User Manual

MIRI® and MIRI® Humidity Multiroom IVF Incubators

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Rx only

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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 medical 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 medical 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 medical 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 medical 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 medical device.
- An improper power supply such as low voltage, incorrect voltage, defective wiring or inadequate fuses.
- Accident, alteration, abuse or misuse of the medical 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 medical 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 medical 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 medical 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 device, which has 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 TECHNOLOGIES, UAB 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 that are needed for operating the equipment on a day-to-day basis; then, review the alarm functions. The menu functions of the user interface detail information that is required 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 33 – 36. The maintenance guide is described in detail in section 37. The installation procedures are described in detail in section 38.

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® Multiroom Incubator or MIRI® Humidity 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 equipment performance.
- Any internal adjustment, modification or maintenance to this equipment must be undertaken by qualified service personnel.
- If the equipment 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 equipment and the support stand/base separately.
- The use of any hazardous materials in this equipment 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 equipment is used in a manner not specified by this manual, the protection provided by this equipment may be impaired.

- 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® family's multiroom IVF incubators are intended to be used to provide a stable culture environment at or near body temperature and CO_2/N_2 or premixed gases and humidification for the development of gametes and embryos during in vitro fertilization (IVF)/assisted reproduction technology (ART) treatments.

4 About the product

The Esco Medical MIRI® and MIRI® Humidity multiroom IVF incubators are CO_2/O_2 gas incubators.

Direct warming of the dishes in the chambers gives superior temperature conditions in comparison to conventional multiroom IVF incubators.

The temperature in the chamber will remain stable up to 1 °C (even when a lid is open for 10s) and will recover within 1 min after the lid is closed.*

The Esco Medical MIRI® and MIRI® Humidity multiroom IVF incubators have 6 completely separate culture heat chambers. Each chamber has its own heated lid and heating optimization plate for a Petri dish. MIRI® and MIRI® Humidity capacity for a 35 mm Petri dish is 48 pcs and the capacity for 60 mm or 4-well Petri dishes is 24 pcs.

To ensure maximum performance, the system of MIRI® and MIRI® Humidity multiroom IVF incubator have 12 separate PID temperature controllers. They control and regulate temperature in culture chambers and lids. Chambers do not affect each other's temperatures in any way. The top and the bottom of each chamber is separated with a PET layer so that the lid temperature would not affect the bottom. For validation purposes, each chamber has a PT-1000 sensor built in. The circuitry is separated from the device's electronics, so it remains a truly separate validation system.

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

The MIRI® and MIRI® Humidity multiroom IVF incubator needs 100% CO_2 and 100% N_2 or premixed gas (for instance 5% CO_2; 5% O_2 and 90% N_2) to control the CO_2 and O_2 concentrations in the culture chambers.

A dual beam infrared CO_2 sensor with extremely low drift rates controls the CO_2 concentration. A chemical medical grade oxygen sensor controls the level of O_2.

Gas recovery time is less than 3 min. after opening the lid for up to 10 seconds.* To validate gas concentration, the MIRI® and MIRI® Humidity multiroom IVF incubator is fitted with 6 gas sample ports that allow the user to sample gas from the individual chamber.

The MIRI® and MIRI® Humidity multiroom IVF incubator features gas recirculation where gas is continuously put into the chamber and taken out at the same rate. Gas is cleaned via 254 nm UVC light with direct gas contact between the bulb and gas, then through a VOC/HEPA filter. The UVC light has filters that inhibit any 185 nm radiation that would produce dangerous ozone. The VOC/HEPA filter is located under the UVC light.

UVC light modules and VOC/HEPA filters are not applied in the MIRI® Humidity multiroom IVF incubator.

Complete gas repletion in the system takes less than 5 min.

The total gas consumption is very low. Less than 2 l/h CO_2 and 12 l/h N_2 in use.

For safety reasons the MIRI® and MIRI® Humidity multiroom IVF incubator has a gas control system that consists of pressure regulator (preventing dangerous gas pressure problems), flow PCB (actual consumption can be accumulated), gas pressure sensors (then user knows that the pressure and variation can be logged to avoid dangerous conditions), gas filters (to avoid valve problems).

Petri dish location in a chamber is easy to reach and locate because of the chamber numbering and the ability to write on the white lid with a pen.

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

☞ **Refer to section "16.4 The culture mode" for more detailed information.**

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

The upright LED display in MIRI® and MIRI® Humidity multiroom IVF incubators is large, clear and easy to read from a distance. The user can tell if the parameters are correct without going near the device.

The user can plug any standard BNC pH probe to the device and measure the pH in the samples at will.

The MIRI® and MIRI® Humidity multiroom IVF incubator can be connected to a PC running the Esco Medical Data logger software for long term data logging and data storage.

MIRI® family`s multiroom IVF incubators are stationary devices. The term refers to equipment that, once installed and placed into service, is not intended to be moved from one place to another.

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

Esco Medical MIRI® family's 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® and MIRI® Humidity multiroom IVF incubators. Also, the MIRI® and MIRI® Humidity 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

The device is packed in a cardboard box, and it is wrapped in polyethylene. The box is affixed to a pallet with special straps.

A visual inspection should be done if there is any damage. If no damage is found, the MIRI® and MIRI® Humidity multiroom IVF incubator can be prepared for transport.

These labels must be glued on the box:

- Label with handling symbols and marked packing date.
- Label with the product name and serial number.

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 for a new release test.
- The device can be stored at temperatures between -20 °C and +50 °C.
- Keep away from direct sunlight.
- Do not use if the packing material is damaged.
- Keep dry.

⚠ **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:

- 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).
- Environmental temperature: 18 – 30 °C.
- Away from direct sunlight.
- Kept dry.
- For indoor use only.

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

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 filter must be discarded following the applicable national regulations for special solid waste.

6 Supplied service parts and accessories

Service parts provided with the device are listed below:

- 1 × VOC/HEPA filter (only for MIRI® model).
- 1 × humidity bottle with 2 humidity bottle tubes (only for MIRI® Humidity model).
- 1 × bottle holder (only for MIRI® Humidity model).
- 2 × external 0.22µm HEPA filters for input gas supply.
- 6 × heating optimization plates.
- 1 × USB stick containing Esco Medical Data logger software and PDF version of the English version of the user manual and all available translations.
- 1 × medical grade power cord.
- 1 × 3.5 mm external alarm jack connector.

⚠ **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® and MIRI® Humidity multiroom IVF incubators.

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
	Fragile

Label	Description
	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 MIRI® and MIRI® Humidity multiroom IVF incubators

Description	Image
USB communication port	

Description	Image
CO_2 inlet*	
N_2 inlet	
BNC pH	
Alarm port	
Chambers numbers are indicated in the top corner of the lid with a label	
Maximum pressure 0.8 bar	
VOC/HEPA filter (only for MIRI® model)	
Gas sample ports	
PT 1000 validation sensors	

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

Chamber numbers are shown in the picture below and are also indicated on the top of the lids with label:

Figure 7.1 Chamber numbers on MIRI® multiroom IVF incubators

* The user should connect the premix gas container to this inlet when intending to use the premix gas mode.

Figure 7.2 Chamber numbers on MIRI® Humidity multiroom IVF incubators

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. Read the user manual thoroughly before use.
3. Always keep these instructions easily accessible near the device.

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 is 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 the device 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 and 100% concentration N_2 gases. Premix gas can also be used (for more information please refer to the 14.1 "Installation procedure at the site" section of the User Manual).
10. Always use an external 0.22µm HEPA filter to input CO_2 and N_2 gases.
11. Do not use the device if the room temperature exceeds 30 °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.
15. Follow the instructions on how to correctly connect MIRI® Humidity multiroom IVF incubator's humidification bottle in the "23.2 MIRI® Humidity multiroom IVF incubator" section of the User Manual.

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 apparatus has been dropped, exposed to rain or moisture or does not operate normally. The MIRI® and MIRI® Humidity 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 lids open for more than 10 sec while in use.
7. The VOC/HEPA filter must be changed every 3 months (it does not apply for MIRI® Humidity multiroom IVF incubator).
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 0.4 – 0.6 bar (5.80 – 8.70 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 (it does not apply for MIRI® Humidity multiroom IVF incubator).

9 Getting started

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

1. Follow the guidelines in the safety instructions and warnings section.
2. Connect the medical grade power cord to the UPS.
3. Connect the power cable to the MIRI® or MIRI® Humidity multiroom IVF incubator.
4. Connect the gas lines.
5. Set the gas pressure on the external gas regulator at 0.4 – 0.6 bar (5.80 – 8.70 PSI).
6. Switch on the MIRI® or MIRI® Humidity multiroom IVF incubator in the back.

7. Observe for standard functionality.
8. Let the device warm up and stabilize for 20 min.
9. Follow the guidelines in the validation guide (refer to the “33 Validation guide" section of the User Manual)
10. Complete user training (instructions must be read prior to setting up the device).
11. After a burn-in phase of 24 hours, the device is ready for use IF the testing is **successful**.

☞ **Clean and disinfect the device before use. It is not delivered sterile or in a clinically acceptable cleanliness state. Refer to the "21 Cleaning instructions" section of the User Manual for the manufacturer's recommended guidelines!**

10 Mains connection

The MIRI® and MIRI® Humidity 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 means to isolate the MIRI® and MIRI® Humidity 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 – 240V AC 50 – 60 Hz.

Figure 10.1 Power supply

11 Gas connections

There are two gas inlets on the back of the device. These ports are marked "CO_2 100% Inlet" and "N_2 100% Inlet".

Figure 11.1 Gas inlets on the back of MIRI® and MIRI® Humidity multiroom IVF incubators

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 2.0% to 9.9%.

The N_2 inlet should be connected to 100% concentration N_2 if low oxygen conditions are required. The O_2 control in the chambers is available in the range from 5.0% - 20.0%. O_2 concentration control is achieved by infusing N_2 to push out excess O_2 in the gas system.

The premixed gas inlet should be connected to the CO_2 inlet.

☞ The inlet's gas pressure should be between 0.4 – 0.6 bar (5.80 – 8.70 PSI) and it must be kept stable!

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

Figure 11.2 Pressure regulator

Connect the 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 sudden pressure

fluctuation. Use the supplied 0.22µm HEPA filter on the gas line just before the inlet on the MIRI® and MIRI® Humidity multiroom IVF incubator. Notice the direction.

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

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

The MIRI® and MIRI® Humidity multiroom IVF incubators can also run on premixed gas. It is a more expensive option for gas consumption. It also means the user cannot adjust the CO_2 and O_2 concentrations without changing the gas supply. Please read the "14 Installation with premixed gas" section below for more detailed information about using the device on premixed gas.

12 VOC/HEPA filter (applicable only for the MIRI® model)

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® family's 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 an 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® multiroom IVF incubator. Before entering the MIRI® 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® multiroom IVF incubator.

The combined VOC/HEPA filter is mounted on the device's back to ease access and replacement.

12.1 Installation procedure of a new VOC/HEPA filter

Two safety caps that are installed on the filter's elbows must be discarded during unpacking. Correct filter placement is crucial for a system's performance.

VOC/HEPA filter must be changed every 3 months. Mark the date when it is put on and make sure to keep this interval!

The VOC/HEPA filter must be changed when there are no embryos in the device.

Start by aligning the blue fittings of the filter into the filter holder sockets. The flow arrow on the MIRI® multiroom IVF incubator and the filter should point in the same direction (see Figure 12.1).

Figure 12.1 The flow arrow on the MIRI® multiroom IVF incubator

Then, simultaneously press both angle fittings (using both hands) into the holes till they snap into place (see Figure 12.2). The last 4 mm step should feel stiff.

Figure 12.2 VOC/HEPA filter insertion and removal procedure

Figure 12.3 Correctly installed VOC/HEPA filter

⚠ **A VOC/HEPA filter that has been installed incorrectly may cause gas leakage and contamination to appear in the incubator.**

The VOC/HEPA filter is removed by gently pulling it straight out using both hands (see Figure 12.2).

