ESCO MEDICAL Life has begun

CE 0088

USER MANUAL

Multi room incubator MIRI®

Rev. 3.2
Date of Revised 06.12.2019
Rx only

CERTIFIED INCUBATION

For Technical Service, contact
North America
Esco Technologies, Inc.
2940 Turnpike Drive, Units 15-16 • Hatboro, PA 19040, USA
Toll-Free USA and Canada 1-877-479-3726
Tel 215-441-9661 • Fax 215-441-9660
us.escoglobal.com • usa@escoglobal.com

Rest of the World
Esco Micro Pte. Ltd.
21 Changi South Street 1 • Singapore 486 777
Tel +65 6542 0833 • Fax +65 6542 6920
www.escoglobal.com • mail@escoglobal.com

Copyright Information

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

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 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. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim.

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

Standard Terms and Conditions

Refunds & Credits

Please note only serialized products (products labelled with a distinct serial number) and accessories are eligible for 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, and 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 which 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 normal use, and service for two (2) years from the date of original purchase, provided the instrument is calibrated and maintained in accordance with 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 and all transportation charges incurred are the responsibility of the purchaser and are not included within this warranty. This warranty extends only to the original purchaser and 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 damage is caused by any of the following:

- Power failure, surges, or spikes
- Damage in transit or when moving the instrument
- 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 the warranty.

Warranty Disclaimer

Should you choose to have your instrument 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 application beyond the published specifications may result in 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 cover to cover. This means that if the manual is read, from start to finish, there will be some repetition and overlap. We recommend the following method to go through the manual: first, familiarize yourself with the safety instructions; then proceed to the basic user functions that are needed for operating the equipment on a day to day basis; then review the alarm functions. The menu function of the user interface details information that is needed for the advanced level of users only. 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 fixed properly 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 individual.
• 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

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® Incubator is intended to be used to provide a controlled environment for the development of gametes and embryos during in vitro fertilization (IVF)/ assisted reproduction technology (ART) treatments. This includes controlled temperature (at or near body temperature), controlled gas levels (CO_2, O_2, and N_2).

4 About the product

The Esco Medical MIRI® incubator is a new generation of desktop CO_2 and O_2 incubator.

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

The MIRI® incubator has 6 fully independent culture heat chambers, each with its own heated bottom, heated lid and a heating optimization plate. The heating optimization plates are customized to accommodate several types of dishes e.g. Falcon®, Nunc®, Sparmed® or Vitrolife®.

For maximum performance, the system has 12 individual temperature controllers, controlling and regulating the temperature in the culture chambers and the lids.

The Incubator needs 100% CO_2 and 100% N_2 in order to be able to control the CO_2 and O_2 concentrations in the culture chambers.

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

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 to open culture mode.

☞ Open culture may lead to evaporation and a change in pH if the correct conditions are not maintained.

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

The device is manufactured under a full EU certified ISO quality management system.

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

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

5 Accessories supplied

- 1 VOC/HEPA filter capsule
- 2 HEPA filters for input gas supply
- 6 warming blocks for Nunc®, Falcon®, Sparmed® or VitroLife®
- 1 USB stick containing Esco Medical Data logger software and PDF versions of the manuals
- 1 data cable
- 1 alarm port jack mono 3.5 mm tubes with fast coupling connectors set

6 Manuals supplied

The MIRI® incubator comes with 3 manuals as standard:

1. The User Manual (this manual)
2. The Validation Manual
3. The Maintenance Manual

Each manual has a specific purpose.

6.1 The user manual

Is intended to provide the user with information necessary for using the device.

☞ **The user manual cannot stand alone nor replace user training.**

6.2 The validation manual

Is intended for trained technical personnel performing the installation, detailing the procedures and specifications needed to ensure that the device is safe and can be taken into clinical use. The manual can also be used as a guide for validation tests that should be performed regularly.

6.3 The maintenance manual

Is also intended for trained technical personnel, detailing the schedules and methods to ensure that the device runs optimally and safely during its lifespan.

☞ **The maintenance specified in the maintenance manual cannot replace the regular maintenance/validation that must be performed by the user.**

7 Safety symbols and labels

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

Table 7.1 Labels

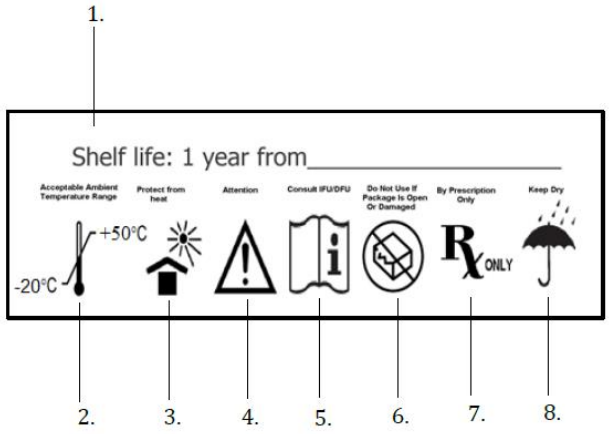
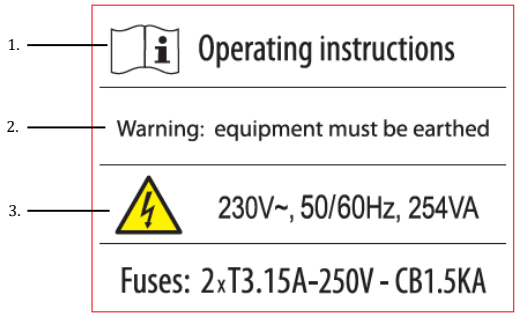
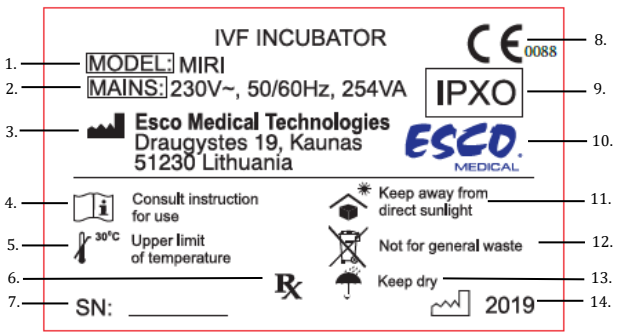
Description	Image
Packing box label: 1. If stored longer than one year from manufacture date, the unit must be returned to the manufacturer for a new release test. 2. Shipping temperature between -20°C and +50°C. 3. Keep away from direct sunlight. 4. Caution: consult the accompanying documents for important safety-related information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself. 5. Consult instructions for proper use of the device. 6. Do not use if the packing material is damaged. 7. Rx Only. 8. Keep dry.	
1. Consult instruction for use. 2. Warning on the back of the device indicates that an earth connection is needed, mains information, and "ON/OFF" push-push button. 3. "Lightning bolt" indicates the potential risk of electrical shock (never remove any cover)	
1. Model 2. Mains power rating 3. Manufacturers address and country of origin 4. Consult instruction for use 5. Temperature limit 6. Rx only 7. Serial number 8. CE mark 9. Not protected against ingress of water 10. Logo 11. Keep away from direct sunlight 12. Observe WEEE 13. Keep dry 14. Year of manufacture	

