ESCO MEDICAL

CE 0123

USER MANUAL

MIRI® II-12 multiroom IVF incubators

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Rx only

CERTIFIED INCUBATION

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Copyright Information

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 instrument. Check the shipping carton for damage. If the damage is found, stop unpacking the instrument. Notify the freight carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument 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 instrument 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 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 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 instrument has been thoroughly tested/inspected and found to meet Esco Medical's manufacturing specifications when shipped from the factory. Calibration measurements and testing are traceable and done according to Esco Medicals ISO certification.

Warranty and Product Support

Esco Medical warrants this instrument 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 instrument is calibrated and maintained following this manual. During the warranty period, Esco Medical 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. 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.

IN NO EVENT SHALL ESCO MEDICAL LTD. 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 instrument
- An improper power supply such as low voltage, incorrect voltage, defective wiring or inadequate fuses
- Accident, alteration, abuse or misuse of the instrument
- Fire, water damage, theft, war, riot, hostility, acts of God such as hurricanes, floods, etc.

Only serialized 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 instrument per Esco Medical's specifications.

When you return an instrument to Esco Medical 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 instrument 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 instrument

Esco Medical will not be responsible for lost shipments or instruments 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 to obtain an RMA number and receive help with shipping/customs

documentation.
Re-calibration of instruments, which have a recommended annual calibration frequency, is not covered under warranty.

Warranty Disclaimer
If your instrument is serviced and/or calibrated by someone other than Esco Medical Ltd. 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 costs, as this seal is key to your original instrument warranty. In an event where the seal must be broken to gain internal access to the instrument, you must first contact Esco Medical Ltd.

You will be required to provide us with the serial number for your instrument, 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 instrument without interruption.

WARNING
Unauthorized user modifications or applications beyond the published specifications may result in electrical shock hazards or improper operations. Esco Medical will not be responsible for any injury sustained due to unauthorized equipment modifications.

ESCO MEDICAL LTD. 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 INSTRUMENT COVER SHALL VOID THIS AND ALL OTHER EXPRESSED OR IMPLIED WARRANTIES.

Table of contents

1 How to use this manual

The manual is designed to be read by sections and not ideally from cover to cover. It means that if the manual is read from start to finish, there will be some repetition and overlap. We recommend the following method for going through the manual: first, familiarize yourself with the safety instructions; then, proceed to the essential user functions needed for operating the equipment on a day to day basis; then, review the alarm functions. The menu function of the user interface details information that is needed only for advanced users. All parts must be read before the device is taken into use. The Validation guide is detailed described in sections 33 – 36. The Maintenance guide is detailed described in section 37. The Installation procedures are detailed described in section 38.

2 Safety warning

- Anyone working with, on or around this equipment should read this manual. Failure to read, understand, and follow the instructions given in this documentation may damage the unit, injure 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, ensure 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 should thoroughly understand the installation procedures and note the environmental/electrical requirements.
- In this manual, important safety-related points will be marked with the following symbols:

NOTE
It is used to direct attention to a specific item.

WARNING
Use caution.

- If the equipment is used in a manner not specified by this manual, the protection provided by this equipment may be impaired.

3 Indication for use

The Esco Medical MIRI® family's multiroom IVF incubators are intended to be used to pro-vide 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

Esco Medical MIRI® II-12 multiroom IVF incubator is a CO_2/O_2 gas incubator.

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

The temperature in the compartment will remain stable up to 1 °C (even when a lid is open for 30s) and will recover within 1 min after the lid is closed.

MIRI® II-12 multiroom IVF incubator has 12 completely separate culture heat chambers. Each chamber has its own heated lid and warming plate for Petri dish. The MIRI® II-12 maximum capacity is 24 pcs of 35 mm Petri dishes and 12 pcs of 60 mm or 4-well Petri dishes.

To ensure maximum performance, the system of the MIRI® II-12 multiroom IVF incubator have 24 completely separate PID temperature controllers. They control and regulate temperature in culture chambers and lids. Compartments do not affect each other`s temperatures in any way. The top and the bottom of each compartment is separated with a PET layer so that the lid temperature would not affect the bottom. For validation purposes, each compartment has a PT-1000 sensor built in. The circuitry is separated from the unit`s electronics so it remains a truly separate validation system.

The multiroom IVF incubator has to be supplied with 100% CO_2 and 100% N_2 in order to be able 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 level. A chemical medical grade oxygen sensor controls the level of O_2.

Gas recovery time is less than 3 min. after opening the lid. To validate gas concentration, the MIRI® II-12 multiroom IVF incubator is fitted with 12 gas sample ports that allow the user to sample gas from the individual compartment.

The multiroom IVF incubator features a recirculated gas system where gas is continuously put into the compartment 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

filter and through a HEPA filter. The UVC light has filters that inhibit any 185 nm radiation that would produce dangerous ozone. The VOC filter is located under the UVC light.

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 5 l/h N_2 in use.

For safety reasons the multiroom IVF incubator has a very complete gas control system that consists of: pressure regulator (preventing dangerous gas pressure problems), gas flow sensors (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 compartment is easy to reach and safe because of the compartment numbering and the ability to write on the white lid with a pen.

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

The multiroom IVF incubator has a built-in PC which operates the Esco Medical Data logger software for long-term data logging and data storage.

USB module enables the QC data to be transferred for off-site evaluation – by performing this, the manufacturer can provide a valuable service to the customers (MIRI® II-12).

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

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.

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® II-12 multiroom IVF incubators. Also, the MIRI® II-12 multiroom IVF incubators does not contains 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 carton 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® II-12 multiroom IVF incubator can be prepared for transport.

These labels should be glued on the box:

- Label with the 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 store under the following conditions:

- The unit can be in storage for one year. If stored longer than one year, the unit must be returned to the manufacturer for a new release test
- The unit can be stored at temperatures between -20 °C and + 50 °C
- Keep away from direct sunlight
- 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
- Do not use if the packing material is damaged
- Keep dry

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

5.3 Disposal

Information on handling of the unit as per 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. Prior to disposal, the whole device must be disinfected or decontaminated.**

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

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

6 Supplied service parts and accessories

Service parts:

- 1 VOC/HEPA filter capsule
- 2 HEPA filters for input gas supply
- 12 warming blocks
- 4 warranty labels
- 1 USB stick containing a PDF version of the user manual
- 1 medical grade power cord
- 1 3.5mm external alarm jack connector
- 1 set of fast male connectors with 15 silicone pipes

Accessories do not apply with the MIRI® II-12 multiroom IVF incubator.

7 Safety symbols and labels

There are several user labels on the surface of MIRI® II-12 multiroom IVF incubator to guide the user. User labels are shown below.

Table 7.1 Packing box and electrical safety labels

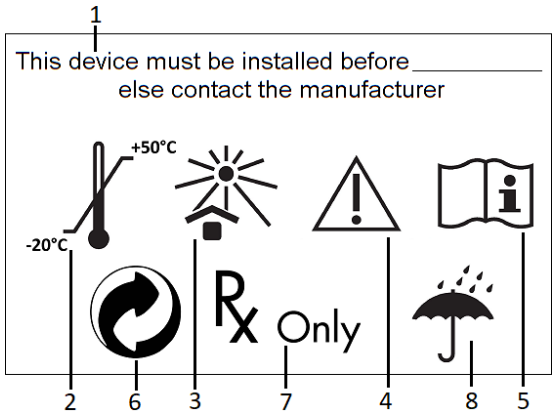
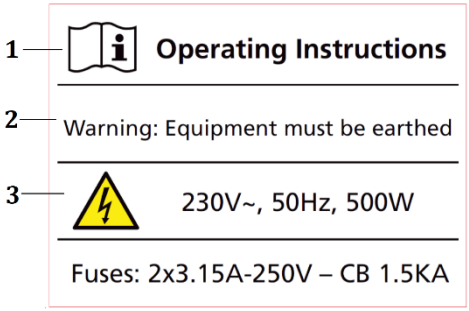
Description	Image
Packing box label: 1. If stored longer than the shelf life, the unit must be returned to the manufacturer for a new release test. 2. Shipping temperature between -20 °C and +50 °C. 3. Keep away from direct sunlight. 4. Caution: consult the accompanying documents for important safety-related information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself. 5. Consult instructions for proper use of the device. 6. Do not use if the packing material is damaged. 7. Rx Only. 8. Keep dry.	
1. Consult instruction for use. 2. Warning on the back of the device indicates that an earth connection is needed and the mains information and an "ON/OFF" push button. 3. "Lightning bolt" indicates the potential risk of electrical shock (never remove any cover).	

Table 7.2 Device label

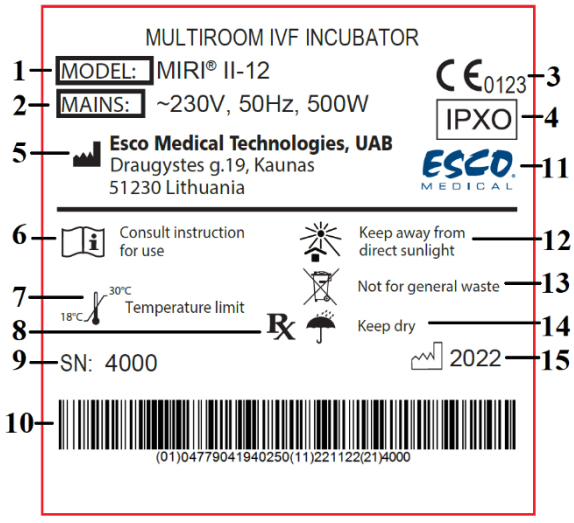
Description	Image
1. Model. 2. Mains power rating. 3. CE mark. 4. Not protected against the ingress of water. 5. Manufacturer's address and country of origin. 6. View instruction for use. 7. Temperature limit. 8. Rx only. 9. Serial number. 10. UDI-DI code. 11. Logo. 12. Keep away from direct sunlight. 13. Observe WEEE. 14. Keep dry. 15. Year of manufacture.	

Table 7.3 Labels on the MIRI® II-12 multiroom IVF incubator

Description	Image
USB communication port	
HDMI communication port	
CO_2 inlet	
N_2 inlet	
BNC pH line	
pH SAFE Sense	
Alarm port	
Compartment numbers are indicated on the top corner of the lid with a label	
Maximum pressure 0.8 bar	
VOC/HEPA filter	
Ethernet	
PC on/off	
PT 1000 validation sensors	
Gas sample ports	

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 USB, Ethernet and HDMI connections.

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

Figure 7.1 Compartment numbers on MIRI® II-12 multiroom IVF incubator

8 Important safety instructions and warnings

8.1 Before installation

1. Do not use the product if the package is damaged. Contact Esco Medical 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 unit on top of other equipment that gives off heat.
2. Place this unit on a flat, hard and stable surface.
3. Do not place the unit on a carpet or similar surfaces.
4. Do not defeat the safety purpose of the grounding-type (earthing) plug.
5. A grounding-type (earthing) plug with two blades and a third prong are provided for your safety. If the provided plug does not fit into your outlet, consult an electrician to replace the outlet.
6. Always connect the power cord to a properly grounded outlet and only use the cord that came with the device.
7. Do not install near any heat sources such as radiators, heat registers, stoves or other apparatus that produce heat.
8. Do not use this device near water sources.
9. Use only 100% concentration CO_2 and 100% concentration N_2 gases.
10. Always use an external HEPA filter for input CO_2 and N_2 gases.
11. Do not use this product if the room temperature exceeds 30 °C.
12. Place this unit 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 unit is intended for indoor purposes only.

14. The unit must be connected to a suitable uninterrupted power supply (UPS) source.

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® II-12 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, convenience receptacles and the point where it exits from the apparatus.
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. VOC/HEPA filters must be changed every 3 months.
8. A maintenance plan must be fulfilled to keep the device safe.
9. NEVER block gas supply holes in the compartment.
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 except Esco Medical filter. Otherwise, the warranty will be void.
12. Do not use the device without a proper Esco Medical VOC/HEPA filter attached.

9 Getting started

⚠ **The MIRI® II-12 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 mains cable to the UPS.
3. Connect the mains cable to the MIRI® II-12 multiroom IVF incubator.
4. Connect 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® II-12 multiroom IVF incubator in the back.
7. Observe for standard functionality.
8. Let the unit warm up and stabilize for 20 min.
9. Follow the guidelines in the Validation guide (see section “33 The validation guide”).
10. Complete user training and finish reading instructions.

