ESCO MEDICAL Life has begun

CE 0088

USER MANUAL

Mini MIRI® Dry / Humidity Multiroom incubators

Rev. 1.0
Date revised 01.11.2021
Rx only

CERTIFIED INCUBATION

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Copyright Information

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

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

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

Unpacking and Inspection

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

Claims

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

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

Standard Terms and Conditions

Refunds & Credits

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

Return Procedure

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

Restocking Charges

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

Certification

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

Warranty and Product Support

Esco Medical warrants this instrument to be free from defects in materials and workmanship under regular use and service for two (2) years from the original purchase date. The provided instrument is calibrated and maintained following this manual. During the warranty period, Esco Medical will, at our option, either repair or replace a product that proves to be defective at no charge, provided you return the product (shipping, duty,

brokerage and taxes prepaid) to Esco Medical. Any transportation charges incurred are the purchaser's responsibility and are not included within this warranty. This warranty extends only to the original purchaser. It does not cover damage from abuse, neglect, accident or misuse, or as the result of service or modification by parties other than Esco Medical.

IN NO EVENT SHALL ESCO MEDICAL LTD. BE LIABLE FOR CONSEQUENTIAL DAMAGES. No warranty shall apply when any of the following causes damage:

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

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

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

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

When you return an instrument to Esco Medical for service, repair or calibration, we recommend shipment using the original shipping foam and container. If the original packing materials are not available, we recommend the following guide for repackaging

- Use a double-walled carton of sufficient strength for the weight being shipped
- Use heavy paper or cardboard to protect all instrument surfaces. Use non-abrasive material around all projecting parts
- Use at least four inches of tightly packed, industrial-approved, shock-absorbent material all around the instrument

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

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

Warranty Disclaimer

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

In all cases, breaking the tamper-resistant Quality Seal should be avoided at all 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 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 the advanced users. All parts must be read before the device is taken into use.

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 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 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 take note of 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 Mini MIRI® 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 (in Mini MIRI® Humidity) for the development of gametes and embryos during in vitro fertilization (IVF) / assisted reproduction technology (ART) treatments.

4 About the product

Esco Medical Mini MIRI® Dry and Mini MIRI® Humidity incubators are multi-room CO_2/O_2 incubators.

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

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

The Esco Medical Mini MIRI® incubators have 2 completely separate culture heat chambers. Each chamber has its heated lid and warming plate for the Petri dish. Mini MIRI® Dry and Mini MIRI® Humidity capacity for 35mm Petri dish are 16 pcs and 60mm and 4-well Petri dishes – 8 pcs.

To ensure maximum performance, the system of Mini MIRI® Dry and Mini MIRI® Humidity has 4 completely separate PID temperature controllers. They control and regulate the temperature in culture chambers and lids. Compartments do not affect each other`s temperatures in any way. The top and the bottom of each compartment are separated with a PET layer so that the lid temperature would not affect the bottom. For validation purposes, each compartment has a PT-1000 sensor built-in. The circuitry is separated from the unit`s electronics, so it remains a 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 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 is less than 3 min after opening the lid. Mini MIRI® Dry and Mini MIRI® Humidity incubators are fitted with two gas sample ports that allow the user to validate gas concentration by sampling gas from the individual compartment.

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 via 254 nm UVC light with direct gas contact between the bulb and gas, then through a VOC filter and a HEPA filter. The UVC light has filters that inhibit any 185 nm radiation that would produce dangerous ozone. The VOC filter is located under the UVC light.

UVC light modules and HEPA-VOC filters are not applied on Mini MIRI® Humidity.

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

The total gas consumption is very low. Less than 2 l/h CO_2 and 5 l/h N_2 in use.

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

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

The incubator has been primarily developed and designed to incubate gametes and embryos with an overlay of either Paraffin or mineral oil.

In the case of Mini MIRI® Dry and Mini 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 type of 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" form more detailed information.**

The incubator can be connected to a PC running the Esco Medical data logging 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.

Personnel Protective Equipment (89/686/EEC) and Machine Directive (2006/42/EC) is not applicable for Mini MIRI® incubators.

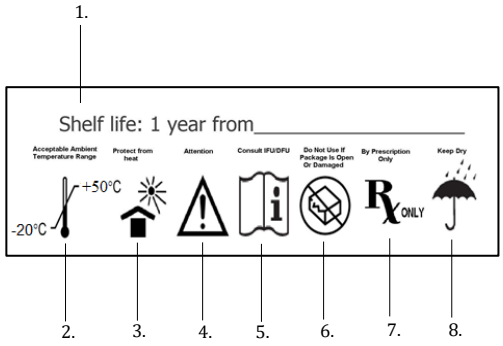
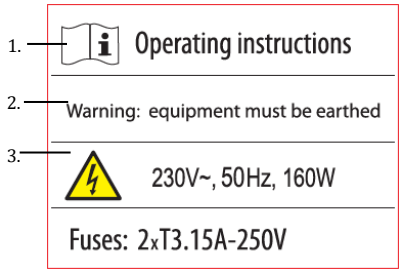
5 Accessories supplied

- 1 VOC/HEPA filter capsule (not available in the Mini MIRI® Humidity incubator)
- 2 HEPA filter for input gas supply
- 2 warming blocks
- 1 USB stick containing Esco Medical Data logger software and PDF versions of the manuals
- 1 medical grade power cord
- 4 warranty labels
- 1 pump box calibration tool (not available in the Mini MIRI® Dry incubator)
- 1 3,5 mm external alarm jack connector
- 1 humidity bottle (not available in the Mini MIRI® Dry incubator)
- 1 set of fast male connectors with 15 silicone pipes

6 Safety symbols and labels

Several user labels on Mini MIRI® Dry and Mini MIRI® Humidity incubators surface to guide the user. User labels are shown below.