Table 7.2 Labels on the back of MIRI®

Description	Image
USB communication port	USB communication port
CO_2 inlet	CO_2 100% Inlet
N_2 inlet	N_2 100% Inlet
BNC pH	BNC pH
Alarm port	Alarm port
Compartments numbers are indicated in the top corner of the lid with a label	1 2 3

Compartment numbers are shown in the picture below and also indicated on the top of the lid 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 completely 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 up
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
9. Use only 100% concentration CO_2 and 100% concentration N_2 gas
10. Always use an external HEPA filter for input CO_2 and N_2 gas
11. Do not use this product at temperatures exceeding 30^{o}C
12. Place this unit in a location with adequate ventilation to prevent internal heat build-up. Allow at least 10 cm clearance from the rear, 30 cm from the top and 20 cm from left and right to prevent overheating, and to 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)

8.3 Post installation

1. Refer all servicing to qualified service personnel
2. Servicing is required according to the service manual, or if the apparatus has been damaged in any way, e.g. if the apparatus has been dropped, exposed to rain or moisture, or does not operate normally. The MIRI® incubator contains high voltage components that may be hazardous
3. Unplug this apparatus during lightning storms or when unused for a long 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. UV lamp must be changed at the interval described in the manuals (not available in the US)
7. O_2 sensor must be changed at the interval described in the manuals
8. Never leave lids open for more than 10 seconds while in use
9. VOC/HEPA filters must be changed at the interval described in the manuals
10. NEVER block gas supply holes in the compartment
11. Make sure that CO_2 and N_2 gas supply pressures are kept stable at 0.6 bar (8.70 PSI)
12. Never use a non-Esco Medical filter; it will void the warranty
13. Do not use the product without a proper Esco Medical VOC/HEPA filter attached

9 Getting started

⚠ **The MIRI® 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® incubator
4. Connect the gas lines
5. Set the gas pressure on the external gas regulator at 0.6 bar (8.70 PSI)
6. Switch on the MIRI® in the back
7. Observe for normal function
8. Let the unit warm up and stabilize for 20 min
9. Follow the guidelines in the validation guide
10. Complete user training and 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 manufacturers recommended guidelines!**

10 Mains connection

The MIRI® 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 in. The on/off switch provides the user with a means to isolate the incubator from the mains.

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

Figure 10.1 Power supply

11 Gas connections

On the back of the unit there are two gas inlets. These ports are marked "CO_2" and "N_2".

Figure 11.1 Gas inlet

The CO_2 inlet should be connected to 100% concentration CO_2.

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 20% - 4.9% by infusing N_2.

Gas pressure for inlet should be 0.6 bar (8.70 PSI) and it must be kept stable!

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

Figure 11.2 Pressure regulator

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

Figure 11.3 Gas filter

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

The MIRI® can also run on premixed gas. It is a more expensive option regarding gas consumption. It also means the user cannot adjust the CO_2 and O_2 levels without changing the gas supply. If premixed gas is used, request a copy of the premixed gas manual from Esco Medical or the local representative.

12 HEPA / VOC filter

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

VOCs can also occur in medical gases, such as CO_2 and nitrogen. It is important to use inline VOC filters for your medical gasses 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, count below 0.5 ppm is recommended; total VOCs should be below <0.2 ppm, or preferably zero.

High VOCs levels (over 1 ppm) are toxic to embryos: You will see poor mouse test results and very poor human embryo development, probably not even making it to 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) is integrated in the construction of the MIRI®. Prior to 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 ease of access and replacement.

12.1 Installation of new filter capsule

The two blue caps that are installed on the filter can be discarded during unwrapping.

Correct filter performance is crucial for the 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 12.1 The flow arrow on the incubator

Figure 12.2 The way of pulling filter

Figure 12.3 Filter in place

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

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

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

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

13 User interface

In the next chapters, the functions associated with the keys and menu items are explained.

The user interface handles the daily use functions and the more advanced adjustments that are possible on the device. The table 13.1 shows the main keys and their purpose.

Table 13.1 Main keys and their purpose

Description	Image
Main keys	
On/off In the REAR of the unit	
Alarm key – Is used to mute an audible alarm and indicates the alarm condition visually by a flashing red circle of light. The audio alarm will automatically 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	
Set point – Is used to select items on the menu to change their status. It is also used to change the temperature and gas set points	
Arrow keys up, down & right – Are used to navigate through the menu, and changing values for temperature and gas concentrations	

13.1 Activating the heat and gas controls

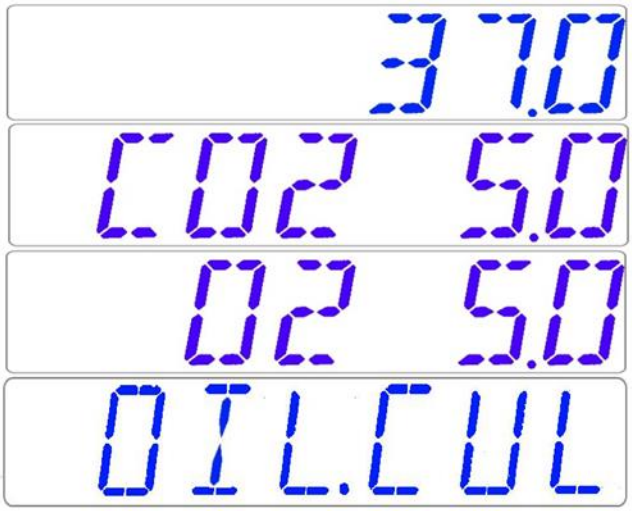
The heat and gas controls are activated using the on/off switch in the rear.

Soon after system activation the main display will alternate the reading between the following 3 parameters:

Temperature	= Temperature in °C
CO_2	= CO_2 Concentration in %
O_2	= O_2 Concentration in %

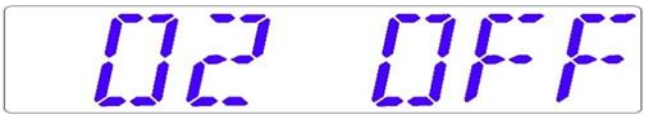
13.2 Status

Alternating between the 4 values under normal running conditions.



Force scroll between parameters with arrow right.

