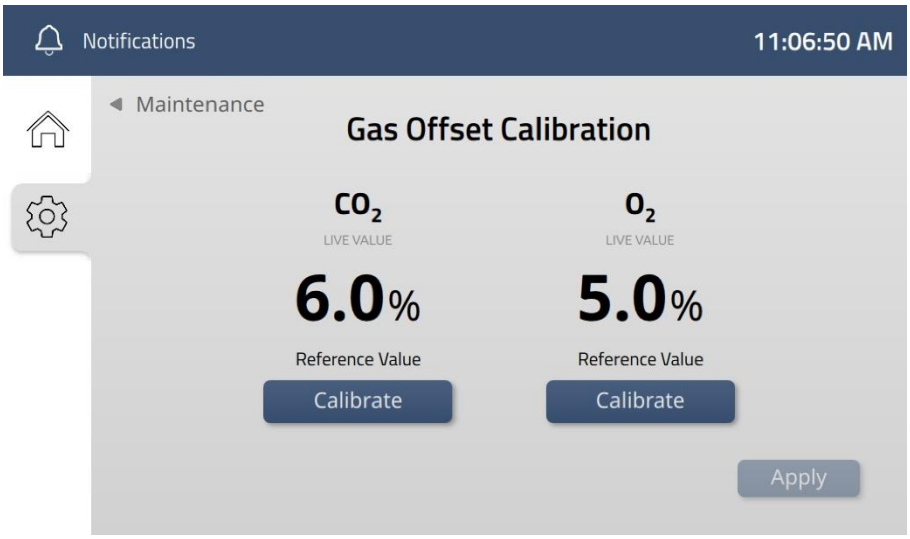


Figure 14.25 Gas offset calibration page

4. Place an external gas sensor in a docked chamber with the lid closed and wait for a stable measurement on the device.
5. If the values don't match the reference values, tap *Calibrate* under the value requiring adjustment to access the tool for inputting the correct values:

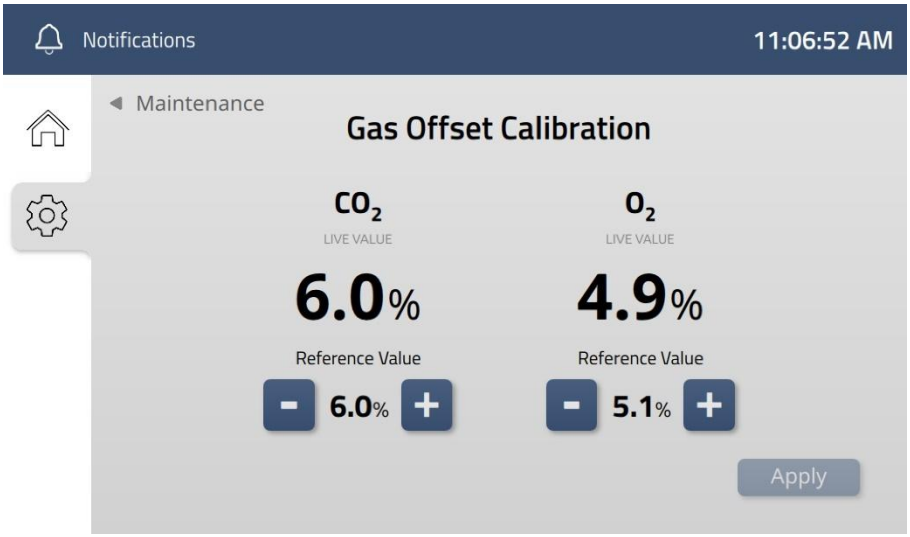


Figure 14.26 Gas offset being calibrated

6. Tap the (-) or (+) keys to calibrate the gas concentration to the correct value.
7. Once completed, tap *Back* on the display.
8. This prompts a 2-step confirmation for updating the calibration timestamp. The same message will appear if the page is left prematurely.

If left inactive, the gas offset calibration page will automatically return to the main page, requiring a new log in to access the maintenance settings again.

14.5.3 Temperature calibration

Each chamber features three temperature zones – two on the bottom and one in the lid. Temperature is regulated by heater circuits integrated into both the bottom and the lid. Calibrating the temperature sensors is a specialized procedure requiring a trained user and is typically performed during planned service.

Calibration values should only be changed by a trained user or technician, according to specific measurements done with the calibrated device.

To calibrate the internal temperature sensors, navigate to *Temperature Calibration* in the maintenance menu. Tapping this will unveils a grid view of the connected Chambers, including dates for last calibrations and greyed out boxes for positions without connected Chambers.

Calibrating the temperature sensors is done for one chamber at a time, and it might, therefore, be best practice to do it during planned services.

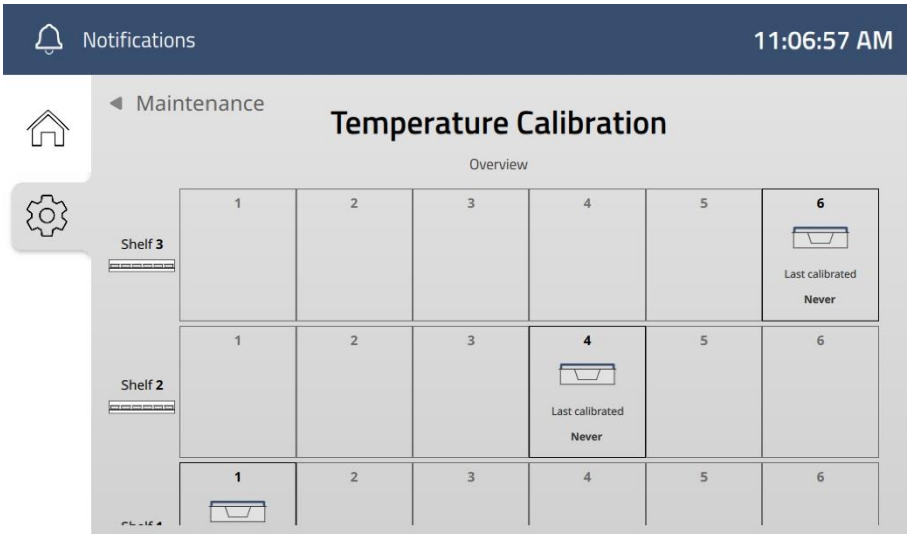


Figure 14.27 Grid view of the connected Chambers

To start the actual calibration, follow these steps:

1. Tap the chamber intended for calibration in the grid view. This will open the calibration view for that chamber:

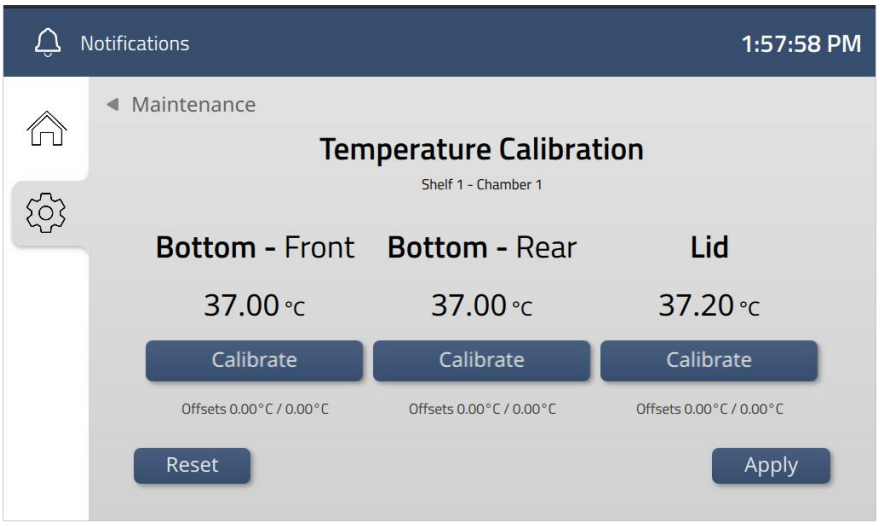


Figure 14.28 Temperature calibration page

Each chamber contains three internal temperature sensors: one in the lid and two in the bottom, each requiring individual calibration when needed.

2. Apply a high-quality thermometer to one of the zones, close the lid and wait for a stable measurement on the device.
3. If the measurement doesn't show the same number as on the docking station display, tap *Calibrate* for the zone in question.
4. Tap the (-) or (+) keys to calibrate it to the correct value.
5. Open the lid and perform the same procedure for the other temperature zones.
6. Once completed, tap *save calibration* to apply the changes to the chamber.
7. Apply the same procedure for other connected Chambers or navigate back to the main page manually.

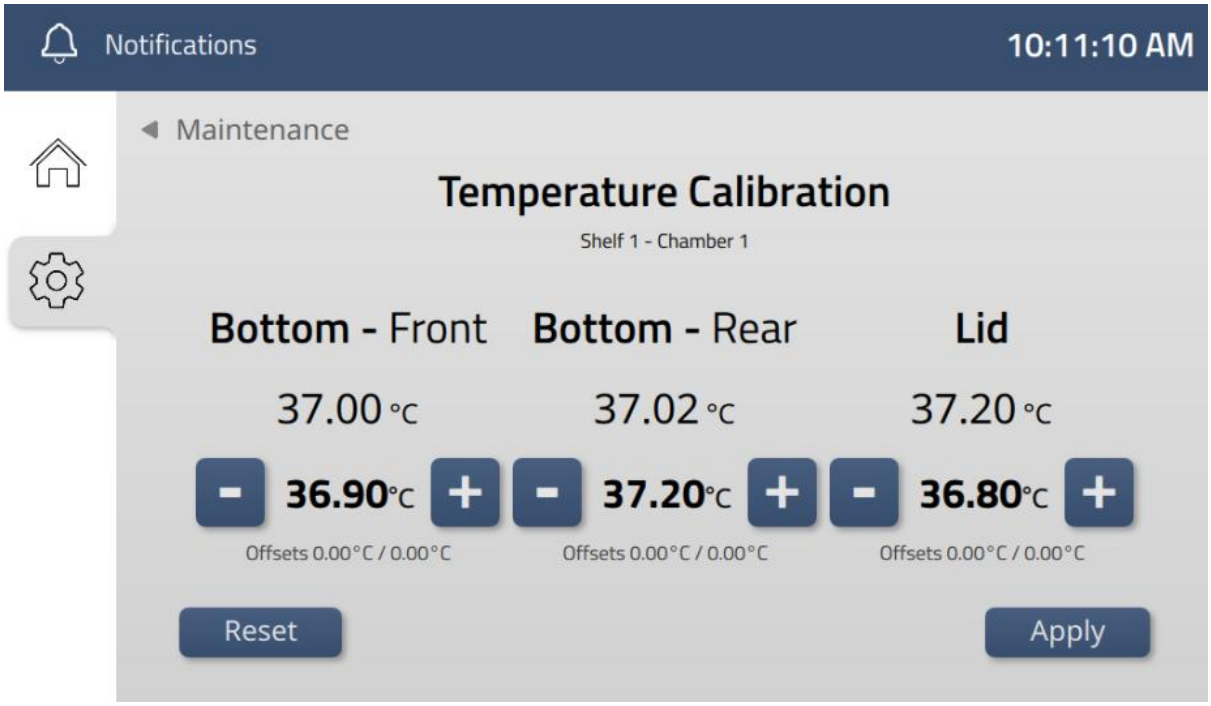


Figure 14.29 Temperature calibration page with calibrated values

If left inactive, the temperature calibration page will automatically return to the main page, requiring a new log in to access the maintenance settings again.

It is possible to abandon the process at any point during the procedure by either tapping *back* or the home button. This will however involve acknowledging on a 2-step confirmation in the display.

After temperature adjustment, give it at least 30 minutes for the temperature to stabilize, use the thermometer to verify the correct temperature on each area.

Be careful when changing the calibration settings – make sure that only the altered value corresponds to where the measurement is done. Give the system some time to adjust.

The lid temperature of each chamber will affect the bottom temperature. The ΔT should always be 0.2 °C. Thus, if the bottom temperature is 37.0 °C, the lid should be 37.2 °C.

14.6 Chamber mobility

The mobility of the MIRI® M multiroom IVF incubators allows any chambers docked in a docking station to be undocked and moved to another docking station and docked there. Both actions are confirmed by visual feedback on the chamber display.

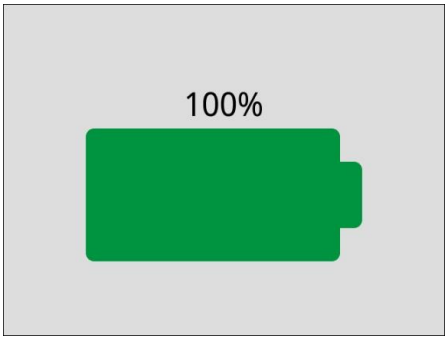


Figure 14.30 Docking and undocking confirmation

14.6.1 Powering a chamber on and off

MIRI® M Chambers can be powered on and off in only two ways. To power the chamber on:

1. Locate a desired turned-off chamber.
2. Dock it in the desired position in the MIRI® M Docking station.

After docking, the MIRI® M Chamber automatically powers on and displays a battery percentage (see Fig. 14.30).

To power off the chamber:

1. Locate a desired chamber that is on.
2. Undock the chamber from the MIRI® M Docking station.
3. Hold the alarm button down until the shutdown countdown (see Fig. 14.31) elapses.

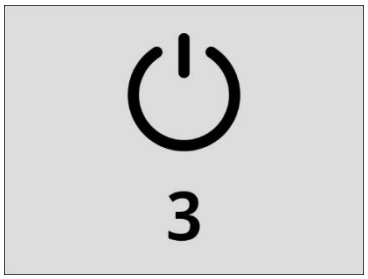


Figure 14.31 Shutdown sequence

After the shutdown countdown elapses, the MIRI® M Chamber is turned off.

⚠ **The chamber should be shut down only when it is empty.**

14.6.2 Undocking a chamber

The process starts with locating the chamber of interest in the docking station. The chambers are distinguishable by their displays, showing the name and ID for the patients.

⚠ **The patient's name and ID displayed on the MIRI® M Chamber screen cannot be considered a replacement for the clinic's witnessing system or SOPs (standard operating procedures) for patient identification and embryo mix-up prevention.**

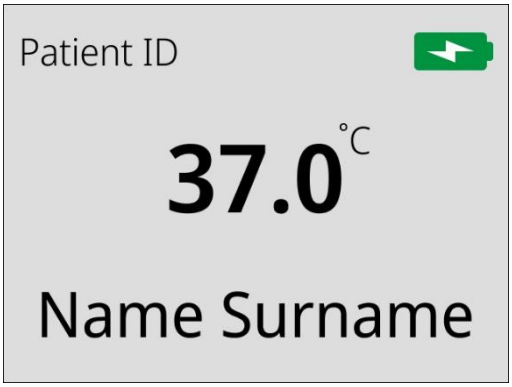


Figure 14.32 A docked chamber assigned to a patient

1. Grab the chamber in question comfortably either at the chamber lid or on each side of the chamber with one hand (see Figure 14.33).
2. Pull the chamber gently towards yourself, ensuring the contents remain, as it is released from its docking position.

☞ **Gas inlets and outlets in both the chamber and in the docking position will automatically close once the chamber is released.**

3. A successful undocking is confirmed by visual feedback on the chamber display and the back panel LEDs ceasing to light up.
4. Once the chamber is free of the metal sheets keeping it in place, readjust your grip if necessary and lift the chamber carefully out of the docking position.
5. The action is logged in the system as an undocking event, visible in the notification log on the docking station display.



Figure 14.33 The recommended docking and undocking approach

Various undocking procedures may be used for chambers located on the lower shelves (shelves 1 and 2). The manufacturer recommends that you first pull the chamber by the lid. After that, transfer the grip in a similar manner, as shown in Figure 14.33. This method ensures the stability of both the chamber and its contents.

MIRI® M Chamber is designed to maintain temperature setpoints using the internal energy of the battery for a maximum duration of 30 minutes.

MIRI® M Chamber is designed to maintain gas concentration setpoints for a maximum duration of 5 minutes. However, when the lid on the disconnected MIRI® M Chamber is opened, all gasses inside the chamber get dispersed. In order for the gas to recover to the required setpoints, the MIRI® M Chamber should be reconnected to the MIRI® M Docking Station.

14.6.3 Carrying a chamber

While undocked, the chamber will continue to display patient information, although with a slight design variation to differentiate its appearance from when it is docked.

The patient's name and ID displayed on the MIRI® M Chamber screen cannot be considered a replacement for the clinic's witnessing system or SOPs (standard operating procedures) for patient identification and embryo mix-up prevention.

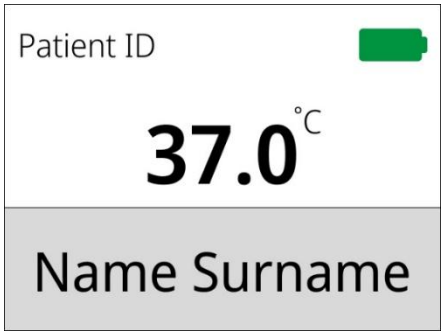


Figure 14.34 An undocked chamber assigned to a patient

The manufacturer recommends carrying the chamber with both hands for better stability. One hand should support the bottom of the chamber, while the other should grip the top using the specially designed ridges. This method ensures the chamber remains stable and protects its contents.



Figure 14.35 Correct chamber carrying procedure

The chamber is balanced around the specially designed ridges, which ensures that it remains level throughout the carrying procedure.



Figure 14.36 Specially designed ridges for chamber carrying

The chamber should be handled with the same care and in the same manner as the dish during normal use.

MIRI® M Chamber is designed to maintain temperature setpoints using the internal energy of the battery for a maximum duration of 30 minutes.

MIRI® M Chamber is designed to maintain gas concentration setpoints for a maximum duration of 5 minutes. However, when the lid on the disconnected MIRI® M Chamber is opened, all gasses inside the chamber get dispersed. In order for the gas to recover to the required setpoints, the MIRI® M Chamber should be reconnected to the MIRI® M Docking Station.

14.6.4 Docking a chamber

To dock a chamber:

1. Bring the chamber to a docking station with available space for docking.
2. Put down the chamber at the front of the docking position and gently push it towards the back panel.
3. Make sure that the chamber is aligned correctly with the metal guides, providing docking assistance (the chamber cannot be moved up or to the sides).
4. A soft close in the back panel will ensure that the content of the chamber is not shaken upon contact with the magnet.
5. Gas valves will connect automatically, ensuring gas flow through the chamber.
6. Successful docking is confirmed by brief visual feedback on the display (see Figure 14.30) and the back panel LEDs lighting up depending on the state of the chamber:
    a. If the chamber is idle, the LEDs will light up in white.
    b. If the chamber is assigned to a patient, it will light up in blue.
    c. If the chamber is docked while being in an alarm state, and the docking action doesn't resolve the issue, it will instead light up in red.
7. Upon completion, the action is logged in the system as a docking event, visible in the notification log on the PC with installed external software.

The user may dock the chamber in any available slot in any docking location within the clinic – they're not limited to specific destinations.

The metal guides in the docking positions prevent the chamber from being moved upwards or sideways, ensuring correct chamber docking and undocking.

If the docking process is unsuccessful, a backlight illuminates with a blinking yellow light to alert the User that the docking action is incomplete. Additionally, the chamber display remains unchanged (see Figure 14.34). To resolve this issue, please undock the chamber and then re-dock it again.

14.6.5 Docking/undocking module

The docking/undocking module is responsible for the secure connection between the docking station and the chamber. The chamber is manually pushed toward the docking station's wall, then magnetic field "grabs and drags" the chamber to the docked position. The soft close feature ensures a gentle docking between the docking station and the chamber, provides to the contents of the patient dish inside the chamber with protection against rapid magnetic field attraction.

Cleaning must be performed carefully, as too much pressure can cause the soft close pins to jam.

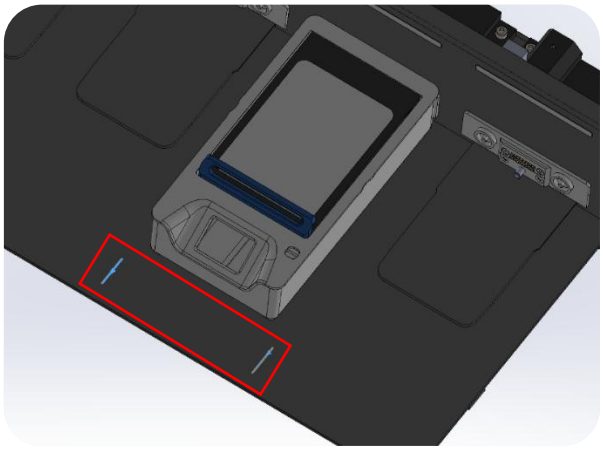


Figure 14.37 The engravings on the shelf to guide the correct alignment of the chamber with the docking interface

While the chamber is connected to the docking station, docking provides the chamber with electricity (charging of its battery) and gases. When docking the turned-off chamber to the docking station, it is automatically turned on.

Do not spill any liquids near the docking/undocking module as it can cause the device to short circuit.

Avoid using metal objects around the module due to the presence of a magnetic field. This will prevent small hard particles from interfering with the chamber connection.

If the docking process is unsuccessful, a backlight illuminates with a blinking yellow light to alert the User that the docking action is incomplete. Additionally, the chamber display remains unchanged (see Figure 14.34). To resolve this issue, please undock the chamber and then re-dock it again.

14.6.6 Resetting a patient

It is possible to reset assigned patient information right on the MIRI® M Chamber. This automatically happens in a sequence when the chamber is getting turned off as well (patient reset → chamber turn off). To reset the patient information:

1. Locate a desired MIRI® M Chamber.

Patient information can be reset on both the docked and undocked MIRI® M Chamber. The procedure remains the same.

2. Hold the alarm button down until the patient reset countdown elapses (see Fig. 14.38)

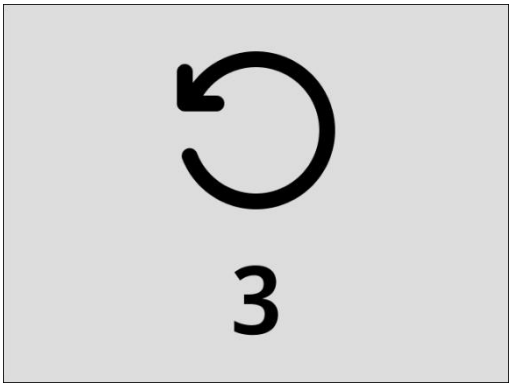


Figure 14.38 Patient reset countdown

3. After the patient reset countdown, the chamber will display default information, depending on whether the chamber is docked or not (see Fig. 14.39 and 14.40).

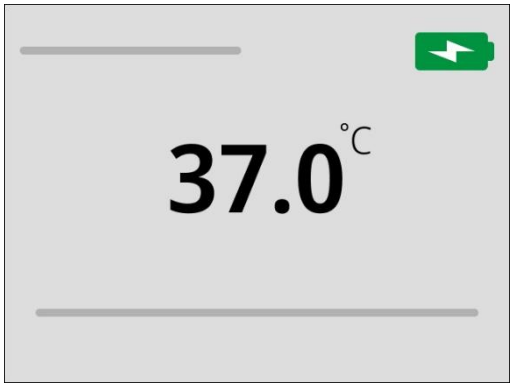


Figure 14.39 Default view (docked)

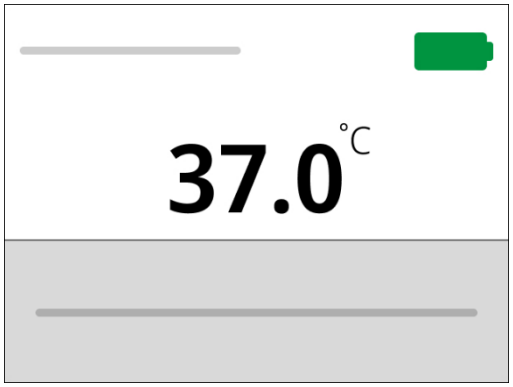


Figure 14.40 Default view (undocked)

⚠ **If the alarm button is held further, the chamber shutdown countdown will begin. The chamber should be shut down only when it is empty.**

14.7 Backlight panel functionality

MIRI® M multiroom IVF incubator uses separate LED backlights to indicate the status of the docked chamber. There are six colours, each signalling a different chamber state:

1. Grey (OFF) – chamber is undocked.
2. White – chamber is docked and steady.
3. Red – chamber is docked, an alarm condition is present.
4. Blue – chamber is docked and steady, patient is assigned.
5. Yellow (pulsating) – chamber is docked unsuccessfully.
6. Violet – chamber calibration is being performed.



Figure 14.41 Backlight panel functionality

15 Alarms & Warnings

When the conditions within the chambers or the docking station either dip below or surpass the preconfigured thresholds, the system will activate an alarm state. These alarms will be communicated through both visual indicators on the displays and audible alerts from a speaker.

The primary course of action should be to promptly resolve the issue causing the alarm, but it is also possible to temporarily silence the alarm by pressing the mute button on any available chambers or by tapping *MUTE* on the docking station display.