Table 6.1 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. Consult instruction for use. 2. Warning on the back of the device indicates that an earth connection is needed and the mains information and an “ON/OFF” push button. 3. “Lightning bolt” indicates the potential risk of electrical shock (never remove any cover).	

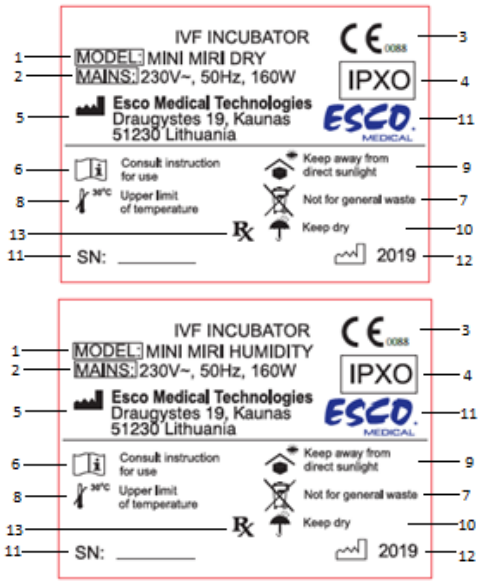
1. Model. 2. Mains power rating. 3. CE mark. 4. Not protected against the ingress of water. 5. Manufacturer's address and country of origin. 6. Consult instruction for use. 7. Observe WEEE. 8. Upper limit of temperature. 9. Keep away from direct sunlight. 10. Keep dry. 11. Logo and serial number. 12.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

Table 6.2 Labels on the back of Mini MIRI® incubators

Description	Image
USB communication port	
CO_2 inlet	
N_2 inlet	
Alarm port	
Compartments numbers are indicated in the top corner of the lid with a label	
Humidification bottle[1]	

[1] Not available in the Mini MIRI® Dry

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

Figure 6.1 Compartment numbers

7 Important safety instructions and warnings

7.1 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.

7.2 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 the device near any heat sources such as radiators, heat registers, stoves or other apparatus that produce heat.
8. Do not use this device near water sources.
9. Use only 100% concentration CO_2 and 100% concentration N_2 or premixed gases.
10. Always use an external HEPA filter for input CO_2/N_2 or premixed gas.
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.

7.3 Post-installation

1. Refer all servicing to qualified service personnel.
2. Servicing is required according to the service manual as well as in 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. Mini MIRI® Dry and Mini MIRI® Humidity incubators contain high voltage components that may be hazardous.
3. Unplug this apparatus 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 of the compartment open for more than 10 sec while in use.
7. VOC/HEPA filters must be changed every 3 months (no change is required in the Mini MIRI® Humidity multiroom incubator).
8. A maintenance plan must be fulfilled to keep the device safe.
9. NEVER block gas supply holes in the compartment.
10. Ensure that CO_2/N_2 or premixed gas supply pressures are kept stable at 0.4 – 0.6 bar (5.80 – 8.70 PSI).
11. Never use any other except Esco Medical filter. Otherwise, the warranty will be void.
12. Do not use the device without a proper Esco Medical VOC/HEPA filter attached.

8 Getting started

⚠ **Mini MIRI® Dry or Mini 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 Mini MIRI® Dry or Mini MIRI® Humidity incubator.
4. Connect gas sample 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 Mini MIRI® Dry or Mini 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.

If the device is going to be used in a clinical setting, clean and disinfect the device before use. It is not delivered sterile or in a clinically acceptable clean state. Consult the cleaning instructions section in this manual for the manufacturer's recommended guidelines!

9 Mains connection

Mini MIRI® Dry and Mini MIRI® Humidity incubators come with a detachable main 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 third prong. It 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 115V 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 9.1 Power supply

10 Gas connections

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

Figure 10.1 Gas inlets

CO_2 inlet should be connected to a 100% concentration CO_2. CO_2 control in the compartment is available in the range from 1.9% 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 3.9% - 19.9% by infusing N_2.

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

☞ Gas pressure for both inlets should be between 0.4 – 0.6 bar (5.80 – 8.70 PSI) and it must be kept stable!

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

Figure 10.2 Pressure regulator

Connect the CO_2 gas to the CO_2 inlet with a suitable silicone tube. Ensure 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 / CO_2 inlet to the premixed Bottle.