11. After a burn-in phase of 24 hours, the unit 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. Consult the cleaning instructions section in this manual for the manufacturer's recommended guidelines!

10 Mains connection

The MIRI® II-12 multiroom IVF incubators come with a detachable mains power cord. The power cord is prepared for the country in which the unit is intended to be used.

The ON/OFF switch provides the user with a means to isolate the MIRI® II-12 multiroom IVF incubator from the mains.

Do not defeat 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 unit. These ports are marked "CO_2 100% Inlet" and "N_2 100% Inlet".

Figure 11.1 Gas inlets on the back of the MIRI® II-12 multiroom IVF incubator

CO_2 inlet should be connected to a 100% concentration of CO_2. CO_2 control in the compartment is available in the range from 3.0% to 10.0%.

N_2 inlet should be connected to a 100% concentration N_2 if low oxygen conditions are required. O_2 control in the compartments is available in the range from 5.0% to 10.0% by infusing N_2 gas.

Gas pressure for both inlets 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 CO_2 gas to the CO_2 inlet with a suitable silicone tube. Ensure that the tube is fastened with a clip so that it does not accidentally loosen itself during a sudden pressure fluctuation. Use the supplied 0.2µ HEPA filter on the gas line just before the inlet on the multiroom IVF incubator. Notice the flow direction.

Connect the N_2 inlet to the Nitrogen Bottle.

Figure 11.3 Gas filter

12 HEPA/VOC filter

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 multiroom IVF incubators for your medical gasses.

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 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 HEPA and VOC filter (carbon filter) are integrated into the construction of the MIRI® II-12 multiroom IVF incubator. Before entering the multiroom IVF incubator, the gas is sent through the filter in a single pass. Then, upon return from the compartment, the gas is filtered again. The recirculation system constantly filters gas in the multiroom IVF incubator.

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

12.1 Installation of a new filter capsule

Two blue caps that are installed on the filter can be discarded during unwrapping. Correct filter performance is crucial for the system’s performance.

☞ Filter element must be changed every 3 months. Mark the date when it is put on and make sure to keep this interval!

Start by putting the blue fittings on the filter into the filter holder sockets. The flow arrow on the MIRI® II-12 multiroom IVF incubator and the filter should point in the same direction.

Figure 12.1 The flow arrow on the multiroom IVF incubator

Figure 12.2 The direction of pulling the filter

Figure 12.3 Filter in place

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

⚠ **A filter element that has been fitted incorrectly will cause the unit to work not as intended. This is dangerous!**

The filter is removed by gently pulling it straight out using both hands.

⚠ **Never run the MIRI® II-12 multiroom IVF incubator if the filter element is missing! Dangerous particle contamination could occur!**

13 User interface

In the following chapters, the functions associated with keys and menu items will be explained.

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

Table 13.1 The main keys and their purpose

Description	Image
Main keys	
ON/OFF keys It is located in the REAR of the unit. 1st key turns on the device and 2nd key turns on the PC.	
Alarm key It mutes an audible alarm and visually indicates the alarm condition by a flashing red circle of light. The audio alarm will come back on automatically after 5 min. It can be muted again.	
Display panel Shows the information about the current status of the unit. The display consists of a 7'' touchscreen display.	

13.1 Activating the heat and gas controls

Heat and gas control systems are activated using the ON/OFF switch in the rear.

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

- Compartments 1 – 12 bottom and lid temperatures.
- CO_2 concentration, CO_2 pressure and incoming CO_2 gas.
- O_2 concentration, N_2 pressure and incoming N_2 gas.
- Temperature Running Mode: Single/Multi.

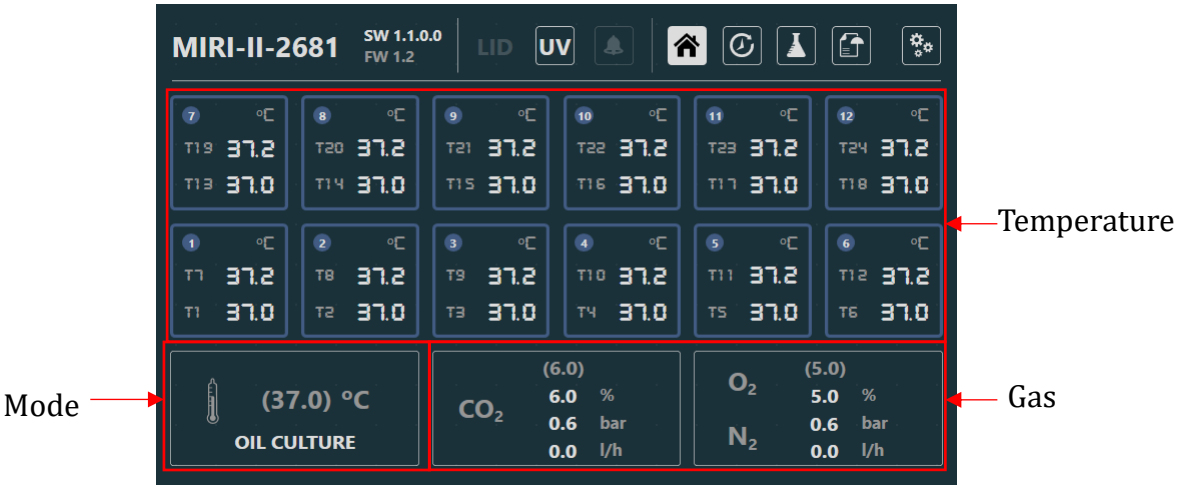


Figure 13.1 Main display view

13.2 Temperature setpoint

The temperature setpoint can be adjusted in the range from 25.0 °C to 40.0 °C.

The default temperature setpoint is 37.0 °C.

To change the temperature setpoint, please follow these instructions:

1. Press one of the compartments boxes to change the temperature setpoint:

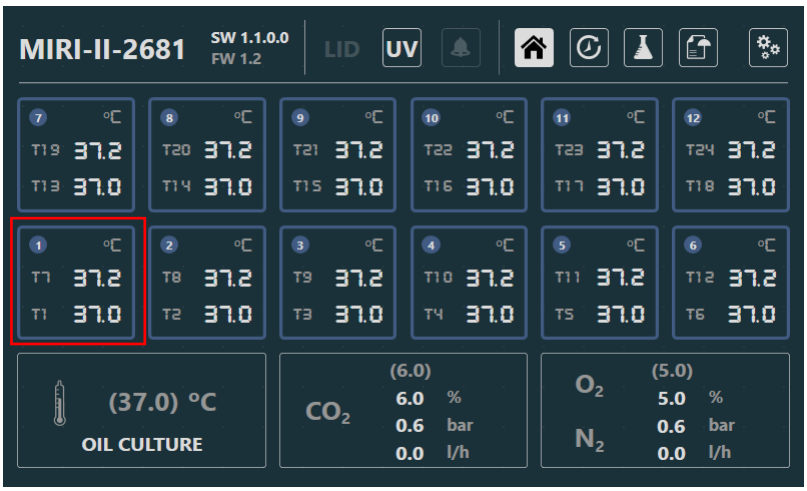


Figure 13.2 Main display view

2. Press (+) or (-) keys to adjust the temperature setpoint. In the picture below, the setpoint for compartment 1 is chosen.

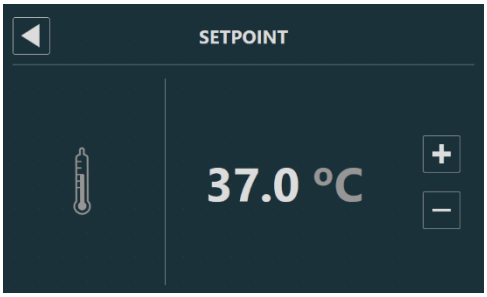


Figure 13.3 Setpoint for compartment 1 view

When using the multi-setpoint, the multi-setpoint must be chosen in the operation mode. When the setpoint is set, press the (◁) key.

Figure 13.4 Operation mode view

If the "SINGLE" temperature setpoint is set, then the value will be applied to all compartments. If the "MULTI" temperature setpoint is set, it means that the compartments' temperature values are individual for each compartment.

13.3 Changing the CO_2 concentration setpoint

The CO_2 setpoint can be adjusted in the range from 3.0% to 10.0%.

The default CO_2 setpoint is 6.0%.

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

1. Press the CO_2 box to change the CO_2 concentration setpoint:

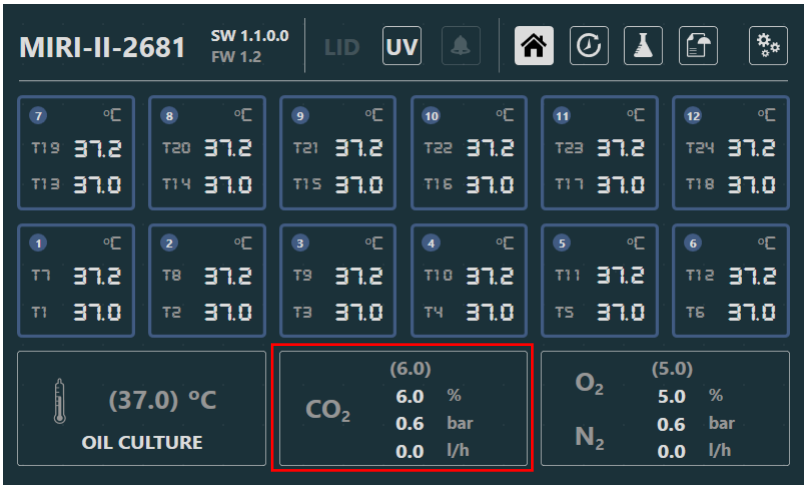


Figure 13.5 Main display view

2. Press (+) or (-) keys to adjust the CO_2 setpoint. In the picture below, the setpoint for CO_2 is chosen.

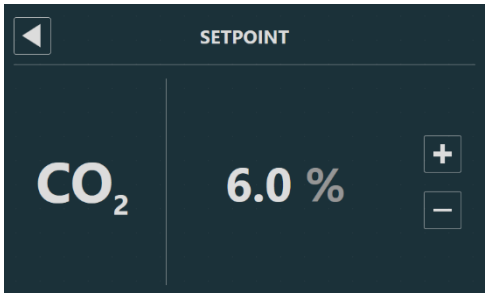


Figure 13.6 CO_2 setpoint view

13.4 Changing the O_2 concentration setpoint

The O_2 setpoint can be adjusted in the range from 5.0% to 10.0%.

The default O_2 setpoint is 5.0%.

