ESCO MEDICAL Life has begun

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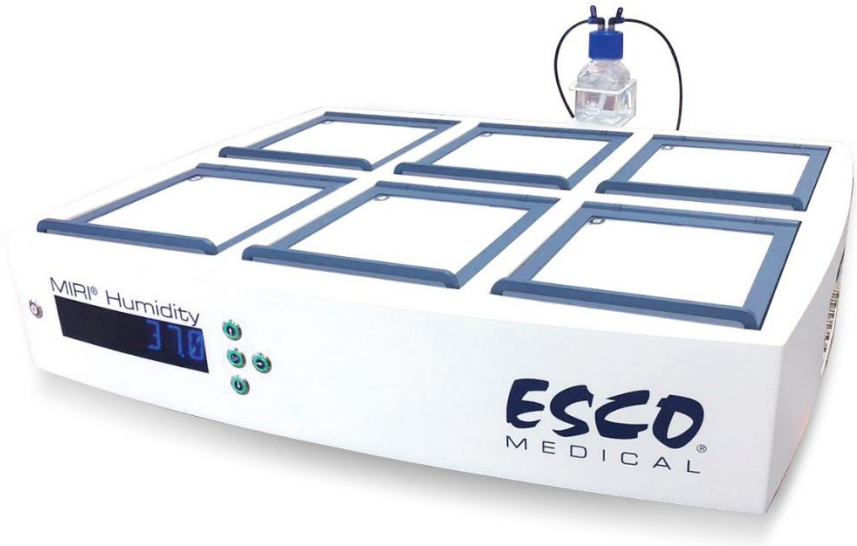

USER MANUAL

MIRI® Humidity Multiroom incubator

Rev. 2.0
Date of Revised 04.23.2021
Rx only

CERTIFIED INCUBATION

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Copyright Information

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

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

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

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

Unpacking and Inspection

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

Claims

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

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

Standard Terms and Conditions

Refunds & Credits

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

Return Procedure

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

Restocking Charges

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

Certification

This instrument has been thoroughly tested/inspected and found to meet Esco Medical's manufacturing specifications when shipped from the factory. Calibration measurements and testing are traceable and done according to Esco Medicals ISO certification.

Warranty and Product Support

Esco Medical warrants this instrument to be free from defects in materials and workmanship under regular use and service for two (2) years from the original purchase date, provided the instrument is calibrated and maintained following this manual. During the warranty period, Esco Medical will, at our option, either repair or replace a product that

proves to be defective at no charge, provided you return the product (shipping, duty, brokerage and taxes prepaid) to Esco Medical. Any transportation charges incurred are the responsibility of the purchaser 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 cost, 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 an electrical shock hazard or improper operation. Esco Medical will not be responsible for any injury sustained due to unauthorized equipment modifications.

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

THIS PRODUCT CONTAINS NO USER-SERVICEABLE COMPONENTS.

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

Table of contents

1 How to use this manual

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

2 Safety warning

- Anyone working with, on or around this equipment should read this manual. Failure to read, understand and follow the instructions given in this documentation may result in damage to the unit, injury to the operating personnel and/or poor equipment performance
- Any internal adjustment, modification or maintenance to this equipment must be undertaken by qualified service personnel.
- If the equipment must be relocated, make sure it is appropriately fixed on a support stand or base and move it on a flat surface. When necessary, move the equipment and the support stand/base separately.
- The use of any hazardous materials in this equipment must be monitored by an industrial hygienist, safety officer or other suitably qualified individuals.
- Before you proceed, you should thoroughly understand the installation procedures and note the environmental/electrical requirements.
- In this manual, important safety-related points will be marked with the following symbols:

NOTE

It is used to direct attention to a specific item.

WARNING

Use caution.

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

3 Indication for use

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

4 About the product

The Esco Medical MIRI® Humidity incubators are multi-room CO_2/O_2 gas incubators.

Direct heat transfer from the inserts to the dishes in the incubator chambers provides superior temperature recovery times compared to conventional incubators.

During lid opening (in regular use, the chamber is expected to be opened approximately 30 sec), the compartment's insert and lid inner surface maintain their temperature within 1 °C from set-point. Complete temperature recovery is expected within 1 min after the lid is closed (when opened for 30 sec).

The MIRI® Humidity incubators have 12 separate heating foils, two for each chamber. Each chamber has a heating foil in its lid and another heating foil in its bottom. The bottom heating foil heats up the insert and is the primary source of the media's heat regulation. MIRI® Humidity has a maximum capacity of 48 pcs. 35 mm and 60 mm Petri dishes and 24 pcs. 4-well Petri dishes.

The system of MIRI® Humidity has 12 completely separate PID temperature controllers to ensure maximum performance. They control and regulate the temperature in culture chambers and lids. PET insulation insures the individual chamber's temperature regulation from affecting the temperature of neighboring chambers. 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 genuinely separate validation system.

The incubators have to be supplied with 100% CO_2 and 100% N_2 or premixed gas (for instance, 5% CO_2; 5% O_2 and 90% N_2) to control the CO_2 and O_2 concentrations in the culture chambers.

A dual-beam infra-red CO_2 sensor with extremely low drift rates controls the CO_2 level. A chemical, medical-grade oxygen sensor controls the level of O_2.

Gas recovery time from a lid opening (30 sec) is expected to be less than 3min. The MIRI® Humidity incubator is fitted with 6 gas sample ports (1 for each chamber) that allow the user to measure any chamber's gas concentration externally.

The incubator features a recirculated gas system where gas is continuously put into the compartment and taken out at the same rate. Gas is cleaned through an in-line HEPA filter.

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

The total gas consumption is low. Typically, less than 2 l/h CO_2 and 5 l/h N_2 when in use. However, multiple repeated door openings will result in increased gas consumption.

For safety reasons, the incubator has a complete gas control system that consists of a pressure regulator (preventing gas pressure problems), gas flow sensors (for calculating injection and

measure consumption), gas pressure sensors (to log and monitor the internal pressure of the gas injection lines, furthermore in the eventuality of a gas bottle depletion the pressure drop will cause the incubator to send out an alarm), HEPA- filters.

For identification purposes, each compartment has been numbered, and each compartment lid has a glass top that can be written upon. Any Petri dish can easily be accessed by opening the relevant chamber (the lid will support itself when opened completely – remember to close the lid after opening).

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

The incubator was designed and developed to incubate gametes and embryos with either Paraffin or mineral oil overlay.

In MIRI® Humidity, 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.

A pH sensor port is part of the DAQ package. The user can plug any standard BNC pH probe into the unit and measure the pH in the samples at will.

If an open culture (any culture where the culture media is not covered with a layer of oil) is used, the user must switch the device to open culture mode.

☞ **Refer to section "15.4 The culture mode" for more detailed information.**

The incubator can be connected to a PC running the Esco Medical Data logger software for long-term data logging and data storage.

The devices are manufactured under a full EU certified 13485 ISO quality management system.

This product fulfills the requirements of EN6060-1 3rd edition standards as a Class I equivalent device suited for continuous operation. It also conforms to the EU Council directive's 93/42/EEC requirements concerning medical devices and is classified as a Class IIa device under rule II.

5 Transport, Storage and Disposal

5.1 Transportation requirements

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

A visual inspection should be done if there is any damage. If no damage is found, the MIRI® II-12 incubator can be prepared for transport.

These labels should be glued on the box:

- Label with the marked packing date
- Label with the product name and serial number
- Label with the country of origin
- Warning labels “Fragile” and “Handle with care”

5.2 Transportation 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:

- Environmental temperatures during regular use must not exceed 30 °C
- Away from direct sunlight
- Kept dry
- For indoor use only

5.3 Disposal

Information on the unit's handling 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. Before disposal, the whole device must be disinfected or decontaminated.**

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

Please note that the HEPA filters must be discarded following the applicable national regulations for particular solid waste.