Figure 10.3 Gas filter

☞ Mini MIRI® Dry or Mini 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 in the "13 Installation with premixed gas" section below for more information about using the device on premixed gas.

11 HEPA/VOC filter (not available in the Mini MIRI® Humidity)

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

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

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

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

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

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

A combined HEPA and VOC filter (carbon filter) are integrated into the Mini MIRI® Dry incubator's construction. Before entering the incubator, the gas is sent through the filter in a single pass. Then upon return from the compartment, the gas is filtered again. The recirculation system constantly filters the gas present in the incubator.

The combined HEPA and VOC filter is mounted on the back of the device for easy access and replacement (only in Mini MIRI® Dry incubator).

11.1 Installation of new filter capsule (only in the Mini MIRI® Dry incubator)

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

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

Start by putting the blue fittings on the filter into the filter holder sockets. The flow arrow on the incubator and the filter should point in the same direction.

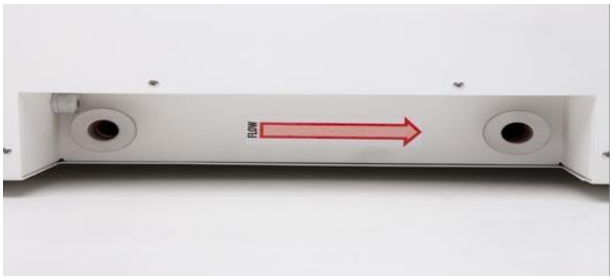


Figure 11.1 The flow arrow on the incubator

Figure 11.2 The way of pulling the filter

Figure 11.3 Filter in place

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

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

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

⚠ **Never run the Mini MIRI® Dry incubator with the filter element missing! Dangerous particle contamination could occur**!

12 User interface

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

User interface handles daily used functions and more advanced adjustments that might be made to the device. The main keys and their purpose are presented in table 12.1.

Table 12.1 The main keys and their purpose

Description	Image
Rotary button Use to toggle and select items on the menu to change their status. It is also used to change the temperature and gas set points values	
ON/OFF button It is 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 automatically 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	

12.1 Activating the heat and gas controls

Heat and gas control systems are activated using the "ON/OFF" switch in the rear.
Soon after system activation the main display will 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 rotatory button for 3 seconds to access menu.

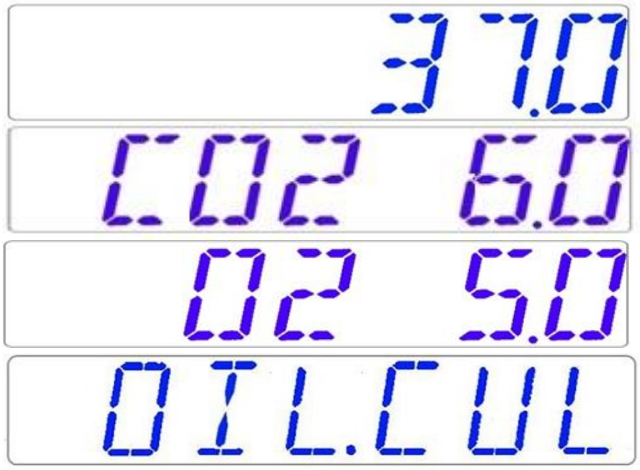
Navigate in the menu by:

- Rotating rotatory button clockwise (↻) or anticlockwise (↺) = previous OR next
- Pressing rotatory button = enter, change OR accept

Rotate the rotatory button (↺) to exit the menu entirely.

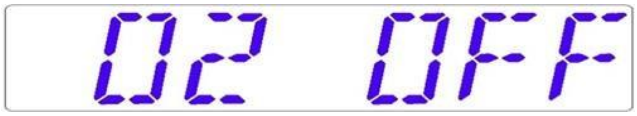
12.3 Status

Alternating between the 4 values under normal running conditions:



Force scroll between parameters with rotating rotatory button (↻) or (↺).

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

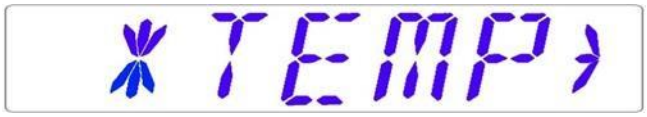


If the use mode is Open Culture (no oil or Paraffin overlay culture), the device shall be set for that and will display:

12.4 Main menu

Press the rotatory button – enter the menu.
You can exit the menu by rotating the rotatory button (↺).

Temperature is the first category when you enter the menu.
You can press the rotatory button to enter the Temperature sub-menu.



Rotate the rotatory button (↻) to scroll further down in the menu.
You can press the rotatory button to enter the CO_2 sub-menu.

Rotate the rotatory button (↻) to scroll further down in the menu.
You can press the rotatory button to enter the O_2 sub-menu.

Rotate the rotatory button (↻) to scroll further down in the menu.
You can press the rotatory button to enter the UVC light sub-menu (not available in Mini MIRI® Humidity).

Rotate the rotatory button (↻) to scroll further down in the menu.
You can press the rotatory button to enter the Service sub-menu.