⚠ **Never run the MIRI® multiroom IVF incubator if the VOC/HEPA filter is missing! Gas leakage and dangerous particle contamination could occur!**

13 User interface

In the following chapters, the functions associated with keys and menu items are going to be explained.

User interface handles daily functions and more advanced adjustments that might be made to the device. The main keys and their functions are presented in Table 13.1.

Table 13.1 Main keys and their purpose

Description	Image
User interface	

Description	Image
ON/OFF switch Located in the REAR of the device	
Alarm button It mutes an audible alarm and visually indicates the alarm condition by a flashing red backlight. The audio alarm will come back on after 5 min. It can be muted again.	
Display panel Shows the information on the current status of the device. The display consists of 7 x high brightness 16 segment LEDs. The first one is red to indicate a user warning. The other 6 are blue and used to display normal running conditions.	
Setpoint key It is used to select items on the menu and to change their status. It is also used to change the temperature and gas setpoints.	
Arrow keys up, down & right It is used to navigate through the menu and to change values for temperature and gas concentrations.	

13.1 Activating the heat and gas controls

Heat and gas controls are activated using the "ON/OFF" switch in the rear of the incubator.

Soon after system activation, the main display will alternate the reading between the following 4 parameters:

Temperature	= System temperature in °C
CO_2	= CO_2 concentration in %
O_2	= O_2 concentration in %
Mode	= Open/Oil Culture

13.2 System menu

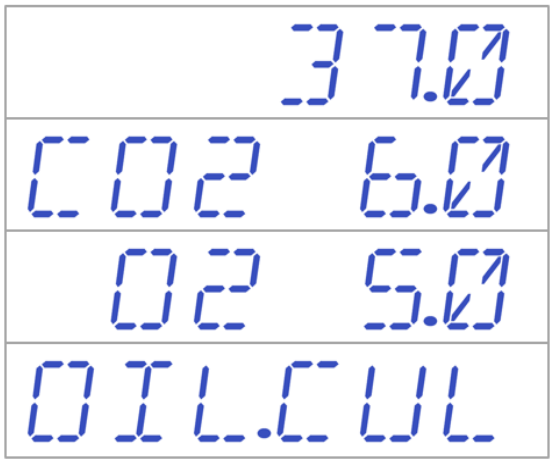
Press and hold (⇧) and (⇩) keys together for 3 seconds to access the menu.
Navigate the menu using:

- Right (⇨) arrow key = enter.
- Up (⇧) and Down (⇩) arrow keys = previous OR next.
- SP/Enter key = change OR accept.

Press and hold (⇧) and (⇩) keys together for 3 seconds to exit the menu entirely.

13.3 Status

Alternating between the 4 values under normal running conditions.



Force the scrolling between parameters with (⇨) key.

☞ **If the O_2 regulator is deactivated, the system will display "O2 OFF".**

☞ **If the intended use mode is "Open Culture" (no oil or Paraffin overlay culture), the device needs to be set to that mode and will display:**

☞ **If any of the lids are opened or not closed properly, the incubator's screen will display:**

13.4 Main menu

Press the (⇨) key to enter the menu.
The user can exit the menu by pressing the (⇧) key.

Temperature is the first category when the user enters the menu.
Press the (⇨) key to enter the Temperature sub-menu.

Press the (⇩) key to scroll further down in the menu.
Press the (⇨) key to enter the CO_2 sub-menu.

Press the (⇩) key to scroll further down in the menu.
Press the (⇨) key to enter the O_2 sub-menu.

Press the (⇩) key to scroll further down in the menu.
Press the (⇨) key to enter the UVC light sub-menu (**not available in the MIRI® Humidity multiroom IVF incubator**).

Press the (⇩) key to scroll to the last category on the menu.
Press the (⇨) key to enter the Service sub-menu.

13.4.1 Temperature sub-menu

Press the (⇨) key on the temperature menu to enter the temperature sub-menu.
Calibrate the temperature by holding down the SP key and using (⇧) and (⇩) keys to adjust the setpoint values. The first item in the temperature sub-menu is T1 sensor calibration:

Use (⇩) or (⇧) keys to move between the sub-menu items. You can also go back to the main menu by pressing the (⇧) key when the menu shows "T1 CAL".

Each chamber has two internal temperature sensors. One in the chamber's lid and another in the chamber's bottom.

Example – how to calibrate the temperature:

During calibration, the temperature must be measured with a suitable and calibrated device. With a quality thermometer, it has been estimated that T1 is 37.4 °C. Locate "T1 CAL" in the sub-menu, press and hold the SP key. The display should show:

Adjust the temperature by pressing the (⇧) key 4 times while still holding the SP key down. The display will show the steps 37.1, 37.2, 37.3 and 37.4. When temperature equals the measured temperature (in this instance it is 37.4), let go of the SP key. The new value is stored and the temperature sensor calibration for the T1 area has been completed.

Calibration procedure is the same for T1 – T12.

Calibration value change procedure should only be done with a calibrated device and by a trained user or the technician, according to specific measurements.

Exit the menu by pressing the (⇧) key.

13.4.2 CO_2 sub-menu

Press the (⇨) key on the CO_2 menu to enter the CO_2 sub-menu.
The first item in the CO_2 sub-menu is CO_2 sensor calibration:

Calibrate the CO_2 by holding down the SP key and using (⇧) and (⇩) keys to adjust the setpoint value. Use (⇩) or (⇧) keys to move between the sub-menu items. You can also go back to the main menu by pressing the (⇧) key when the menu shows "CO2.CAL".

Toggle CO_2 regulation on/off by holding the SP key and pressing (⇧) or (⇩) keys.

The default status for the CO_2 control is OFF.

Press the (⇩) key to move to the next item in the CO_2 sub-menu. Here you can see the CO_2 flow rate display (the flow rate cannot be adjusted):

It shows the present flow of CO_2 gas through the flow sensor. The volume is shown in liters/hour. It will usually change depending on the current concentration of CO_2 in the system.

Press the (⇩) key to move to the next item in the CO_2 sub-menu. Here you can see the CO_2 internal pressure (it cannot be adjusted on the MIRI® and MIRI® Humidity multiroom IVF incubator. It is adjusted on the external gas regulator):

The value is in bar and it must be 0.4 – 0.6 bar (5.80 – 8.70 PSI) at all times.

Example – how to calibrate CO_2:

CO_2 gas concertation must be measured with a suitable and calibrated device. The real CO_2 concertation has been estimated to be 6.4% on one of the gas sample ports. Every port is suitable for this purpose.

Locate "CO2 CAL" in the CO_2 sub-menu and press and hold the SP key. The display will show:

Adjust the calibration to the desired level by pressing (⇧) or (⇩) keys. In this case, we want to adjust the value to 6.4%. Press (⇧) key 4 times. The display will show 6.0, 6.1, 6.2, 6.3 and 6.4. When CO_2 equals measured CO_2, (in this instance it is 6.4) let go of the SP key. The new value is stored and the CO_2 sensor calibration has been completed.

☞ **CO_2 gas recovery to 6% is less than 3 minutes while inflating 100% CO_2 gas.***

☞ **Calibration is performed by adjusting the CO_2 concentration according to the gas sampling outlet's measurement by an external reliable CO_2 measurement device.**

⚠ **Calibration value change procedure should only be done with a calibrated device and by a trained user or the technician, according to specific measurements.**

Exit the menu by pressing the (⇧) key.

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

13.4.3 O_2 sub-menu

Press the (⇨) key on O_2 to enter the O_2 sub-menu.
The first item in the O_2 sub-menu is O_2 sensor calibration:

Calibrate O_2 by holding down the SP key and using (⇧) and (⇩) keys to adjust the setpoint value.

Use (⇩) or (⇧) keys to move between the sub-menu items. You can also go back to the main menu by pressing the (⇧) key when the menu shows "O2 CAL".

Toggle O_2 regulation on/off by holding the SP key and pressing (⇧) or (⇩) keys.

The Default status for the O_2 control is OFF.

Press the (⇩) key to move to the next item in the O_2 sub-menu. Here you can see the N_2 flow rate display (the flow rate cannot be adjusted):

It shows the present flow of N_2 gas through the flow sensor. The volume is shown in liters/hour. It will usually change depending on the current concentration of O_2 in the system.

Press (⇩) key to move to the next item in the O_2 sub-menu.

Here you can see the N_2 internal pressure (it cannot be adjusted on the MIRI® and MIRI® Humidity multiroom IVF incubator. It is adjusted on the external gas regulator):

The value is in bar and it must be 0.4 – 0.6 bar (5.80 – 8.70 PSI) at all times.

Example – how to calibrate the O_2:

O_2 gas concentration must be measured with a suitable and calibrated device. The real O_2 concentration has been estimated to be 5.3% on one of the gas sample ports. Every port is suitable for this purpose.

Locate "O2 CAL" in the O_2 sub-menu and press and hold the SP key. The display will show:

Adjust the calibration to the desired level by pressing (⇧) or (⇩) keys. In this case, we want to adjust to 5.3%. Press (⇧) key 3 times. The display will show 5.0, 5.1, 5.2 and 5.3. When O_2 equals measured O_2 (in this instance it is 5.3), let go of the SP key. The new value is stored and the O_2 sensor calibration has been modified.

☞ **Calibration is performed by adjusting the O_2 concentration according to the gas sampling outlet's measurement by an external reliable O_2 measurement device.**

☞ **Calibration value change procedure should only be done with a calibrated device and by a trained user or the technician, according to specific measurements.**

Exit the menu by pressing the (⇧) key.

13.4.4 UVC light sub-menu (applicable only for the MIRI® model)

Press the (⇨) key on UV-C to enter the UVC light sub-menu.

Toggle UV-C light regulation on/off by holding the SP key and pressing (⇧) or (⇩) keys.

☞ **The default status for the UV-C light is "ON".**

The UV light will automatically switch off when the device is powered off.

☞ **For optimal air cleaning, it is recommended to have the UV-C light set to "ON" when the device is used.**

Exit the menu by pressing the (⇧) key.

13.4.5 Service sub-menu

Press the (⇨) key on the service menu to enter the service sub-menu.
The service sub-menu is locked as default.

If the right (⇨) arrow key is pressed for longer than 10 sec., the service menu will be unlocked, and the display will show the current firmware version number:

☞ **Ver 2.0 is only shown as an EXAMPLE. Please refer to the "19 Firmware" section of the User Manual for the latest firmware version.**

Use (⇩) or (⇧) keys to move between the sub-menu items.

The display will show the "GAS" function:

Press the (⇨) key to enter and press (⇩) or (⇧) keys to choose "PREMIX" or "CO_2/N_2" options while holding the SP key. Let go of the SP key when the desired gas mode is displayed. It will be now stored.

When choosing the gas mode, screen will alternate between:

When using the premixed gas mode, it is necessary to use a premixed gas with HIGHER gradation than the setpoint. For example, if you need to achieve 5% CO_2 gas setpoint, premixed gas should have AT LEAST 6% CO_2 in its mixture.

Exit the menu by pressing the (⇧) key.

14 Installation with premixed gas

The MIRI® and MIRI® Humidity multiroom IVF incubators have primarily been designed to run on 100% CO_2 and 100% N_2. However, it can also run with premixed gas. Nevertheless, running on 100% CO_2 and 100% N_2 gases, the device accuracy will be significantly higher (< 0.2% from the selected setpoint) compared to using the device on premixed gas. A premixed gas is usually used for simpler incubation systems that do not contain any CO_2 and O_2 sensors and have no gas mixing capabilities.

This section describes how to install the MIRI® or MIRI® Humidity multiroom IVF incubator at an IVF clinic running with premixed gas.

The premixed gas concentration must be chosen specifically to match the requirement of the culture medium. As the MIRI® and MIRI® Humidity multiroom IVF incubators cannot alter the concentration, the media's resulting pH will depend on the correct concentration choice.

Be advised that premixed gas consumption will be significantly higher compared to pure gas. Also, recovery time to the setpoint will be longer.

14.1 Installation procedure at the site

Follow all the instructions in the installation manual, the guidelines of the User Manual's safety instructions and the warnings section.