6 Accessories supplied

- 1 humidity bottle
- 1 bottle holder
- 2 HEPA filters for input gas supply
- 6 warming blocks
- 4 warranty labels
- 1 pump box calibration tool
- 1 USB stick containing Esco Medical Data logger software and a PDF version of the user manual
- 1 medical grade power cord
- 1 3.5 mm external alarm jack connector
- 1 set of fast male connectors with 15 silicone pipes

7 Safety symbols and labels

There are several user labels on the surface of MIRI® Humidity incubators to guide the user. User labels are shown below.

Table 7.1 Packing box and electrical safety labels

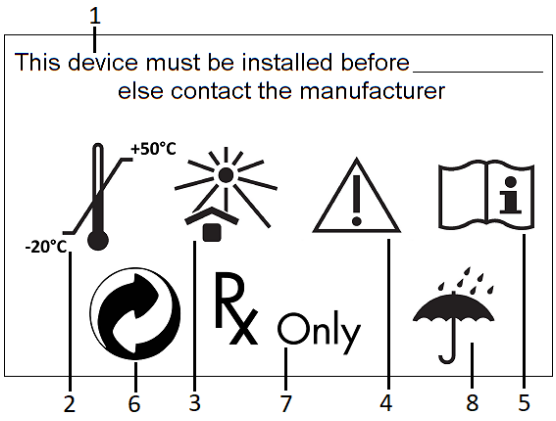
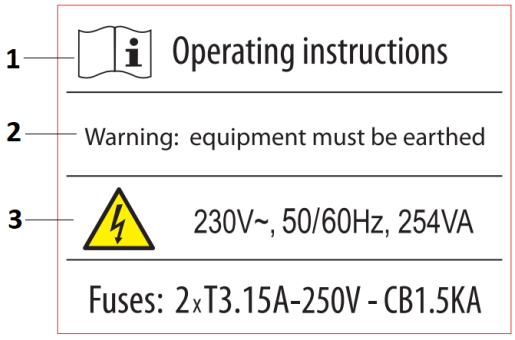
Description	Image
Packing box label: 1. If stored longer than the shelf life, the unit must be returned to the manufacturer for a new release test. 2. Shipping temperature between -20 °C and +50 °C. 3. Keep away from direct sunlight. 4. Caution: consult the accompanying documents for important safety-related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

Table 7.2 Device and "For research use only" labels

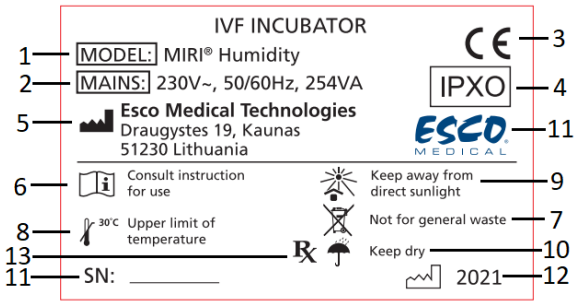
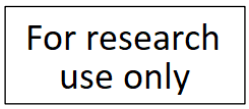
Description	Image
1. Model. 2. Mains power rating. 3. CE mark. 4. Not protected against the ingress of water. 5. Manufacturer's address and country of origin. 6. View instruction for use. 7. Observe WEEE. 8. Upper limit of temperature. 9. Keep away from direct sunlight. 10. Keep dry. 11. Logo and serial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

Table 7.3 Info labels on the MIRI® Humidity incubator

Description	Image
USB communication port	
CO_2 inlet	
N_2 inlet	
BNC pH	
Alarm port	
Compartments numbers are indicated in the top corner of the lid with a label	
Maximum pressure 0.8 bar	
pH Safe sense	
Gas sample ports	
PT 1000 validation sensors	

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

Figure 7.1 Compartment numbers

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 might heat it.
2. Place this unit on a flat, hard and stable surface.
3. Never 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 has two blades and a third prong is provided for your safety. If the provided plug does not fit into your outlet, consult an electrician to replace the outlet.
6. Always connect the power cord to a properly grounded outlet and only use the cord that came with the device.
7. Do not install near any heat sources such as radiators, heat registers, stoves or other apparatus that produce heat.
8. Do not use this device near water sources.
9. Use only 100% concentration CO_2 and 100% concentration N_2 gases.
10. Always use an external HEPA filter for input CO_2 and N_2 gases.
11. Do not use this product if the room temperature exceeds 30 °C.

12. Place this unit in a location with adequate ventilation to prevent internal heat build-up. Leave at least 10 cm clearance from the rear, 30 cm from the top and 20 cm from left and right to prevent overheating and allow access to the ON/OFF switch in the back.
13. This unit is intended for indoor purposes only.
14. The unit must be connected to a suitable uninterrupted power supply (UPS) source.

8.3 Post-installation

1. Refer all servicing procedures to qualified service personnel.
2. Servicing is required according to the service manual as well as cases when the device has been damaged in any way, e. g. suppose the apparatus has been dropped, exposed to rain or moisture or does not operate normally. The MIRI® Humidity incubator contains 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. A maintenance plan must be fulfilled to keep the device safe.
8. NEVER block gas supply holes in the compartment.
9. Ensure that CO_2 and N_2 gas supply pressures are kept stable at 0.4 – 0.6 bar (5.80 – 8.70 PSI).
10. Never use any other except Esco Medical filter. Otherwise, the warranty will be void.

9 Getting started

⚠ **MIRI® Humidity 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® Humidity 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 MIRI® Humidity incubator in the back.
7. Observe for standard functionality.
8. Let the unit warm up and stabilize for 20 min.
9. Follow the guidelines in the Validation guide.
10. Complete user training and finish reading instructions.
11. After a burn-in phase of 24 hours, the unit is ready for use IF the testing is successful.

☞ **Clean and disinfect the device before use. It is not delivered sterile or in a clinically acceptable cleanliness state. Consult the cleaning instructions section in this manual for the manufacturer's recommended guidelines!**

10 Mains connection

MIRI® Humidity incubator comes with a detachable mains power cord. The power cord is prepared for the country in which the unit is intended to be used.

⚠ **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 50 Hz OR 120V 60Hz. The built-in power supply has a switch mode that automatically adjusts to the correct mains power between 100V-250V AC 50-60 Hz.

Figure 10.1 Power supply

11 Gas connections

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

Figure 11.1 Gas inlets

CO_2 inlet should be connected to a 100% concentration of CO_2. CO_2 control in the compartment is available in the range from 2.0% to 9.9%.

The N_2 inlet should be connected to 100% concentration N_2 if low oxygen conditions are required. The O_2 control in the compartments is available in the range from 5.0% to 20.0% by infusing N_2.

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

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

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

Figure 11.3 Pressure regulator

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

Connect the N_2 inlet to the Nitrogen Bottle in a similar way.

Figure 11.4 Gas filter

MIRI® Humidity incubators can also run on premixed gas. It is a more expensive option for gas consumption. It also means the user cannot adjust the CO_2 and O_2 levels without changing the gas supply. Please read the "13 Installation with premixed gas" section below for more detailed information about using the device on premixed gas.

12 User interface

In the following chapters, the functions associated with keys and menu items are going to 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 12.1.

Table 12.1 The main keys and their purpose

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

12.1 Activating the heat and gas controls

Heat and gas controls are activated using the “ON/OFF” switch in the rear.

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

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

12.2 System menu

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

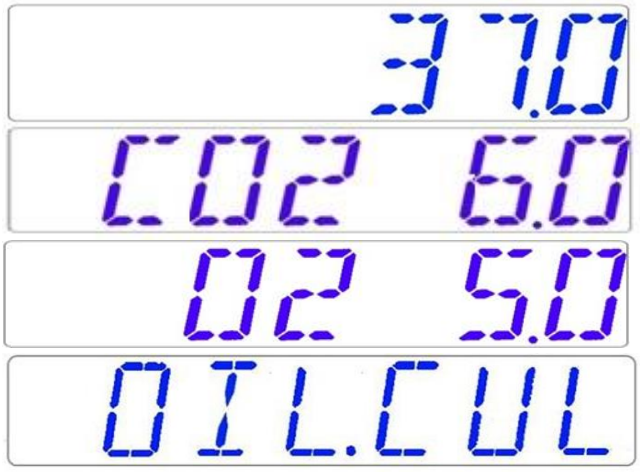
Navigate in menu using:

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

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

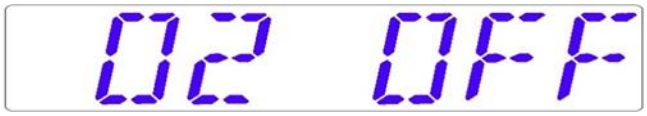
12.3 Status

Alternating between the 4 values under normal running conditions.