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

1. Press the O_2 box to change the O_2 concentration setpoint:

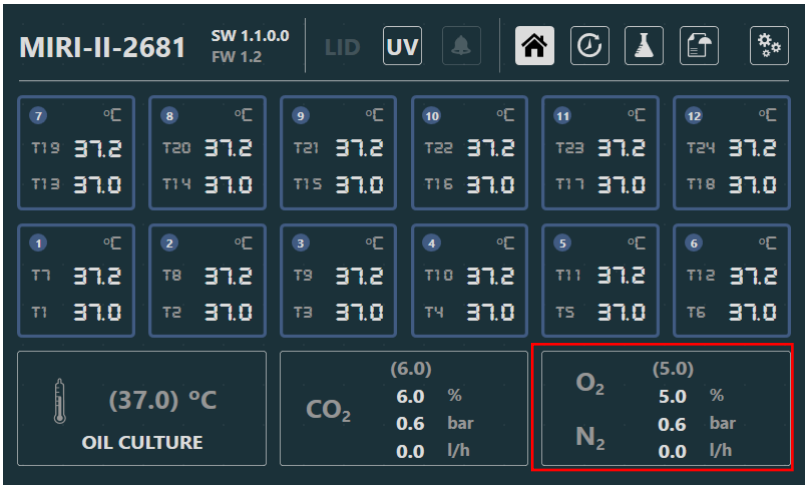


Figure 13.7 Main display view

2. Press (+) or (-) keys to adjust the O_2 setpoint. In the picture below, the setpoint for O_2 is chosen:

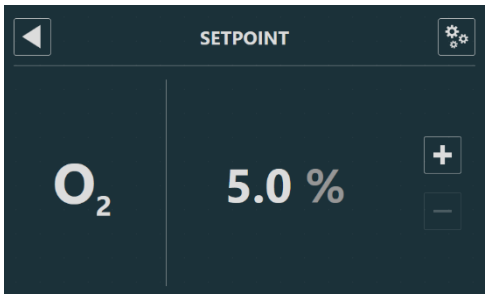


Figure 13.8 O_2 setpoint view

3. Press the SETUP key in the "O_2 setpoint" page to turn the O_2 regulation ON/OFF.

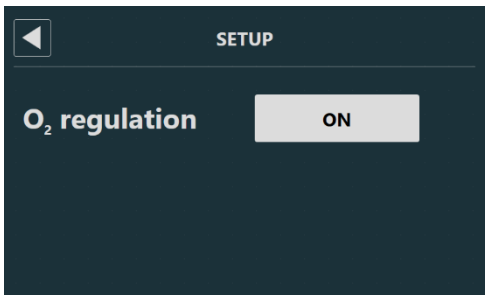


Figure 13.9 O_2 regulation view

13.5 System menu

Press the SETTINGS key to enter the menu. The key is located on the right top side of the main display:

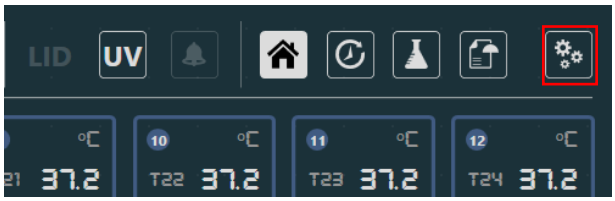


Figure 13.10 Setup key location view

Press the RUNNING MODE key to enter the mode setting. The key is located on the left bottom side of the main display:

Figure 13.11 Running mode key location on the main display

Press the LOGGER key to enter the data logger. The key is located on the top of the main display:

Figure 13.12 Logger key location on the main display

Press the UV LAMP key to turn the UV lamp ON/OFF. The key is located on the top of the main display:

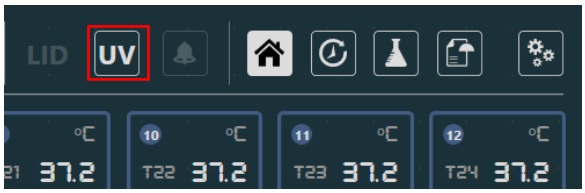


Figure 13.13 UV lamp key location on the main display

Press the pH key to enter pH measuring. The key is located on the top of the main display:

Figure 13.14 pH measuring key location on the main display

Press the REPORT EXPORT key to enter data-logging graphs. The key is located on the top of the main display:

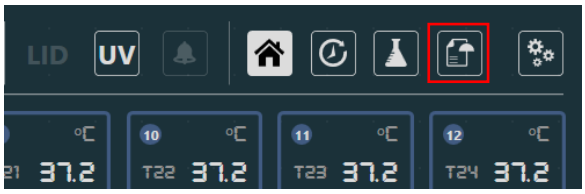


Figure 13.15 Report export key location on the main display

13.5.1 General menu page

Press the SETTINGS key to enter the general menu page. The key is located on the right top side of the main display:

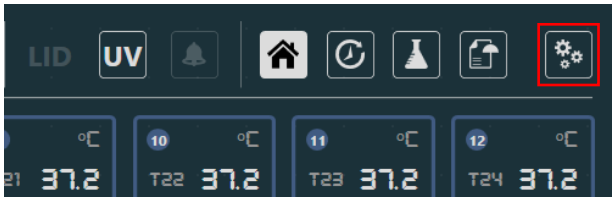


Figure 13.16 Setup key location view

The general menu page is shown below:

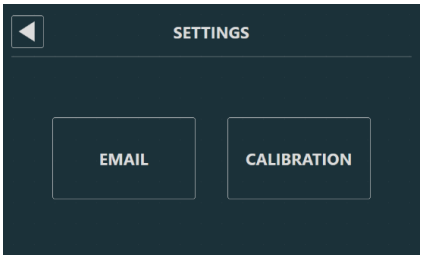


Figure 13.17 General menu view

- Press the EMAIL key to enter the email page.
- Press the CALIBRATION key to enter the calibration page.
- Press the (◁) key at the top to return to the main page.

13.5.2 Calibration menu

The calibration menu page is shown below:

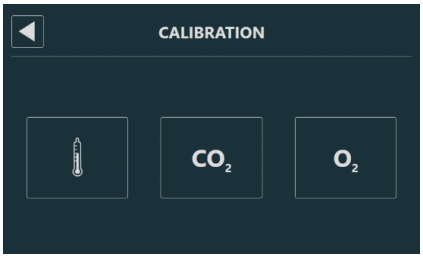


Figure 13.18 Calibration menu view

- Press the TEMPERATURE key to enter the temperature calibration page.
- Press the CO_2 key to enter the CO_2 calibration page.
- Press the O_2 key to enter the O_2 calibration page.

13.5.3 Temperature calibration menu

The temperature calibration menu page is shown below:

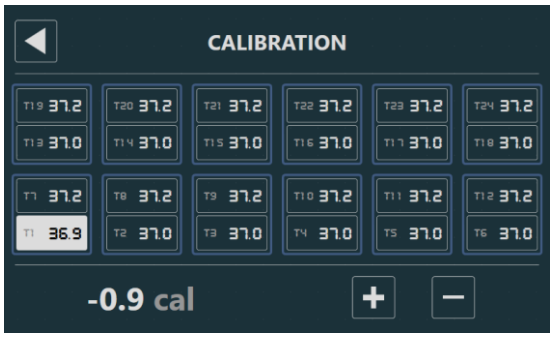


Figure 13.19 Calibration of the T1 zone temperature view

In the above picture, zone T1 is chosen. Press (+) or (–) keys to calibrate T1. The same applies to other temperature zones.

Press the (◁) key at the top to return to the calibration menu page.

Each compartment has two internal temperature sensors. One in the compartment lid and another in the compartment bottom.

Example – how to calibrate temperature:

The temperature has to be measured with a suitable and calibrated device. With a high-quality thermometer, it has been estimated that T1 is 37.4 °C. Calibrate and adjust the temperature by pushing (+) or (-) keys.

Adjust the temperature by pressing the (+) key 5 times when T1 is chosen. The display will show the steps from 36.9 °C, 37.0 °C, 37.1 °C, 37.2 °C, 37.3 °C and 37.4 °C. The new value is now stored and T1 sensor calibration is modified.

☞ **The calibration procedure is the same for T1 – T24.**

☞ **"T1" is used to adjust the bottom temperature of compartment 1. "T7" is used to adjust the lid's temperature in the same compartment. Remember that the delta-T between the top and bottom should always be 0.2 °C.**

☞ **Adjust according to a high-precision measurement done with a suitable sensor placed in a dish with media and a mineral oil overlay. Place the dish in one of the designated spots indicated on the heating insert.**

☞ **Proceed to validate if the lid temperature is precisely 0.2 °C higher than the bottom temperature.**

☞ **Stick a suitable calibrated sensor to the middle of the lid area and close the lid. Wait 15 minutes and record the temperature reading. Adjust "T7" to the desired level, using the same procedure as described above. It may be necessary to do iterations before the zone is completely calibrated.**

13.5.4 CO_2 calibration menu

The CO_2 calibration menu page is shown below:

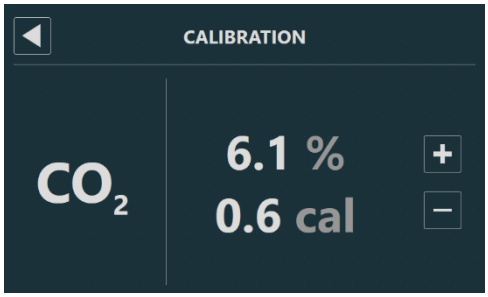


Figure 13.20 CO_2 calibration page view

Press the (◁) key at the top to return to the calibration menu page.

Example – how to calibrate CO_2:

The real CO_2 concentration is measured with a suitable and calibrated device on one of the gas sample ports (all ports can be used for this purpose). It was estimated to be 6.4%.

☞ **Calibration is performed by adjusting the CO_2 level according to the measurement taken from the gas sampling outlet by an external reliable CO_2 measurement device.**

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

Adjust the calibration to the desired level by pressing the (+) and (-) keys. In this case, the goal is to adjust CO_2 gas levels to 6.4%. The display will show 6.0, 6.1, 6.2, 6.3 and 6.4%. The new value is now stored and CO_2 sensor calibration is modified.

☞ **The offset value is displayed in the CO_2 calibration window along with the CO_2 concentration value. In this case, the real CO_2 concentration was measured to be 6.4%. By pressing the "+" button three times, it will take time to change the display's CO_2 concentration value, but the offset value will change immediately (in this case, the window will show 0.9 cal). By following this value, the user can see how much the CO_2 calibration value changed without delay.**

13.5.5 O_2 calibration menu

The O_2 calibration menu page is shown below:

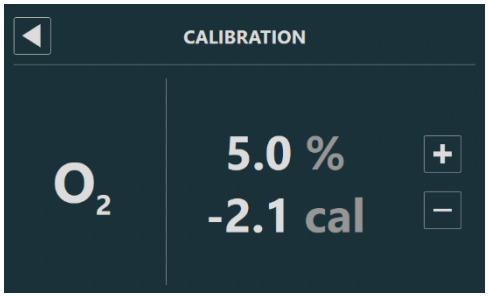


Figure 13.21 O_2 calibration page view

Press the (◁) key at the top to return to the calibration menu page.

Example – how to calibrate O_2:

The real O_2 concentration is measured with a suitable and calibrated device on one of the gas sample ports (all ports can be used for this purpose). It was estimated to be 5.3%.

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

☞ **Calibration values should only be changed by a trained user or the technician,**

according to specific measurements. Done with the calibrated device.

Adjust the calibration to the desired level by pressing the (+) and (-) keys. In this case, the goal is to adjust to O_2 gas levels to 5.3%. The display will show 5.0, 5.1, 5.2, and 5.3%. The new value is now stored and O_2 sensor calibration is modified.

☞ **The offset value is displayed in the O_2 calibration window along with the O_2 concentration value. In this case, the real O_2 concentration was measured to be 5.3%. By pressing the "+" button three times, it will take time to change the display's CO_2 concentration value, but the offset value will change immediately (in this case, the window will show -1.8 cal). By following this value, the user can see how much the O_2 calibration value changed without delay.**

13.5.6 Running mode page

The running mode page is shown below:

Figure 13.22 Operation mode page view

1. Choose between the SINGLE or MULTI temperature setpoint.

☞ **If the "SINGLE" temperature setpoint is set, then the value will be applied to all compartments. If the "MULTI" temperature setpoint is set, it means that the compartments' temperature values are individual for each compartment.**

☞ **When choosing between the "SINGLE" or "MULTI" temperature setpoint, all compartments' temperature setpoint is set according to T1 by default setting. In "SINGLE" mode, changing any compartment's temperature setpoint value will apply to all remaining compartments. In "MULTI" mode, each compartment has different setpoint values. When returning from "MULTI" mode to "SINGLE", all setpoints are automatically set to the T1 area value.**

☞ **It is recommended to keep the setting for a "SINGLE" setpoint if all compartments run at the same temperature. It will be easier to make adjustments to the setpoint as the adjustment will only have to be done once instead of twelve**

times (i.e., for individual compartments).

2. Press the (◁) key to return to the main page.

14 Alarms

On fault condition, the display will show the values in red. An audio signal will go off, but it can be muted by pressing the ALARM key once (toggled on/off for 5 minutes). An arrow will also appear and it will indicate whether the alarm is triggered due to too high or too low values. The audio on/off key will blink red:

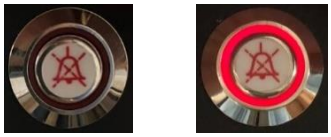


Figure 14.1 The alarm key which indicates the alarm condition

The audio pattern is 3 short beeps followed by a 3-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!**

14.1 Temperature alarms

All 12 compartments can trigger the temperature alarm if the temperature in them deviates more than ±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. It applies for all calibration adjustments.**

In the picture below, the temperature in compartment 6 is too high compared to the setpoint.