☞ **If 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:**

13.3 System menu

- Press and hold arrow up (⇧) and arrow down (⇩) together for 3 seconds to access menu
- Navigate in menu using:
  - arrow right (⇨) = enter
  - up and down (⇧) and (⇩) = previous OR next
  - SP/Enter = change OR accept
- Press and hold (⇧) and (⇩) together for 3 seconds to exit the menu completely

13.3.1 Main menu

Press (⇨) – enter menu
You can exit the menu by pressing (⇧)

Temperature is the first category when you enter the menu

You can press (⇨) to enter the Temperature sub-menu

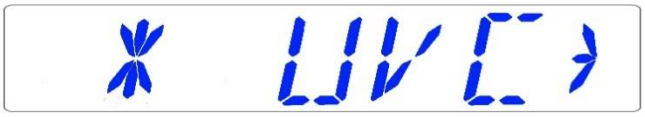
Press (⇩) to scroll further down in menu

You can press (⇨) to enter the CO_2 sub-menu

Press (⇩) to scroll further down in menu

You can press (⇨) to enter the O_2 sub-menu

Press (⇩) to scroll further down in menu



You can press (⇨) to enter the UVC light sub-menu

Press (⇩) to scroll to the last category on the menu

You can press (⇨) to enter the Service sub-menu

13.3.2 Temperature sub-menu

Press (⇨) on temp to enter the temperature sub-menu

Calibrate holding down the SP key and using (⇧) and (⇩) to adjust

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

Note: calibration procedure it the same for T1 – T12.

Example - How to calibrate the temperature:
Note: (the procedure is same for T1 – T12)

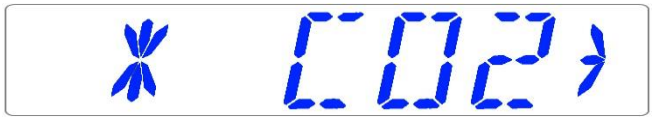
With a quality thermometer, it has been noted that T1 is 37.4°C. Locate T1 in the sub-menu:

1. Press and hold the SP key. This display will show:

2. Adjust the temperature by pressing (⇧) 4 times while still holding the SP key down. The display will show the steps from 37.1°C, 37.2°C, 37.3°C and 37.4°C.

3. Let go of the SP key: The value is now stored and calibration value for the T1 area temperature has been modified.

13.3.3 CO_2 sub-menu



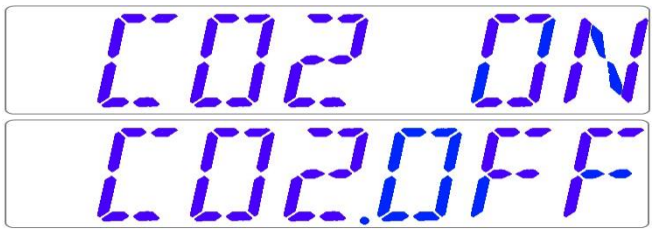
Press (⇨) on CO_2 to enter the CO_2 sub-menu

First item in the CO_2 sub-menu is CO_2 sensor calibration:

Calibrate holding down the SP key and using (⇧) and (⇩) to adjust

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

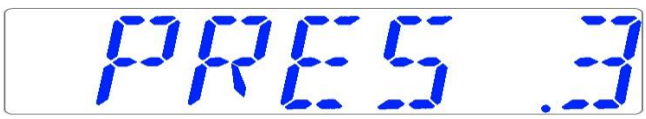
Toggle CO_2 regulation on/off by holding SP key and pressing (⇧) or (⇩)



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

CO_2 flow rate is shown, it cannot be adjusted. This is the amount of CO_2 gas put into the system while regulating. The volume is shown in liters/hour. Normally it will fluctuate along with the CO_2 regulation

Press (⇩) to move to the next item in the CO_2 sub-menu:



CO_2 internal pressure rate is shown. The value is in bar. It must be >0.2 to ≤0.8 bar (2.90 – 11.60 PSI) at all times. It cannot be adjusted on the incubator and is adjusted on the external gas regulator

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 recorded 5.4% on one of the gas sample ports. Each port is suitable for this purpose.

☞ 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.

1. Navigate through the menu and find:

2. When the SP key is pressed the display will show:

3. Adjust the calibration to the desired level by pressing (⇧) or (⇩). In this case, we want to adjust to 5.4%. Press (⇧) 4 times. The display will show 5.0; 5.1; 5.2; 5.3 and 5.4.

4. Let go of the SP key. The value is now stored, and the CO_2 sensor calibration has been modified.

13.3.4 O_2 sub-menu

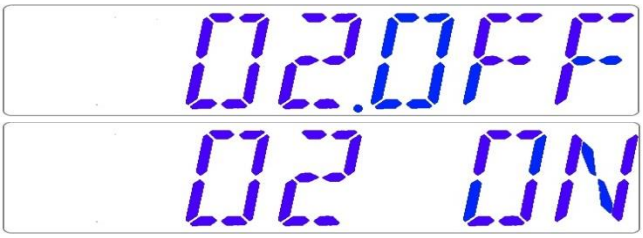
Press (⇨) on O_2 to enter the O_2 sub-menu

First item in the O_2 sub menu is O_2 sensor-1 calibration:

Calibrate holding down the SP key and using (⇧) and (⇩) to adjust

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

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

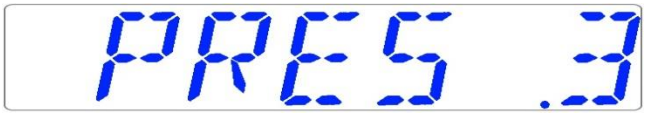


The Default status for the O_2 control is OFF.

Press (⇩) to move to the next item in the O_2 sub menu:

N_2 flow rate is shown. This is the amount of N_2 gas put into the system while regulating. The volume is shown in liters/hour. It cannot be adjusted. Normally it will fluctuate along with the O_2 regulation.

Press (⇩) to move to the next item in the O_2 sub menu:



N_2 internal pressure rate is shown. The value is in bar. It must be >0.2 to ≤0.8 bar (2.90 – 11.60 PSI) at all times. It cannot be adjusted on the incubator, and is adjusted on the external gas regulator.

Example - How to calibrate the O_2:

Using a suitable and calibrated device on one of the gas sample ports, the real O_2 concentration has been recorded as 5.3%. Either of the ports will do for this purpose.

☞ 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.

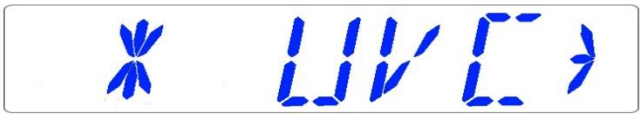
1. Navigate through the menu and find:

2. When the SP key is pressed the display will show:

3. Adjust the calibration to the desired level by pressing (⇧) or (⇩). In this case, we want to adjust to 5.3 %. Press (⇧) 3 times. The display will show 5.0; 5.1; 5.2; and 5.3.

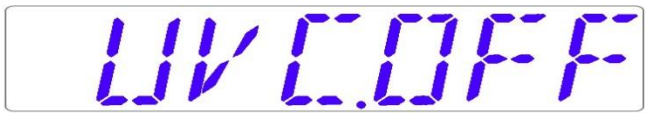
4. Let go of the SP key. The value is now stored, and the O_2 sensor calibration has been modified.