Force scroll between parameters with (⇨) key.

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



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

12.4 Main menu

Press the (⇨) key to enter the menu.

You can exit the menu by pressing the (⇧) key.

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

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

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

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

12.4.1 Temperature sub-menu

Press the (⇨) key on the temperature menu to enter the temperature sub-menu.
Calibrate holding down the SP key and using (⇧) and (⇩) keys to adjust.

Move to the next sub-menu item with (⇩) key or one step up with (⇧) key.

Example – how to calibrate the temperature:

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

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

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

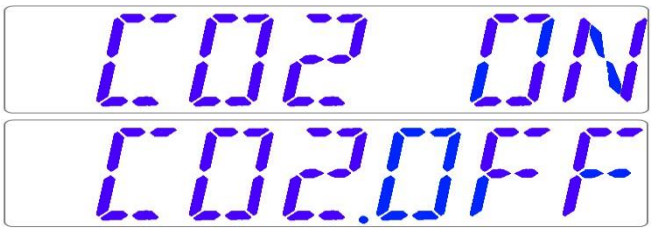
☞ **Calibration procedure is the same for T1 – T12.**

12.4.2 CO_2 sub-menu

Press the (⇨) key on the CO_2 menu to enter the CO_2 sub-menu.
The first item in the O_2 sub-menu is O_2 sensor calibration:

Calibrate CO_2 by holding down the SP key and using (⇧) and (⇩) keys to adjust.
Move to the next CO_2 sub-menu item with (⇩) key or one step up with (⇧) key.

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



☞ **The default status for the CO_2 control is OFF.**

Move to the next CO_2 sub-menu item with (⇩) key or one step up with (⇧) key.
CO_2 flow rate is shown (it cannot be adjusted):

It shows the amount of CO_2 gas put into the system while regulating. The volume is shown in liters/hour. It usually will fluctuate along with the CO_2 regulation.

Press the (⇩) key to move to the next item in the CO_2 sub-menu. CO_2 internal pressure rate is shown (it cannot be adjusted on the incubator. It is adjusted on the external gas regulator):

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

Example – how to calibrate CO_2:

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

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

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

☞ **Pure CO_2 100% gas recovery till 5% is less than 4 minutes.**

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

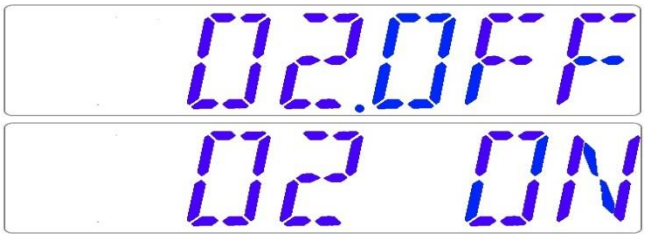
☞ **Calibration values should only be changed by a trained user or the technician, according to specific measurements. Measurements should only be performed with a calibrated device.**

12.4.3 O_2 sub-menu

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

Calibrate O_2 by holding down the SP key and using (⇧) and (⇩) keys to adjust.
Move to the next O_2 sub-menu item with (⇩) key or one step up with (⇧) key.

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



☞ **The Default status for the O_2 control is OFF.**

Move to the next O_2 sub-menu item with (⇩) key or one step up with (⇧) key.
N_2 flow rate is shown (it cannot be adjusted):

It shows the amount of N_2 gas put into the system while regulating. The volume is shown in liters/hour. It usually will fluctuate along with the O_2 regulation.

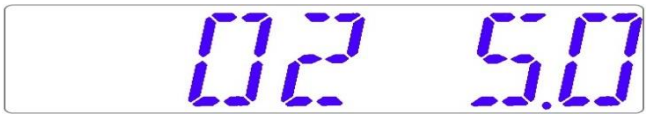
Press (⇩) key to move to the next item in the O_2 sub-menu.
O_2 internal pressure rate is shown (it cannot be adjusted on the incubator. It is adjusted on the external gas regulator):

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

Example – how to calibrate the O_2:

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

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



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

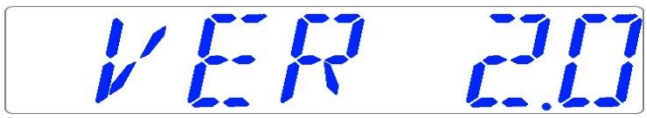
☞ **Calibration is performed by adjusting the O_2 level according to the measurement taken from the gas sampling outlet by an external reliable O_2 measurement device.**

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

12.4.4 Service sub-menu

Press the (⇨) key on the service menu to enter the service sub-menu.
The service sub-menu is locked as default. The display will alternate between:

And the currently installed firmware version:



Ver 2.0 is only shown as an example. Consult Esco Medical or the local representative for the number of the latest version.

Move to the next service sub-menu item with (⇩) key or one step up with (⇧) key.

The display will show the “GAS” function:

Press the (⇨) key to enter and press (⇩) or (⇧) keys to choose “PREMIX” or “CO_2/N_2”. Press the SP key and by pressing (⇩) or (⇧) keys, select “PREMIX” or “CO_2/N_2” gas mode. Let go of the SP key and the selected mode is now stored.

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

Exit the menu by pressing the (⇧) key.

13 Installation with premixed gas

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

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

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

Be advised that premixed gas consumption will be significantly higher compared to pure gas. Recover to the setpoint will be longer.

13.1 Installation procedure at the site

Follow all the instructions in the installation manual and the guidelines in the user manual's safety instructions and warnings section.

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

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

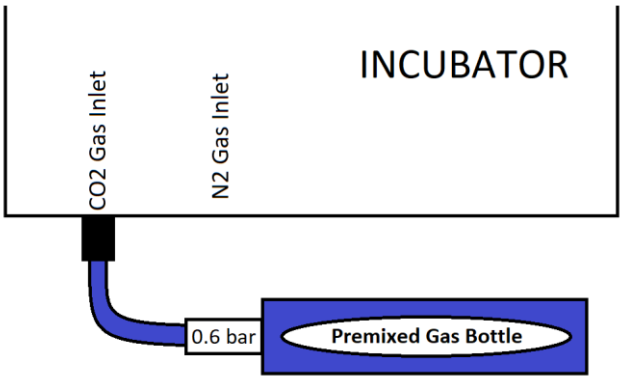


Figure 13.1 Premixed gas connections to the incubator

Please read the "11 Gas connection" section in this manual above for more detailed gas connection requirements.

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

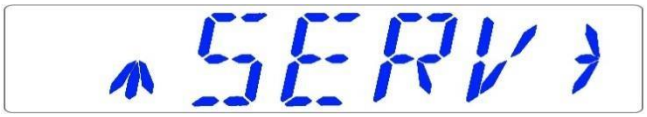
CO_2 regulation must be "ON" in the MIRI® Humidity incubators menu. CO_2 is generally as a default set to "ON" and O_2 to "OFF".

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

Please follow these instructions:

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

Press the (⇨) key to enter the Service sub-menu.



The display will show the currently installed firmware version. Move to the next service sub-menu item with (⇩) key or one step up with (⇧) key.

The display will show the “GAS” function:

Press the (⇨) key to enter and press (⇩) or (⇧) keys to choose “PREMIX” or “CO_2/N_2”. Press the SP key and by pressing (⇩) or (⇧) keys, select “PREMIX” or “CO_2/N_2” gas mode. Let go of the SP key and the selected mode is now stored.

Exit the menu by pressing the (⇧) key.

☞ The CO_2 setpoint must be 0.1% lower than the premixed gas measured value (i.e., 4.9% if 5.0% measured).

☞ The O_2 setpoint must be 1% higher than the premixed gas measured value gas (i.e., 5.0% if 6.0% measured).