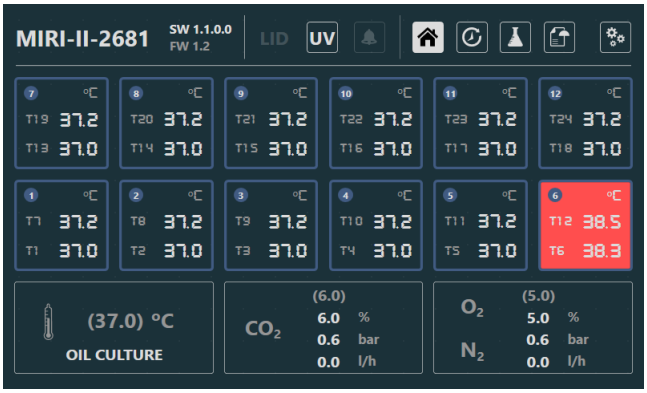


Figure 14.2 High-temperature alarm view on the main display

Temperature is too high in Compartment 6. The affected compartment will appear in red on display.

If the mute key is pressed, the display will still show a red value and the sound will be muted for 5 minutes until the audio alarm goes off again. The mute alarm key will still show the alarm condition by blinking red when the alarm is muted.

☞ Please refer to the 29 "Emergency procedure" section on how to behave when there is a temperature alarm.

14.2 Gas level alarms

14.2.1 CO_2 alarms

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

☞ Remember that changing the setpoint more than ±1% from the current gas level will result in a CO_2 level alarm. It applies for all calibration adjustments.

In the picture below, the CO_2 concentration is too low compared to the setpoint.

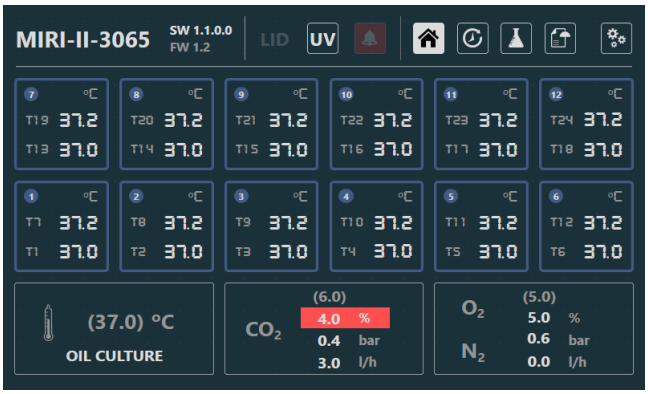


Figure 14.3 Low CO_2 concentration alarm view on the main display

The percentage of CO_2 is too low. CO_2 concentration will appear in red on display.

If the mute key is pressed, the display will still show a red value and the sound will be muted for 5 minutes until the audio alarm goes off again. The mute alarm key will still show the alarm condition by blinking red while the alarm is muted.

☞ Please refer to the 29 "Emergency procedure" section on how to behave when there is a CO_2 level alarm.

14.2.2 O_2 alarms

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

Remember that changing the setpoint more than ±1% from the current gas level will result in an O_2 level alarm. It applies for all calibration adjustments.

In the picture below, the O_2 concentration is too high compared to the setpoint.

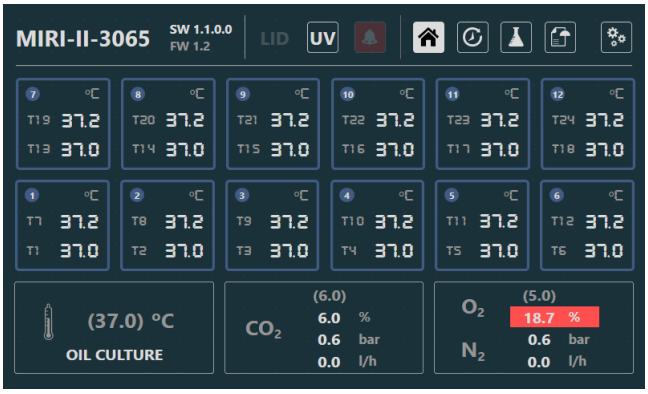


Figure 14.4 High O_2 concentration alarm view on the main display

The percentage of O_2 is too high. The display will lock on the alarm condition and will stop alternating between the standard status messages.

If the mute key is pressed, the display will still show a red value and the sound will be muted for 5 minutes until the audio alarm goes off again. The mute alarm key will still show the alarm condition by blinking red when the alarm is muted.

Please refer to the 29 "Emergency procedure" section on how to behave when there is an O_2 level alarm.

14.3 Gas pressure alarms

14.3.1 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® II-12 multiroom IVF incubator will go into CO_2 pressure alarm mode. CO_2 pressure will be displayed in red, indicating the wrong 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.

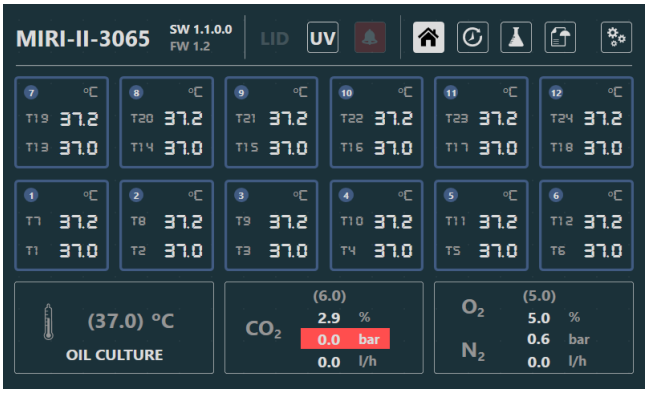


Figure 14.5 CO_2 gas pressure alarm view on the main display

☞An audible alarm is also activated, but it can be muted by pressing the alarm key. If the mute key is pressed, the audio sound will be muted for 5 minutes.

☞ Please refer to the 29 "Emergency procedure" section on how to behave when there is a CO_2 pressure alarm.

14.3.2 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, the MIRI® II-12 multiroom IVF incubator will go into N_2 pressure alarm mode. N_2 pressure will be displayed in red, indicating the wrong 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.

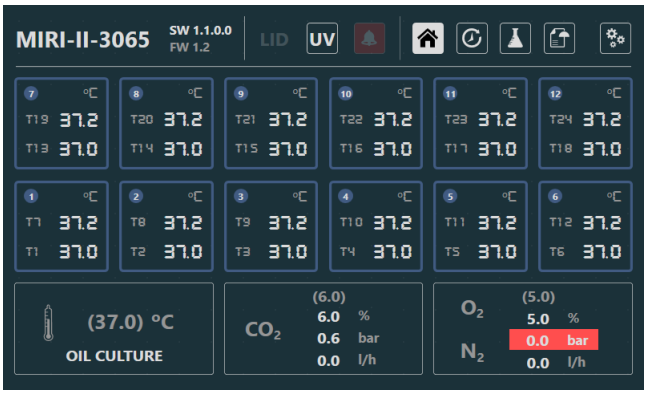


Figure 14.6 N_2 gas pressure alarm view on the main display

☞ An audible alarm is also activated, but it can be muted by pressing the alarm key. If the mute key is pressed, the audio sound will be muted for 5 minutes.

☞ Please refer to the 29 "Emergency procedure" section on how to behave when there is an N_2 pressure alarm.

14.4 Service UVC light

The service UV-C light will appear only as a warning message during the normal status.

An audio alarm will not go off.

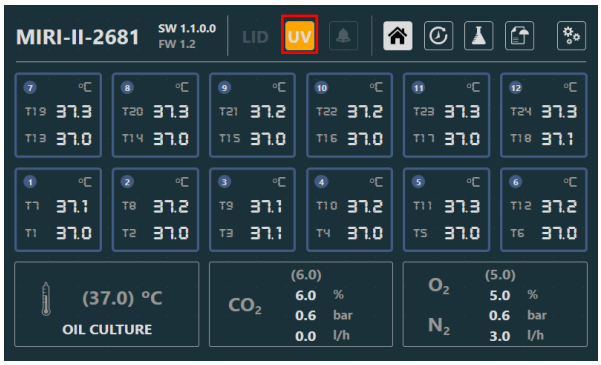


Figure 14.7 UV-C light malfunction

The user should consult the distributor for further guidance or service inspection. The "UV" will disappear only when the UV-C light will be working again.

Please contact your Esco Medical distributor for more details.

14.5 Multiple alarms

In the picture below, in compartment 6 the temperature is too high, the CO_2 is not connected, or the CO_2 pressure is incorrect and there is also a UV-C light malfunction.

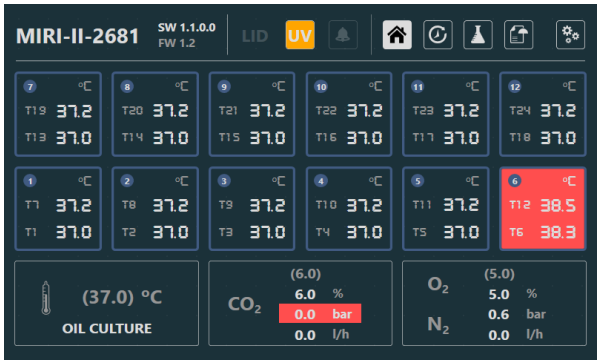


Figure 14.8 Multiple alarm view on the main display

When there are multiple affected parameters, all of them will appear red in the display.

If the mute key is pressed, the display will show a red value and the sound will be muted for 5 minutes until the audio alarm goes off again. The mute alarm key will still show the alarm condition by blinking red when the alarm is muted.

Please refer to the 29 "Emergency procedure" section on how to behave when there is a multiple alarm.

14.6 Loss of power alarm

If the multiroom IVF incubator power is disconnected, an audio alarm will go on for approximately 4 seconds, and the LED in the mute alarm key will flash.

Figure 14.9 The alarm key which indicates the alarm condition

Please refer to the 30 "Emergency procedure" section on how to behave when there is a loss of power alarm.

14.6 Summary of the alarms

In the table below, there is a list of every possible alarm in the MIRI® II-12 multiroom IVF incubators.

Table 14.1 Every possible alarm in the MIRI® II-12 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 compartment'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 compartment's bottom temperature		Technical	High priority alarm
Low CO_2 level	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 level	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 level	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 level	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 name	Conditions	How it is determined	Alarm group	Alarm 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

14.7 Alarm verification

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

Table 14.2 Alarm verification in the MIRI® II-12 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 in the middle of the compartment and close the lid	
High CO_2 level	Decrease the setpoint value by 3.0% from the current setpoint	
Low O_2 level	Increase the setpoint value by 3.0% from the current setpoint	
High O_2 level	Open the lid and leave it open for 5 min	
Low CO_2 level	Open the lid and leave it open for 3 min	
Low incoming CO_2 level	Disconnect the incoming CO_2 gas	
Low incoming N_2 pressure	Disconnect the incoming N_2 gas	

15 Surface temperatures and measuring temperature

In this section, the MIRI® II-12 multiroom IVF incubator temperature control system is described in more detail.

The MIRI® II-12 multiroom IVF incubator is equipped with 12 completely separate PID controllers for temperature measurement. Each controller is responsible for controlling the temperature in a particular 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.

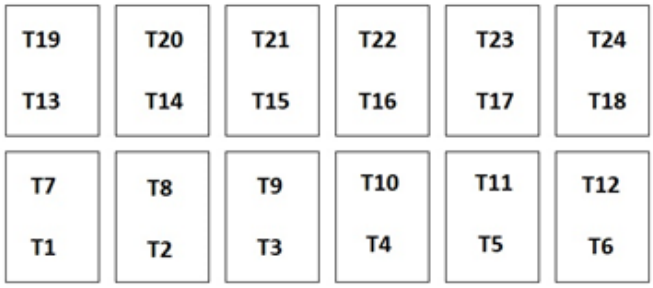


Figure 15.1 Temperature zones in the MIRI® II-12 multiroom IVF incubator

Each area can be calibrated separately, using the item corresponding to the respective area in the menu.

These items are placed in the menu and they are named the following: T1, T2, T3, T4, T5, T6, T7, T8, T9, T10, T11, T12, T13, T14, T15, T16, T17, T18, T19, T20, T21, T22, T23 and T24.