Instead of connecting MIRI® or MIRI® Humidity multiroom IVF incubators to either only 100% CO_2 or both 100% CO_2 and 100% N_2, the incubator is attached to only a premixed source.

Premixed gas should only be connected to the CO_2 gas port (a 4 mm diameter hose barb).

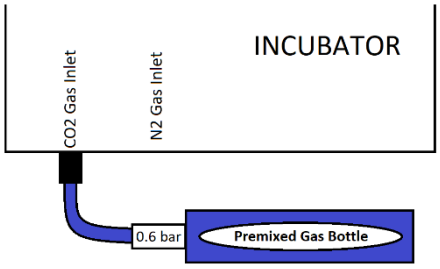


Figure 14.1 Premixed gas connections to the incubator

Please read the "11 Gas connection" section of the User Manual above for more detailed gas connection requirements.

Measure the gas concentration from the premixed gas bottle with a calibrated gas analyzer. The result of the measurement is significant for the set-up of the device and the correct operation.

CO_2 regulation must be "ON" in the MIRI® or MIRI® Humidity multiroom IVF incubator menu. Both CO_2 and O_2 are set to "OFF" option by default.

The MIRI® or MIRI® Humidity multiroom IVF incubator must be set to premix gas work mode.

Please follow these instructions:

Press and hold (⇧) and (⇩) keys together for 3 seconds to access the menu.
Press the (⇨) key to enter the menu.

The user can exit the menu by pressing the (⇧) key.

Use (⇩) or (⇧) keys to move between the menu items.
When “SERV” is displayed, press the (⇨) key to enter the Service sub-menu.

The display will show the currently installed firmware version (if the menu is unlocked. For more information refer to the "13.4.5 Service sub-menu" section of this User Manual).

Use (⇩) or (⇧) keys to move between the sub-menu items.
The display will show the "GAS" function:

Press the SP key and select the "PREMIX" or "CO_2/N_2" gas mode by pressing (⇩) or (⇧) keys.

When choosing the gas mode, screen will alternate between:

Let go of the SP key when the “PREMIX” gas mode is displayed. The selected mode is now stored.

Exit the menu by pressing the (⇧) key.

☞ **When using the premixed gas mode, it is necessary to use a premixed gas with HIGHER gradation than the setpoint. For example, if you need to achieve 5% CO_2 gas setpoint, premixed gas should have AT LEAST 6% CO_2 in its mixture.**

⚠ **O_2 control TURNS OFF when premix mode is activated.**

For changing the CO_2 and O_2 setpoints, please read the "16.2 The CO_2 gas concentration setpoint" and "16.3 The O_2 gas concentration setpoint" sections of the User Manual.

⚠ **If the setpoints are not set up correctly, a continual gas flow may occur, which will lead to high gas consumption and incorrect recovery times.**

⚠ **The MIRI® or MIRI® Humidity multiroom IVF incubators contain high-grade CO_2 and O_2 sensors. They will measure the gas concentration in the system. Make sure that the sensors are reading the correct gas concentration that is provided on the gas bottle. If this is not the case, it must be verified if the gas' concentration in the bottle is the same as declared. If so, the MIRI® and MIRI® Humidity multiroom IVF incubators sensors must be calibrated. Refer to the "13.4.2 CO_2 sub-menu" and "13.4.3 O_2 sub-menu" sections of the User Manual for gas calibration. If the gas canister does not contain the expected mixture, contact the gas canister supplier.**

14.2 User training

Explain to the user:

1. The CO_2 gas concentration setpoint value must be 1% LOWER than the CO_2 concentration in the premix gas canister. If they try to change the setpoint or the calibration to get rid of the offset, the regulation will not work.
2. When using premixed gas, the user cannot set the setpoints they would typically do when using 100% CO_2 and 100% N_2 as the source gas. Only the setpoint for CO_2 can be set – it is an inherent compromise of using premixed gas. The MIRI® and MIRI® Humidity multiroom IVF incubators cannot change the gas composition of the premixed gas.
3. If the media's pH is not correct, they must get a new mixture of premixed gas. They cannot adjust anything on the MIRI® and MIRI® Humidity multiroom IVF incubator.
4. If they change to another concentration, the MIRI® or MIRI® Humidity multiroom IVF incubators setpoints must be adjusted accordingly, as described above.

15 Alarms

In the case of an alarm condition, alarm button and an audible alarm signal will turn on while the corresponding alarm(s) will be visible on the segment display matrix. An audio signal can be muted by pressing the alarm button once (muted ON/OFF for 5-minutes). A red "A" will be displayed on the LED matrix, followed by an alarm cause and an arrow pointing up or down (depending on the nature of the alarm condition) and the value of the alarm cause. For

example: if temperature is too low in chamber 1, the display will show "A1↓ 36.3". The alarm button backlight will pulse if at least one error condition is present in the system.

Figure 15.1 Alarm button that indicates the alarm condition

The audio pattern is 3 and 2 short beeps separated by a 1-second pause. All alarms have the same audio pattern. The audio sound pressure level is 61.1 dB(A).

⚠ **Make sure that the ambient sound pressure level does not exceed 62 dB(A) because the user will not hear the alarm!**

15.1 Temperature alarms

All 6 chambers can trigger a temperature alarm if their temperature varies over ±0.5 °C from the setpoint.

☞ **Remember that changing the setpoint more than ±0.5 °C from the current temperature will result in an alarm. The same goes for all calibration adjustments.**

The number, following the letter "A", will indicate the zone triggering the alarm.
Temperature is too high in chamber 3:

Temperature is too low in chamber 1:

The display will indicate the errors only while the audible alarm is on. If the audible alarm is muted using the alarm button, the alarm menu will be turned off and the user menu will be available. The audible alarm will restart after 5 minutes, and the display will show the alarm menu again until the alarm button is pressed. The mute alarm button will still show the alarm condition by blinking red while the alarm is muted.

Please refer to the "29 Emergency procedures" section of the User Manual on how to behave when there is a temperature alarm.

The zone layout and sensor placement are described in the “17 Surface temperatures and measuring temperature" section of the User Manual.

If a temperature sensor malfunctions, it will be indicated by the following warning:

It denotes that the sensor in chamber 2 has failed. As a safety precaution, the heating of the affected area will be switched off.

15.2 Gas concentration alarms

15.2.1 CO_2 alarms

The CO_2 gas concentration alarm is activated if the concentration of the CO_2 gas deviates more than ±1% from the setpoint.

Remember that changing the setpoint more than ±1% from the current gas concentration will result in a gas concentration alarm. The same goes for all calibration adjustments.

CO_2 gas % is too low:

CO_2 gas % is too high:

The display will lock on the alarm condition and will stop alternating between the standard status messages. If the mute button is pressed, the display will shift to normal status and show the parameters for 5 minutes until the audio alarm comes back on again. The mute alarm button will still show the alarm condition by blinking red while the alarm is muted.

Please refer to the "29 Emergency procedures" section of the User Manual on how to behave when there is a CO_2 concentration alarm.

15.2.2 O_2 alarms

The O_2 gas concentration alarm is activated if the concentration of the O_2 gas deviates more than ±1% from the setpoint.

Remember that changing the setpoint more than ±1% from the current gas concentration will result in a gas concentration alarm. The same goes for all calibration adjustments.

O_2 gas % is too low:

O_2 gas % is too high:

The display will lock on the alarm condition and will stop alternating between the standard status messages. If the mute button is pressed, the display will shift to normal status and show the parameters for 5 minutes until the audio alarm comes back on again. The mute alarm button will still show the alarm condition by blinking red while the alarm is muted.

Please refer to the "29 Emergency procedures" section of the User Manual on how to behave when there is an O_2 concentration alarm.

15.3 Gas pressure alarms

15.3.1 CO_2 pressure alarm

If the CO_2 gas supply is not attached correctly or incorrect CO_2 gas pressure is applied to the system, the MIRI® and MIRI® Humidity multiroom IVF incubators will go into CO_2 pressure alarm mode. The display will show "CO2 P", which indicates an incorrect incoming gas pressure. If the pressure falls below 0.3 bar (4.40 PSI) or rises above 0.7 bar (10.20 PSI), it will trigger the alarm.

"P" stands for pressure.

The display will lock on the alarm condition and will stop alternating between the standard status messages. If the mute button is pressed, the display will shift to normal status and show the parameters for 5 minutes until the audio alarm comes back on again. The mute alarm button will still show the alarm condition by blinking red while the alarm is muted.

Please refer to the "29 Emergency procedures" section of the User Manual on how to behave when there is a CO_2 pressure alarm.

15.3.2 N_2 pressure alarm

If the N_2 gas supply is not attached correctly or incorrect N_2 gas pressure is applied to the system, MIRI® and MIRI® Humidity multiroom IVF incubators will go into N_2 pressure alarm mode. The display will show "N2 P", which indicates an incorrect incoming gas pressure. If the pressure falls below 0.3 bar (4.40 PSI) or rises above 0.7 bar (10.20 PSI), it will trigger the alarm.

"P" stands for pressure.

The display will lock on the alarm condition and will stop alternating between the standard status messages. If the mute button is pressed, the display will shift to normal status and show the parameters for 5 minutes until the audio alarm comes back on again. The mute alarm button will still show the alarm condition by blinking red while the alarm is muted.

Please refer to the "29 Emergency procedures" section of the User Manual on how to behave when there is an N_2 pressure alarm.

15.4 Multiple alarms

When there are two or more alarms, the display will indicate this by showing first "A MULTI" and then the alarm conditions:

Alarm type will be indicated according to their priority status. The temperature alarms have 1st, gas concentration alarms have 2nd, and gas pressure alarms have 3rd priority.

Please refer to the "29 Emergency procedures" section of the User Manual on how to behave when there are multiple alarms.

15.5 Alarm UVC light (applicable only for the MIRI® model)

Alarms on UV-C light will show only as a warning message during the normal status. A red "S" will appear. **There will be no audio alarm.**

The user should consult the distributor for further guidance or service inspection. Only when the UV-C light works again will the "S" disappear.

Please contact your Esco Medical distributor for more details.

15.6 Loss of power alarm

If the power is disconnected, the MIRI® and MIRI® Humidity multiroom IVF incubator will give a short audible alarm, and the LED in the mute alarm button will flash.

Figure 15.2 Alarm button that indicates the alarm condition

Please refer to the "29 Emergency procedures" section of the User Manual on how to behave when there is a loss of power alarm.

15.7 Summary of the alarms

In the table below, there is a list of every possible alarm in the MIRI® and MIRI® Humidity multiroom IVF incubators.

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

Alarm name	Conditions	How it is determined	Alarm group	Alarm priority
Low-temperature alarm	If the temperature falls below 0.5 °C from the SP. It is applicable for all chamber's bottom temperature	Each temperature zone sensor reading	Technical	High priority alarm
High-temperature alarm	If the temperature rises above 0.5 °C from the SP. It is applicable for all chamber's bottom temperature		Technical	High priority alarm
Low CO_2 concentration	When the CO_2 concentration drops by 1% from the SP, after 3 min the alarm will turn on	CO_2 sensor reading	Technical	High priority alarm
High CO_2 concentration	When the CO_2 concentration rises by 1% from the SP, after 3 min the alarm will turn on		Technical	High priority alarm
Low O_2 concentration	When the O_2 concentration drops by 1% from the SP, after 5 min the alarm will turn on	O_2 sensor reading	Technical	High priority alarm
High O_2 concentration	When the O_2 concentration rises by 1% from the SP, after 5 min the alarm will turn on		Technical	High priority alarm
Low incoming CO_2 pressure	If the pressure falls below 0.3 bar	Pressure sensor reading	Technical	High priority alarm
High internal CO_2 pressure	If the pressure rises above 0.7 bar	Pressure sensor reading	Technical	High priority alarm
Low incoming N_2 pressure	If the pressure falls below 0.3 bar	Pressure sensor reading	Technical	High priority alarm
High internal N_2 pressure	If the pressure rises above 0.7 bar	Pressure sensor reading	Technical	High priority alarm
UV alarm	If the UV lamp is malfunctioning	UV sensor reading	Technical	Informative alarm

15.8 Alarm verification

In the table below, there is a list of how and when to verify the functionality of the alarm system.