For changing the CO_2 and O_2 setpoints, please read the 15.2 and 15.3 sections in this manual.

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

⚠ The MIRI® Humidity incubator contains a high-grade CO_2 and O_2 sensor. They will measure the incoming premixed gas. Make sure that sensors are reading the anticipated gas percentage in the display of the device. That is a percentage that is the proximity of the values on the certificate of the gas bottle. If this is not the case, it must be established if the bottle's concentration per the certificate is correct. If so, the MIRI® Humidity sensors must be calibrated. Refer to the user manual for gas calibration. If the gas bottle does not contain the expected mixture, contact the gas bottle supplier.

13.2 User training

Explain the user:

1. As seen in the display, the gas concentration values must be 0.1% (CO_2 lower and O_2 higher) from the values they expect. If they try to change the setpoint or the calibration to get rid of the offset, the regulation will not work.
2. They cannot set the setpoints they would typically do when using 100% CO_2 and 100% N_2 as the source gas. It is an inherent compromise of using premixed gas. The MIRI® Humidity incubator cannot change the gas composition of the premixed gas.
3. If the media's pH is not correct, they must get a new mixture of premixed gas. They cannot adjust anything on the incubator.

4. If they change to another concentration, the MIRI® Humidity incubator setpoints must be adjusted accordingly, as described above. They should also check the flow rates when they change to a new bottle if it does not precisely contain the same gas mixture.

14 Alarms

The display will show a red “A” and the affected parameter's status message on a single fault condition. An audio signal can be muted by pressing the alarm key once (toggled on/off for 5-minutes). There will be a red arrow that indicates if the alarm is triggered due to too high or too low values, and 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.

14.1 Temperature alarms

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

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

The number will indicate the zone triggering the alarm following “A”.

Temperature is too high in compartment 3:

Temperature is too low in compartment 1:

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

The zone layout and sensor placement are described in the section “16 Surface temperatures and measuring temperature”.

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

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

14.2 Gas level alarms

14.2.1 CO_2 alarms

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

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

CO_2 gas % is too low:

CO_2 gas % is too high:

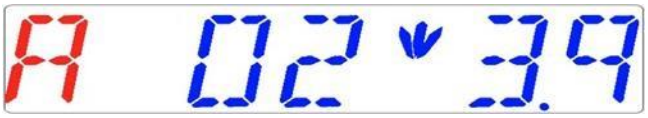
The display will lock on the alarm condition and will stop alternating between the standard status messages. If the mute key is pressed, the display will shift to normal status and show the parameters for 5 minutes until the audio alarm comes back on again. The mute alarm key will still show the alarm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

14.2.2 O_2 alarms

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

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

O_2 % is too low:



O_2 % is too high:

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

14.3 Gas pressure alarms

14.3.1 CO_2 pressure alarm

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

"P" stands for pressure.

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

14.3.2 N_2 pressure alarm

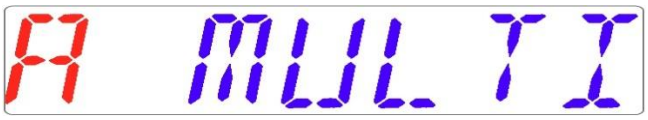
If the N_2 gas supply is not attached correctly or incorrect N_2 gas pressure is applied to the system, the MIRI® Humidity incubator will go into N_2 pressure alarm mode. The display will show "N2 P", which indicates an incorrect incoming gas pressure. If the pressure falls below 0.3 bar (4.40 PSI) or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

"P" stands for pressure.

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

14.4 Multiple alarms

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



The flow will be forced according to the alarms. The temperature alarms have 1st priority, gas level alarms 2nd, and pressure 3rd.

14.5 Loss of power alarm

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

Figure 14.2 Alarm key which indicates the alarm condition

15 Changing the setpoints

15.1 The temperature setpoint

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

The default temperature setpoint is 37.0 °C.

To change the temperature setpoint, follow these instructions:

1. When the display shows the current temperature:

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

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

15.2 The CO_2 gas concentration setpoint

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

☞ **The default CO_2 setpoint is 6.0%.**

To change the CO_2 concentration setpoint, follow these instructions:

1. When the display shows the CO_2 gas concentration:

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

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

15.3 The O_2 gas concentration setpoint

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

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

To change the O_2 concentration setpoint, follow these instructions:

1. When the display shows the O_2 concentration:

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

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

15.4 The culture mode

The culture mode can be set for under “oil culture” or “open culture”. “Under oil” culture mode is used when the culture media has an oil or Paraffin overlay. “Open culture” mode is used when the culture media does not have any overlay.

☞ **The default setting is “Oil culture” mode.**

To change the culture mode, follow these instructions:

1. When the display shows the culture mode:

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

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

Open culture is possible in a 4-well (or similar type of dish) in volumes not under 0.8 mL per well without oil overlay for up to a maximum of 4 hours. The Osmolality will change rapidly after that and reach over 300 mOsm/kg. “Open culture“ mode used for an extended incubation period eventually causes severe osmolality changes in media and is thus not to be used for long term incubation.

In “Oil culture” mode, the lid temperature is kept 0.2 – 0.3 °C above the temperature setpoint. In “Open culture” mode, the lid temperature will be increased by an additional 1.0 °C above the temperature setpoint (thus making the lid 1.2 – 1.3 °C warmer than the insert surface).

Difference between open culture mode and oil culture mode

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

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

If you have any questions or uncertainty, consult Esco Medical or your local representative before using open culture mode in the MIRI® Humidity incubator.

16 Surface temperatures and measuring temperature

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

The MIRI® Humidity incubator is equipped with 6 completely separate PID controllers for temperature measurement. Each controller is responsible for controlling the temperature of a separate area.

Each of the 6 available areas is equipped with its separate temperature sensor and heater, allowing the user to adjust the temperature in every area separately, thus achieving higher precision.

Figure 16.1 Temperature zones in MIRI® Humidity

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

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

Table 16.1 Areas associated with sensors

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

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

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

⚠ **After temperature adjustment, give it at least 15 minutes for the temperature to stabilize, use the thermometer to verify the correct temperature on each area.**

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

☞ **There is no crossover heating between the 6 compartments: this is a unique feature of the MIRI® Humidity 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 37.0 °C, the lid should be 37.2 °C.**

Note: how to calibrate the temperature at the T1 area can be found in this manual's 12.4.1 section.

☞ **"T1" is used to adjust the bottom temperature of compartment 1. "T7" is used to adjust the temperature on the lid 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 on one of the designated spots indicated on the heating insert.**

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

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

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

17 Pressure

17.1 CO_2 gas pressure

The CO_2 pressure can be read out in the CO_2 sub-menu:

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

☞ Remember 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.

17.2 N_2 gas pressure

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

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

☞ Remember 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).

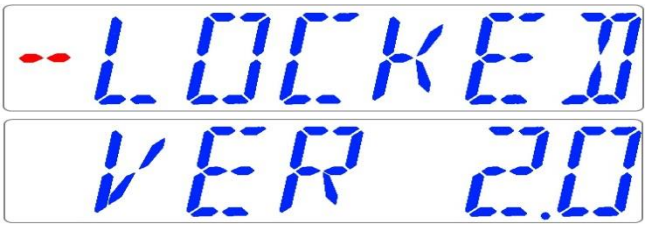
☞ The internal pressure sensor cannot be calibrated by the user. Under normal circumstances, the pressure sensor is replaced every 2 years according to the maintenance plan.

18 Firmware

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

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

1. In the menu, locate the Service sub-menu “Serv” and press the (⇨) key to enter. The service sub-menu is locked as default. The display will alternate between “Locked” and the currently installed firmware version:



Ver 2.0 is only shown as an example. Consult Esco Medical or the local representative for the number of the latest version.

2. Press the (⇧) key to exit back into the sub-menu.

19 pH measuring (the functionality is not available in the US)

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

The MIRI® Humidity incubators 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.

Figure 19.1 pH probe connected to the BNC

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

All readings from the pH system and calibration dialogue are shown in the PC Data logger software.