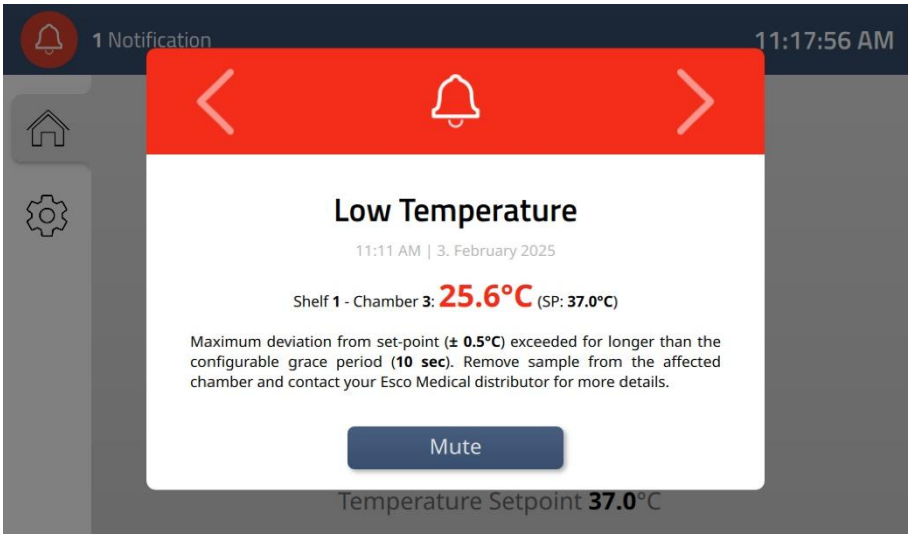


Figure 15.1 The alarm indication on the docking station display with a mute option

The audio pattern for MIRI® M Docking Station alarms is 10 beeps repeating every 2.5 seconds. The audio pattern for MIRI® M Chamber alarms is 10 beeps repeating every 5 seconds. The audio sound pressure level for the MIRI® M Chamber is 66.4 dB(A), and for the MIRI® M Docking Station, it is 74.6 dB(A).

⚠ **Make sure that the ambient sound pressure level does not exceed 67 dB(A) because the user will not hear the alarm in the MIRI® M Chamber!**

If the source of the alarm can be traced to a specific chamber in the docking station, that chamber will assist in drawing attention to itself. The backlight panel at its docking location will pulsate in red, and the chamber will display a red background colour.

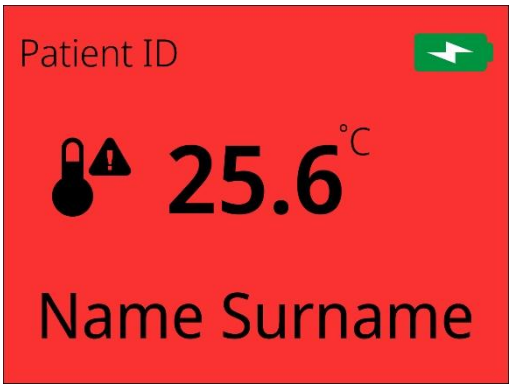


Figure 15.2 The alarm indication on the display of a docked chamber

The audio pattern for MIRI® M Docking Station alarms is 10 beeps repeating every 2.5 seconds. The audio pattern for MIRI® M Chamber alarms is 10 beeps repeating every 5 seconds. The audio sound pressure level for the MIRI® M Chamber is 66.4 dB(A), and for the MIRI® M Docking Station, it is 74.6 dB(A).

⚠ **Make sure that the ambient sound pressure level does not exceed 67 dB(A) because the user will not hear the alarm in the MIRI® M Chamber!**

⚠ **The docking station display serves as the primary indicator for alarms in the main system. Refer to that display for guidance on resolving the alarm state.**

If the alarm is triggered within an undocked chamber, the device will operate autonomously without impacting or being impacted by any nearby docking stations or other chambers, as each chamber is equipped with its own display, sounder, and mute button. In this scenario, the alarm will instead be displayed as depicted below for a temperature alarm.

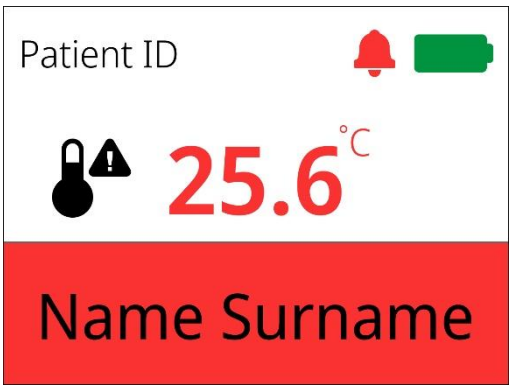


Figure 15.3 Example of the alarm indication on an undocked chamber

⚠ **Alarms always follow the device where they're active. If a chamber is undocked, any present alarms will therefore be limited to that chamber.**

Similar to when an alarm is triggered in the main system, the chamber allows you to mute an alarm for a 5-minute period by pressing the mute button. However, a simpler solution could be to simply dock the chamber into a docking station. Should the cause of the alarm not be resolved by this, the docking station will instead take over and display the alarm.



Figure 15.4 Alarm mute button

All alarms will be collected in the notification log with other system events. To access this log, tap the notifications icon 

in the top-left corner of the docking station display. This will reveal a list of current events, listed in a prioritized order of severity. If no recent events have occurred, the list will simply be empty.

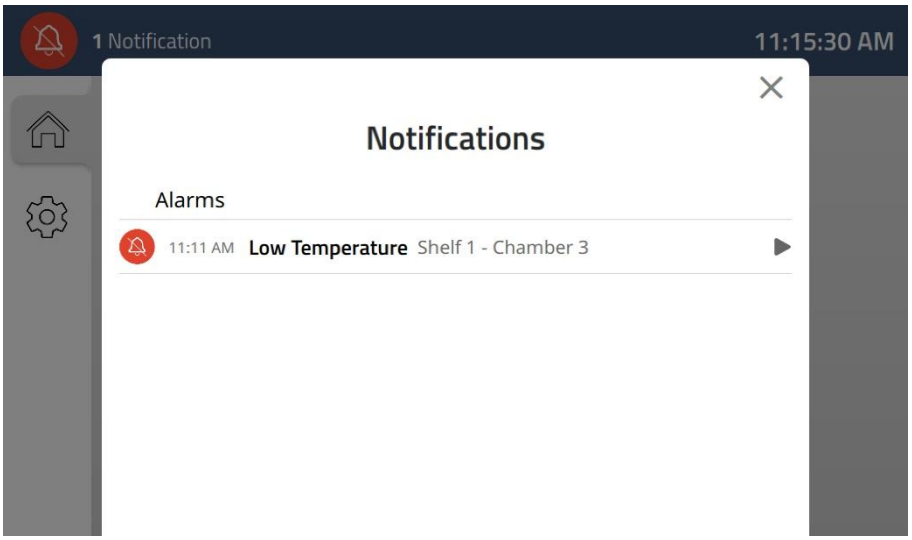


Figure 15.5 The notification log with a muted alarm

⚠ **Alarms and events happening in the chamber while undocked will be added to a system's notification log when the chamber is docked in it.**

15.1 Temperature level alarms

Each chamber is equipped with three temperature zones — two on the bottom and one on the lid. However, the temperature is displayed to the user as a single value. If the temperature of any of the temperature zones deviates by more than 0.5°C for more than 30 seconds, an alarm will trigger in that chamber.

Should the alarm be triggered while the chamber is connected to a docking station, the docking station display will be the primary communicator (see Figures 15.6 and 15.7), with the chamber display aiding in bringing attention to itself (see Figures 15.8 and 15.9).

When the temperature is too high/too low in a docked chamber, a pop-up alarm notification is displayed on the docking station's display panel. It includes:

- A headline, outlining the overall issue, including a timestamp for when the issue occurred.
- A live value compared to the setpoint value, and which chamber is involved as it is a chamber-specific alarm.
- Additional help text detailing the reason for the alarm and recommended actions to resolve the issue.

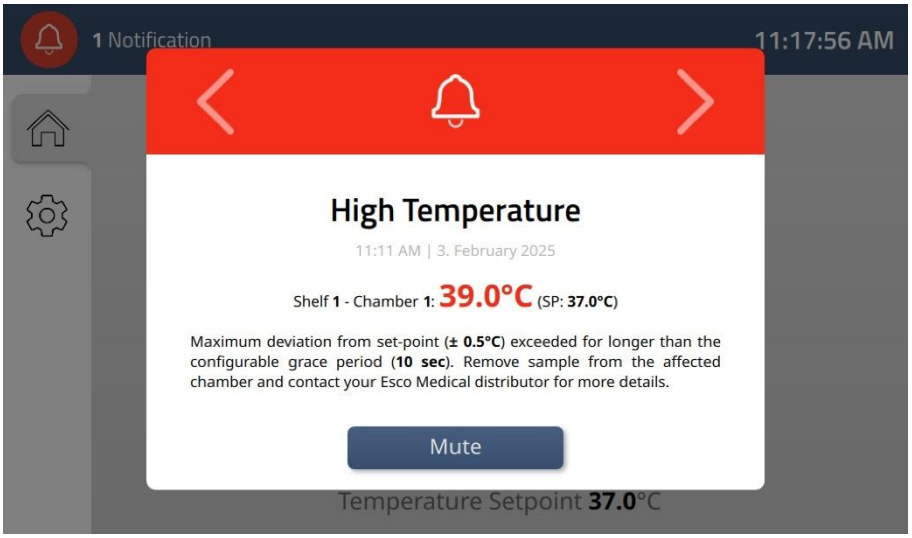


Figure 15.6 High-temperature alarm indication on the docking station's display panel

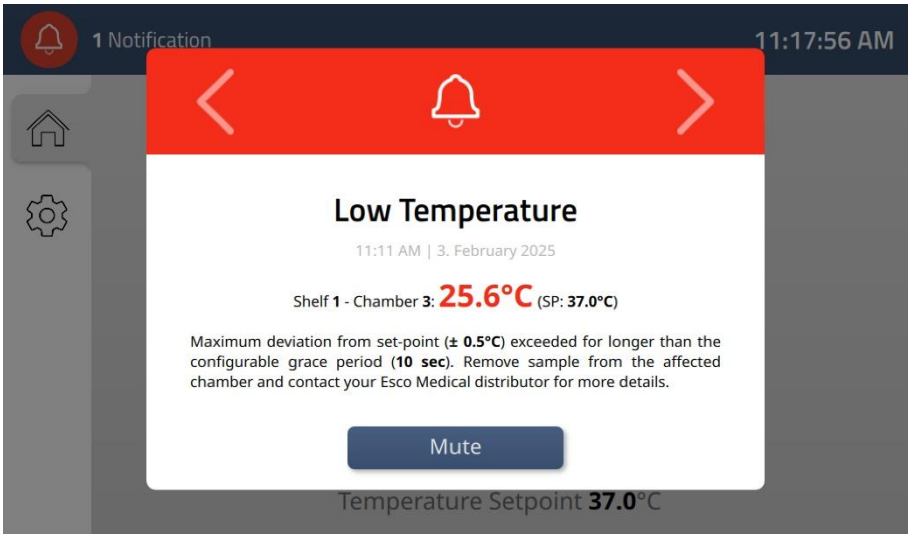


Figure 15.7 Low-temperature alarm indication on the docking station's display panel

If the chamber is undocked, the chamber display will provide the only visual feedback of this alarm state, but if the chamber is docked, it will also serve as a secondary visual communicator:

1. **Undocked** – the alarm icon is present next to the temperature value, where the bottom bar and the temperature value itself are highlighted in red (Figure 15.8).
2. **Docked** – the entire display background is coloured in red (the docking station's display panel serves as the primary communicator in this scenario) (Figure 15.9).

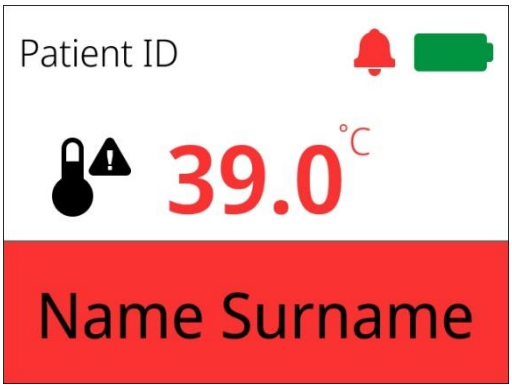


Figure 15.8 High-temperature alarm indication on the undocked chamber's display

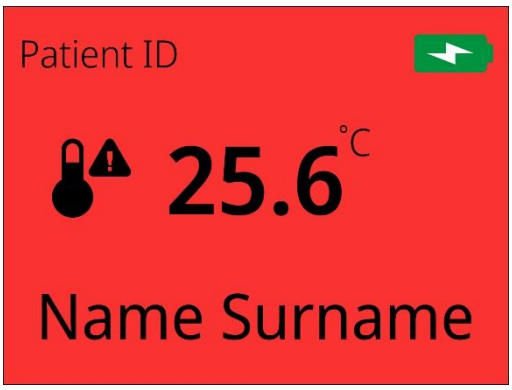


Figure 15.9 Low-temperature alarm indication on the docked chamber's display

Both of these designs have an alarm bell icon next to the chamber's battery level indicator.

Patient name, patient ID, temperature value and current battery level are displayed continuously.

Changing the setpoint will start an acclimatization phase. During this, temperature alarms are temporarily disabled until the setpoint has been reached once or 30 minutes have passed.

A temperature alarm in an undocked chamber may be resolved by docking the chamber in a docking station, but it is also possible to mute the alarm. Pressing the mute button temporarily disables the alarm state, including the audible alarm, for a 5-minute period. The

temperature indication will remain red, and if the cause of the alarm isn't resolved during this period, the alarm will resume.

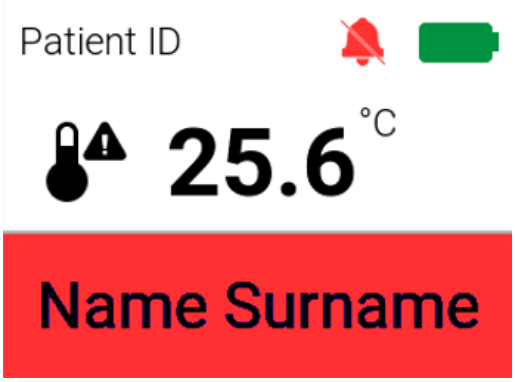


Figure 15.10 A muted temperature alarm in an undocked chamber

The maximum deviation from the setpoint of ± 0.5 °C is set by default, but it can be customized in the settings accessible on the docking station display.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond to a temperature alarm in one or multiple Chambers.

15.2 Gas concentration alarms

15.2.1 CO_2 concentration alarms

The CO_2 concentration alarm is triggered if the concentration of CO_2 gas deviates more than ±0.5% from the setpoint for a minimum of 30 seconds.

Changing the current CO_2 concentration setpoint will start an acclimatization phase. During this, all gas alarms are temporarily disabled until the setpoint has been reached once or 60 minutes have passed.

When the CO_2 concentration is too high/too low in the system, a pop-up alarm notification is displayed on the docking station's display panel (see Figures 15.11 and 15.12). It persists until the alarm is muted, the issue is resolved or the alarm resolves itself.

The pop-up alarm notification includes:

- A headline outlining the overall issue, including a timestamp for when the issue occurred.
- A live value compared to the setpoint value.
- Additional help text detailing the reason for the alarm and recommended actions to resolve the issue.

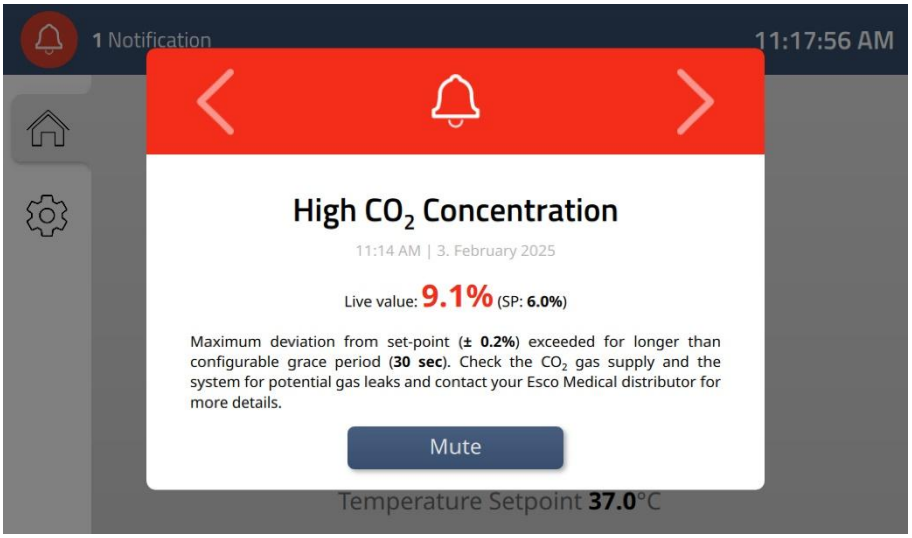


Figure 15.11 High CO_2 concentration alarm indication on the docking station's display panel

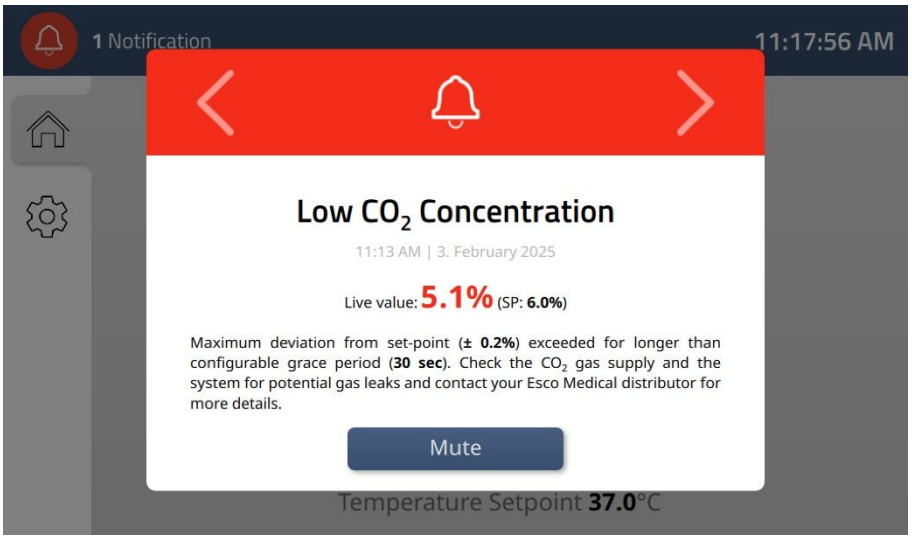


Figure 15.12 Low CO_2 concentration alarm indication on the docking station's display panel

Tapping the mute button temporarily disables the alarm state, including the audible alarm, for a 5-minute period. If the cause of the alarm isn't resolved during this period, the alarm will resume.

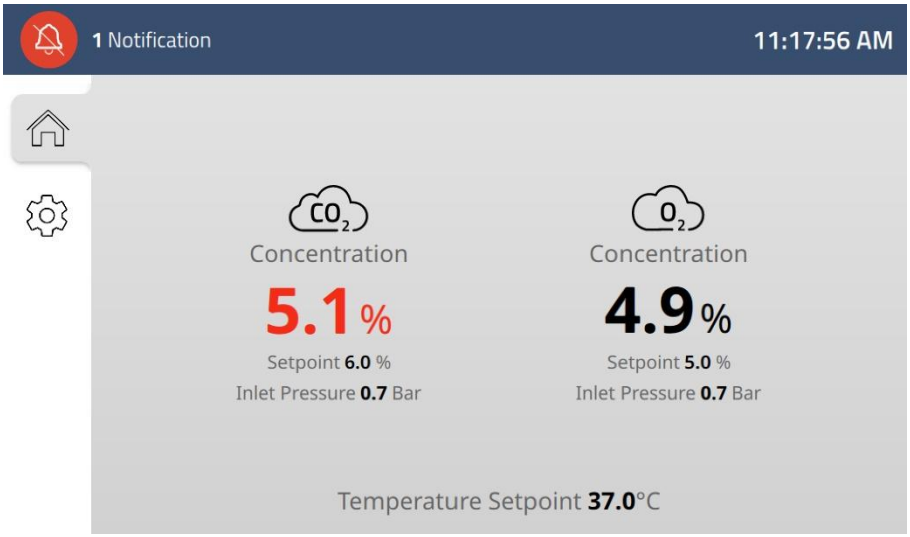


Figure 15.13 A muted CO_2 concentration alarm on the main display

The maximum deviation from the setpoint of ± 0.2% as well as the minimum time of 30 seconds before the alarm is triggered are set by default. They can be customized in the settings accessible on the docking station display.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond to a CO_2 concentration alarm in the system.

15.2.2 O_2 concentration alarms

The O_2 concentration alarm is triggered if the concentration of O_2 gas deviates more than ±0.5% from the setpoint for a minimum of 30 seconds.

Changing the current O_2 concentration setpoint will start an acclimatization phase. During this, all gas alarms are temporarily disabled until the setpoint has been reached once or 60 minutes have passed.

When the O_2 concentration is too high/too low in the system, a pop-up alarm notification is displayed on the docking station's display panel (see Figures 15.14 and 15.15). It persists until the alarm is muted, the issue is resolved, or the alarm resolves itself.

The pop-up alarm notification includes:

- A headline outlining the overall issue, including a timestamp for when the issue occurred.
- A live value compared to the setpoint value.
- Additional help text detailing the reason for the alarm and recommended actions to resolve the issue.

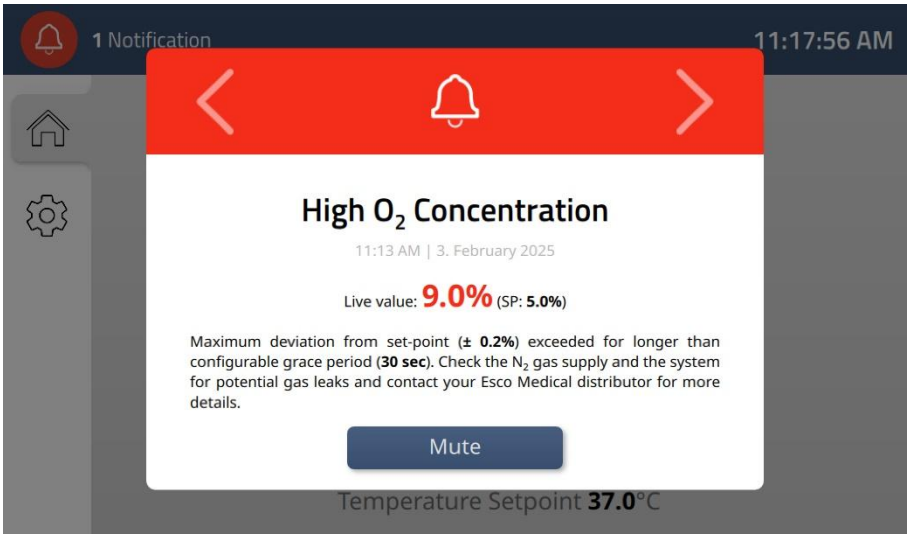


Figure 15.14 High O_2 concentration alarm indication on the docking station's display panel

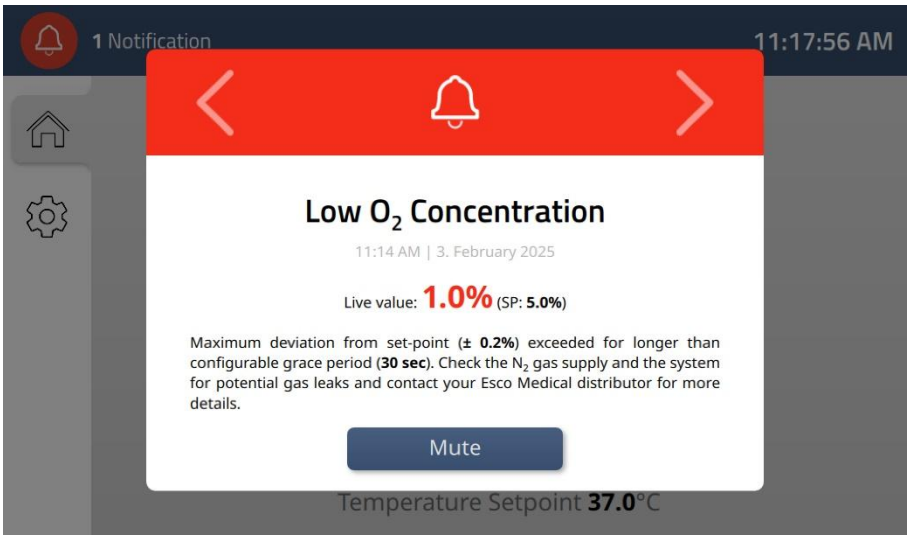


Figure 15.15 Low O_2 concentration alarm indication on the docking station's display panel

Tapping the mute button temporarily disables the alarm state, including the audible alarm, for a 5-minute period. If the cause of the alarm is not resolved during this period, the alarm will resume.

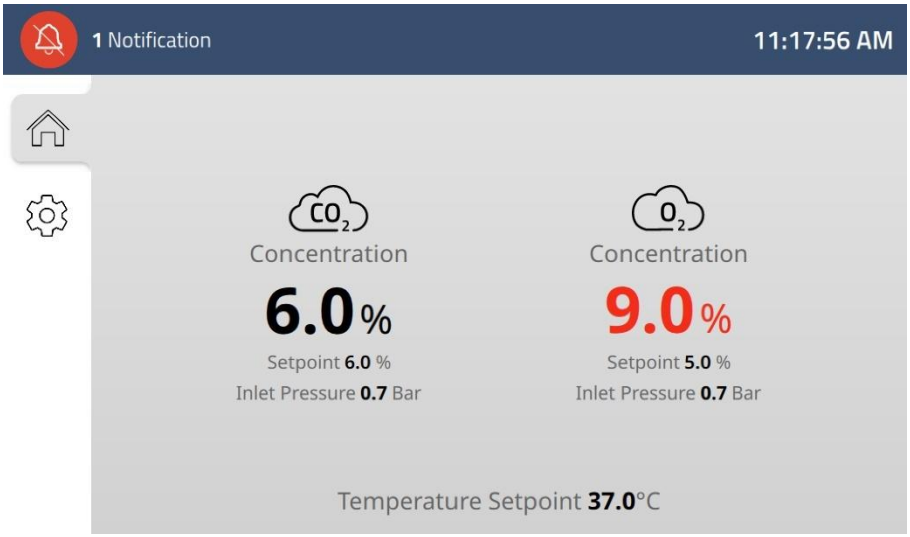


Figure 15.16 A muted O_2 concentration alarm on the main display

The maximum deviation from the setpoint of ± 0.2% and the 30-second period before the alarm is triggered are set by defaults. They can be customized in the settings accessible on the docking station display.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond to a O_2 concentration alarm in the system.