12.4.1 Temperature sub-menu

Press the rotatory button on the temperature menu to enter the temperature sub-menu.
Calibrate temperature by pressing the rotatory button and rotating it (↻) or (↺) to adjust.

Move to the next sub-menu item with (↻) rotation or one step up with (↺) rotation.

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 the rotatory button. The display should show:

Rotate the rotatory button (↻) until the temperature measured by the thermometer is displayed on the panel. In this case, we want to adjust to 37.4 °C. Rotate (↻) till the display shows 37.0, 37.1, 37.2, 37.3 and 37.4. When temperature equals measured temperature, press the rotatory button. The value is stored and the temperature sensor for the T1 area has been modified.

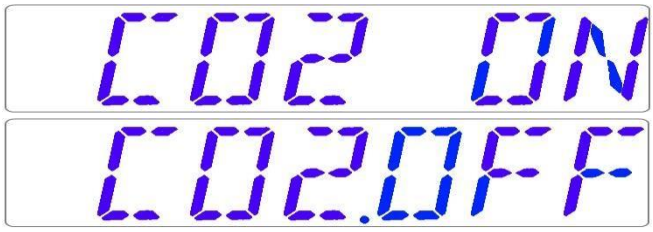
☞ **Calibration procedure is the same for T1 – T4.**

12.4.2 CO_2 sub-menu

Press the rotatory button on the CO_2 menu to enter the CO_2 sub-menu.
Calibrate CO_2 by pressing the rotatory button and rotating it (↻) or (↺) to adjust.

Move to the next CO_2 sub-menu item with (↻) rotation or one step up with (↺) rotation.

Toggle CO_2 regulation on/off by pressing the rotatory button and rotating it (↻) or (↺).

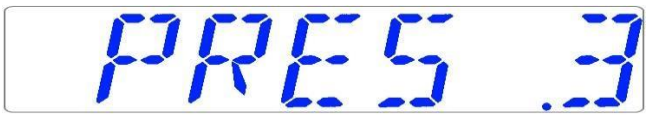


☞ **The Default status for the CO_2 control is OFF.**

Move to the next CO_2 sub-menu item with (↻) rotation or one step up with (↺) rotation. 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.

Move to the next CO_2 sub-menu item with (↻) rotation or one step up with (↺) rotation. CO_2 internal pressure rate is shown (it cannot be adjusted on the incubator and 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 concentration 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 rotatory button. The display should show:

Rotate rotator button (↻) to adjust the CO_2 calibration to the desired level by (↻) or (↺) rotation. In this case, we want to change to 6.4%. Rotate (↻) till the display shows 6.0, 6.1, 6.2, 6.3 and 6.4. When CO_2 equals measured CO_2, press the rotatory button. The value is stored and the CO_2 sensor calibration has been modified.

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

☞ **Calibration is done by adjusting the CO_2 level according to a measurement taken from the gas sampling outlet, using a precision CO_2 measurement device only.**

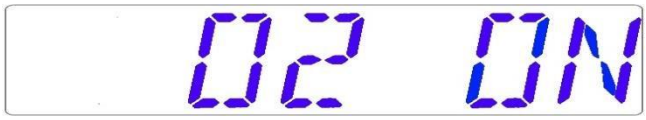
⚠ **Calibration values should only be changed based on measurements taken by a trained user or technician.**

12.4.3 O_2 sub-menu

Press the rotatory button on the O_2 menu to enter the O_2 sub-menu.
Calibrate O_2 by pressing the rotatory button and rotating it (↻) or (↺) to adjust.

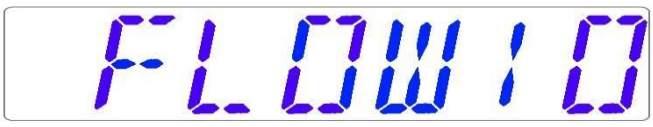
Move to the next O_2 sub-menu item with (↻) rotation or one step up with (↺) rotation.

Toggle O_2 regulation on/off by pressing the rotatory button and rotating it (↻) or (↺).



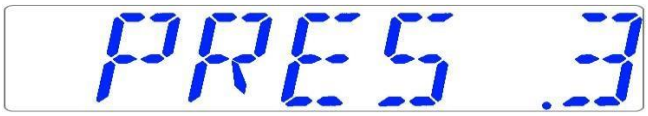
☞ **The Default status for the O_2 control is OFF.**

Move to the next O_2 sub-menu item with (↻) rotation or one step up with (↺) rotation.
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.

Move to the next O_2 sub-menu item with (↻) rotation or one step up with (↺) rotation.
N_2 internal pressure rate is shown (it cannot be adjusted on the incubator and 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 O_2:

O_2 gas concentration has to be measured with a suitable and calibrated device. The real O_2 concertation 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 rotatory button. The display should show:

Rotate rotator button (↻) to adjust the O_2 calibration to the desired level by (↻) or (↺) rotation. In this case, we want to change to 5.3%. Rotate (↻) till the display shows 5.0, 5.1, 5.2 and 5.3. When O_2 equals to measured O_2, press the rotatory button. The value is stored and the O_2 sensor calibration has been modified.