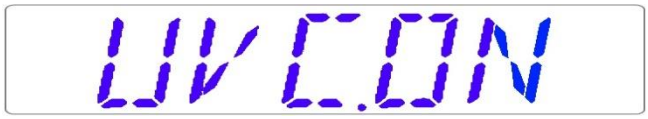
13.3.5 UVC light sub-menu (not available in the US):



Press (⇨) on UVC to enter the UVC light sub-menu

Toggle UVC light on/off by holding SP key and pressing (⇧) or (⇩)





☞ The default status for the UVC light is on.

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

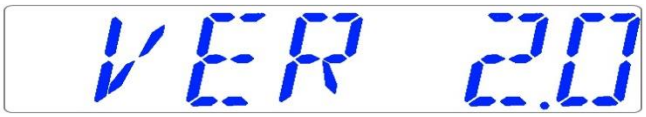
For optimal air cleaning it is recommended to have the UVC light set to ON when unit is being used.

13.3.6 Service sub-menu

Press (⇨) on serv 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.

Press (⇧) *to exit the menu.*

14 Alarms

On single fault condition, the display will show a red “A” along with the status message of the affected parameter. There will be an audio signal that can be muted by pressing the alarm key once (toggled on/off, for a period of 5-minutes). There will also be an arrow indicating 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 indicate 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 set point.

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

Temperature is too high in compartment 3. The display will lock-on the alarm condition and will stop alternating between the normal 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 alarm mute key will still show the alarm condition by blinking red while the alarm is muted.
The zone triggering the alarm will be indicated by the number following "A".
The zone layout and sensor placement are described in section 16.

Temperature is too low in compartment 4.

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

This denotes that the sensor in compartment 2 has failed. As a safety precaution the affected zone's heating will be shut down.

14.2 Gas level alarms

14.2.1 CO_2 alarms

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

☞ Remember that changing the set point more than ±1% from the current gas level will result in a CO_2 level alarm. The same goes for all calibration adjustments.

CO_2 % is too low. The display will lock-on the alarm condition and will stop alternating between the normal status messages.

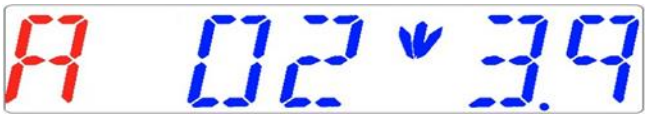
If the mute key is pressed, the display will shift to normal status and show the parameters for 5 minutes, until the audio alarm comes back on again. The alarm mute key will still show the alarm condition by blinking red while the alarm is muted.

CO_2 % is too high.

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 value.

☞ Remember that changing the set point more than ±1% from the current gas level will result in an O_2 level alarm. The same goes for all calibration adjustments.



O_2 % is too low. The display will lock-on the alarm condition and will stop alternating between the normal 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 alarm mute key will still show the alarm condition by blinking red while the alarm is muted.

O_2 % is too high.

14.3 Gas pressure alarms

14.3.1 CO_2 pressure alarm

If the CO_2 gas supply is not attached correctly or an incorrect CO_2 gas pressure is applied to the system, the MIRI® will go into CO_2 pressure alarm mode. “CO2 P” will be displayed, indicating wrong incoming gas pressure. The alarm level is < 0.2 and > 0.8 bar (2.90 – 11.60 PSI).

‘P’ stands for pressure

An audible alarm is also activated which can be muted by pressing the alarm key. 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 alarm mute key will still show the alarm condition by blinking red while the alarm is muted.

14.3.2 N_2 pressure alarm

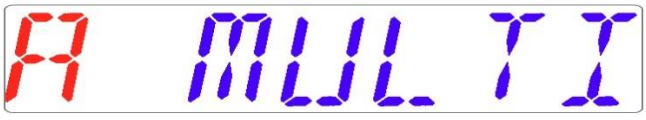
If the N_2 gas supply is not attached correctly or an incorrect N_2 gas pressure is applied to the system, the MIRI® will go into N_2 pressure alarm mode. “N2 P” will be displayed, indicating wrong incoming gas pressure. The alarm level is < 0.2 and > 0.8 bar (2.90 – 11.60 PSI).

‘P’ stands for pressure.

An audible alarm is also activated which can be muted by pressing the alarm key. 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 alarm mute 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 pressure 3rd.

14.5 Alarm UVC light (the functionality is not available in the US)

Alarms on UVC light will show only as a warning message during the normal status:

A red "S" will appear. **There will not be an audio alarm**.

User should consult the distributor for further guidance or service inspection. Only when the UVC light works again will the "S" 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 alarm mute key will flash.

Figure 14.2 Alarm key which indicate the alarm condition

15 Changing the set points

15.1 The temperature set point

The temperature set point can be adjusted in the range between 25.0°C to 40.0°C.

The default temperature set point is 37.0°C

To change the temperature set point, follow these instructions:

1. When the display shows the current temperature:

2. Hold down the SP key and use (⇧) and (⇩) to adjust the set point: one key press corresponds to a 0.1°C change.

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

15.2 The CO2 concentration set point

The CO_2 concentration can be adjusted in the range between 1.9% to 10.0%.

☞ The default CO_2 set point is 5.0 %.

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

1. When the display shows the CO_2 concentration:

2. Hold down the SP key and use (⇧) and (⇩) to adjust the set point: one key press corresponds to a 0.1 % change.

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

15.3 The O_2 concentration set point

The O_2 concentration can be adjusted in the range between 5% to 20%.

☞ The default O_2 set point is 5.0 %

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

1. When the display shows the O_2 concentration:

2. Hold down the SP key and use (⇧) and (⇩) to adjust the set point: one key press corresponds to a 0.1 % change.

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

15.4 The culture mode

The culture mode can be set for under oil culture or open culture.

Under oil culture is used if 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 "Under oil culture"

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 (⇩) 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, (⇨) will toggle between the temperature, CO_2, O_2 and mode readings.

Open culture is possible in a Nunc 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 36-hours. The Osmolality will change rapidly after that and reach over 300 mOsm/kg. Up to 8-hours culturing in 0.8 mL volumes can be done with near unchanged osmolality.

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

16 Surface temperatures and measuring temperature

In this section, the temperature controls of the MIRI® are described in more detail.

There are 12 completely separate PID controllers for temperature on the MIRI®. Each controller is responsible for controlling the temperature of a separate area.

Each of the 12 available areas is equipped with its own independent temperature sensor and heater, allowing the user to adjust the temperature in every area individually with precision.