15.3 Gas pressure alarms

15.3.1 CO_2 pressure alarm

If the incoming CO_2 pressure drops below or rises above the acceptable range of 0.7 bar (10.15 PSI) - 1.5 bar (21.76 PSI), the system will trigger a CO_2 pressure alarm, visualized as a pop-up notification on the docking station display panel (see Figure 15.17). It persists until the alarm is muted, the issue is resolved, or the alarm resolves itself.

The recommended pressure is 1 bar (14.50 PSI).

The pop-up alarm notification includes:

- A headline describing the overall issue, including a timestamp for when the issue occurred.
- A live value compared to the intended range for the CO_2 pressure.
- Additional help text detailing the reason for the alarm and recommended actions to resolve the issue.

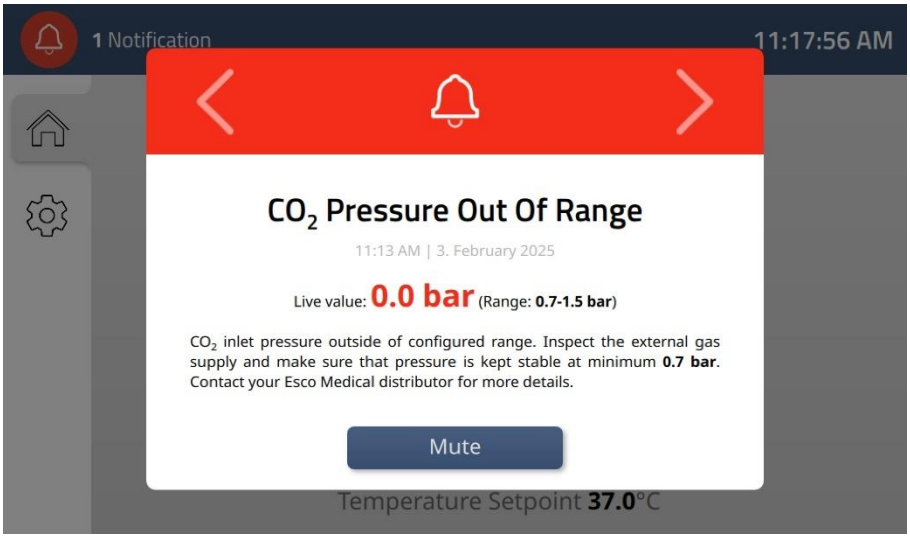


Figure 15.17 CO_2 pressure out-of-range alarm indication on the docking station's display panel

Tapping the mute button temporarily disables the alarm state, including the audible alarm, for a 5-minute period. If the cause of the alarm is not resolved during this period, the alarm will resume.

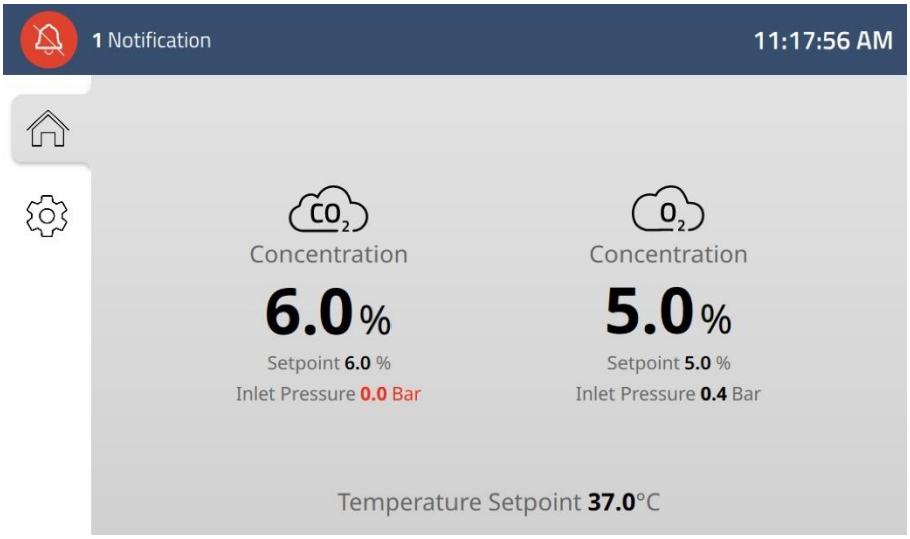


Figure 15.18 A muted CO_2 gas pressure alarm view on the main display

The reason for a CO_2 pressure alarm may be that the CO_2 gas supply is not attached correctly, an incorrect CO_2 gas pressure is applied to the system, or that the CO_2 gas supply is empty.

The safe range of 0.7 bar – 1.5 bar is set by default, but it can be customized in the settings accessible on the docking station display.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond to a CO_2 pressure alarm in the system.

15.3.2 N_2 pressure alarm

If the incoming N_2 pressure drops below or rises above the acceptable range of 0.7 bar (10.15 PSI) - 1.5 bar (21.76 PSI), the system will trigger an N_2 pressure alarm, visualized as a pop-up notification on the docking station display panel (see Figure 15.19). It persists until the alarm is muted, the issue is resolved, or the alarm resolves itself.

The recommended pressure is 1 bar (14.50 PSI).

The pop-up alarm notification includes:

- A headline outlining the overall issue, including a timestamp for when the issue occurred.
- A live value compared to the intended range for the N_2 pressure.
- Additional help text detailing the reason for the alarm and recommended actions to resolve the issue.

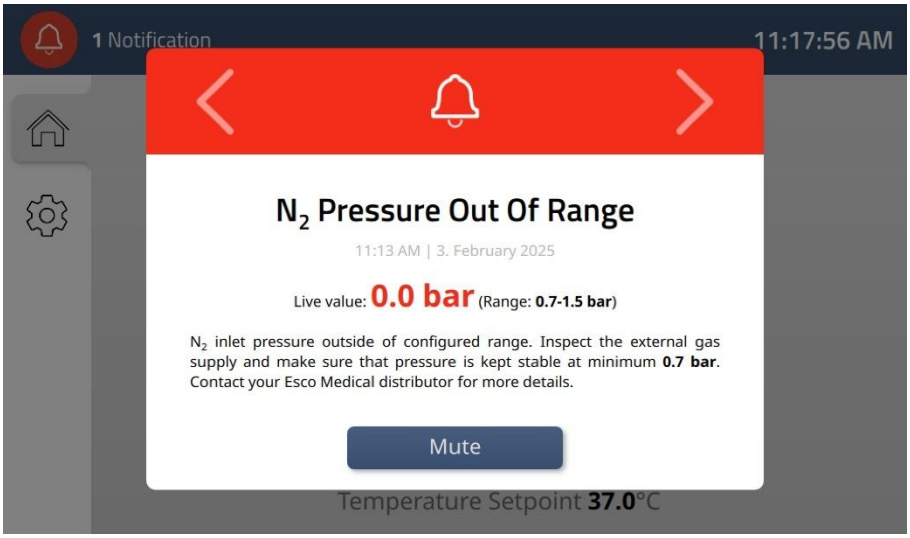


Figure 15.19 N_2 pressure out-of-range alarm indication on the docking station's display panel

Tapping the mute button temporarily disables the alarm state, including the audible alarm, for a 5-minute period. If the cause of the alarm is not resolved during this period, the alarm will resume.

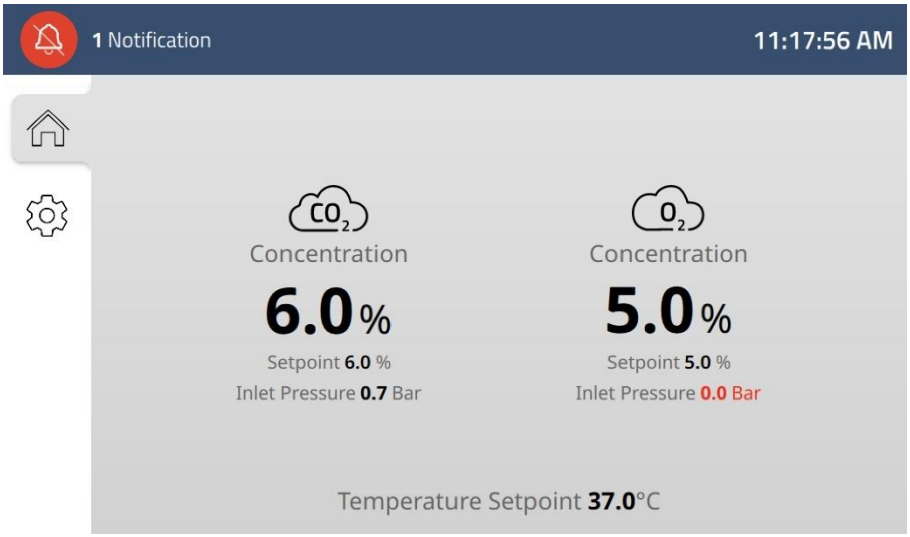


Figure 15.20 A muted N_2 gas pressure alarm view on the main display panel

The reason for an N_2 pressure alarm may be that the N_2 gas supply is not attached correctly, an incorrect N_2 gas pressure is applied to the system, or that the N_2 gas supply is empty.

The safe range of 0.7 bar – 1.5 bar is set by default, but it can be customized in the settings accessible on the docking station display.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond to a N_2 pressure alarm in the system.

15.4 Main gas pump fault state

In case of fault conditions in the main gas pump, such as the pump malfunctioning or stopping entirely, it will trigger an alarm in the system, visualized as a pop-up notification on the docking station display panel (see Figure 15.21). It persists until the alarm is muted, the issue is resolved, or the alarm resolves itself.

The pop-up alarm notification includes:

- A headline outlining the overall issue, including a timestamp for when the issue occurred.
- Additional help text detailing the reason for the alarm and recommended actions to resolve the issue.

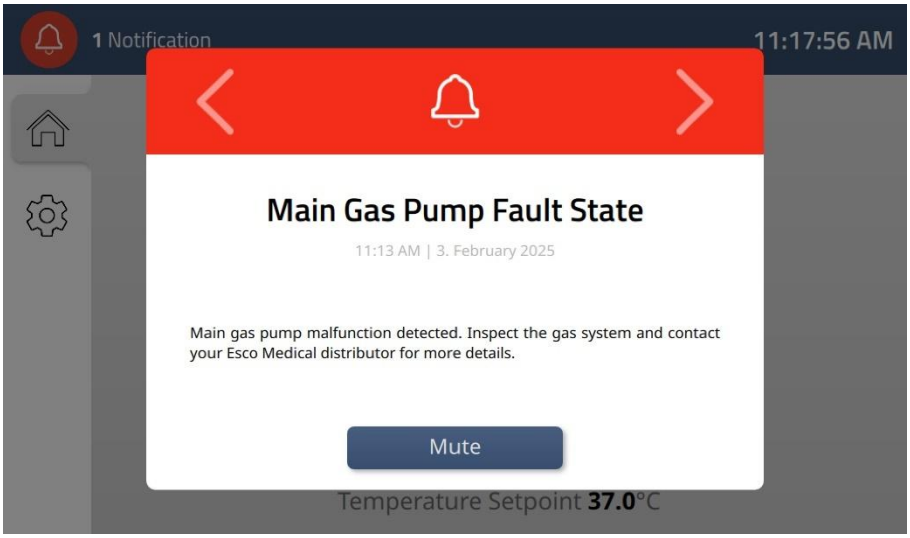


Figure 15.21 Gas Pump fault state alarm indication on the docking station's display panel

To resolve fault conditions in the main gas pump, please consult Esco Medical or your distributor for further guidance or service inspection. The alarm will disappear only when the gas pump is running correctly again.

If the pump pressure exceeds the maximum range or its maximum running hours, it will only trigger a warning in the system.

The performance of the main gas pump may decline over time, and it must therefore be replaced once every 2 years to maintain a fast recovery time.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond if the main gas pump is in a fault state and contact your Esco Medical or distributor for more details.

15.5 Gas sensor fault state

15.5.1 CO_2 sensor fault state

The CO_2 concentration in the system is continuously monitored by a dual-beam infrared CO_2 sensor with low drift rates. If this sensor malfunctions, the system may stop receiving updated gas concentration readings, triggering an alarm. To resolve this issue, please contact your Esco Medical distributor for further guidance or a service inspection. The alarm will only be ceased when the CO_2 sensor is no longer in a fault state.

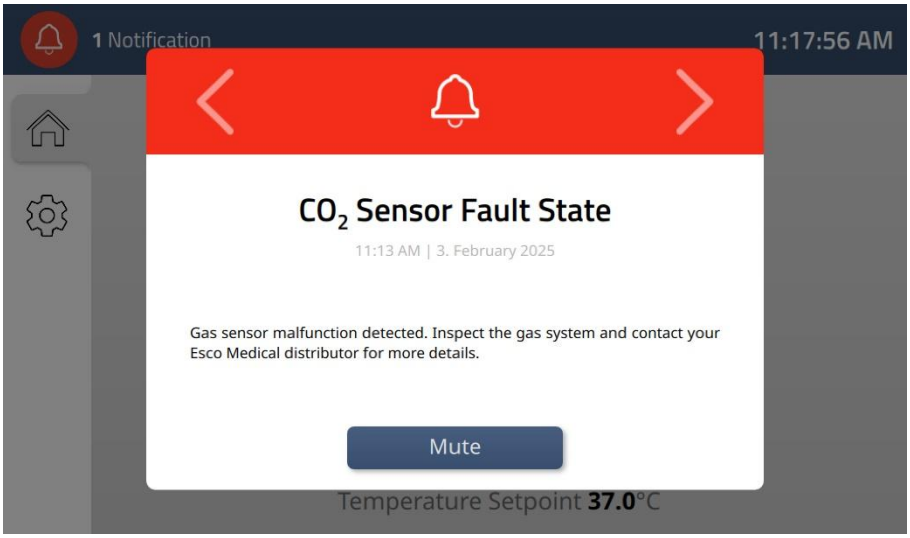


Figure 15.22 CO_2 sensor fault state alarm on the docking station display

For safety reasons the CO_2 sensor should be replaced once every 5 years.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond if the CO_2 sensor is in a fault state and contact your Esco Medical or distributor for more details.

15.5.2 O_2 sensor fault state

The O_2 concentration is monitored by a medical-grade chemical oxygen sensor. If this sensor malfunctions, the system may stop receiving updated gas concentration readings, triggering an alarm. To resolve this issue, please contact your Esco Medical distributor for further guidance or a service inspection. The alarm will only be ceased when the O_2 sensor is no longer in a fault state.

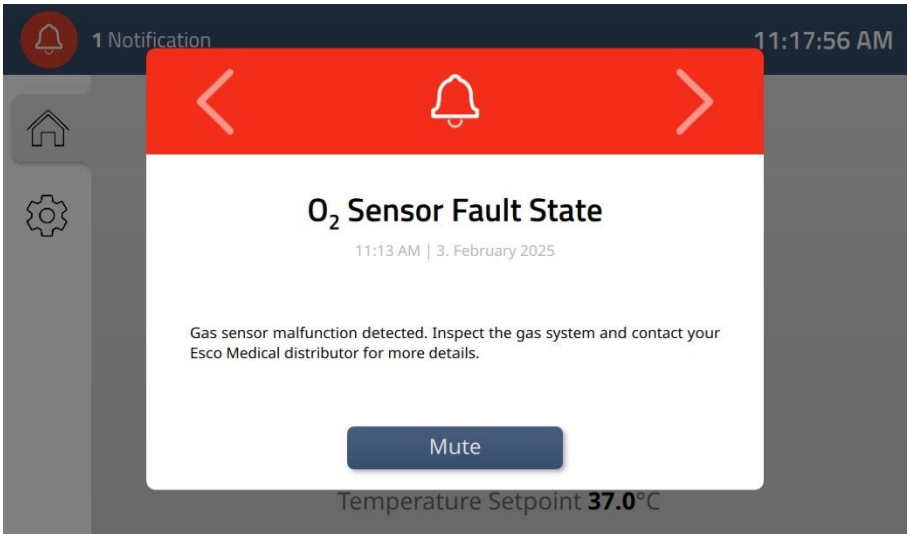


Figure 15.23 O_2 sensor fault state alarm on the docking station display

The O_2 sensor must be replaced at least once every year from the date it was installed in the device, irrespective of the incubator being used or not.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond if the O_2 sensor is in a fault state and contact your Esco Medical or distributor for more details.

15.6 Gas connection lost

If the gas system stops responding due to a communication failure or a malfunction in the gas system itself, a *"gas connection lost"* alarm will be triggered. The device will then no longer receive updated gas readings which may affect the incubation conditions, and the device will not function normally until communication with the gas system is re-established.

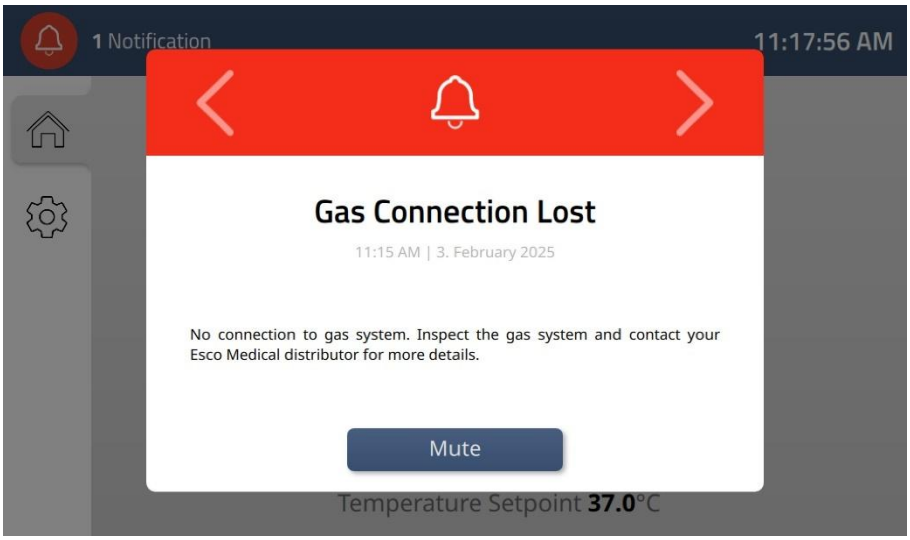


Figure 15.24 Gas connection lost alarm on the docking station display

To resolve this issue, contact your Esco Medical distributor for assistance. A service inspection may be required to restore proper functionality in the device.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond if the gas connection is lost and contact your Esco Medical or distributor for more details.

15.7 Gas system unavailable

If there is no detectable connection between the device and the gas system, whether due to a physical disconnection, hardware failure, or a disruption in the gas supply, a *"gas system unavailable"* alarm will be triggered. Without an active connection to the gas system, the

device cannot regulate or monitor gas levels, which may impact incubation conditions, and the device will not function normally until connection to the gas system is re-established.

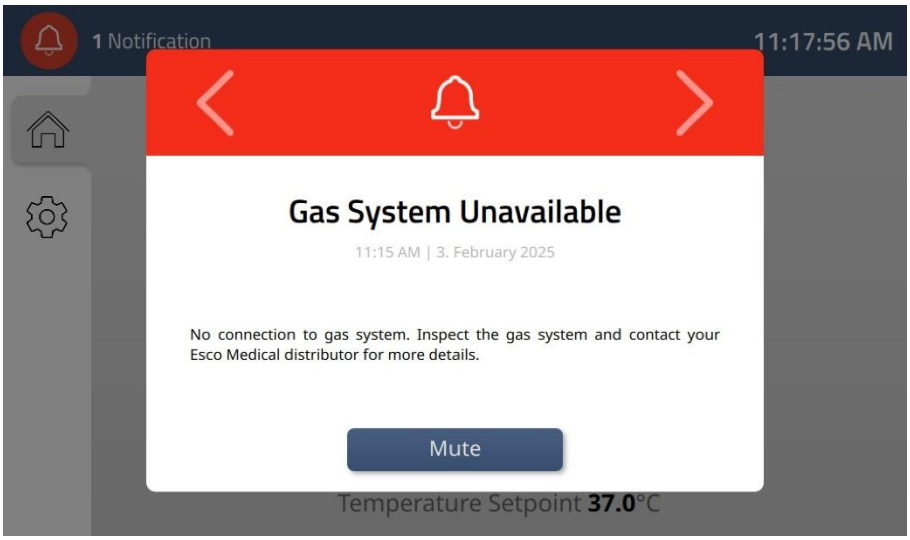


Figure 15.25 Gas system unavailable alarm on the docking station display

To resolve this issue, contact your Esco Medical distributor for assistance. A service inspection may be required to restore proper functionality in the device.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond if the gas system is unavailable and contact your Esco Medical or distributor for more details.

15.8 Chamber slot alarms

15.8.1 Chamber slot fault state

If the chamber slot fault state alarm is triggered in the system, it indicates that the technical connection for a chamber in a docking position is malfunctioning, meaning the system is not capable of detecting whether a chamber is docked in this position. The alarm pop-up includes:

- A headline outlining the issue, including a timestamp for when it occurred.
- Identification of the specific slot affected (whether a chamber is docked or not).
- Additional help text detailing recommended actions to resolve the issue.

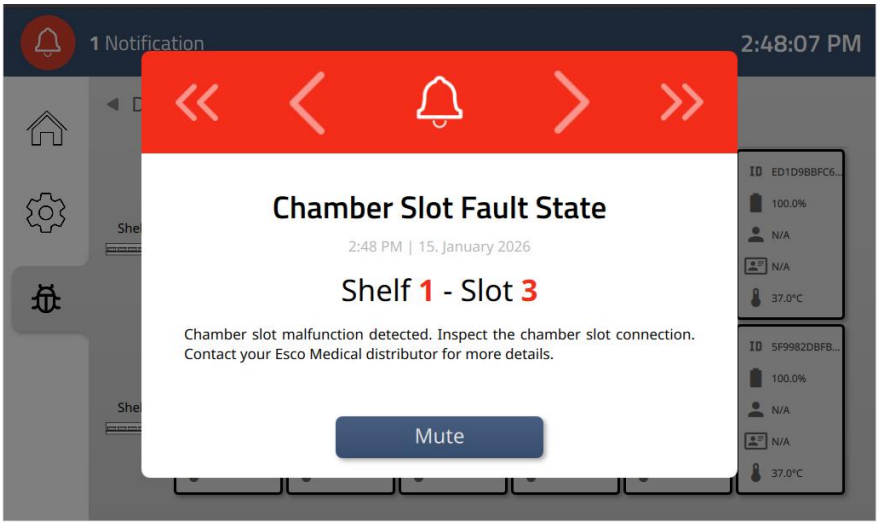


Figure 15.26 Chamber slot fault state alarm

To resolve this issue, please contact Esco Medical or your local distributor for further guidance or service inspection. The alarm will only clear once the fault condition in the chamber slot connection is resolved.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond if the chamber slot connection is in a fault state and contact your Esco Medical or distributor for more details.

15.8.2 Chamber slot power supply fault state

If the chamber slot power supply fault state alarm is triggered in the system, it indicates a fault in the docking position's ability to supply power to a chamber. Unlike the Chamber Slot Fault State alarm, the system may still be able to detect that a chamber is docked, but it is unable to charge the chamber's battery. The alarm pop-up includes:

- A headline outlining the issue, including a timestamp for when it occurred.
- Identification of the specific slot affected (whether a chamber is docked or not).
- Additional help text detailing recommended actions to resolve the issue.

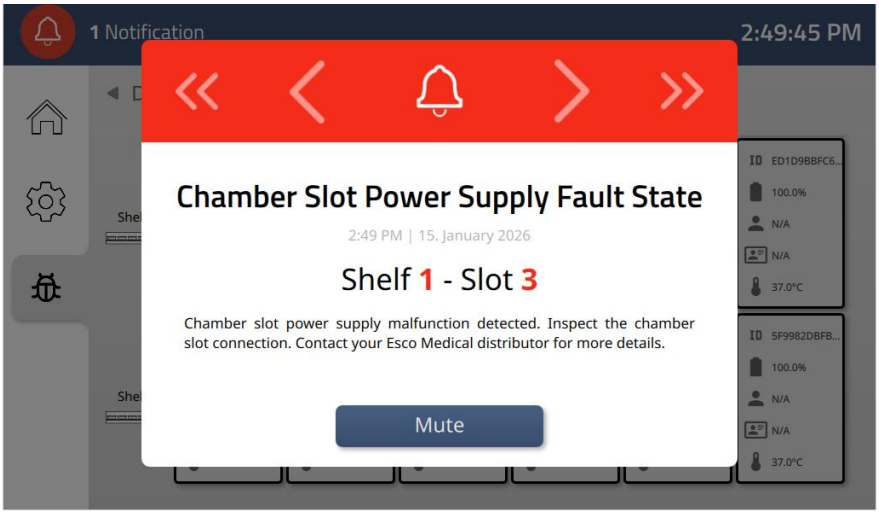


Figure 15.27 Chamber slot power supply fault state alarm

To resolve this issue, please contact Esco Medical or your local distributor for further guidance or service inspection. The alarm will only clear once the fault condition in the chamber slot power supply is resolved.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond if the chamber slot power supply is in a fault state and contact your Esco Medical or distributor for more details.

