



USER MANUAL

MIRI[®] TL family`s multiroom IVF incubators

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Rx only



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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.

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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 labelled 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 Medical's 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.

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1 How to use this manual

The manual is designed to be read by sections and not ideally from cover to cover. It means that if the manual is read from start to finish, there will be some repetition and overlap. We recommend the following method for going through the manual: first, familiarize yourself with the safety instructions; then, proceed to the essential user functions needed for operating the 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 35 – 38. The Maintenance guide is detailed described in section 39. The Installation procedures are detailed described in section 40.

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 Intended purpose

Esco Medical MIRI® TL family's multiroom IVF incubators are intended to provide an environment with controlled temperature, CO₂ and other gases for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. The device use is limited up to six days (199 hours), covering the time from post-fertilization to day 6 of the development.

4 About the product

The Esco Medical MIRI® TL family's multiroom IVF incubator are a CO₂/O₂ incubators with time-lapse capability. In the MIRI® TL6 it possible to incubate up to 84 embryos, whereas MIRI® TL12 – up to 168 embryos. The multiroom IVF incubators can generate time-lapse images and provide them to identify development quality and stages.

The only dish used with MIRI® TL6 and MIRI® TL12 multiroom IVF incubators is the CultureCoin®.

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.

The Esco Medical MIRI® TL6 multiroom IVF incubator has 6 completely separate culture heat chambers, whereas MIRI® TL12 – 12 chambers. Each chamber has its own heated lid and a room for one CultureCoin® dish.

To ensure maximum performance, the system of MIRI® TL6 multiroom IVF incubator has 12 completely separate PID temperature controllers, whereas MIRI® TL12 – 24. 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% CO₂ and 100% N₂ in order to be able to control the CO₂ and O₂ gas concentrations in the culture chambers.

A dual beam infrared CO₂ sensor with extremely low drift rates controls the CO₂ level. A chemical medical grade oxygen sensor controls the level of O₂.

Gas recovery time is less than 3 min after opening the lid. To validate gas concentration, the MIRI® TL6 multiroom IVF incubator is fitted with 6 gas sample ports that allow the user to sample gas from the individual compartment, whereas MIRI® TL12 – 12.

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 CO₂ and 5 l/h N₂ 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).

The CultureCoin® 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 upright LED display is large, clear and easy to read from a distance. The user can tell if the parameters are correct without going near the unit.

The software is running on the built-in touchscreen. PC controls a microscopy system that can generate an image every 5 min. When compiled, these images can be viewed as a time-lapse movie.

The Software contains logging functions for a long-term data logging and storage. Web 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.

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

MIRI® TL 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® TL family`s multiroom IVF incubators. Also, the MIRI® TL family`s 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® TL6 or MIRI® TL12 multiroom IVF incubator can be prepared for transport.

These labels should be glued on the box:

- Label with handling symbols and 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
- 4 warranty labels
- 1 USB stick containing a PDF version of the user manual
- 1 medical grade power cord
- 1 3.5 mm external alarm jack connector
- 3 5m LAN cables
- 1 set of fast male connectors with 15 silicone pipes
- 1 Asus router

Accessories:

- 1 CultureCoin® dish package (25 units of dish)

7 Safety symbols and labels

There are several user labels on the surface of the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators to guide the user. User labels are shown below.

Table 7.1 Packing box and electrical safety labels

Description	Image				
<p>Packing box label:</p> <ol style="list-style-type: none"> 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. 					
<ol style="list-style-type: none"> 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 border="1"> <tr> <td data-bbox="831 1104 906 1464" style="writing-mode: vertical-rl; transform: rotate(180deg);">MIRI® TL6</td> <td data-bbox="906 1104 1453 1464"> </td> </tr> <tr> <td data-bbox="831 1464 906 1825" style="writing-mode: vertical-rl; transform: rotate(180deg);">MIRI® TL12</td> <td data-bbox="906 1464 1453 1825"> </td> </tr> </table>	MIRI® TL6		MIRI® TL12	
MIRI® TL6					
MIRI® TL12					

Table 7.2 Device label

Description	Image
<ol style="list-style-type: none"> 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 	<p>The image shows two identical labels for multiroom IVF incubators. The top label is for the MIRI® TL6 model and the bottom for the MIRI® TL12 model. Both labels include the following information:</p> <ul style="list-style-type: none"> MODEL: MIRI® TL6 (top) / MIRI® TL12 (bottom) MAINS: ~230V, 50Hz, 330W (top) / ~230V, 50Hz, 650W (bottom) CE mark: CE 0123 IPXO (Not protected against the ingress of water) Manufacturer: Esco Medical Technologies, UAB, Draugystes g.19, Kaunas, 51230 Lithuania ESCO MEDICAL logo Instructions: Consult instruction for use (with 'i' icon) Temperature limit: 18°C and 30°C (with thermometer icon) Rx only: Rx symbol Warnings: Keep away from direct sunlight (with sun icon), Not for general waste (with trash can icon), Keep dry (with umbrella icon) Year of manufacture: 2022 Barcode: (01)04779041940281(11)221228(21)3105 (top) / (01)04779041940304(11)221126(21)2915 (bottom)

Table 7.3 Labels on the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators

Description	Image
USB communication port ¹	
USB communication port line 1 ²	
USB communication port line 2 ²	
CO ₂ inlet	

¹ Only in the MIRI® TL6 model

² Only in the MIRI® TL12 model

Description	Image
N ₂ inlet	
BNC pH	
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	
TL 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 and Ethernet connections.**

Compartment numbers are shown in the pictures below and also indicated on top of lids with a label.



Figure 7.1 Compartment numbers on the MIRI® TL6 multiroom IVF incubator



Figure 7.2 Compartment numbers on the MIRI® TL12 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 CO₂ and 100% concentration N₂ gases.
10. Always use an external HEPA filter for input CO₂ and N₂ 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® TL6 and MIRI® TL12 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 CO₂ and N₂ 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® TL6 and MIRI® TL12 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® TL6 or MIRI® TL12 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® TL6 or MIRI® TL12 multiroom IVF incubator in the back.
7. Switch on the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator PC on the back.
8. Observe for standard functionality.
9. Let the unit warm up and stabilize for 20 min.
10. Follow the guidelines in the Validation guide (see section 35 “The validation guide”).
11. Complete user training and finish reading instructions.
12. 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® TL6 and MIRI® TL12 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® TL6 and MIRI® TL12 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 "CO₂ 100% Inlet" and "N₂ 100% Inlet".



Figure 11.1 Gas inlets

CO₂ inlet should be connected to a 100% concentration of CO₂. CO₂ control in the compartment is available in the range from 2.9% to 9.9% in both MIRI® TL6 and MIRI® TL12 multiroom IVF incubators.

N₂ inlet should be connected to a 100% concentration N₂ if low oxygen conditions are required. O₂ control in the compartments is available in the range from 2.0% to 20.0% in the MIRI® TL6 multiroom IVF incubator and in the range from 5.0% to 20.0% in the MIRI® TL12 multiroom IVF incubator by infusing N₂ 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 CO₂ gas to the CO₂ 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 N₂ 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 CO₂ and N₂. 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® TL6 and MIRI® TL12 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.

👉 The 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® TL6 and MIRI® TL12 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® TL6 or MIRI® TL12 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
<p>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.</p>	
<p>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.</p>	

Description	Image
<p>Touch display panel Shows the information about the current status of the unit. The display is used to navigate through the menu and change values for temperature and gas concentrations.</p>	

13.1 Activating the heat and gas controls

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



Figure 13.1 MIRI® TL6 multiroom IVF incubators rear

The "Please Wait" message appears on the screen while the system is booting up for work.



Figure 13.2 Loading view

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

- Compartments 1 – 6 bottom and lid temperatures (only in the MIRI® TL6 model)
- Compartments 1 – 12 bottom and lid temperatures (only in the MIRI® TL12 model)
- CO₂ concentration, CO₂ pressure and incoming CO₂ gas.
- O₂ concentration, N₂ pressure and incoming N₂ gas.

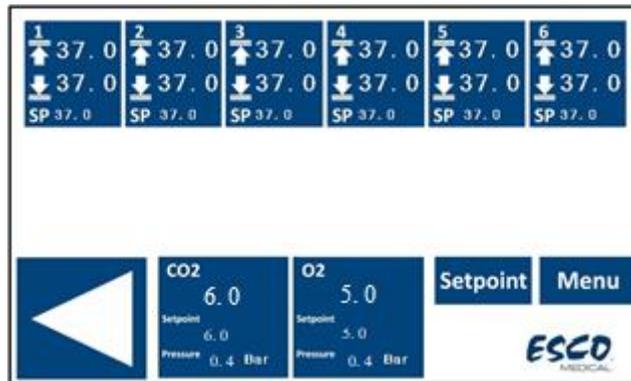


Figure 13.3 Main display in the MIRI® TL6 multiroom IVF incubator

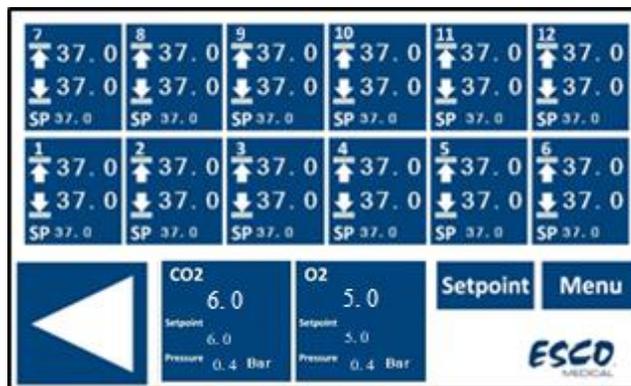


Figure 13.4 Main display in the MIRI® TL12 multiroom IVF incubator

The user can directly access the second main display from the main display by pressing the (←) button.

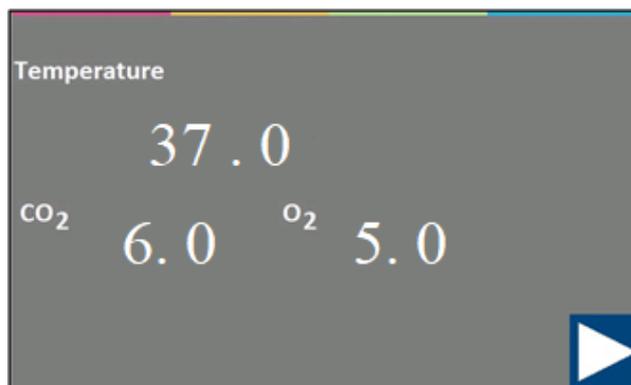


Figure 13.5 The second main display

The second display shows temperature, CO₂ and O₂ setpoint values. If the O₂ regulation is turned off, the display will show "OFF".

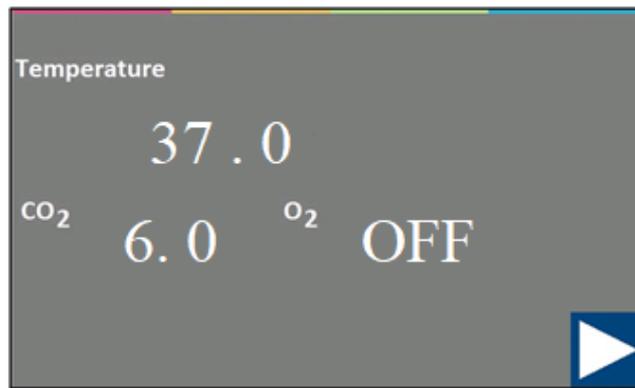


Figure 13.6 The second main display

Exit back to the main display by pressing the (▷) button.

13.2 Temperature setpoint

👉 The MIRI® TL6 multiroom IVF incubator user interface images will be used as an example for all the temperature setpoints.

The temperature setpoint can be adjusted in the range of 28.7 °C to 41.0 °C in both MIRI® TL6 and MIRI® TL12 multiroom IVF incubators.

👉 The default temperature setpoint is 37.0 °C.

In the MIRI® TL6 multiroom IVF incubator, the user can choose to set one common setpoint for all 6 compartments or set 6 independent temperature setpoints (one for each compartment) MIRI® TL12 multiroom IVF incubator – 12.

Multiple setpoints are labelled according to the compartment numbers and the temperature sensors at the compartment's bottom. Compartment one is T1; compartment two is T2, etc.

For more information about multiple temperature setpoints, please read “13.5.4 Temperature Setpoint sub-menu” section below.

To change the temperature setpoint, please follow these instructions:

1. In the main display, press the "Setpoint" button:

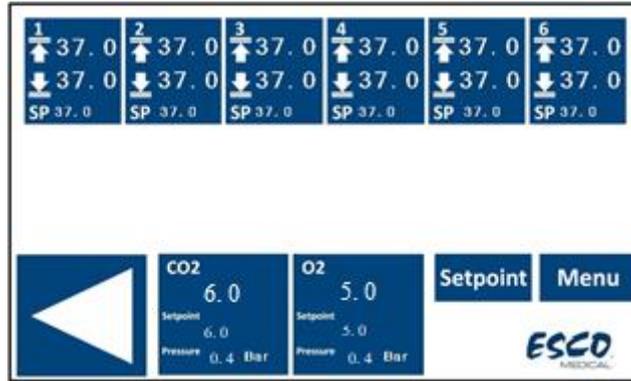


Figure 13.7 Main display view in the MIRI® TL6 multiroom IVF incubator

2. The new setpoint page will appear. Press the "Temperature Setpoint" button:

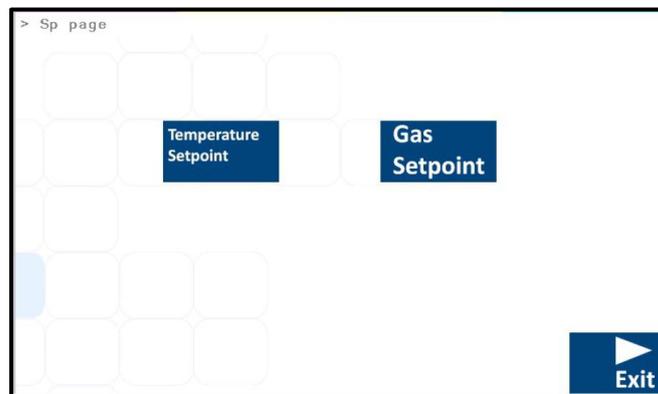


Figure 13.8 Setpoint page display view in the MIRI® TL6 multiroom IVF incubator

3. In the new window, the user can choose the compartment for which he wants to set the setpoint.

To choose the compartment for which the setpoint value should be stated, press the button with the corresponding number.

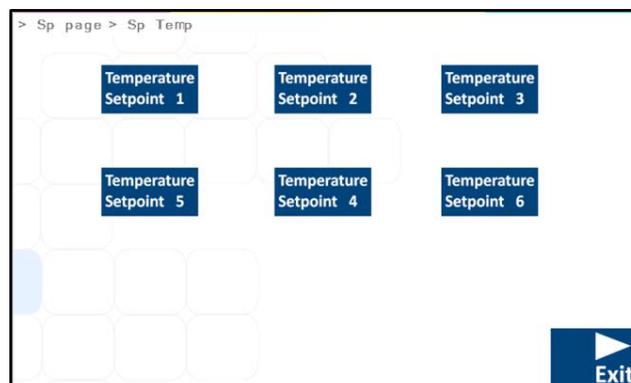


Figure 13.9 Compartment setpoints view in the MIRI® TL6 multiroom IVF incubator

4. Use arrow up and down buttons to set the value: the arrow "DOWN" decreases the value, the arrow "UP" increases the value. One-click changes the value by 0.1 °C.

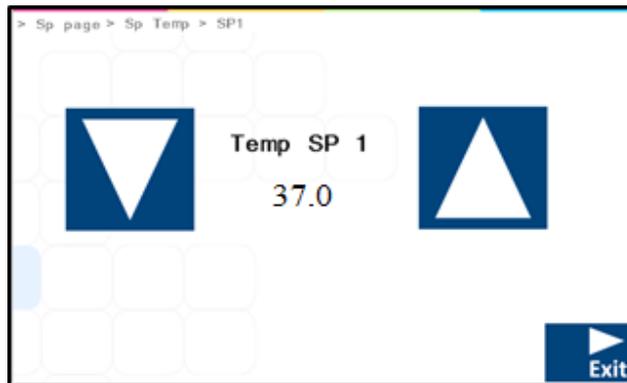


Figure 13.10 Temperature setpoint view in the MIRI® TL6 multiroom IVF incubator

When the desired value is set, press the "EXIT" button. The value will be saved automatically.

Repeat steps for other compartments if "Multi-Temperature SP" is "ON". If "Multi-Temperature SP" is "OFF", the temperature value will automatically be applied to other remaining compartments.

13.3 CO₂ setpoint

👉 The MIRI® TL6 multiroom IVF incubator user interface images will be used as an example for all the CO₂ setpoints.

The CO₂ setpoint can be adjusted in the range from 2.9% to 9.9% in both MIRI® TL6 and MIRI® TL12 multiroom IVF incubators.

👉 The default CO₂ setpoint is 6.0%.