Table 15.2 Alarm verification in the MIRI® and MIRI® Humidity multiroom IVF incubators

Alarm name	How to verify an alarm	When to verify an alarm
High-temperature alarm	Decrease the setpoint value by 3.0 °C from the current setpoint	If you have a suspicion that alarms are malfunctioning
Low-temperature alarm	Put cold metal part (disinfected prior use) in the middle of the compartment and close the lid	
High CO_2 concentration	Decrease the setpoint value by 3.0% from the current setpoint	

Alarm name	How to verify an alarm	When to verify an alarm
Low O_2 concentration	Increase the setpoint value by 3.0% from the current setpoint	
High O_2 concentration	Open the lid and leave it open for 5 min	
Low CO_2 concentration	Open the lid 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	

16 Changing the setpoints

16.1 The temperature setpoint

The temperature setpoint can be adjusted in the range between 24.9 °C to 40.0 °C.

The default temperature setpoint is 37.0 °C.

To change the temperature setpoint, follow these instructions:

1. When the display shows the current temperature:

2. Hold down the SP key and use (⇧) and (⇩) keys to adjust the setpoint: one keypress corresponds to a 0.1 change.
3. After changing the temperature, let go of the SP key. The value is now stored.

If the display does not show the current temperature reading, the (⇨) key will toggle between the temperature, CO_2, O_2 and culture mode options.

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

16.2 The CO_2 gas concentration setpoint

The CO_2 concentration can be adjusted in the range between 2.0% to 9.9%.

The default CO_2 setpoint is 6.0%.

To change the CO_2 concentration setpoint, follow these instructions:

1. When the display shows the CO_2 gas concentration:

2. Hold down the SP key and use (⇧) and (⇩) keys to adjust the setpoint: one keypress corresponds to a 0.1 change.
3. After changing the CO_2 gas concentration setpoint, let go of the SP key. The value is now stored.

If the display does not show the current CO_2 reading, the (⇨) key will toggle between the temperature, CO_2, O_2 and culture mode options.

16.3 The O_2 gas concentration setpoint

The O_2 concentration can be adjusted in the range between 5.0% to 20.0%.

☞ **The default O_2 setpoint is 5.0%.**

To change the O_2 concentration setpoint, follow these instructions:

1. When the display shows the O_2 concentration:

2. Hold down the SP key and use (⇧) and (⇩) keys to adjust the setpoint: one keypress corresponds to a 0.1 change.
3. After changing the O_2 gas concentration setpoint, let go of the SP key. The value is now stored.

If the display does not show the current O_2 reading, the (⇨) key will toggle between the temperature, CO_2, O_2 and culture mode options.

16.4 The culture mode

The culture mode can be set to "Oil culture" or "Open culture". "Oil culture" culture mode is used when the culture media has an oil or Paraffin overlay. "Open culture" mode is used when the culture media does not have any overlay.

☞ **The default setting is "Oil culture" mode.**

To change the culture mode, follow these instructions:

1. When the display shows the culture mode:

2. Hold down the SP key and use (⇧) and (⇩) keys to change the mode.
3. When the display shows the desired/correct mode, let go of the SP key. The culture mode is now saved.

If the display does not show the mode reading, the (⇨) key will toggle between the temperature, CO_2, O_2 and mode readings.

Open culture is possible in a 4-well (or similar type of dish) in volumes equal or over 0.8 mL per well without an oil overlay for up to a **maximum of 4 hours**. The Osmolality will change rapidly after that and reach over 300 mOsm/kg. In a more extended period risk of osmolality changes in media will increase rapidly.

In "Oil culture" mode, the lid temperature is kept 0.2 °C above the temperature setpoint. In "Open culture" mode, the lid temperature will be increased by 1.0 °C above the temperature setpoint. These temperature differences are kept avoiding condensation of water on chamber lid and to reduce evaporation of media.

Difference between open culture mode and oil culture mode

The significant difference between open culture mode and oil culture mode is the amount of heat in the lid. Oil accumulates temperature, so higher lid temperature can be accumulated in oil and transferred in media, elevating temperature around the embryo.

Open culture mode is designed for media equilibration or transfer (if there is a need), not for embryo culturing. Do not use open culture mode longer than 4 h. Media volume should be equal to or over 0.8 mL (in 4 well dishes). If the media stays longer without oil coverage there is a high risk of media osmolality changes.

If you have any questions or if there is uncertainty about these settings, consult Esco Medical Technologies, UAB or your local representative before using open culture mode in the MIRI® and MIRI® Humidity multiroom IVF incubator.

17 Surface temperatures and measuring temperature

In this section, the MIRI® or MIRI® Humidity multiroom IVF incubators temperature controls system is described in more detail.

The MIRI® or MIRI® Humidity multiroom IVF incubators are equipped with 12 separate PID controllers for temperature measurement. Each controller is responsible for controlling the temperature of a separate area.

Each of the 12 available areas is equipped with its separate temperature sensor and heater, allowing the user to adjust the temperature in every area separately, thus achieving higher precision.

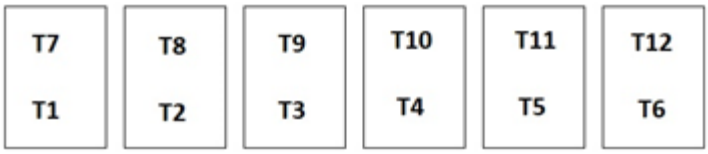


Figure 17.1 Temperature zones in MIRI® and MIRI® Humidity multiroom IVF incubators

Each area can be calibrated separately, using the item corresponding to the respective area in the menu. These items are placed in the Temperature sub-menu and are named: T1 CAL, T2 CAL, T3 CAL, T4 CAL, T5 CAL, T6 CAL, T7 CAL, T8 CAL, T9 CAL, T10 CAL, T11 CAL and T12 CAL.

An overview of the areas associated with the sensor names is shown in the table below:

Table 17.1 Areas associated with sensors

Area	Bottom	Lid
Chamber 1	T1	T7
Chamber 2	T2	T8
Chamber 3	T3	T9
Chamber 4	T4	T10
Chamber 5	T5	T11
Chamber 6	T6	T12

To calibrate the temperature in a particular area, please find the corresponding sensor name and adjust it according to a measurement taken using a high-precision thermometer.

⚠ **Temperature calibration is done by adjusting the Tx (where x is the sensor number) according to a measurement done on the spot relevant to the dish placement.**

⚠ **After temperature adjustment, give it at least 15 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 the altered value corresponds only to where the measurement is done. Give the system time to adjust.

☞ **There is no crossover heating between the 6 chambers: this is a unique feature of MIRI® and MIRI® Humidity multiroom IVF incubators. Lid temperature will, however, affect the bottom temperature in the same chamber.**

☞ **"T1" is used to adjust the bottom temperature of chamber 1. "T7" is used to adjust the temperature on the lid in the same chamber. Remember that the ΔT between the top and bottom should always be 0.2 °C*.**

☞ **How to calibrate the temperature at the T1 area can be found in the "13.4.1 Temperature sub-menu" section of the User Manual.**

Temperature calibration procedure for Chamber 1:

1. Adjust the temperatures according to a high precision measurement done with a suitable sensor.
2. To adjust the temperature of the chamber's bottom. Place the sensor in the middle of the heating optimization plate. Wait 15 minutes and record the temperature reading. Adjust the "T1" to the desired level, as described in the "13.4.1 Temperature-sub menu" section of the User Manual. It may be necessary to do iterations before the zone is completely calibrated.
3. Then, stick a suitable and calibrated sensor to the middle of the lid area and close the lid. Wait 15 minutes and record the temperature reading. Adjust the "T7" to the desired level, as described in the "13.4.1 Temperature-sub menu" section of the User Manual. It may be necessary to do iterations before the zone is completely calibrated.
4. Proceed to validate if the lid temperature is precisely 0.2 °C higher than the bottom temperature.

The chambers 2-6 are adjusted/calibrated in a similar manner.

☞ **The user may check the temperature inside the dish by placing the sensor inside the dish with media and mineral oil overlay.**

* This statement only applies when the „Oil culture" mode is used. In "Open culture" mode, the lid temperature will be increased by 1.0 °C above the temperature setpoint.

⚠ **Calibration value change procedure should only be done with a calibrated device and by a trained user or the technician, according to specific measurements.**

18 Pressure

18.1 CO_2 gas pressure

The CO_2 pressure can be viewed in the CO_2 sub-menu:

The CO_2 pressure is shown in bar. External pressure must be between 0.4 – 0.6 bar (5.80 – 8.70 PSI) at all times. It cannot be adjusted on the MIRI® and MIRI® Humidity multiroom IVF incubator; it must be done on the external gas regulator.

☞ **There is a pressure alarm set for pressure limits. The alarm goes off when pressure falls below 0.3 bar or rises above 0.7 bar (4.40 - 10.20 PSI).**

☞ **The internal pressure sensor cannot be calibrated by the user. Under normal circumstances, the pressure sensor is replaced every 2 years in accordance to the maintenance plan.**

18.2 N_2 gas pressure

The N_2 pressure can be viewed in the O_2 sub-menu:

The N_2 pressure is shown in bar. External pressure must be between 0.4 – 0.6 bar (5.80 – 8.70 PSI) at all times. It cannot be adjusted on the MIRI® and MIRI® Humidity multiroom IVF incubator; it must be done on the external gas regulator.

☞ **There is a pressure alarm set for pressure limits. The alarm goes off when pressure falls below 0.3 bar or rises above 0.7 bar (4.40 - 10.20 PSI).**

The internal pressure sensor cannot be calibrated by the user. Under normal circumstances, the pressure sensor is replaced every 2 years in accordance with the maintenance plan.

19 Firmware

The firmware installed on your MIRI® or MIRI® Humidity multiroom IVF incubators is upgradeable. Whenever a critical update is available, it will be provided to our distributors around the world – they will make sure that your MIRI® and MIRI® Humidity multiroom IVF incubator runs with the newest available firmware. A service technician can do this during the scheduled annual service.

Please follow these steps to check the firmware which is currently installed on your device:

1. Press the (⇨) key on the service menu to enter the service sub-menu.
   The service sub-menu is locked as default.

2. If the right (⇨) arrow key is pressed for longer than 10 sec., the service menu will be unlocked, and the display will show the current firmware version number:

Ver 2.0 is only shown as an **example**.

The current MIRI® multiroom IVF incubator firmware version is **6.5A**, and the MIRI® Humidity multiroom IVF incubator firmware version is **7.4A**.

3. Press the (⇧) key to exit back into the main menu.

20 pH measuring

Validating the pH of the culture media should be a standard procedure.

The MIRI® or MIRI® Humidity multiroom IVF incubators are equipped with a high-grade pH measuring system.

A standard male BNC connector is located in the back of the device. It can be connected to most standard pH combination probes. Probes that require a separate reference cannot be used. According to the temperature level set in the calibration dialogue window on the screen, the system does temperature correction (ATC) according to the calibration dialogue window's temperature level. An external ATC probe cannot be used with the system.

Figure 20.1 pH probe connected to the BNC

The temperature level must be set to a correct level in the calibration dialogue window on the screen (corresponding to a measurement done with an external device). Otherwise, the measurement will be incorrect as pH is a temperature-dependent measurement.

All readings from the pH system and calibration dialogue are shown in the PC Data logger software (current version – 2.1.1.0).