☞ **Calibration is done by adjusting the O_2 level according to a measurement taken from the gas sampling outlet, using a precision O_2 measurement device only.**

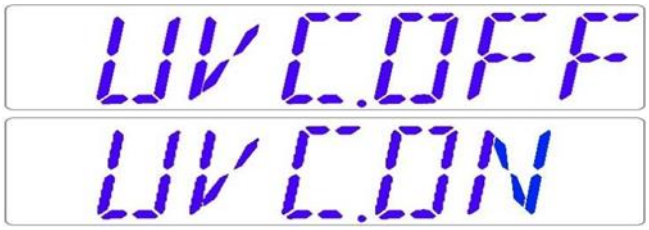
☞ **Calibration values should only be changed based on measurements taken by a trained user or technician.**

12.4.4 UV-C light sub-menu (the functionality is not available in the US):

☞ **UVC light function is not available in the Mini MIRI® Humidity incubator.**

Press the rotatory button on the UV-C menu to enter the UV-C light sub-menu.

Toggle UV-C light regulation on/off by pressing the rotatory button and rotating it (↻) or (↺).



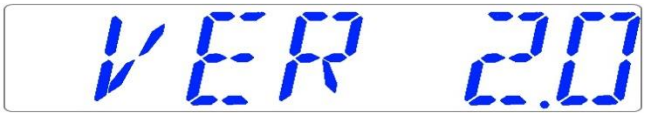
The default status for the UV-C light is on.

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

For optimal air cleaning, it is recommended to have the UV-C light set to ON when the unit is being used.

12.4.5 Service sub-menu

Press the rotatory button on the service menu to enter the service sub-menu.
The display will show 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 (↻) rotation or one step up with (↺) rotation.

The display will show the "GAS" function:

Press the rotatory button to enter the service sub-menu and rotate (↻) or (↺) to choose "PREMIX" or "CO_2/O_2". Press the rotatory button to chooses premixed or CO_2/O_2 gas mode.

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 a 5% CO_2 gas setpoint, premixed gas should have 6 % CO_2 in its mixture.

Then exit the menu by (↺) or press the rotatory button and hold it until the main menu does not appear.

13 Installation with premixed gas

Mini MIRI® Dry and Mini 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. 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 Mini MIRI® Dry or Mini 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 concentration cannot be altered by Mini MIRI® Dry or Mini MIRI® Humidity incubators, the media's resulting pH will depend on the correct choice of concentration.**

☞ **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 Mini MIRI® Dry or Mini MIRI® Humidity incubators to either only 100% CO_2 or both 100% CO_2 and 100% N_2, the incubator is attached to only a premixed source.

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

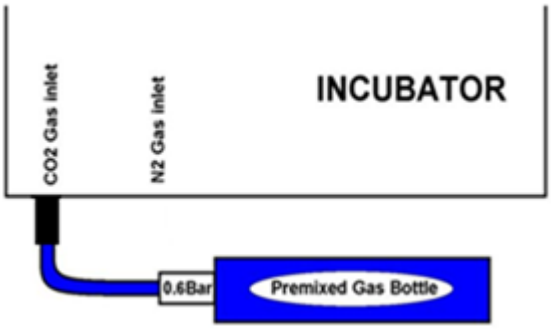


Figure 13.1 Premixed gas connections to the incubator

Please read the "10 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.

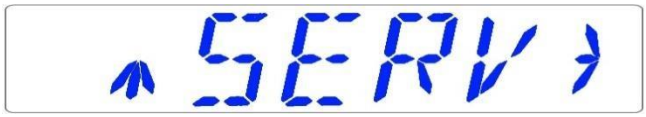
CO_2 regulation must be "ON" in Mini MIRI® Dry and Mini MIRI® Humidity incubators menu. CO_2 is generally as a default set to "ON" and O_2 to "OFF".

Mini MIRI® Dry and Mini MIRI® Humidity incubators must be set to premix gas work mode.

Please follow these instructions:

Press the rotatory button – enter the menu.
You can exit the menu by rotating the rotatory button (↺).

Press the rotatory button on the service menu to enter the service sub-menu.



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

The display will show the "GAS" function:

Press the rotatory button to enter the service sub-menu and rotate (↻) or (↺) to choose "PREMIX". Press the rotatory button to select the premixed gas work mode.

Then exit the menu by (↺) or press the rotatory button and hold it until the main menu does not appear.

☞ 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 0.1 higher than the premixed gas measured value gas (i.e., 5.1% if 5.0% 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.

⚠ Mini MIRI® Dry and Mini MIRI® Humidity incubators contain 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, Mini MIRI® Dry and Mini 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. Mini MIRI® Dry and Mini MIRI® Humidity incubators cannot change the gas composition of the premixed gas.
3. If the media's pH is not correct, they must get a new mixture of premixed gas. They cannot adjust anything on the incubator.
4. If they change to another concentration, Mini MIRI® Dry and Mini MIRI® Humidity 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 2 compartments can trigger a temperature alarm if their temperature varies over ± 0.5 °C from the set point.