To change the setpoint for CO₂ concentration, follow these instructions:

1. In the main display, press the "Setpoint" button:

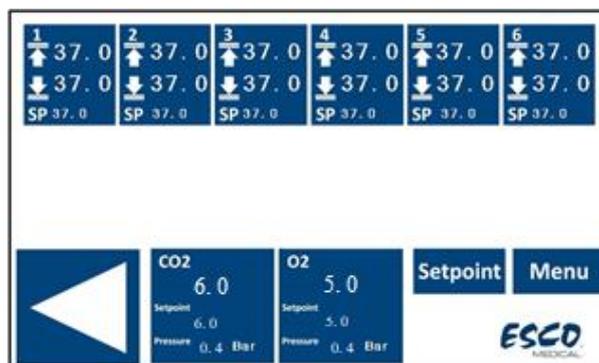


Figure 13.11 Main display view in the MIRI® TL6 multiroom IVF incubator

2. The new setpoint page will appear. Press the "Gas Setpoint" button:

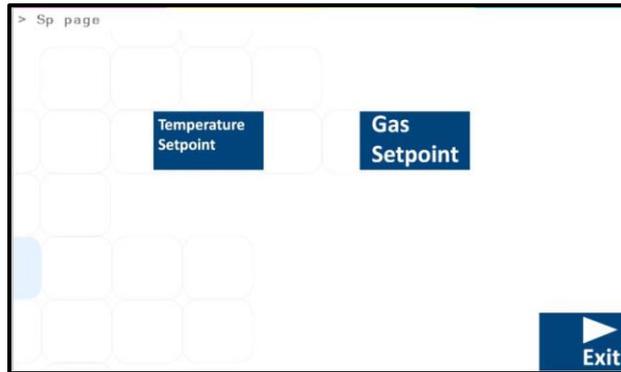


Figure 13.12 Setpoint page view in the MIRI® TL6 multiroom IVF incubator

3. Use arrow up and down buttons to set the value: the arrow "DOWN" decreases the value, the arrow "UP" increases the value. One-click changes the value by 0.1 °C.

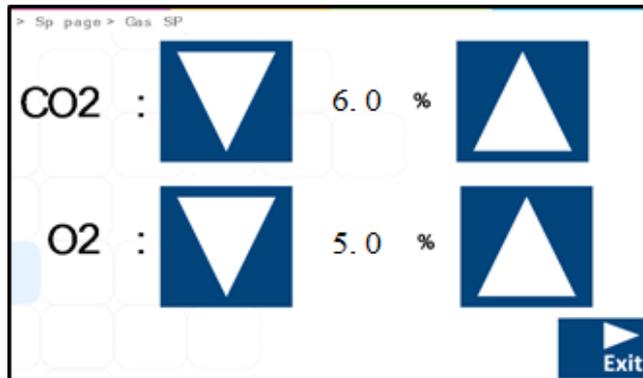


Figure 13.13 Gas setpoint view in the MIRI® TL6 multiroom IVF incubator

When the desired value is set, press the "EXIT" button. The value will be saved automatically.

13.4 O₂ setpoint

👉 The MIRI® TL6 multiroom IVF incubator user interface images will be used as an example for all the O₂ setpoints.

The O₂ setpoint can be adjusted from 2.0% to 20.0% in the MIRI® TL6 multiroom IVF incubator and in the range from 5.0% to 20.0% in the MIRI® TL12 multiroom IVF incubator.

👉 The default CO₂ setpoint is 5.0%.

To change the setpoint for O₂ concentration, follow these instructions:

1. In the main display, press the "Setpoint" button:

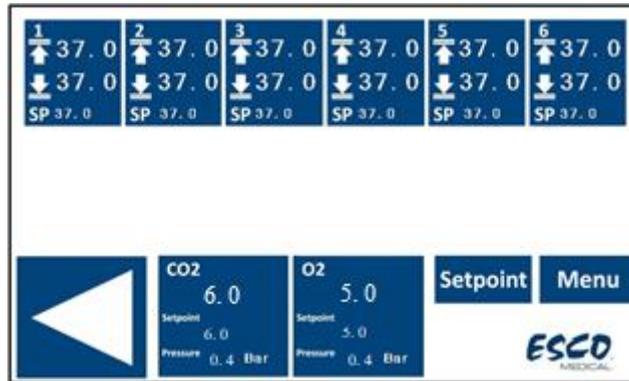


Figure 13.14 Main display view in the MIRI® TL6 multiroom IVF incubator

2. The new setpoint page will appear. Press the "Gas Setpoint" button:

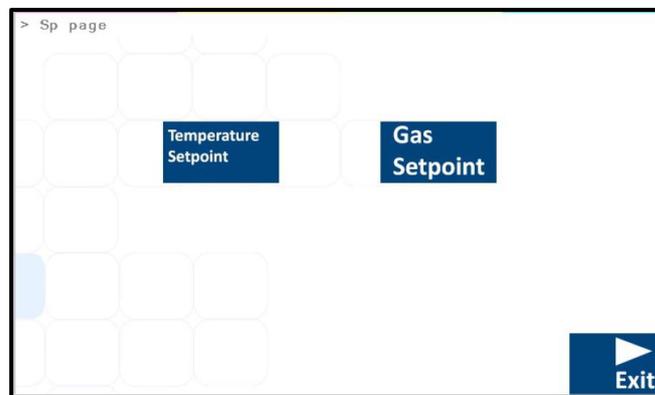


Figure 13.15 Setpoint page view in the MIRI® TL6 multiroom IVF incubator

3. Use arrow up and down buttons to set the value: the arrow "DOWN" decreases the value, the arrow "UP" increases the value. One-click changes the value by 0.1 °C.

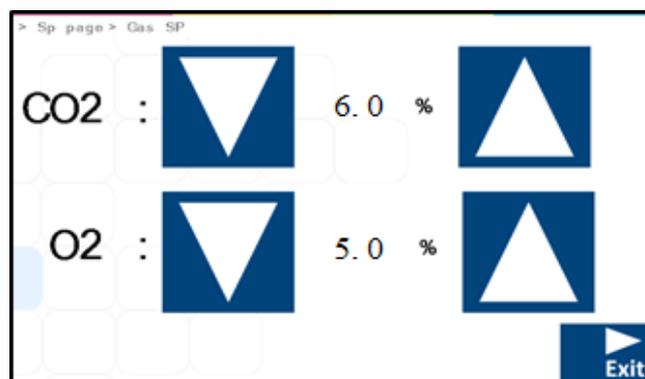


Figure 13.16 Gas setpoint view in the MIRI® TL6 multiroom IVF incubator

When the desired value is set, press the "EXIT" button. The value will be saved automatically.

13.5 System menu

In the main display, press the "Menu" button. The main menu consists of 5 sub-menu applications: "Calibration", "CO₂ Setup", "O₂ Setup", "Temperature Setpoint", "UV-C Light".

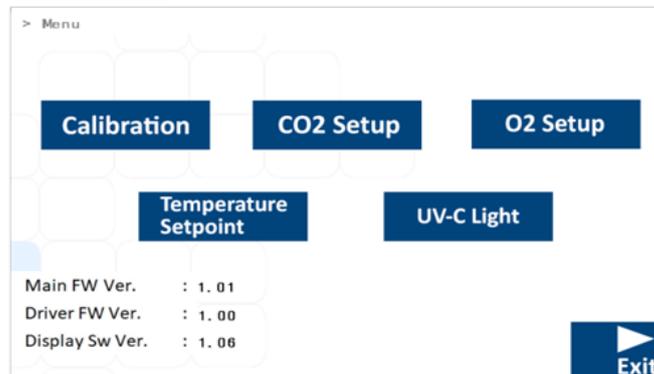


Figure 13.17 System menu view in the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators

13.5.1 Calibration sub-menu

Press the "Calibration" button in the main menu view. Calibration can be performed on temperature, CO₂ and O₂ gases.

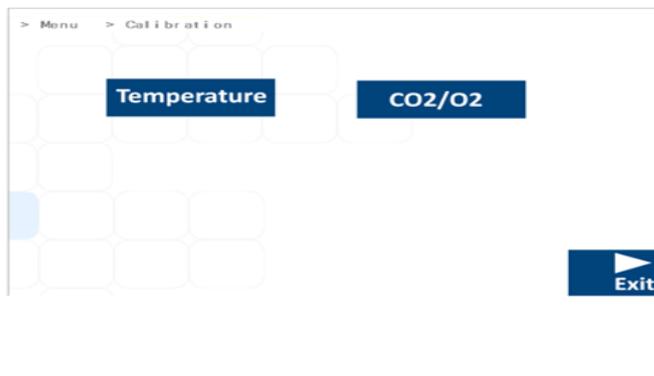


Figure 13.18 Calibration sub-menu view in the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators

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

13.5.1.1 Temperature calibration

Temperature calibration in the MIRI® TL6 multiroom IVF incubator consists of 12 calibration zones.

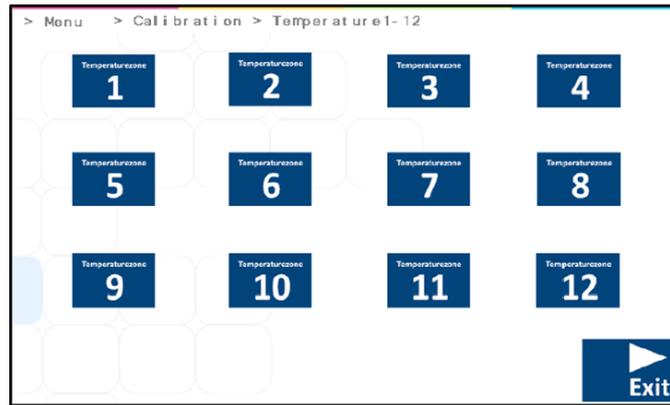


Figure 13.19 12 calibration zones in the MIRI® TL6 multiroom IVF incubator

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

Temperature calibration in the MIRI® TL12 multiroom IVF incubator consists of two separate calibration zones: "Compartment 1-6" and "Compartment 7-12".



Figure 13.20 Calibration zones of Compartments 1-6 and Compartments 7-12 in the MIRI® TL12 multiroom IVF incubator

Select the compartment that needs to be calibrated. When a specific compartment for calibration is chosen, a new display window will appear.

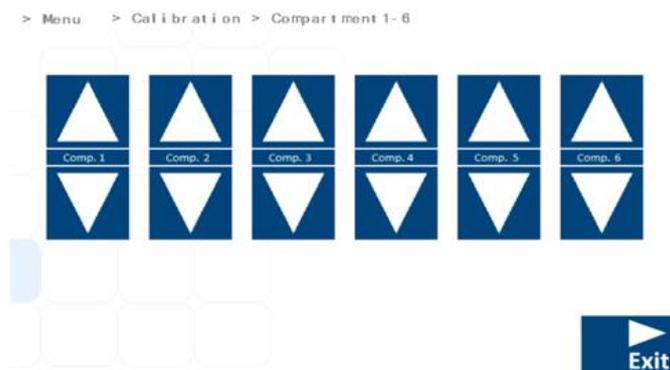


Figure 13.21 Temperature calibration zones for Compartments 1-6 in the MIRI® TL12 multiroom IVF incubator

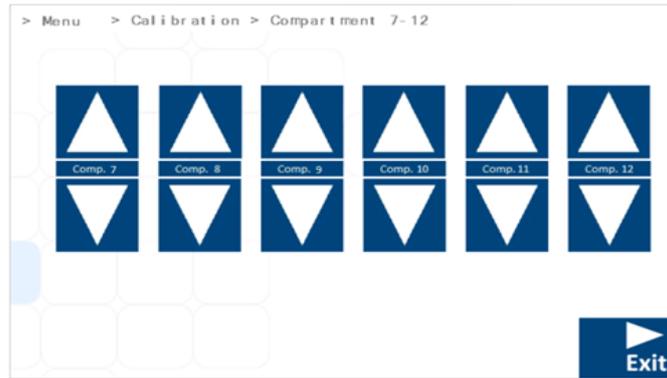


Figure 13.22 Temperature calibration zones for Compartments 7-12 in the MIRI® TL12 multiroom IVF incubator

In the MIRI® TL12 multiroom IVF incubator, each 12 compartment consists of "UP" and "DOWN" buttons. To calibrate the compartment's top temperature, use the "UP" button and calibrate the compartment's bottom temperature and use the "DOWN" button.

In the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators, zone 1 temperature calibration can be done using the "UP" and "DOWN" buttons.

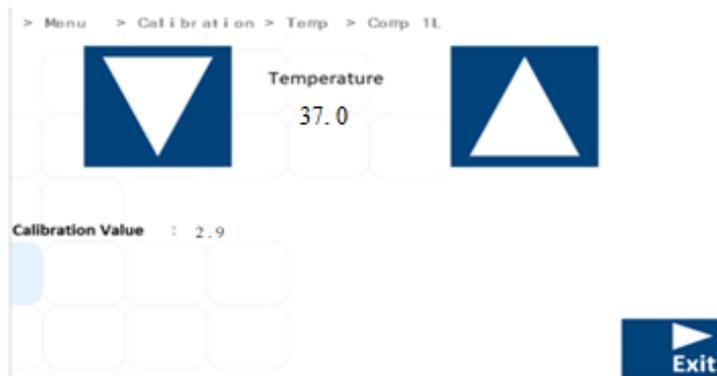


Figure 13.23 Zone T1 calibration view in the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators

👉 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 determined that T1 is 37.4 °C. Calibrate and adjust the temperature by pushing (+) or (-) keys.

Adjust the temperature by pressing the (+) key 4 times when T1 is chosen. The display will show the steps from 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 - T12 (for the MIRI® TL6 multiroom IVF incubator) and T1 - T24 (for the MIRI® TL12 multiroom IVF incubator).

☞ "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.

13.5.1.2 CO₂/O₂ calibration

The CO₂ and O₂ calibration menu page are shown below:

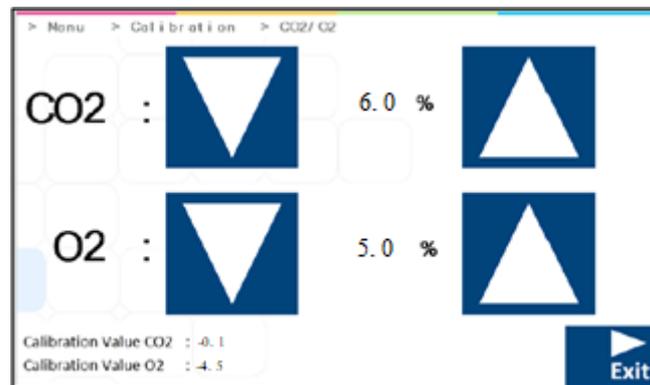


Figure 13.24 CO₂ and O₂ calibration view in the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators

Calibrate the CO₂ and O₂ gas concentration setpoints by pressing the "UP" or "DOWN" buttons.

Example – how to calibrate CO₂:

The real CO₂ 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 determined to be 6.4%.

 Calibration is performed by adjusting the CO₂ level according to the measurement taken from the gas sampling outlet by an external reliable CO₂ 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 “UP” and „DOWN“ buttons. In this case, the goal is to adjust CO₂ 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 the CO₂ sensor calibration is modified.

 The offset value is displayed in the CO₂ calibration window along with the CO₂ concentration value. In this case, the real CO₂ concentration was measured to be 6.4%. By pressing the “UP” button four times, it will take time to change the display's CO₂ concentration value, but the offset value will change immediately. By following this value, the user can see how much the CO₂ calibration value changed without delay.

Example – how to calibrate O₂:

The real O₂ 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 determined to be 5.3%.

 Calibration is performed by adjusting the O₂ level according to the measurement taken from the gas sampling outlet by an external reliable O₂ 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 “UP” and “DOWN” buttons. In this case, the goal is to adjust O₂ 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 the O₂ sensor calibration is modified.

 The offset value is displayed in the O₂ calibration window along with the O₂ concentration value. In this case, the real O₂ concentration was measured to be 5.3%. By pressing the "UP" button three times, it will take time to change the display's O₂ concentration value, but the offset value will change immediately. By following this value, the user can see how much the O₂ calibration value changed without delay.

13.5.2 CO₂ Setup sub-menu

Press the “CO₂ Setup” button in the main menu view. The user can activate or deactivate the CO₂ regulation. If the CO₂ regulation is activated, the setpoint value must be set.



Figure 13.25 CO₂ Setup sub-menu view in the MIRI® TL6 and MIRI® TL12 multiroom IVF incubator

 **The default status for CO₂ control is “OFF”.**

The CO₂ flow rate is shown when the setpoint value is set. The flow rate cannot be adjusted because this is the amount of CO₂ gas put into the system while regulating. The volume is shown in liters per hour. It usually will fluctuate along with the CO₂ regulation.

The CO₂ 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.

13.5.3 O₂ Setup sub-menu

Press the “O₂ Setup” button in the main menu view. The user can activate or deactivate the O₂ regulation. If the O₂ regulation is activated, the setpoint value must be set.



Figure 13.26 O₂ Setup sub-menu view in the MIRI® TL6 and MIRI® TL12 multiroom IVF incubator

 **The default status for O₂ control is "OFF".**

The O₂ flow rate is shown when the setpoint value is set. The flow rate cannot be adjusted because this is the amount of O₂ gas put into the system while regulating. The volume is shown in liters per hour. It usually will fluctuate along with the CO₂ regulation.

The O₂ 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.

13.5.4 Temperature Setpoint sub-menu

Choose temperature setpoint settings according to the desired working conditions.

If "Multi Temp SP" is "ON", it means that temperature values in compartments are individual. If "Multi Temp SP" is "OFF", it means that temperature values in compartments are combined.



Figure 13.27 Multi-temperature setpoint view in the MIRI® TL6 and MIRI® TL12 multiroom IVF incubator

When the desired option is set, press the "EXIT" button. The option will be saved automatically.