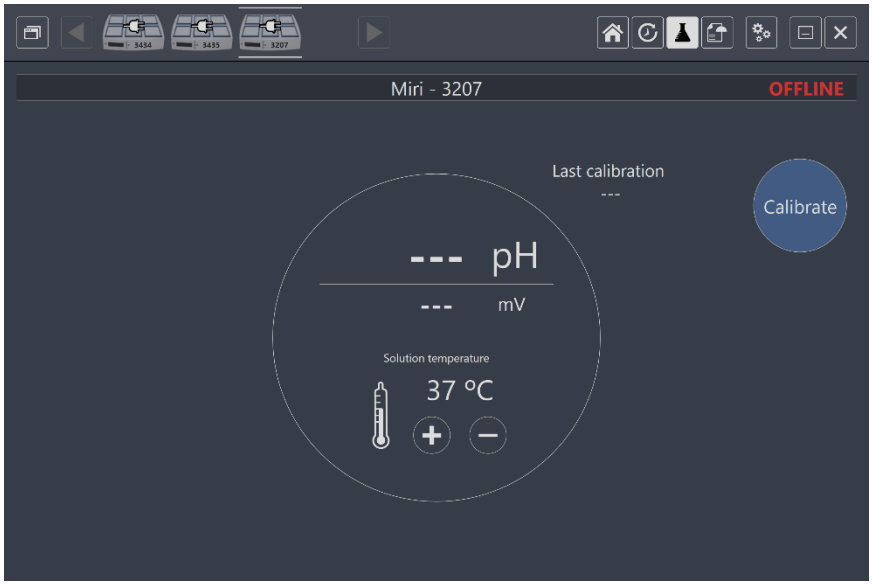


Figure 19.2 pH view in the Datalogger

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

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

Figure 19.3 4-well dish with 3 buffers and media

For calibration, at least two buffers are needed. We recommend 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.

To be accurate, the technique requires the user to be quick, as the pH starts to shift very quickly once the lid is opened. The optimal time to complete the procedure is tested to be 15 seconds, giving the same results as the continuous measurement described below.

Press the “Calibrate” key:

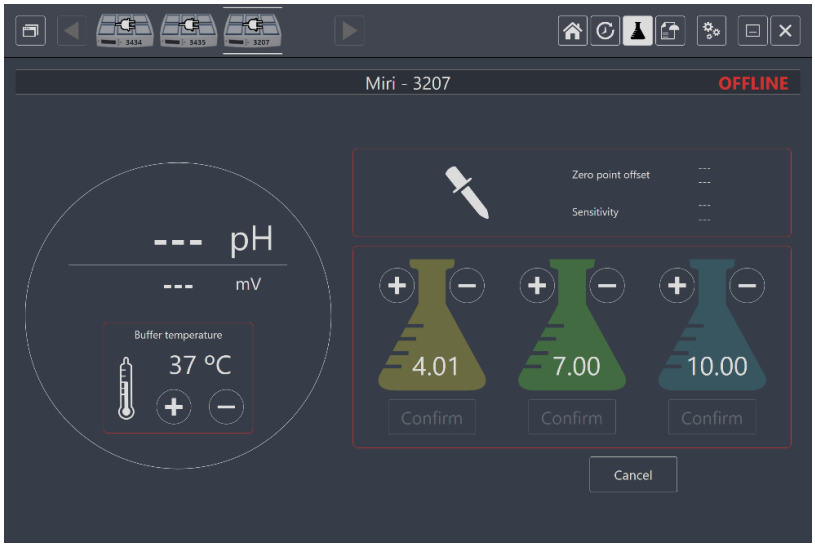


Figure 19.4 4-well dish with 3 buffers and media

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

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

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

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

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

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

20 SAFE Sense function

There is a possibility to purchase the MIRI® Humidity 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.

21 Cleaning instructions

21.1 Considerations about a sterile device

The MIRI® Humidity incubator is not a sterile device. It is not delivered sterile state and it is not possible to keep them sterile when in use.

However, their design was created with great care to make it easy for the user to keep the device sufficiently clean during use and 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 removable heat optimization plate can be removed and cleaned (cannot be autoclaved!). As this serves as the main holding area for samples, this should be the highest priority to keep clean
- Compartments with sealed edges that can be cleaned
- Use of aluminum and PET parts that withstand cleaning well

21.2 Manufacturer recommended cleaning procedure

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

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

Periodic cleaning of the device (with no embryos inside)

Wearing gloves and good handling techniques are essential to successful cleaning.

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

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

21.3 Manufacturer recommended disinfection procedure

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® Humidity incubator (rear panel).
2. Open the lids.
3. Use the required disinfectant to disinfect the internal surface and a glass plate on the lid's top. Use sterile wipes to apply the disinfectant.
4. Wipe all internal surfaces and the top of the lid with three wipes at least. Repeat until the wipes are no longer discolored.
5. Change your gloves, and after 10 minutes of contact time, spray sterile water on the surfaces and wipe them with a sterile wipe.
6. Inspect the device – if it is visually clean, consider it ready for use. If the device is visually not clean, go to step 3 and repeat the procedure.
7. Turn on the MIRI® Humidity incubator (rear panel).

22 Heat optimization plates

Insert the heat optimization plate. The heat optimization plate will ensure full contact with the dish. It generally means much more stable temperature conditions for the cells. The plate fits the compartment. The plate fits the compartment, and it is taken out for cleaning.

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

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

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

Figure 22.1 Heat optimization plate

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

23 Humidification

The MIRI® Humidity incubator system has a built-in humidity sensor. The water bottle is located on the unit's side for easy control of water level and refilling.

The device is designed to run an open culture mode that will ensure a higher humidification rate than the environment. Still, even using humidification, media in dishes must be covered with oil overlay, which reduces evaporation from the media.

☞ **"Open culture" mode is designed not for embryo culturing but (if there is a need) for media equilibration.**

Open culture is possible in a 4-well (or similar type of dish) in volumes not under 0.8 mL per well without oil overlay for up to a maximum of 4 hours. The Osmolality will change rapidly after that and reach over 300 mOsm/kg. "Open culture" mode used for an extended incubation period eventually causes severe osmolality changes in media and is thus not to be used for long term incubation.

Please consult Esco Medical or your local representative before using "Open culture" mode in the MIRI® Humidity incubator if you have any questions.

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

24 Temperature validation

The MIRI® Humidity incubator is equipped with 6 PT-1000 Class-B sensors located in the center of the bottom of each compartment.

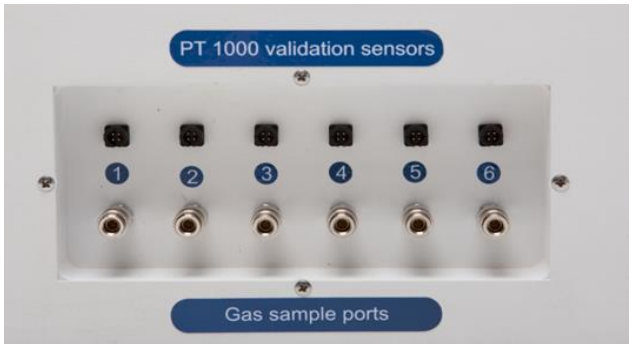


Figure 24.1 PT-1000 Class B sensors

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

The compartment's temperature conditions can be continuously logged through the external connectors on the unit's side without compromising its performance.

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

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

25 Gas level validation

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

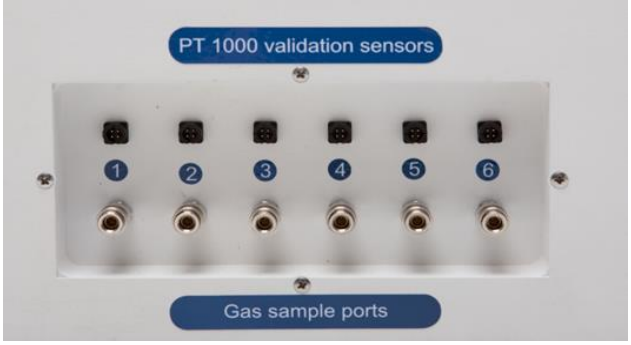


Figure 25.1 Gas sample ports

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

An external automatic gas sampler can be connected to the ports for continual validation.