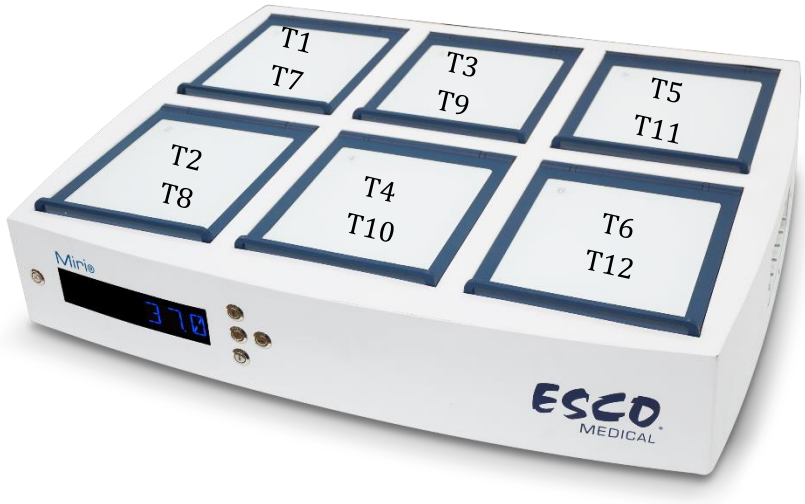


Figure 16.1 Temperature zones

Each area can be calibrated independently, using the item that corresponds to the respective area in the menu.

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

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

In order to calibrate the temperature of an area, please find the corresponding sensor name and adjust it based on measurement taken using a high precision thermometer.

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

⚠ **After temperature adjustment, allow 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, that only the value altered is corresponding to the place where the measurement is actually done. Give the system time to adjust.

☞ **There is no crossover heating between the 6 compartments. This is a unique feature of MIRI® incubator. Lid temperature will however affect the bottom temperature in a compartment. The delta T should always be 0.2 ^{0}C. Thus, if the bottom temperature 37.0 ^{0}C, the lid should be 37.2 ^{0}C.**

16.1 Example: Calibration of compartment 1

The item called "T1" in the menu is used to calibrate the temperature at the bottom of compartment 1.

☞ **'T1' is used to adjust the bottom temperature of compartment 1 (7" the lid of the same compartment). Remember that the delta-T between the top and bottom should always be 0.2 ^{0}C.**

☞ **Adjust using high precision measurements taken 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.**

Using a suitable high-quality thermometer, the temperature on T1 has been measured as 37.4^{o}C.

1. Locate T1 in the sub menu:

2. Press and hold the SP key. This display will show:

3. Adjust the temperature by pressing (⇧) 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)

4. Release the SP key; the value is now stored and the T1 area temperature has been modified.

Validate that the lid temperature is exactly 0.2°C higher than the bottom as follows.

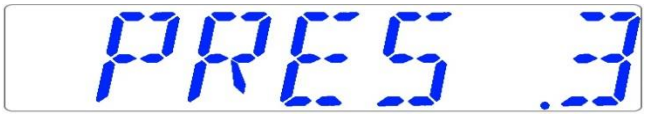
Stick a suitable and calibrated sensor to the middle of the lid area and close the lid. Wait 15 minutes and record the temperature reading. Adjust the "T7" to the desired level using the same procedure as described above. It may be necessary to do iterations before the zone is completely calibrated.

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

17 Pressure

17.1 Pressure of CO_2 gas

In the CO_2 sub-menu the pressure can be read out.



The CO_2 pressure is shown in bar. **External pressure must be 0.6 bar (8.70 PSI) at all times**. It cannot be adjusted on the incubator but is adjusted on the external gas regulator.

Remember there is a pressure alarm on the pressure limits: If the pressure falls below 0.2 bar or rises above 0.8 bar (2.90 – 11.60 PSI).

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

17.2 Pressure N_2 gas

In the O_2 sub-menu the N_2 pressure can be read out.

The N_2 pressure is shown in bar. **External pressure must be 0.6 bar (8.70 PSI) at all times**. It cannot be adjusted on the incubator but is adjusted on the external gas regulator.

Remember there is a pressure alarm on the pressure limits if the pressure falls below 0.2 bar or rises above 0.8 bar (2.90 – 11.60 PSI).

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

18 Firmware

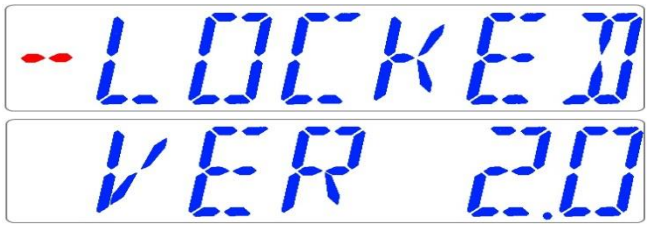
The firmware installed on your MIRI® incubator is upgradeable. Whenever an important update is available it will be provided to our distributors around the world who will ensure that your incubator runs with the newest available logic firmware. This can be done by a service technician during the scheduled 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”:

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

   The service sub menu is locked as default. The display will alternate between ‘Locked’ and the currently installed firmware version:



3. Press (⇧) to exit sub-menu.

19 pH measuring (functionality not available in the US)

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

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

A standard male BNC connector is located at the back of the unit. This can be connected to most standard pH combination probes. Probes that require a separate reference cannot be

used. Automatic Temperature correction (ATC) is done by the system according to the temperature level set in the calibration dialogue window on the PC Data logger. An external ATC probe cannot be used with the system.

Figure 19.1 pH probe connected to the BNC

If measurements are done in liquids that are not being incubated in the compartments of the MIRI®, the liquids must be maintained at 37.0 ⁰C (or the set - point of the incubator), or the temperature must be set to the correct level in the calibration dialogue window on the PC Data logger (corresponding to a measurement done with an external device). Otherwise the measurement will be incorrect, as pH is temperature dependent.

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

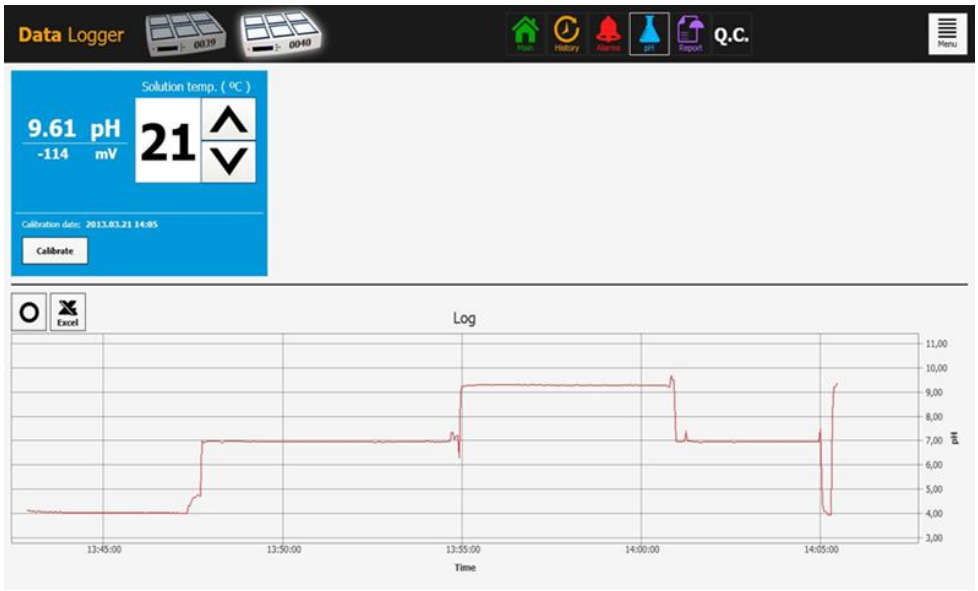


Figure 19.2 pH view in the Data logger

Temperature can be changed in one-degree steps using (⇧) and (⇩) buttons. The pH readings are in both pH scale and mV.