👉 When the MULTI temperature setpoint is "OFF", all compartments' temperature setpoint is set according to T1 by default setting. If the MULTI temperature setpoint is "OFF", changing any compartment's temperature setpoint value will apply to all remaining compartments. If the MULTI temperature setpoint is "ON", each compartment has different setpoint values. When returning from "ON" mode to "OFF", all setpoints are automatically set to the T1 area value.

👉 It is recommended to keep the MULTI temperature settings to "OFF" 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).

13.5.5 UV-C Light sub-menu

Press the “UV-C Light” button in the main menu view.



Figure 13.28 UV-C Light regulation in the MIRI® TL6 and MIRI® TL12 multiroom IVF incubator

 **The default status for the UVC light is "ON".**

The UV-C light will automatically switch off when the unit is turned off.

 **For gas disinfection insurance, it is recommended to have the UV-C light set to "ON" when the unit is being used.**

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 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!**

 **The MIRI® TL6 multiroom IVF incubator user interface images will be used as an example for all the alarms.**

14.1 Temperature alarms

All 6 compartments in the MIRI® TL6 multiroom IVF incubator and 12 compartments in the MIRI® TL12 multiroom IVF incubator can trigger a temperature alarm if the temperature in them deviates more than ± 0.5 °C from the setpoint.

 **Remember that changing the setpoint to 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 the T4 zone in compartment 4 is too high compared to the setpoint. The affected area's value will appear red on display.

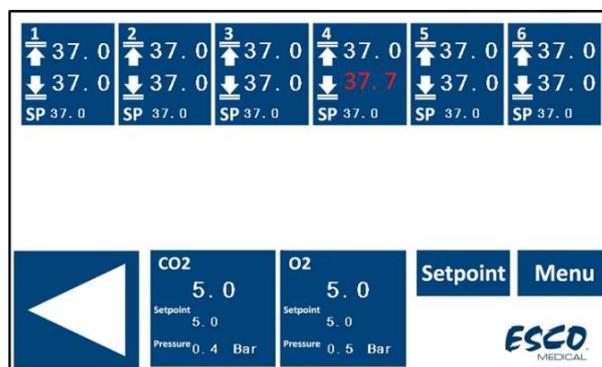


Figure 14.2 High-temperature alarm view on the main display in the MIRI® TL6 multiroom IVF incubator

In the picture below, the temperature in the T1 zone in compartment 1 is too low compared to the setpoint. The affected area's value will appear red on display.

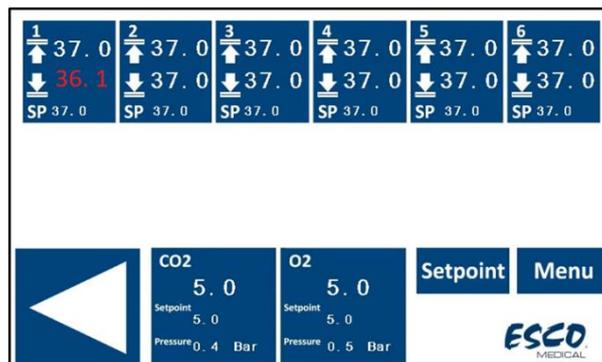


Figure 14.3 Low-temperature alarm view on the main display in the MIRI® TL6 multiroom IVF incubator

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 31 "Emergency procedure" section on how to behave when there is a temperature alarm.**

If there is a malfunction with the temperature sensors, it will be indicated by the warning:

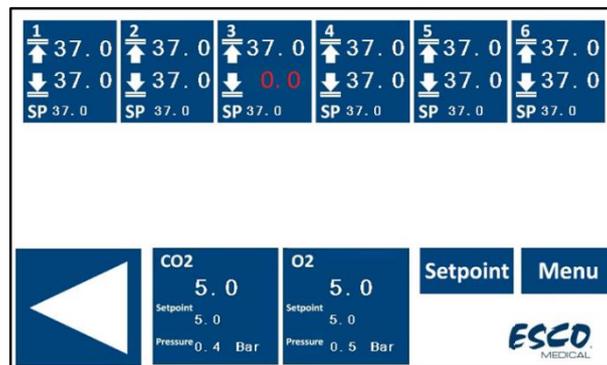


Figure 14.4 Temperature sensor malfunction view on the main display in the MIRI® TL6 multiroom IVF incubator

The T3 temperature sensor in compartment 3 is malfunctioning, and as a safety precaution, the heating for the affected zone will be shut down.

14.2 Gas level alarms

14.2.1 CO₂ alarms

The CO₂ level alarm is activated if the concentration of CO₂ gas deviates more than $\pm 1\%$ from the set value.

Remember that changing the setpoint more than $\pm 1\%$ from the current gas level will result in a CO₂ level alarm. It applies for all calibration adjustments.

In the picture below, the CO₂ concentration is too low compared to the setpoint.

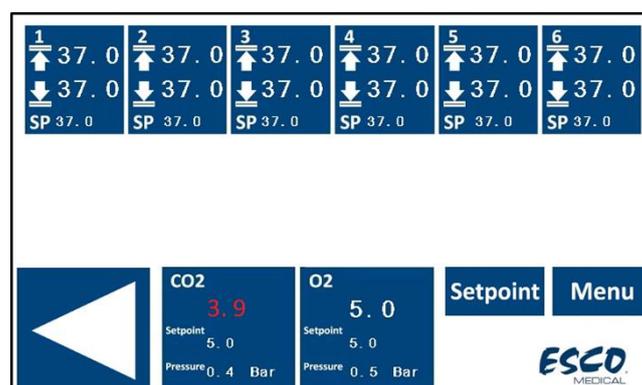


Figure 14.5 Low CO₂ concentration alarm view on the main display in the MIRI® TL6 multiroom IVF incubator

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 31 "Emergency procedure" section on how to behave when there is a CO₂ level alarm.

14.2.2 O₂ alarms

The O₂ level alarm is activated if the concentration of O₂ 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 O₂ level alarm. It applies for all calibration adjustments.

In the picture below, the O₂ concentration is too high compared to the setpoint.

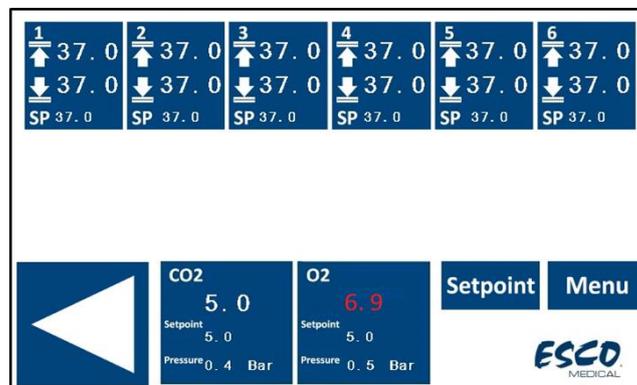


Figure 14.6 High O₂ concentration alarm view on the main display in the MIRI® TL6 multiroom IVF incubator

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 31 "Emergency procedure" section on how to behave when there is an O₂ level alarm.

14.3 Gas pressure alarms

14.3.1 CO₂ pressure alarm

If the CO₂ gas supply is not attached correctly or incorrect CO₂ gas pressure is applied to the system, the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator will go into CO₂ pressure alarm mode. CO₂ 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.

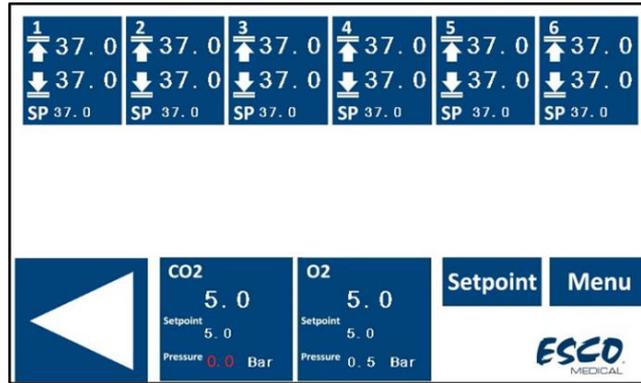


Figure 14.7 CO₂ gas pressure alarm view on the main display in the MIRI® TL6 multiroom IVF incubator

👉 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 31 "Emergency procedure" section on how to behave when there is a CO₂ pressure alarm.

14.3.2 N₂ pressure alarm

If the N₂ gas supply is not attached correctly or incorrect CO₂ gas pressure is applied to the system, the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator will go into N₂ pressure alarm mode. N₂ 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 14.8 N₂ gas pressure alarm view on the main display in the MIRI® TL6 multiroom IVF incubator

👉 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 31 "Emergency procedure" section on how to behave when there is an N₂ pressure alarm.

14.4 Alarm UV-C light

The service UV-C light will appear only as a warning message during the normal status. An audio alarm will not go off.

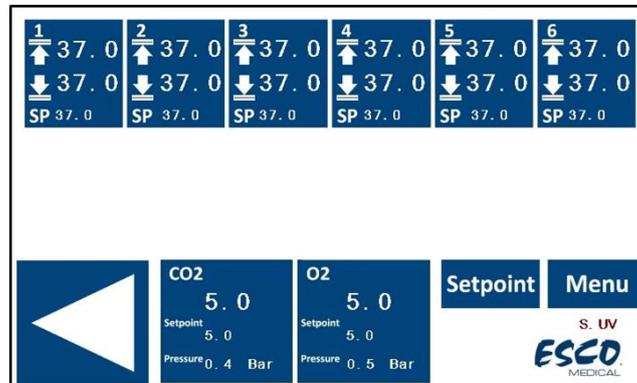


Figure 14.9 UV-C light malfunction alarm view on the main display in the MIRI® TL6 multiroom IVF incubator

The user should consult the distributor for further guidance or service inspection. The "S. 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, the temperature is too high in the T1 zone, the CO₂ gas is not connected, or the CO₂ pressure is incorrect and there is also a UV-C light malfunction.



Figure 14.10 Multiple alarm view on the main display in the MIRI® TL6 multiroom IVF incubator

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 31 "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 14.11 Alarm key which indicates the alarm condition

 Please refer to the 31 "Emergency procedure" section on how to behave when there is a loss of power alarm.

14.7 Summary of the alarms

In the table below, there is a list of every possible alarm in the MIRI® TL family's multiroom IVF incubators.

Table 14.1 Every possible alarm in the MIRI® TL family's 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

Alarm name	Conditions	How it is determined	Alarm group	Alarm priority
High internal CO ₂ pressure	If the pressure rises above 0.7 bar	Pressure sensor reading	Technical	High priority alarm
Low incoming N ₂ pressure	If the pressure falls below 0.3 bar	Pressure sensor reading	Technical	High priority alarm
High internal N ₂ pressure	If the pressure rises above 0.7 bar	Pressure sensor reading	Technical	High priority alarm
UV alarm	If the UV lamp is malfunctioning	UV sensor reading	Technical	Informative alarm

14.8 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® TL family's 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 top CultureCoin® placement spot 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 calibration

The MIRI® TL6 or MIRI® TL12 multiroom IVF incubator temperature control system is described in more detail in this section.

The MIRI® TL6 multiroom IVF incubator is equipped with 6 completely separate PID controllers for temperature measurement, whereas the MIRI® TL12 multiroom IVF incubator – 12. Each controller is responsible for controlling the temperature in a particular area.

Each of the 6 available areas in the MIRI® TL6 multiroom IVF incubator or 12 in MIRI® TL12 multiroom IVF incubator are equipped with its separate temperature sensor and heater, allowing the user to adjust the temperature in every area separately, thus achieving higher precision.

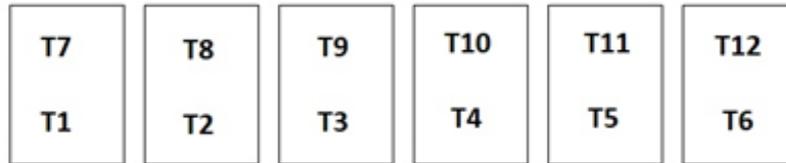


Figure 15.1 Temperature zones in the MIRI® TL6 multiroom IVF incubator

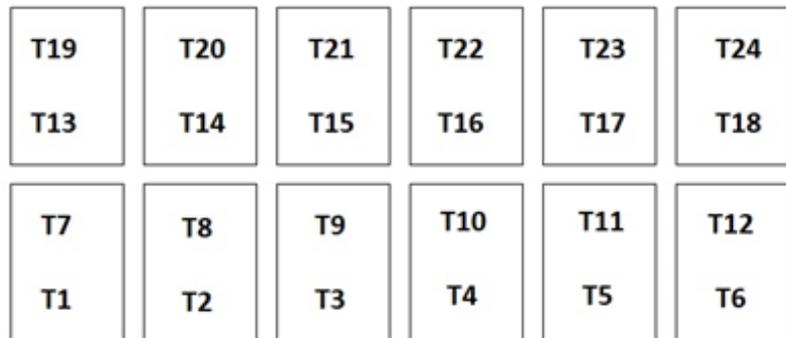


Figure 15.2 Temperature zones in the MIRI® TL12 multiroom IVF incubator

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

These items are placed in the MIRI® TL6 multiroom IVF incubator menu, and they are named: T1, T2, T3, T4, T5, T6, T7, T8, T9, T10, T11 and T12.

These items are placed in the MIRI® TL12 multiroom IVF incubator menu, and they are named: 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 the sensor names is shown in the tables below.

Table 15.1 Areas associated with sensors in the MIRI® TL6 multiroom IVF incubator

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

Table 15.1 Areas associated with sensors in the MIRI® TL12 multiroom IVF incubator

Area	Bottom	Lid
Compartment 1	T1	T7
Compartment 2	T2	T8
Compartment 3	T3	T9
Compartment 4	T4	T10
Compartment 5	T5	T11

Area	Bottom	Lid
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® TL6 and MIRI® TL12 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 CO₂ gas pressure

The CO₂ pressure can be seen in the main display and the “CO₂ Setup sub-menu” (Please look in Figures 13.11 and 13.25 above).

The CO₂ 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 N₂ gas pressure

The N₂ pressure can be seen in the main display and the “O₂ Setup sub-menu” (Please look in Figures 13.14 and 13.26 above).

The CO₂ 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.**

17 Firmware

The firmware installed on your MIRI® TL6 and MIRI® TL12 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® TL6 multiroom IVF incubator firmware version is 1.05 for Master PCB and 1.04 for Slave PCB. The current MIRI® TL12 multiroom IVF incubator firmware version is 1.08 for both Master and Slave PCB.

18 pH measuring

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

The MIRI® TL6 and MIRI® TL12 multiroom IVF incubator are 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.

👉 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:

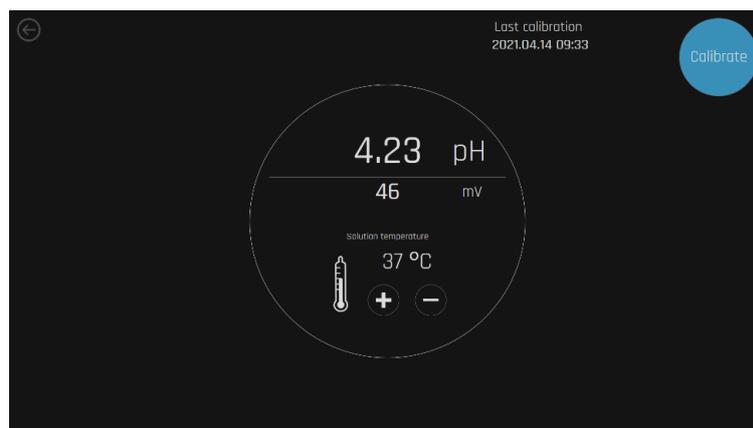


Figure 18.1 pH system and calibration dialogue screen view in the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator

The recommended method to use the system is to fill a CultureCoin® dish with 3 types of buffers in 3 of the wells (one type in each). Leave empty wells in between so there is no contact between the buffers. Fill the pH reservoir of the CultureCoin® dish that is used for incubation with the culture media. Put the PDMS silicone plug in so that evaporation would not occur. Place the dish in one empty compartment and leave it to equilibrate.

👉 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" button:

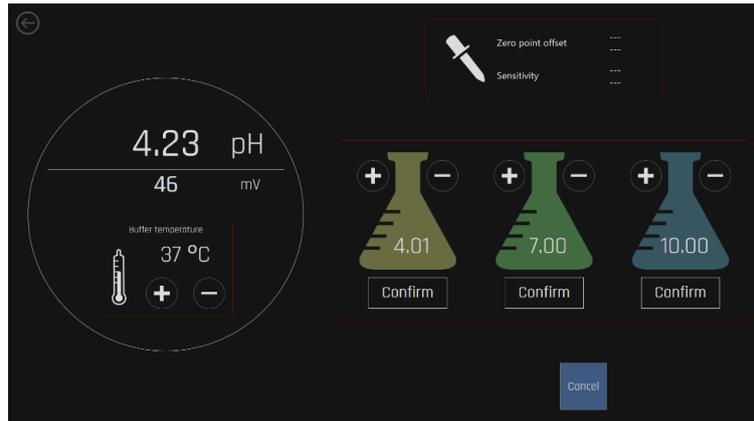


Figure 18.2 pH calibration screen view in the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator

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 CultureCoin® pH reservoir media. Remove the PDMS silicone lid before insertion of the micro probe. The actual pH measured by the probe will be shown in the display.

👉 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 in a droplet.