15.9 Chamber battery critically low

Once a chamber is undocked, it operates on its internal battery, and this will gradually deplete over time. Transporting undocked chambers is therefore intended only for short durations - especially when the chambers contain samples involved in treatments. The battery icon in the chamber display reflects the battery level in the chamber, and when this level drops to 50% of its full capacity, the icon changes from green to yellow, as the battery level becomes low.

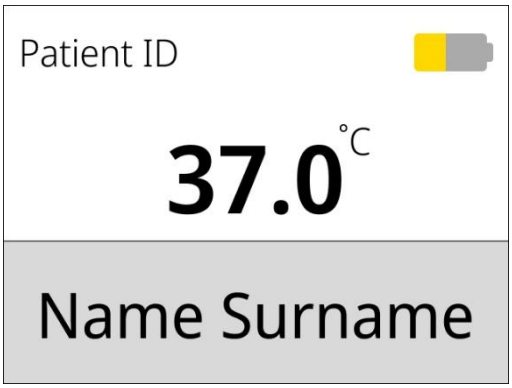


Figure 15.28 Chamber battery low warning

However, should the battery drop to 15% of its full capacity, the battery level instead becomes critically low, and this will trigger an alarm, as the chamber goes into survival mode:

- Heating is disabled, and the chamber focuses on preserving basic functionality for as long as possible.
- The battery icon reflects the critically low battery level in the chamber by adding an exclamation mark on top of the icon.
- An alarm bell icon is added next to the battery icon and the background colour for the bottom bar changes to red.

Patient name, patient ID, temperature value and current battery level are displayed continuously.

For safety and to prevent battery damage, the chamber will automatically turn off when the battery charge drops below 10%. Please recharge the battery promptly to resume operation.

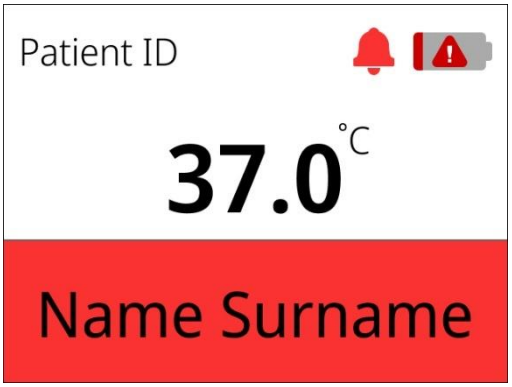


Figure 15.29 Critically low battery alarm

The issue is resolved by connecting the chamber to a power supply, but it is also possible to mute the alarm for 5 minutes by pressing the chamber's mute button. The battery icon will remain red, and if the cause of the alarm is not resolved during this period, it will resume.

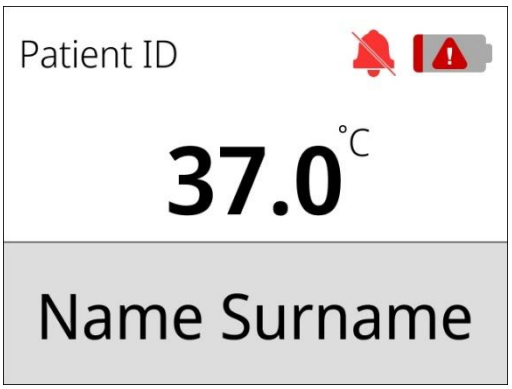


Figure 15.30 Muted critically low battery alarm

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond, if a chamber's battery level becomes critically low.

15.10 Chamber tilt alarms

Chambers containing embryos must at all times be kept levelled to ensure that embryos stay in their intended positions. If an undocked chamber is tilted beyond a 5° angle, an alarm will be triggered. This alarm is not cleared by docking the chamber in the docking station, so the system provides two visual feedback signals depending on whether the chamber is docked or undocked.

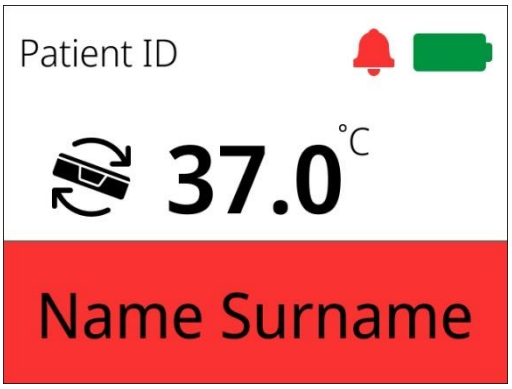


Figure 15.31 Tilt alarm indication on an undocked chamber's display

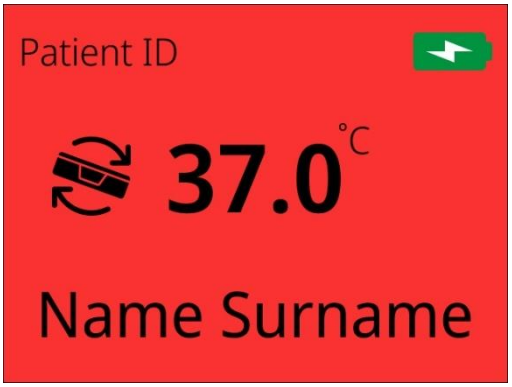


Figure 15.32 Tilt alarm indication on a docked chamber's display

Both of these designs have an icon next to the chamber's temperature value that describes the current issue.

Patient name, patient ID, temperature value and current battery level are displayed continuously.

Should the chamber with an active tilt alarm indication be docked, the docking station display will be the primary communicator, but the chamber display will aid in bringing attention to itself (see Figure 15.32).

When the tilt alarm is present in a docked chamber, a pop-up alarm message is displayed on the docking station display. It includes:

- A headline describing the alarm, including a timestamp for when it occurred.
- A specification of where the issue is occurring as it is a chamber-specific alarm.
- Additional help text detailing the reason for the alarm and recommended actions to resolve the issue.

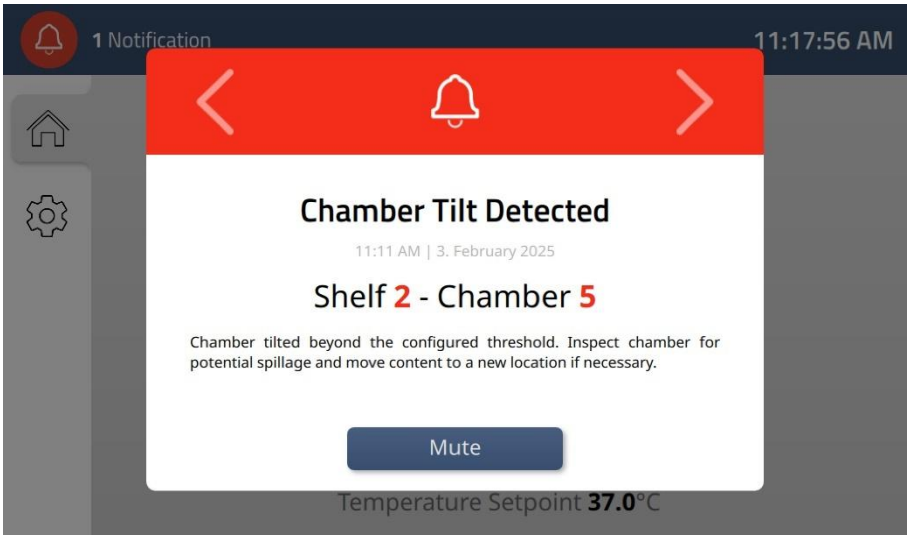


Figure 15.33 Chamber tilt alarm indication on the docking station's display panel

To resolve this alarm state, the chamber lid must be opened and closed again, whether docked or undocked, signalling to the system that the user has inspected the chamber's content. However, it is also possible to mute the alarm. Pressing the mute button on the undocked chamber temporarily disables the alarm state, including the audible alarm, for a 5-minute period. The tilt icon remains, and if the cause of the alarm is not resolved during this period, the alarm will resume.

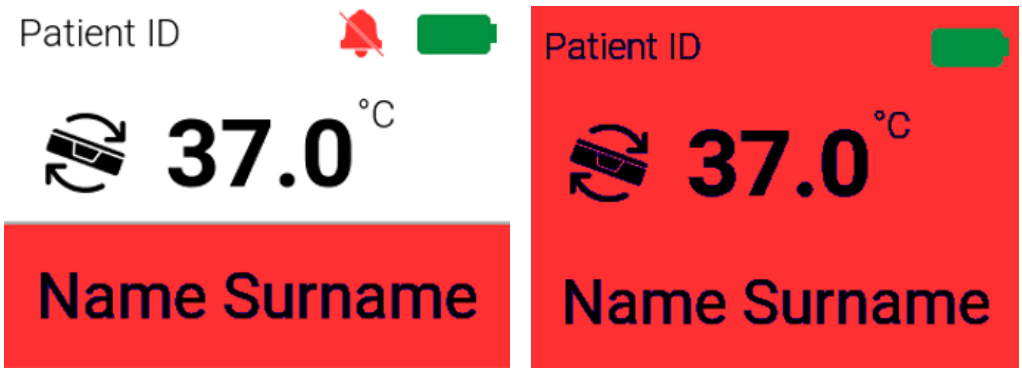


Figure 15.34 Muted tilt alarm in an undocked (left) and docked (right) chamber

The chamber tilt alarm has a deviation of ± 1°. This deviation does not have a significant impact on the overall usability of the chamber.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond to a tilt alarm in a chamber.

15.11 Multiple alarms and warnings

If multiple alarms and warnings are triggered simultaneously, or if a new alarm is triggered while another is still active, only a single pop-up notification appears on the docking station display, similar to a single alarm scenario but with key differences:

1. The arrows (“<” and “>”; “<<” and “>>”) in the top bar become interactive, allowing users to cycle through the previous, next, first, or last active notification.
2. The total number of notifications is displayed in the upper-left corner, with the most critical alarm in the first position and warnings ranked lowest in severity.

The ranking of severity is determined by what is most crucial for ensuring the survival of embryos in the system. This means that temperature alarms hold the highest priority, followed by gas concentration alarms, and so forth.

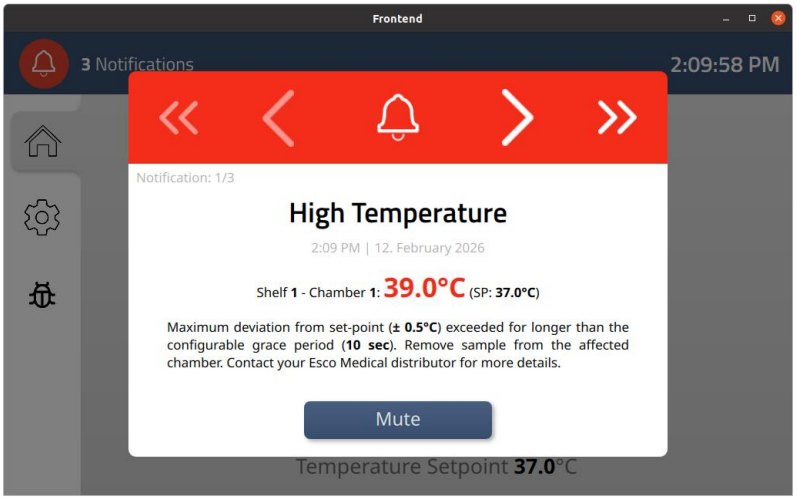


Figure 15.35 Multiple alarm indication on the docking station’s display panel

When the alarms are muted, the number of notifications is indicated by the icon in the top-left corner. When clicked, this icon shows a notifications log, where all active alarms and warnings can be viewed.
Additionally, the **Notification Log** button provides access to all current and previous alarms, warnings, and other notifications.

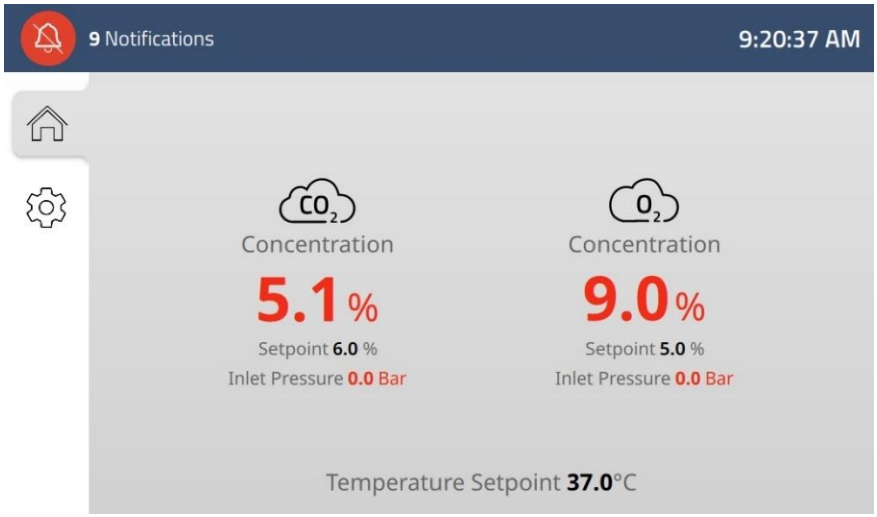


Figure 15.36 Multiple alarms in the main display

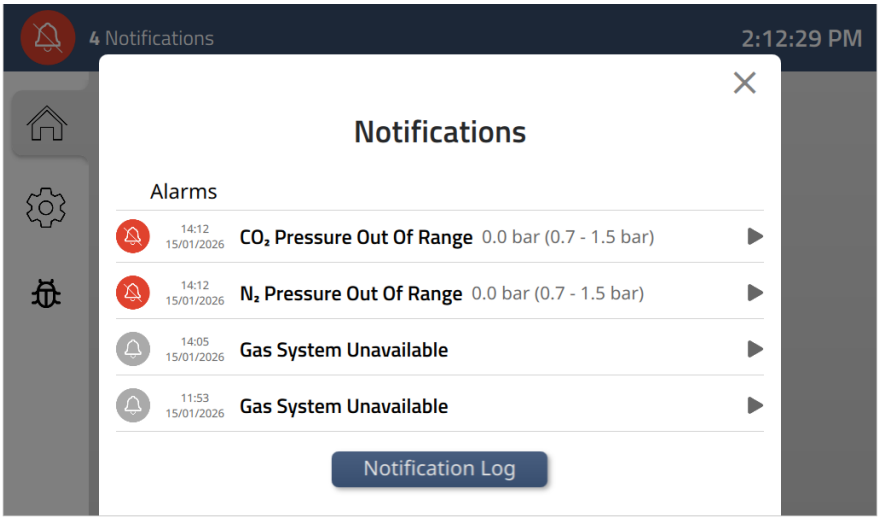


Figure 15.37 Notifications log showing multiple alarms

The alarms are mainly associated with errors in the CO_2 supply, but there is also a temperature alarm in one of the connected chambers. This will, therefore, appear first on the pop-up notification and on the chamber display. The alarm will resume if the mute timer expires before the alarms are resolved. If only the most critical alarm is resolved, the next alarm in the ranking will then become the most critical and appear on the pop-up notification first, and so on.

If a chamber has multiple alarms active, the visualization is similar to when alarms are triggered separately, with a **key difference**: the icon next to the temperature reading cycles between alarm instances every 1.5 seconds.

Depending on whether the chamber is docked into the docking station, there are two separate chamber display designs:

1. **Undocked** – the alarm icon is present next to the temperature value, where the bottom bar is coloured in red (Figure 15.38).
2. **Docked** – the entire display background is coloured in red (the docking station's display panel serves as the primary communicator in this scenario) (Figure 15.39).

If one of the multiple alarms concerns the temperature, the temperature value will also be highlighted in red.

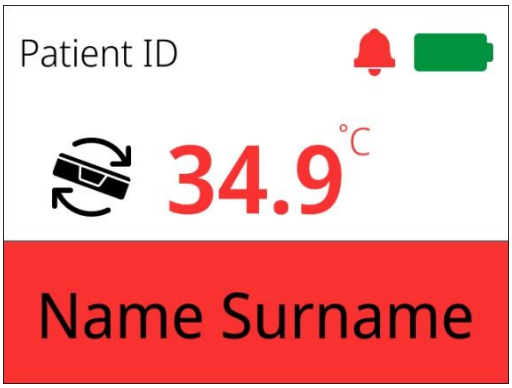


Figure 15.38 Multiple alarm indication on the undocked chamber's display (tilt/temperature alarms active)

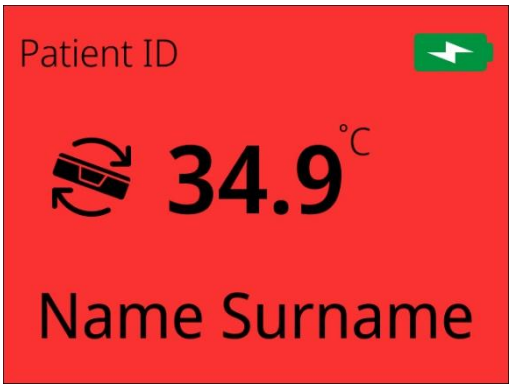


Figure 15.39 Multiple alarm indication on the docked chamber's display (tilt/temperature alarms active)

It is also possible to mute the alarms. Pressing the mute button on the undocked chamber temporarily disables the alarm states, including the audible alarm, for a 5-minute period. The alarm icons will remain active, and if the cause of the alarm is not resolved during this period, the alarm will resume.

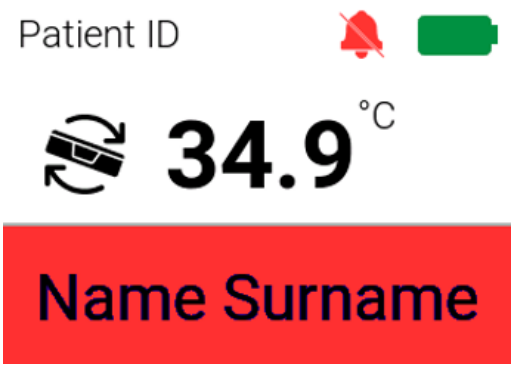


Figure 15.40 Multiple alarms muted alarm in a chamber

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond if there are multiple simultaneous alarms.

15.12 Unacknowledged alarms

So far it has been described how pressing a mute button will pause alarm feedback for a 5-minute period, allowing the user time to address the underlying issue. However, pressing a mute button also serves as an acknowledgment that the user is aware of the alarm condition. If the alarm is resolved without ever being muted, it will disappear, but the system will treat it as “unacknowledged.” This is indicated by a grey notification icon in the top-left corner.

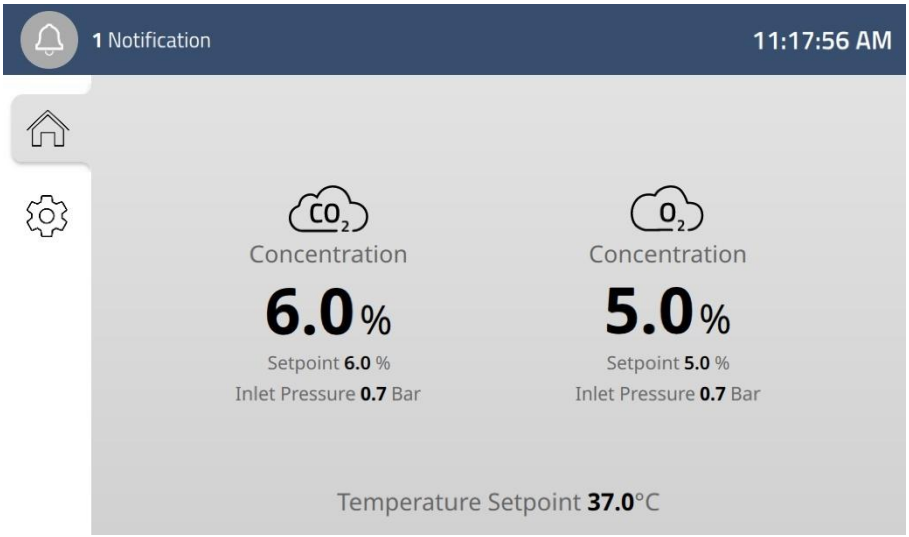


Figure 15.41 The unacknowledged alarm indication on the main display

To resolve this, the system must be informed that the user is aware of this previous active alarm state. This is done by tapping the notification icon in the top-left corner to open the list of notifications. Simply opening and then closing this list again will indicate to the system that the alarm has been acknowledged by a user.

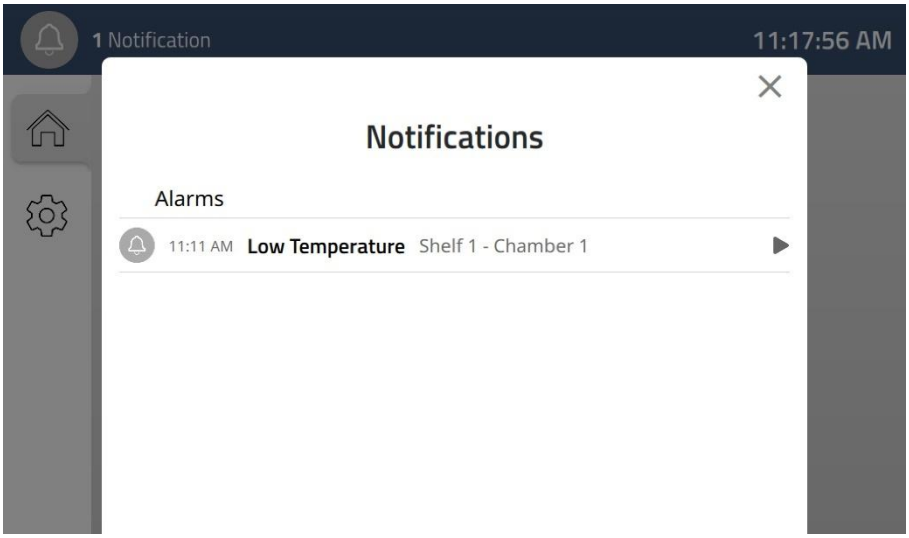


Figure 15.42 An unacknowledged alarm in the notification list

Tapping the notification unacknowledged alarm in the notification list will open its pop-up and allow for further inspection. In this state, the red colour is replaced by a grey colour, and the pop-up now includes timestamps for when the alarm was issued and when it was ceased. For alarms involving live values, these are still shown, now in black instead of red.

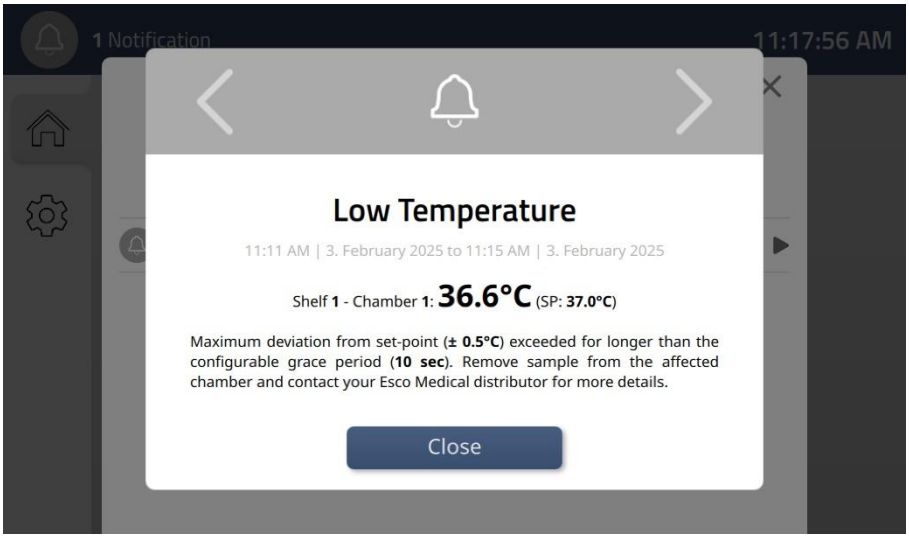


Figure 15.43 An unacknowledged alarm in the notification list

⚠ **The presence of unacknowledged alarms in undocked chambers will not be indicated on the chamber display but will instead appear in the notification log on the docking station display, when the chamber is docked.**

15.13 Loss of power

If power to the MIRI® M docking station is lost, the system will shut down, meaning that the power connection to the chambers also will be lost. All connected chambers will therefore

experience it as being undocked. The battery levels in the chambers will start to decrease and the chambers should be moved to other power sources unless power to the docking station can be reestablished.

If an external monitoring system is connected to the jack connector on the rear of the docking station, it's possible to receive alarm notifications about the loss of power on an external device.

Please refer to section "27 Emergency Procedures" in the user manual for instructions on how to respond if there is a loss of power to the docking station.

15.14 Lid opened warning

When the lid of an undocked chamber is opened, a warning will be displayed, alerting that gas has dispersed from the chamber. This includes adding a gas icon near the temperature value.

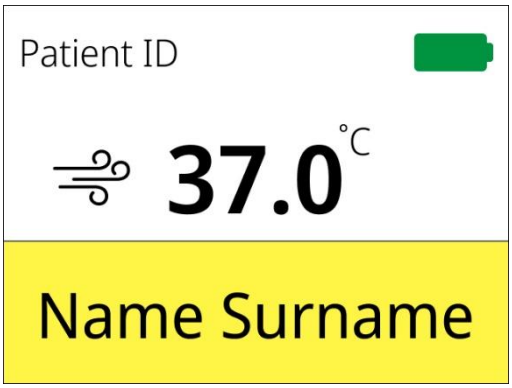


Figure 15.44 "Lid opened" warning in an undocked chamber

Upon closing the lid, the warning will disappear, but the gas icon will remain in the display, signalling that the chamber is now without gas. To restore the gas concentration level, return the chamber to a gassed docking station. Once connected, the chamber will be gassed, and the icon will then disappear.