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

Taking out a large sample volume may affect gas regulation.

Make sure that the gas analyzer is calibrated before use.

26 Alarm switch for an external system

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

Whenever an alarm goes off (that could be temperature alarm, gas alarms for CO_2 or O_2 levels, low-pressure or high-pressure alarms for CO_2 and N_2 gases) or if the power supply to the unit 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 is illustrated below.

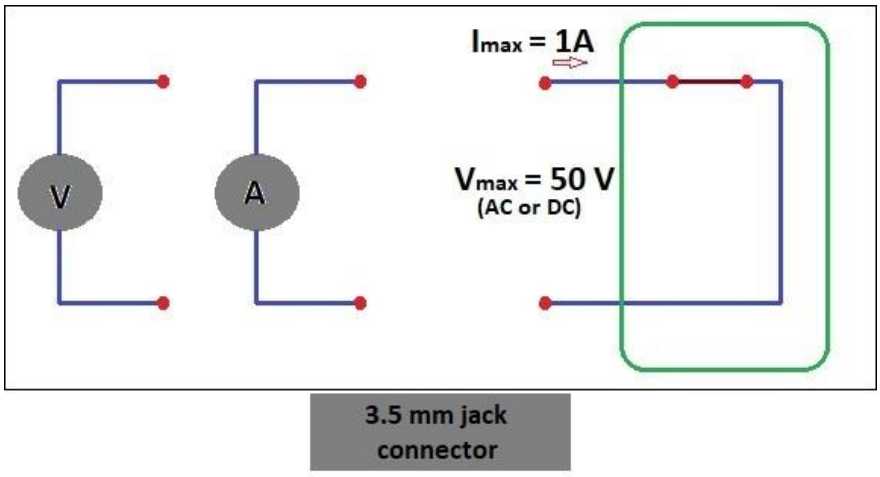


Figure 26.1 No alarm mode

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

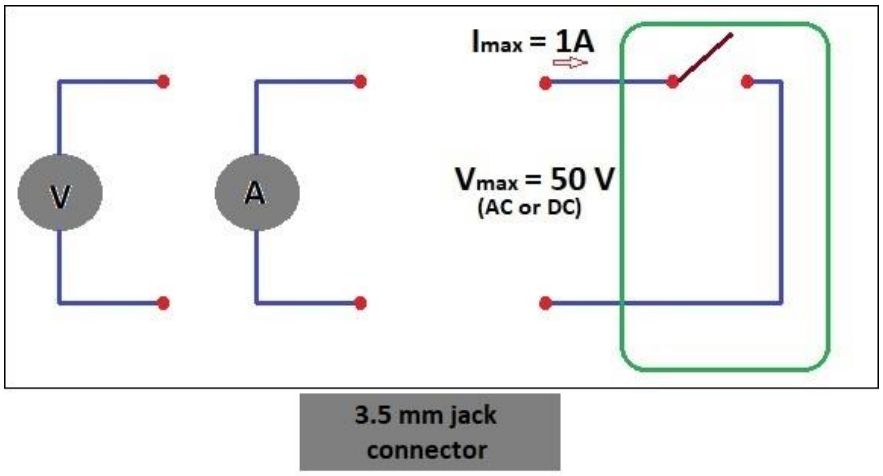


Figure 26.2 "Open circuit" alarm mode

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

27 Writing area on the compartment lids

Each compartment lid on the MIRI® Humidity incubator is made from white glass, optimized for writing text. The compartment's patient data or content can be noted down for easy reference during the incubation process.

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

Figure 27.1 Area for patient information

28 Maintenance

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

1. Correct calibration of temperature and gas level, using high-precision equipment in the intervals prescribed based on clinical practice at the laboratory, where the MIRI® Humidity incubator is used. The manufacturer recommends that the period between validation should be no longer than 14 days.
2. VOC/HEPA filters must be replaced every 3 months.
3. In-line HEPA filters must be replaced yearly during annual maintenance.
4. According to the clinical practice intervals, suitable cleaning is in the laboratory where the MIRI® Humidity incubator is used. The manufacturer does not recommend periods longer than 14 days between cleaning.

It is essential to perform the inspection and service at the intervals indicated in the "38 The Maintenance guide" section. Failure to do so can have serious adverse outcomes, causing the unit to stop functioning as expected and cause damage to samples, patients or users.

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

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

29 Emergency Procedures

Total loss of power to or on 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® Humidity incubator will drop below 35 °C after being 10 minutes in an ambient environment of 20 °C.
- The CO_2 concentration will remain within 1% of the setpoint for 30 minutes if the lids remain closed.
- If a longer time to turn the power back on is needed, it may be useful to cover the unit with insulating blankets to slow the temperature drop.

If a single temperature alarm goes off:

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

If multiple temperature alarms go off:

- Remove the samples from the affected compartments. They can be relocated to any of the other compartments, which happens to be unoccupied. All compartments are separate so that the remaining ones will function normally.
- Alternatively, remove the samples from all the affected compartments and place them in an alternative or backup device that is not affected by the problem.

If the CO_2 level alarm goes off:

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

If the O_2 level alarm goes off:

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

If the CO_2 pressure alarm goes off:

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

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

In case of a gas pressure alarm on the unit:
Inspect the external gas supply and the gas supply lines. If the problem is external and not readily fixed, or if the problem is internal, follow the guidelines under gas level alarm.

30 User Troubleshooting

Table 30.1 Heating system

Symptom	Cause	Action
No heating, the display is off	The unit is switched off at the back or not connected to the power	Switch the device on or connect the power
No heating	The setpoint for temperature is wrong	The temperature is more than 0.5 °C off the set temperature
		Check the desired temperature setpoint
Uneven heating	System not calibrated	Calibrate each zone according to the user manual, using a high precision thermometer

Table 30.2 CO_2 gas regulator

Symptom	Cause	Action
No CO_2 gas regulation	The system is not powered	Check power mains
	The system is on standby or 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 or wrong gas attached to CO_2 gas input	Check the CO_2 gas supply, make sure that pressure is kept stable at 0.4 – 0.6 bar (5.80 – 8.70 PSI)
	The actual gas concentration is higher than the setpoint	Check CO_2 gas setpoint
Poor CO_2 gas regulation	Lid(s) are left open	Close lid(s)
	Seals missing on the lid(s)	Replace the seals on the lid(s)
"A CO2" is shown on the display	CO_2 gas concentration more than ±1 from the setpoint	Allow the system to stabilize by closing all lids
"CO2 P" is shown on the display	No/wrong CO_2 gas pressure to the system	Check the CO_2 gas supply, make sure that pressure is kept stable at 0.4 – 0.6 bar (5.80 – 8.70 PSI)

Table 30.3 O_2 gas regulator

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

Table 30.4 Datalogger

Symptom	Cause	Action
No data is sent to the PC	System not powered	Check mains
	The system is on standby or switched off	Switch the system on
	The data cable between Incubator and PC not correctly attached	Check connection. Use only the cable supplied with the unit
	Data logger software/USB driver not correctly installed	Please refer to the software installation guide

Table 30.5 Display

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

Table 30.6 Keyboard

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

31 Specifications

Table 31.1 MIRI® Humidity incubator specifications

Technical specifications	MIRI® Humidity
Overall dimensions (WxDxH)	700 x 645 x 280 mm
Weight	40 kg
Material	Mild steel / Aluminum / PET / Stainless steel
Power supply	115V 60Hz OR 230V 50Hz
Power consumption	280 W
Temperature control range	24.9 °C – 40.0 °C
Gas consumptions (CO_2)[1]	< 4 liters per hour
Gas consumption (N_2)[2]	< 12 liters per hour
Premixed gas consumption	In purge < 50 liters per hour In normal run < 20 liters per hour
CO_2 control range	2.0% – 9.9%
O_2 control range	5.0% – 20.0%
CO_2 gas pressure (input)	0.4 – 0.6 bar (5.80 – 8.70 PSI)
N_2 gas pressure (input)	0.4 – 0.6 bar (5.80 – 8.70 PSI)
Alarms	Audible and visible for out-of-range temperature, gas concentration and gas pressure.
Shelf life	1 year
Use life	6 years

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

32 Electromagnetic compatibility

Table 32.1 Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The MIRI® Humidity incubator is intended for use in the electromagnetic environment specified below. The customer or the MIRI® Humidity 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® Humidity incubator does 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® Humidity incubator is suitable for use in a hospital environment. It is not suited for domestic establishments.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

Table 32.2 Electromagnetic immunity

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

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

Table 32.3 Recommended separation distances

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

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

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

33 The Validation guide

33.1 Product release criteria

The Esco Medical MIRI® Humidity incubator undergoes a strict quality and performance testing before being released for sale.