19 SAFE Sense function

There is a possibility to purchase the MIRI® TL6 and MIRI® TL12 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 Cybersecurity

The objectives of the IT security are as follows:

1. To ensure the operational state of the MIRI® TL family's multiroom IVF incubator system.
2. To protect computer and network resources from the cybersecurity breach.
3. To protect the used data from tampering.

MIRI® TL6 and MIRI® TL12 multiroom IVF incubators must be connected to a network using equipment provided by Esco Medical. The connection procedure should be completed according to the provided schemes:

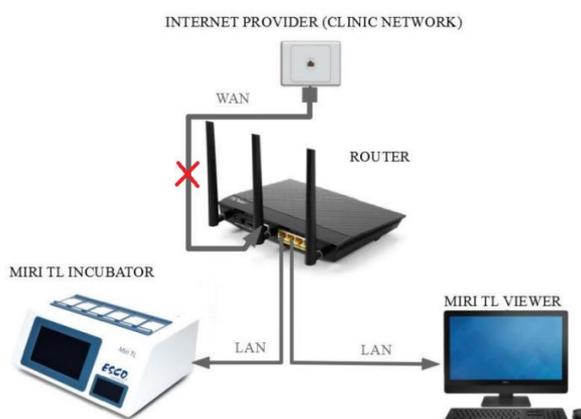


Figure 20.1 MIRI® TL family's multiroom incubator's connection scheme without the incorporated server

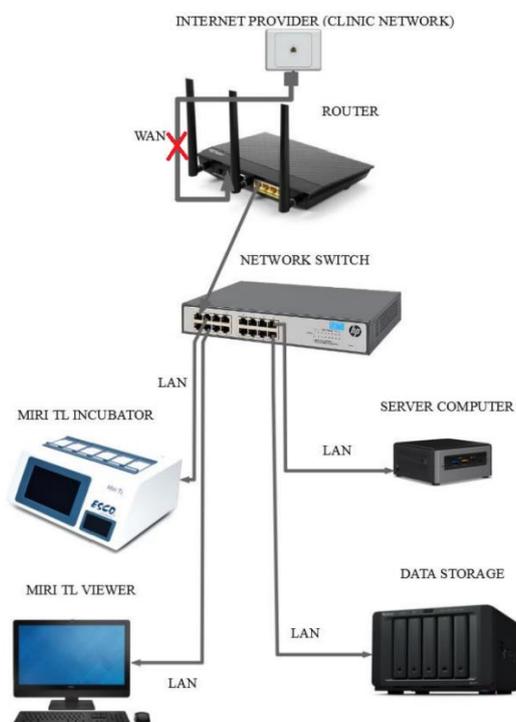


Figure 20.2 MIRI® TL family's multiroom incubator's connection scheme with the incorporated server and its components

Compromised cybersecurity has risks related to the functions of the MIRI® TL family's multiroom IVF incubators:

- Embryo time-lapse function ceasing to work;
- Possible deletion, modification or leaking of the data, entered on the MIRI® TL Viewer software.

The system has been designed in a way where the incubator's power control switch is separated from the rest of the Viewers software. This ensures that the breach of the Viewers software could not impact the power state of the incubator.

 **In a critical situation, where the Viewer software is disconnected from the network, the incubator can maintain the set parameters and log the necessary information on its own.**

 **If there is a suspicion that the cybersecurity of the system has been compromised, the MIRI® TL family's multiroom incubator should be disconnected from the network and the incident should be reported to the Esco Medical Technical support as soon as possible. Further guidance for diagnosis and troubleshooting should be followed.**

21 Screen functions

The screen works as the user interface for the time-lapse functions, the data-logging functions, alarm overview and the pH measuring function. The interaction with the screen is single-click touch-based.

The current MIRI® TL6 and MIRI® TL12 multiroom IVF incubators software version is 1.26.0.0.

Working lines from 1-6 are changed to 7-12 with the button near the screen in the MIRI® TL12 multiroom IVF incubator. 2 green lights indicate which line is working.



Figure 21.1 The MIRI® TL12 multiroom IVF incubator's front view with marked altering working lines button and indication

 **Unauthorized access to the laboratory should be controlled!**

 **The MIRI® TL6 multiroom IVF incubator user interface images will be used as an example for all the temperature setpoints.**

21.1 The main screen

The main screen has an overview of the 6 compartments, showing their current bottom temperature and lid temperature. The circle shows the status of a time-lapse: is it active or inactive. If it is active, the time count will run on the screen.

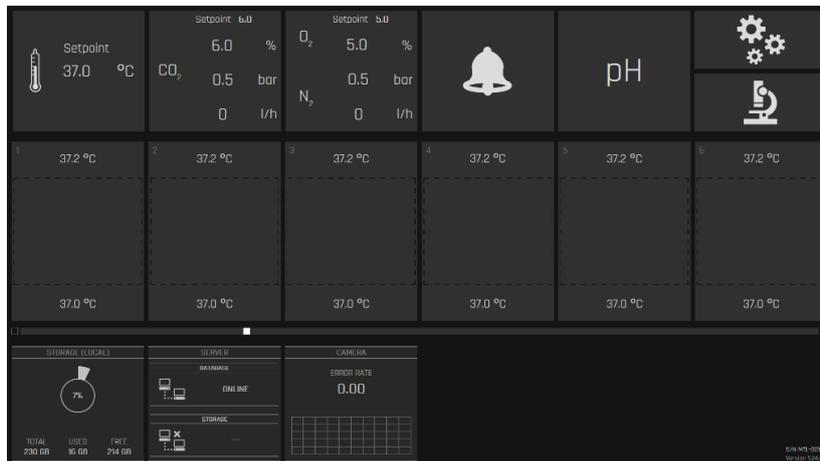


Figure 21.2 No active time-lapses view

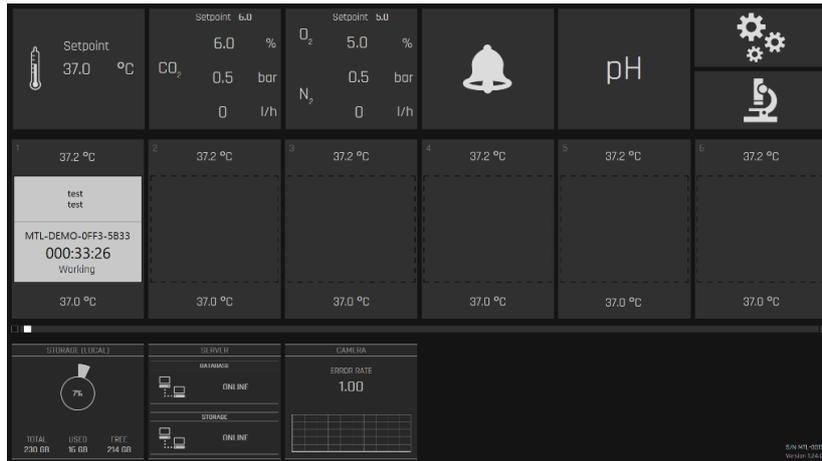


Figure 21.3 One active time-lapse view

When a time-lapse is running normally, there will appear a green status indication in the main view.

If the MIRI® TL6 multiroom IVF incubators find the correct positions for the wells, the system will show a status sign which indicates that it is "Calibrating".

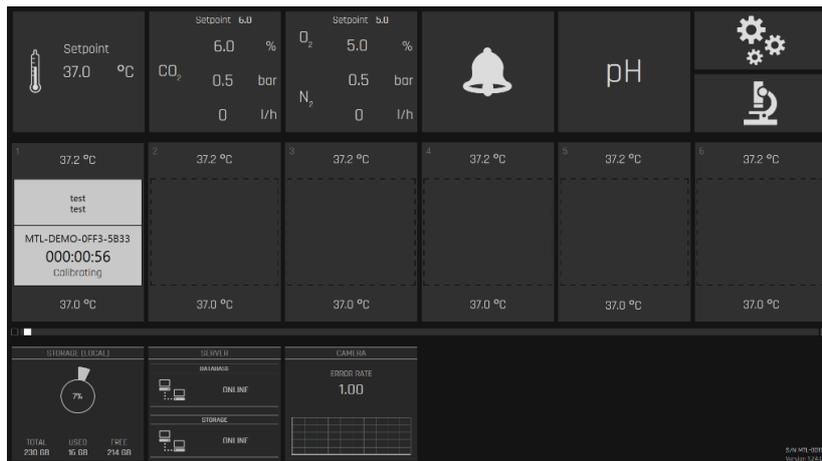


Figure 21.4 Time-lapse calibrating view

If the time-lapse is paused, the system will indicate "Suspended".

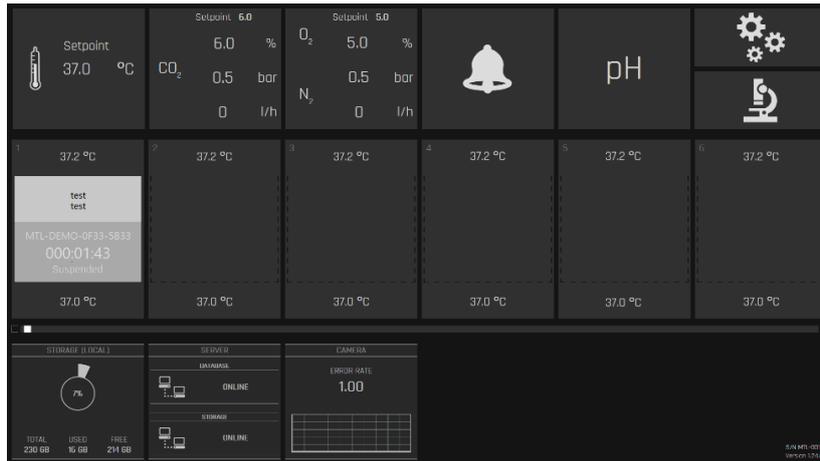


Figure 21.5 Suspended time-lapse view

👉 A time-lapse may be suspended if, for instance, the dish is removed for a culture media change, manual observation or manipulation of the embryo.

21.1.1 Starting a time-lapse

When the circle of an empty compartment in the main view is pressed, a time-lapse dialogue window will open. First, select a patient from the list.

👉 Patients can only be created or edited on the MIRI® TL6 or MIRI® TL12 multiroom IVF incubators Viewer. For more information, please read the MIRI® TL multiroom IVF incubator Viewer User Manual. The patient data must be allocated to the MIRI® TL6 or MIRI® TL12 multiroom IVF incubators to appear on the list.

Press the "Refresh" button to update the list.

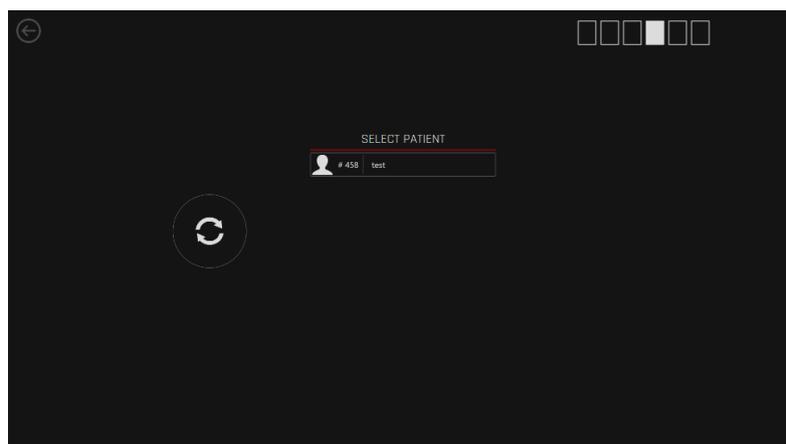


Figure 21.6 Patient selection main window view

The 6 squares icons on the top left side in the display indicate compartment number.

Select the correct patient from the list.

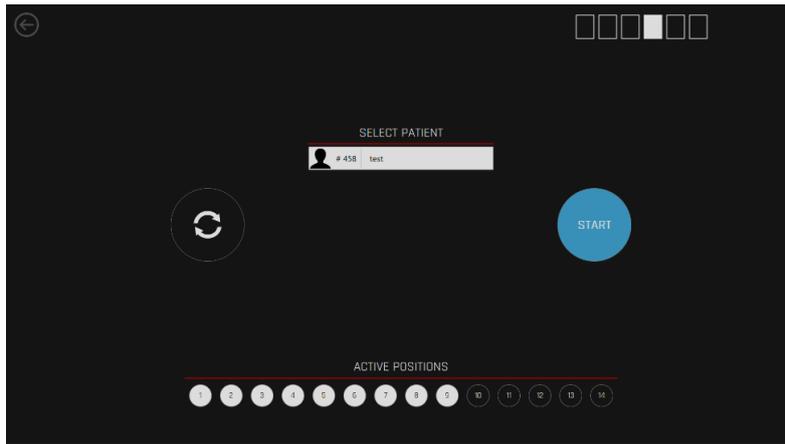


Figure 21.7 Test patient selection view

If no patient is sent from the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator Viewer, the following screen will appear:

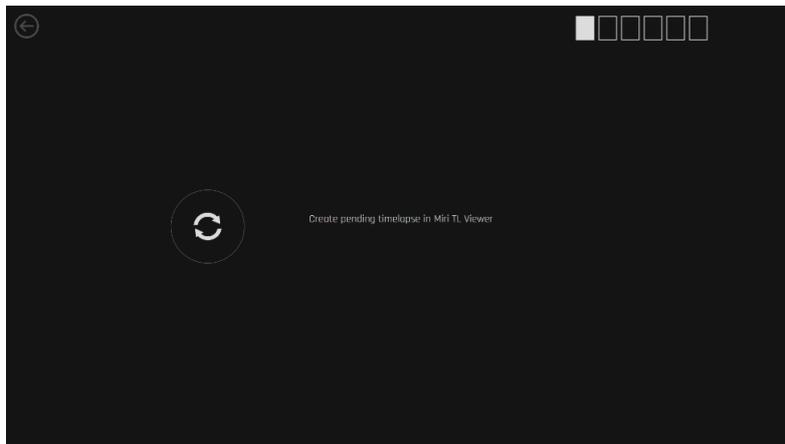


Figure 21.8 No patient from MIRI® TL6 multiroom IVF incubator Viewer is sent to the incubator
If the required network connection is interrupted, the following screen will appear:

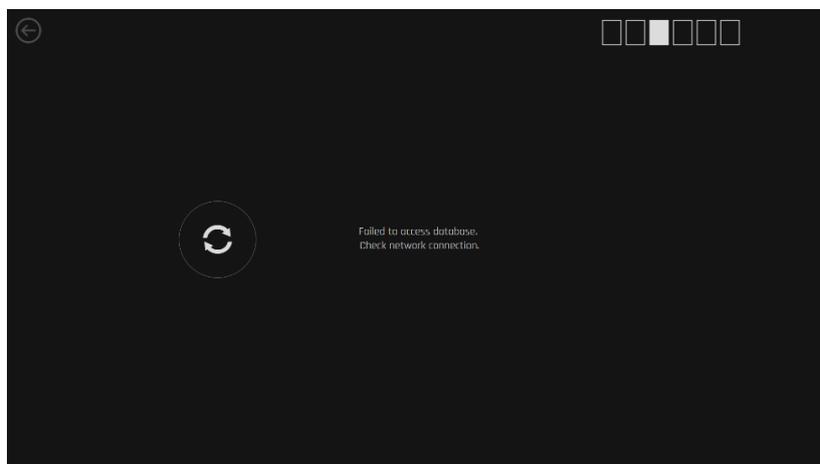


Figure 21.9 Network connection interruption view

When the correct patient has been selected, the active positions in the CultureCoin® must be selected (the wells that will contain an embryo). Positions 1 – 14 represent the 14 wells on the CultureCoin® dish.

👉 Only the selected positions in the CultureCoin® dish will be used for the time-lapse. Any mistake made here will result in an empty well being photographed and no film made of the well containing the embryo.

The active position buttons can be toggled on/off until the correct pattern is displayed. After that, press the "Start time-lapse" button – it will start an automatic calibration process. In the picture below, positions 1 – 9 are selected as active.

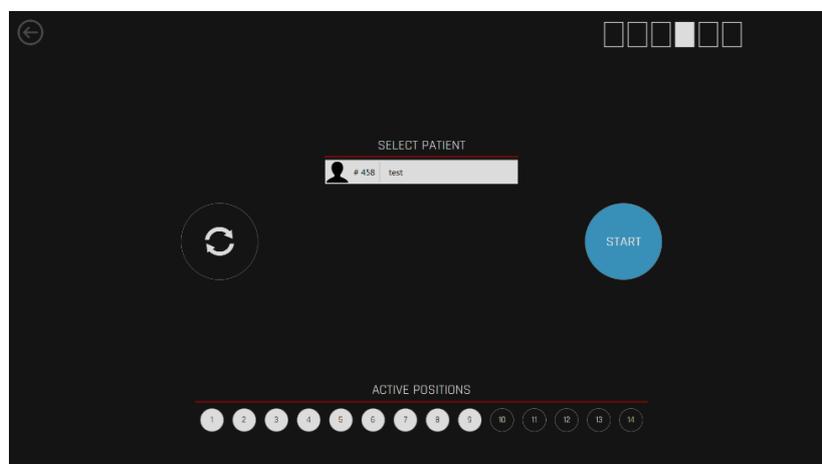


Figure 21.10 Positions 1 – 9 selected as active

Before starting time-lapse, it is essential to place the CultureCoin® in the compartment properly. To ensure the correct position of the CultureCoin® (so that the camera can identify all the wells), place the CultureCoin® in its place and secure its position by pushing it **downwards and towards you**, then to the **left edge**.