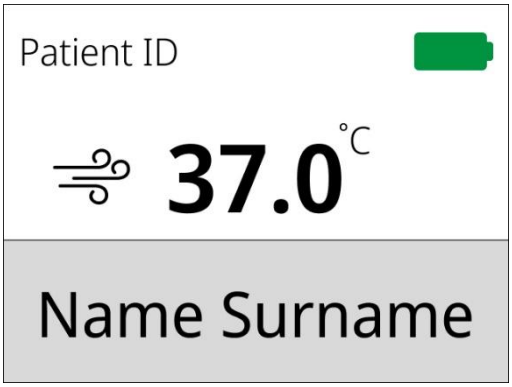


Figure 15.45 Display indicating that gas has dispersed

15.15 UV-C light warnings

15.15.1 UV-C light fault state

The UV-C light fault state notification will only appear as a warning during normal operation, meaning no pop-up message will appear on the display automatically, and no audible alarms will be triggered.

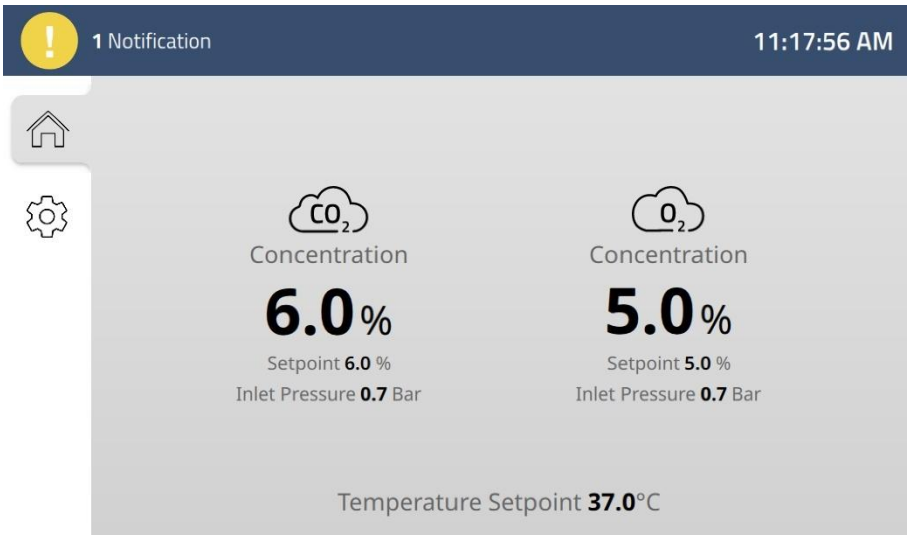


Figure 15.46 The visual warning feedback on the docking station display

To open the full warning message, tap the notifications icon in the top-left corner and tap the specific notification in the log. This will make the warning pop-up over the log.

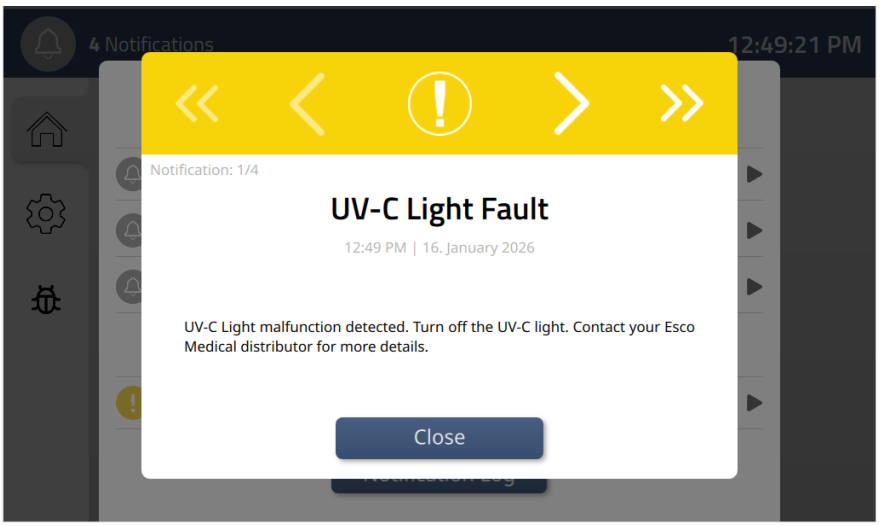


Figure 15.47 UV-C light fault state warning

To resolve the warning state, please consult your Esco Medical distributor for further guidance or service inspection. The warning will disappear only when the UV-C light is no longer in a fault state.

Please contact your Esco Medical distributor for more details if the UV-C light is in a fault state.

15.15.2 UV-C light circuit fault state

Similar to the UV-C light fault state warning, the UV-C light circuit fault state warning will not produce audible feedback, and no visual feedback will pop up automatically. The difference between these two warnings lies in where the issue exactly is.

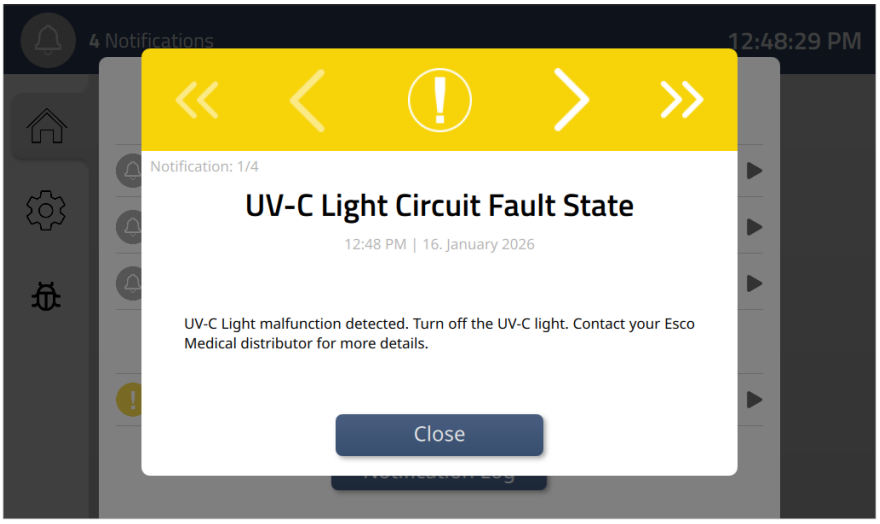


Figure 15.48 UV-C light circuit fault state warning

To resolve the warning state, please consult your Esco Medical distributor for further guidance or service inspection. The warning will disappear only when the UV-C light circuit is no longer in a fault state.

Please contact your Esco Medical distributor for more details if the UV-C light circuit is in a fault state.

15.16 Exceeding maximum running hours for service parts

Some system parts must be serviced periodically to maintain the proper functionality of the incubator. If these service parts are not changed before their maximum number of running hours run out, they will cause a system warning.

15.16.1 UV-C Light

If the maximum running hours for the UV-C Light are exceeded, it will cause a warning in the system. For the warning state to be resolved, please consult your Esco Medical distributor for further guidance or service inspection. The warning will disappear only when the UV-C Light has been replaced, and the running hours counter has been reset.

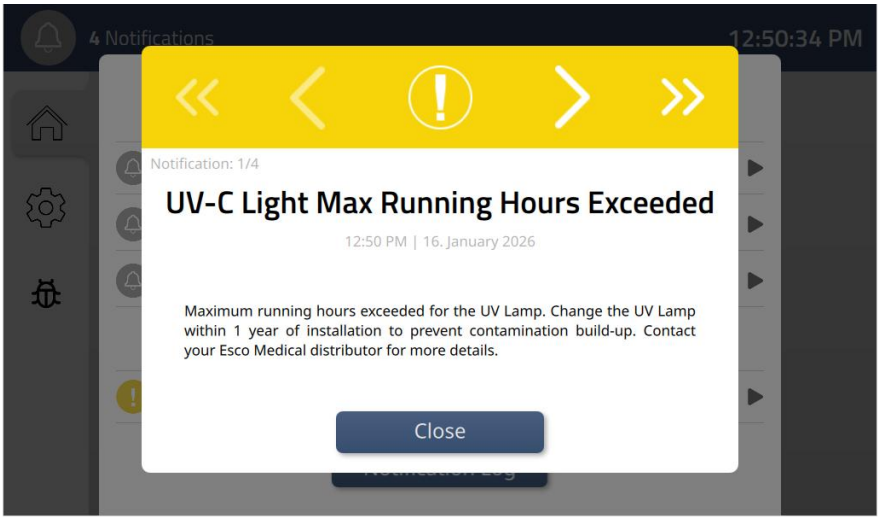


Figure 15.49 UV-C light running hours exceeded warning

The UV-C Light cleans the recirculating air and must be replaced once every year to avoid contamination build-up.

Please contact your Esco Medical distributor for more details if the maximum running hours for the UV-C Light are exceeded.

15.16.2 VOC/HEPA filter

If the maximum running hours for the VOC/HEPA filters are exceeded, it will cause a warning in the system. For the warning state to be resolved, please consult your Esco Medical distributor for further guidance or service inspection. The warning will disappear only when the VOC/HEPA filter is replaced, and the running hours counter has been reset.

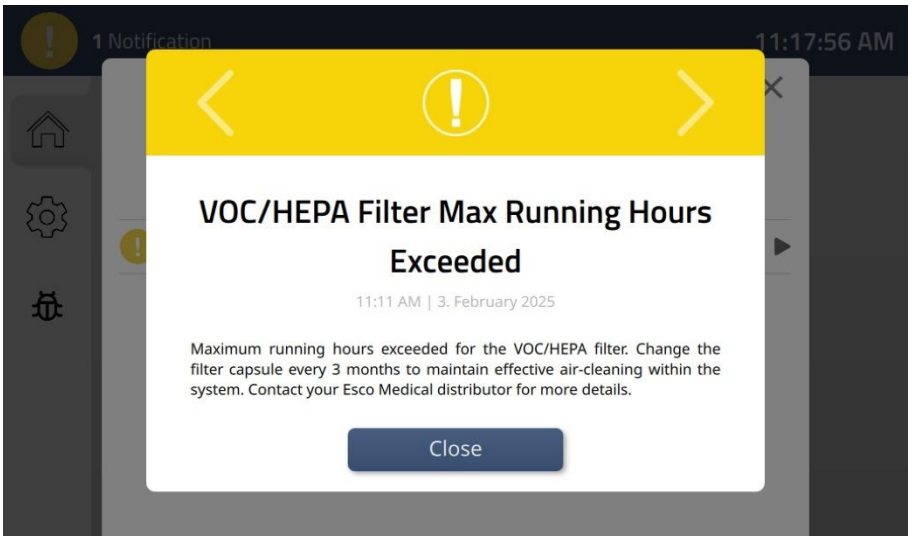


Figure 15.50 VOC/HEPA filter running hours exceeded warning

The VOC/HEPA filter removes particles found in the incoming gasses, and they must be replaced once every 3 months to ensure the sensors calculate the correct amounts of CO_2 and O_2 in the system.

Please contact your Esco Medical distributor for more details if the maximum running hours for the VOC/HEPA filters are exceeded.

15.16.3 Main gas pump

If the main gas pump's maximum running hours are exceeded, the system will display a warning. To resolve the warning state, please consult your Esco Medical distributor for further guidance or service inspection. The warning will disappear only when the gas pump is replaced, and the running hours counter is reset.

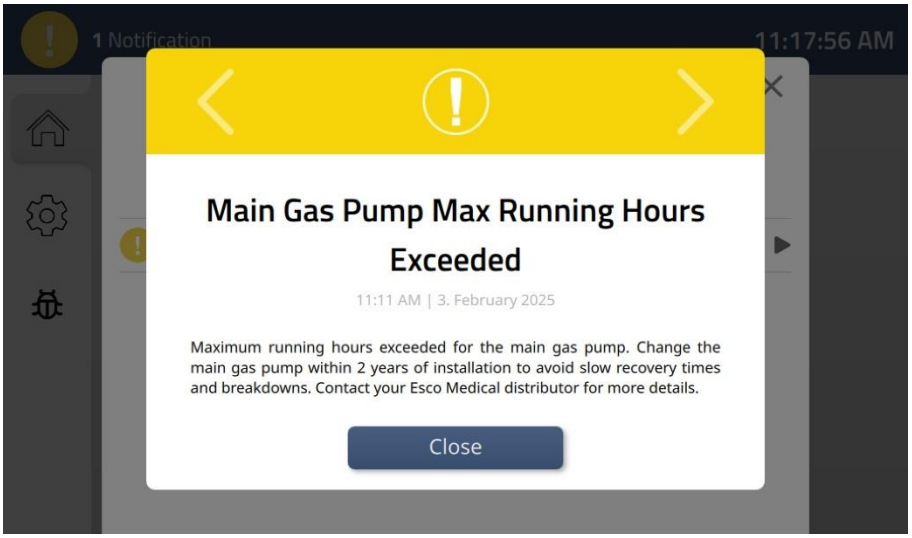


Figure 15.51 Main gas pump running hours exceeded warning

The main gas pump is used to transport the mixed gas through the system and must be replaced once every 2 years to maintain fast gas recovery in the connected chambers, as its performance can be affected over time.

Please contact your Esco Medical distributor for more details if the maximum running hours for the main gas pump are exceeded.

15.17 Main gas pump pressure out of range

The main gas pump operates at a default pressure of 6 mbar. If this pressure deviates by more than ±1 mbar, it falls out of its allowed range, and this will trigger a warning in the system.

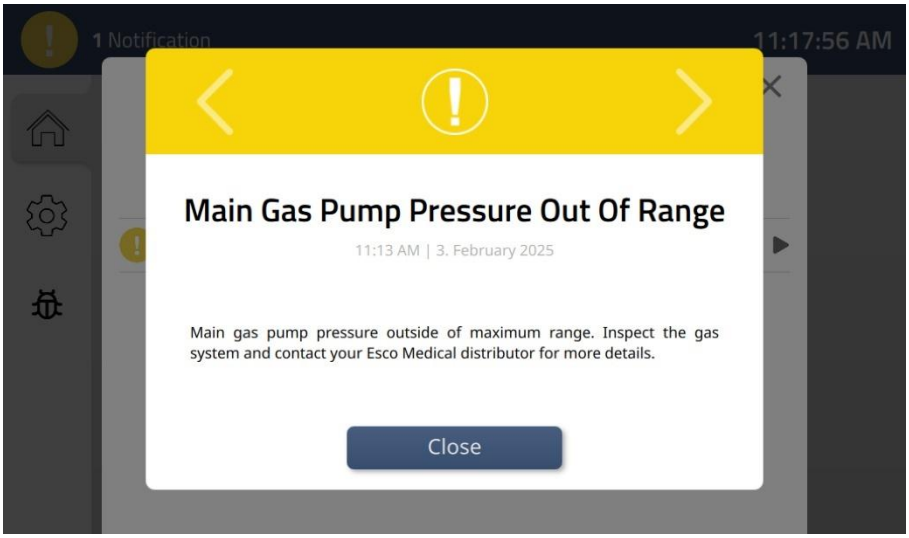


Figure 15.52 Main gas pump pressure out of range warning

This issue may be caused by CO_2 or N_2 supply pressures being too low or too high and adjusting this may solve the issue. However, any adjustments to the gas supply should be made according to the guidelines provided by your Esco Medical distributor or handled by a qualified service technician.

Please contact your Esco Medical distributor for more details if the main gas pump pressure falls out of range.

15.18 Three-way valve fault state

When the gas sensor calibration process is initiated, the three-way valve closes off the main gas flow and only directs the gasses towards the CO_2 and O_2 sensors. If the valve fails to open due to a malfunction, the system will trigger a three-way valve fault state warning.

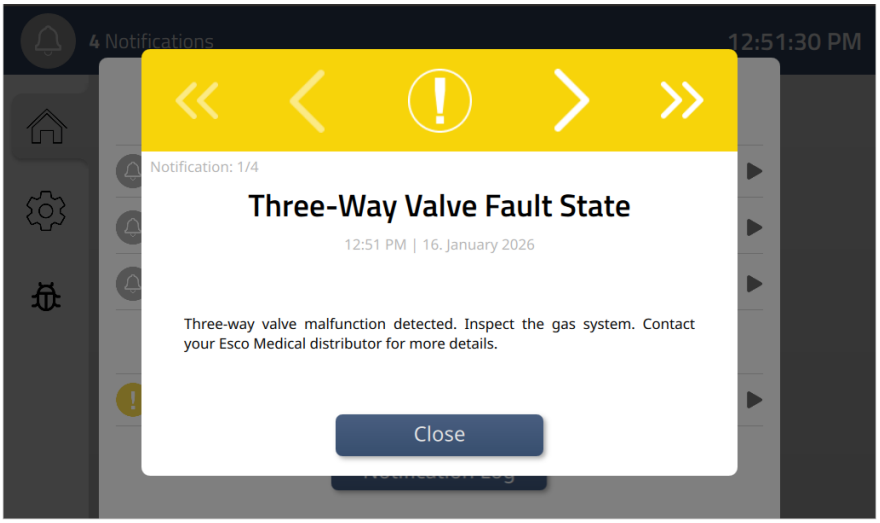


Figure 15.53 Three-way valve fault state warning

This issue must be handled by a service technician, as the valve is controlled by internal electronics located on a circuit board, inaccessible to users.

Please contact your Esco Medical distributor for more details if the three-way valve is in a fault state.

15.19 Release valve fault state

The release valve remains closed at all times during normal operation. However, during sensor calibration, it opens to vent the reference gasses used in the process. If the valve fails to open due to a malfunction, the system will trigger a release valve fault state warning.

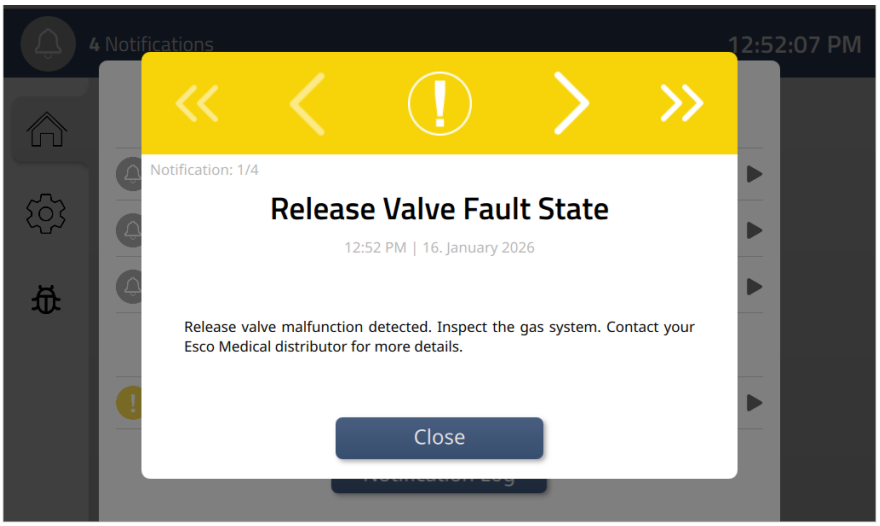


Figure 15.54 Release valve fault state warning

This issue must be handled by a service technician, as the valve is controlled by internal electronics located on a circuit board, inaccessible to users.

Please contact your Esco Medical distributor for more details if the release valve is in a fault state.

15.20 Chamber communication unavailable

When a chamber is docked in the docking station, it establishes an electrical connection. If communication between the chamber and its docking position is lost for more than 10 seconds, the system will trigger a chamber communication unavailable warning. The chamber may still be charging (charging status will be indicated in the chamber display), but treatment management functions could be lost, including the transmission of setpoint settings. In such cases, updating the setpoint may be not possible.

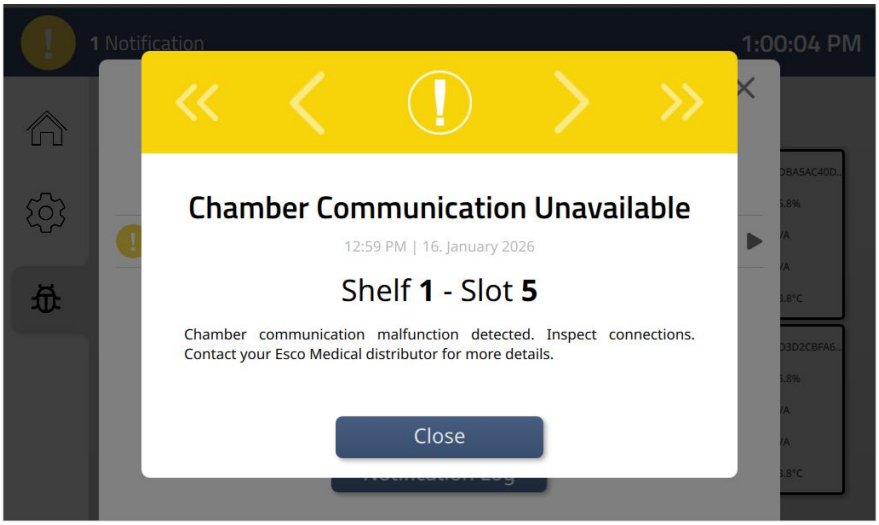


Figure 15.55 Chamber communication unavailable warning

This issue must be handled by a service technician, as the warning only is ceased once the communication is re-established. Until service can be done, correct operation of the chamber cannot be guaranteed, so any samples inside the chamber should be relocated to another chamber and the chamber should be turned off.

Please contact your Esco Medical distributor for more details if the communication between the docking station and a number of chambers malfunctions.

15.21 External server unavailable

Connection to an external server enables treatment management in the MIRI® M multiroom IVF incubator from a PC, including assigning patients to docked chambers and accessing logged system data. If this connection is unexpectedly lost, the system will trigger a warning.

Confirm the device's disappearance from the server's database from a PC that is also connected to the server and used for managing treatments in the device in question.

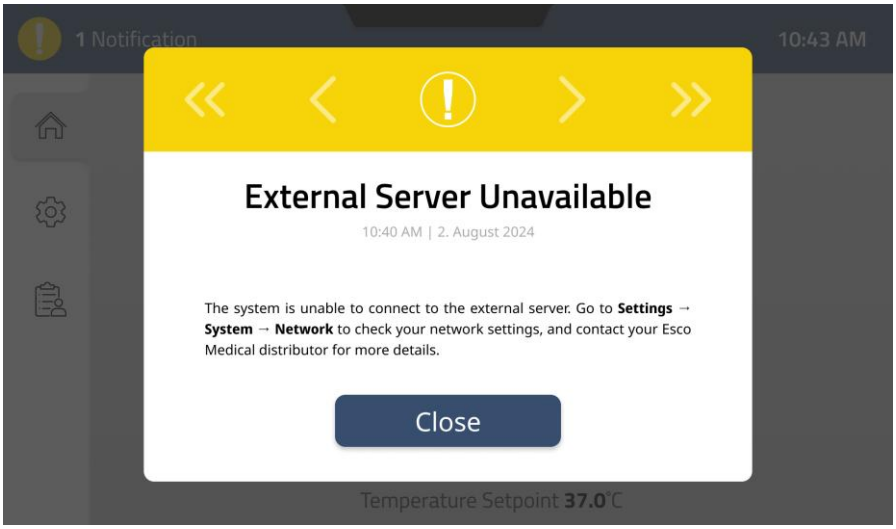


Figure 15.56 External server unavailable warning

This warning indicates a disruption in the network connection. To resolve the issue, check the status of the local network and restore connectivity. Once the network connection has been reestablished, confirm on the docking station display that communication with the server has resumed as depicted on Figure 15.56.

Please contact your Esco Medical distributor for more details if the external server connection is lost.

15.22 Software update available

During service inspection, software updates for the MIRI® M multiroom IVF incubator are brought on a USB-unit. Once connected, and the system detects the presence of a software update, the system will trigger a warning. To resolve this warning, simply follow the instructions in the pop-up and update the system software.

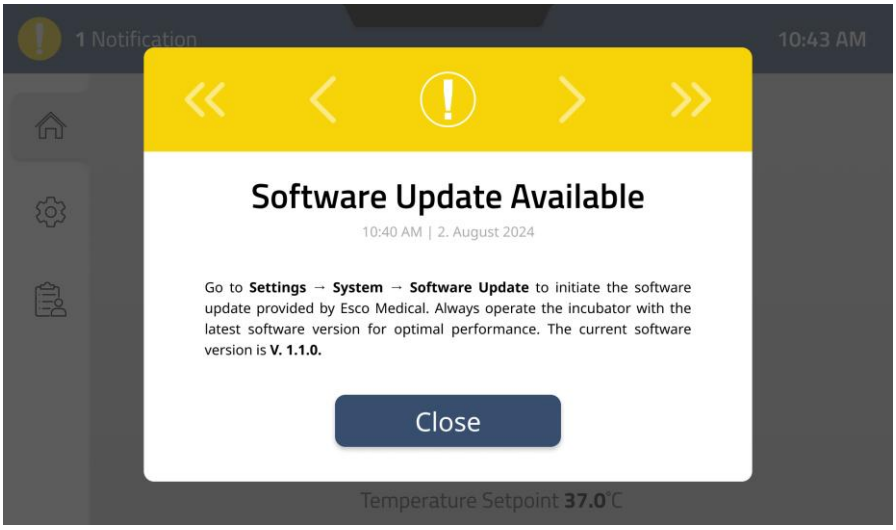


Figure 15.57 Software update available warning

Always operate the system with the latest software version provided by Esco Medical for optimal performance.