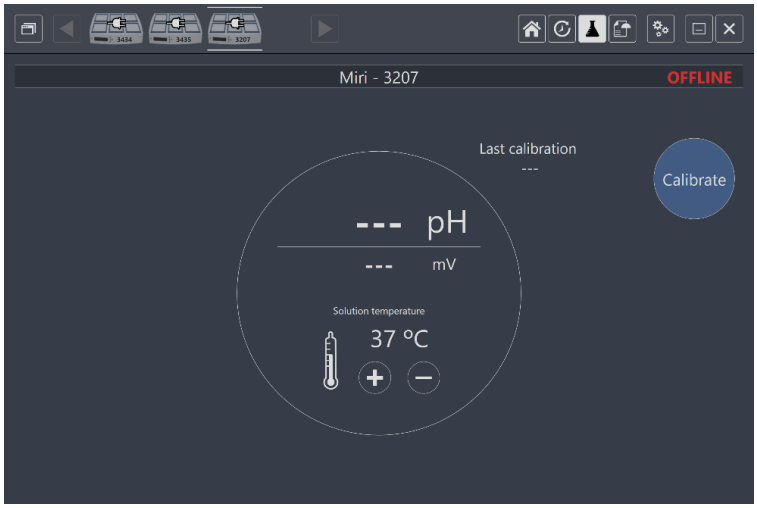


Figure 20.2 pH view in the Datalogger

The recommended method to use the system is to fill a 4-well dish with 3 types of buffers in 3 of the wells (one type in each) and fill the 4th well with the culture media. Place the 4-well dish in one empty chamber and leave it to equilibrate.

Before measuring in the culture media, calibrate the probe in the 3 buffers. Rinse the probe between each insertion.

Figure 20.3 4-well dish with 3 buffers and media

For calibration, at least two buffers are needed. However, we recommend using 3 buffers. One of the buffers should have a pH of 7. Any other pH buffer can be used as the user's buffer levels can be set in the calibration dialogue window. If only one or two buffers are available, the system can still be used but with reduced accuracy.

For the measurement to be accurate, the procedure must be completed quickly, as the pH starts to shift very rapidly once the lid is opened. The optimal time to complete the procedure is tested to be 15 seconds, giving the same results as the continuous measurement described below.

Press the "Calibrate" key:

Figure 20.4 4-well dish with 3 buffers and media

Set the buffer levels with the (+) and (-) keys to correspond to the buffers used.

Before measuring in the culture media, calibrate the probe in 2 or 3 buffers. It is necessary to rinse the probe between each insertion.

After the calibration is performed and saved, quick pH measurement can be done in the culture media. Ensure the probe tip is well covered by media and that the opening through the test lid is sealed sufficiently to maintain gas concentrations (use tape or rubber seal).

This set-up can measure the pH continually. However, the button for the graph can be clicked.

☞ **Conventional pH probes will be affected by protein clogging the sensor. This causes false readings over time (time varies depending on the type of probe).**

When choosing an electrode (probe), it is necessary to consider the probe's size, as measurements will be made on either a 4-well dish or a droplet.

21 Cleaning instructions

21.1 Considerations about a sterile device

The MIRI® and MIRI® Humidity multiroom IVF incubators are not sterile devices. They are not delivered in a sterile state and it is not possible to keep them sterile when in use.

However, their design was created with great care to make it easy for the user to keep the device sufficiently clean during use and to avoid contamination.

The design features intended to provide cleanliness include:

- A circulated air system.
- External 0.22µm filter, which cleans the incoming gas.
- A VOC/HEPA filter, which continuously cleans the air inside the system (does not apply for the MIRI® Humidity multiroom IVF incubator).
- A removable heating optimization plate that can be cleaned (**cannot be autoclaved!**). It serves as the main holding area for samples, therefore it should have the highest priority to be kept clean.
- Chambers with sealed edges that can be cleaned.
- Use of aluminum and PET parts that withstand cleaning well.

21.2 Manufacturer's recommended cleaning procedure

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

The routine cleaning procedure is recommended for regular processing and maintenance. The combination of standard cleaning procedures and disinfection procedures using alcohol-free detergents is recommended for event-related concerns such as media spills, visual accumulation of soil and/or other evidence of contamination. It is also recommended to clean and disinfect the MIRI® and MIRI® Humidity multiroom IVF incubators immediately after any media spills.

Periodic cleaning of the device (with no embryos inside)

Wearing gloves and GLP (good laboratory practice) techniques are essential to the successful cleaning of the device.

1. Clean the incubator with a suitable detergent that does not contain alcohol, i.e. benzyl-alkyldimethyl chloride. Wipe external device surfaces with wipes and repeat the process until the wipes are no longer discolored.
2. After cleaning leave the device for some time to ensure that all detergent fumes have evaporated.
3. Change your gloves and after 10 minutes of contact time, spray sterile or purified water on the surfaces and wipe them with a sterile wipe.
4. Once it is visually clean, it is ready to be used again.

If the device is not visually clean, repeat the process from step 1.

21.3 Manufacturer's recommended disinfection procedure

Disinfection of the device (with no embryos inside)

Wearing gloves and GLP (good laboratory practice) techniques are essential to the successful disinfection of the device.

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® or MIRI® Humidity multiroom IVF incubator (rear panel).
2. Open the lids.
3. Use the required disinfectant that does not contain alcohol, i.e. benzyl-alkyldimethyl chloride, to disinfect the internal surface and a glass plate on the lid's top. Use sterile wipes to apply the disinfectant.
4. Wipe all internal surfaces and the top of the lid with wipes and repeat the process until the wipes are no longer discolored.

5. Change your gloves, and after 10 minutes of contact time, spray sterile water on the surfaces and wipe them with a sterile wipe.
6. Inspect the device – if it is visually clean, consider it ready for use. If the device is visually not clean, go to step 3 and repeat the procedure.
7. Turn on the MIRI® or MIRI® Humidity multiroom IVF incubator (rear panel).

22 Heating optimization plates

Insert the heating optimization plate.

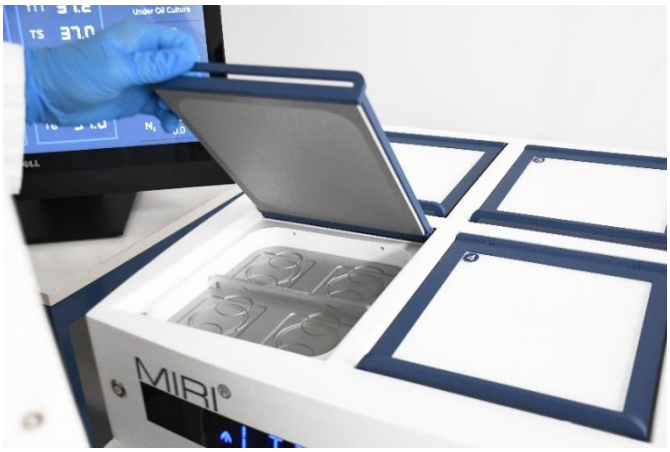


Figure 22.1 Heating optimization plate inside the MIRI® multiroom IVF incubator

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 it 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®, VitroLife®, GPS® and BIRR® dishes. Additionally, we have the plain version of the heating optimization plate.

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

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

23 Humidification

23.1 MIRI® multiroom IVF incubator

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

⚠ **MIRI® 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.**

23.2 MIRI® Humidity multiroom IVF incubator

The water bottle is mounted on the side of the device for the easy control of water level and refilling.

The design runs a simulated humidity routine that will ensure that no evaporation occurs in all standard dishes if they are normally covered with the lid that comes with the dish.

The MIRI® Humidity multiroom IVF incubator maintains humidity levels by circulating gas through the system using a humidification bottle. However, the MIRI® Humidity multiroom IVF incubator does not actively control the humidification level in the system to reach certain humidity levels (despite gas humidification being a continuous process).

Humidification bottle connection procedure (see Figure 23.1 below):

1. Use one tube to connect the “IN” elbow on the humidification bottle and the “IN” elbow in the device.
2. Use one tube to connect the “OUT” elbow on the humidification bottle and the “OUT” elbow in the device.

Figure 23.1 Tube connection on the humidification bottle and the MIRI® Humidity multiroom IVF incubator

There is no difference in the tube connection order. Just make sure that the elbows get connected correctly.

The humidification bottle must be changed each month.

Water in the humidification bottle must be changed at least once per week.

The humidification bottle should contain sterile water filled to the specified fill line in order for the MIRI® Humidity multiroom IVF incubator to work properly and maintain the required humidity in the system.

Figure 23.2 Fill line on the humidification bottle

24 Temperature validation

The MIRI® or MIRI® Humidity multiroom IVF incubators are equipped with 6 PT-1000 Class-B sensors located in the center of the bottom of each chamber.

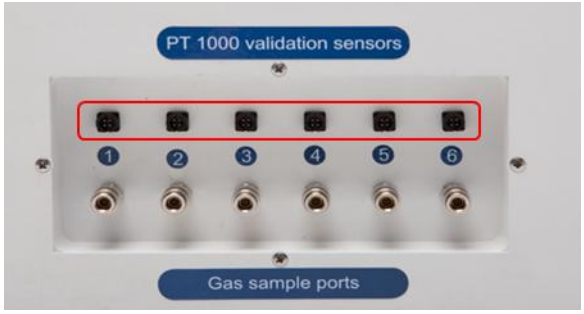


Figure 24.1 PT-1000 Class B sensors

The sensors serve for external validation purposes. They are entirely separate from the main circuit of the device.

The chamber's temperature conditions 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) to be used with the sensors.

25 Gas concentration validation

Gas concentration in each chamber of the MIRI® and MIRI® Humidity multiroom IVF incubator can be validated by taking a gas sample from one of the 6 gas sample ports on the device's side, using a suitable gas analyzer.

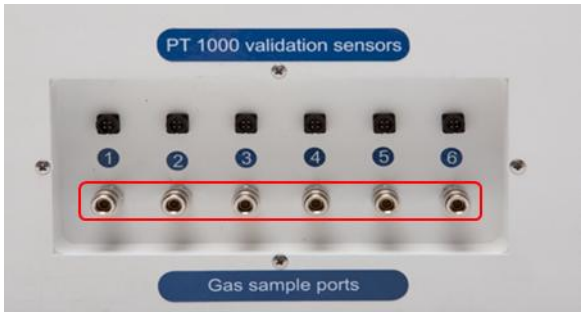


Figure 25.1 Gas sample ports

Each sample port is directly connected to the corresponding chamber with the same number. The gas sample will be taken ONLY from the specific chamber.

An external automatic gas sampler can be connected to the ports 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 the gas concentration in the system.

Make sure that the gas analyzer is calibrated before use.

26 Alarm switch for an external system

The MIRI® and MIRI® Humidity multiroom IVF incubator can be connected to an external monitoring system, ensuring maximum safety, especially during nights and weekends. The MIRI® or MIRI® Humidity multiroom IVF incubator is equipped with a 3.5 mm jack connector on the back that can be connected to a monitoring device.

Whenever an alarm goes off (that could be the temperature alarm, gas alarms for CO_2 or O_2 concentrations, low-pressure or high-pressure alarms for CO_2, N_2 gases or premixed gas) 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 is illustrated below.

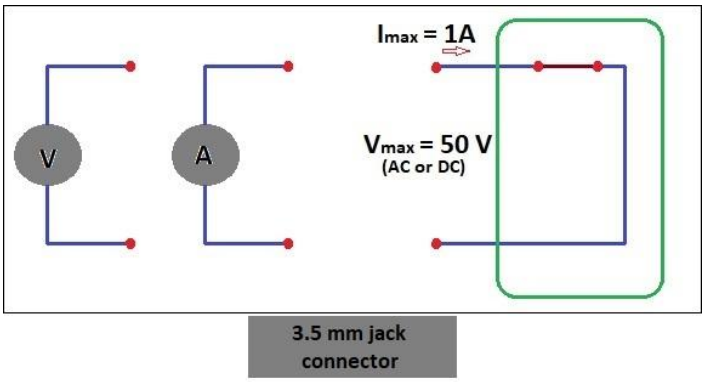


Figure 26.1 No alarm mode

Whenever the MIRI® or MIRI® Humidity multiroom IVF incubator goes into an alarm mode, the switch will become an "open circuit". It means that no current can run through the system anymore.