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

Table 15.1 Areas associated with sensors

Area	Bottom	Lid
Compartment 1	T1	T7
Compartment 2	T2	T8
Compartment 3	T3	T9
Compartment 4	T4	T10
Compartment 5	T5	T11
Compartment 6	T6	T12
Compartment 7	T13	T19
Compartment 8	T14	T20
Compartment 9	T15	T21
Compartment 10	T16	T22
Compartment 11	T17	T23
Compartment 12	T18	T24

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

⚠ **Temperature calibration is done by adjusting the Tx (where x is the sensor number) according to the 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 only the altered value corresponds to where the measurement is done. Give the system some time to adjust.

There is no crossover heating between the 12 compartments: This is a unique feature of the MIRI® II-12 multiroom IVF incubator. Lid temperature will, however, affect the bottom temperature in a compartment. The delta-T should always be 0.2 °C. Thus, if the bottom temperature is 37.0 °C, the lid should be 37.2 °C.

16 Pressure

16.1 CO_2 gas pressure

The CO_2 pressure can be seen in the CO_2 box on the main page, as shown below.

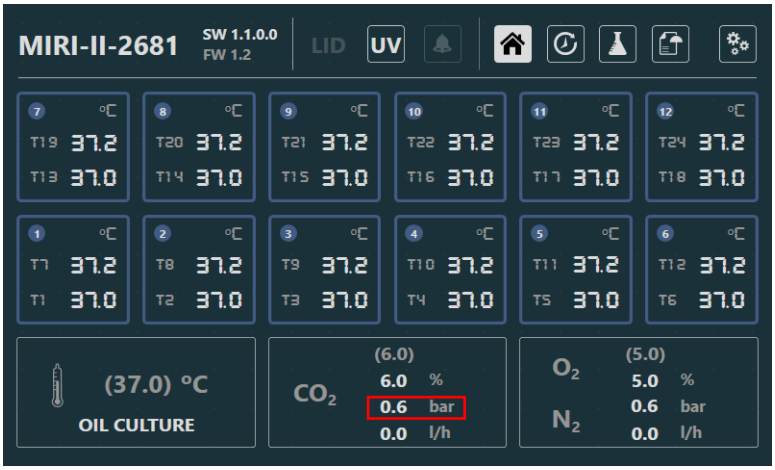


Figure 16.1 CO_2 pressure on the main display

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

Remember that there is a pressure alarm on the pressure limits if the 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 according to the maintenance plan.

16.2 N_2 gas pressure

The N_2 pressure can be seen in the N_2 box on the main page, as shown below.

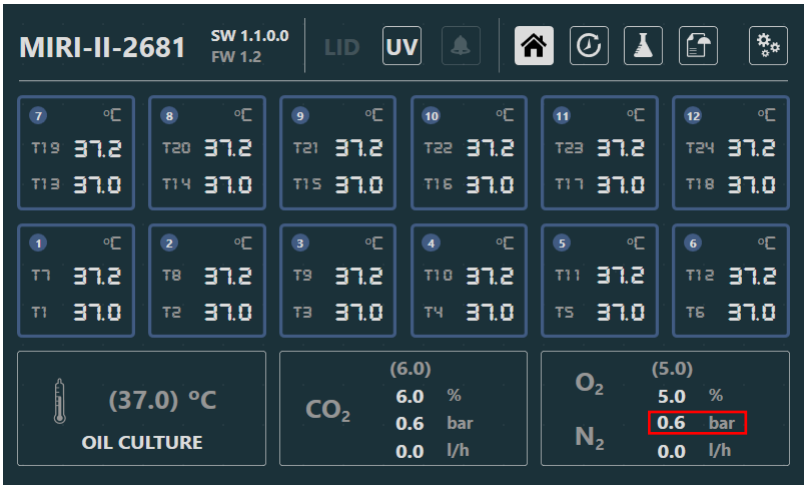


Figure 16.2 O_2 pressure on the main display

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

Remember that there is a pressure alarm on the pressure limits if the 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 according to the maintenance plan.

17 Firmware

The firmware installed on your MIRI® II-12 multiroom IVF incubator is upgradeable. Whenever an important update is available, it will be provided to our distributors around the world – they will ensure that your incubator runs with the newest available firmware. A service technician can do this during a scheduled annual service.

The current MIRI® II-12 multiroom IVF incubator firmware version is 1.2.

18 pH measuring

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

The MIRI® II-12 multiroom IVF incubator is equipped with a high-grade pH measuring system.

A standard male BNC connector is located in the back of the unit. 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.

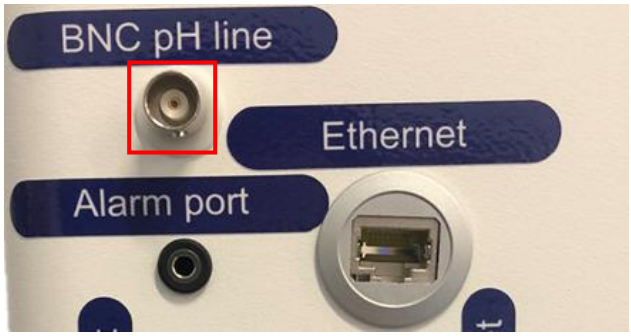


Figure 18.1 BNC pH line connection

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 on the main display:

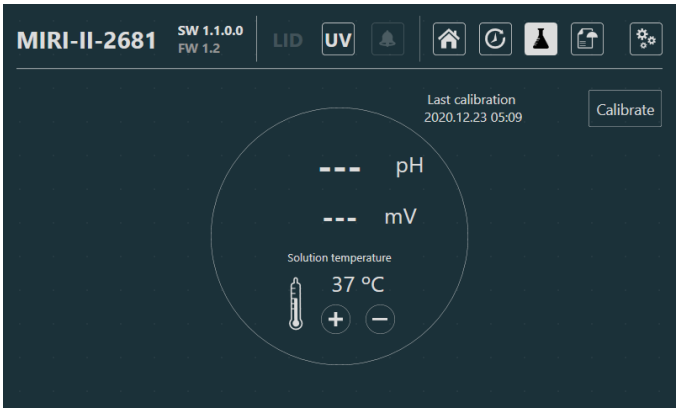


Figure 18.2 pH system and calibration dialogue screen view

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 compartment 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 18.3 4-well dish with 3 buffers and media

For calibration, at least two buffers are needed. We recommended using 3 buffers. One of the buffers should have a 7 pH. Any 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.

The technique requires the user to be quick, as the pH starts to shift very quickly 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:

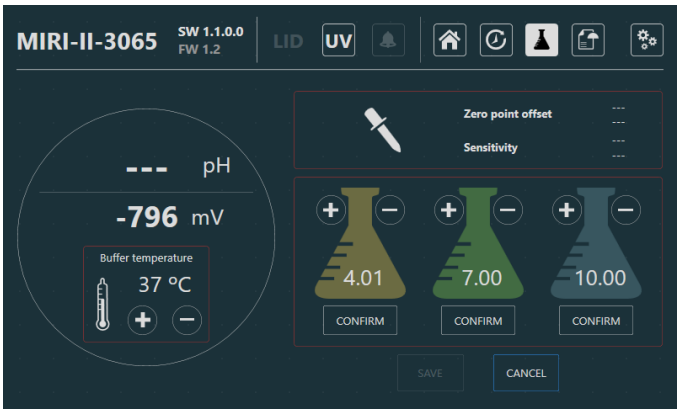


Figure 18.4 pH calibration screen view

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 with media and that the opening

through the test lid is sealed sufficiently to maintain gas levels (use tape or rubber seal).

The 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, which 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.

19 SAFE Sense function

There is a possibility to purchase the MIRI® II-12 multiroom IVF incubator with an integrated SAFE Sense system.

BCSI created this system to provide pH monitoring within a closed environment (an incubator) to measure pH without disturbing the maintained optimal conditions.

Please read more about SAFE Sense software in the SAFE Sense User manual, which can be accessed in their website: https://www.safesens.com/trakstation-users-manual/

20 Data-logging

The current MIRI® II-12 multiroom IVF incubator software version is 1.2.0.0.

20.1 Data-logging temperature view

Pressing the temperature icon will change the view to temperature chart view.

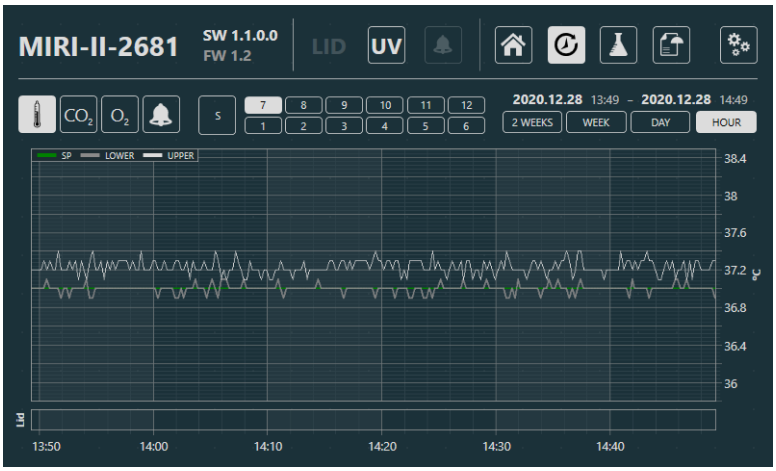


Figure 20.1 Temperature data graph

The history view allows for seeing temperature data graphs. It is possible to toggle ON/OFF compartment graphs 1-12 in the MIRI® II-12 multiroom IVF incubator by pressing the corresponding circled number.

With the period buttons “Hour”, “Day”, “Week” and “2 weeks”, it is possible to change the viewing period.

It is possible to enlarge a particular area by dragging a finger over it. Zooming can be repeated in steps. To get back to the original size, press the “Reset” button.

20.2 Data-logging CO_2 view

By pressing the “CO_2” button, the view will change to the CO_2 graph.

CO_2 “Setpoint”, “Concentration”, “Flow” and “Pressure” graphs can be toggled ON/OFF. The period and zoom-in functions are the same as in the temperature view.

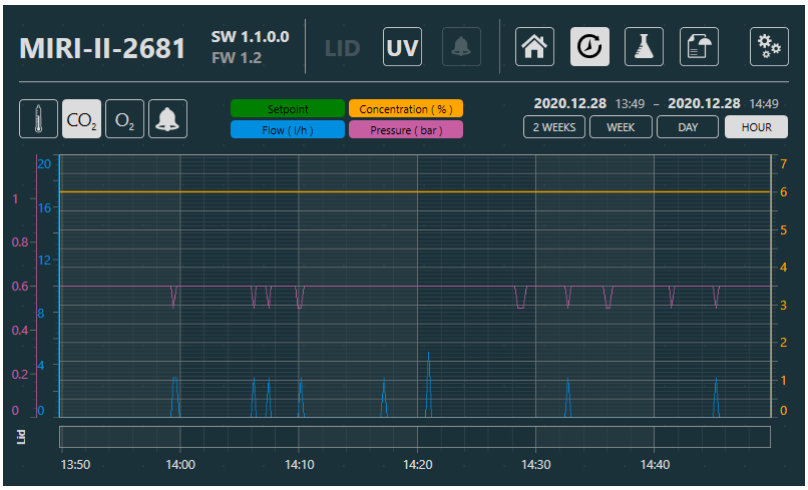


Figure 20.2 CO_2 data graph

20.3 Data-logging O_2 view

By pressing the “O_2” button, the view will change to the O_2 graph.

O_2 “Setpoint”, “Concentration”, “Flow” and “Pressure” graphs can be toggled ON/OFF. The period and zoom-in functions are the same as in the temperature view.