33.1.1 Performance

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

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

Pass I: Internal sensor temperature variation from setpoint within ± 0.1 °C absolute.
Pass II: Internal sensor CO_2 concentration variation from setpoint within ± 0.2% absolute.
Pass III: Internal sensor N_2 concentration variation from setpoint within ± 0.2% absolute.
Pass IV: Gas flow CO_2 less than 4 l/h.
Pass V: Gas flow N_2 less than 12 l/h.

33.1.2 Electrical safety

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

33.1.3 Communication & data logging

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

33.1.4 Gas concentration levels and consumption

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

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

The gas flow under regular operation is less than 4 liters per hour, and thus, the average should be below 4 liters.

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

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

33.1.5 Cosmetic

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

34 Validation on-site

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

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

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

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

34.1 Mandatory equipment

☞ **All equipment must be of high quality and calibrated.**

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

34.2 Recommended additional equipment

☞ **All equipment must be of high quality and calibrated.**

- A VOC meter able to measure the most common volatile organic compounds at least at the ppm level.
- With the laser particle counter, a sample should be taken just above the MIRI® Humidity incubator. The reading should be noted down as the background particle level.

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

35 Testing

35.1 Gas supply CO_2

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

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

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

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

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

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

35.1.1 About CO_2

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

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

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

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

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

35.2 Gas supply N_2

For the regulation to maintain the correct O_2 concentration levels in the MIRI® Humidity incubator compartments, the device must be connected to a stable source of 100% N_2 at 0.4 – 0.6 bar (5.80 – 8.70 PSI) of pressure.

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

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

☞ **A gas analyzer that can measure 0% O_2 accurately can be used. 100% N_2 = 0 % O_2.**

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

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

35.2.1 About N_2

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

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

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

- Research Grade 99.9995%.
- Contaminant.
- Argon (Ar) 5.0 ppm.
- Carbon Dioxide (CO_2) 1.0 ppm.
- Carbon Monoxide (CO) 1.0 ppm.
- Hydrogen (H_2) 0.5 ppm.
- Methane 0.5 ppm.
- Oxygen (O_2) 0.5 ppm.
- Water (H_20) 0.5 ppm.

35.3 CO_2 gas pressure check

The MIRI® Humidity requires a pressure of 0.4 – 0.6 bar (5.80 – 8.70 PSI) on the input CO_2 gas line. This gas pressure must be held stable at all times.

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

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

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the User manual sections for more information.

35.4 N_2 gas pressure check

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

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

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

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the User manual sections for more information.

35.5 Voltage supply

The voltage on-site must be verified.

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

Use a multimeter set for AC.

PASS: 230V ± 10.0%
115V ± 10.0%

35.6 CO_2 gas concentration check

The CO_2 gas concentration is checked for deviation. The gas sample port on the side of the unit is used. Use sample port-6 for validation.

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

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

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

Please refer to the "12.4.2 CO_2 sub-menu" section for more information on how to perform the CO_2 gas calibration.

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

35.7 O_2 gas concentration check

The O_2 gas concentration is checked for deviation. The gas sample port on the side of the unit is used. Use sample port-6 for validation.

Remember not to open any lid at least 10 min before starting the test nor during the testing itself.

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

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

Please refer to the "12.4.3 O_2 sub-menu" section for more information on how to perform the CO_2 gas calibration.

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

35.8 Temperature check: Compartment bottoms

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

At least 6 dishes prepared in advance (with at least one microdroplet of media approximately 10 – 100 µL in each dish). The media should be covered with a layer of Paraffin oil. The dishes do not need to be equilibrated, as the pH will not be measured during the validation tests.

The dishes are placed with at least one dish in each compartment. The dishes should be placed on the corresponding size slot on the heat optimization plates.

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

Open a compartment lid, remove the cover from the dish and place the sensor tip inside the droplet.

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

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

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

If calibration is needed, please refer to the "12.4.1 Temperature sub-menu" section for more information on how to perform the temperature calibration.

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

35.9 Temperature check: Compartment lids

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

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

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

Place the thermometer on each zone and verify the temperature.

Pass: all temperatures measured on the compartments' lid must not deviate more than ± 0.2 °C from the setpoint.

If calibration is needed, please refer to the "12.4.1 Temperature sub-menu" section for more information on how to perform the temperature calibration.

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

35.10 6-hour stability test

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

The device must be set up as closely as to the condition under which it will be running in clinical use.

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

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

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

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

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

Pass I: Internal sensor temperature variation from set point is within ± 0.1 °C absolute.
Pass II Internal sensor CO_2 concentration variation from setpoint within ± 0.2% absolute.
Pass III: Internal sensor N_2 concentration variation from setpoint within ± 0.2% absolute.
Pass IV: Gas flow CO_2 less than 4 l/h.
Pass V: Gas flow N_2 less than 12 l/h.

35.11 Cleaning

☞Always validate the cleaning procedures locally or consult the manufacturer or the distributor for more guidance.

After the testing has been conducted successfully, it should be cleaned again before the device is taken into clinical use.

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

- Clean the unit externally with a lint-free cloth moistened with a 70% alcohol solution.
- Switch off the device and remove the mains lead.
- Remove all heat optimization plates and clean them with a lint-free cloth soaked with a 70% alcohol solution.
- Wipe the inside of the 6 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 6 compartments and the heat optimization plates with a lint-free cloth soaked in sterilized water.
- Wipe the lids in the same way.
- Let the lids remain open for 10 minutes.
- Re-insert the heat optimization plates.
- Close the lids.
- Attach the power and switch on the incubator.
- Let the incubator run empty for at least 20 minutes before inserting a sample.

35.12 Test documentation form

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

35.13 Recommended additional testing

35.13.1 A laser particle counter

A sample should be taken just above the MIRI® Humidity incubator with the laser particle counter. The reading should be noted down as the background particle level. Then a sample is taken from the gas sample port number – 6.

Pass: 0.3-micron < 100 ppm.

Ensure that the sample lines do not contain any particles.

36 Clinical use

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

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

Do not attempt to run the MIRI® Humidity incubator for clinical purposes without access to high-grade quality control validation equipment.

Table 36.1 Validation intervals

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

36.1 Temperature check

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

Please refer to the "12.4.1 Temperature sub-menu" section for more information on how to perform the temperature calibration.

PASS:

- **All temperatures measured on the bottom of the compartment in the locations where the dishes would be placed must not deviate more than ± 0.2 °C from the set-point.**
- **All temperatures measured on the lid must not deviate more than ± 0.5 °C from the setpoint.**

36.2 CO_2 gas concentration check

The CO_2 gas concentration is checked for deviations. The gas sample port on the side of the unit is used for this. Use sample port-6 for validation. It is essential to have a high-precision gas analyzer for CO_2 and O_2 available to do the test.

Please follow these simple rules while testing gas concentration:

- Check the CO_2 gas setpoint.
- Check the actual CO_2 gas concentration to ensure the setpoint is reached, and gas concentration is stabilized around the setpoint.
- Remember not to open any lids for at least 10 min, before starting the test or during the testing itself.

Please refer to the "12.4.2 CO_2 sub-menu" section for more information on how to perform the CO_2 gas calibration.

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

36.3 O_2 gas concentration check

The O_2 gas concentration is checked for deviations. The gas sample port on the side of the unit is used for this. Use sample port-6 for validation. It is essential to have a high-precision gas analyzer for CO_2 and O_2 available to do the test.