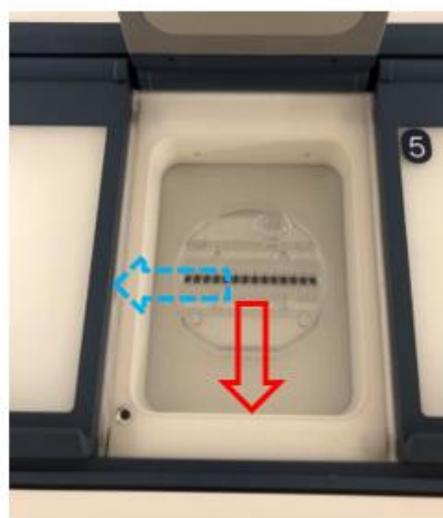


Figure 21.11 Positioning CultureCoin® in the compartment

Press the "Start time-lapse" button. Now the time-lapse calibration will start.

21.1.2 Calibration processes

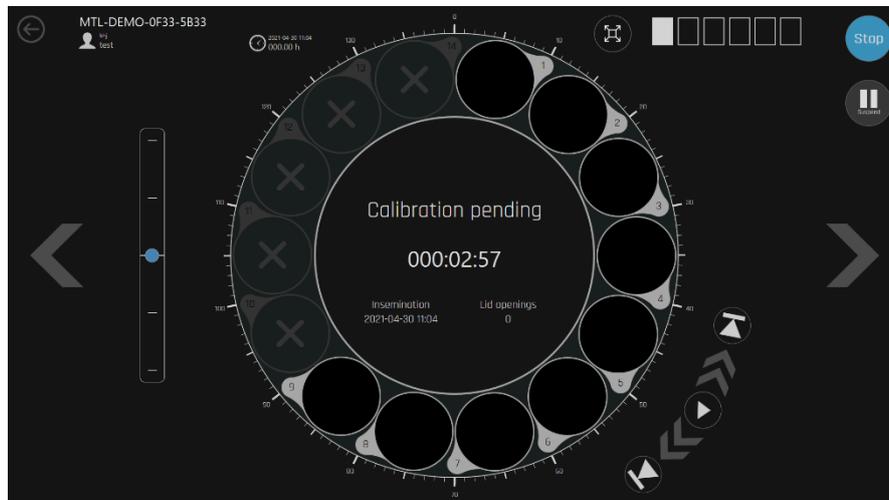


Figure 21.12 Test patient calibration pending

First, the screen will show the compartment view with the "Calibration pending" message. Suppose the CultureCoin® is correctly placed in the compartment, and embryos are placed in the middle of an intended area (for more information, please see the 22 "CultureCoin®" section below). In this case, the MIRI® TL6 or MIRI® TL12 multiroom IVF incubators should find the positions automatically.

During the calibration process, in the middle area it will indicate that the calibration process is active.

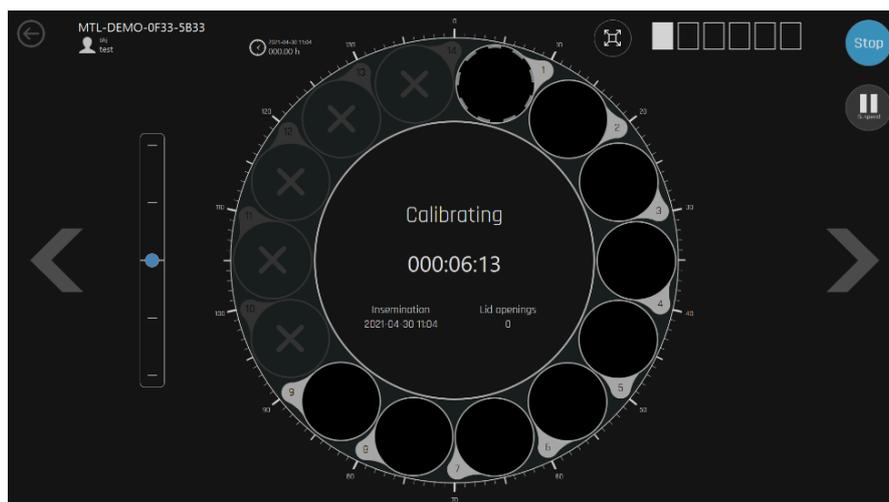


Figure 21.13 Active automatic calibration process indication

After the automatic calibration, it is necessary to pay attention to whether all the wells have been detected correctly. Manual calibration of a particular well must be done on

LiveView Mode if not all well positions were detected/focused correctly, and some wells are marked with red/yellow/purple colour (see section 21.1.5).



Figure 21.14 Example of a failed automatic calibration

👉 Well that is marked in red colour (Failed) means that the camera wasn't able to detect the compartment correctly.

👉 Well that is marked in yellow (Interpolated) colour means that the calibration data of position are calculated based on calibration information around the exact position. For example, if 1st and 3rd wells were calibrated, to calibrate 2nd well, an average of Z (focus) are taken from 1st and 3rd wells.

👉 Well that is marked in purple (Image mismatch) means there is image mismatch after the system comparing the last two images. This message could appear if the embryo moved too much than usual or an air bubble formed in the selected well.

21.1.3 Compartment view

The compartment view shows detailed information for the selected compartment. If the compartment has an active time-lapse, the compartment view will show the activity.

The 14 circles in the "revolver" view show 14 wells of the CultureCoin®. They are arranged in this manner (and not in the linear pattern as on the physical dish) to make it easier to see an overview at a glance.



Figure 21.15 14 wells of the selected compartment

The timeline around the large circle shows the elapsed time.

Video player buttons are located on the lower right side of the large circle. They help to navigate back and forward in the generated time-lapse movie. The circle's center holds status information indicating a number of the time-lapse, patient name, insemination time, lid openings and the elapsed time. Compartment numbers can be seen from the squares in the top left-hand corner.

3 buttons on the right allow the user to stop the time-lapse, suspend it or start the calibration procedure again.

A time-lapse can be suspended if the dish needs to be removed to make culture media changes or perform a manual observation with a microscope. When the dish is put back, the time-lapse can be resumed so that the final result will be one continuous film. Resuming the time-lapse will initiate automatic calibration as the removal of the dish may cause parameters to shift.

If the stop button is pressed, a confirmation dialogue will be displayed.



Figure 21.16 Sleeping mode confirmation view

To the left of the big circle, the focal planes are located. By tapping on them, it is possible to move up and down in the focal planes. The blue dot indicates the current level displayed. The focal planes in all the images will shift at the same time.

When the system shows the "Sleeping" sign, it means that the camera system generates images in another position. As there is only one camera in the device, it must move around to generate the images of each position.

It is possible to maximize the view of one time-lapse position. By clicking on the small embryo picture, a large version of it will appear in the circle's center. It can be minimized again the same way, i. e. by clicking on the large image. A maximized time-lapse image is shown below.

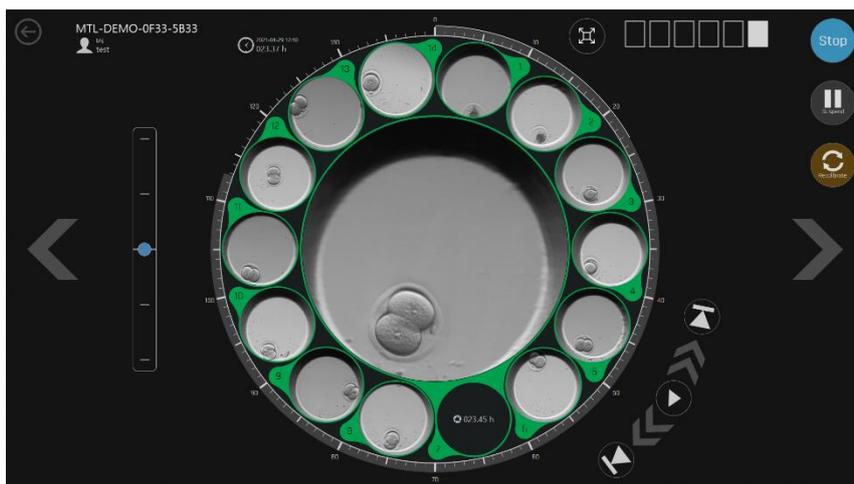


Figure 21.17 Maximized time-lapse position view

Scrolling through the 6 compartments can be done with the arrow keys "LEFT" and "RIGHT". The circled arrow left in the top left-hand corner will take you back to the main view.

If no time-lapse is running in the compartment, the screen will indicate that the compartment is empty.



Figure 21.18 Empty time-lapse view

21.1.4 Settings

Pressing the "Settings" button in the main view will open a window where the number of focal planes and the time interval between each image can be set (cycle time).

By default, the cycle times can be set at 5, 10 or 20 minutes. The focal planes can be set at 3, 5 or 7.

 **Note that 7 focal planes and a cycle time of 5 minutes will result in a large time-lapse file.**

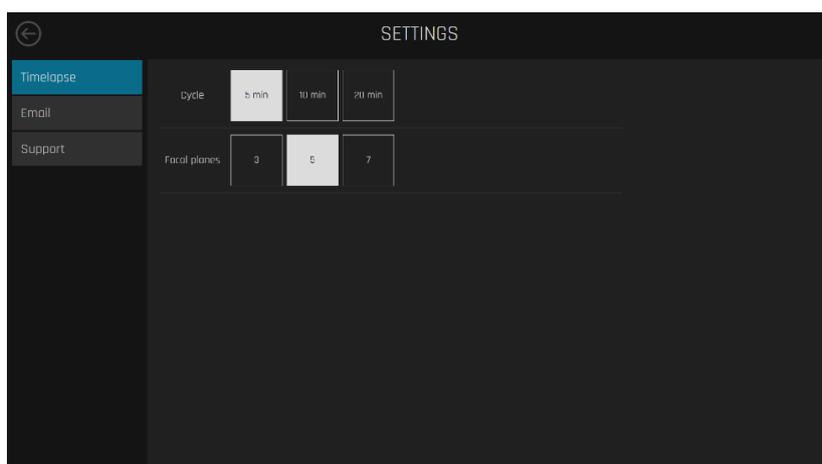


Figure 21.19 Cycle and focal planes settings screen

Press buttons corresponding to the desired choices.

👉 The cycle times cannot be set when a time-lapse has been started. End all time-lapses to adjust the cycle time.

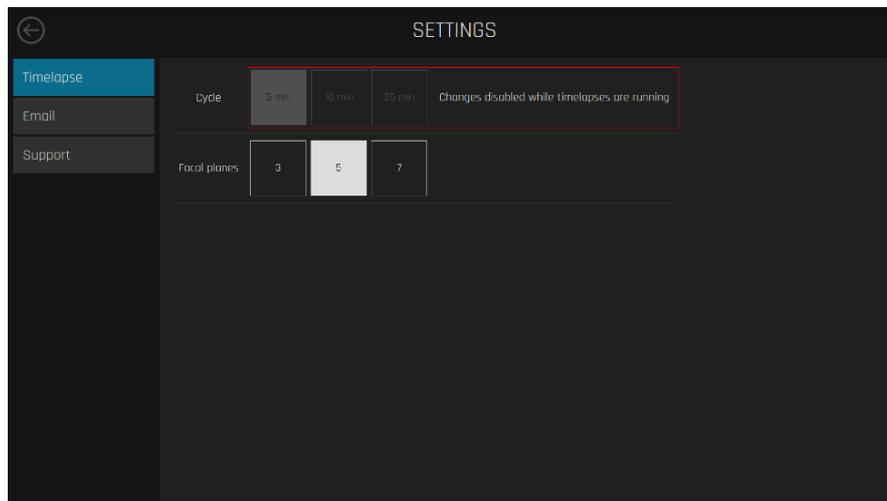


Figure 21.20 Changes are disabled while time-lapses are running

21.1.5 Manual calibration of the well position

If the automatic calibration process failed, the LiveView mode might be used for manual adjustments and calibration.

First, try to adjust CultureCoin® position and then rerun the automatic calibration.

👉 The automatic search for the correct well is sensitive to errors when the embryo is on the side of the well. It is essential to position embryos carefully so they would be in the center of the well circle.

As the live view function will allocate the camera system to a specific position, any running time-lapses will be suspended. If a time-lapse is running, a confirmation dialogue will be shown.

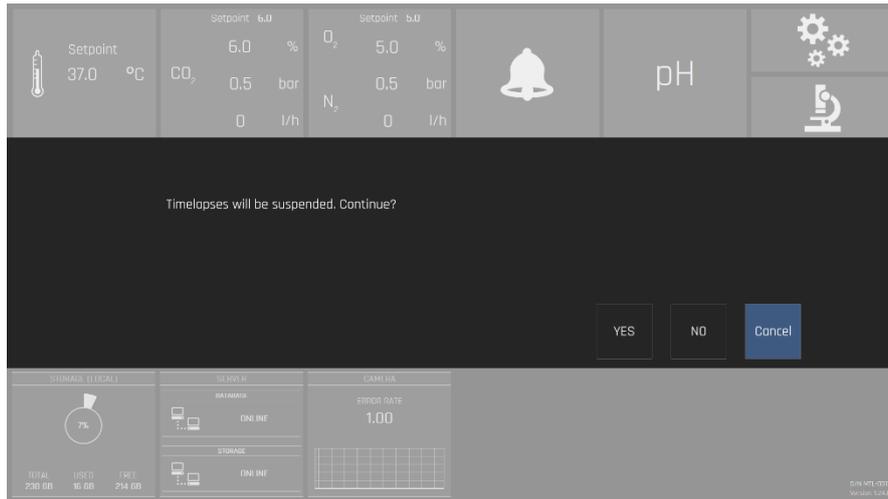


Figure 21.21 Confirmation dialogue view

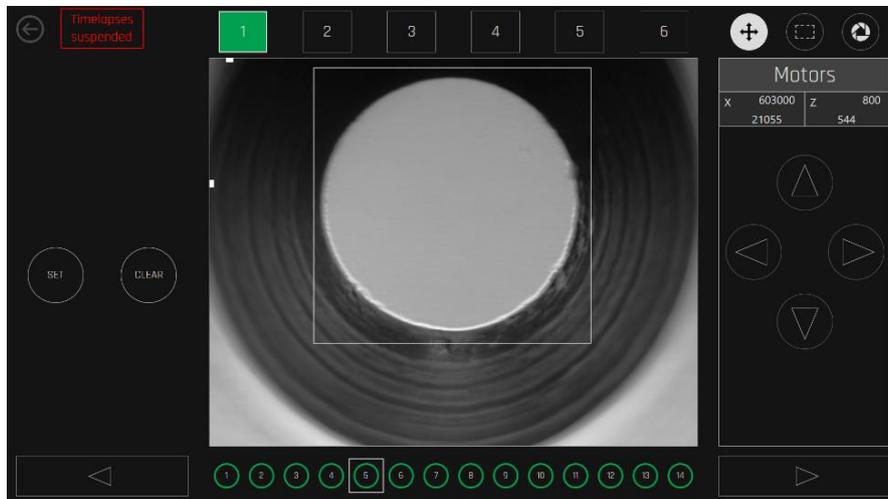


Figure 21.22 Suspended time-lapses view

The black background indicates that there is no active time-lapse running in the compartment. The green background indicates that the time-lapse is running and is in regular operation. The red background indicates that there are calibration failures for some positions.

When a compartment with an active time-lapse is selected, 14 dish positions will be shown at the bottom of the screen.

The white position background indicates that it is not calibrated yet. Black background indicates that the position is not active (not selected when a time-lapse started). Green or red colours indicate that the position is active and that it is or is not calibrated correctly.

It is possible to navigate among the compartments and the 14 positions. The system will indicate such movement.

Buttons in the top right corner offer the selection of the motor control, a square selection tool and an exposure time.

Enter LiveView mode by pressing the microscope button marked red on the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator screen.



Figure 21.23 LiveView mode button on the main MIRI® TL6 or MIRI® TL12 multiroom IVF incubator screen

In LiveView Mode, select the required compartment from the compartment bar above and the required position from the bar below in the main screen.



Figure 21.24 Compartments bar in the LiveView Mode



Figure 21.25 Position bar in the LiveView Mode

Once the well position, which must be calibrated, is chosen, please ensure that the well is in the middle of the camera view screen in the X-axis.

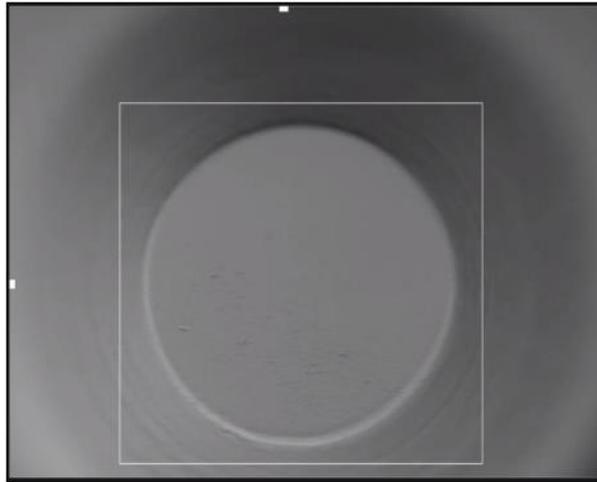


Figure 21.26 Example of a correct well position in the camera view screen

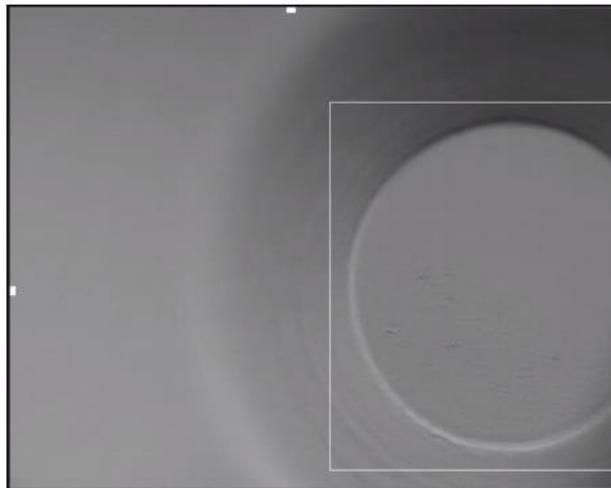


Figure 21.27 Example of an incorrect well position in the camera view screen

If necessary, adjust the X-axis position with the "LEFT" or/and "RIGHT" arrows under the "Motor" icon (located in the upper right corner of the screen).