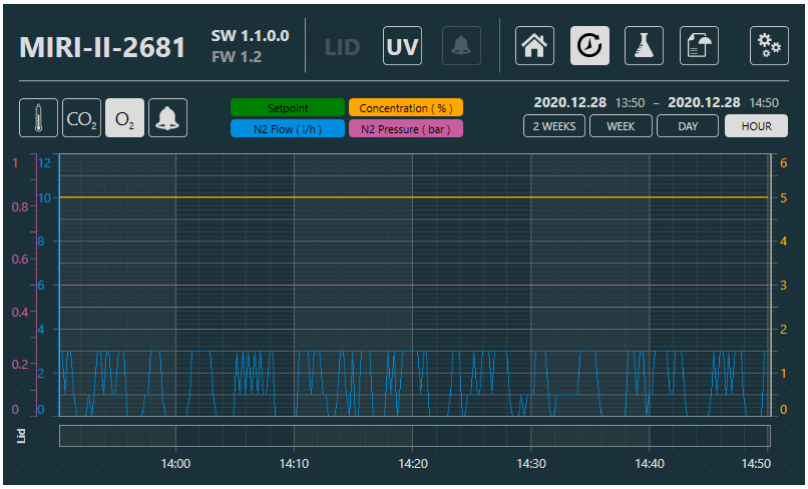


Figure 20.3 O_2 data graph

20.4 Data-logging alarm view

By pressing the alarm bell button, the alarm view opens up. The alarm view depicts all the parameters and any alarm statuses in a quick graphical overview. A red block represents each alarm – the longer the alarm lasts, the more that block increases in size.

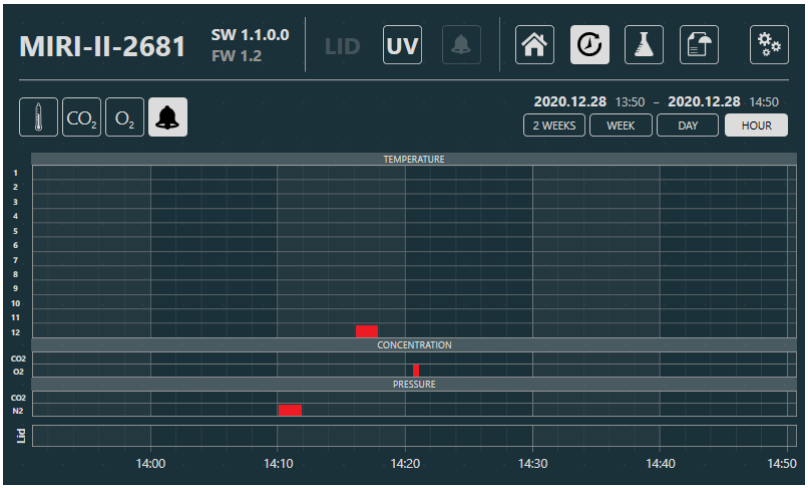


Figure 20.4 Temperature, concentration and pressure alarm view

The "Lid" section has 12 rows in the MIRI® II-12 multiroom IVF incubator. Each row indicates a single lid opening case in a particular compartment, counting from the top. White blocks depend on the lid opening time – the longer the lid was open, the more those blocks increase.

21 Cleaning instructions

21.1 Consideration about a sterile device

The MIRI® II-12 multiroom IVF incubator is not a sterile device. It is not delivered in a sterile state and it will not be possible to keep it sterile while in use.

However, the device's design was created with great care to make it easy for the user to keep the device sufficiently clean during use and not contaminate the key components.

The design features intended to provide cleanliness include:

- A circulated air system
- A HEPA filter continually cleans the incoming gas
- A HEPA/VOC filter, which continually cleans the air inside the system
- A removable heat optimization plate in each compartment that can be removed and cleaned (not autoclaved!); this part serves as the main holding area for samples – it should be the highest priority to keep it clean
- A compartment with sealed edges that can be cleaned
- The use of aluminum and PET parts that withstand cleaning well

21.2 Cleaning procedure recommended by the manufacturer

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

The periodic cleaning procedure is recommended for routine processing and maintenance. The combination of periodic cleaning procedures and disinfection procedures is recommended for event-related concerns such as media spills, visual accumulation of soil and/or other contamination evidence. Also, it is recommended to clean and disinfect the MIRI® II-12 multiroom IVF incubator immediately after any media spills.

Periodic cleaning of the device (with no embryos inside)

The use of gloves and good handling techniques are essential for successful cleaning.

1. It is recommended to clean the unit with aqueous 70% isopropyl alcohol. Moisten a sterile wipe and clean all the device's internal and external surfaces by rubbing the wipe against the surfaces.
2. After wiping, leave the device's lids open for some time to ensure that all alcohol fumes would evaporate.
3. Finally, use purified or sterile water to wipe the surfaces of the device.
4. Inspect the device – if it is visually clean, consider it ready for use.

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

21.3 Disinfection procedure recommended by the manufacturer

Disinfection of the device (with no embryos inside)

The use of gloves and good handling techniques are essential for successful disinfection.

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® II-12 multiroom IVF incubator(rear panel)
2. Open the lids
3. Use the required disinfectant to disinfect the internal surfaces, the heating inserts, and the 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 three wipes at least. Repeat 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® II-12 multiroom IVF incubator (rear panel).

22 Heat optimization plates

Insert the heat optimization plate. The heat optimization plate will ensure full contact with the dish. It generally results in much more stable temperature conditions concerning the cells. The plate fits the compartment and it can be taken out for cleaning.

⚠ **Do not use autoclave at the inserts. It will damage the inserts as high temperature bends them out of shape.**

Place the dish where it fits the pattern. The heat optimization plates can be applicable for both Nunc® and Falcon® dishes.

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

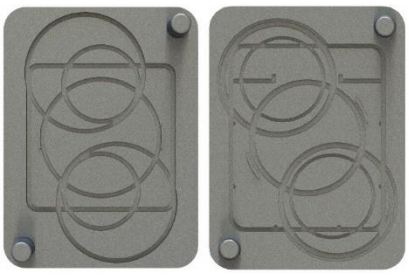


Figure 22.1 Heat optimization plates (standard version)

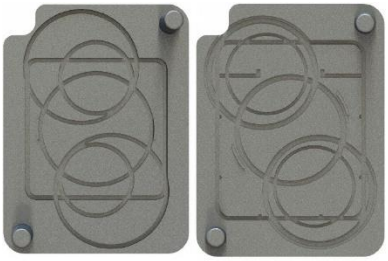


Figure 22.2 Heat optimization plates (SAFE Sense version)

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

23 Humidification

The MIRI® II-12 multiroom IVF incubator has been primarily developed and designed for incubation of gametes and embryos with an overlay of either Paraffin or mineral oil.

The MIRI® II-12 multiroom IVF incubator must not be irrigated. Humidification of the MIRI® II-12 multiroom IVF incubator will damage the device – condensation will block internal pipes and damage electronic parts.

⚠ **MIRI® II-12 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.**

24 Temperature validation

The MIRI® II-12 multiroom IVF incubator is equipped with 2 x 6 PT-1000 Class B sensors that are located in the center of the bottom of each compartment.

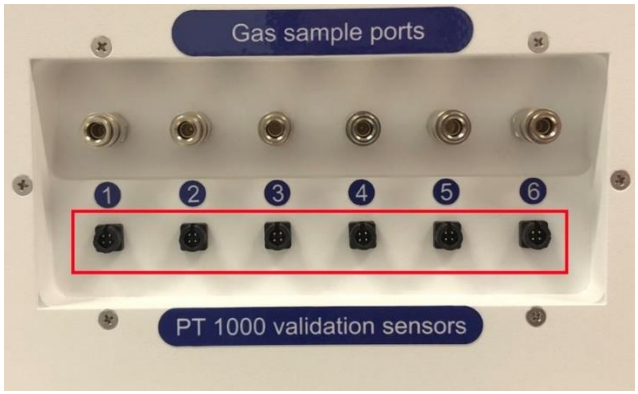


Figure 24.1 PT-1000 Class B sensors

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

Temperature conditions in the compartments can be continuously logged through the external connectors on the unit's side without compromising its performance.

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

Esco Medical can supply an external logging system (MIRI®-GA12) for the sensors.

25 Gas level validation

Gas concentration in each compartment of the MIRI® II-12 multiroom IVF incubator may be validated by taking a gas sample from one of the 12 gas sample ports on the unit's side, using a suitable gas analyzer.

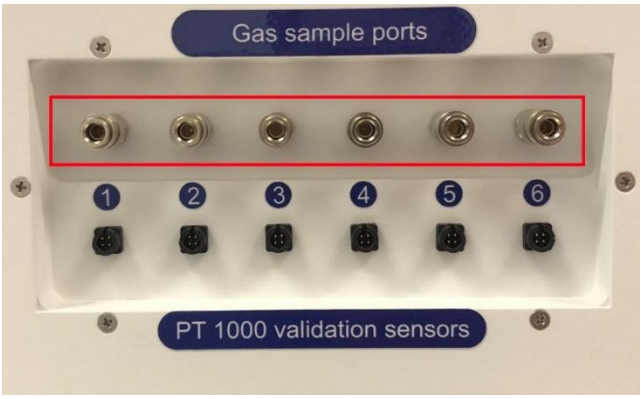


Figure 25.1 Gas sample ports

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

An external automatic gas sampler can be connected to the ports for continuous validation. The gas analyzer must have the possibility to return the gas sample to the incubator. Otherwise, sampling can affect gas regulation and also gas analyzer reading.

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

Taking out a large sample volume may affect gas regulation.

Make sure that the gas analyzer is calibrated before use.

26 Alarm switch for an external system

In order to connect the MIRI® II-12 multiroom IVF incubator to an external monitoring system and ensure maximum safety, especially during nights and weekends, the incubator is equipped with a 3.5 mm jack connector on the back, which can be connected to a monitoring device.

Whenever an alarm goes off (that could be temperature alarm, gas alarms for CO_2 or O_2 levels, low pressure or high-pressure alarms for CO_2 and N_2 gases) or if the power supply to the unit is suddenly cut, the switch is indicating that the unit 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 unit will be in the „ON“ position, as illustrated below.

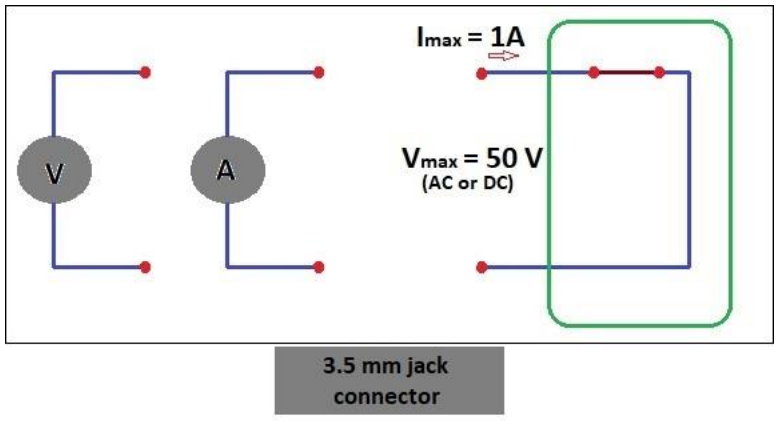


Figure 26.1 No alarm mode

Whenever the MIRI® II-12 multiroom IVF incubator goes into an alarm mode, the switch status will change into ‘open circuit’. It means that no current can run through the system anymore.

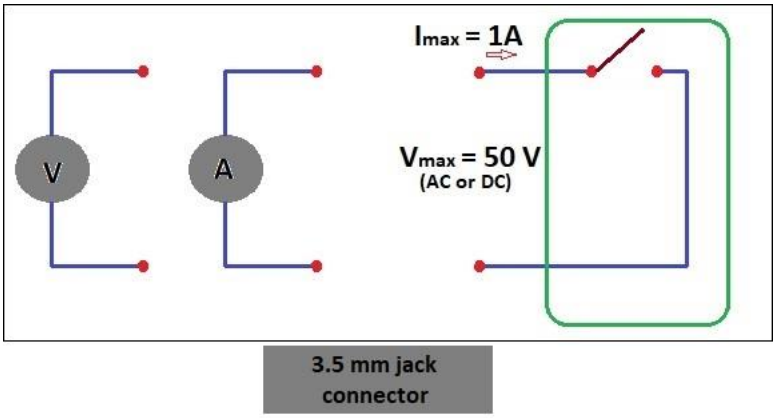


Figure 26.2 "Open circuit" alarm mode

Whenever the 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 compartment lids

Each compartment lid on the MIRI® II-12 multiroom IVF incubator is made from white glass, optimized for writing text. The patient data or the compartment's content can be noted 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® II-12 multiroom IVF incubator is designed to be user-friendly. Reliable and safe operation of this equipment is based on the following conditions:

1. Correct calibration of temperature and gas level, using high-precision equipment in the intervals prescribed based on clinical practice at the laboratory, where the MIRI® II-12 multiroom IVF incubator is used. The manufacturer recommends that the period between validations should be no longer than 14 days.