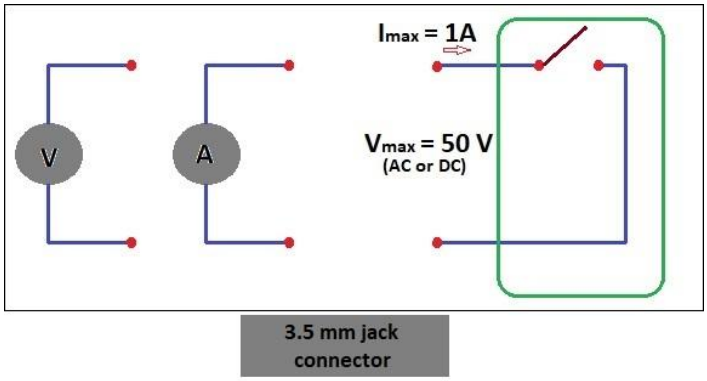


Figure 26.2 "Open circuit" alarm mode

Whenever the MIRI® or MIRI® Humidity multiroom IVF incubator's power cord is disconnected from the power source, this switch will automatically indicate an alarm! It is an extra safety feature intended to alert the personnel in case of a power cut in the laboratory.

27 Writing area on the chamber lids

Each chamber's lid on the MIRI® or MIRI® Humidity multiroom IVF incubator is made from white glass, 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 afterward. Use only a suitable non-toxic pen that allows the text to be erased later and will not damage the incubated samples.

Figure 27.1 Area for patient information

28 Maintenance

The MIRI® and MIRI® Humidity multiroom IVF incubators are 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® and MIRI® Humidity multiroom IVF incubators are used. The

manufacturer recommends that the period between validation should be no longer than 14 days.

2. VOC/HEPA filters must be replaced every 3 months.
3. External HEPA filter must be replaced yearly during annual maintenance.
4. According to the clinical practice intervals, suitable cleaning procedures must be employed in the laboratory where the MIRI® and MIRI® Humidity multiroom IVF incubators are used. The manufacturer does not recommend periods longer than 14 days between cleaning.

⚠ **It is essential to perform the inspection and service at the intervals indicated in the "37 Maintenance guide" section of the User Manual. Failure to do so can have serious adverse outcomes, causing the device to stop functioning as expected and cause damage to samples, patients or users.**

⚠ **Warranty void if service and maintenance procedures are not followed or if service and maintenance procedures are done not by trained and authorized personnel.**

29 Emergency procedures

Total loss of power to or on the device:

- Remove all the samples and place them in an alternative or backup device that is not affected by the problem.
- Without the power source, the internal temperature of the MIRI® and MIRI® Humidity multiroom IVF incubator will drop below 35 °C after being 10 minutes in an ambient environment of 20 °C.
- The CO_2 concentration will remain within 1% of the setpoint for 30 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 a single temperature alarm turns ON:

- Remove the samples from the affected chamber. They can be relocated to any of the other chambers, which happens to be unoccupied. All chambers are separate so that the remaining ones will function normally.

If multiple temperature alarm turns ON:

- Remove the samples from the affected chambers. They can be relocated to any of the other chambers, which happens to be unoccupied. All chambers are separate so that the remaining ones will function normally.

- Alternatively, remove the samples from all the affected chambers and place them in an alternative or backup device that is not affected by the problem.

If the CO_2 concentration alarm turns ON:

- There will be a 30-minute-long interval during which the user can assess if the condition is temporary or permanent. If the state is permanent, remove all the samples and place them in an alternative or backup device that is not affected by the problem. If the condition is temporary and the CO_2 concentration is low, keep the lids shut. If the state is temporary and the CO_2 concentration is high, open a few lids to vent out some CO_2.

If the O_2 concentration alarm turns ON:

- Usually, no Emergency procedures are necessary in this case. If the condition is judged to be permanent, it may be advantageous to switch off O_2 regulation in the menu.

If the CO_2 pressure alarm turns ON:

- Inspect the external gas supply and gas supply lines. If the problem is external and not readily fixed, follow the guidelines under the "15.3.1 CO_2 pressure alarm" section of the User Manual.

If the N_2 pressure alarm turns ON:

- Inspect the external gas supply and gas supply lines. If the problem is external and not readily fixed, follow the guidelines under the "15.3.2 N_2 pressure alarm" section of the User Manual.

30 User troubleshooting

Table 30.1 Heating system

Symptom	Cause	Action
No heating, the display is off	The device is switched off at the back or not connected to the power	Switch the device on or connect the power source
Temperature alarm is on	The heating is off because the temperature deviated more than 0.5 °C from the set temperature	Contact your Esco Medical distributor for details
No heating	The setpoint for temperature is wrong	Check the desired temperature setpoint
Uneven heating	System not calibrated	Calibrate each zone according to the user manual, using a high precision thermometer

Table 30.2 CO_2 gas regulator

Symptom	Cause	Action
No CO_2 gas regulation	The system is not powered	Check power mains
		Switch the system on

Symptom	Cause	Action
	CO_2 gas regulator is off	Activate CO_2 gas regulator by setting "CO_2" to "ON" in the menu
	No CO_2 or wrong gas attached to CO_2 gas input	Check the CO_2 gas supply, make sure that pressure is kept stable at 0.4 – 0.6 bar (5.80 – 8.70 PSI)
	The actual gas concentration is higher than the setpoint	Check CO_2 gas setpoint. If the issue persists, contact Esco Medical support
Poor CO_2 gas regulation	Lid(s) are left open	Close lid(s)
	Seals missing on the lid(s)	Replace the seals on the lid(s)
"A CO2" is shown on the display	CO_2 gas concentration more than ±1% from the setpoint	Allow the system to stabilize by closing all lids
"CO2 P" is shown on the display	No/wrong CO_2 gas pressure to the system	Check the CO_2 gas supply, make sure that pressure is kept stable at 0.4 – 0.6 bar (5.80 – 8.70 PSI)

Table 30.3 O_2 gas regulator

Symptom	Cause	Action
No O_2 gas regulation	System not powered	Check mains
		Switch the system on
	O_2 gas regulator is off	Activate the O_2 gas regulator by setting "O_2" to "ON" in the menu
	No N_2 or wrong gas type attached to N_2 gas input	Check gas supply, make sure that pressure is kept stable at 0.4 – 0.6 bar (5.80 – 8.70 PSI)
	The actual gas concentration is higher than the setpoint	Check O_2 setpoint. If the issue persists, contact Esco Medical support
Poor O_2 gas regulation	Lid(s) are left open	Close lid(s)
	Seals missing on the lid(s)	Replace the seals on the lid(s)
"A O2" is shown on the display	O_2 gas concentration more than ±1% from the setpoint	Allow the system to stabilize by closing all lids
"N2 P" is shown on the display	No/wrong N_2 gas pressure to the system	Check N_2 gas supply and ensure that pressure is stable at 0.4 – 0.6 bar (5.80 – 8.70 PSI). If O_2 regulation is not needed, set the "O2" to "OFF" in the menu to deactivate O_2 gas regulation and abort the N_2 gas alarm

Table 30.4 Datalogger

Symptom	Cause	Action
No data is sent to the PC	System not powered	Check mains
		Switch the system on
	The data cable between multiroom IVF incubator and PC not correctly attached	Check connection. Use only the cable supplied with the device

Symptom	Cause	Action
	Data logger software/USB driver not correctly installed	Please refer to the software installation guide

Table 30.5 Display

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

Table 30.6 Keyboard

Symptom	Cause	Action
The absent or erratic function of keys	Failure in the keys	Contact your Esco Medical Distributor to replace the keys

31 Specifications

Table 31.1 MIRI® multiroom IVF incubator's specifications

Technical specifications	MIRI®
Overall dimensions (W×D×H)	700 × 585 × 165 mm
Weight	40 kg
Material	Mild steel / Aluminum / PET / Stainless steel
Power supply	115V 60Hz or 230V 50Hz
Power consumption	300 W
Temperature control range	24.9 °C – 40.0 °C
Temperature deviation from the setpoint	± 0.1 °C
Gas consumptions (CO_2)[3]	< 2 liters per hour
Gas consumption (N_2)[4]	< 12 liters per hour
Premixed gas consumption	In purge < 50 liters per hour In normal run < 20 liters per hour
CO_2 range	2.0% – 9.9%
O_2 range	5.0% – 20.0%
CO_2 and O_2 concentration deviation from the setpoint	± 0.2 %
Gas pressure CO_2 (input)	0.4 – 0.6 bar (5.80 – 8.70 PSI)
Gas pressure N_2 (input)	0.4 – 0.6 bar (5.80 – 8.70 PSI)
Alarms	Audible and visible for out-of-range temperature, gas concentration and gas pressure.
Operating altitude	Up to 2000 meters (6560 feet or 80kPa – 106kPa)
Shelf life	1 year

Table 31.2 MIRI® Humidity multiroom IVF incubator's specifications

Technical specifications	MIRI® Humidity
Overall dimensions (W×D×H)	700 × 645 × 280 mm
Weight	40 kg
Material	Mild steel / Aluminum / PET / Stainless steel
Power supply	115V 60Hz or 230V 50Hz
Power consumption	300 W
Temperature control range	24.9 °C – 40.0 °C
Temperature deviation from the setpoint	± 0.1 °C
Gas consumptions (CO_2)[3]	< 4 liters per hour
Gas consumption (N_2)[4]	< 12 liters per hour
Premixed gas consumption	In purge < 50 liters per hour In normal run < 20 liters per hour
CO_2 range	2.0% – 9.9%
O_2 range	5.0% – 20.0%
CO_2 and O_2 concentration deviation from the setpoint	± 0.2 %
Gas pressure CO_2 (input)	0.4 – 0.6 bar (5.80 – 8.70 PSI)
Gas pressure N_2 (input)	0.4 – 0.6 bar (5.80 – 8.70 PSI)
Alarms	Audible and visible for out-of-range temperature, gas concentration and gas pressure.
Operating altitude	Up to 2000 meters (6560 feet or 80kPa – 106kPa)
Shelf life	1 year

[3] Under normal conditions (CO_2 setpoint reached at 6.0%, all lids closed)
[4] Under normal conditions (O_2 setpoint reached at 5.0%, all lids closed)

32 Electromagnetic compatibility

Table 32.1 Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The MIRI® and MIRI® Humidity multiroom IVF incubators are intended for use in the electromagnetic environment specified below. The customer or the user of the MIRI® and MIRI® Humidity multiroom IVF incubator should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The MIRI® and MIRI® Humidity multiroom IVF incubators do not use RF energy. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The MIRI® and MIRI® Humidity multiroom IVF incubators are suitable for use in a hospital environment. It is not suited for domestic establishments.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

Table 32.2 Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The MIRI® and MIRI® Humidity multiroom IVF incubators are intended for use in the electromagnetic environment specified below. The customer or the user of the MIRI® and MIRI® Humidity multiroom IVF incubator should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines		
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % 100V (>95%dip in 100V) for 0.5 cycle 40% 100V (60% dip in 100V) for 5 cycles 70% 100V (30% dip in 100V) for 25 cycles) dip in 100V) for 5 sec		
Power frequency (50/60 Hz) magnetic field	3 A/m	Performance A	The power-frequency magnetic fields' level should be characteristic of a specific location

Guidance and manufacturer's declaration – electromagnetic immunity			
IEC 61000-4-8			in a commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The MIRI® and MIRI® Humidity multiroom IVF incubators are intended for use in the electromagnetic environment specified below. The customer or the user of the MIRI® and MIRI® Humidity multiroom IVF incubator should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment-guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	10 Vrms 150kHz to 80 MHz in ISM bands 3 V/m 80 MHz to 2.5 GHz	3V/m from 80MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of MIRI® and MIRI® Humidity multiroom IVF incubators, including cables, than the recommended separation distance calculated according to the equation, applicable to the transmitter's frequency. **Recommended separation distance** $d = 0.35\ P$ $d = 0.35$ P, 80MHz to 800MHz $d = 0.7$ P, 800MHz to 2.5GHz P is the maximum power output rating of the transmitter in watts (W) according to the transmitter manufacturer, *d* is the recommended separation distance in meters (m). As determined by an electromagnetic site survey, field strengths from fixed RF transmitters should be lower than the compliance level in each frequency range. Interference may occur in the vicinity of the equipment.