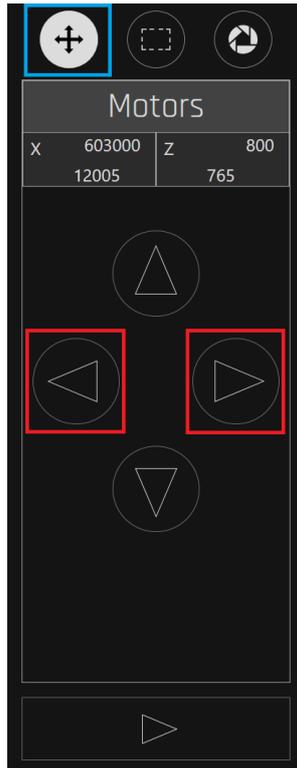


Figure 21.28 Well position adjustment instrument in the X-axis

Make sure that your well/embryo is well focused (has good focus). If necessary, adjust the Z-axis position with the "UP" or/and "DOWN" arrows under the "Motor" icon (located in the upper right corner of the screen).

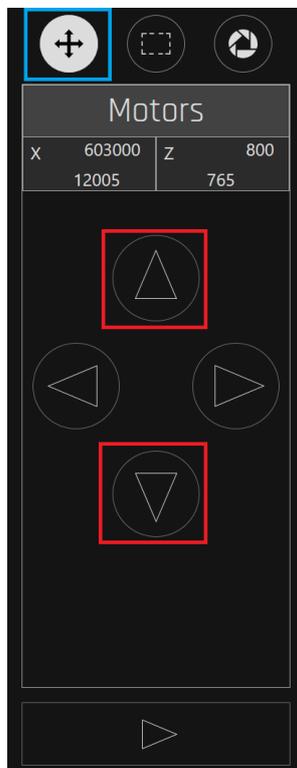


Figure 21.29 Well position adjustment instrument in the Z-axis

Make sure that the well is inside the marked square limit, as shown below.



Figure 21.30 Well position inside the marked square limit

⚠️ If the well position is out of the limit mark square, it could result in cropped images during Time-lapse. It could cause a system error, and the images of the well would not be taken.

An inactive position can be activated by pressing the "SET" button ("X-axis", "Z-axis" and square limit must be adjusted as noted above). An active position can be deactivated by pressing the "CLEAR" button.

When a position is activated, it will appear in the compartment (time-lapse view). When it is deactivated, it will disappear from the compartment (time-lapse view). Any previously taken images will remain, but no new ones will be acquired.

Exposure control can be set according to variations in light conditions.



Figure 21.31 Exposure control screen view

When the correct position and the desired focus are found and the set button is pressed, the system will confirm the user calibration.



Figure 21.32 Correctly adjusted well's view

⚠ Manually overriding automatic features of the system should be done only in such cases when the system repeatedly fails to find the correct calibration. Since the user manually controls the motors in the LiveView, it is possible to move the motors out of bounds and trigger mechanical limit switches.

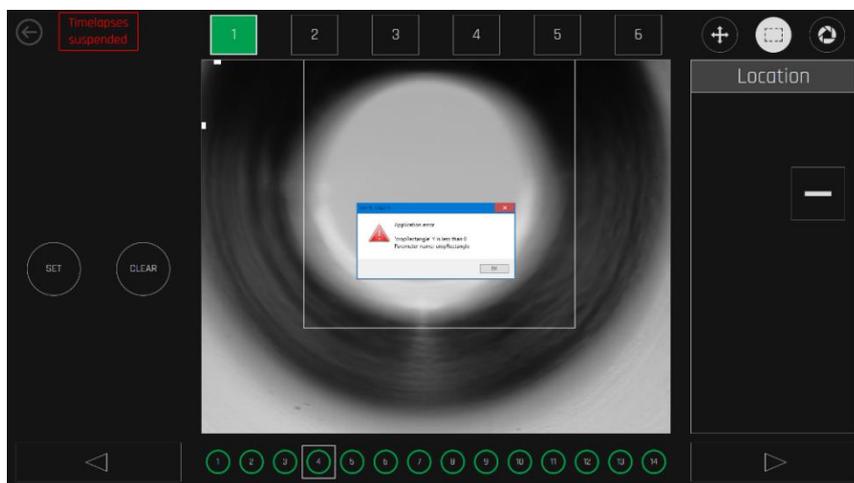


Figure 21.33 Limit switch alarm

Limit switch alarms are shown as a red horizontal indication on the top or at the bottom of the image. In the picture above, the top limit switch for the "Z" has been activated.

21.1.6 Alarms

Alarms regarding lid openings, temperature, CO₂/O₂ status, network connectivity, PC and HDD power status are shown in the main view.

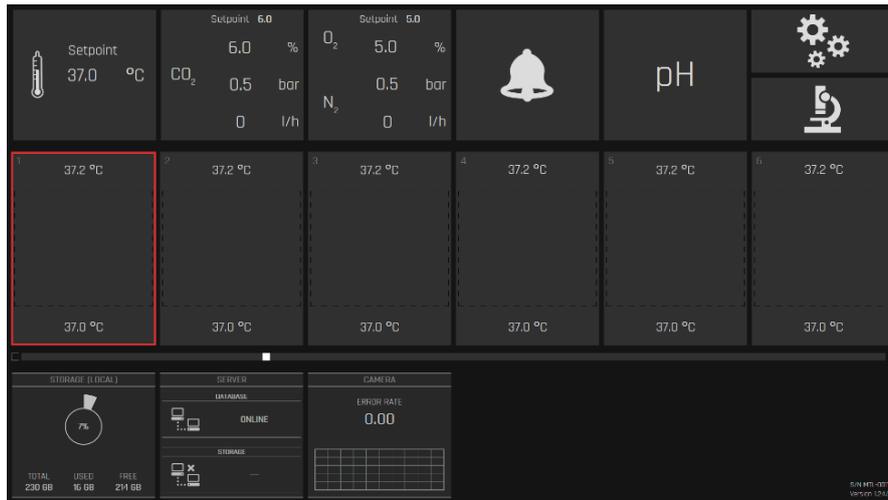


Figure 21.34 Lid opening alarm view

Clear the alarm by pressing on the area – it will take you to the compartment view. Then either end the time-lapse, suspend, recalibrate or just confirm that the patient is still there.

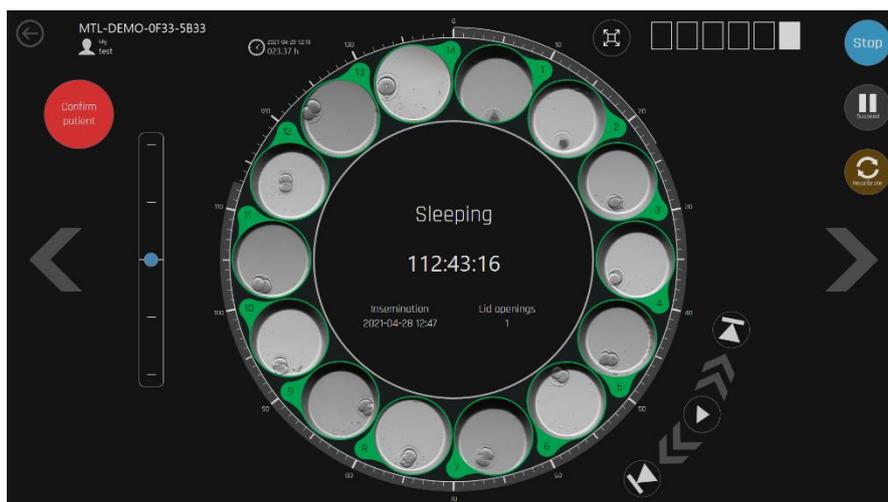


Figure 21.35 Compartment view after opening a lid

⚠ The system will continue to generate time-lapse images after the lid is opened. Suppose the user changed the dish with another patient without correctly ending the prior and starting the new patient. In that case, the final time-lapse movie will contain images from two different patients.



Figure 21.36 Temperature alarm screen view

⚠ Remove the dish immediately if temperature conditions become dangerous for the embryos. The compartments are entirely separate, so the dish can be safely moved to another position if the temperature in that particular compartment is stable. Remember to end an old time-lapse and start the new at the changed position.

Loss of server connection is indicated at the bottom. As long as the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators have available storage capacity, time-lapses will continue on the local storage system. Once the network is connected again and running, the system will automatically transfer the data.

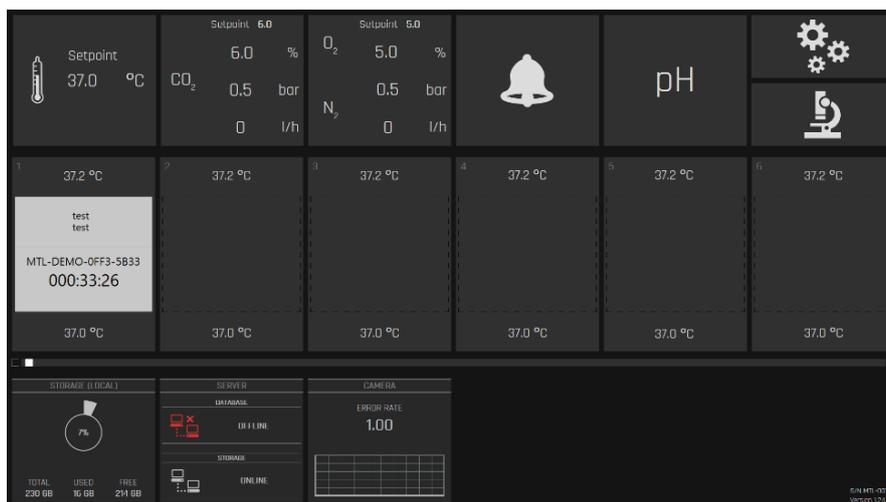


Figure 21.37 Disconnected server alarm view

While the server is disconnected, it is impossible to start new time-lapses as patients cannot be allocated to the unit.

All incubation functions have level alarms indicated in the image by the relevant button turning red. All of the alarms can be seen in the alarm view, which displays the alarm history.

CO₂ concentration alarm view is shown in the picture below:

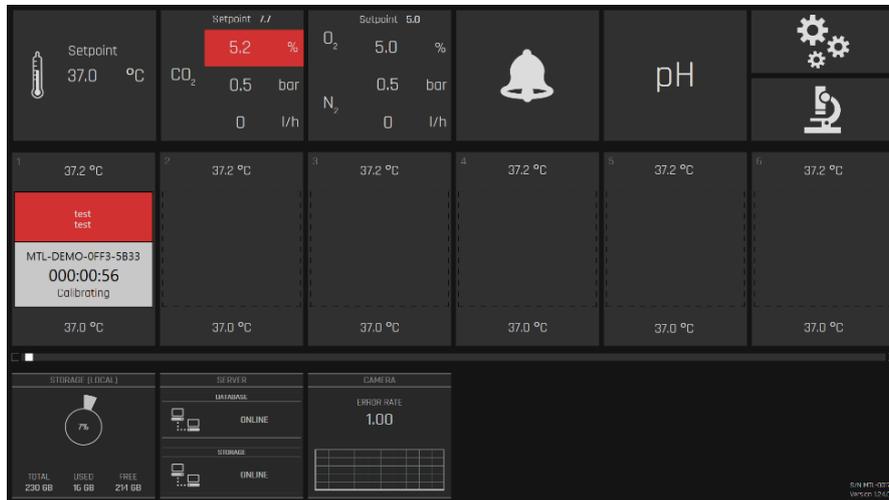


Figure 21.38 CO₂ concentration alarm view

CO₂ pressure alarm view is shown in the picture below:

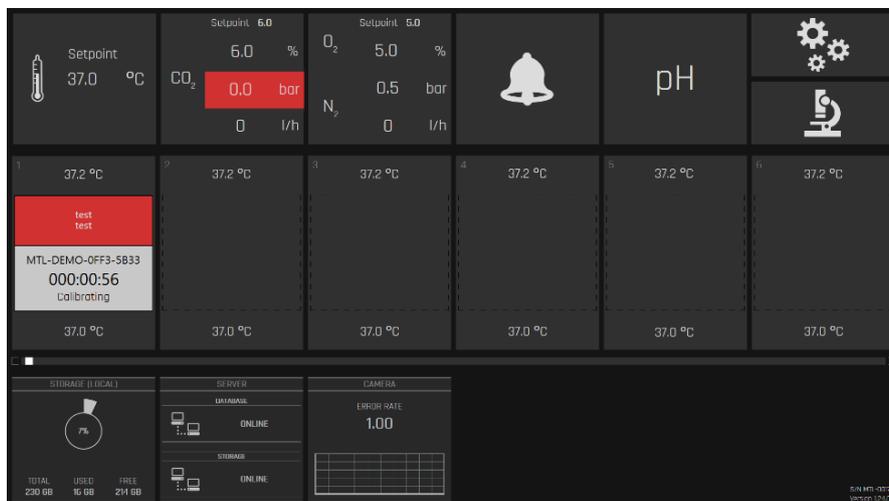


Figure 21.39 CO₂ pressure alarm view

O₂ alarms are shown in the same way – just under O₂ for level and N₂ for pressure.

Full HDD (transfer data to an external drive or connect to the server) memory alarm view is shown in the picture below:



Figure 21.40 HDD full memory alert view

21.1.7 Data-logging temperature view

Pressing the temperature button will change the view to temperature data graph view.

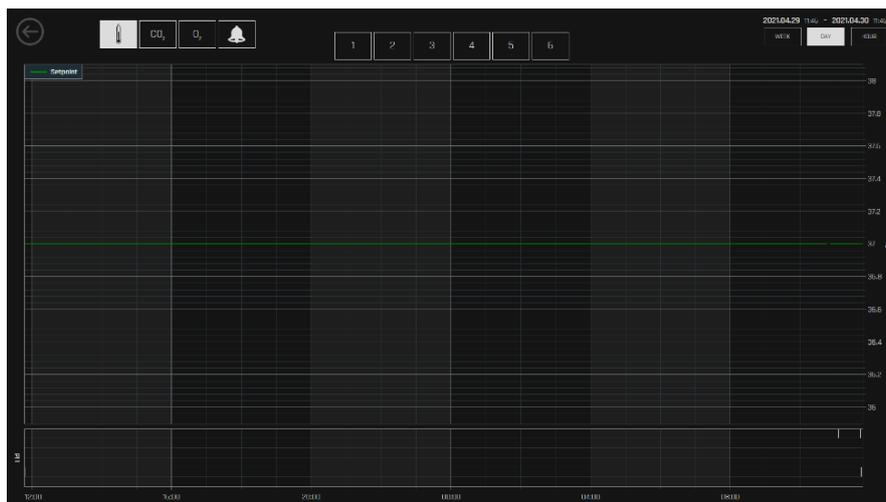


Figure 21.41 Temperature data graph view

The history view allows seeing temperature data graphs. It is possible to toggle on/off compartment graphs 1-6 in the MIRI® TL6 multiroom IVF incubator and graphs 1-12 in the MIRI® TL12 multiroom IVF incubator pressing the corresponding circled number.

With the period buttons "Hour", "Day" and "Week", it is possible to change the period viewed.

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.

21.1.8 Data-logging CO₂ view

By pressing the "CO₂" button, the view will change to the CO₂ data graph view.

The CO₂ "Setpoint", "Concentration", "Flow" and "Pressure" graphs can be toggled on/off by pressing on them at the top of the display view. The period and zoom-in functions are the same as in the temperature view.



Figure 21.42 CO₂ data graph view

21.1.9 Data-logging O₂ view

By pressing the "O₂" button, the view will change to the O₂ data graph view.

The O₂ "Setpoint", "Concentration" and N₂ "Flow" and "Pressure" graphs can be toggled on/off by pressing on them at the top of the display view. The period and zoom-in functions are the same as in the temperature view.

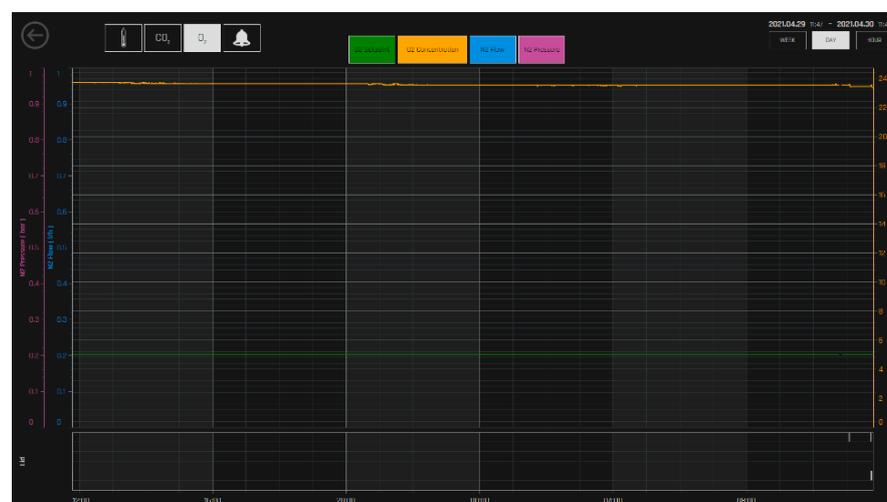


Figure 21.43 O₂ data graph view

21.1.10 Data-logging alarm view

By pressing the alarm bell, 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.