2. VOC/HEPA filters must be replaced every 3 months.
3. In-line HEPA filters must be replaced yearly during annual maintenance.
4. Suitable cleaning, according to the intervals prescribed by the clinical practice in the laboratory where the MIRI® II-12 multiroom IVF incubator is in use. The manufacturer does not recommend periods longer than 14 days between cleanings.

⚠ **It is essential to perform the inspection and service at the intervals indicated in the "38 The Maintenance guide" section. Failure to do so can have a severe adverse outcome, causing the unit to stop performing as expected and causing damage to samples, patients or users.**

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

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

29 Emergency procedures

Total loss of power to or inside the unit:

- 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® II-12 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 unit with insulating blankets to slow the temperature drop.

If a single temperature alarm goes off:

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

If multiple temperature alarms go off:

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

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

If the CO_2 level alarm goes off:
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 level is low, keep the lids shut. If the state is temporary and the CO_2 level is high, open a few lids to vent out some CO_2.

If the O_2 level alarm goes off:
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 goes off:
Inspect the external gas supply and gas supply lines. If the problem is external and not readily fixed, follow the guidelines under the section "CO_2 level alarm".

If the O_2 pressure alarm goes off:
Inspect the external gas supply and gas supply lines. If the problem is external and not readily fixed, follow the guidelines under the"O_2 level alarm" section.

30 User troubleshooting

Table 30.1 Heating system

Symptom	Cause	Action
No heating, the display is off	The unit is switched off at the back or not connected to the power source	Switch on the device or connect to the power source
No heating	The temperature setpoint is incorrect	Check the desired temperature setpoint
Heating is uneven	The system is not calibrated	Calibrate each zone according to the User manual, using a high-precision thermometer

Table 30.2 CO_2 gas regulator

Symptom	Cause	Action
No CO_2 gas regulation	The system is not powered	Check the power mains
	The system is switched off	Switch the system on
	CO_2 gas regulator is off	Activate CO_2 gas regulator by setting "CO2" to "ON" in the menu
	No CO_2 gas or wrong gas attached to CO_2 gas input	Check gas supply, make sure that gas pressure of 0.6 bar (8.70 PSI) is supplied
	The actual gas concentration is higher than the setpoint	Check the CO_2 setpoint
Poor CO_2 gas regulation	Lid(s) are left open	Close the lid(s)
	Seals are missing on the lid(s)	Replace the seals on the lid(s)
CO_2 gas concentration indicated red on the display	CO_2 gas concentration deviates more than ±1 from the setpoint	Allow the system to stabilize by closing all the lids
CO_2 gas pressure indicated red on the display	No/wrong CO_2 gas pressure in the system	Check CO_2 gas supply; make sure that the pressure is kept stable at 0.6 bar (8.70 PSI)

Table 30.3 O_2 gas regulator

Symptom	Cause	Action
No O_2 gas regulation	The system is not powered	Check the power mains
	The system is on standby or switched off	Switch the system on
	O_2 gas regulator is off	Activate the O_2 gas regulator by setting "O2" to "ON" in the menu
	No N_2 or wrong gas type attached to N2 gas input	Check gas supply; make sure that 0.6 bar of N_2 gas is applied
	The actual gas concentration is higher than the setpoint	Check the O_2 setpoint
Poor O_2 gas regulation	Lid(s) are left open	Close the lid(s)
	Seals are missing on the lid(s)	Replace the seals on the lid(s)
O_2 gas concentration indicated red on the display	O_2 gas concentration deviates more than ±1 from the setpoint	Allow the system to stabilize by closing all the lids
N_2 gas pressure indicated red on the display	No/wrong N_2 gas pressure in the system	Check the N_2 gas supply; ensure that the pressure is stable at 0.6 bar (8.70 PSI). If O_2 regulation is not needed, set the O_2. to "OFF" in the menu to deactivate oxygen regulation and abort the N_2 alarm

Table 30.4 Data logger

Symptom	Cause	Action
No data is sent to PC	The system is not powered	Check the power mains
	The system is on standby or switched off	Switch the system on
	The data cable between incubator and PC is not properly attached	Check the connection. Use only the cable supplied with the unit
	Data logger software/USB driver is not installed correctly	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 for PCB replacement

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 The MIRI® II-12 multiroom IVF incubator specifications

Technical specifications	MIRI® II-12
Overall dimensions (W x D x H)	740 × 575 × 215 mm
Weight	47 kg
Material	Mild steel / Aluminum / PET / Stainless steel
Power supply	115V 60Hz or 230V 50Hz
Power consumption	500 W
Temperature range	25.0 – 40.0 °C
Temperature deviation from the setpoint	± 0.1 °C
Gas consumption (CO_2)[1]	< 2 liters per hour
Gas consumption (N_2)[2]	< 12 liters per hour
CO_2 range	3.0% – 10.0%
O_2 range	5.0% – 10.0%
CO_2 and O_2 concentration deviation from the setpoint	± 0.2%
CO_2 gas pressure (input)	0.4 – 0.6 bar (5.80 – 8.70 PSI)
N_2 gas pressure (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.
Shelf life	1 year

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

32 Electromagnetic compatibility

Table 32.1 Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The MIRI® II-12 multiroom IVF incubators are intended for use in the electromagnetic environment specified below. The customer or the user of the MIRI® II-12 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® II-12 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® II-12 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® II-12 multiroom IVF incubators are intended for use in the electromagnetic environment specified below. The customer or the user of the MIRI® II-12 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	Flooring should be wood, concrete or ceramic tiles. If the floor is 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 IEC 61000-4-8	3 A/m	Performance A	The power-frequency magnetic fields' levels should be characteristic of a specific location in a typical commercial or hospital environment

Guidance and manufacturer's declaration – electromagnetic immunity			
The MIRI® II-12 multiroom IVF incubators are intended for use in the electromagnetic environment specified below. The customer or the user of the MIRI® II-12 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 the MIRI® II-12 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 Where *P* is the maximum the power output rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, 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 the MIRI® II-12 multiroom IVF incubators
The MIRI® II-12 multiroom IVF incubators are intended to be used in an electromagnetic environment in which radiated RF disturbances are controlled. The customer, or the MIRI® II-12 multiroom IVF incubator user, can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters). The MIRI® II-12 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 reflections 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® II-12 multiroom IVF incubators complies with the medical electromagnetic compatibility standard and checks before use that no interference is evident or possible. If the interference is suspected or potential, switching off the offending device is the standard solution as it is the usual practice in aircraft and medical facilities.

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

33 The Validation guide

33.1 Product release criteria

The Esco Medical MIRI® II-12 multiroom IVF incubator undergoes strict quality and performance testing before being released for sale.

33.1.1 Performance

Each component used in the MIRI® II-12 multiroom IVF incubator is tested during the manufacturing process to ensure a defect-free unit.

Before release, the incubator is tested per a release test having a duration of at least 24 hours, using high-performance thermometers and gas analyzers, along with real-time data logging to ensure that the unit lives up to expected performance standards.

Pass I: Internal sensor temperature variation from setpoint within ± 0.1 °C absolute.
Pass II: Internal sensor CO_2 concentration variation from setpoint within ± 0.2% absolute.
Pass III: Internal sensor N_2 concentration variation from setpoint within ± 0.2% absolute.
Pass IV: Gas flow CO_2 less than 2 l/h.
Pass V: Gas flow N_2 less than 12 l/h.

33.1.2 Electrical safety

An electric safety test is also carried out using a high-performance medical safety tester with each unit to ensure that electric requirements for medical devices defined by the EN60601-1 3rd edition standards are met.

33.1.3 Communication & data logging

Each unit is connected to a computer running the MIRI® data logging software. Gas is supplied to the unit, and the system is activated. The data received by the PC program is analyzed to ensure communication between the incubator and the PC.

33.1.4 Gas concentration levels and consumption

A leak test is performed on each compartment. The maximum leakage allowed through the seals is 0.0 l/h.

The average CO_2 gas variation must stay within SP ± 0.2% absolute on all external sampling and internal sensor readings.

The gas flow under regular operation is less than 2 liters per hour, and thus, the average should be below 2 liters.

The average N_2 gas variation must stay within SP ± 0.2% absolute on all external sampling and internal sensor readings.

The gas flow under regular operation is less than 12 liters per hour, and thus, the average should be below 12 liters.

33.1.5 Cosmetic

- No misalignment in the lids.
- Each lid should be opened and closed easily.
- The seals for the lids must be appropriately attached and aligned.
- There will not be any scratches or missing paint on the cabinet.
- Overall, the device must be presentable as a high-quality item.
- The heat optimization plates are checked for misalignment and shape. These are placed into the compartments to check for any mismatch due to the compartment and aluminum blocks' sizes.

34 Validation on-site

Even though at Esco Medical, we strive to do the most comprehensive tests before the device is shipped to the customer, there is no way to be sure that everything is still OK at the location when the device is 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 into clinical use.

In the following, 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 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 resolution minimum of 0.1 °C
- A thermometer with a suitable sensor for measuring on an aluminum surface with a resolution minimum of 0.1 °C
- A CO_2 analyzer with a range of 0.0 – 10.0%.
- An O_2 analyzer with a range of 0.0 – 20.0%.

- A Pressure tester with a 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® II-12 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® II-12 multiroom IVF incubator compartments, the device must be connected to a stable source of 100% CO_2 at 0.4 – 0.6 bar (5.80 – 8.70 PSI) of pressure.

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

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

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

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

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

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 atmospheric pressure.

⚠ **A high concentration of carbon dioxide (10.0% or more) can asphyxiate quickly without warning with no possibility of self–rescue regardless of the oxygen concentration.**

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

For the regulation to maintain the correct O_2 concentration levels in the MIRI® II-12 multiroom IVF incubator compartments, the device must be connected to a stable source 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. 100% N_2 = 0 % O_2.

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

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

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® II-12 multiroom IVF incubator requires a pressure of 0.4 – 0.6 bar (5.80 – 8.70

PSI) on the input CO_2 gas line. This gas pressure must be held stable at all times.

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

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

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the User manual sections for more information.

35.4 N_2 gas pressure check

The MIRI® II-12 multiroom IVF incubator requires a pressure of 0.4 – 0.6 bar (5.80 – 8.70 PSI) on the input N_2 gas line. This gas pressure must be held stable at all times.

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

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

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the User manual sections for more information.

35.5 Voltage supply

The voltage on-site must be verified.

Measure the output plug on the UPS that the MIRI® II-12 multiroom IVF incubator 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 unit 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 incubator (i.e., another compartment). Only measure while the value on the gas analyzer stabilizes.

Please refer to the "13.5.4 CO_2 calibration menu" section 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 unit is used. Use sample port-6 for validation.

Remember not to open any lid at least 10 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 incubator (i.e., another compartment). Only measure while the value on the gas analyzer stabilizes.

Please refer to the "13.5.5 O_2 calibration menu" section for more information on how to perform the CO_2 gas calibration.

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

35.8 Temperature check: Compartment 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 with at least one dish in each compartment. The dishes should be placed on the corresponding size slot on the heat optimization plates.

Let the incubator warm the dishes and stabilize for at least 1-hour.

Open a compartment 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 led to a spot inside the compartment 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 "13.5.3 Temperature calibration menu" section for more information on how to perform the temperature calibration.

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

35.9 Temperature check: Compartment 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 compartments' lid must not deviate more than ± 0.2 °C from the setpoint.

If calibration is needed, please refer to the "13.5.3 Temperature calibration menu" section for more information on how to perform the temperature calibration.

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

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 parameter 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 set point is within ± 0.1 °C absolute.
Pass II Internal sensor CO_2 concentration variation from setpoint within ± 0.2% absolute.
Pass III: Internal sensor N_2 concentration variation from setpoint within ± 0.2% absolute.
Pass IV: Gas flow CO_2 less than 2 l/h.
Pass V: Gas flow N_2 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.