On the lower portion of the window a graph can be displayed and the data exported to Excel. Clicking on the 'Calibrate' button opens the section for calibration values and buffers.
The buffer levels can be user set to any desired value using (⇧) and (⇩) buttons. When the probe has been placed in the relevant buffer and has stabilized, clicking the 'Confirm' button stores the calibration for that buffer.

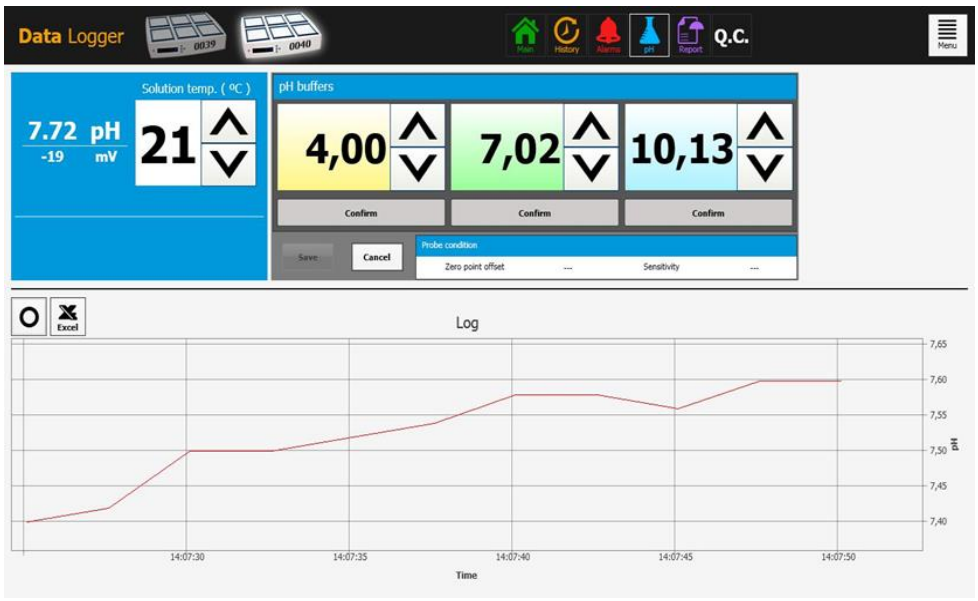


Figure 19.3 1, 2 or 3 buffers can be used

For highest accuracy choose 2 or 3 buffers (4 pH, 7 pH, 14 pH) that are close to the area of pH where the measurement should be done.

Any pH buffer can be used, as the buffer levels can be set by the user in the calibration dialogue window. If only one or two buffers are available the system can still be used but with reduced accuracy.

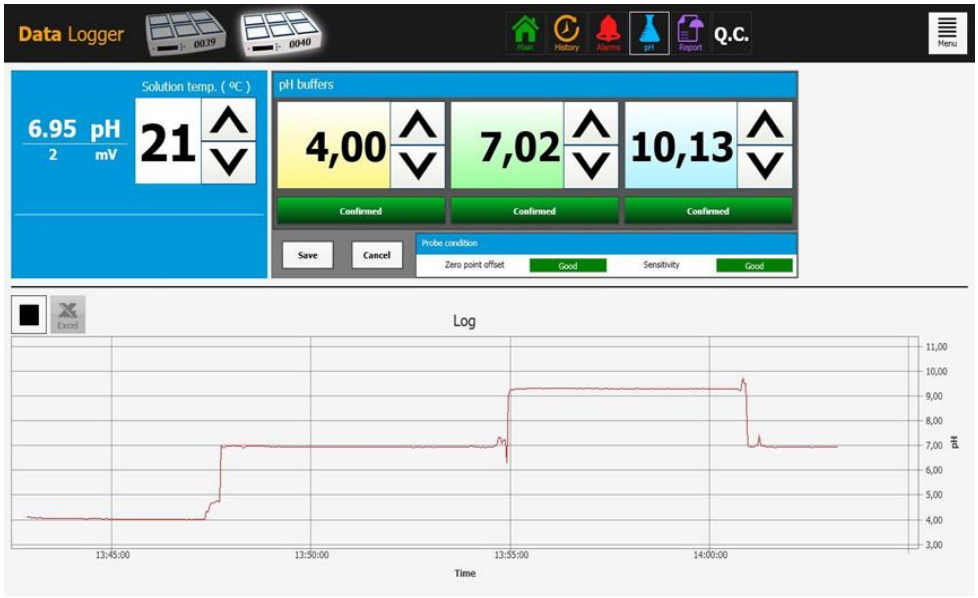


Figure 19.4 Calibration confirmed

The recommend 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 19.5 4 well with buffers and media

The calibration and measurement can be done rapidly by following the directions described above. This also circumvents most frequent source of error, when calibration with buffers is done at different temperature levels.

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 continuous measurement described below.
For continuous measurement, a test lid that covers the compartment can be supplied.

Set-up the 4-well dish as in the first method and calibrate the probe. Ensure that the well with the culture media is placed below the opening in the test lid.

Make sure 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 a rubber seal).

The set-up is able to measure the pH continually., however, the button for the graph cannot 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).

A micro probe to measure pH in a droplet can also be supplied.

Figure 19.7 Micro pH probe for 0.5 µl drop measurement

20 Cleaning instructions

20.1 Considerations about a sterile device

The MIRI® incubator is not a sterile device: It is not delivered sterile, and it is not assumed to be possible to keep it sterile when in use.

However, great care has been taken in the design to make it easy for the user to keep the device sufficiently clean during use, and to decontaminate key components.

The design features intended to provide cleanliness are:

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

20.2 Manufacturer recommended cleaning procedure

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

The periodic cleaning procedure is recommended for routine processing and maintenance. The periodic cleaning procedure combined with the disinfection procedure is recommended for event-related concerns such as media spills, visible soiling and/or other evidence of contamination. Also, it is recommended to clean and disinfect the MIRI® immediately after any media spills.