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 2:

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.

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 set point 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:

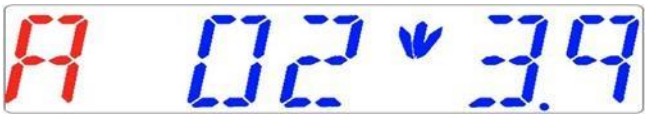
The display will lock-on the alarm condition and will stop alternating between the standard status messages. If the mute key is pressed, the display will shift to normal status and show the parameters for 5 minutes until the audio alarm comes back on again. The mute alarm key will still show the alarm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

14.2.2 O_2 alarms

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

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

O_2 gas % is too low:



O_2 gas % is too high:

The display will lock-on the alarm condition and will stop alternating between the standard status messages. If the mute 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 Mini MIRI® incubator will go into CO_2 gas 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 Mini MIRI® Multiroom incubator will go into N_2 gas pressure alarm mode. The display will show "N_2 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

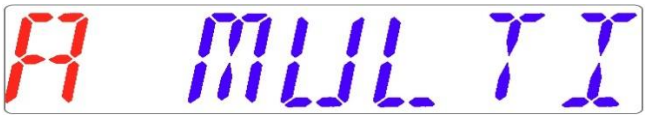
the alarm.

"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 concurrent 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 gas pressure alarms 3rd.

14.5 Alarm UV-C light (the functionality is not available in the US)

UV-C light function is not available in the Mini MIRI® Humidity incubator.

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

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

14.6 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 set points

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 set point is 37.0 °C.

To change the temperature setpoint, follow these instructions:

1. When the display shows the current temperature:

2. Press the rotatory button and rotate (↻) or (↺) to adjust the set point.
3. After changing the temperature value, press the rotatory button to save the set-point.

If the display does not show the current temperature reading, rotatory button rotation (↻) or (↺) will toggle between the temperature, CO_2, O_2 and mode readings.

15.2 CO_2 gas concentration set point

The CO_2 concentration can be adjusted in the range between 1.9% to 9.9%.

The default CO_2 setpoint is 6.0%.

To change the CO_2 gas concentration set point, follow these instructions:

1. When the display shows the CO_2 gas concentration:

2. Press the rotatory button and rotate (↻) or (↺) to adjust the set point.

3. After changing the value, press the rotatory key once more to save the value.

If the display does not show the current temperature reading, rotatory button rotation (↻) or (↺) will toggle between the temperature, CO_2, O_2 and mode readings.

15.3 O_2 gas concentration set point

The O_2 concentration can be adjusted in the range between 3.9% to 19.9%.

☞The default O_2 setpoint is 5.0 %

To change the O_2 gas concentration set point, follow these instructions:

1. When the display shows the O_2 gas concentration:

2. Press the rotatory button and rotate (↻) or (↺) to adjust the set point.
3. After changing the value, press the rotatory key once more to save the value.

If the display does not show the current temperature reading, rotatory button rotation (↻) or (↺) 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 in the culture media has an oil or paraffin overlay. Open culture is used if 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. Press the rotatory button and rotate (↻) or (↺) to change the mode.
3. When the display shows the desired/correct mode, press the rotatory button. The mode is now set.

If the display does not show the current mode reading, rotatory button rotation (↻) or (↺) 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. Culturing up to 8 hours in 0.8 mL volumes can be done with a nearly unchanged osmolality.

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 dish). If the media stays longer without oil coverage, a high risk of media osmolality changes appear.

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

16 Surface temperatures and measuring temperature

In this section, Mini MIRI® Dry and Mini MIRI® Humidity incubators temperature controls system is described in more detail.

Mini MIRI® Dry and Mini MIRI® Humidity incubators are equipped with 4 completely separate PID controllers for temperature measurement. Each controller is responsible for controlling the temperature of a separate area.

Each of the 4 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

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 and T4 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	T3
Compartment 2	T2	T4

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 correct temperatures 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 2 compartments: this is a unique feature of Mini MIRI® Dry and Mini MIRI® Humidity incubators. Lid temperature will, however, affect the bottom temperature in a compartment. The delta-T should always be 0.2 °C. Thus, if the bottom temperature is 37.0 °C, the lid should be 37.2 °C.**

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

☞ **"T1" is used to adjust the bottom temperature of compartment 1. "T3" is used to adjust the temperature on the lid in the same compartment. Remember that the delta-T between the top and the bottom should always be 0.2 °C.**

☞ **Adjust according to a high precision measurement done with a suitable sensor**

placed in a dish with media and a mineral oil overlay. Place the dish in one of the designated spots indicated on the heating insert.

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

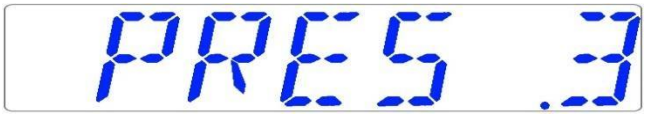
Stick a suitably calibrated sensor to the middle of the lid area and close the lid. Wait 15 minutes and record temperature reading. Adjust "T3" to the desired level, using the same procedure as described above. It may be necessary to do iterations before the zone is thoroughly calibrated.