15.23 Summary of the alarms and warnings

The table below lists every alarm and warning scenario that may occur in the MIRI® M multiroom IVF incubators, including the underlying conditions, and how they are determined.

Table 15.1 Every possible alarm and warning in the MIRI® M multiroom IVF incubators

Alarm name	Conditions	How it is determined	Alarm group	Alarm priority
Low-temperature alarm	If the temperature of any temperature zone falls below 0.5 °C from the SP for more than 30 seconds.	Each temperature zone sensor reading	Technical	High priority alarm
High-temperature alarm	If the temperature of any temperature zone rises above 0.5 °C from the SP for more than 30 seconds.		Technical	High priority alarm
Low CO_2 concentration	When the CO_2 concentration drops by 0.2% from the SP, after 30 seconds the alarm will turn on	CO_2 sensor reading	Technical	High priority alarm
High CO_2 concentration	When the CO_2 concentration rises by 0.2% from the SP, after 30 seconds the alarm will turn on		Technical	High priority alarm
Low O_2 concentration	When the O_2 concentration drops by 0.2% from the SP, after 30 seconds the alarm will turn on	O_2 sensor reading	Technical	High priority alarm
High O_2 concentration	When the O_2 concentration rises by 0.2% from the SP, after 30 seconds the alarm will turn on		Technical	High priority alarm
Low incoming CO_2 pressure	If the pressure falls below 0.7 bar	Pressure sensor reading	Technical	High priority alarm
High internal CO_2 pressure	If the pressure rises above 1.5 bar	Pressure sensor reading	Technical	High priority alarm
Low incoming N_2 pressure	If the pressure falls below 0.7 bar	Pressure sensor reading	Technical	High priority alarm
High internal N_2 pressure	If the pressure rises above 1.5 bar	Pressure sensor reading	Technical	High priority alarm

Alarm name	Conditions	How it is determined	Alarm group	Alarm priority
Main gas pump fault state	If the main gas pump is malfunctioning or has stopped	No more electrical pulse feedback (tacho signals)	Technical	High priority alarm
CO_2 sensor fault state	If the CO_2 sensor is in a fault state	Sensor board circuit overload	Technical	High priority alarm
O_2 sensor fault state	If the O_2 sensor is in a fault state	Sensor board circuit overload	Technical	High priority alarm
Gas connection lost	Gas system unresponsive	No connection to gas system	Technical	High priority alarm
Gas system unavailable	Gas system unresponsive	Gas system unresponsive despite connection present	Technical	High priority alarm
Chamber slot fault state	Chamber slot connection is in a fault state	Extension board circuit overload	Technical	High priority alarm
Chamber slot power supply fault state	Chamber not charging despite established connection between chamber and slot	Extension board circuit malfunction related to power activation	Technical	High priority alarm
Chamber battery level critically low	If the battery level in a chamber drops to 15% of its full capacity	Fuel gauge monitoring of capacity	Technical	High priority alarm
Chamber tilt	If the chamber is tilted beyond a 5° angle	Gyroscope	Technical	High priority alarm
Lid Opened (*Chamber gas levels depleted*)	If the lid is opened while in use (gas will disperse)	Open the lid of a chamber while docked and undocked	Technical	Warning
UV-C light fault state	If the UV lamp is in a fault state	UV sensor reading	Technical	Warning
UV-C light circuit fault state	If the UV-C light circuit is in a fault state	UV-C light circuit overload	Technical	Warning
VOC/HEPA max running hours	If the HEPA filter has exceeded its maximum running hours	Time since last filter change	Technical	Warning
UV-C max running hours	If the UV Lamp has exceeded its maximum running hours	Time since last UV light change	Technical	Warning
Main gas pump max running hours	If the main gas pump has exceeded its maximum running hours	Time since last gas pump change	Technical	Warning
Chamber battery low	If the battery level in a chamber drops to 50% of its full capacity	Fuel gauge monitoring of capacity	Technical	Warning
Main gas pump pressure out of range	If the pump pressure deviates beyond the maximum range.	Pressure sensor reading	Technical	Warning

Alarm name	Conditions	How it is determined	Alarm group	Alarm priority
Three-way valve fault state	If the three-way valve is in a fault state	Three-way valve circuit overload	Technical	Warning
Release valve fault state	If the release valve is in a fault state	Release valve circuit overload	Technical	Warning
Chamber communication unavailable	Chamber unresponsive despite charging	Pogo pins damaged, extension board circuit overload, etc.	Technical	Warning
External server unavailable	No connection to the external server from the system	Network down / server crashed etc.	Technical	Warning
Software update available	USB unit with new software version connected to the system.	Available software update identified by the system	Technical	Warning
VOC/HEPA filter replacement	Upcoming deadline for VOC/HEPA filter replacement	Running time counter is within the configured reminder threshold	Technical	Information

15.24 Alarm verification

The table below lists how and when to verify and test the functionality of the alarm system.

Table 15.2 Alarm verification in the MIRI® M multiroom IVF incubators

Alarm name	How to verify an alarm	When to verify an alarm
High-temperature alarm	Put warm metal part in the middle of a chamber and close the lid	If you have a suspicion that alarms are malfunctioning
Low-temperature alarm	Put cold metal part in the middle of a chamber and close the lid	
High CO_2 concentration	Decrease the acclimatization phase length and decrease the setpoint enough to make it impossible for the system to adapt in time	
Low O_2 concentration	Increase the acclimatization phase length and decrease the setpoint enough to make it impossible for the system to adapt in time	
High O_2 concentration	Open the lid of a docked chamber and leave it open for 5 min	
Low CO_2 concentration	Open the lid of a docked chamber and leave it open for 3 min	
Low incoming CO_2 pressure	Disconnect the incoming CO_2 gas	
Low incoming N_2 pressure	Disconnect the incoming N_2 gas	
Chamber tilt	Tilt an undocked chamber beyond an angle of 5°	
Chamber battery level critically low	Undock a chamber and leave it undocked for over 30 minutes	
Main gas pump fault state	Disconnect the cable for the electrical pulse feedback from the mainboard PCB of the gas system.	

16 Pressure

16.1 CO_2 gas pressure

The CO_2 pressure is displayed in bar below the CO_2 concentration on the main page of the docking station display. The external pressure must be between 0.7 – 1.5 bar (10.15 – 21.76 PSI) at all times. It cannot be adjusted on the multiroom IVF incubator; it must be done on the external gas regulator.

Remember that the pressure limits have a pressure alarm if the pressure falls below 0.7 bar or rises above 1.5 bar (10.15 – 21.76 PSI).

The user cannot calibrate the internal pressure sensor.

16.2 N_2 gas pressure

The N_2 pressure is displayed in bar below the O_2 concentration on the main page of the docking station display. The external pressure must be between 0.7 – 1.5 bar (10.15 – 21.76 PSI) at all times. It cannot be adjusted on the multiroom IVF incubator; this must be done on the external gas regulator.

O_2 concentration control is achieved by infusing N_2 to push out excess O_2 in the gas system.

Remember that the pressure limits have a pressure alarm if the pressure falls below 0.7 bar or rises above 1.5 bar (10.15 – 21.76 PSI).

The user cannot calibrate the internal pressure sensor.

17 Software

The software installed on your MIRI® M multiroom IVF incubator is upgradeable. Whenever an important update is available, it will be provided to our distributors around the world – they will ensure that your incubator runs with the newest available software. A service technician can do this during a scheduled annual service.

The current MIRI® M multiroom IVF incubator software version is v1.2.0.

18 Data Logging

The data logging features are not built into the device but are managed through external software. This software allows you to record, track, and analyse data as needed for your application. For detailed setup instructions, configuration options, and troubleshooting, please refer to “MIRI® Evidence for MIRI® M multiroom IVF incubator User Manual”.

⚠ **The patient’s name and ID displayed on the MIRI® M Chamber screen cannot be considered a replacement for the clinic’s witness system or SOPs (standard operating procedures) for patient identification and embryo mix-up prevention.**

19 Cleaning Instructions

19.1 Consideration about a sterile device

The MIRI® M multiroom IVF incubator is not a sterile device. It is not delivered in a sterile state, and it will not be possible to keep it sterile while in use. However, the device's design was created with great care to make it easy for the user to keep the device sufficiently clean during use and not contaminate the key components.

The design features intended to provide cleanliness include:

- A circulated air system.
- External 0.22µm and internal 0.2µm HEPA filters which clean the incoming gas.
- A VOC/HEPA filter, which continually cleans the air inside the system.
- A removable heat optimization plate that can be cleaned (**not autoclaved!**); this part serves as the main holding area for samples – it should be the highest priority to be kept clean.
- A chamber with sealed edges that can be cleaned.
- The use of aluminium and PET parts that withstand cleaning well.

19.2 Manufacturer’s recommended cleaning procedure

Routine cleaning is recommended for regular maintenance. For event-related concerns such as media spills, visible accumulation of soil, or signs of contamination, the combination of standard cleaning procedures with a 70% ethyl alcohol solution and disinfection procedures using alcohol-free detergents is recommended. Clean and disinfect the MIRI® M multiroom IVF incubator immediately after a spill.

☞ **Always validate cleaning procedures locally; for more guidance, consult either your manufacturer or the distributor.**

19.2.1 Periodic cleaning of the chamber

Cleaning of the device (with no embryos inside).

Periodic cleaning of the chamber is required to ensure a sterile environment for future treatments. After ending a treatment and the sample is removed from the chamber, bring it to a clean surface. Good laboratory practice (GLP) such as wearing gloves is essential for ensuring the chamber is properly cleaned.

☞ **The specific timing of periodic cleanings may be decided entirely by the clinics. The manufacturer however recommends implementing some form of routine cleaning and disinfection.**

1. Ensure the chamber has been reset by pressing and holding the mute button for 3 seconds. At the end of the countdown, the chamber will reset.
2. Ensure the chamber is powered off by holding the alarm button for 3 more seconds. At the end of the countdown, the chamber will power off.
3. Clean the chamber with a 70% ethyl alcohol solution and wipe all surfaces with three wipes at least. Repeat until the wipes are no longer discoloured.
4. Change your gloves after 10 minutes of contact time and then spray sterile water on the surfaces before wiping them with a sterile wipe.
5. After cleaning, leave the device for some time to ensure that all detergent fumes have evaporated.
6. Finally, use purified or sterile water to wipe the surfaces of the device.
7. Dry the surface with clean and dry wipe.
8. Inspect the device:
    - If it is visually clean, consider it ready for use. Return the chamber to a docking station to re-gain the desired power, gas, and temperature levels.
    - If the device is not visually clean, repeat the process from step 3.

☞ **In the event of a spillage, it is important to note that the source may be external and not come from the dish in the chamber. In this scenario, the spillage can still contaminate the chamber along with the dish, and it is therefore recommended to immediately transfer that dish to another chamber. If the chamber is docked and the chamber lid can be opened enough to grab dish safely, do so. If it is not possible, carefully undock the chamber, bring it to a flat surface, and move the dish.**

19.2.2 Periodic cleaning of the docking station

1. For a thorough cleaning of the docking station, it is advised to undock all chambers docked in the docking station.

2. Power off the docking station and ensure that the power is disconnected.
3. Clean the device with a suitable 70% ethyl alcohol solution and wipe all surfaces with three wipes at least. Repeat until the wipes are no longer discoloured.
4. Change your gloves after 10 minutes of contact time and spray sterile water on the surfaces before wiping them with a sterile wipe.
5. After cleaning, leave the device for some time to ensure that all detergent fumes have evaporated.
6. Finally, use purified or sterile water to wipe the surfaces of the device.
7. Dry the surface with clean and dry wipe.
8. Inspect the device:
    - If it is visually clean, consider it ready for use. Reconnect the power supply and power on the docking station (refer to “9.1 Starting up the system”).
    - If the device is not visually clean, repeat the process from step 3.

⚠ **If the POGO pins of the Docking Station need to be cleaned, a cotton swab and a 70% ethyl alcohol solution should be used.**

19.3 Manufacturer’s recommended disinfection procedure

Disinfection of the device (with no embryos inside).

Good laboratory practice (GLP) such as wearing gloves is essential for ensuring the chamber is properly disinfected.
Proceed with the following steps (this procedure has been demonstrated during the on-site training program as part of the installation protocol):

1. Power off the MIRI® M multiroom IVF incubator (rear panel).
2. Open the lids.
3. Use a suitable detergent that does not contain alcohol, such as benzyl-alkyldimethyl chloride, to disinfect the internal surfaces, the heating optimization plates, and the lid’s top surface. Use sterile wipes to apply the alcohol-free disinfectant.
4. Wipe all internal surfaces and the top of the lid with three wipes at least. Repeat until the wipes are no longer discoloured.
5. Change your gloves and after 10 minutes of contact time, spray sterile water on surfaces and wipe them with a sterile wipe.
6. Inspect the device:
    - If it is visually clean, consider it ready for use. Reconnect the power supply and power on the docking station (refer to “9.1 Starting up the system”).
    - If the device is not visually clean, repeat the process from step 3.

20 Heating Optimization Plates

Insert the heating optimization plate. The heating optimization plate will ensure full contact with the dish which means that much more stable temperature conditions for the cells can be maintained. The heating optimization plate is designed to fit the chamber and can be easily removed for cleaning purposes.

⚠ **Do not autoclave the heating optimization plates. It will damage the plates as high temperature bends them out of shape.**

Place the dish where it fits the pattern. The heating optimization plates can be applicable for Nunc™, Falcon®, Oosafe®, and BIRR brand dishware. There is also a possibility to have a "plain-type" heating optimization plate.

☞ **Use only the correct type of heat optimization plates for your dishes.**



Figure 20.1 Examples of heating optimization plates

⚠ **Never incubate without the plates in place, and never use non-Esco Medical Technologies, UAB, approved heating optimization plates. This may cause dangerous and unpredictable temperature conditions that may be harmful to the specimens.**

21 Humidification

The MIRI® M multiroom IVF incubator has been primarily developed and designed for the incubation of gametes and embryos with an overlay of either Paraffin or mineral oil.

The MIRI® M multiroom IVF incubator must not be irrigated. Humidification of the MIRI® M multiroom IVF incubator will damage the device – condensation will block internal pipes and damage electronic parts.

⚠ **MIRI® M multiroom IVF incubator is not created to work with a water container inside. Otherwise, the device will be damaged. The safety and performance of the device will be**

affected.

22 Temperature Validation

The MIRI® M multiroom IVF incubator is equipped with 4 PT-1000 Class B sensors, their connections are located on the left side of the incubator behind push-to-open doors, above the VOC/HEPA filter.

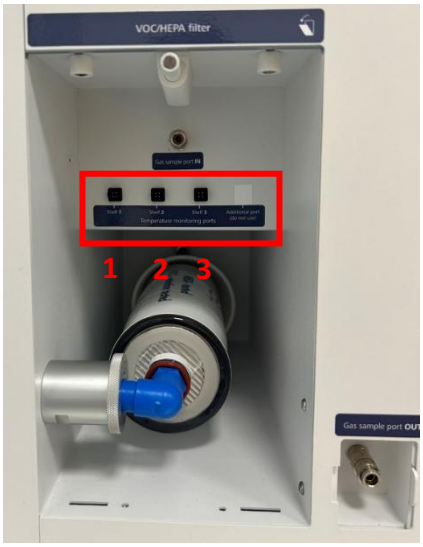


Figure 22.1 Connections of PT-1000 Class B sensors

Validation port allocation:

1. Port #1 is used for the bottom shelf (chamber #1).
2. Port #2 is used for the middle shelf (chamber #1).
3. Port #3 is used for the top shelf (chamber #1).
4. Port #4 is currently not usable.

For more information, please refer to section “7 Safety Labels and Symbols” of the User Manual.

These sensors serve external validation purposes. They are completely separated from the circuit of the device.

Temperature conditions in the chambers can be continuously logged through the external connectors on the device’s side without compromising its performance.

Any logging system that uses standard PT-1000 sensors may be used.

Esco Medical Technologies, UAB can supply an external logging system (MIRI® GA) for use with the PT1000 validation sensors.

23 Gas Concentration Validation

Gas concentration in the MIRI® M multiroom IVF incubator may be validated by taking a gas sample from gas sample port (**#1**) on the device's side, using a suitable gas analyser.

The gas analyser must have the possibility to return the gas sample to the incubator (**#2**). Otherwise, sampling can affect gas regulation and the gas analyser's reading.

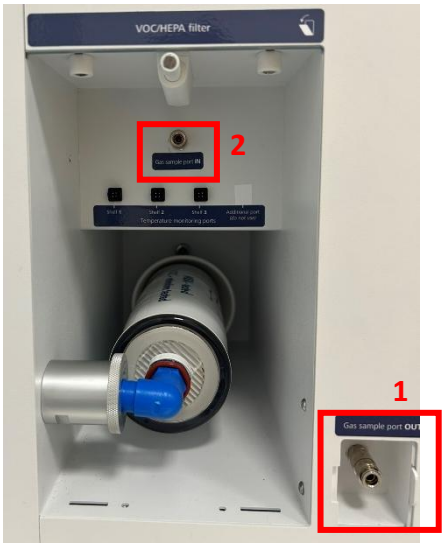


Figure 23.1 Gas sample ports

An external automatic gas sampler can be connected to the port for continuous validation.

Before any gas measurement, make sure that the lids have not been opened for at least 5 minutes.

Taking out a large sample volume may affect gas concentration in the system.

Make sure that the gas analyser is calibrated before use.

24 Alarm Switch for an External System

In order to connect the MIRI® M multiroom IVF incubator to an external monitoring system and ensure maximum safety, especially during nights and weekends, the incubator is equipped with a 3.5 mm jack connector on the back, which can be connected to a monitoring device.

When connecting the external alarm system using the 3.5mm jack, ensure that the cable length is more than 3 meters.

Whenever an alarm goes off (that could be a temperature alarm, gas alarm for CO_2 or O_2 levels, or pressure or high-pressure alarms for CO_2 and N_2 gases) or if the power supply to the device is suddenly lost, the switch indicates that the device needs to be inspected by the user. The connector can be connected either to a voltage source OR to a current source.

Note that if a current source is attached to the 3.5 mm jack connector, the maximum current rating is between 0 – 1.0 Amp.

If a voltage source is attached, then the limitation is between 0 – 50V AC or DC.

If there is no alarm, the switch within the device will be in the "ON" position, as illustrated below.

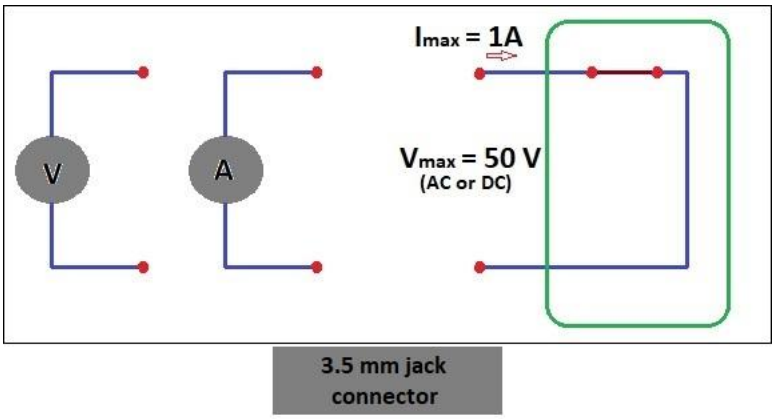


Figure 24.1 No alarm mode

Whenever the MIRI® M multiroom IVF incubator goes into an alarm mode, the switch status will change into 'open circuit'. It means that no current can run through the system anymore.

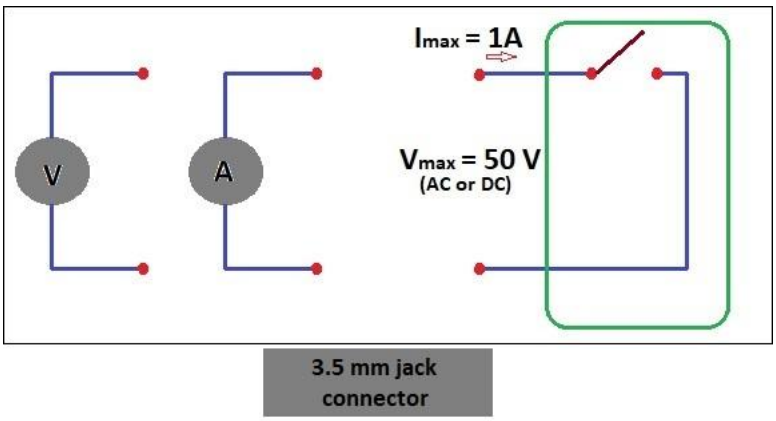


Figure 24.2 "Open circuit" alarm mode

25 Writing Area on the Chamber Lid

Each MIRI® M multiroom IVF incubator chamber's lid top is made from a whiteboard-type material optimized for writing text. The chamber's patient data or content can be noted down for easy reference during the incubation process.

The text can be wiped off with a cloth afterwards. Use only a suitable non-toxic pen that allows the text to be erased later and will not damage the incubated samples.



Figure 25.1 Area of the chamber lid for writing

26 Maintenance

The MIRI® M multiroom IVF incubator is designed to be user-friendly. Reliable and safe operation of this equipment is based on the following conditions:

1. Correct calibration of temperature and gas concentration, using high-precision equipment in the intervals prescribed based on clinical practice at the laboratory, where the MIRI® M multiroom IVF incubator is used. The manufacturer recommends that the period between validations should be no longer than 14 days.
2. VOC/HEPA filters must be replaced every 3 months.
3. In-line HEPA filters must be replaced every to years during annual maintenance.
4. Suitable cleaning, according to the intervals prescribed by the clinical practice in the laboratory where the MIRI® M multiroom IVF incubator is in use. The manufacturer does not recommend periods longer than 14 days between cleanings.

⚠ **It is essential to perform the inspection and service at the intervals indicated in the "35 Maintenance Guide" section of the User Manual. Failure to do so can have a severe adverse outcome, causing the device to stop performing as expected and causing damage to samples, patients, or users.**

⚠ **Warranty is considered void if service and maintenance procedures are not followed.**

⚠ **Warranty is considered void if service and maintenance procedures are carried out not by trained and/or unauthorized personnel.**

27 Emergency Procedures

If a temperature alarm is triggered in an undocked chamber:

- Dock the chamber in a docking station and observe whether the temperature reverts to the setpoint value.
- Alternatively, if the issue persists, relocate the samples from the affected chamber to a new unoccupied chamber, either promptly or by bringing both chambers to a flat surface and making the switch. Dock the new chamber in a docking station and remember to assign it to the patient in question.

If a temperature alarm is triggered in a docked chamber:

- Undock the chamber and dock it again in a different position in the docking station. Observe whether the temperature reverts to the setpoint value.
- Alternatively, if the issue persists, relocate the samples from the affected chamber to a new unoccupied chamber, either promptly or by bringing both chambers to a flat surface and making the switch. Dock the new chamber in a docking station and remember to assign it to the patient in question.

If multiple temperature alarms are triggered simultaneously:

- Relocate the samples from the affected chambers to new unoccupied chambers, either promptly or by bringing the chambers to a flat surface with the new chambers and making the switch. Dock the new chambers in a docking station and remember to assign it to the patient in question.
- Alternatively, should the issue occur in docked chambers, relocate the samples to a backup device not affected by the problem.

If the CO_2 concentration alarm is triggered:

- If the condition is temporary and the CO_2 concentration is too low, keep the lids shut. If the state is temporary and the CO_2 concentration is too high, open a few lids to vent out some CO_2.
- If the condition persists after a 60-minute period, undock the chambers containing samples and dock them in a different docking station not affected by the problem. Alternatively, relocate all samples to a backup device not affected by the problem. In all cases, the mobility of the chambers, allows the user to undock the chambers and dock them in another docking station while the condition is investigated.

If the O_2 concentration alarm is triggered:

- Usually, no emergency procedures are necessary in this case. If the condition persists after a 60-minute period, it may be advantageous to switch the gas system mode to CO_2 only (please refer to the section “14.3.7 Changing gas system mode”).

If the CO_2 pressure alarm is triggered:

- Inspect the external gas supply and gas supply lines. If the problem is external and not readily fixed, follow the guidelines under the “If the CO_2 concentration alarm is triggered” section.

If the N_2 pressure alarm is triggered:

- Inspect the external gas supply and gas supply lines. If the problem is external and not readily fixed, follow the guidelines under the “If the O_2 concentration alarm is triggered” section.

If a gas pump fault state alarm is triggered or the pump stops entirely:

- Inspect the internal gas pump. If the problem is not readily fixed it will cause both gas concentration and gas pressure alarms in the system. It is therefore recommended to follow the guidelines under the “If the CO_2 concentration alarm is triggered” section.

If connection to the gas connection is lost or unavailable:

- Inspect the connection the gas system. If the gas connection is unavailable, the technical connection is there but unresponsive, and if the gas connection is lost, then the technical connection is missing. If the problem is not readily fixed, follow the guidelines under the “If the O_2 concentration alarm is triggered” section.

If the chamber slot connection or the chamber slot power supply is in a fault state:

- Undock any chamber from where the issue is reported and dock it in another slot. Inspect the docking connections and continue operating the system with the remaining slots, until a service inspection has been conducted.