Table 32.3 Recommended separation distances

Recommended separation distances between portable and mobile RF communication equipment and MIRI® or MIRI® Humidity multiroom IVF incubators			
The MIRI® and MIRI® Humidity multiroom IVF incubators are intended to be used in an electromagnetic environment in which radiated RF disturbances are controlled. The customer, or the MIRI® and MIRI® Humidity multiroom IVF incubator user, can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters). The MIRI® and MIRI® Humidity multiroom IVF incubators are recommended below, according to the communications equipment's maximum output power.			
The rated maximum output power of the transmitter	**Separation distance according to the frequency of the transmitter (m)**		
	150 kHz to 80 MHz d = 1.2√P	**80 MHz to 800 MHz d = 1.2√P**	**800 MHz to 2.5GHz d = 2.3√P**
0.01 W	0.1m	0.1m	0.2m
0.1 W	0.4m	0.4m	0.7m
1 W	1.2m	1.2m	2.3m
10 W	3.7m	3.7m	7.4m
100 W	11.7m	11.7m	23.3m
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (w), according to the transmitter manufacturer. **NOTE 1**: at 80 MHz and 800 MHz, the higher frequency range's separation distance applies. **NOTE 2**: these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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® or MIRI® Humidity multiroom IVF incubators product complies with the medical electromagnetic compatibility standard and checks before use that no interference is evident or possible. If the interference is suspected or probable, switching off the offending device is the specific solution as it is the usual practice in aircraft and medical facilities.

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

33 Validation guide

33.1 Product release criteria

In Esco Medical Technologies, UAB, MIRI® and MIRI® Humidity multiroom IVF incubators undergo strict quality and performance testing before being released for sale.

33.1.1 Performance

Each component used in the MIRI® and MIRI® Humidity 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 analyzers, 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.

33.1.2 Electrical safety compliance test

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

33.1.3 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.

33.1.4 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.

33.1.5 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 33.1 Burn-in tests and acceptance criteria

Test	Acceptance Criteria
Temperature Stability Test	± 0.1 °C
Gas Concentration Stability Test	± 0.1 %
pH Test	Measured pH = Buffer pH

33.1.6 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.

33.1.7 Visual inspection

- No misalignment in the lids.
- Each lid opens and closes easily.
- The seals for the lids are 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.

34 Validation on-site

Even though at Esco Medical Technologies, UAB we strive to do the most comprehensive tests before the device is shipped to the customer, there is a chance that the device may have been damaged on purpose or accidentally during transportation or set up.

Therefore, 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 for clinical use.

In the following sections, we describe these tests and the equipment necessary to perform them.

A test documentation form is also provided. A copy must be provided to Esco Medical Technologies, UAB for internal device tracking and device history record.

34.1 Mandatory equipment

All equipment must be of high quality and calibrated.

- A thermometer with a suitable sensor for measuring in a droplet of media covered with Paraffin oil with a minimum resolution of 0.1 °C.
- A thermometer with a suitable sensor for measuring on an aluminum surface with a minimum resolution of 0.1 °C.
- A CO_2 analyzer with a minimum range of 0.0 – 10.0%.
- An O_2 analyzer with a minimum range of 0.0 – 20.0%.
- A Pressure tester with a minimum range of 0.0 – 1.0 bar.
- A Multimeter.

34.2 Recommended additional equipment

All equipment must be of high quality and calibrated.

- A VOC meter able to measure the most common volatile organic compounds at least at the ppm-level.

- With the laser particle counter, a sample should be taken just above the MIRI® or MIRI® Humidity multiroom IVF incubator. The reading should be noted down as the background particle level.

Recommended additional equipment can be used for further installation testing that will minimize the likelihood of problems on-site.

35 Testing

35.1 Gas supply CO_2

For the regulation system to maintain the correct CO_2 concentration level in the MIRI® or MIRI® Humidity multiroom IVF incubator chambers, the device must be connected to a stable supply of 100% CO_2 with a pressure of 0.4 – 0.6 bar (5.80 – 8.70 PSI).

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 continuously 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.

The sample should be taken 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 PCB. Moisture level must be verified on the gas manufacturer's certificate: only 0.0 ppm v/v Max is permissible.

35.1.1 About CO_2

Carbon dioxide (CO_2) is a colorless, 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 normal atmospheric pressure.

⚠ **A high concentration of carbon dioxide (10.0% or more) in the surrounding atmosphere can 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.

35.2 Gas supply N_2

In order for the regulation system to maintain the correct O_2 concentration levels in the MIRI® or MIRI® Humidity multiroom IVF incubator chambers, the device must be connected to a stable supply of 100% N_2 at 0.4 – 0.6 bar (5.80 – 8.70 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 analyzer.

☞ **A gas analyzer 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 PCB. Moisture level must be verified on the gas manufacturer's certificate: only 0.0 ppm v/v Max is permissible.**

35.2.1 About N_2

Nitrogen makes up a significant portion of the earth's atmosphere with 78.08% by volume. Nitrogen is a colorless, odorless, 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_20) 0.5 ppm.

35.3 CO_2 gas pressure check

The MIRI® and MIRI® Humidity multiroom IVF incubators require a pressure of 0.4 – 0.6 bar (5.80 – 8.70 PSI) on the input CO_2 gas line. This gas pressure must always be held stable.

For safety, both medical devices have built-in digital gas pressure sensors that monitor the incoming gas pressure and alert the user if the pressure drops below 0.3 bar or rises above 0.7 bar.

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 0.4 – 0.6 bar.

Please refer to the "18.1 CO_2 gas pressure" section of the User Manual for more information.

35.4 N_2 gas pressure check

The MIRI® and MIRI® Humidity multiroom IVF incubators require a pressure of 0.4 – 0.6 bar (5.80 – 8.70 PSI) on the input N_2 gas line. This gas pressure must always be held stable.

For safety, both medical devices have built-in digital gas pressure sensors that monitor the incoming gas pressure and alert the user if the pressure drops below 0.3 bar or rises above 0.7 bar.

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 0.4 – 0.6 bar.

Please refer to the "18.2 N_2 gas pressure" section of the User Manual for more information.

35.5 Voltage supply

The voltage on-site must be verified.

Measure the output plug on the UPS that the MIRI® or MIRI® Humidity multiroom IVF incubators will be connected. 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%

35.6 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. Use sample port-6 for validation.

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

Connect the gas analyzer 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 analyzer must have a gas return port connected to the MIRI® or MIRI® Humidity multiroom IVF incubator (i.e., another chamber). Only measure while the value on the gas analyzer stabilizes.

Please refer to the "13.4.2 CO_2 sub-menu" section of the User Manual for more information on how to perform the CO_2 gas calibration.

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

35.7 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-6 for validation.

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

Hook-up the gas analyzer 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 analyzer must have a gas return port connected to the MIRI® or MIRI® Humidity multiroom IVF incubator (i.e., another chamber). Only measure while the value on the gas analyzer stabilizes.

Please refer to the "13.4.3 O_2 sub-menu" section of the User Manual for more information on how to perform the O_2 gas calibration.

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

35.8 Temperature check: chamber bottoms

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 6 dishes 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 one by one into individual chambers. The dishes should be placed on the corresponding size slot on the heating optimization plates.

1-hour stabilization time is required to complete this test after all previous steps have been 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 "13.4.1 Temperature sub-menu" 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.

35.9 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 on each zone and verify the temperature.

Pass: all temperatures measured on the chambers' lids must not deviate more than ± 0.5 °C from the setpoint.

If calibration is needed, please refer to the "13.4.1 Temperature sub-menu" section of the User Manual 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.

35.10 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 as closely as to the condition under which it will be running in clinical use.

If the preference of CO_2 setpoint is 6.0% or temperature is different from the default setting, an adjustment needs to be done before the test.
If the device will not be clinically operational 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 N_2 gas supply.

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

Make sure that the Esco Medical data logger software is running.

Check that parameters are logged and give a meaningful reading. Let the device run without interfering for at least 6 hours. Analyze the results on the graphs.

Pass I: Internal sensor temperature variation from setpoint 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.
Pass IV: Gas flow of CO_2 is less than 2 l/h (for MIRI® Humidity model – less than 4 l/h).
Pass V: Gas flow of N_2 is less than 12 l/h.

35.11 Cleaning

Always validate the cleaning procedures locally or consult the manufacturer 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 "21 Cleaning instructions" section of the User Manual).

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

35.12 Test documentation form

The "Installation report" form must be completed by installation personnel and submitted to Esco Medical Technologies, UAB before the device is taken into clinical use.

35.13 Recommended additional testing

35.13.1 A VOC meter (applicable only for the MIRI® model)

With the VOC meter, a sample should be taken just above the MIRI® and MIRI® Humidity multiroom IVF incubator. The reading should be noted down as the background VOC level. Then a sample is taken from the gas sample port number – 6.

Pass: 0.0 ppm VOC.

Ensure that the sample lines do not contain any VOC.

35.13.2 A laser particle counter

A sample should be taken just above the MIRI® or MIRI® Humidity 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 number – 6.

Pass: 0.3-micron < 100 ppm.

Ensure that the sample lines do not contain any particles.

36 Clinical use

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

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® or MIRI® Humidity multiroom IVF incubator for clinical purposes without access to high-grade quality control validation equipment.**

Table 36.1 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		×

36.1 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 "13.4.1 Temperature sub-menu" section of the User Manual 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 ± 0.5 °C from the setpoint.**

36.2 CO_2 gas concentration check

The CO_2 gas concentration is checked for deviations. The gas sample port on the side of the device is used for this. Use sample port-6 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.

Please refer to the "13.4.2 CO_2 sub-menu" section of the User Manual for more information on how to perform the CO_2 gas calibration.

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

36.3 O_2 gas concentration check

The O_2 gas concentration is checked for deviations. The gas sample port on the side of the device is used for this. Use sample port-6 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.

Please refer to the "13.4.3 O_2 sub-menu" section of the User Manual for more information on how to perform the O_2 gas calibration.

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

Gas analyzers use a small pump to draw out gas from the location being sampled. The pump capacity varies from brand to brand. The gas analyzer's ability to return the gas sample to the MIRI® or MIRI® Humidity multiroom IVF incubator (loop sampling) avoids negative pressure and ensures accuracy. Contact Esco Medical Technologies, UAB or the local distributor for further guidance.

36.4 CO_2 gas pressure check

The MIRI® or MIRI® Humidity multiroom IVF incubators require a pressure of 0.4 – 0.6 bar on the input CO_2 gas line. This gas pressure must be held stable at any time.

For safety, both medical devices have built-in digital gas pressure sensors that monitor the incoming gas pressure and alert the user if the pressure drops below 0.3 bar or rises above 0.7 bar.

It is recommended to check the CO_2 gas pressure in the menu by inspecting the value for an item called 'CO2 P' (CO_2 pressure).

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the "18.1 CO_2 gas pressure" section of the User Manual for more information.

36.5 N_2 gas pressure check

The MIRI® or MIRI® Humidity multiroom IVF incubators requires a pressure of 0.4 – 0.6 bar on the input N_2 gas line. This gas pressure must be held stable at any time.

For safety, both medical devices have built-in digital gas pressure sensors that monitor the incoming gas pressure and alert the user if the pressure drops below 0.3 bar or rises above 0.7 bar.

It is recommended to check the N_2 gas pressure in the menu by inspecting the value for an item called 'N2 P' (N_2 pressure).

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the "18.2 N_2 gas pressure" section of the User Manual for more information.

36.6 pH check

Validating the pH of the culture media should be a standard procedure. It can never be accurately predicted what the media pH will be at a certain CO_2 concentration.

CO_2 is pressure-dependent and thus, at different altitudes, higher concentrations of CO_2 are needed to maintain the same pH. Even changes in barometric pressure under standard weather systems will affect CO_2 concentration.

MIRI® and MIRI® Humidity multiroom IVF incubators are equipped with a high-grade pH measuring system.

Please refer to the "20 pH measuring" section of the User Manual for more information on performing pH calibration.

37 Maintenance guide

Your MIRI® or MIRI® Humidity 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 periodically according to instructions given in the "33 Validation guide" section of the User Manual.

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

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 37.1 and 37.2.

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 MIRI® or MIRI® Humidity multiroom IVF incubator.