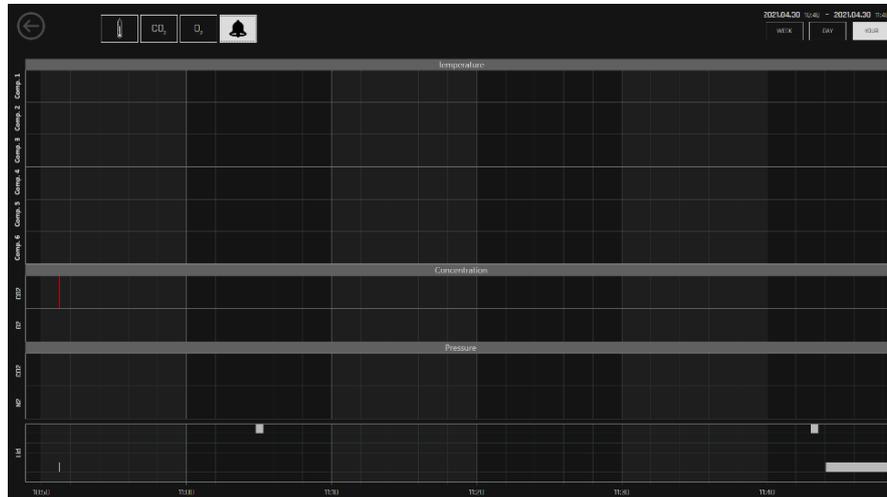


Figure 21.44 Alarm data view

The "Lid" section has six rows in the MIRI® TL6 multiroom IVF incubator, whereas in MIRI® TL12 multiroom IVF incubator – 12. 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.

22 CultureCoin®

The only dish used with MIRI® TL6 and MIRI® TL12 multiroom IVF incubators is the CultureCoin®. The bottom of MIRI® TL6 and MIRI® TL12 multiroom IVF incubators compartments are shaped to fit the contour of the dish. There is only one way it can be put in the compartment, as the dish is not a perfect circle and has a flat side that makes it impossible to fit the dish in the compartment the wrong way.

CultureCoin® is a single-use sterile class IIa medical device.



Figure 22.1 The CultureCoin® dish

⚠ Never attempt to reuse a single-use device. The device cannot be cleaned or sterilized again. Dangerous contamination will occur.

The CultureCoin® dish features 14 wells for incubation and four washing wells for cell manipulations, washing media or replacement media.

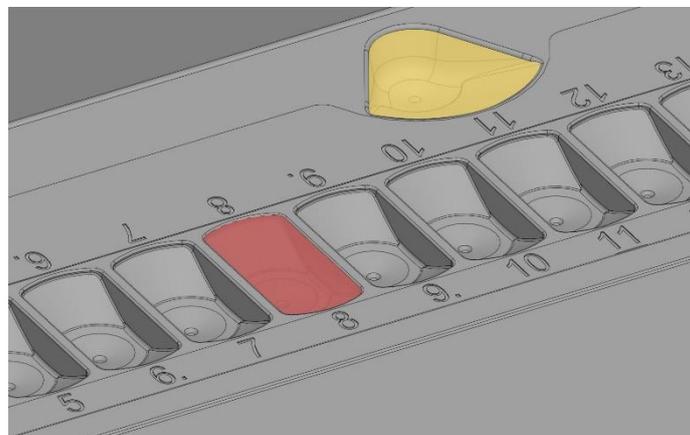


Figure 22.2 Culture wells of a CultureCoin® dish

Each of the 14 wells is filled with approximately 25 μl culture medium. The washing wells can also be filled (approximately with 23 μl), but it is not a requirement. The embryo is placed at the bottom of the culturing area.

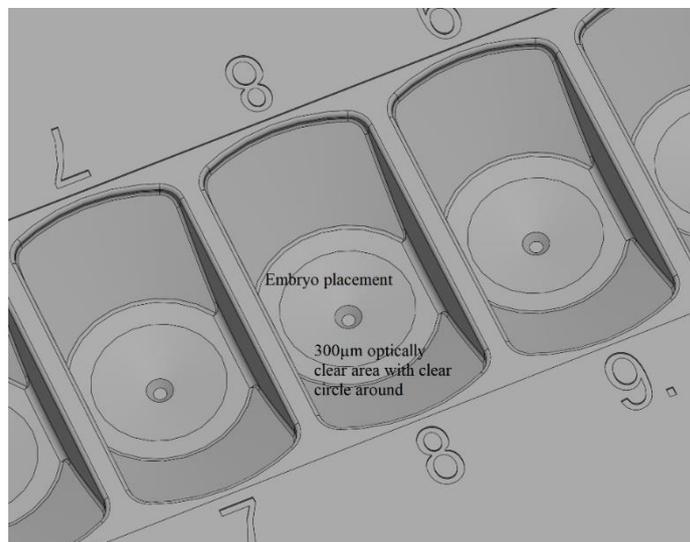


Figure 22.3 Embryo Placement in detail on the 300 μm optically clear area

👉 The process of locating the correct well is sensitive to errors. When the embryo is positioned at the side of the well, it rests against the side. Positioning embryos carefully to be in the center of the well circle can avoid this problem.

The identification process is easy because the wells are numbered.

Media and embryo handling are ergonomically optimized as it is possible to angle the pipette when loading the well.

👉 Air bubbles in the media can be easily removed by pushing them up with the pipette tip. Air bubbles in the media will push the embryo out from the correct position, and no time-lapse images will be generated. Usually, when air bubbles are present, a black cloud can be seen to move around the images or cover the whole view.

Mark the lid and the dish with the patient's name and unique identifier. It is possible to write directly on the dish or put it on a label.

Once filled with the culture media, the culture wells must be covered by a confluent oil layer. It is impossible to use an open culture (any culture media where a layer of oil does not cover the culture media).

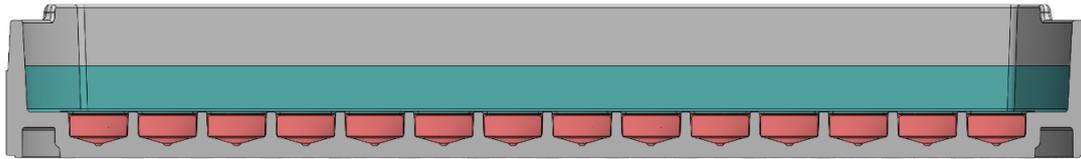


Figure 22.4 The culture wells are covered with a mineral or Paraffin oil layer, and the lid is put on

A large reservoir outside the culturing area can be used for pH validation (please look at Figure 22.2). The reservoir can be closed with a gas permeable silicone plug which will stop evaporation. In this way, no oil layer is necessary, as it would cause problems for most pH probes while measuring pH anyway. Fill the reservoir and measure pH with a combination probe and the pH measuring system built into the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators.

23 The MIRI® TL multiroom IVF incubators Viewer

The MIRI® TL multiroom IVF incubators viewer and server is a graphical software system operated by touch, which is used for storing time-lapse images and working with them.

The current MIRI® TL Viewer software version is 1.21.0.0.

For more information, please see User manual of MIRI® TL family's multiroom IVF incubators Viewer Software.



Unauthorized access to the laboratory should be controlled!

24 Cleaning instructions

24.1 Consideration about a sterile device

The MIRI® TL6 and MIRI® TL12 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 compartment with sealed edges that can be cleaned
- The use of aluminum and PET parts that withstand cleaning well

24.2 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® TL6 or MIRI® TL12 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.

24.3 Cleaning 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® TL6 or MIRI TL12 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 discoloured.
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® TL6 or MIRI® TL12 multiroom IVF incubator (rear panel).

25 Humidification

The MIRI® TL family's multiroom IVF incubators have been primarily developed and designed for the incubation of gametes and embryos with an overlay of either Paraffin or mineral oil.

The MIRI® TL family's multiroom IVF incubators must not be irrigated. Humidification of the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators will damage the devices – condensation will block internal pipes and damage electronic parts.

⚠ MIRI® TL6 and MIRI® TL12 multiroom IVF incubators are not created to work with a water container inside. Otherwise, the devices will be damaged. The safety and performance of the device will be affected.

26 Temperature validation

The MIRI® TL6 multiroom IVF incubator is equipped with 6 PT-1000 Class B sensors, whereas the MIRI® TL12 multiroom IVF incubator – 12, that are located in the center of the bottom of each compartment.

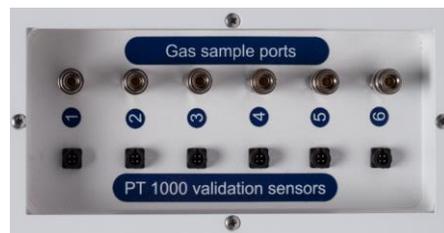


Figure 26.1 PT-1000 Class B sensors in the MIRI® TL6 multiroom IVF incubator

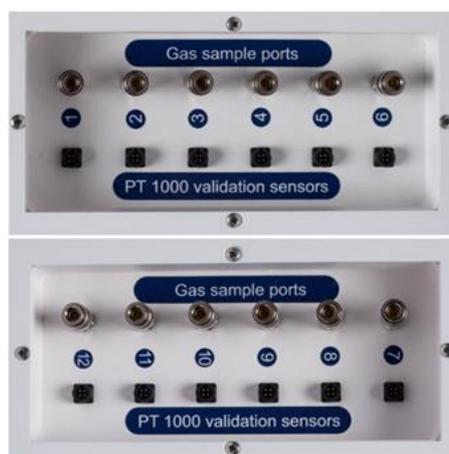


Figure 26.2 PT-1000 Class B sensors in the MIRI® TL12 multiroom IVF incubator

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.

27 Gas level validation

Gas concentration in each compartment of the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator may be validated by taking a gas sample from one of the 6 (MIRI® TL6 model) or 12 (MIRI® TL12 model) gas sample ports on the unit's side, using a suitable gas analyzer.

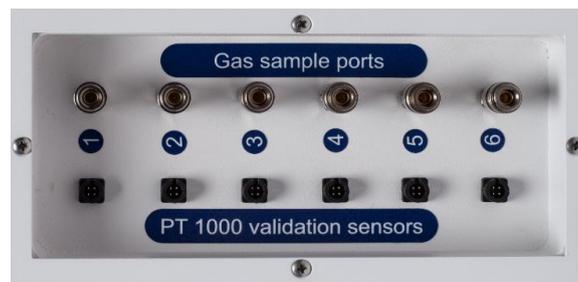


Figure 27.1 PT-1000 Class B sensors in the MIRI® TL6 multiroom IVF incubator

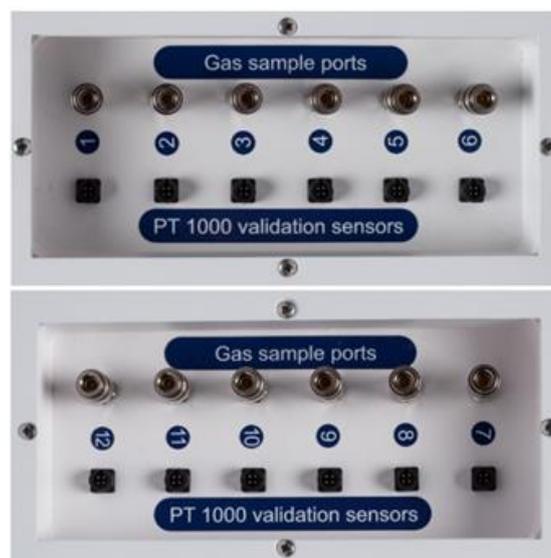


Figure 27.2 PT-1000 Class B sensors in the MIRI® TL12 multiroom IVF incubator

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.

28 Alarm switch for an external system

In order to connect the MIRI® TL6 or MIRI® TL12 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 CO₂ or O₂ levels, low pressure or high-pressure alarms for CO₂ and N₂ 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.

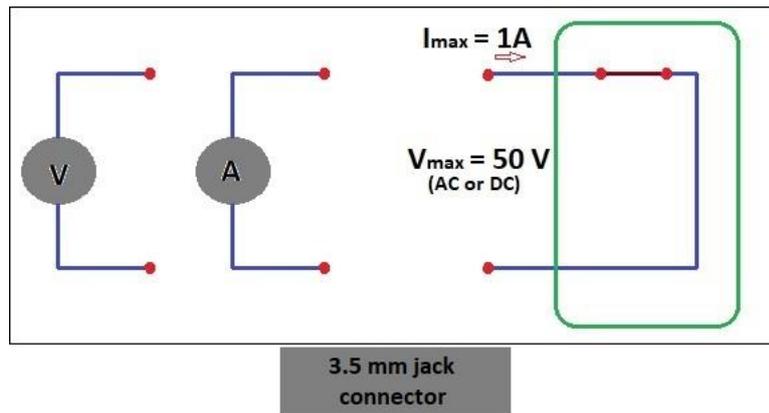


Figure 28.1 No alarm mode

Whenever the MIRI® TL6 or MIRI® TL12 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.

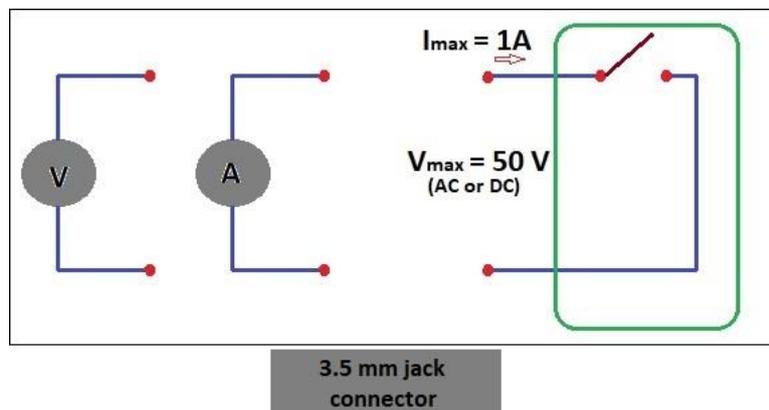


Figure 28.2 “Open circuit” alarm mode

👉 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.

29 Writing area on the compartment lids

Each compartment lid on the MIRI® TL6 and MIRI® TL12 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 29.1 Area for patient information

30 Maintenance

The MIRI® TL6 and MIRI TL12 multiroom IVF incubator are designed to be user-friendly. Reliable and safe operation of this equipment is based on the following conditions:

1. Correct calibration of temperature and gas level, using high-precision equipment in the intervals prescribed based on clinical practice at the laboratory, where the MIRI® TL6 or MIRI® TL12 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. According to the intervals prescribed by the clinical practice in the laboratory where the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator is in use, Suitable cleaning 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 “40 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.

31 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® TL6 and MIRI® TL12 multiroom IVF incubator will drop below 35 °C after being 10 minutes in an ambient environment of 20 °C.
- The CO₂ 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 CO₂ 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 CO₂ level is low, keep the lids shut. If the state is temporary and the CO₂ level is high, open a few lids to vent out some CO₂.

If the O₂ 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 O₂ regulation in the menu.

If the CO₂ 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 “CO₂ level alarm”.

If the O₂ 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 “O₂ level alarm” section.