The 2nd compartment is adjusted/calibrated in the same manner.

17 Pressure

17.1 CO_2 gas pressure

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



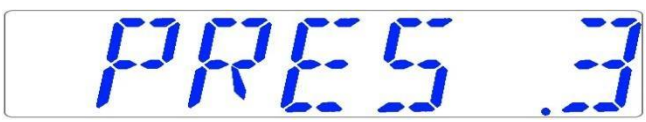
The CO_2 pressure is shown in a bar. External pressure must be between 0.4 – 0.6 bar (5.80 –8.70 PSI) at all times. It cannot be adjusted on the incubator; it must be done on the external gas regulator.

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, it will remain without drift for the device's lifetime.

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 a 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).

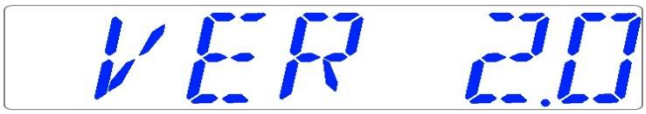
☞The internal pressure sensor cannot be calibrated by the user. Under normal circumstances, it will remain without drift for the device's lifetime.

18 Firmware

The firmware installed on your Mini MIRI® Dry or Mini MIRI® Humidity incubators is upgradeable. Whenever a critical update is available, it will be provided to our distributors around the world – they will make sure that your 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 rotate the rotatory button (↻). The display will show 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. Rotate the rotatory button (↺) to exit back to the menu.

19 Safe sense function

There is a possibility to purchase Mini MIRI® Dry or Mini 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.

20 Cleaning instructions

20.1 Considerations about a sterile device

Mini MIRI® Dry and Mini MIRI® Humidity incubators are not sterile devices. They are not delivered sterile state and it is not possible to keep them sterile while 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 HEPA filter continually cleans the incoming gas
- A HEPA/VOC filter, which continually cleans the air inside the system (not available in the Mini MIRI® Humidity)
- 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

20.2 Manufacturer recommended cleaning procedure

Always validate the cleaning procedures locally; for more guidance, consult 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. Also, it is recommended to clean and disinfect Mini MIRI® incubators 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 (Gamma Wipe® 300) and clean all the device's internal and external surfaces by rubbing the wipe against the surfaces.
2. After wiping, leave the device's lids open for some time to ensure that all alcohol fumes evaporate.
3. Finally, use purified or sterile water is used to wipe the surfaces of the device.
4. Inspect the device – if it is visually clean, consider it ready for use.

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

20.3 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 Mini MIRI® Dry or Mini MIRI® Humidity incubator (rear panel).
2. Open the lids.
3. Use EcaFlo® Anolyte to disinfect the internal surface and a glass plate on the top of the lid. Use sterile wipes (Gamma Wipe® 300) to apply EcaFLo® Anolyte.
4. Wipe all internal surfaces and the top of the lid with three wipes at least. Repeat until the wipes are not 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 (Gamma Wipe® 300).
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 Mini MIRI® incubator (rear panel).

21 Heat optimization plates

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

⚠ **Do not use autoclave at the inserts. It will damage the inserts as high temperature bends them out of shape.**
Place the dish where it fits the pattern. The heat optimization plates can be applicable for both Nunc® or Falcon® dishes.

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

Figure 21.1 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.**

22 Humidification

22.1 The Mini MIRI® Humidity incubator

The Mini 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.

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

22.2 The Mini MIRI® Dry incubator

The Mini MIRI® Dry incubator is used for culture with mineral oil or Paraffin overlay. Set the culture mode for "Oil culture". It cannot be used for open culture mode.

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

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. Culturing up to 8 hours in 0.8 mL volumes can be done with a nearly unchanged osmolality.

If you have any questions, please consult Esco Medical or your local representative before you do open culture in the Mini MIRI® Dry incubator.

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

23 Temperature validation

Mini MIRI® Dry and Mini MIRI® Humidity incubators are equipped with 2 PT-1000 Class-B sensors located in the center of each compartment's bottom.

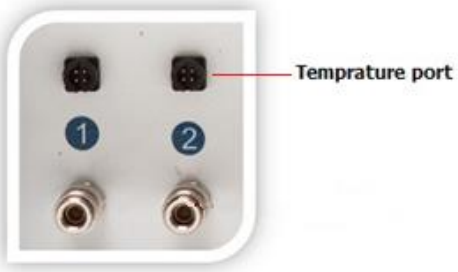


Figure 23.1 PT-1000 Class B sensors

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.

24 Gas level validation

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

Figure 24.1 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 continuous 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.

25 Alarm switch for an external system

Mini MIRI® Dry and Mini 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 illustrated below.