Total loss of power to or inside the device:

- Remove all connected chambers containing active samples and dock them in another docking station. Alternatively, relocate the samples entirely to a backup device that is not affected by the problem.
- Without the power source, the internal temperature of the MIRI® M multiroom IVF incubator chambers will drop below 35 °C after being 3 minutes in an ambient environment of 20 °C.*

- The CO_2 concentration will remain within 0.5% of the setpoint for 5 minutes if the lids remain closed.*
- If a longer time to turn the power back on is needed, it may be useful to cover the device with insulating blankets to slow the temperature drop.

If the battery level in a chamber is critically low:

- Dock the chamber in any docking station with an active power supply and wait for the chamber to recharge its battery level. If the chamber battery is malfunctioning or doesn't recharge, it's recommended to relocate the sample in the chamber to a new unoccupied chamber

Chamber tilt alarms:

- Place the chamber in a workstation or on a flat surface and inspect the sample. Opening and closing the chamber lid resolves the alarm state in the chamber. If the condition of the sample has not been affected by the tilt, close the lid again and continue with initial task.
- If the condition of sample has been affected by the tilt and has caused a spillage in the chamber, bring a new unoccupied chamber to the workstation, and relocate the sample to that. Dock the new chamber in a docking station and remember to assign it to the patient in question before continuing with the initial task.

⚠ **Warnings do not require immediate user intervention, as they don't lead directly to loss of incubation or sample degeneration, similar to alarms. However, warnings may escalate into alarm conditions if left unresolved, so prompt attention is recommended.**

* Based on internal testing. Performance may vary depending on various factors and environmental conditions.

28 User Troubleshooting

Table 28.1 Heating system (Docking station & docked chambers)

Symptom	Cause	Action
No heating, the display is off	The docking station is switched off on the ON/OFF Button on the back or not connected to the power source	Switch on the docking station or connect it to its power source
Temperature alarm is on	Temperature deviated more than 0.5 °C from the setpoint	Contact your Esco Medical distributor
No heating	The temperature setpoint is incorrect	Check the desired temperature setpoint
Heating is uneven	The system is not calibrated	Calibrate each zone according to the User manual, using a high-precision thermometer (see section 14.5.3)

Table 28.2 Heating system (Undocked chambers)

Symptom	Cause	Action
No heating, the display is off	Chamber is powered OFF or battery is depleted	Dock the chamber in an available slot in the docking station
Temperature alarm is on	Temperature deviated more than 0.5 °C from the setpoint	Dock the chamber in the docking station. If the issue persists, relocate any samples in the chamber and contact your Esco Medical distributor.

Table 28.3 CO_2 gas regulation

Symptom	Cause	Action
No CO_2 gas regulation	The system is not powered	Check the power mains
	The system is switched off	Switch the system on
	No CO_2 gas or wrong gas attached to CO_2 gas input	Check gas supply, make sure that the pressure is kept stable at 1.0 bar (14.50 PSI)
	The actual gas concentration is higher than the setpoint	Check the CO_2 setpoint
Poor CO_2 gas regulation	Chamber lid(s) are left open while docked	Close the lid(s)
	Seals are missing on the lid(s)	Undock the chamber(s) and contact your Esco Medical distributor
CO_2 gas concentration indicated red on the display	CO_2 gas concentration deviates more than ± 0.2% from the setpoint for at least 30 seconds	Allow the system to stabilize by closing all the lids
CO_2 gas pressure indicated red on the display	No/wrong CO_2 gas pressure in the system	Check CO_2 gas supply, make sure that the pressure is kept stable at 1.0 bar (14.50 PSI)

Symptom	Cause	Action
CO_2 sensor fault state alarm is triggered	Sensor board circuit overload	Contact your Esco Medical distributor

Table 28.4 O_2 gas regulation

Symptom	Cause	Action
No O_2 gas regulation	The system is not powered	Check the power mains
	The system is on standby or switched off	Switch the system on
	Gas system mode is set to only CO_2	Set the gas system mode to CO_2 and O_2 (see section 14.3.7)
	No N_2 or wrong gas type attached to N_2 gas input	Check N_2 gas supply, make sure that the pressure is kept stable at 1.0 bar (14.50 PSI)
	The actual gas concentration is higher than the setpoint	Check the O_2 setpoint
Poor O_2 gas regulation	Chamber lid(s) are left open while docked	Close the lid(s)
	Seals are missing on the lid(s)	Undock the chamber(s) and contact your Esco Medical distributor
O_2 gas concentration indicated red on the display	O_2 gas concentration deviates more than ± 0.2% from the setpoint for at least 30 seconds	Allow the system to stabilize by closing all the lids
N_2 gas pressure indicated red on the display	No/wrong N_2 gas pressure in the system	Check the N_2 gas supply, make sure that the pressure is kept stable at 1.0 bar (14.50 PSI). If O_2 regulation is not needed, set the gas system mode to CO_2 only (see section 14.3.7) to deactivate O_2 regulation and abort the N_2 alarm.
O_2 sensor fault state alarm is triggered	Sensor board circuit overload	Contact your Esco Medical distributor

Table 28.5 Gas system

Symptom	Cause	Action
Main gas pump fault state alarm is triggered	No more electrical pulse feedback from the main gas pump	Contact your Esco Medical distributor
Gas connection lost	No connection to the gas system	
Gas system Unavailable	Gas system unresponsive despite connection present	

Table 28.6 Display

Symptom	Cause	Action
Missing segment(s) in display	Failure in the PCB	Contact your Esco Medical distributor

Table 28.7 Chamber

Symptom	Cause	Action
Chamber tilt alarm is triggered	The chamber is tilted beyond a 5° angle	Inspect the chamber content on a flat surface and keep the chamber levelled during transport.
Docking position cannot detect the presence of a docked chamber	Chamber slot fault state	Dock the chamber in a different position and contact your Esco Medical distributor
Battery low warning or battery critical low alarm	Low battery level detected	Dock the chamber in the docking station for charging
Battery not charging after chamber is docked correctly	Chamber slot power supply fault state	Dock the chamber in a different position and contact your Esco Medical distributor
Unexpected chamber shutdown or chamber not operating while undocked	Fault in charging circuit	Relocate any samples in the chamber and contact your Esco Medical distributor
Physical Signs of Battery Damage (Swelling, Heat, Odor, or Leakage)	Internal battery failure or damage	Immediately relocate any samples and undock the chamber (if safe to do so). Move it away from flammable materials and use a Class D fire extinguisher in case of fire. Contact emergency services and notify your Esco Medical distributor (see section 13).

29 Specifications

Table 29.1 The MIRI® M multiroom IVF incubator specifications

Technical specifications	MIRI® M Docking Station
Overall dimensions (W × D × H)	806 × 670 × 643 mm
Weight	85.6 kg
Material	Mild steel / Aluminium / PET / Stainless steel
Power supply	115-230VAC, 50/60Hz, 1.2kW
Temperature range	35.0 – 39.0 °C
Temperature deviation from the setpoint	± 0.1 °C
Gas consumption (CO_2)[1] System stable (setpoint reached) - 6 chambers docked System stable (setpoint reached) - 18 chambers docked	 < 0.3 litre/hour < 0.5 litre/hour
Gas consumption (N_2)[2] System stable (setpoint reached) - 6 chambers docked System stable (setpoint reached) - 18 chambers docked	 < 3.0 litre/hour < 5.0 litre/hour
CO_2 range	3.0 – 12.0%
O_2 range	3.0 – 10.0%
CO_2 and O_2 concentration deviation from the setpoint	± 0.2%
CO_2 gas pressure (input)	0.7 – 1.5 bar (10.15 – 21.76 PSI)
N_2 gas pressure (input)	0.7 – 1.5 bar (10.15 – 21.76 PSI)
Alarms	Audible and visible for out-of-range temperature, gas concentration and/or gas pressure, low chamber battery, chamber tilt, main gas pump fault state
Operating altitude	Up to 2000 meters (6560 feet or 80kPa – 106kPa)
Shelf life	1 year
Lifetime	10 years

Table 29.2 The MIRI® M Chamber's specifications

Technical specifications	MIRI® M Chamber
Overall dimensions (W × D × H)	113 x 215 x 59 mm
Weight	1.03 kg
Material	Aluminium / PET / Stainless steel
Power input	24V DC, 1.58A, 38W
Battery	3.6V, 12.42 Wh, Li-Ion
Alarms	Audible and visible for out-of-range temperature, low chamber battery, and chamber tilt
Undocked chamber battery time	30 minutes (without the lid opening)
Lifetime	10 years

[1]Under normal conditions (CO_2 setpoint reached at 6.0%, all lids closed)

[2]Under normal conditions (O_2 setpoint reached at 5.0%, all lids closed)

30 Electromagnetic Compatibility

Electromagnetic Compatibility (EMC) refers to the ability of a device to function as intended in its electromagnetic environment without causing or experiencing unacceptable electromagnetic interference. It ensures that medical devices, like the MIRI® M multiroom IVF incubator, comply with standards such as IEC 60601-1 and IEC 60601-1-2, which address safety and performance in the presence of electromagnetic disturbances.

EMC tests applicable to the MIRI® M multiroom IVF incubator are outlined below:

Table 30.1 Applicable electromagnetic compatibility tests

<table>
<tr><th>Group/Test</th><th>Standard</th><th colspan="2">Compliance to standard</th></tr>
<tr><td colspan="4">Emissions tests</td></tr>
<tr><td>RF emissions</td><td>CISPR 11</td><td colspan="2">Yes, Group 1, Class A</td></tr>
<tr><td>Conducted Emissions (AC Port)</td><td>CISPR 11</td><td colspan="2">Yes, Group 1, Class A</td></tr>
<tr><td>Conducted Emissions (LAN Port)</td><td>CISPR 32</td><td colspan="2">Yes, Group 1, Class A</td></tr>
<tr><td>Harmonic Current Emissions</td><td>IEC 61000-3-2</td><td colspan="2">Yes, Class A</td></tr>
<tr><td>Voltage Changes, Voltage Fluctuations, Flicker</td><td>IEC 61000-3-3</td><td colspan="2">Yes</td></tr>
<tr><td colspan="4">The MIRI® M multiroom IVF incubator is suitable for use in professional healthcare facilities in environments not connected to the public low-voltage network.</td></tr>
<tr><td colspan="4">Immunity tests</td></tr>
<tr><td>Radio Frequency Radiated Electromagnetic Field Immunity</td><td>IEC 61000-4-3</td><td colspan="2">3 V/m
80 MHz to 2.7 GHz, 80% AM @ 1 kHz</td></tr>
<tr><td rowspan="8">Proximity to RF wireless fields</td><td rowspan="8">IEC 61000-4-3</td><td>Test freq. MHz</td><td>V/m</td></tr>
<tr><td>385</td><td>27</td></tr>
<tr><td>450</td><td>28</td></tr>
<tr><td>710, 745, 780</td><td>9</td></tr>
<tr><td>810, 870, 030</td><td>28</td></tr>
<tr><td>1720, 1845, 1970</td><td>28</td></tr>
<tr><td>2450</td><td>28</td></tr>
<tr><td>5240, 5500, 5785</td><td>9</td></tr>
<tr><td>RF Conducted Immunity</td><td>IEC 61000-4-6</td><td colspan="2">150 kHz to 80 MHz
3 V r.m.s before modulation
(6 V ISM bands)</td></tr>
<tr><td>Power frequency magnetic field</td><td>IEC 61000-4-8</td><td colspan="2">30 A/m at
50/60 Hz</td></tr>
<tr><td>Electric Fast Transients / Burst</td><td>IEC 61000-4-4</td><td colspan="2">± 2 kV power line
± 1 kV signal lines
(100 kHz repetition)</td></tr>
<tr><td>Voltage Dips and Interruptions</td><td>IEC 61000-4-11</td><td colspan="2">0%, 0.5 cycles
@ 0; 45; 90; 135; 180; 225; 270; 315°
0%, 1 cycle
70%, 25/30 cycles
Interruptions:
0%, 250/300 cycles</td></tr>
</table>

Group/Test	Standard	Compliance to standard	
Surge	IEC 61000-4-5	± 2kV line-to-ground ± 1kV line to line	
Electrostatic Discharge	IEC 61000-4-2	± 8kV contact Up to ± 15 kV air	
Proximity Magnetic Field	IEC 61000-4-39	Test frequency	A/m
		30 kHz	8
		134.2 kHz	65
		13.56 MHz	7.5

Medical Devices may be affected by cellular telephones and other personal or household devices not intended for medical facilities. It is recommended to ensure that all equipment used near the MIRI® M multiroom IVF incubators complies with the medical electromagnetic compatibility standard and checks before use that no interference is evident or possible. If the interference is suspected or potential, switching off the offending device is the standard solution, as is the usual practice in aircraft and medical facilities.

According to the EMC information, medical electrical equipment must be treated with special precautions indicated by EMC and installed and put into service. Portable and mobile RF communications equipment can affect medical electrical equipment.

Esco Medical Technologies, UAB certifies that the product has undergone testing in accordance with the specified EMC standards and has demonstrated expected performance under these conditions.

⚠ **The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it used in a residential environment (fort which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocation or re-orienting the equipment.**

⚠ **Do not use portable RF communications equipment closer than 30 cm (12 inches) to any part of the MIRI® M multiroom IVF incubator or its cables, as this can affect the equipment's performance.**

⚠ **Stacking and location of other electronic equipment close to any part of MIRI® M multiroom IVF incubator or its cables should be avoided as this can affect the performance of the equipment.**

⚠ **Cables and accessories other than those specified by the manufacturer must not be**

used, as their use may compromise safety and negatively affect EMC performance.

31 Validation Guide

31.1 Product release criteria

In Esco Medical Technologies, UAB, MIRI® M multiroom IVF incubator undergoes strict quality and performance testing before being released for sale.

31.1.1 Performance

Each component used in the MIRI® M multiroom IVF incubator is tested during the manufacturing process to ensure a defect-free device.

Before release, the incubators are tested in a release test lasting at least 24 hours, using accredited high-performance thermometers and gas analysers, along with real-time data logging, to ensure that the device lives up to expected performance standards.

Test I – Electrical safety compliance test
Test II – Functional test
Test III – Setup and calibration test
Test IV – Burn-in test
Test V – Release and calibration test

Additional visual inspection tests are also performed.

31.1.2 Electrical safety compliance test

Each device is subjected to an electric safety test using an electrical safety analyser to enable compliance with the international safety standard **IEC 60601**.

31.1.3 Functional test

Each device is subjected to functional tests using high-performance medical safety testers and measurement devices. These tests ensure that the device is assembled according to internal standards.

31.1.4 Setup and calibration test

Each device is subjected to setup and calibration tests using high-performance medical safety testers and measurement devices. These tests ensure that the device is assembled according to internal standards.

1. A chamber leakage test is performed in order to check the overall gas tightness of the

system. This test is performed in each chamber.

2. A gas concentration adjustment test is performed by calibrating the gas sensors and observing the readings afterwards.
3. A temperature adjustment test is performed by calibrating the temperature sensors and observing the readings afterwards.
4. A gas input pressure adjustment test is performed by adjusting the gas pressure valves on an external pressure regulator and observing the readings afterwards.
5. A chamber recovery test is performed by measuring the time the gas concentration inside the chamber takes to recover to the setpoint after a lid opening.

31.1.5 Burn-in test

Each device is subjected to a burn-in test using high-performance medical safety testers and measurement devices. This test ensures that the device is assembled according to internal standards and performs as expected during prolonged use.

Table 31.1 Burn-in tests and acceptance criteria

Test	Acceptance Criteria
Temperature Stability Test	± 0.1 °C
Gas Concentration Stability Test	± 0.1 %

31.1.6 Release and calibration test

Each device is subjected to a final release and calibration test using high-performance medical safety testers and measurement devices. This test ensures that the device is assembled according to internal standards, performs as expected during prolonged use and has not been affected by the tests done prior. In addition, final calibration procedures are performed before finishing.

Acceptance Criteria:
CO_2 and O_2 concentration readings deviate not more than ± 0.2 % from the setpoint.
Temperature readings deviate not more than ± 0.1 °C from the setpoint.

31.1.7 Visual inspection

- No misalignment in the lids.
- Each lid opens and closes easily.
- The seals for the lids must be appropriately attached and aligned.
- There are no unacceptable scratches or missing paint on the device.
- Overall, the device is presentable as a high-quality item.
- The heating optimization plates are checked for misalignment and shape inconsistencies. These are placed into the chambers to check for any mismatch due to the chamber and aluminum blocks' sizes.

- VOC/HEPA filter fits correctly and is easy to remove and insert.

32 Validation On-site

In keeping with established good medical device practice, we have set up a validation test regimen that must be completed before the device can be accepted into clinical use.

For more information, please refer to the Service manual of MIRI® M multiroom IVF incubator.

33 Testing

The following section outlines all testing procedures that must be completed and successfully passed before the device can be utilized for its intended purpose.

33.1 CO_2 gas supply

For the regulation system to maintain the correct CO_2 concentration in the MIRI® M multiroom IVF incubator chambers, the device must be connected to a stable source of 100% CO_2 at 0.7 – 1.5 bar (10.15 – 21.76 PSI) of pressure.

Measure the CO_2 concentration in the gas supply by routing the gas line into a bottle without a lid and a suitably large opening. Set the pressure/flow so that the bottle is flushed continually with gas, without increasing pressure in the bottle (i.e., the amount of gas exiting the bottle should be equal to the gas volume entering the bottle).

Pressure build-up will affect the measured CO_2 concentration, as CO_2 concentration is pressure dependent.

Sample from the bottle near the bottom with the gas analyzer.

PASS: CO_2 concentration measured must be between 98.0% – 100%.

Use of CO_2 gas with moisture will damage the flow sensors. Moisture level must be verified on the gas manufacturer's certificate: only 0.0 ppm v/v Max is permissible.

33.1.1 About CO_2 gas

Carbon dioxide (CO_2) is a colourless, odorless, non-combustible gas. Carbon dioxide above the triple point temperature of -56.6 °C and below the critical point temperature of 31.1 °C can exist in both a gaseous and a liquid state.

Bulk liquid carbon dioxide is commonly maintained as a refrigerated liquid and vapor at pressures between 1,230 kPa (approx. 12 bar) and 2,557 kPa (approx. 25 bar). Carbon dioxide may also exist as a white opaque solid with a temperature of -78.5 °C under atmospheric pressure.

⚠ **A high concentration of carbon dioxide (10.0% or more) in the surrounding atmosphere may cause rapid asphyxiation.**

The User should make sure the CO_2 used is safe and moisture-free. Below is a list of some standard component concentrations. Please note that the values given are NOT the proper amounts, only an example:

- Assay 99.9% v/v min.
- Moisture 50 ppm v/v max. (20 ppm w/w max).
- Ammonia 2.5 ppm v/v max.
- Oxygen 30 ppm v/v max.
- Oxides of Nitrogen (NO/NO_2) 2.5 ppm v/v max each.
- The non-volatile residue (particulates) 10 ppm w/w max.
- The non-volatile organic residue (oil and grease) 5 ppm w/w max.
- Phosphine 0.3 ppm v/v max.
- Total volatile hydrocarbons (calculated as methane) 50 ppm v/v max. of which 20 ppm v/v.
- Acetaldehyde 0.2 ppm v/v max.
- Benzene 0.02 ppm v/v max.
- Carbon Monoxide 10 ppm v/v max.
- Methanol 10 ppm v/v max.
- Hydrogen Cyanide 0.5 ppm v/v max.
- Total Sulphur (as S) 0.1 ppm v/v max.

33.2 N_2 gas supply

For the regulation to maintain the correct O_2 concentration in the MIRI® M multiroom IVF incubator chambers, the device must be connected to a stable source of 100% N_2 at 0.7 – 1.5 bar (10.15 – 21.76 PSI) of pressure.

Measure the N_2 concentration in the gas supply by routing the gas line into a bottle without a lid and a suitably large opening. Set the pressure/flow so that the bottle is flushed continually with gas, without increasing pressure in the bottle (i.e., the amount of gas exiting the bottle should be equal to the gas volume entering the bottle).

Sample from the bottle near the bottom with the gas analyser.

A gas analyser that can measure 0% O_2 accurately can be used.

PASS: N_2 concentration measured must be between 95.0% – 100%.

The use of N_2 gas with moisture will damage the flow sensors. Moisture level must be verified on the gas manufacturer's certificate: only 0.0 ppm v/v Max is permissible.

33.2.1 About N_2 gas

Nitrogen, at 78.08% by volume, makes up a significant portion of the Earth's atmosphere. It is a colourless, odourless, tasteless, non-toxic, and almost inert gas. Nitrogen is principally shipped and used in either gaseous or liquid form.

N_2 gas can act as a simple asphyxiant by displacing air.

The User should make sure the N_2 used is safe and moisture-free. Below is a list of some standard component concentrations. Please note that the values given are NOT the proper amounts, only an example:

- Research Grade 99.9995%.
- Contaminant.
- Argon (Ar) 5.0 ppm.
- Carbon Dioxide (CO_2) 1.0 ppm.
- Carbon Monoxide (CO) 1.0 ppm.
- Hydrogen (H_2) 0.5 ppm.
- Methane 0.5 ppm.
- Oxygen (O_2) 0.5 ppm.
- Water (H_2O) 0.5 ppm.

33.3 CO_2 gas pressure check

The MIRI® M multiroom IVF incubator requires a pressure of at 0.7 – 1.5 bar (10.15 – 21.76 PSI) on the input CO_2 gas line. This gas pressure must be held stable at all times.

For safety, this device has a built-in digital gas pressure sensor that monitors the incoming gas pressure and alerts the User if any drop is detected.

Remove the inlet gas line for the CO_2 gas. Attach the gas line to the gas pressure measuring

device.

PASS: The value must be at 0.7 – 1.5 bar.

Please refer to the "16.1 CO_2 gas pressure" section of the User Manual for more information.

33.4 N_2 gas pressure check

The MIRI® M multiroom IVF incubator requires a pressure of at 0.7 – 1.5 bar (10.15 – 21.76 PSI) on the input N_2 gas line. This gas pressure must be held stable at all times.

For safety, this device has a built-in digital gas pressure sensor that monitors the incoming gas pressure and alerts the User if any drop is detected.

Remove the inlet gas line for the N_2 gas. Attach the gas line to the gas pressure measuring device.

PASS: The value must be at 0.7 – 1.5 bar.

Please refer to the "16.2 N_2 gas pressure" section of the User Manual for more information.

33.5 Voltage supply

The voltage on-site must be verified.

Measure the output plug on the UPS that the MIRI® M multiroom IVF incubator will be connected to. Also, check that the UPS is attached to a properly grounded mains outlet.

Use a multimeter set for AC.

PASS: 230V ± 10.0%
115V ± 10.0%

33.6 CO_2 gas concentration check

The CO_2 gas concentration is checked for deviation. The gas sample port on the side of the device is used.

Remember not to open any lid at least 15 min before starting the test or during the testing itself.

Connect the gas analyser inlet tube to the sample port. Make sure that the fit is perfect and

that no air can enter or exit the system.

The gas analyser must have a gas return port connected to the incubator (i.e., another chamber). Only measure while the value on the gas analyser stabilizes.

For more information on performing the gas system calibration, please refer to the "14.5.1 Gas sensor calibration" and "14.5.2 Gas offset calibration" sections of the User Manual.

PASS: CO_2 concentration measured must not deviate more than ± 0.2% from the setpoint.

33.7 O_2 gas concentration check

The O_2 gas concentration is checked for deviation. The gas sample port on the side of the device is used. Use sample port on the side of the unit.

Remember not to open any lid at least 15 min before starting the test nor during the testing itself.

Connect the gas analyser inlet tube to the sample port. Make sure that the fit is perfect and that no air can enter or exit the system.

The gas analyser must have a gas return port connected to the incubator (i.e., another chamber). Only measure while the value on the gas analyser stabilizes.

For more information on performing the gas system calibration, please refer to the "14.5.1 Gas sensor calibration" and "14.5.2 Gas offset calibration" sections of the User Manual.

PASS: O_2 concentration measured must not deviate more than ± 0.2% from the setpoint.

33.8 Temperature check: chamber bottom

The first part of the temperature check is performed using a thermometer with a sensor suitable for measuring temperature in a droplet of media covered with Paraffin oil, with a resolution of 0.1°C as a minimum.

At least the maximum number of available chambers, but not more than 18 dishes, need to be prepared in advance (with at least one microdroplet of media approximately 10 – 100 µL in each dish). The media should be covered with a layer of Paraffin oil. The dishes do not need to be equilibrated, as the pH will not be measured during the validation tests.

The dishes are placed with at least one dish in each chamber. The dishes should be placed on

the corresponding size slot on the heat optimization plates.

1-hour stabilization time is required to complete this test after all previous steps are completed.

Open the chamber's lid, remove the cover from the dish and place the sensor tip inside the droplet.

If the measuring device has a fast response time (less than 10 seconds), the quick droplet measurement method should give a useful result.

If the measuring device is slower, a method for retaining the sensor in the droplet spot must be found. Usually, taping the sensor to a spot inside the chamber's bottom is possible. Then close the lid and wait until the temperature has stabilized. Be careful when closing the lid so as not to dislocate the sensor placement in the droplet.

Place the thermometer sensor on each zone and verify the temperature.

If calibration is needed, please refer to the "14.5.3 Temperature calibration" section of the User Manual for more information on how to perform the temperature calibration.

PASS: all temperatures measured on the bottom of the chambers where the dishes are located must not deviate more than ± 0.1°C from the setpoint.

33.9 Temperature check: chamber lids

The second part of the temperature validation is performed using a thermometer with a suitable sensor for measuring temperature on an aluminum surface, with a resolution of 0.1 °C as a minimum.

Tape the sensor to the center of the lid and carefully close the lid. Ensure that the tape keeps the sensor in complete contact with the surface area of the aluminum.