32 User troubleshooting

Table 32.1 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
Temperature alarm is on	The heating is off, because, temperature deviated more than 0.5 °C from the set temperature	Contact your Esco Medical distributor for details
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 32.2 CO₂ 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 "CO ₂ " 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 32.3 O₂ 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 "O ₂ " to "ON" in the menu
	No N ₂ or wrong gas type attached to N ₂ gas input	Check gas supply; make sure that 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 32.4 Viewer communication

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
	Viewer software/USB driver is not installed correctly	Please refer to the software installation guide

Table 32.5 Display

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

Table 32.6 Keyboard

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

33 Specifications

Table 33.1 The MIRI® TL6 multiroom IVF incubator specifications

Technical specifications	MIRI® TL6
Overall dimensions (W x D x H)	805 x 590 x 375 mm
Weight	60 kg
Material	Mild steel/Aluminum/PET/Stainless steel
Dish type	CultureCoin®
Power supply	115V 60Hz OR 230V 50Hz
Power consumption	330 W
Temperature range	28.7 – 41.0 °C
Temperature deviation from the setpoint	± 0.1 °C
Gas consumptions (CO ₂) ¹	< 2 liters per hour
Gas consumption (N ₂) ²	< 5 liters per hour
CO ₂ range	2.9% – 9.9%
O ₂ range	2.0% – 20.0%
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, gas pressure
Shelf life	1 year

Table 33.2 The MIRI® TL12 multiroom IVF incubator specifications

Technical specifications	MIRI® TL12
Overall dimensions (W x D x H)	950 x 685 x 375 mm
Weight	93 kg
Material	Mild steel/Aluminum/PET/Stainless steel
Dish type	CultureCoin®
Power supply	115V 60Hz OR 230V 50Hz
Power consumption	650 W
Temperature range	28.7 – 41.0 °C
Temperature deviation from the setpoint	± 0.1 °C
Gas consumptions (CO ₂) ¹	< 2 liters per hour
Gas consumption (N ₂) ²	< 5 liters per hour
CO ₂ range	2.9% – 9.9%
O ₂ range	5.0% – 20.0%
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, gas pressure
Shelf life	1 year

¹ Under normal conditions (CO₂ setpoint reached at 6.0%, all lids closed)

² Under normal conditions (O₂ setpoint reached at 5.0%, all lids closed)

34 Electromagnetic compatibility

Table 34.1 Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The MIRI® TL6 and MIRI® TL12 multiroom IVF incubators are intended for use in the electromagnetic environment specified below. The customer or the user of the MIRI® TL6 or MIRI® TL12 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® TL6 or MIRI® TL12 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® TL6 and MIRI® TL12 multiroom IVF incubators are suitable for use in a hospital environment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

Table 34.2 Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The MIRI® TL6 and MIRI® TL12 multiroom IVF incubators are intended for use in the electromagnetic environment specified below. The customer or the user of the MIRI® TL6 or MIRI® TL12 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	±8 kV contact discharge ±8 kV, ±4 kV, ±8 kV, ±15 kV air discharge	Level 4	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	Level 3	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Class 2	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (95% dip in UT for 0.5 cycles) < 40% UT (60% dip in UT for 5 cycles) < 70% UT (30% dip in UT for 25 cycles) NOTE UT is the a.c. mains voltage prior to application of the test level	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	N/A	N/A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Guidance and manufacturer's declaration – electromagnetic immunity			
The MIRI® TL6 and MIRI® TL12 multiroom IVF incubators are intended for use in the electromagnetic environment specified below. The customer or the user of the MIRI® TL6 or MIRI® TL12 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	6 Vrms 150kHz to 80 MHz in ISM bands 30 V/m 80 MHz to 2.7 GHz	Level 4	Portable and mobile RF communications equipment should be used no closer to any part of the MIRI® TL6 and MIRI® TL12 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 34.3 Recommended separation distances

Recommended separation distances between portable and mobile RF communication equipment and the MIRI® TL6 or MIRI® TL12 multiroom IVF incubators			
The MIRI® TL6 and MIRI® TL12 multiroom IVF incubators are intended to be used in an electromagnetic environment in which radiated RF disturbances are controlled. The customer, or the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator user, can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters). The MIRI® TL6 and MIRI® TL12 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5GHz $d = 2.3\sqrt{P}$
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 that all equipment used near the MIRI® TL6 and MIRI® TL12 multiroom IVF incubators comply 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.

35 The Validation guide

35.1 Product release criteria

The Esco Medical MIRI® TL6 and MIRI® TL12 multiroom IVF incubators undergo strict quality and performance testing before being released for sale.

35.1.1 Performance

Each component used in the MIRI® TL6 and MIRI® TL12 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 CO₂ concentration variation from setpoint within $\pm 0.2\%$ absolute.

Pass III: Internal sensor N₂ concentration variation from setpoint within $\pm 0.2\%$ absolute.

Pass IV: Gas flow CO₂ less than 2 l/h.

Pass V: Gas flow N₂ less than 5 l/h.

35.1.2 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.

35.1.3 Communication & data logging

Each unit is connected to a computer running the MIRI® TL6 or MIRI® TL12 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.

35.1.4 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 CO₂ gas variation must stay within $SP \pm 0.2\%$ 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 for both MIRI® TL6 and MIRI® TL12 multiroom IVF incubators.

The average N₂ 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 5 liters per hour, and thus, the average should be below 5 liters for both MIRI® TL6 and MIRI® TL12 multiroom IVF incubators.

35.1.5 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 bottom of the compartments is checked for misalignment and shape. CultureCoin® is placed into the chambers to check for mismatches due to the sizes of the chamber and aluminum cut-outs.

36 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.

36.1 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 CO₂ analyzer with a range of 0.0 – 10.0%.

- An O₂ analyzer with a range of 0.0 – 20.0%.
- A Pressure tester with a range of 0.0 – 1.0 bar.
- A Multimeter.

36.2 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® TL6 and MIRI® TL12 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.

37 Testing

37.1 Gas supply CO₂

For the regulation system to maintain the correct CO₂ concentration level in the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator compartments, the device must be connected to a stable source of 100% CO₂ at 0.4 – 0.6 bar (5.80 – 8.70 PSI) of pressure.

Measure the CO₂ 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 CO₂ concentration, as CO₂ concentration is pressure-dependent.**

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

PASS: CO₂ concentration measured must be between 98.0% – 100%.

 **Use of CO₂ 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.**

37.1.1 About CO₂

Carbon dioxide (CO₂) is a colourless, odourless, 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 CO₂ 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/NO₂) 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.

37.2 Gas supply N₂

For the regulation to maintain the correct O₂ concentration levels in the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator compartments, the device must be connected to a stable source of 100% N₂ at 0.4 – 0.6 bar (5.80 – 8.70 PSI) of pressure.

Measure the N₂ 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% O₂ accurately can be used. 100% N₂ = 0% O₂.**

PASS: N₂ concentration measured must be between 95.0%– 100%.

 **The use of N₂ 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.**

37.2.1 About N₂

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

 **N₂ gas can act as a simple asphyxiant by displacing air.**

The User should make sure the N₂ 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 (CO₂) 1.0 ppm.
- Carbon Monoxide (CO) 1.0 ppm.
- Hydrogen (H₂) 0.5 ppm.
- Methane 0.5 ppm.
- Oxygen (O₂) 0.5 ppm.
- Water (H₂O) 0.5 ppm.

37.3 CO₂ gas pressure check

The MIRI® TL6 and MIRI® TL12 multiroom IVF incubator require a pressure of 0.4 – 0.6 bar (5.80 – 8.70 PSI) on the input CO₂ 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 CO₂ 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.

37.4 N₂ gas pressure check

The MIRI® TL6 and MIRI® TL12 multiroom IVF incubator require a pressure of 0.4 – 0.6 bar (5.80 – 8.70 PSI) on the input N₂ 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 N₂ 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.

37.5 Voltage supply

The voltage on-site must be verified.

Measure the output plug on the UPS that the MIRI® TL6 and MIRI® TL12 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%

37.6 CO₂ gas concentration check

The CO₂ 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 multiroom IVF incubator (i.e., another compartment). Only measure while the value on the gas analyzer stabilizes.

Please refer to the "13.5.1.2 CO₂/O₂ calibration" section for more information on how to perform the CO₂ gas calibration.

PASS: CO₂ concentration measured must not deviate more than $\pm 0.2\%$ from the setpoint.

37.7 O₂ gas concentration check

The O₂ 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 multiroom IVF incubator (i.e., another compartment). Only measure while the value on the gas analyzer stabilizes.

Please refer to the "13.5.1.2 CO₂/O₂ calibration" section for more information on how to perform the CO₂ gas calibration.

PASS: O₂ concentration measured must not deviate more than $\pm 0.2\%$ from the setpoint.

37.8 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 "13.5.1.1 Temperature calibration " 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.

37.9 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 "13.5.1.1 Temperature calibration" section for more information on how to perform the temperature calibration.

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

37.10 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 CO₂ 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 O₂ regulation activated, but there is N₂ gas available, the test should be conducted with O₂ regulation switched on and with N₂ gas supply.

If the N₂ is not available, the test can be done without it.

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

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

Pass I: Internal sensor temperature variation from set point is within ± 0.1 °C absolute.

Pass II Internal sensor CO₂ concentration variation from setpoint within $\pm 0.2\%$ absolute.

Pass III: Internal sensor N₂ concentration variation from setpoint within $\pm 0.2\%$ absolute.

Pass IV: Gas flow CO₂ less than 2 l/h.

Pass V: Gas flow N₂ less than 5 l/h.

37.11 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.

37.12 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.**

37.13 Recommended additional testing

37.13.1 A VOC meter

With the VOC meter, a sample should be taken just above the MIRI® TL6 and MIRI® TL12 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 (in the MIRI® TL6 model) or 12 (in the MIRI® TL12 model).

Pass: 0.0 ppm VOC.

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

37.13.2 A laser particle counter

A sample should be taken just above the MIRI® TL6 or MIRI® TL12 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 (in the MIRI® TL6 model) or 12 (in the MIRI® TL12 model).

Pass: 0.3-micron < 100 ppm.

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

38 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® TL6 and MIRI® TL12 multiroom IVF incubator for clinical purposes without access to high-grade quality control validation equipment.**

Table 38.1 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

38.1 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 "13.5.1.1 Temperature calibration" 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.**

38.2 CO₂ gas concentration check

The CO₂ 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 CO₂ and O₂ available to do the test.

Please follow these simple rules while testing gas concentration:

- Check the CO₂ gas setpoint.
- Check the actual CO₂ 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 "13.5.1.2 CO₂/O₂ calibration" section for more information on how to perform the CO₂ gas calibration.

PASS: CO₂ concentration measured must not deviate more than $\pm 0.2\%$ from the setpoint.

38.3 O₂ gas concentration check

The O₂ 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 CO₂ and O₂ available to do the test.

Please follow these simple rules while testing gas concentration:

- Check the O₂ gas setpoint.
- Check the actual O₂ 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 "13.5.1.2 CO₂/O₂ calibration" section for more information on how to perform the CO₂ gas calibration.

PASS: O₂ concentration measured must not deviate more than $\pm 0.2\%$ 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® TL6 and MIRI® TL12 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.

38.4 CO₂ gas pressure check

The MIRI® TL6 or MIRI® TL12 multiroom IVF incubator requires a pressure of 0.4 – 0.6 bar on the input CO₂ 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 CO₂ gas pressure in the menu by inspecting the value for an item called 'CO2 P' (CO₂ pressure).

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the "16.1 CO₂ gas pressure" section for more information.

38.5 N₂ gas pressure check

The MIRI® TL6 or MIRI® TL12 multiroom IVF incubator requires a pressure of 0.4 – 0.6 bar on the input N₂ 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 N₂ gas pressure in the menu by inspecting the value for an item called 'N2 P' (N₂ pressure).

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the “16.2 N₂ gas pressure” section for more information.

38.6 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 CO₂ level.

CO₂ is pressure-dependent, and thus, at different altitudes, higher concentrations of CO₂ are needed to maintain the same pH. Even changes in barometric pressure under standard weather systems will affect CO₂ levels.

The MIRI® TL6 and MIRI® TL12 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.

39 The Maintenance guide

Your MIRI® TL6 or MIRI® TL12 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 "35 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 39.1.

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 39.1.



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 39.1 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	
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			

39.1 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® TL6 or MIRI® TL12 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.

39.2 In-line HEPA filter for CO₂ gas

The round-shape in-line 0.2µ HEPA filter for CO₂ gas removes any particles found in the incoming CO₂ gas. Failure to use the HEPA filter may cause damage to the high precision flow sensor, calculate the amount of CO₂ gas entering the system, and disturb the CO₂ 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 CO₂ gas.
- Warranty void if wrong/ non-original filter is used.

Please refer to the service manual for replacement instructions.

39.3 In-line HEPA filter for N₂ gas

The round-shape in-line 0.2µ HEPA filter for N₂ gas removes any particles found in the incoming N₂ gas. Failure to use the HEPA filter may cause damage to the high precision flow sensor, calculate the amount of N₂ gas entering the system, and disturb the N₂ 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 N₂ gas.
- Warranty void if wrong/ non-original filter is used.

Please refer to the service manual for replacement instructions.

39.4 O₂ sensor

The oxygen regulation uses the Oxygen sensor to keep the O₂ 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® TL6 and MIRI® TL12 multiroom IVF incubators.

After 1-year, the chemical process in the sensor core stops and the sensor must be replaced. Therefore, it is essential to replace this sensor **WITHIN 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® TL6 or MIRI® TL12 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 O₂ sensor change.

Please follow these safety precautions when changing sensor:

- Always use an original O₂ sensor (contact Esco Medical or your local distributor for more details or ordering).
- Change the O₂ 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 O₂ concentration.
- Warranty void if wrong/ non-original sensor is used.

Please refer to the service manual for replacement instructions.

39.5 CO₂ sensor

The CO₂ regulation uses the CO₂ 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 CO₂ sensor (contact Esco Medical or your local distributor for more details or ordering).
- Change the CO₂ sensor within 4 years from the date of installation.
- Failure to change the CO₂ sensor on time can result in low/no CO₂ gas concentration regulation.
- Warranty void if wrong/ non-original sensor is used.

Please refer to the service manual for replacement instructions.

39.6 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.

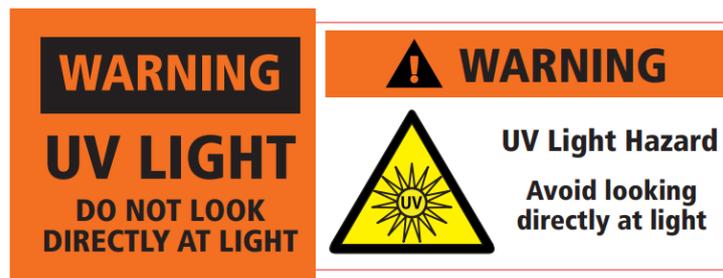


Figure 39.1 UV light warning

 **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.

39.7 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.

39.8 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.

39.9 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.

39.10 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.



All gas lines/hoses must be visually checked during the annual maintenance service visit.



All service engineers must have extra internal gas lines/hoses in order to be able to replace them during a maintenance service visit.

Please follow these safety precautions when changing gas lines:

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

Please refer to the service manual for replacement instructions.

39.11 Flow sensors

The flow sensors are used by the CO₂/N₂ 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 CO₂ and O₂ gas concentration regulation.
- Warranty void if wrong/ non-original sensors are used.

Please refer to the service manual for replacement instructions.

39.12 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.

39.13 Internal 0.2 μ filter for CO₂ gas

The round-shape in line 0.2 μ HEPA filter for CO₂ gas removes any particles found in the incoming CO₂ gas. Failure to use the HEPA filter may cause damage to the high precision flow sensor, calculate the amount of CO₂ gas entering the system, and disturb the CO₂ 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 CO₂ gas.
- Warranty void if wrong/ non-original filter is used.

Please refer to the service manual for replacement instructions.

39.14 Internal 0.2 μ filter for N₂ gas

The round-shape in line 0.2 μ HEPA filter for N₂ gas removes any particles found in the incoming N₂ gas. Failure to use the HEPA filter may cause damage to the high precision flow sensor, calculate the amount of N₂ gas entering the system, and disturb the N₂ 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 N₂ gas.
- Warranty void if wrong/ non-original filter is used.

Please refer to the service manual for replacement instructions.

39.15 Firmware update

If Esco Medical has released a newer version of the firmware, this should be installed on the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator during the yearly scheduled service.

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

39.16 Software update

If Esco Medical has released a newer version of the software, this should be installed on the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator during the yearly scheduled service.

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

40 The Installation guide

This section describes when and how to install the MIRI® TL6 or MIRI TL12 multiroom IVF incubator in the IVF clinic.

40.1 Responsibilities

All technicians or embryologists installing the MIRI® TL6 or MIRI® TL12 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.

40.2 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® TL6 and MIRI® TL12 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® TL6 multiroom IVF incubator weight is approximately 60 kg and MIRI® TL12 multiroom IVF incubator weight is approximately 93 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. CO₂ gas outlet with 0.6 – 1.0 atm above ambient.
8. N₂ 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.

40.3 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® TL6 and MIRI® TL12 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 software. Bring these files on a labeled memory stick to the service site.

40.4 Bring the following to the installation site

- "Installation report" form.
- Service manual for the MIRI® TL6 or MIRI® TL12 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 CO₂ and O₂ and the possibility of returning gas samples to the incubator.
- Extension cable for USB connection.

40.5 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® TL6 or MIRI® TL12 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® TL6 or MIRI® TL12 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 "35 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.

40.6 User training

1. Mains switch on/off.
2. Explain the MIRI® TL6 or MIRI® TL12 multiroom IVF incubators essential function and incubation with a multi-room facility to store the samples.
3. Explain temperature control in the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator (direct heat transfer with heated lids).
4. Gas regulation on/off.
5. Setpoint for temperature, CO₂ and O₂.
6. Explain how N₂ is used to suppress the O₂ level.
7. Alarm turn off procedure (temperature, CO₂, O₂) and revert times.
8. Emergency procedures (can be found in the "30 Emergency Procedures" section).
9. Explain how to clean the device.

10. External measurement and calibration of temperature.
11. External measurement and calibration of gas concentration.
12. How to add and remove a CultureCoin®.
13. The MIRI® TL6 and MIRI® TL12 multiroom IVF incubators screen functionality and how the connection to the MIRI® TL Viewer works.
14. Loading a CultureCoin® with media and oil.
15. pH measuring in the CultureCoin®.
16. Demonstrate how to replace the VOC-HEPA filter (can be found in the "12.1 Installation of new filter capsule" section).
17. 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.**

40.7 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® TL6 or MIRI® TL12 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® TL6 or MIRI® TL12 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® TL6 or MIRI® TL12 multiroom IVF incubator must be taken out of service until it is repaired/exchanged, or anew test approves the MIRI® TL6 or MIRI® TL12 multiroom IVF incubator. The User and owner must be informed about this and arrangements to solve the problems must be initiated.**

41 Other countries

41.1 Switzerland

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



Figure 41.1 Swiss Authorised Representative

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

42 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.