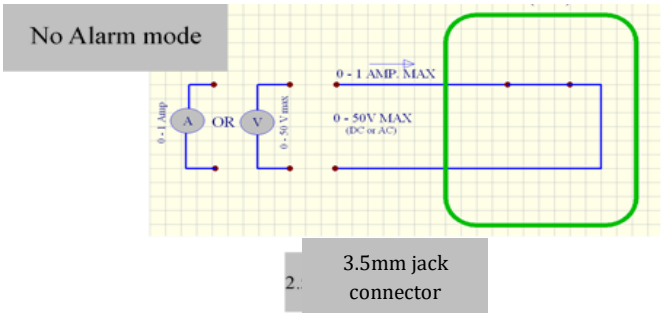


Figure 25.1 No alarm mode

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

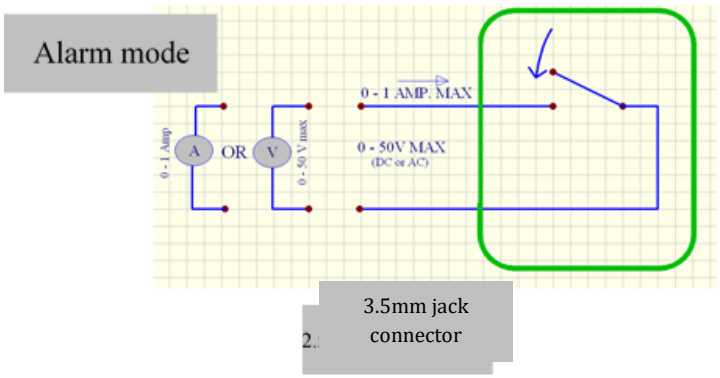


Figure 25.2 "Open circuit" alarm mode

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.

26 Writing area on the compartment lids

Each compartment lid on the Mini MIRI® Dry or Mini 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 26.1 Area for patient information

27 Maintenance

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

1. Correct calibration of temperature and gas level, using high-precision equipment in the intervals prescribed based on clinical practice at the laboratory, where the Mini MIRI® Dry or Mini MIRI® Humidity incubators are in use. The manufacturer recommends that the period between validation should be no longer than 14 days.
2. Replacement of VOC/HEPA filter and in-line HEPA filters at the correct intervals: 3 months for the VOC/HEPA filter and once at every changeover of the gas bottle for the in-line HEPA filters.
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 Mini MIRI® Dry and Mini MIRI® Humidity incubators are used. The manufacturer does not recommend periods longer than 14 days between cleaning.

⚠ **It is essential to perform the inspection and service at the intervals indicated in the MAINTENANCE manual. Failure to do so can have serious adverse outcomes, causing the unit to stop performing 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.**

28 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 Mini MIRI® Dry and Mini MIRI® Humidity 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 CO_2 level is low; keep the lids shut. If the state is temporary CO_2 level is high; open a few lids to vent out some of the 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 superficial 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.

29 User Troubleshooting

Table 29.1 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 29.2 CO_2 gas regulator

Symptom	Cause	Action
No CO_2 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 'CO2' to 'on' in the menu
	No CO_2 gas 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 set point
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 set point	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 29.3 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 O_2 gas regulator by setting 'O2' to 'on' in the menu
	No N_2 gas or wrong gas type attached to N_2 gas input	Check the N_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 O_2 gas set point
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 set point	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 the N_2 gas supply, make sure that pressure is kept 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 29.4 Data Logger

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 29.5 Display

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

Table 29.6 Keyboard

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

30 Specifications

Table 30.1 Mini MIRI® Dry and Mini MIRI® Humidity incubators specification

Technical specifications	Mini MIRI® Dry or Mini MIRI® Humidity incubator
Overall dimensions (WxDxH)	525 x 420 x 230 mm
Net weight	22 kg
Shipping weight	32 kg
Shipping dimensions (WxDxH)	700 x 600 x 470 mm
Material	Mild steel / Aluminum / PET / Stainless steel
Power supply	115V 60Hz OR 230V 50Hz
Power consumption	90 W
Temperature control range	24.9 – 40 °C
Gas consumptions (CO_2)[2]	<2 liters per hour
Gas consumption (N_2)[3]	<5 liters per hour
Premixed gas consumption	In purge < 50 l/h In normal c run < 1 l/h
CO_2 control range	1.9 % – 9.9%
O_2 control range	3.9 % – 19.9%
CO_2 gas pressure (input)	0.4 – 0.6 bar (5.80 – 8.70 PSI)
N_2 gas pressure (input)	0.4 – 0.6 bar (5.80 – 8.70 PSI)
Alarms	Audible and visible for out-of-range temperature, gas concentration and gas pressure.
Shelf life	1 year

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

31 Electromagnetic compatibility

Table 31.1 Electromagnetic emissions

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

Table 31.2 Electromagnetic immunity

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

Guidance and manufacturer's declaration – electromagnetic immunity			
Mini MIRI® Dry and Mini MIRI® Humidity incubators are intended for use in the electromagnetic environment specified below. The customer or the user of Mini MIRI® Dry or Mini MIRI® Humidity incubators should assure 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 Mini MIRI® Dry or Mini 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be lower than the compliance level in each frequency range Interference may occur in the vicinity of the equipment.

Table 31.3 Recommended separation distances

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

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

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