Taping the inside of the lid is not an optimal procedure, as the tape will act as an insulator from the heat generated by the bottom heater. However, it is a usable compromise if the taped area's size is kept small and the tape used is strong, thin and light.

Place the thermometer in each zone and verify the temperature.

PASS: all temperatures measured on the chambers' lid must not deviate more than ± 0.1 °C from the setpoint.

If calibration is needed, please refer to the "14.5.3 Temperature calibration" section for more information on how to perform the temperature calibration.

An iterative process may be needed if differences in the temperature levels are found and compensated through the calibration procedures. Bottom and lid temperatures will affect each other to some extent. There will be no crossover heat noticeable between chambers.

33.10 6-hour stability test

Following the careful validation of the single parameter, a 6-hour (minimum duration) check must be initiated.

The device must be set up according to the conditions under which it will be used in clinical practice.

If the preference of the CO_2 setpoint is 6.0% or the temperature is different from the set by default, an adjustment needs to be done before the test.

If the device will not be clinically operated with the O_2 regulation activated, but there is N_2 gas available, the test **should be conducted with O_2 regulation switched on and with an N_2 gas supply**.

If the N_2 is not available, the test can be done without it.

Check that parameters are logged and give meaningful readings. Let the device run without interfering for at least 6 hours. Analyse the graphs' results.

Pass I: Internal sensor temperature variation from set point is within ± 0.1°C absolute.
Pass II Internal sensor CO_2 concentration variation from setpoint within ± 0.2% absolute.
Pass III: Internal sensor O_2 concentration variation from setpoint within ± 0.2% absolute.

33.11 Cleaning

Always validate the cleaning procedures locally or consult Esco Medical Technologies, UAB or the distributor for more guidance.

After the testing has been conducted successfully, it should be cleaned again before the device is taken into clinical use (for cleaning instructions refer to the "19 Cleaning instructions" section of the User Manual).

- Inspect the device for physical signs of dirt or dust. The device should look generally tidy.

33.12 Test documentation form

☞ **Installation personnel must complete the "Installation report" form and submit it to Esco Medical Technologies, UAB before the device is used in clinical practice.**

33.13 Recommended additional testing

33.13.1 A VOC meter

With the VOC meter, a sample should be taken just above the MIRI® M multiroom IVF incubator. The reading should be noted down as the background VOC level. Then a sample is taken from the gas sample port.

PASS: 0.0 ppm VOC.

☞ **Ensure that the sample lines do not contain any VOC.**

33.13.2 A laser particle counter

A sample should be taken just above the MIRI® M multiroom IVF incubator with the laser particle counter. The reading should be noted down as the background particle level. Then a sample is taken from the gas sample port.

PASS: 0.3-micron < 100 ppm.

☞ **Ensure that the sample lines do not contain any particles.**

34 Clinical Use

Congratulations! Your device is now ready for clinical use with the validation tests completed and the test report submitted to Esco Medical.

It is necessary to monitor the performance of the device continuously.

Use the table below for in-use validation.

⚠ **Do not attempt to run the MIRI® M multiroom IVF incubator for clinical purposes without access to high-grade quality control validation equipment.**

Table 34.1 Validation intervals

Task	Every day	Every week
Temperature check		×
CO_2 gas concentration check	×	
O_2 gas concentration check	×	
Check log for anomalies		×
CO_2 gas pressure check	×	
N_2 gas pressure check	×	
pH check		×

34.1 Temperature check

The temperature check is performed using a high-precision thermometer. Place the thermometer on each zone and verify the temperature. Calibrate if necessary.

Please refer to the "14.5.3 Temperature calibration" section for more information on how to perform the temperature calibration.

PASS:

- **All temperatures measured on the bottom of the chamber in the locations where the dishes would be placed must not deviate more than ± 0.1°C from the setpoint.**
- **All temperatures measured on the lid must not deviate more than ± 0.1°C from the setpoint.**

34.2 CO_2 gas concentration check

The CO_2 gas concentration is checked for deviations. The gas sample port on the left side of the device is used for this. Use sample port for validation. It is essential to have a high-precision gas analyzer for CO_2 and O_2 available to do the test.

Please follow these simple rules while testing gas concentration:

- Check the CO_2 gas setpoint.
- Check the actual CO_2 gas concentration to ensure the setpoint is reached and gas concentration is stabilized around the setpoint.
- Remember not to open any lids for at least 15 min, before starting the test or during the testing itself.

For more information on performing the CO_2 gas calibration, please refer to the "14.5.1 Gas sensor calibration" and "14.5.2 Gas offset calibration" sections of the User Manual.

PASS: CO_2 concentration measured must not deviate more than ± 0.2% from the setpoint.

34.3 O_2 gas concentration check

The O_2 gas concentration is checked for deviations. The gas sample port on the left side of the device is used for this. Use sample port for validation. It is essential to have a high-precision gas analyzer for CO_2 and O_2 available to do the test.

Please follow these simple rules while testing gas concentration:

- Check the O_2 gas setpoint.
- Check the actual O_2 gas concentration to ensure the setpoint is reached and gas concentration is stabilized around the setpoint.
- Remember not to open any lids for at least 15 min before starting the test or during the testing itself.

For more information on performing the O_2 gas calibration, please refer to the "14.5.1 Gas sensor calibration" and "14.5.2 Gas offset calibration" sections of the User Manual.

PASS: O_2 concentration measured must not deviate more than ± 0.2% from the setpoint.

Gas analysers use a small pump to draw out gas from the location being sampled. The pump capacity varies from brand to brand. The gas analyser's ability to return the gas sample to the incubator (loop sampling) avoids negative pressure and ensures accuracy. The performance of the MIRI® M multiroom IVF incubator will not be affected, as the gas in the chamber is not under pressure, and the reading is just an artefact based on unsuitable measuring equipment. Contact Esco Medical or the local distributor for further guidance.

34.4 CO_2 gas pressure check

The MIRI® M multiroom IVF incubator requires a pressure of 0.7 – 1.5 bar (10.15 – 21.76 PSI) on the input CO_2 gas line. This gas pressure must be held stable at any time.

For safety reasons, this device has a built-in digital gas pressure sensor control that monitors the incoming gas pressure and alerts the user if any drop is detected.

The CO_2 pressure is displayed in the bar below the CO_2 concentration on the main page of the docking station display.

PASS: The value must be 0.7 – 1.5 bar.

Please refer to the "16.1 CO_2 gas pressure" section of the User Manual for more information.

34.5 N_2 gas pressure check

The MIRI® M multiroom IVF incubator requires a pressure of 0.7 – 1.5 bar (10.15 – 21.76 PSI) on the input N_2 gas line. This gas pressure must be held stable at any time.

For safety reasons, this device has a built-in digital gas pressure sensor control that monitors the incoming gas pressure and alerts the user if any drop is detected.

The N_2 pressure is displayed in the bar below the O_2 concentration on the main page of the docking station display.

PASS: The value must be 0.7 – 1.5 bar.

Please refer to the “16.2 N_2 gas pressure” section of the User Manual for more information.

35 Maintenance Guide

Your MIRI® M multiroom IVF incubator from Esco Medical Technologies, UAB contains high precision quality components. These components are chosen to ensure the high durability and performance of the equipment.

However, continuous validation of the performance is necessary.

User validation should be done to a minimum according to instructions given in the "32 Validation On-Site" section of the User Manual.

If problems are encountered, contact Esco Medical or your local representative.

⚠ **Any maintenance should only be done by a trained service engineer.**

However, to sustain the high-performance level and avoid system errors, the owner is responsible for having a certified technician who performs components replacements according to Tables 35.1 and 35.2.

These components must be replaced in the time intervals specified below. Failure to follow these instructions may, in the worst-case scenario, result in damage to the specimens in the incubator.

⚠ **Warranty void if service intervals are not followed according to Tables 35.1 and 35.2.**

⚠ **Warranty void if non-original parts are used or non-trained and/or non-authorized personnel carry out the servicing.**

The tables below show time intervals at which components must be replaced.

Table 35.1 Service interval plan for MIRI® M Docking Station

Component name	Every 3 months	Years 1, 3, 7, 9	Years 2, 4, 6, 8	Year 5	Year 10
VOC/HEPA filter capsule	×				
External 0.22µm HEPA filter for incoming CO_2/N_2 gas		×	×	×	×
Internal 0.2µm PTFE 50mm filter			×		×
O_2 sensor		×	×	×	×
CO_2 sensor				×	×
UV light		×	×	×	×
UV ballast				×	×
Cooling fan				×	×
Gas pump			×		×
RTC battery				×	×

Table 35.2 Service interval plan for MIRI® M Chamber

Component name	Every 5 years
Li-Ion battery	×

⚠ Service of the MIRI® M Chamber can only be done by trained service engineers at Esco Medical Technologies, UAB.

Table 35.3 Miscellaneous parts and their inspection intervals

Component name	Every year
Festo tubes	×
Silicone tubes	×
Soft-close mechanisms	×

35.1 VOC/HEPA filter capsule

The VOC/HEPA filter capsule is placed on the incubator device's left side behind push-to-open doors for easy replacement. In addition to the active carbon component, this capsule also has an integrated HEPA filter inside, enabling it to remove particles and volatile organic compounds from the air being re-circulated to the chambers. Because of the carbon component's lifespan, all VOC filters' lifetime is limited, and they must be replaced often. According to Table 35.1, the VOC/HEPA filter installed in the MIRI® M multiroom IVF incubator must be replaced every 3 months.

Please follow these safety precautions when changing the VOC/HEPA filter:

- Always use the original filter (contact Esco Medical or your local distributor for more details or ordering).
- Change the filter every 3 months.
- Failure to change the filter on time will result in low/no air-cleaning within the system.
- Warranty is void if a wrong/non-original filter is used.

Please refer to the “12.1 Installation procedure of a new VOC/HEPA filter” section for the replacement instructions.

35.2 External 0.22µm HEPA filter for incoming CO_2 and N_2 gas

The bigger 64mm round-shape external 0.22µm HEPA filter for CO_2 and N_2 gas removes any particles found in the incoming gas. Failure to use the external HEPA filter may cause damage to the high precision flow sensor or compromise the CO_2/N_2 regulation system.

Please follow these safety precautions when changing the filter:

- Always use the original filter (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the filter once every year.
- Failure to change the filter on time will result in low/no cleaning of incoming CO_2/N_2 gas.
- Warranty is void if a wrong/non-original filter is used.

Please refer to the service manual for replacement instructions.

35.3 Internal in-line 0.2µm HEPA filter for incoming CO_2 and N_2 gas

The smaller 33mm round-shape internal in-line 0.2µm HEPA filter for CO_2 and N_2 gas further acts to remove any particles left in the incoming gas that have passed through the external HEPA filter. Failure to use the internal HEPA filter may cause damage to the high-precision flow sensor or compromise the CO_2/N_2 regulation system.

Please follow these safety precautions when changing the filter:

- Always use the original filter (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the filter once every 2 years.
- Failure to change the filter on time will result in low/no cleaning of incoming CO_2/N_2 gas.
- Warranty is void if a wrong/non-original filter is used.

Please refer to the service manual for replacement instructions.

35.4 O_2 sensor

Gas regulation uses the reading of the O_2 sensor to calculate the O_2 concentration where a solenoid valve is used to input fresh N_2 gas if the concentration of O_2 gas is too high. The lifetime of this sensor is limited due to its construction. From the day the sensor is unpacked, a chemical process is activated within the sensor core. The chemical reaction is entirely harmless to its surroundings, but it is necessary for measuring the amount of oxygen with a very high precision that is needed in the MIRI® M multiroom IVF incubators.

After 1-year, the chemical process in the sensor core stops and the sensor must be replaced. Therefore, it is essential to replace this sensor **WITHIN a year from the date it was unpacked and installed.**

Oxygen sensors must be replaced at least once every year from the date they were installed in the device, regardless of whether the incubator is being used.

In the MIRI® M multiroom IVF incubator "Installation report" form, the user will see when this sensor was installed. This date must be used to calculate the date for the following O_2 sensor change.

Please follow these safety precautions when changing the sensor:

- Always use an original O_2 sensor (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the O_2 sensor every 1 year from the date of the previous sensor installation.
- Failure to change the oxygen sensor on time will result in low/no regulation of O_2 concentration.
- Warranty is void if a wrong/non-original sensor is used.

Please refer to the service manual for replacement instructions.

35.5 CO_2 sensor

Gas regulation uses the reading of the CO_2 sensor to calculate the CO_2 concentration where a solenoid valve is used to input fresh CO_2 gas if the concentration of CO_2 gas is too low.

Esco Medical recommends the sensor to be replaced once every 5 years.

Please follow these safety precautions when changing the sensor:

- Always use an original CO_2 sensor (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).

- Change the CO_2 sensor every 5 years from the date of installation.
- Failure to change the CO_2 sensor on time can result in low/no CO_2 gas concentration regulation.
- Warranty is void if a wrong/non-original sensor is used.

Please refer to the service manual for replacement instructions.

35.6 UV light

For safety reasons and to clean the recirculating air, this device has a 254 nm UV light installed. The UV-C light has a limited lifetime and must be replaced every year, according to Table 35.1.



Figure 35.1 UV light warning

Exposure to UV-C radiation may cause severe damage to your skin and eyes. Always power off before removing any cover.

UV light should only be changed by a trained user or technician.

Please follow these safety precautions when changing the UV-C light:

- Always use an original UV-C light bulb (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change UV-C light bulb within 1 year from date of installation.
- Failure to change the UV-light bulb on time can result in contamination build-up.
- Warranty is void if the wrong/non-original UV-light bulb is used.

Please refer to the service manual for replacement instructions.

35.7 UV ballast

For safety reasons and to clean the recirculating air, this device has a 254 nm UV light installed. UV ballast enables the UV light to operate correctly. Failure to maintain this part may impact the functionality of the UV-C light.

⚠ **Exposure to UV-C radiation may cause severe damage to your skin and eyes. Always power off before removing any cover.**

⚠ **UV ballast should only be changed by a trained user or technician.**

Please follow these safety precautions when changing the UV ballast:

- Always use an original UV ballast (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change UV ballast every 5 years from date of installation.
- Failure to change the UV ballast on time can result in UV light malfunctions.
- Warranty is void if the wrong/non-original UV ballast is used.

Please refer to the service manual for replacement instructions.

35.8 Cooling fan

The cooling fan is responsible for cooling down the electronics installed in the device. A breakdown of the cooling fan will stress the components due to temperature rise within the system. It may cause the electronics to drift, resulting in incorrect temperature and gas regulation.

To avoid this, Esco Medical recommends that the cooling fan be replaced once every 5 years.

Please follow these safety precautions when changing the cooling fan:

- Always use an original fan (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the fan every 5 years from the date of installation.
- Failure to change the fan may cause the electronics to drift, resulting in low temperature and gas regulations.
- Warranty is void if the wrong/non-original fan is used.

Please refer to the service manual for replacement instructions.

35.9 Gas pump

The gas pump is used to mix and recirculate gases in the device through the VOC/HEPA filter, UV light and the chambers. In time the performance of this pump can be affected, causing a longer recovery time. Therefore, this pump must be replaced **every two years** to maintain the fast recovery time after lid openings.

Please follow these safety precautions when changing the gas system pump:

- Always use an original gas pump (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the gas pump every 2 years from the date of installation.
- Failure to change the pump may cause slow recovery times or breakdowns.
- Warranty is void if the wrong/non-original pump is used.

Please refer to the service manual for replacement instructions.

35.10 RTC battery

A coin-cell battery maintains the Real-Time Clock (RTC) and system time when the main power is off. It is located on the single-board computer inside the MIRI® M Docking Station. If this battery fails, the computer will lose its system time and date upon shutting down, which may result in corrupted data logs. Therefore, this battery must be replaced **every five years** to maintain the integrated computer's full functionality.

Please follow these safety precautions when changing the coin-cell battery:

- Always use a coin-cell battery (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the coin-cell battery every 5 years from the date of installation.
- Failure to change the battery may cause slow recovery times or breakdowns.
- Warranty is void if the wrong/non-original battery is used.

Please refer to the service manual for replacement instructions.

35.11 Festo tubes

The internal Festo tubes are used to transport mixed gas through the VOC/HEPA filter, UV light and the Chambers. Over time, some particles or residue can build up and have slight effect on gas recirculation.

⚠ **All Festo tubes must be visually checked during the annual maintenance service visit.**

☞ **All service engineers must have extra Festo tubes in order to be able to replace them during a maintenance service visit.**

Please follow these safety precautions when changing gas lines:

- Always use original Festo tubes (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Failure to change the Festo tubes may cause slow recovery times or breakdowns.
- Warranty void if wrong/non-original Festo tubes are used.

Please refer to the service manual for replacement instructions.

35.12 Silicone tubes

The internal silicone tubes are used to transport mixed gas through the VOC/HEPA filter, UV light and the Chambers. Over time, some particles or residue can build up and have slight effect on gas recirculation.

⚠ **All silicone tubes must be visually checked during the annual maintenance service visit.**

☞ **All service engineers must have extra silicone tubes in order to be able to replace them during a maintenance service visit.**

Please follow these safety precautions when changing gas lines:

- Always use original silicone tubes (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Failure to change the silicone tubes may cause slow recovery times or breakdowns.
- Warranty void if wrong/non-original silicone tubes are used.

Please refer to the service manual for replacement instructions.

35.13 Soft-close mechanism

Soft-close mechanisms are used to ensure smooth and easy docking of the MIRI® M Chamber to the MIRI® M Docking Station. Over time, due to constant use, some internal parts can get worn out and can impact their effectiveness.

⚠ **All soft-close mechanisms must be visually checked during the annual maintenance service visit.**

☞ **All service engineers must have extra soft-close mechanisms in order to be able to replace them during a maintenance service visit.**

Please follow these safety precautions when changing gas lines:

- Always use original soft-close mechanisms (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Failure to change the soft-close mechanisms may impact their effectiveness.
- Warranty void if wrong/non-original soft-close mechanisms are used.

Please refer to the service manual for replacement instructions.

35.14 Li-Ion battery

All MIRI® M Chambers have integrated Li-Ion batteries that can be recharged and deliver power to certain components, ensuring the chamber's full functionality. However, due to continuous use, battery degradation occurs over time, impacting the battery's overall lifespan. Therefore, this battery must be replaced **every five years** to maintain full functionality of the MIRI® M Chamber.

Please follow these safety precautions when changing the Li-Ion battery:

- Always use a Li-Ion battery (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the Li-Ion battery every 5 years from the date of installation.
- Failure to change the battery may cause reduced lifespan and lower overall battery runtime.
- Warranty is void if the wrong/non-original battery is used.

Please refer to the service manual for replacement instructions.

⚠ **Service of the MIRI® M Chamber can only be done by trained service engineers at Esco Medical Technologies, UAB.**

⚠ **Unauthorized handling may cause electric shock, fire, or device failure.**

35.15 Software update

If Esco Medical has released a newer version of the software or firmware, they should be installed on the MIRI® M multiroom IVF incubator (docking station and chambers) during the yearly scheduled service.

Please refer to the service manual for instructions on how to update the software and firmware.

36 Installation Guide

This section describes when and how to install the MIRI® M multiroom IVF incubator in the IVF clinic.

36.1 Responsibilities

All technicians or embryologists installing the MIRI® M multiroom IVF incubator must identify problems and perform any necessary calibrations, adjustments and maintenance.

Installation personnel performing MEA (Mouse Embryo Assay) must be thoroughly familiar with the MEA and all functions of the device, calibration and testing procedures, and devices used in the device's testing. MEA test is a supplemental installation test and is not mandatory.

All individuals who will perform installation, repair and/or maintenance of the device must be trained by Esco Medical. Experienced service technicians or embryologists conduct training to ensure that the installation personnel clearly understand the device's functions, performance, testing, and maintenance.

Installation personnel must be updated regarding alterations or additions to this document and the "Installation report" form.

36.2 Before installation

2 – 3 weeks before the installation is due, the user/owner at the clinic is contacted via e-mail to plan the exact time to perform the installation. When a convenient time has been determined, travel and accommodation arrangements can be made.

The released the MIRI® M multiroom IVF incubator must be sent 1 – 3 weeks before installation, depending on the clinic location. Check with shippers about local customs regulations and delays that could arise from that.

The clinic must be informed about the site requirements before installation and should have signed the customer requirement checklist:

1. The lab must have an idle sturdy and stable lab bench for standing operation.
2. The MIRI® M multiroom IVF incubator weighs approximately 85.6 kg, one chamber weights 1.03 kg.
3. The required space for placement is 0.8 m (width) × 0.7 m (depth) × 0.7 m (height).
4. Temperature control should be able to maintain a stable temperature, environmental temperature shall never exceed 30 °C or fall below 18 °C.
5. Uninterrupted power supply (UPS) with 115/230 V~, 50/60Hz, minimum 1.2 kW.
6. Proper grounding.

7. CO_2 gas outlet with 0.7 – 1.5 bar above ambient, recommended is 1.0 bar.
8. N_2 gas outlet with 0.7 – 1.5 bar above ambient if the clinic uses reduced oxygen concentrations, recommended is 1.0 bar.
9. If premixed gas used gas outlet used 0.7 – 1.5 bar above ambient, recommended is 1.0 bar.
10. Tubes that fit 4 mm hose end and HEPA filter.

36.3 Preparing for installation

For more information, please refer to the Service manual of MIRI® M multiroom IVF incubator.

36.4 Installation procedure at the site

For more information, please refer to the Service manual of MIRI® M multiroom IVF incubator.

36.5 User training

1. Mains switch on/off.
2. Explain the MIRI® M multiroom IVF incubators essential functions and incubation with a multi-room facility to store the samples.
3. Explain temperature control in the MIRI® M multiroom IVF incubator (direct heat transfer with heated lids).
4. Demonstrate how to dock chambers in the docking station safely, including how new chambers may be commissioned to an active device.
5. Demonstrate how to undock chambers from the docking station safely.
6. Explain how chambers may be moved freely from one docking station to another, including how bringing a chamber to a docking station with different setpoints will overwrite the chamber's stored setpoints from the previous docking station.
7. Explain how to add and remove a sample from an undocked chamber (including why it's not practical to do while the chamber is docked).
8. Explain how to insert and remove heating optimization plates from chambers.
9. Explain how to establish a connection and re-connection to an external server.
10. Explain how patient assignment and un-assignment are done from a PC connected to the device via the external server.
11. Explain the visual aids for connecting gas supplies to the corresponding gas inlets.
12. Explain how to interact with the touch interface on the docking station display, including how to navigate to the various settings.
13. Explain how to change setpoints for temperature, CO_2 and O_2.
14. Explain how N_2 is used to suppress the O_2 concentration.
15. Explain how to change gas regulation mode from CO_2 and O_2 to only CO_2.

16. Demonstrate how to replace the VOC/HEPA filter, including how to reset the VOC/HEPA filter counter (Instructions are located in section "12.1 Installation procedure of a new VOC/HEPA filter" in the User Manual).
17. Demonstrate how to reset the patient information in a chamber, whether docked or undocked.
18. Demonstrate how to power off an undocked chamber, including how powering it back on is done by simply docking the chamber again.
19. Demonstrate how to perform measurement and calibration of temperature with external equipment.
20. Demonstrate how to perform measurement and calibration of gas concentrations with external equipment.
21. Explain the correct approach for ceasing alarms occurring in the docking station, including how to mute active alarms and acknowledge already ceased alarms.
22. Explain the correct approach for ceasing alarms occurring in undocked chambers, including how to mute active alarms and acknowledge already ceased alarms.
23. Explain the correct approach for handling multiple alarms and warnings occurring in the device at the same time, including locating the notifications log and understanding the order of severity for the notifications.
24. Explain the correct approach for handling warnings occurring in the device.
25. Explain how to clean the device and heating optimization plates.
26. Emergency procedures (are located in section "27 Emergency Procedures" in the User Manual).

The user/owner is informed that the first VOC/HEPA filter change is 3 months after installation and after that in 3-month intervals. The first service check under normal circumstances is after 1 year.

36.6 After the installation

When the installation trip is finished, a copy of the original "Installation report" form must be signed by installation personnel and sent to Esco Medical support team <support-medical@escolifesciences.com>. It will be saved with the device records. According to the ISO procedure and Medical Device Regulation, a paper copy of the completed and signed installation test form is stored in the unique device's device history record. The date of installation is written in the device overview file.

Suppose the MIRI® M multiroom IVF incubator user or owner make inquiries about a written "Installation report". The completed and signed "Installation report" form must be sent to the clinic. Any deviations/complaints/suggestions from the Installation visit are managed according QMS procedures. If a critical error has occurred, information about this will be reported directly to QA/QC.

⚠ **If the MIRI® M multiroom IVF incubator fails any of the "Installation report" form acceptance criteria, or it in any way suffer from a severe error and incubation parameters are compromised, the MIRI® M multiroom IVF incubator must be taken out of service until it is repaired/exchanged, or a new test approves the MIRI® M multiroom IVF incubator. The User and owner must be informed about this and arrangements to solve the problems must be initiated.**

37 Other Countries

37.1 Switzerland

The Swiss Authorised Representative CH-REP symbol is placed on each medical device.



Figure 37.1 Swiss Authorised Representative

Swiss Authorised Representative's contact e-mail is “Vigilance@medenvoyglobal.com”.

38 Reporting on Serious Incidents

In case of any serious incidents that have occurred in relation to the device should be reported to Esco Medical Technologies, UAB by contacts, written on the contact information page, and the Authorised Representative in which the user and/or patient is established.

For contacting Authorised Representative, please refer to the "Other Countries" section of the User Manual according to your country.