Periodic cleaning of the device (with no embryos in)

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

1. It is recommended that the unit is cleaned with aqueous 70% isopropyl alcohol: Moisten a sterile wipe (Gamma Wipe® 300) and clean all internal and external surfaces of the device by rubbing the wipe on the surfaces
2. After wiping, leave the lids of the device open to allow enough time to ensure dissipation of all alcohol fumes
3. Finally, purified or sterile water is used to wipe the device surfaces
4. Inspect the device: If visually clean, the device is ready for use

If not visually clean, repeat process from step 1.

20.3 Manufacturer recommended disinfection procedure

Disinfection of the device (with no embryos in)

Wearing gloves and good handling techniques are important to 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® (rear panel)
2. Open the lids
3. Disinfect the internal surfaces, the heating inserts plus the glass plate on the top of the lid with EcaFlo® Anolyte. Apply EcaFlo® Anolyte using sterile wipes (Gamma Wipe® 300)
1. Wipe all internal surfaces and the top of the lid with at least three wipes. Repeat until the wipes are no longer discolored
4. Change the gloves and after a 10-minute contact time spray sterile water and wipe with a sterile wipe (Gamma Wipe® 300)

5. Inspect the device and if visually clean the device is ready for use. If not visually clean go to step 3 and repeat the procedure
6. Turn on the MIRI® (rear panel)

21 Heat optimization plates.

Insert the heat optimization plate. The heat optimization plate will ensure full contact with the dish. This generally means much more stable temperature conditions for the cells. The plate fits the compartment. The plate can be taken out for cleaning.

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

Place the dish where it fits the pattern. There are a heat optimization plates for Nunc®, Falcon®. Sparmed® and VitroLife® dishes.

☞ **Use only the correct type for your dishes.**

Figure 20.1 Heating optimization plate

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

22 Humidification

If the MIRI® incubator is used for open culture conditions the mode for culture must be set for “Open culture”.

There is no need for humidification in the compartment.

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

If the MIRI® incubator is used for culture with a mineral overlay it is not necessary to use the simulated humidification. Set the culture mode for “Oil culture”.

Dry incubation under oil and simulated humidity is less risky in terms of possible contamination.

Open culture is possible in a Nunc™ 4-well (or similar type of dish) in volumes not under 100 mL per well without oil overlay, for up to a maximum of 36 hours. The osmolality will change rapidly after that and reach over 300 mOsm/kg. Up to 24-hour culturing in 100 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 MIRI®.

23 Temperature validation

The MIRI® incubator is equipped with six (6) PT-1000 Class-B sensors, each one located in a central position in the bottom of each compartment.

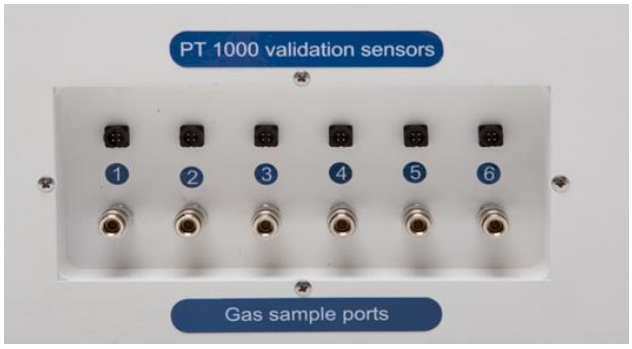


Figure 23.1 PT-1000 Class B sensors

The sensors are there for external validation purposes. They are completely separate from the circuit of the unit.

Through the external connectors on the side of the unit the temperature conditions in the compartments can be logged continually, without compromising the unit’s performance.

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

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

24 Gas level validation

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

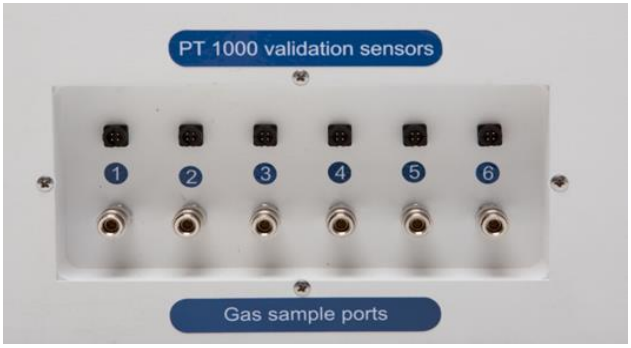


Figure 24.1 Gas sample ports

Each sample port is directly connected to the corresponding compartment with the corresponding 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.

☞ Prior to any gas measurement ensure that the Lids have not been opened for at least 5 minutes.

⚠ Taking out a large sample volume may affect gas regulation.

⚠ Ensure that the gas analyzer is calibrated before use.

25 Alarm switch for an external system

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

Whenever there is an alarm (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 interrupted) the switch is de-activated indicating that the unit needs inspection by a user.

The connector can either be connected to a voltage source OR to a current source.

⚠ **Note that if a current source is attached to the 3.5mm 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 'ON' position as it is illustrated below.

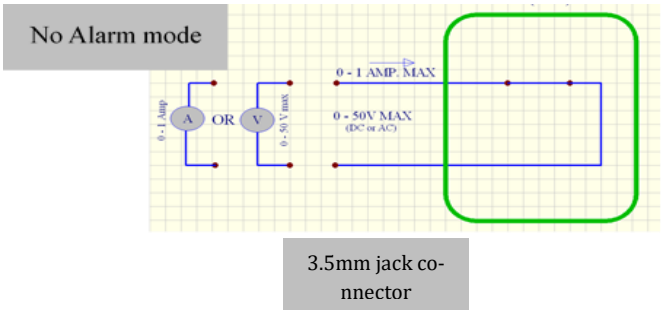


Figure 25.1 Alarm position "ON"

Whenever the MIRI® goes into an alarm mode, the switch will become an 'open circuit'. This means that no current is able to run through the system any more.

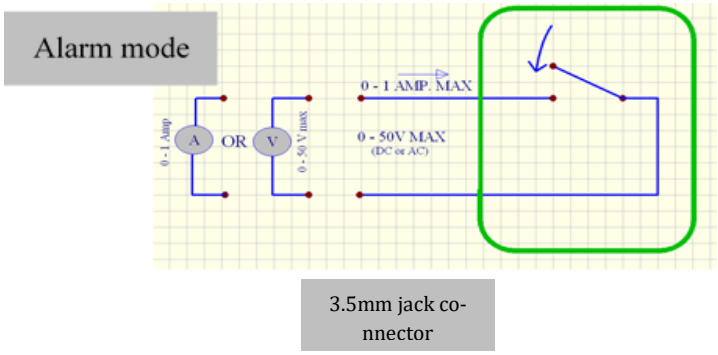


Figure 25.2 "Open circuit" alarm mode

☞ **Whenever the incubator power cord is disconnected from the power source, this switch will automatically indicate an alarm! This is an extra safety feature added to alert the personnel in case of power cut in the laboratory.**

26 Writing area on the compartment lids.

Each compartment lid on the MIRI® incubator is made from white glass optimized for writing text. The patient data or content of the compartment can be written for easy reference during the incubation run.