⚠ **Warranty void if service intervals are not followed according to Tables 37.1 and 37.2.**

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

The table below shows time intervals in which components must be replaced:

Table 37.1 Service interval plan for the MIRI® multiroom IVF incubators

Component name	Every 3 months	Years 1, 5, 7	Years 2, 10	Years 3, 9	Years 4, 8	Year 6
VOC/HEPA filter capsule	×					
External 0.22µm HEPA filter for incoming CO_2 and N_2 gas		×	×	×	×	×
O_2 sensor		×	×	×	×	×
CO_2 sensor					×	
UV light		×	×	×	×	×
Cooling fan				×		×
Internal gas pump			×		×	×
Proportional valves				×		×
Flow PCB			×		×	×
Pressure regulators					×	

Table 37.2 Service interval plan for the MIRI® Humidity multiroom IVF incubators

Component name	Every month	Years 2, 6, 10	Years 4, 8
Humidification Bottle	×		
External 0.22µm HEPA filter for incoming CO_2 and N_2 gas		×	×
O_2 sensor		×	×
CO_2 sensor			×

Component name	Every month	Years 2, 6, 10	Years 4, 8
Cooling fan			×
Pump module		×	×
Proportional valves		×	×
Flow PCB		×	×
Pressure regulators			×

37.1 VOC/HEPA filter capsule (applicable only for the MIRI® model)

The VOC/HEPA filter capsule is placed on the MIRI® multiroom IVF incubator device's back 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 recirculating air in the system. Because of the carbon component's lifespan, all VOC/HEPA filters' lifetimes are limited, and they must be replaced often. According to table 37.1, the VOC/HEPA filter installed in the MIRI® 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 Technologies, UAB or your local distributor for more details or ordering).
- Change filter every 3 months.
- Failure to change the filter on time will result in low/no air-cleaning within the system.
- Warranty void if wrong/non-original filter is used.

Please refer to "12.1 Installation procedure of a new VOC/HEPA filter" section of the User Manual for the replacement instructions.

37.2 Humidification bottle (applicable only for the MIRI® Humidity model)

A humidification bottle contains water that is used to maintain the humidity in the chamber. It should be changed each month.

Water in the humidification bottle must be changed at least once per week.

37.3 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 1 year in MIRI® multiroom IVF incubator.
- Change the filter once every 2 years in MIRI® Humidity multiroom IVF incubator.
- Failure to change the filter on time will result in low/no cleaning of incoming CO_2/N_2 gas.
- Warranty void if wrong/non-original filter is used.

Please refer to the service manual for replacement instructions.

37.4 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® and MIRI® Humidity 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 the applicable replacement interval (1 year for MIRI® and 2 years for MIRI® Humidity multiroom IVF incubators) 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 MIRI® multiroom IVF incubators, and at least once every two years in MIRI® Humidity multiroom IVF incubators, irrespective of whether the incubator is in use or not.

In the MIRI® or MIRI® Humidity multiroom IVF incubator "Installation report", the User will see when this sensor was installed. This date must be used to calculate the date for the next O_2 sensor change.

Please follow these safety precautions when changing 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 in MIRI® multiroom IVF incubator from the date of the previous sensor installation.
- Change the O_2 sensor every 2 years in MIRI® Humidity multiroom IVF incubator 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 void if wrong/ non-original sensor is used.

Please refer to the service manual for replacement instructions.

37.5 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.

This sensor's lifetime is more than 6 years, but for safety reasons, Esco Medical Technologies, UAB recommends the sensor to be replaced once every 4-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 4 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 void if wrong/non-original sensor is used.

Please refer to the service manual for replacement instructions.

37.6 UV light (applicable only for the MIRI® model)

For safety reasons and to clean the re-circulating air, this equipment has a 254 nm UV light installed. The UV-C light has a limited lifetime and must be replaced every year, according to Table 37.1.

Figure 37.1 UV light warning

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

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 every 1 year from date of installation.
- Failure to change the UV-light bulb on time can result in contamination build-up.
- Warranty void if wrong/non-original UV-light bulb is used.

Please refer to the service manual for replacement instructions.

37.7 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 Technologies, UAB recommends that the cooling fan be replaced once every 3 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 3 years in MIRI® multiroom IVF incubator from the date of installation.
- Change the fan every 4 years in MIRI® Humidity multiroom IVF incubator from the date of installation.
- Failure to change the fan may cause the electronics to drift, resulting in low temperature and gas regulations.
- Warranty void if wrong/non-original fan is used.

Please refer to the service manual for replacement instructions.

37.8 Internal gas pump (applicable only for the MIRI® model)

The internal 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 once every 2 years to maintain the fast recovery time after lid openings.

Please follow these safety precautions when changing the internal gas 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 void if wrong/non-original pump is used.

Please refer to the service manual for replacement instructions.

37.9 Pump module (applicable only for the MIRI® Humidity model)

The pump is used to mix and recirculate gases in the device. In time the performance of this pump can be affected, causing a longer recovery time.

Therefore, this pump must be replaced once every 2 years to maintain the fast recovery time after lid openings.

Please follow these safety precautions when changing the internal gas 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 void if wrong/non-original pump is used.

Please refer to the service manual for replacement instructions.

37.10 Proportional valves

The integrated proportional valves control gas injection into the system. If the proportional valves are worn, gas regulation may be affected. It may cause more prolonged recovery time, incorrect gas concentration or breakdown. Therefore, these proportional valves must be replaced once every 3 years in the MIRI® Multiroom IVF Incubator and every 2 years in the MIRI® Humidity multiroom IVF incubator to maintain system safety and stability.

Please follow these safety precautions when changing valves:

- Always use original proportional valves (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the valves every 3 years in MIRI® multiroom IVF incubator from the date of installation.
- Change the valves every 2 years in MIRI® Humidity multiroom IVF incubator from the date of installation.
- Failure to change the valves may cause slow recovery times or breakdowns.
- Warranty void if wrong/non-original valves are used.

Please refer to the service manual for replacement instructions.

37.11 Gas lines

The internal gas lines 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 gas lines/hoses must be visually checked during the annual maintenance service visit.**

☞ **All service engineers must have extra internal gas lines/hoses 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 gas lines (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Failure to change the gas lines may cause slow recovery times or breakdowns.
- Warranty void if wrong/non-original gas lines are used.

Please refer to the service manual for replacement instructions.

37.12 Flow PCB

The flow PCB is used in gas regulation and for accumulating gas consumption.

This PCB's lifetime is more than 3 years, but Esco Medical Technologies, UAB recommends the PCB to be replaced once every 2 years for safety reasons.

Please follow these safety precautions when changing PCB:

- Always use an original flow PCB (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change flow PCB every 2 years from the date of installation.
- Failure to change the flow PCB on time may result in low/no CO_2 and O_2 gas concentration regulation.
- Warranty void if wrong/non-original Flow PCB is used.

Please refer to the service manual for replacement instructions.

37.13 Pressure regulators

The internal pressure regulators protect the system from too high external gas pressures that would damage the gas circuit's sensitive parts. If the pressure regulators are worn, they may begin to drift and not offer the protection they are supposed to. It could cause breakdowns or leaks in the internal gas circuit. Therefore, the regulators must be replaced once every 4 years to maintain the system safe and stable.

Please follow these safety precautions when changing regulators:

- Always use original pressure regulators (contact Esco Medical Technologies, UAB or your local distributor for more details or ordering).
- Change the regulators every 4 years from the date of installation.
- Failure to change the regulators may cause breakdowns.
- Warranty void if wrong/non-original regulators are used.

Please refer to the service manual for replacement instructions.

37.14 Firmware update

If Esco Medical Technologies, UAB has released a newer version of the firmware, it should be installed on the MIRI® and MIRI® Humidity multiroom IVF incubators during the scheduled maintenance yearly.

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

38 Installation guide

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

38.1 Responsibilities

All technicians or embryologists installing the MIRI® or MIRI® Humidity 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 Technologies, UAB or at a qualified training center. Experienced

service technicians or embryologists conduct training to ensure that the installation personnel clearly understand the device's functions, performance, testing, and maintenance.

Personnel, responsible for installation, must be informed regarding alterations or additions to this document and the "Installation report" form.

38.2 Before installation

2 – 3 weeks before the upcoming installation date, the user/owner at the clinic is contacted via e-mail to plan the exact time to perform the installation.

The released MIRI® or MIRI® Humidity 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® or MIRI® Humidity multiroom IVF incubator weight is approx. 40 kg.
3. The required space for placement is 1.0 m x 0.6 m.
4. Temperature control should be able to maintain a stable temperature, never exceeding 30 °C.
5. Humidity control to avoid condensation.
6. Uninterrupted power supply (UPS) with 115 or 230 V, minimum 120 W.
7. Proper grounding.
8. CO_2 gas outlet with 0.6 – 1.0 atm above ambient.
9. N_2 gas outlet with 0.6 – 1.0 atm above ambient if the clinic uses reduced oxygen levels.
10. Tubes that fit 4 mm hose end and HEPA filter.
11. Access to a PC with USB for the data logging.

38.3 Preparing for installation

- Bring the "Installation report" form. Make sure it is the latest and current version only.
- Fill out the following blank boxes in the form: the MIRI® or MIRI® Humidity multiroom IVF incubator serial number (S/N) and customer.
- The service tool kit is checked for content before every installation trip to ensure it contains the necessary tools.
- Always bring the latest versions of firmware and data logging software. Bring these files on a labeled memory stick to the service site.

38.4 Bring the following to the installation site

- "Installation report" form.
- Service manual for the MIRI® and MIRI® Humidity multiroom IVF incubators.
- Updated service tool kit.
- Memory stick with the latest released firmware & software.
- High precision thermometer with a resolution of not less than 0.1 °C.
- Calibrated gas analyzer with precision of at least 0.1% for CO_2 and O_2 and the possibility of returning gas samples to the MIRI® or MIRI® Humidity multiroom IVF incubator.
- Extension cable for USB connection.

38.5 Installation procedure at the site

For the correct installation procedure please refer to the "9 Getting started" section of the User Manual.

38.6 User training

1. Main power switch on/off.
2. Explain the MIRI® and MIRI® Humidity multiroom IVF incubators essential function and incubation with a multi-room facility to store the samples.
3. Explain temperature control in MIRI® and MIRI® Humidity multiroom IVF incubators (direct heat transfer with heated lids).
4. Gas regulation on/off.
5. Setpoint for temperature, CO_2 and O_2.
6. Explain how N_2 is used to suppress the O_2 concentration.
7. Alarm turn off procedure (temperature, CO_2, O_2) and revert times.
8. Insertion and removal of heating optimization plates from the MIRI® or MIRI® Humidity multiroom IVF incubator.
9. How to toggle the "Oil culture" and "Open culture" modes, and when which mode should be used.
10. Emergency procedures (can be found in the "29 Emergency procedures" section of the User Manual).
11. Explain how to clean the device and heating optimization plates.
12. External measurement and calibration of temperature.
13. External measurement and calibration of gas concentration.
14. How to add and remove a sample.
15. Demonstrate how to replace the VOC/HEPA filter (can be found in the "12.1 Installation procedure of a new VOC/HEPA filter" section of the User Manual). Not applicable in the MIRI® Humidity multiroom IVF incubator.
16. Datalogger functionality, how to establish a connection and re-connection.

☞ **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.**

38.7 After the installation

When the installation trip is finished, a copy of the original "Installation report" form must be sent to Esco Medical Technologies, UAB. It will be saved with the device records. According to the ISO procedure and Medical Device Directive, 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. The date of installation is also written in the service schedule.

Suppose the MIRI® or MIRI® Humidity 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 reported in the CAPA system. If a critical error has occurred, information about this will be reported directly to QC or QA.

⚠ **If the MIRI® or MIRI® Humidity 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® or MIRI® Humidity multiroom IVF incubator must be taken out of service until it is repaired/exchanged, or a new test approves the MIRI® or MIRI® Humidity multiroom IVF incubator. The User and owner must be informed about this and arrangements to solve the problems must be initiated.**

39 Other countries

39.1 Switzerland

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

Figure 39.1 Swiss Authorised Representative

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

40 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.