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

- Clean the unit externally with a lint-free cloth moistened with a 70% alcohol solution.
- Switch off the device and remove the mains lead.
- Remove all heat optimization plates and clean them with a lint-free cloth soaked with a 70% alcohol solution.
- Wipe the inside of the 12 compartments with a lint-free cloth moistened with a 70% alcohol solution.
- Wipe the lids in the same way.
- Let the lids remain open for 5 minutes.
- Wipe the 12 compartments and the heat optimization plates with a lint-free cloth soaked in sterilized water.
- Wipe the lids in the same way.
- Let the lids remain open for 10 minutes.
- Re-insert the heat optimization plates.
- Close the lids.
- Attach the power and switch on the incubator.
- Let the incubator run empty for at least 20 minutes before inserting a sample.

35.12 Test documentation form

☞ **The "Installation report" form must be completed with the tests-passed status filled by installation personnel and submitted to Esco Medical before the device is taken into clinical use.**

35.13 Recommended additional testing

35.13.1 A VOC meter

With the VOC meter, a sample should be taken just above the MIRI® II-12 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® II-12 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.

It should provide many years of stable service.
It is necessary to monitor the performance of the device continually.
Use the below scheme for in-use validation.

Do not attempt to run the MIRI® II-12 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		X
CO_2 gas concentration check	X	
O_2 gas concentration check	X	
Check log for anomalies		X
CO_2 gas pressure check	X	
N_2 gas pressure check	X	
pH check		X

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 "13.5.3 Temperature calibration menu" section for more information on how to perform the temperature calibration.

PASS:

- **All temperatures measured on the bottom of the compartment in the locations where the dishes would be placed must not deviate more than ± 0.2 °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 unit 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 10 min, before starting the test or during the testing itself.

Please refer to the "13.5.4 CO_2 calibration menu" section 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 unit 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 10 min, before starting the test or during the testing itself.

Please refer to the "13.5.5 O_2 calibration menu" section for more information on how to perform the CO_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 outgas 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 incubator (loop sampling) avoids negative pressure and ensures accuracy. The performance of the MIRI® II-12 multiroom IVF incubator will not be affected, as the gas in the compartment is not under pressure, and the reading is just an artifact based on unsuitable measuring equipment. Contact Esco Medical or the local distributor for further guidance.

36.4 CO_2 gas pressure check

The MIRI® II-12 multiroom IVF incubator requires 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 reasons, this unit has a built-in digital gas pressure sensor control that monitors the incoming gas pressure and alerts the user if any drop is detected.

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 "16.1 CO_2 gas pressure" section for more information.

36.5 N_2 gas pressure check

The MIRI® II-12 multiroom IVF incubator 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 reasons, this unit has a built-in digital gas pressure sensor control that monitors the incoming gas pressure and alerts the user if any drop is detected.

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 "16.2 N_2 gas pressure" section 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 will be the media pH at a certain CO_2 level.

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 levels.

The MIRI® II-12 multiroom IVF incubator are equipped with a high-grade pH measuring system.

Please refer to the "18 pH measuring" section for more information on performing pH calibration.

37 The Maintenance guide

Your MIRI® II-12 multiroom IVF incubator from Esco Medical contains high precision quality components. These components are chosen to ensure the high durability and performance of the equipment.

However, continual validation of the performance is necessary.

User validation should be done as a minimum according to instructions given in the "33 The Validation guide" section.

If problems are encountered, contact Esco Medical 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 table 37.1.

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

⚠ **Warranty void if service intervals are not followed according to table 37.1.**

⚠ **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

Component name	Every 3 month	Every year	Every 2 years	Every 3 years	Every 4 years
VOC/HEPA filter capsule	X				
HEPA in-line filter for CO_2 gas		X			
HEPA in-line filter for N_2 gas		X			
O_2 sensor		X			
CO_2 sensor					X
UV light		X			
Cooling fan				X	
Internal gas pump			X		
Proportional valves				X	
Gas lines				X	
Flow sensors			X		
Pressure regulators					X
Internal 0.2µ filter for CO_2		X			
Internal 0.2µ filter for N_2		X			
A firmware update (if a new version has been released)		X			

37.1 VOC/HEPA filter capsule

The VOC/HEPA filter capsule is placed on the incubator unit'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 air being re-circulated to the compartments. Because of the carbon component's lifespan, all VOC filters' lifetime is limited, and they must be replaced often. According to table 37.1, the VOC filter installed in the MIRI® II-12 multiroom IVF incubator must be replaced every 3 months.

Please follow these safety precautions when changing the VOC filter:

- Always use the original filter (contact Esco Medical 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 the “12.1 Installation of a new filter capsule” section for the replacement instructions.

37.2 In-line HEPA filter for CO_2 gas

The round-shape in-line 0.2µ HEPA filter for CO_2 gas removes any particles found in the incoming CO_2 gas. Failure to use the HEPA filter may cause damage to the high precision flow sensor, calculate the amount of CO_2 gas entering the system, and disturb the CO_2 regulator system.

Please follow these safety precautions when changing the filter:

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

Please refer to the service manual for replacement instructions.

37.3 In-line HEPA filter for N_2 gas

The round-shape in-line 0.2µ HEPA filter for N_2 gas removes any particles found in the incoming N_2 gas. Failure to use the HEPA filter may cause damage to the high precision flow sensor, calculate the amount of N_2 gas entering the system, and disturb the N_2 regulator system.

Please follow these safety precautions when changing the filter:

- Always use the original filter (contact Esco Medical or your local distributor for more details or ordering).
- Change the filter once every year.
- Failure to change the filter on time will result in low/no cleaning of incoming 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

The oxygen regulation uses the Oxygen sensor to keep the O_2 gas concentration at a desired level inside the chambers. 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 very high precision needed in the

MIRI® II-12 multiroom IVF incubator.

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 year from the date it was unpacked and installed.**

☞ Oxygen sensors must be replaced at least once every year from the date they were installed in the unit, irrespective of the incubator being used or not.

In the MIRI® II-12 multiroom IVF incubator "Installation report" form, the User will see when this sensor was installed. This date must be used to calculate the date for the following O_2 sensor change.

Please follow these safety precautions when changing sensor:

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

Please refer to the service manual for replacement instructions.

37.5 CO_2 sensor

The CO_2 regulation uses the CO_2 sensor to keep the gas concentration at the chambers' desired level.

This sensor's lifetime is more than 6 years, but for safety reasons, Esco Medical 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 or your local distributor for more details or ordering).
- Change the CO_2 sensor within 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

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 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 or your local distributor for more details or ordering).
- Change UV-C light bulb within 1 year from date of installation.
- Failure to change the UV-light bulb on time can result in contamination build-up.
- Warranty 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 unit. 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 low temperature and gas regulation.

To avoid this, Esco Medical 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 or your local distributor for more details or ordering).

- Change the fan within 3 years from the date of installation.
- Failure to change the fan may cause the electronics to drift, resulting in low temperature and gas regulations.
- Warranty void if wrong/ non-original fan is used.

Please refer to the service manual for replacement instructions.

37.8 Internal gas pump

The internal gas pump is used to transport the mixed gas 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 or your local distributor for more details or ordering).
- Change the gas pump within 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 Proportional valves

The internal valves make gas regulation possible. 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 to maintain system safety and stability.

Please follow these safety precautions when changing valves:

- Always use original proportional valves (contact Esco Medical or your local distributor for more details or ordering).
- Change the valves within 3 years 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.

37.10 Gas lines

The internal gas lines are used to transport mixed gas through the VOC/HEPA filter, UV light and the chambers. Over time, the lines' performance can be affected, causing more extended recovery time due to clogging.

Therefore, the gas lines must be replaced once every 3 years to maintain the fast recovery time after lid opening.

Please follow these safety precautions when changing gas lines:

- Always use original gas lines (contact Esco Medical or your local distributor for more details or ordering).
- Change the gas lines within 3 years from the date of installation.
- 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.

37.11 Flow sensors

The flow sensors are used by the CO_2/N_2 regulations and for logging the unit's gas consumption.

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

Please follow these safety precautions when changing sensors:

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

Please refer to the service manual for replacement instructions.

37.12 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 or your local distributor for more details or ordering).
- Change the regulators within 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.

37.13 Internal 0.2µ filter for CO_2 gas

The round-shape in line 0.2µ HEPA filter for CO_2 gas removes any particles found in the incoming CO_2 gas. Failure to use the HEPA filter may cause damage to the high precision flow sensor, calculate the amount of CO_2 gas entering the system, and disturb the CO_2 regulator system.

Please follow these safety precautions when changing the filter:

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

Please refer to the service manual for replacement instructions.

37.14 Internal 0.2µ filter for N_2 gas

The round-shape in line 0.2µ HEPA filter for N_2 gas removes any particles found in the incoming N_2 gas. Failure to use the HEPA filter may cause damage to the high precision flow sensor, calculate the amount of N_2 gas entering the system, and disturb the N_2 regulator system.

Please follow these safety precautions when changing the filter:

- Always use the original filter (contact Esco Medical or your local distributor for more details or ordering).
- Change the filter once every year.

- Failure to change the filter on time will result in low/no cleaning of incoming N_2 gas.
- Warranty void if wrong/ non-original filter is used.

Please refer to the service manual for replacement instructions.

37.15 Firmware update

If Esco Medical has released a newer version of the firmware, this should be installed on the MIRI® II-12 multiroom IVF incubator during the yearly scheduled service.

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

38 The Installation guide

This section describes when and how to install the MIRI® II-12 multiroom IVF incubator in the IVF clinic.

38.1 Responsibilities

All technicians or embryologists installing the MIRI® II-12 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 instrument, calibration and testing procedures, and instruments used in the instrument'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 instrument must be trained by Esco Medical or at a qualified training center. Experienced service technicians or embryologists conduct training to ensure that the installation personnel clearly understand the instrument's functions, performance, testing, and maintenance.

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

38.2 Before installation

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

The released the MIRI® II-12 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® II-12 multiroom IVF incubator weight is approximately 47 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. Uninterrupted power supply (UPS) with 115 or 230 V, minimum 120 W.
6. Proper grounding.
7. CO_2 gas outlet with 0.6 – 1.0 atm above ambient.
8. N_2 gas outlet with 0.6 – 1.0 atm above ambient if the clinic uses reduced oxygen levels.
9. Tubes that fit 4 mm hose nipple and HEPA filter.

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® II-12 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® II-12 multiroom IVF incubator.
- Updated service tool kit.
- Memory stick with the latest released firmware & software.
- High precision thermometer with a resolution not less than 0.1 °C.
- Calibrated gas analyzer with precision at least 0.1% for CO_2 and O_2 and the possibility of returning gas samples to the incubator.
- Extension cable for USB connection.

38.5 Installation procedure at the site

1. Follow the guidelines in the safety instructions and warnings section ("2 Safety warning" section).

2. Connect the power cable to the UPS.
3. Connect the power cable to the MIRI® II-12 multiroom IVF incubator.
4. Connect the gas lines.
5. Set gas pressure on the external gas regulator at 0.4 – 0.6 bar (5.80 – 8.70 PSI).
6. Switch on the MIRI® II-12 multiroom IVF incubator on the back.
7. Observe for standard functionality.
8. Let the unit warm up and stabilize for 30 min.
9. Follow the guidelines in the “33 The Validation guide” section.
10. Complete user training and finish reading instructions.
11. After a burn-in phase of 24-hours, the unit is ready for use IF the testing is successful.

38.6 User training

1. Mains switch on/off.
2. Explain the MIRI® II-12 multiroom IVF incubators essential function and incubation with a multi-room facility to store the samples.
3. Explain temperature control in the MIRI® II-12 multiroom IVF incubator (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 level.
7. Alarm turn off procedure (temperature, CO_2, O_2) and revert times.
8. Insertion and removal of heating inserts from the incubator.
9. How to toggle the "Under oil" and "Open culture" modes, and when which mode should be used.
10. Emergency procedures (can be found in the "29 Emergency Procedures" section).
11. Explain how to clean the device and heating inserts.
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 of new filter capsule" section).
16. Data logger functionality, how to establish a connection and re-connection.

☞ Use the User manual section as much as possible to get the User well acquainted with it.

☞ The user/owner is informed that the first VOC filter change is 3 months after installation and 3-month intervals. The first service check is under normal circumstances 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 Ltd. 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 instrument overview file. The date of installation is also written in the service schedule.

Suppose the MIRI® II-12 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® II-12 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® II-12 multiroom IVF incubator must be taken out of service until it is repaired/ exchanged, or anew test approves the MIRI® II-12 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 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 according to your country.