The text can be wiped off with a cloth afterwards.

Only write with a suitable non-toxic pen that allows the text to be erased afterwards, and will not harm the samples being incubated.

Figure 26.1 Area for patient information

27 Maintenance

The MIRI® incubator is designed to be easy to use, but reliable and safe operation of this equipment is based on the following conditions:

1. Correct calibration of temperature and gas using high precision equipment per the intervals prescribed by clinical practice at the laboratory where the MIRI® is in use. Intervals longer than 14-days between validation are not recommended by the manufacturer
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 gas bottles for the in-line HEPA filters
3. In the case of centralize gas supply pipes, the in-line HEPA filters can be changed annually
4. Suitable cleaning according to the intervals prescribed by the clinical practice in the laboratory where the MIRI® is in use. Intervals longer than 14-days between cleaning are not recommended by the manufacturer.

⚠ **It is essential to perform the inspection and servicing at the intervals described in the MAINTENANCE manual. Failing to do so can have serious adverse outcome causing the unit to stop performing as expected, and cause damage to samples, patients or users.**

⚠ **Warranty voids if service and maintenance are not followed.**

⚠ **Warranty voids if service and maintenance are not done 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.

- In an ambient environment temperature of 20°C the MIRI® will lose its internal temperature below 35°C in 10-minutes.

- The CO_2 concentration will remain within 1% of the set point for 30-minutes, if the lids are not opened.
- In case longer time is needed it may be beneficial to cover the unit with insulating blankets to slow the temperature drop.

In case of a single temperature alarm on the unit:

- Remove the samples from the affected compartment. They can be relocated to any of the other compartments where there is room. Each compartment is independent, so the other compartments will function normally.

In case of a multiple temperature alarm on the unit:

- Remove the samples from the affected compartments. They can be relocated to any of the other compartments where there is room. Each compartment is independent, so the other compartments 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.

In case of a CO_2 level alarm on the unit:

There will be a 30-minutes time interval during which it can be assessed if the condition is temporary or permanent. If the condition 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 level is low, keep the lids shut. If the condition is temporary and the level is high, open a few lids to vent out some of the CO_2.

In case of a O_2 level alarm on the unit:

Normally it will not be necessary to perform any emergency procedures. If the condition is judged to be permanent, it may be advantageous to switch off the O_2 regulation in the menu.

In case of a CO_2 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 CO_2 level alarm.

In case of an O_2 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 O_2 level alarm.

29 User Troubleshooting

Table 29.1 Heating system

Symptom	Cause	Action
No heating, display is off	The unit is switched off at the back or not connected to the power	Switch the device on or connect power
No heating	The set point for temperature is wrong	Check the desired temperature set point
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 gas regulation	System is not powered	Check power mains
	System is switched off	Switch the system on.
	CO_2 gas regulator is off	Activate CO_2 gas regulator by setting 'CO_2' to 'on' in menu
	No CO_2 or wrong gas attached to CO_2 gas input	Check the gas supply, make sure that 0.6 bar (8.70 PSI) of gas pressure is applied
	Actual gas concentration is higher than set point	Check CO_2 set point
Poor CO_2 gas regulation	Lid(s) are left open	Close lid(s)
	Seals missing on 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 system to stabilize by closing all lids
'CO2 P' is shown on the display.	No/wrong CO_2 gas pressure to the system	Check CO_2 gas supply; make sure that pressure is kept stable at 0.6 bar (8.70 PSI)

Table 29.3 O_2 gas regulator

Symptom	Cause	Action
No O_2 gas regulation	System not powered	Check mains
	System is on standby or switched off	Switch the system on
	O_2 gas regulator is off	Activate O_2 gas regulator by setting 'O_2' to 'on' in the menu
	No N_2 or wrong gas type attached to N_2 gas input	Check gas supply; make sure that 0.6 bar of N_2 gas is applied
	Actual gas concentration is higher than the set point	Check O_2 set point
Poor O_2 gas regulation	Lid(s) are left open	Close lid(s)
	Seals missing on lid(s)	Replace the seals on the lid(s)
'A O2.' is shown on the display	O_2 gas concentration more than ±1 from set point	Allow 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, make sure that pressure is stable at 0.6 bar (8.70 PSI) If O_2 regulation is not needed set the O_2. to 'off' in the menu to deactivate oxygen regulation and abort the N_2 alarm

Table 29.4 Data logger

Symptom	Cause	Action
No data is sent to PC	System not powered	Check mains
	System is on standby or switched off	Switch the system on
	Data cable between Incubator and PC not properly attached	Check connection. Use only the cable supplied with the unit
	Data logger software/USB driver not properly installed	Please refer to 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
Absent or erratic function of keys	Failure in the keys	Contact your Esco Medical Distributor to replace the keys

30 Specifications

Table 30.1 MIRI® specifications

Technical specifications	MIRI®
Overall dimensions (WxDxH)	700 x 580 x 160 mm
Weight	35 kg
Material	Mild steel / Aluminum / POM / Stainless steel
Power supply	115V 60Hz OR 230V 50Hz
Power consumption	280 W
Heating elements	240 W
Temperature range	25 – 40°C
Gas consumptions (CO_2)[1]	<2 liters per hour
Gas consumption (N_2)[2]	<12 liters per hour
CO_2 range	1.9 – 10%
O_2 range	5 – 20%
Gas pressure CO_2 (input)	0.6 bar (8.70 PSI)
Gas pressure N_2 (input)	0.6 bar (8.70 PSI)
Alarms	Audible and visible for out of range temperature, gas concentration, gas pressure.

31 Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emissions		
The MIRI® is intended for use in the electromagnetic environment specified below. The customer or the user of MIRI® should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The MIRI® 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® is 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	

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The MIRI® is intended for use in the electromagnetic environment specified below. The customer or the user of the MIRI® should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compli-ance level**	**Electromagnetic environ-ment- guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, con-crete 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	Perfor-mance A	Power frequency magnetic fields should be at levels characteristic of a typical loca-tion in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The MIRI® is intended for use in the electromagnetic environment specified below. The customer or the user of the MIRI® 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 the MIRI® including cables, than the recommended separation distance calculated form the equation applicable to the frequency of the transmitter **Recommended separation distance** $d = 0.35\ P$ $d = 0.35\ P$ 80MHz to 800MHz $d = 0.7\ P$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment.

Recommended separation distances between portable and mobile RF communication equipment and the MIRI®

The MIRI® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MIRI® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MIRI® as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of 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 separation distance for the higher frequency range 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 that all equipment used near the MIRI® product comply with the medical electromagnetic compatibility standard and to check before use that no interference is evident or possible. If the interference is suspected or possible, switching off the offending device is the normal solution, as is required in aircraft and medical facilities.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided. Portable and mobile RF communications equipment can affect medical electrical equipment.