Please follow these simple rules while testing gas concentration:

- Check the O_2 gas setpoint.
- Check the actual O_2 gas concentration to ensure the setpoint is reached, and gas concentration is stabilized around the setpoint.
- Remember not to open any lids for at least 10 min, before starting the test or during the testing itself.

Please refer to the "12.4.3 O_2 sub-menu" section for more information on how to perform the CO_2 gas calibration.

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

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

36.4 CO_2 gas pressure check

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

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

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

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the "17.1 CO_2 gas pressure" section for more information.

36.5 N_2 gas pressure check

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

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

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

PASS: The value must be 0.4 – 0.6 bar.

Please refer to the "17.2 N_2 gas pressure" section for more information.

36.6 pH check

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

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

The MIRI® Humidity incubator is equipped with a high-grade pH measuring system.

Please refer to the "19 pH measuring" section for more information on performing pH calibration.

37 The Maintenance guide

The MIRI® Humidity incubator from Esco Medical contains high precision quality components. These components are chosen to ensure the high durability and performance of the equipment.

However, continual validation of the performance is necessary.

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

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

However, to sustain the high-performance level and avoid system errors, the owner is responsible for having a certified technician who performs components replacements according to table 37.1.

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

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

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

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

Table 37.1 Service interval plan

Component name	Every month	Every year	Every 2 years	Every 3 years	Every 4 years
Humidification Bottle	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
Cooling fan				X	
Pump module			X		
Proportional valves				X	
Gas lines				X	
Flow sensors			X		
Pressure regulators					X
Internal 0.2µ filter for CO_2		X			
Internal 0.2µ filter for N_2		X			
A firmware update (if a new version has been released)		X			

37.1 Humidification bottle

A humidification bottle contains water that is used to maintain the humidity in the chamber.

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

37.2 In-line HEPA filter for CO_2 gas

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

Please follow these safety precautions when changing the filter:

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

Please refer to the service manual for replacement instructions.

37.3 In-line HEPA filter for N_2 gas

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

Please follow these safety precautions when changing the filter:

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

Please refer to the service manual for replacement instructions.

37.4 O_2 sensor

The oxygen regulation uses the Oxygen sensor to keep the O_2 gas concentration at a desired level inside the chambers. The lifetime of this sensor is limited due to its construction. From the day the sensor is unpacked, a chemical process is activated within the sensor core. The chemical reaction is entirely harmless to its surroundings, but it is necessary for measuring the amount of oxygen with very high precision needed in the MIRI® Humidity incubator.

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

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

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

Please follow these safety precautions when changing sensor:

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

Please refer to the service manual for replacement instructions.

37.5 CO_2 sensor

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

This sensor's lifetime is more than 6 years, but for safety reasons, Esco Medical recommends the sensor to be replaced once every 4-years.

Please follow these safety precautions when changing the sensor:

- Always use an original CO_2 sensor (contact Esco Medical or your local distributor for more details or ordering).
- Change the CO_2 sensor within 4 years from the date of installation.
- Failure to change the CO_2 sensor on time can result in low/no CO_2 gas concentration regulation.
- Warranty void if wrong/ non-original sensor is used.

Please refer to the service manual for replacement instructions.

37.6 Cooling fan

The cooling fan is responsible for cooling down the electronics installed in the unit. A breakdown of the cooling fan will stress the components due to temperature rise within the system. It may cause the electronics to drift, resulting in low temperature and gas regulation.
To avoid this, Esco Medical recommends that the cooling fan be replaced once every 3 years.

Please follow these safety precautions when changing the cooling fan:

- Always use an original fan (contact Esco Medical or your local distributor for more details or ordering).
- Change the fan within 3 years from the date of installation.
- Failure to change the fan may cause the electronics to drift, resulting in low temperature and gas regulations.
- Warranty void if wrong/ non-original fan is used.

Please refer to the service manual for replacement instructions.

37.7 Pump module

The pump is used to transport the mixed gas through the chambers. In time the performance of this pump can be affected, causing a longer recovery time.

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

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

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

Please refer to the service manual for replacement instructions.

37.8 Proportional valves

The internal valves make gas regulation possible. If the proportional valves are worn, gas regulation may be affected. It may cause more prolonged recovery time, incorrect gas concentration or breakdown. Therefore, these proportional valves must be replaced once every 3 years to maintain system safety and stability.

Please follow these safety precautions when changing valves:

- Always use original proportional valves (contact Esco Medical or your local distributor for more details or ordering).
- Change the valves within 3 years from the date of installation.
- Failure to change the valves may cause slow recovery times or breakdowns.
- Warranty void if wrong/ non-original valves are used.

Please refer to the service manual for replacement instructions.

37.9 Gas lines

The internal gas lines are used to transport mixed gas through the chambers. Over time, the lines' performance can be affected, causing more extended recovery time due to clogging.

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

Please follow these safety precautions when changing gas lines:

- Always use original gas lines (contact Esco Medical or your local distributor for more details or ordering).
- Change the gas lines within 3 years from the date of installation.
- Failure to change the gas lines may cause slow recovery times or breakdowns.
- Warranty void if wrong/ non-original gas lines are used.

Please refer to the service manual for replacement instructions.

37.10 Flow sensors

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

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

Please follow these safety precautions when changing sensors:

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

Please refer to the service manual for replacement instructions.

37.11 Pressure regulators

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

Please follow these safety precautions when changing regulators:

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

Please refer to the service manual for replacement instructions.

37.12 Internal 0.2µ filter for CO_2 gas

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

Please follow these safety precautions when changing the filter:

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

Please refer to the service manual for replacement instructions.

37.13 Internal 0.2µ filter for N_2 gas

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

Please follow these safety precautions when changing the filter:

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

Please refer to the service manual for replacement instructions.

37.14 Firmware update

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

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

38 The Installation guide

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

38.1 Responsibilities

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

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

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

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

38.2 Before installation

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

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

38.3 Preparing for installation

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

38.4 Bring the following to the installation site

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

38.5 Installation procedure at the site

1. Follow the guidelines in the safety instructions and warnings section ("2 Safety warning" section).
2. Connect the power cable to the UPS.
3. Connect the power cable to the MIRI® Humidity 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® Humidity incubator on the back.
7. Observe for standard functionality.
8. Let the unit warm up and stabilize for 30 min.
9. Follow the guidelines in the “33 The Validation guide” section.
10. Complete user training and finish reading instructions.
11. After a burn-in phase of 24-hours, the unit is ready for use IF the testing is successful.

38.6 User training

1. Mains switch on/off.
2. Explain the MIRI® Humidity incubator's essential function and incubation with a multi-room facility to store the samples.
3. Explain temperature control in the MIRI® Humidity incubator (direct heat transfer with heated lids).
4. Gas regulation on/off.
5. Setpoint for temperature, CO_2 and O_2.
6. Explain how N_2 is used to suppress the O_2 level.
7. Alarm turn off procedure (temperature, CO_2, O_2) and revert times.
8. Insertion and removal of heating inserts from the incubator.
9. How to toggle the "Under oil" and "Open culture" modes, and when which mode should be used.
10. Emergency procedures (can be found in the "29 Emergency Procedures" section).
11. Explain how to clean the device and heating inserts.
12. External measurement and calibration of temperature.
13. External measurement and calibration of gas concentration.
14. How to add and remove a sample.

15. 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.

38.7 After the installation

When the installation trip is finished, a copy of the original "Installation report" form must be sent to Esco Medical Ltd. It will be saved with the device records. According to the ISO procedure and Medical Device Directive, a paper copy of the completed and signed installation test form is stored in the unique device's device history record. The date of installation is written in the instrument overview file. The date of installation is also written in the service schedule.

Suppose the MIRI® Humidity incubator user or owner makes inquiries about a written "Installation report" form. 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® Humidity 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® Humidity incubator must be taken out of service until it is repaired/exchanged, or a new test approves the MIRI® Humidity incubator. The User and owner must be informed about this, and arrangements to solve the problems must be initiated.